Court File No. 36654

IN THE SUPREME COURT OF CANADA
(ON APPEAL FROM THE FEDERAL COURT OF APPEAL)

B E T W E E N:

ASTRAZENECA CANADA INC.
ASTRAZENECA AKTIEBOLAG and ASTRAZENECA UK LIMITED

Appellants

– and –

APOTEX INC. and
APOTEX PHARMACHEM INC.

Respondents

MOTION RECORD OF THE PROPOSED INTERVENER CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

(Motion for Intervention pursuant to Rules 47, 55, 56, 57 and 59 of the *Rules of the Supreme Court of Canada*)

AITKEN KLEE LLP
Suite 300, 100 Queen Street
Ottawa, ON K1P 1J9

Jonathan Stainsby
Marcus Klee
Devin Doyle

Tel: 647-317-6868
613-903-5100
613-903-5105
Fax: 613-695-5854
E-mail:
jstainsby@aitkenklee.com
mklee@aitkenklee.com
ddoyle@aitkenklee.com

Solicitors for the Moving Party, Canadian Generic Pharmaceutical Association

AITKEN KLEE LLP
Suite 300, 100 Queen Street
Ottawa, ON K1P 1J9

Jonathan Stainsby
Marcus Klee
Devin Doyle

Tel: 647-317-6868
613-903-5100
613-903-5105
Fax: 613-695-5854
E-mail:
jstainsby@aitkenklee.com
mklee@aitkenklee.com
ddoyle@aitkenklee.com

Agents for Solicitors for the Moving Party, Canadian Generic Pharmaceutical Association

ORIGINAL TO: **The Registrar**
Supreme Court of Canada
301 Wellington Street
Ottawa ON K1A 0J1

COPY TO:

Counsel for the Appellants

SMART & BIGGAR
Barristers and Solicitors
438 University Avenue, Suite 1500
Toronto, ON M5G 2K8

Gunars A. Gaikas
Yoon Kang
Y. Lynn Ing

Tel: 416-593-5514
Fax: 416-591-1690
Email:
ggaikis@smart-biggar.ca
ykang@smart-biggar.ca
yling@smart-biggar.ca

Agent for the Appellants

SMART & BIGGAR
Barristers and Solicitors
55 Metcalfe St., 10th Floor
Ottawa, Ontario
KIP 6L5

Colin B. Ingram

Tel: 613-232-2486
Fax: 613-238-8440
Email: cbingram@smart-biggar.ca

AND TO:

Counsel for the Respondents

GOODMANS LLP
3400 - 333 Bay Street
Toronto, Ontario
M5H 2S7

Counsel Harry B. Radomski
Richard Naiberg
Sandon Shogilev

Tel: 416-979-2211
Fax: 416-979-1234
Email: hradomski@goodmans.ca

Agent for the Respondents

NELLIGAN O'BRIEN PAYNE LLP
1500-50 O'Connor Street
Ottawa, Ontario
K1P 6L2

Christopher Rootham

Tel: 613-231-8311
Fax: 613-788-3667
Email: christopher.rootham@nelligan.ca

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MOTION RECORD OF THE CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION ("CGPA") (Proposed Intervener)
(Motion for Intervention pursuant to Rules 47, 55, 56, 57 and 59 of the *Rules of the Supreme Court of Canada*)

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NOTICE OF MOTION OF THE PROPOSED INTERVENER
CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

(Motion for Intervention pursuant to Rules 47, 55, 56, 57 and 59
of the *Rules of the Supreme Court of Canada*)

TAKE NOTICE that the Canadian Generic Pharmaceutical Association "(CGPA") hereby applies to a judge of this Court, pursuant to Rules 47, 55, 56, 57 and 59 of the *Rules of the Supreme Court of Canada*, for an order granting the CGPA leave to intervene in this appeal, to file a factum not to exceed 20 pages in length and to make oral argument at the hearing of the appeal for not more than 20 minutes, and any further or other order that the Judge may deem appropriate.

AND FURTHER TAKE NOTICE that the motion shall be made on the following grounds:

The CGPA

1. The CGPA is an industry association that represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. The members of the CGPA provide substantial cost savings to Canadian governments and private payers of prescription medications, by introducing lower-cost versions of drugs to the Canadian market.

2. Approximately 986 applications relating to patents for pharmaceutical products have been commenced under the *Patented Medicines (Notice of Compliance) Regulations* since those regulations were promulgated in 1993 and approximately 155 patent actions have been commenced in the Federal Court since 2000 regarding pharmaceutical products. Most have involved members of the CGPA.

3. This Court has recognized the CGPA's interest in the development of patent law, and in particular the law relating to pharmaceutical patents, by granting it leave to intervene in the last six Supreme Court of Canada cases involving pharmaceutical patents, namely, *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533, *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560, *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 and *Teva Canada Limited v. Pfizer Canada Inc.*, 2012 SCC 60, [2013] 3 S.C.R. 625, *Apotex Inc., et al. v. Sanofi-Aventis, et al.*, Supreme Court Docket 35562 (discontinued prior to hearing), and *Sanofi-Aventis v. Apotex Inc.*, 2015 SCC 20, [2015] 2 S.C.R. 136.

The appeal

4. On this appeal, the Court will be asked by the Appellants to set aside the judgment of the Federal Court of Appeal and to depart from existing jurisprudence by rejecting the long-standing principle that patentees are to be held to the promises they make regarding the utility of their patented inventions.

The CGPA has an interest in the appeal

5. The CGPA has no specific interest in the validity of the patent-in-suit, but is vitally interested in ensuring that the Canadian law relating to fundamental requirements of patent validity is given appropriate direction.

6. No industry in Canada follows patent jurisprudence more closely than the pharmaceutical industry and there is no industry whose members are more affected by changes to, or uncertainty in, patent law. The CGPA's members are regularly engaged in the costly and time-consuming endeavour of deciding whether to pursue a generic version of a drug, which requires that they undertake detailed analyses of the validity of the relevant patents. It is critical to the CGPA and its members that the requirements for a valid patent receive a fair and consistent treatment in the jurisprudence.

The CGPA's submissions will be useful and different

7. The parties to this appeal will necessarily focus their submissions on the validity of the specific patent in issue and the facts of this particular case. As an intervener without a direct interest in the validity of the patent-in-suit, the CGPA can provide a different perspective than the parties and will address the broader issues of utility and the "promise doctrine" and its importance to the Canadian patent system and the pharmaceutical industry in Canada.

8. The CGPA seeks leave to intervene to make the following submissions:

A. Uncertainty, the bargain and the balance

9. The judgment under appeal engages issues regarding the fundamental balance between, on one hand, of the rights of patentees, and on the other hand, the rights of the CGPA's members and ultimately, the Canadian public.

10. Utility is a core requirement in Canadian law. As of the filing date, the patentee must have either demonstrated or soundly predicted that the invention will do what the patent has chosen to say that the ptented invention will do. The so-called "promise doctrine" is no more than a reference to the need to construe the patent to ascertain what the patentee has chosen to say the patented invention will do.

11. The legal framework that this Court ultimately adopts will have significant and lasting ramifications for the Canadian pharmaceutical industry as a whole. The issues for determination could tip the delicate balance between the entitlement of a patentee to obtain a monopoly and prevent the market entry of a generic version and the entitlement of generic manufacturers to enter the Canadian market. Changing the long-standing approach to utility will not only tip the delicate balance inherent in the patent bargain, but will also inject uncertainty and arbitrariness into the framework for assessing patent validity.

12. The CGPA will provide this Court with guidance as to the broader effects on the pharmaceutical industry of the Appellants' proposed change to Canadian patent law and will submit that the decision below is properly grounded in Canadian patent law and fosters and promotes the fundamental balance that Parliament sought to achieve under the *Patent Act* and which is reflected in existing jurisprudence.

B. Comparative International Law

13. The judgment below and the doctrine of promised utility do not place Canada out-of-step with international jurisprudence or international obligations.

14. Pharmaceutical patents are not more frequently invalidated in Canada than elsewhere.

15. There is no overarching requirement that the patent laws of different countries be "harmonized," nor any clear direction as to which jurisdiction ought to be the focus of any efforts to "harmonize".

16. As the issue of harmonization was not considered by the Courts below, there is no developed record on which this Court could consider this issue.

17. Such further and other grounds as counsel may advise and this Court permit.

DATED at Ottawa, Ontario, this 28th day of July, 2016.

AITKEN KLEE LLP
Suite 300, 100 Queen Street
Ottawa, ON K1P 1J9

Jonathan Stainsby
Marcus Klee
Devin Doyle

Tel: 647-317-6868
613-903-5100
613-903-5105
Fax: 613-695-5854
E-mail:
jstainsby@aitkenklee.com
mklee@aitkenklee.com
ddoyle@aitkenklee.com

Solicitors for the Moving Party, Canadian Generic Pharmaceutical Association

AITKEN KLEE LLP
Suite 300, 100 Queen Street
Ottawa, ON K1P 1J9

Jonathan Stainsby
Marcus Klee
Devin Doyle

Tel: 647-317-6868
613-903-5100
613-903-5105
Fax: 613-695-5854
E-mail:
jstainsby@aitkenklee.com
mklee@aitkenklee.com
ddoyle@aitkenklee.com

Agents for Solicitors for the Moving Party, Canadian Generic Pharmaceutical Association

ORIGINAL TO: **The Registrar**
Supreme Court of Canada
301 Wellington Street
Ottawa ON K1A 0J1

COPY TO:

Counsel for the Appellants

SMART & BIGGAR
Barristers and Solicitors
438 University Avenue, Suite 1500
Toronto, ON M5G 2K8

Gunars A. Gaikas
Yoon Kang
Y. Lynn Ing

Tel: 416-593-5514
Fax: 416-591-1690
Email:
ggaikis@smart-biggar.ca
ykang@smart-biggar.ca
yling@smart-biggar.ca

Agent for the Appellants

SMART & BIGGAR
Barristers and Solicitors
55 Metcalfe St., 10th Floor
Ottawa, Ontario
KIP 6L5

Colin B. Ingram

Tel: 613-232-2486
Fax: 613-238-8440
Email: cbingram@smart-biggar.ca

AND TO:

Counsel for the Respondents

GOODMANS LLP
3400 - 333 Bay Street
Toronto, Ontario
M5H 2S7

Counsel Harry B. Radomski
Richard Naiberg
Sandon Shogilev

Tel: 416-979-2211
Fax: 416-979-1234
Email: hradomski@goodmans.ca

Agent for the Respondents

NELLIGAN O'BRIEN PAYNE LLP
1500-50 O'Connor Street
Ottawa, Ontario
K1P 6L2

Christopher Rootham

Tel: 613-231-8311
Fax: 613-788-3667
Email: christopher.rootham@nelligan.ca

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Suite 300, 100 Queen Street
Ottawa, ON K1P 1J9

Jonathan Stainsby
Marcus Klee
Devin Doyle

Tel: 647-317-6868
613-903-5100
613-903-5105
Fax: 613-695-5854
E-mail:
jstainsby@aitkenklee.com
mklee@aitkenklee.com
ddoyle@aitkenklee.com

Solicitors for the Moving Party, Canadian Generic Pharmaceutical Association

AITKEN KLEE LLP
Suite 300, 100 Queen Street
Ottawa, ON K1P 1J9

Jonathan Stainsby
Marcus Klee
Devin Doyle

Tel: 647-317-6868
613-903-5100
613-903-5105
Fax: 613-695-5854
E-mail:
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AFFIDAVIT OF JAMES KEON

(Filed by the Proposed Intervener, Canadian Generic Pharmaceutical Association, pursuant to Rules 47 and 57 of the *Rules of the Supreme Court of Canada*)

I, James Keon, of the Town of Aurora, in the Province of Ontario, SWEAR THAT:

1. I am the President of the Canadian Generic Pharmaceutical Association ("CGPA"). I have held this position since 1998.

The CGPA

2. The CGPA is an industry association that represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. A current list of CGPA's members is attached as **Exhibit "A"** to my affidavit.

3. Prescription drugs are the fastest rising component of health care spending in Canada. According to IMS Health data, total expenditures on prescription drugs were $24.8 billion in 2015. To help control these mounting costs, Canada depends on a steady supply of safe generic medicines. In 2015, generic drug sales accounted for 68.6% of all prescriptions, but only 22% of dollar value of the total Canadian prescription drug market, totalling approximately $5.46 billion in sales. According to 2015 IMS Health data, the average cost of brand-name prescriptions was $91.92, while the average cost of a generic prescription was $20.92. The availability of generic drugs in Canada has a very significant effect on drug expenditures in Canada by public provincial drug plans, private drug insurance plans and the Canadian public not covered by either public or private drug plans. The CGPA estimates that the use of generic drugs saved Canadians approximately $15 billion in 2015. If generic drug manufacturers were to be impeded in their efforts to bring new products to market, the cost to governments and Canadian consumers would soar.

4. The generic drugs marketed by the members of the CGPA are essential to the health of Canadian citizens, both because having lower-cost versions of drugs means greater access to those drugs for all, and also because the substantial difference between the monopoly prices charged by the "brand" drug industry and the members of the CGPA means that for many important drugs in Canada, only generic versions are now available. For those important drugs, the "brand" companies have stopped selling them entirely, rather than competing on price.

5. To encourage the marketing of generic drugs in Canada, the *Food and Drugs Act* permits a generic drug company to seek regulatory approval for a drug by submitting to Health Canada an abbreviated new drug submission ("ANDS") comparing its drug product to a brand name drug product which has already been approved by Health Canada through the issuance of a notice of compliance ("NOC"). By comparing a generic drug with a previously approved brand name drug the generic drug company avoids the need to undertake costly and time consuming clinical trials thereby expediting low-cost generic drug entry.

6. To bring a new generic medicine to market, generic drug manufacturers must comply with the *Patented Medicines (Notice of Compliance) Regulations* (the "*Regulations*"). The CGPA has been involved in consultations with Industry Canada regarding the *Regulations* since they were first enacted in 1993. Representatives of the CGPA have appeared at hearings several times before Parliamentary committees concerning the *Regulations*. The CGPA also follows all litigation developments under the *Regulations* closely, including the listing of patents on the patent register. I have personally directed such consultations and appearances and have monitored all such developments on behalf of the CGPA. As a result, I am personally familiar with the practices of brand name pharmaceutical companies in listing patents on the patent register and in seeking to extend patent protection for their brand name drug products.

7. The *Regulations* require the delivery of a Notice of Allegation alleging that a party seeking approval of a proposed generic product will not infringe any patent(s) listed on the Patent Register maintained by Health Canada in respect of the patented medicine, or that the patent(s) in question are invalid. In response, the brand name manufacturer may commence an application under section 6 of the *Regulations* for an order prohibiting The Minister of Health (the "Minister") from issuing a NOC to the generic drug company for its generic drug until after the expiry of the patent. On the commencement of such an application, a statutory stay arises under section 7 of the *Regulations* prohibiting the Minister from issuing the NOC until the earlier of the dismissal or withdrawal of the application or the expiry of two years from the date of the commencement of the application, or such later period as the Federal Court may order.

8. Since the *Regulations* came into force in 1993, approximately 986 applications for prohibition orders relating to the validity or infringement of patents for pharmaceutical products have been commenced. Almost all of those applications have involved members of the CGPA.

9. Members of the CGPA are regularly parties to actions seeking declarations regarding the validity and/or infringement of pharmaceutical patents. This appeal arose

from the judgment of the Federal Court of Appeal following an action brought by AstraZeneca seeking to enforce the patent in suit against Apotex.[1]

10. Since 2000, approximately 155 actions have been commenced in the Federal Court seeking declarations of invalidity and/or infringement of pharmaceutical patents. The vast majority of these actions have involved members of the CGPA, and some have followed the determination of applications made under the *Regulations* (Canada is the only jurisdiction that permits dual litigation on pharmaceutical patents).

11. There is no industry in Canada that follows patent jurisprudence more closely than the pharmaceutical industry and no industry whose members are more affected by changes or uncertainty in patent law. Decisions in cases under the *Regulations* make up the vast majority of recent patent jurisprudence and these cases invariably involve CGPA members. It follows that there is no other industry association in Canada that has a greater interest in the state and the development of patent law than the CGPA. The CGPA seeks leave to intervene on this appeal to address issues that are vital to the generic pharmaceutical industry.

12. The practice of brand name drug companies of listing uninventive patents relating to the active pharmaceutical ingredient, formulations for their drug products or uses of their drug products, on the Patent Register is a major concern for the members of the CGPA. This practice can impede or substantially delay generic drug entry in Canada and substantially increase drug prices to public and private drug plans and to the public in Canada.

13. In considering whether to pursue regulatory approval of a generic drug product, CGPA members will typically seek legal advice as to the validity of patents listed on the Patent Register for the purpose of determining whether an allegation of invalidity would likely be held justified in an application under the *Regulations*. Members of the CGPA are continually involved in the evaluation of patents and the preparation of Notices of

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[1] Canadian Patent number 2,139,653.

Allegation that set out the detailed factual and legal basis of any grounds of invalidity upon which they intend to rely. This is a costly and time-consuming endeavour.

14. The substantive content of Canadian patent law, including the review and construction of pharmaceutical patents listed on the Patent Register (as well as others relating to "brand" pharmaceutical products), is a critical element of the development process for generic pharmaceutical companies.

15. The members of the CGPA benefit from certainty in the law and believe that current jurisprudence on the substantive patent law issues raised on this appeal reflects and promotes the existing balance between patentees and the public. Any change to the law, in particular the changes proposed by the Appellants, would create uncertainty and come at significant economic costs to the CGPA's members.

16. The CGPA and its members are directly and significantly affected by changes to the law of patents in Canada, including by any change to the utility analysis (the so called "promise" of the patent), which is at issue on this appeal.

17. The CGPA does not, however, have a direct interest in the validity of the specific patent-in-suit. While the respondent, Apotex Inc. ("Apotex"), is a member of the CGPA, so, too, are its direct competitors in the generic industry. Neither these members nor Apotex speaks for or controls the CGPA, nor does the CGPA speak for or control Apotex or these other members.

18. This Court has recognized CGPA's interest in the development of patent law, and in particular the law relating to pharmaceutical patents, by granting it leave to intervene in the last six Supreme Court of Canada cases involving pharmaceutical patents, namely, *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, *Teva Canada Limited v. Pfizer Canada Inc.*, 2012 SCC 60, *Apotex Inc., et al. v. Sanofi-Aventis, et al.* Supreme Court Docket 35562 (appeal discontinued prior to the hearing), and *Sanofi-Aventis v. Apotex Inc.*, 2015 SCC 20.

19. If granted leave to intervene, the CGPA will provide a different perspective from Apotex (and from the Appellants on the appeal) by focusing on the broader issues of national importance. The CGPA will make the following submissions: (1) that effecting the changes to Canadian patent law propounded by the Appellants would constitute a departure from long-standing Canadian jurisprudence that respects and promotes the fundamental balance established in Canadian patent law and, in so doing, would create uncertainty and inject unpredictability into Canadian patent law; and (2) that it would not be appropriate or even possible on this appeal to attempt to "harmonize" Canadian patent law with the patent laws of foreign jurisdictions.

20. The parties to the appeal will focus on the particularities of the patent at issue. This Honourable Court will benefit from the broader perspective of the CGPA and its members, who have great experience in the substance of Canadian patent law. This Honourable Court's decision will obviously have an effect on the patent at issue and the parties to the appeal. However, this Court's decision will also have broader implications about which the CGPA seeks leave to make submissions. The broader implications will have a significant effect on the CGPA and its members in present and future cases. The CGPA therefore seeks leave to intervene to provide the Canadian generic drug industry's perspective on the issues on this appeal.

SWORN BEFORE ME at the City of Toronto, in the Province of Ontario, this 28th day of July 2016.

Commissioner for taking affidavits

JAMES KEON

This is **Exhibit "A"** to the Affidavit of James Keon
sworn before me on this 28th day of July, 2016

Commissioner for taking affidavits

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CGPA

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MEMBERS

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Actavis Pharma Company
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Suite 400
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Fax: 416-814-8696
(1.866.260.6292)
www.actavis.ca

Apotex Inc.
150 Signet Drive
Toronto (Weston), Ontario
M9L 1T9

Tel: 416-749-9300
Fax: 416-401-3849
www.apotex.ca

APOTEX
À L'AVANT-GARDE DES GÉNÉRIQUES

Fresenius Kabi Group
45 Vogell Road, Suite 200
Richmond Hill, ON L4B 3P6

Tel. 905-770-3711
Fax. 905-770-4811
www.fresenius-kabi.ca

FRESENIUS KABI
prendre soin de la vie

Marcan Pharmaceuticals Inc.
77 Auriga Dr., Unit # 4,
Ottawa, ON, K2E 7Z7

Tel: 613-228-2600
Toll Free: 1-855-627-2261
Fax: 613-224-0444
Email:
info@marcanpharma.com
www.marcanpharma.com

MARCAN
PHARMACEUTICALS INC.

Mylan
85 Advance Road,
Etobicoke, Ontario,
M8Z 2S6

Tel: 416-236-2631
Toll Free North-America: (877)
540-7377
Fax: (416) 236-2940
www.mylan.ca

Mylan

Pharmascience Inc.
6111 Ave Royalmount, Suite 100
Montréal, Quebec
H4P 2T4

Tel.: (514) 340-9800
1-800-363-8805 CDA & US
Fax: (514) 342-7764
www.pharmascience.com

pharma science

Sandoz Canada Inc.
145, Jules-Léger
Boucherville, Quebec
J4B 7K8

Tel: 450- 641-4903
Toll Free: 1-800-343-8839
Fax: 514- 596-1460
www.sandoz.ca

SANDOZ

Taro Pharmaceuticals
130 East Drive
Brampton, Ontario
L6T 1C1

Tel: 905-791-8276
Fax: 905-791-4473
www.taro.ca

TARO

Teva Canada Limited
Corporate Head Office
30 Novopharm Ct.
Toronto, Ontario
Canada M1B 2K9

Tel: 1-800-268-4127
Fax: 416-291-1874
www.tevacanada.com

Industry Suppliers/Active Ingredient Manufacturers

ACIC
81 Sinclair Boulevard
Brantford, Ontario
N3S 7X6

Tel: 519-751-3668
(1.800.265.6727)
Fax: 519-751-1378
www.acic.com

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AFFIDAVIT OF ANNA HUCMAN

(Filed by the Proposed Intervener, Canadian Generic Pharmaceutical Association, pursuant to Rules 47 and 57 of the *Rules of the Supreme Court of Canada*)

I, Anna Hucman, of the City of Mississauga, in the Province of Ontario, SWEAR THAT:

1. I am employed as a law clerk by Aitken Klee LLP, counsel to the proposed intervener, the Canadian Generic Pharmaceutical Association. I have knowledge of the matters I depose to in this affidavit.

2. Attached as exhibits "A" to "F" to my affidavit are copies of the following documents, provided to me by counsel for proposed intervener:

(a) World Intellectual Property Organization, *Draft Substantive Patent Law Treaty* online: http://www.wipo.int/patent-law/en/draft_splt.htm (hard copy attached as **Exhibit "A"**).

(b) Gold, R., and Shortt, M., "The Promise of the Patent In Canada and Around the World", 30 CIPR 35 (June 2014) (**Exhibit "B"**).

(c) Vaver, D., "Is Canada's Patent Law Out of Step?": Reworked Remarks for University of Toronto 2nd Patent Law Colloquium, November 22, 2013 (**Exhibit "C"**).

(d) Reichman, H. & Cooper Dreyfuss, R., "Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty" (2007) 57 Duke LJ 85 (**Exhibit "D"**).

(e) *Marrakesh Agreement Establishing the World Trade Organization, Annex 1C*, 15 April 1994, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (*TRIPs*) (**Exhibit "E"**).

(f) Chapter 17 of the *North American Free Trade Agreement*, 32 I.L.M. 289 and 605 (**Exhibit "F"**).

3. I make this affidavit in connection with CGPA's motion for leave to intervene and for no other purpose.

SWORN BEFORE ME at the City of Toronto, in the Province of Ontario, this 27th day of July 2016.

Commissioner for taking affidavits

ANNA HUCMAN

This is **Exhibit "A"** to the Affidavit of Anna Hucman
sworn before me on this 27th day of July, 2016

Commissioner for taking affidavits

WIPO
WORLD INTELLECTUAL PROPERTY ORGANIZATION

Draft Substantive Patent Law Treaty

In November 2000, the need for patent law harmonization going beyond formalities led WIPO's Standing Committee on the Law of Patents (SCP), at its fourth session, to decide to initiate work on harmonization of substantive patent law with a view to concluding a Substantive Patent Law Treaty (SPLT). The SCP agreed to focus initially on a number of issues of direct relevance to the grant of patents, in particular, the definition of prior art, novelty, inventive step/non-obviousness, industrial applicability/utility, the drafting and interpretation of claims and the requirement of sufficient disclosure of the invention.

In May 2001 at its fifth session, the SCP considered a first draft of the SPLT, including draft Regulations and Practice Guidelines. At its sixth session in November 2001, the SCP revised the draft provisions, and agreed on an approach to establishing a seamless interface between the SPLT, the PLT and the Patent Cooperation Treaty (PCT). It also agreed to create a Working Group on Multiple Invention Disclosures and Complex Applications mandated, in particular, to work on the following issues: (i) unity of invention; (ii) the linking of claims; (iii) the number of claims; (iv) the requirement of "clear and concise" claims and (v) special procedures to treat complex applications, such as mega-applications or large sequence listings.

During the subsequent sessions of the SCP the contents of the draft SPLT were progressively broadened. While the SCP agreed in principle on a number of issues, such as the scope of the SPLT and the right to a patent, some provisions, such as patentable subject matter or the grounds for refusal of a claimed invention, raised concerns about the available flexibility in respect of national policies, recognized under current international treaties.

Following these developments, at the tenth session of the SCP in 2004, the United States of America, Japan and the European Patent Office submitted a joint proposal designed to focus on an initial package of priority items including the definition of prior art, grace period, novelty and inventive step which was, in essence, submitted as a proposal to the General Assemblies.

As no consensus was reached at the Assemblies, following the informal consultations held in 2005 in Casablanca, Morocco, the Director General submitted recommendations to the SCP. While delegations recognized the importance of the work of the SCP and emphasized that the work on patent law harmonization should progress taking into account the interests of all parties, they did not reach agreement as to the modalities and scope of the future work of the Committee.

As a result, the SPLT negotiations were put on hold in 2006. Further developments within the SCP can be consulted under the “History” of the SCP.

This is **Exhibit "B"** to the Affidavit of Anna Hucman
sworn before me on this 27th day of July, 2016

Commissioner for taking affidavits

THE PROMISE OF THE PATENT IN CANADA AND AROUND THE WORLD*

*Richard Gold and Michael Shortt***

ABSTRACT

All states require that patents be issued for "useful" inventions only. But recent invocations in Canada surrounding the "promise of the patent" have provoked controversy both at home and within the international pharmaceutical industry, with some alleging that promises represent a novel and unjustified increase to the utility standard. This article shows that these allegations are unfounded. The promise of the patent is a long-established rule in Canadian, Australian, New Zealand, and British patent law, and one that possesses sound policy justifications. Equally, promises are recognized and enforced in various guises by the patent law of the United States, Australia, New Zealand, and the European Patent Office. We conclude the paper by examining some of the open issues and unanswered questions that exist in courts' approach to the promise of the patent.

RÉSUMÉ

Dans tous les États, les brevets ne doivent être délivrés que pour des inventions « utiles ». Toutefois, certaines allégations récentes au Canada entourant la notion de « promesse du brevet » ont suscité la controverse tant au pays qu'au sein de l'industrie pharmaceutique internationale, d'aucuns affirmant qu'elles représentent un rehaussement nouveau et injustifié de la norme d'utilité. L'article montre que ces allégations ne sont pas fondées. La promesse du brevet est une ancienne règle du droit des brevets au Canada, en Australie, en Nouvelle-Zélande et en Royaume-Uni, et cette règle y repose sur de solides justifications stratégiques. De la même manière, la notion de promesse du brevet existe sous différentes formes et est reconnue dans le droit des

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brevets des États-Unis, d'Australie, de Nouvelle-Zélande et de l'Office européen des brevets. L'article se termine par un examen de quelques questions laissées sans réponse par les tribunaux dans leur façon de traiter cette notion.

CONTENTS

1.0 INTRODUCTION

Apart from related developments in the field of sound prediction, the "promise of the patent" is probably the most controversial issue in contemporary Canadian patent law. Not only has Eli Lilly & Co. attacked it before the Supreme Court of Canada (unsuccessfully) and in a NAFTA direct investor challenge (pending),[1] but it was mentioned in a recent Priority Watch List report by the United States Trade Representative[2] and has been the subject of doctrinal criticism.[3]

Most of those who argue against enforcing promises argue that doing so is a new and unjustified addition to Canadian law, which is particularly detrimental to the pharmaceutical industry. Our research indicates that, far from being a recent Canadian innovation, the promise of the patent is a legal concept with deep historical roots and global reach. In particular, this article demonstrates that the promise of the patent is a concept with a long history in Canadian, Australian, New Zealand, and British law, and that under the laws of the United States and Europe patent applicants are held to the promises—under various names and doctrinal guises—they make in patent specifications. We also show how the promise of the patent is not, strictly speaking, an independent legal rule, but rather a corollary of the method of purposive construction for interpreting patent claims. Just as the scope of patent claim is determined from the perspective of the skilled reader, so too is the promise of the patent.

Analysis of the promise of the patent to date has been limited in two important ways, giving rise to the mistaken impression that the promise of the patent is new law or without policy justification. First, the extant literature has either missed or given insufficient attention to critical Canadian cases that developed the importance of a patent's promise in the mid- to late-20th century. Second, comparative legal analysis has been overly narrow, looking for exact equivalents within the utility criterion of other jurisdictions rather than following accepted comparative law practice of examining foreign legal systems as a whole and searching for functional equivalents to the promise of the patent. This article aims to remedy both the above issues. In so doing, it contributes to a small but growing literature on the promise of the patent.[4] In particular, it is the first to provide a rigorous comparative analysis

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1 *Eli Lilly of Canada v Novopharm* (FC) (civil) (by leave) (SCC case no 35067); *Eli Lilly v Canada*, Second Notice of Intent to submit a Claim to Arbitration under NAFTA Chapter 11 (13 July 2013), online: <www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/disp-diff/eli-02.pdf>.

2 US Trade Representative, *2013 Special 301 Report* (Washington: Office of the USTR, 2013) at 46.

3 Norman Siebrasse, "The False Doctrine of False Promise" (2013) 29:1 CIPR 3 [Siebrasse].

4 See e.g. Andrew Bernstein & Yael Bienenstock, "Unpacking the 'Promise of the Patent'" (2012) 28:2 CIPR 245; Mark Edward Davis, "Holding Patentees to Account: Utility and the Promise of the Patent" (2012) 27:2 CIPR 355; Jenna Wilson & Cristina Mihalceanu, "When a Patent's Promise Is Put to the Test" (2012) 32:9 Lawyer's Weekly 13; Fiona E Legere, "The Pitfalls of 'the Promise of the Patent'" (2013) 29:1 CIPR 57 [Legere]; Siebrasse, *supra* note 3.

of the Canadian promise of the patent in relation to that of the United States and Europe.[5]

We define a promise as "a representation contained in a patent specification, whether implicit or explicit, that the patented invention will achieve one or more desirable outcomes, or will avoid one or more undesirable outcomes." Whereas some writers refer to the promise of the patent as the "promise doctrine," we find no support for a court ever referring to it as a doctrine unto itself.[6] We thus avoid the term "promise doctrine."

This article is divided into eight sections, section 1 being the Introduction. Section 2 explains the policy goals achieved by the promise of the patent. Section 3 summarizes the current state of the law of promises in Canada. Section 4 reviews the origins of the promise of the patent in British jurisprudence of the 18th and 19th centuries, and its reception into Canada. Section 5 shows that there is no uniform international standard for patentable utility. Sections 6 and 7 conduct a comparative law analysis that demonstrates how promises play an important role in both US and European patent law, albeit under different names and rules than in Canada. Section 8 concludes the article by examining open issues and unanswered questions of the Canadian law of promises.

2.0 POLICY GOALS OF ENFORCING A PATENT'S PROMISE

Patent law represents a balancing of interests to both maximize technological innovation in the future and access innovation in the present. Given that patent litigation in Canada is overwhelmingly directed at pharmaceutical patents, Canadian patent law has been largely shaped by the need to achieve balance between the interests of brand-name pharmaceutical companies, their generic counterparts, patients, and the publicly funded health-care system. This complex balance is reflected by patent law's requirements for patentability, of which the law of utility, in general, and the particular rules surrounding a patent's promise are components.

In examining how courts have approached the issue, we have identified three goals served by enforcing a patentee's promise contained within a patent specification:

1. holding patentees to account for the public benefit they promise in exchange for the patent monopoly;

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[5] We note that an article prepared for Eli Lilly by lawyers—Jay A Erstling, Amy M Salmela & Justin N Woo, "Usefulness Varies by Country: The Utility Requirement of Patent Law in the United States, Europe and Canada" (2012) 3:1 Cybaris 1—attempts to undertake such an analysis. Unfortunately, it falls victim to the methodological shortcomings mentioned above.

[6] A search of eCarswell's Lawsource, on 19 May 2013, using the search string "patent & utility & (promise /s doctrine)" with no time limitation, identified only 8 decisions, none of which involved a patent.

2. ensuring that the patentee actually has conducted enough research and development to understand and communicate how the invention works in all its claimed instantiations; and

3. preventing double patenting, notably with respect to selection patents.

We remain, however, mindful that legal rules rarely exist in perfect isolation; thus other aspects of patent law may also contribute to achieving these same objectives.

First, the promise of the patent is a key element in ensuring that patentees actually deliver a concrete and tangible benefit to the public in exchange for their 20-year exclusivity. As the US Supreme Court has stated: "[A] patent is not a hunting licence. It is not a reward for the search, but compensation for its successful conclusion."[7] The House of Lords made a similar statement in the seminal promise case of *Hatmaker v Joseph Nathan & Co*: "In other words, [patent] protection is purchased by the promise of results. It does not, and ought not to, survive the proved failure of the promise to produce the results."[8] If a patentee claims to have successfully concluded the innovation process by promising that the invention will achieve a certain result, it would be unjust if the patentee suffered no disadvantage when it subsequently came to light that he or she did not, in fact, have a sufficient basis on which to support the promise on the filing date.

This concern is particularly important given that promises of utility made by patentees during the prosecution process may influence the grant of the patent because an impressive promise of utility is likely to persuade the examiner that the patent is non-obvious. For example, an invention that promised to cure AIDS would almost certainly be found non-obvious, because there is currently no known or obvious cure for that disease. By contrast, an invention that mitigated the symptoms or slowed the progress of AIDS, while important, might or might not be found obvious, because there are existing treatments that can achieve those goals. The fact that groundbreaking inventions are less likely to be found obvious may create temptations for patentees to over-promise on utility in order to protect their invention from obviousness challenges.

Second, because each claim in the patent must satisfy the promise, courts will strike down claims that are overly broad or include subject matter that cannot achieve the stated promise as of the filing date. This imposes good discipline on claim-drafting practices by patentees, requiring them to ensure that they do not claim subject matter that goes beyond known or soundly predicted results on that date.

Third, enforcing the promise plays a special role in preventing the abuse of selection patents in order to "evergreen" an invention. Selection patents involve claims to a compound or a small number of compounds that belong to a broader

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[7] *Brenner v Manson*, 383 US 519 at 536, 1966 US LEXIS 2907 [*Brenner* cited to US].

[8] (1919), 36 RPC 231 at 237 (HL (Eng)) [*Hatmaker*], Lord Birkenhead.

class of compounds (often numbering in the millions) that have previously been patented. A valid selection patent must promise that a "substantial advantage" will be secured (or a substantial disadvantage will be avoided) by using the selected compounds relative to the class from which they were drawn.[9] This advantage must be clearly promised in the patent itself.[10] Substantially all members of the selected class must fulfill the promise, while almost none of the remaining class compounds may possess the same advantage.[11] In other words, all selection patents must contain a promise, and this promise must be fulfilled, both by the presence of the advantage in the selected compounds and by the absence of that advantage in remaining compounds.

3.0 THE PROMISE OF THE PATENT IN CANADA

3.1 The Promissory Approach to Utility

The "promise of the patent" holds a patent claim invalid for lack of utility if the patented invention fails to achieve a promise made in the specification, even if the invention may otherwise possess a scintilla of usefulness.[12]

Consider an inventor who files a patent claiming a new type of solar power panel. In the patent description, the inventor states that this new solar panel "generates at least 20 percent more energy under cloudy conditions relative to prior art." Suppose that, for whatever reason—for example, faulty or insufficient testing data—the inventor's statement is untrue on the filing date, and the panel performs no better under cloudy conditions than do existing solar power panels. Applying the promise of the patent, Canadian courts would find this patent claim to lack utility because it failed to achieve its promise. The fact that the solar panel functions as a normal solar panel (and thus has a scintilla of utility) is irrelevant; once a patent's promise has been broken, the invention lacks utility; the fact that the invention achieves some lower level of usefulness will not save it.

3.2 Current State of the Law: Purposive Construction and a Patent's Promise

As a general matter, the Federal Court of Appeal has integrated issues relating to a patent's promise into the larger paradigm of purposive construction. This leads to four specific issues: (1) where should courts look to find the promise in the patent (3.2.1); (2) to what extent does the skilled addressee of the patent affect the interpretation of the promise (3.2.2); (3) to what extent does the nature of the patented

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[9] *Apotex v Sanofi-Synthelabo Canada*, 2008 SCC 61 at para 10, [2008] 3 SCR 265 [*Plavix* NOC], citing *Re IG Farbenindustrie AG's Patent* (1930), 47 RPC 289 (Ch Div) [*IG Farbenindustrie*].

[10] *IG Farbenindustrie*, *ibid* at 318, 320.

[11] *Plavix* NOC, *supra* note 9 at para 10.

[12] *Sanofi-Aventis v Apotex Inc*, 2013 FCA 186 at paras 47-49 [*Plavix Impeachment*].

invention affect the promise (3.2.3); and (4) how should courts deal with patents containing multiple promises (3.2.4)?

According to the Federal Court of Appeal, interpreting the promise of the patent is an aspect of construing the patent,[13] and thus courts are to approach promises by employing purposive construction:

> The promise is to be construed by the trial judge within the context of the patent as a whole, through the eyes of the POSITA [that is, the skilled reader (the person of ordinary skill in the art)] in relation to the science and information available at the time of filing. The promise of the patent is fundamental to the utility analysis.[14]

Thus, just as purposive construction aids courts in discerning the scope of a patent claim,[15] so it assists courts in determining whether a patent contains a promise and, if so, how a skilled reader would interpret that promise. In conducting their analysis, courts are to construe the patent in its entirety, examining both claims and the disclosure.[16]

Courts' use of purposive construction to identify the promise of a patent not only follows naturally from the law on purposive construction, but aligns patent law with business practice. On the first point, the Supreme Court in *Whirlpool Corp* established the centrality of purposive construction as a necessary first step prior to analysis of either patent validity or infringement.[17] Because purposive construction is necessary for the novelty and non-obviousness analysis, it would be strange indeed if it did not also underlie the utility analysis. As to the second point, the skilled reader is not just a hypothetical person conjured up to solve legal questions; the skilled reader is a reflection of the real-world readership of issued patents. Patents are commonly read and relied on by experts in the relevant field for research purposes. It is these real-life skilled readers who will rely on the promises contained in patents, and this in turn makes it sensible to interpret the promise through their eyes.

3.2.1 Location of the Promise of the Patent

Even if the promise of the patent is assessed through purposive construction and using the "patent as a whole," this still leaves open the question of how much weight should be given to the various elements of the patent: for example, claims, disclosure, abstract, and drawings.

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[13] *Apotex v ADIR*, 2009 FCA 222 at para 101 [*ADIR*]; *Plavix Impeachment*, *supra* note 12 at para 55.

[14] *Eli Lilly Canada v Novopharm*, 2010 FCA 197 at para 93 [*Eli Lilly*] (citations omitted).

[15] *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 45, [2000] 2 SCR 1067.

[16] *Metalliflex Ltd v Rodi & Wienenberger AG*, 19 Fox Pat C 49, 1959 CarswellQue 14 at paras 16-18 (Que QB (App Div)), aff'd [1961] SCR 117 [*Metalliflex*]; *Eli Lilly*, *supra* note 14 at para 93; *Feherguard Products Ltd v Rocky's of BC Leisure Ltd*, 60 CPR (3d) 512, [1995] FCJ 620 at para 19 [*Feherguard Products*].

[17] *Supra* note 15.

We can begin by stating unequivocally where the promise is *not* found: the patent's abstract.[18] The Federal Court of Appeal has held that because the promise of the patent is "an aspect of claims construction," it falls within the scope of rule 175(1) of the *Patent Rules*,[19] and thus no reference to the patent abstract is permitted. This represents an overruling of earlier cases that relied on the patent's abstract.[20]

Some cases have placed significant emphasis on the claims themselves. In a 2012 decision, Justice Zinn took the position that, absent exceptionally clear language, promises should normally be found in the claims, not in the description:

> Where that promise … is clearly and unequivocally expressed by the inventor in the claims of the patent, then that expression ought to be viewed as the promise of the patent. Any statement found elsewhere should be presumed to be a mere statement of advantage unless the inventor clearly and unequivocally states that it is part of the promised utility.[21]

While Justice Zinn's view is the most extreme example of this position, there are other cases that adopt a similar approach. For example, in *Bauer Hockey Corp v Easton Sports Canada*, Justice Gauthier stated: "It is settled law that results or advantages *included in the claims* must be met."[22] Other judges have justified focusing primarily on the claims by adopting the general rule of purposive construction that the claims have primacy over the disclosure in the interpretative process.[23] Some writers have also taken the position that only promises contained in the claims should be enforced by the courts.[24]

The majority tendency is, however, to look to the patent as a whole, including both the claims and the disclosure, in order to construe the promise.[25] As long ago

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[18] *ADIR*, *supra* note 13 at para 104, affirming on this point 2008 FC 825.

[19] *ADIR*, supra note 13 at para 105. See *Patent Rules*, SOR/96-423, r 175(1): "An application shall contain an abstract that provides technical information and that cannot be taken into account for the purpose of interpreting the scope of protection sought or obtained."

[20] See e.g. *Pfizer Canada v Canada (Minister of Health)*, 2005 FC 1205 at para 64, aff'd without discussion on this point 2007 FCA 209.

[21] *Fournier Pharma v Canada (Health)*, 2012 FC 741 at para 126.

[22] 2010 FC 361 at para 289 (emphasis added) (although most of the evidence Justice Gauthier relies on in interpreting the promise is drawn from the disclosure).

[23] *Teva Canada v Novartis AG*, 2013 FC 141 at paras 76-77 [*Novartis AG*].

[24] See e.g. Legere, *supra* note 4 at 60-61. Legere incorrectly asserts that leading British cases on the promise of the patent only enforced promises that were found in a patent's claims on the basis of a misreading of the relevant case law. The promise in *Alsop* was located in the description (*Re Alsop's Patent* (1907), 24 RPC 733 at 734, 738, 752-53 (Ch D) [*Alsop*]), as were the promises in *Hatmaker*. The promise in *Alsop* was thus derived from the description alone, while in *Hatmaker* Lord Birkenhead held that promise emerged when the claims and specification were read together (*Hatmaker*, *supra* note 8 at 236).

[25] See e.g. *Metalliflex*, *supra* note 16 at paras 16-18, aff'd [1961] SCR 117; *Amfac Foods v Irving Pulp & Paper*, 12 CPR (3d) 193, [1986] FCJ 659 (FCA) [*Amfac Foods* cited to Quicklaw]; *Pfizer*

as 1959, in a decision affirmed by the Supreme Court of Canada, the Quebec Court of Queen's Bench (Appeal Side) held that an invention's utility is to be assessed on the basis of a holistic reading of both the claims and the description:

> The answer is to be found in Fox—*Canadian Patent Law and Practice*—3rd Ed. Vol. I, p. 301:
>
> > The invention must … be useful as specified and for the purpose stated in the specifications and claims (*Von der Linde v. Brummerstaedt & Co.* (1909), 26 R.P.C. 289)
>
> As to the meaning of "utility as specified," Fox, at p. 300, borrows the following explanation from Bennett J. in *Unifloc Reagents Ltd. v. Newstead Colliery Ltd.* [1943], 60 R.P.C. 165 at 184):
>
> > If when used in accordance with the directions contained in the specifications, the promised results are obtained, the invention is useful in the sense in which that term is used in the patent law.[26]

The result of looking to the patent specification as a whole is inevitably that the disclosure will furnish most promises, because patentees are rarely required to discuss utility directly in the claims.[27] In most promise cases, the promise is found in an explicit statement in the disclosure that explains the invention's intended purpose, such as "carboxyalkyldipeptides … are useful as inhibitors of angiotensin-converting enzyme and as anti-hypertensive agents … . The compounds of this invention have useful pharmacological properties. They are useful in the treatment of high blood pressure."[28] Some courts have found implicit promises, such as an implicit promise of clinical effectiveness that is deducible from the use of phrases such as "the medicine of the patent," along with references to "effective amounts" of the drug, and the presence of dosage regimes in the patent itself.[29]

Attempts to read promises into tables of data or isolated statistics have generally proven unsuccessful. Most trial judges have rejected the idea that a table of data, without more, can give rise to a promise.[30] Where trial judges have found promises

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Canada v Canada (Minister of Health), 2008 FCA 108 [*Pfizer Canada*]; *Laboratoires Servier v Apotex*, 2008 FC 825 at para 270; *Eli Lilly*, *supra* note 14 at para 93; *Feherguard Products*, *supra* note 16 at para 19.

[26] *Metalliflex*, *supra* note 16 at paras 16-17.

[27] *Shell Oil Co v Canada (Commissioner of Patents)*, [1982] 2 SCR 536 [*Shell Oil*]; *Aventis Pharma v Apotex*, 2005 FC 1283 at para 82 [*Aventis Pharma*]; *Janssen-Ortho Inc v Novopharm Limited*, 2006 FC 1234 at para 96 [*Janssen-Ortho*].

[28] *Aventis Pharma*, *supra* note 27 at para 279.

[29] These three examples are drawn from *Apotex v Sanofi-Aventis*, 2011 FC 1486 at paras 93, 114, 116-18 [*Sanofi-Aventis*]. See, however, *Plavix Impeachment*, *supra* note 12 at para 49, which suggests that promises can only be explicit.

[30] See e.g. *Apotex v H Lundebeck A/S*, 2012 FC 192 at paras 244-53. See also *Eurocopter v Bell Helicopter Textron Canada*, 2012 FC 113 at paras 340-44 [*Eurocopter*].

based primarily on numerical tables, they have been overturned by the Federal Court of Appeal.[31] Thus far, no promise cases have been decided on the basis of drawings contained in the patent, although the drawings are occasionally discussed.[32]

3.2.2 The Importance of the Skilled Reader

Because the promise of the patent is assessed using purposive construction, the identity of the skilled reader should have a strong impact on the interpretation of the promise. Indeed, where the skilled reader of a pharmaceutical patent is or includes a practising physician or psychiatrist, courts have been more likely to find a promise of therapeutic effectiveness.[33] However, some doubt was recently cast on this conclusion by the Federal Court of Appeal in the *Plavix Impeachment* case, to which we return below.

The reason that holding the skilled reader to be a medical practitioner typically results in a finding that the promise relates to clinical or therapeutic efficacy is straightforward: the practitioner is only interested in how a drug actually acts on a patient. Thus a practitioner is likely to read a statement such as "useful in the treatment of hypertension" as a promise of clinical effectiveness because a drug that has no therapeutically useful effect in humans would not be useful to a practising physician.

This understanding of what a medical practitioner is likely to expect is best illustrated by the Federal Court of Appeal's judgment in *Eli Lilly & Co v Teva Canada Ltd*.[34] In that case, the skilled reader of the patent had been found to include psychiatrists and pediatricians, and the court made this finding a key factor in its interpretation of the patent's promise that it offered a "treatment for ADHD":

> In my view, this definition of the qualifications of the POSITA relevant to this patent, and especially the inclusion of a psychiatrist and a paediatrician, indicates that he or she would interpret the promise from the perspective of a person involved in the clinical treatment of ADHD. A POSITA would thus understand the promise to mean that atomoxetine will alleviate the symptoms of the disorder in some patients to a clinically meaningful extent. This is not to say that the promise means that clinicians will necessarily prescribe atomoxetine for their patients, because there may be more effective

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[31] *Pfizer Canada*, *supra* note 25 at paras 54-55, rev'g 2007 FC 91.

[32] See *Eurocopter*, *supra* note 30 at para 350; *Wandscheer v Sicard Ltd*, [1948] SCR 1 at 14-17, 19, Kellock J, dissenting, 1947 CanLII 27 [*Wandscheer*]. See also *Gold v Serratus Mountain Products*, 2004 FC 815 at para 53 (no relation).

[33] See e.g. *Apotex v Pfizer Canada*, 2011 FCA 236 [*Apotex*]; *Sanofi-Aventis*, *supra* note 29; *Teva Canada*, 2011 FCA 220 [*Teva Canada*]; *Pfizer Canada v Pharmascience*, 2013 FC 120. However, this rule is by no means absolute, and more modest promises have been found despite the skilled reader being a medical practitioner: *Pfizer Canada v Canada (Health)*, 2009 FC 1294, aff'd 2011 FCA 102.

[34] *Supra* note 33, aff'g 2010 FC 915.

> medicines available on the market. The promise does mean, however, that atomoxetine would be regarded by a physician as a realistic option for the treatment of ADHD.[35]

As noted above, however, this trend of giving greater voice to medical practitioners has been called into question by the Federal Court of Appeal's recent decision in *Plavix Impeachment*.[36] There, the court held that the trial judge was wrong to rely on the evidence of a clinical hematologist to find a promise of therapeutic effectiveness, because the remaining experts (all of whom were pharmaceutical formulators, rather than clinicians) did not believe that the patent promised therapeutic effectiveness in humans.[37]

3.2.3 The Importance of the Invention

As mentioned in section 3.2.1, promises can theoretically be implicit and explicit. This section examines how the nature of the invention itself will influence the interpretation of explicit promises or even lead to the recognition of implicit promises. It focuses on three areas: medicines that treat chronic diseases, selection patents, and patents for new uses of existing compounds.

Patents for medicines that treat chronic diseases have been interpreted as promising chronic treatment. This interpretation has been accepted for patents dealing with the treatment of glaucoma,[38] attention deficit hyperactivity disorder,[39] and schizophrenia.[40] However, this seems to have been a rule of general application, because in the two leading cases,[41] the Federal Court of Appeal stated the proposition in broad terms applicable to all chronic diseases or conditions.

In other words, if a medicine targets a chronic disease, and there is nothing in the specification to the contrary, it will not be enough that the medicine works only for a short time. Because the disease is a chronic, long-term condition, a claim to have found a pharmaceutical treatment has been typically interpreted as promising long-term effectiveness, although effective treatment need not last a lifetime.[42]

In its recent *Plavix Impeachment* decision, the Federal Court of Appeal cast doubt on this entire line of cases, holding that a promise exists only "if a person skilled in the art would understand [the patent] to contain an explicit promise that the invention will achieve a specific result … . If there is no explicit promise of a

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35 *Teva Canada*, *supra* note 33 at paras 22-23.

36 *Supra* note 12.

37 *Ibid* at paras 55-63.

38 *Apotex*, *supra* note 33 at paras 24-31, rev'g 2010 FC 447.

39 *Teva Canada*, *supra* note 33 at paras 18-27.

40 *Eli Lilly Canada v Novopharm*, 2011 FC 1288 at paras 230, 232.

41 *Teva Canada*, *supra* note 33; *Apotex*, *supra* note 33.

42 *Teva Canada*, *supra* note 33 at paras 26-27.

specific result, then a mere scintilla of utility will do."[43] Because the court did not overturn its previous decisions, it is unclear how clear a statement must be in order for the skilled reader to find an explicit promise.

Promises contained in selection patents have also received special consideration. The classic case of *Re IG Farbenindustrie AG's Patent* involved a selection patent over a class of compounds used to make dyes for clothing.[44] The compounds within the class had low fastness (that is, resistance to the dye leaching out of the fabric) when subjected to a process called "kier boiling." Their fastness was so low, in fact, that fabrics dyed with them could not be kier boiled at all. The selection patent at issue promised "quite excellent" fastness with respect to kier boiling. The question that arose in *IG Farbenindustrie* was whether the promise of "quite excellent" fastness referred to a *relative* improvement over the genus patent's fastness or an *absolutely* excellent fastness. Justice Maugham determined that the promise must be one of absolute excellence, pointing out that a relative improvement would be of little practical utility, because even improved fastness might still leave the dyes unable to be kier boiled given the genus patent's poor fastness.[45] Only a promise of "absolutely" excellent fastness would guarantee that the selection patent provided a substantial advantage over the genus patent.[46]

The reasoning of *IG Farbenindustrie* can be interpreted in two ways: narrowly, it stands for the proposition that a patentee must promise a substantial advantage in a selection patent; more broadly, it stands for the proposition that a patentee cannot make a promise devoid of practical utility. The broader ground, which could be called a "rule against useless promises," would explain the outcome of the Canadian chronic disease cases: a promise of treating a life-long condition for a week or a day is simply not a meaningful promise.

Similar reasoning has been adopted in Canadian selection patent cases, but faces an uncertain future after *Plavix Impeachment*. At trial, Justice Boivin had interpreted a selection patent as promising use in humans partially on the basis that the genus patent promised utility in humans, and thus the selection patent could not adopt a less-useful promise of mere *potential* use in humans.[47] The Federal Court of Appeal reversed on this point, arguing that the selection patent ought to be viewed independently of the underlying genus claims and not limited to the uses to which that genus patent were put.[48] According to the court, the patentee of a selection patent is

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[43] *Plavix Impeachment*, *supra* note 12 at para 50.

[44] *Supra* note 10. The relevant claims did not contain any promise, but merely recited the claimed chemical formulae.

[45] *Ibid* at 318, 321.

[46] *Ibid*.

[47] *Sanofi-Aventis*, *supra* note 29 at paras 169-70. See also *Glaxosmithkline v Pharmascience*, 2008 FC 593 at para 66. See also *Eurocopter*, *supra* note 30 at para 337.

[48] *Plavix Impeachment*, *supra* note 12 at para 69.

the sole author of the invention's advantages, and recourse should not be had to the genus patent.

3.2.4 Multiple Promises

Although legal and academic debate typically refers to "the" promise of the patent, there is no legal rule that limits a patent to a single promise. Canadian courts have often been willing to find multiple promises in a single patent. For example, in *Allergan v Canada (Health)*, Justice Hughes found no less than seven promises in the patent at issue, each applicable to the inventive concept of the patent as a whole.[49] In *Novartis AG*, Justice Snider found four promises in the patent, each one covering a different claim or group of claims.[50] Multi-promise patents also feature prominently in the British and Australian jurisprudence.[51]

This raises the obvious question of what to do with a patent claim in which the invention fulfills some, but not all, of the promises. The traditional British position is that a claim that does not fulfill *all* of its promises is void.[52] In *Hatmaker*, the patented process fulfilled its first promise—namely, to create dried milk of "excellent quality."[53] However, the House of Lords found that it failed to achieve its second promise—namely, that the milk would be transformed into a "dry but otherwise unaltered condition," because experiments showed that the casein proteins in the milk were altered by the evaporation process, and the lipids in the milk would separate into a fatty layer if the reconstituted milk were allowed to stand.[54] Having failed one of its two promises, the patent was void. The ruling in *Alsop* is to the same effect: the patented process was successful in bleaching flour, but failed to either increase the protein content of the flour or decrease its carbohydrate content.[55] Failure to achieve the latter two promises voided the patent.[56]

The Canadian position on multipromise patents is less clear. To date, the question has not been explicitly raised, and thus has not been explicitly answered. However, the Canadian Intellectual Property Office takes the position that all promises appearing in a patent must be fulfilled.[57] We return to the issue of multiple promises in Canadian law in section 8.0, Conclusion.

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[49] 2012 FC 767 at para 114 [*Allergan*], rev'd on other grounds 2012 FCA 308.

[50] *Novartis AG*, *supra* note 23 at para 194.

[51] See e.g. *Alsop*, *supra* note 24; *Hatmaker*, *supra* note 8; *Pracdes Pty Ltd v Stanilite Electroncis Pty Ltd* (1995), 35 IPR 259 at 273-75 (Sup Ct NSW) [*Pracdes*].

[52] *Alsop*, *supra* note 24; *Hatmaker*, *supra* note 8.

[53] *Hatmaker*, *ibid* at 238.

[54] *Ibid* at 239.

[55] *Alsop*, *supra* note 24 at 754.

[56] *Ibid* at 754-55.

[57] Canadian Intellectual Property Office (CIPO), *Manual of Patent Office Practice* (Ottawa: CIPO, 2009) at 12.08.01, online: CIPO <www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03153.html> [MPOP].

4.0 THE ORIGINS OF THE PROMISE OF THE PATENT IN BRITISH AND CANADIAN LAW

This section discusses the origins of the patent's promise in British and Canadian law, including both the key jurisprudence and the legal and policy justifications that judges provided for their rulings.

4.1 British Origins

We focus on British law prior to 1977, because the *Patents Act, 1977*[58] removed any reference to "utility" from the statute, substituting the concept of "industrial application" in order to bring UK law into compliance with the *European Patent Convention*.[59] Thus, while British jurisprudence rendered under the pre-1977 Patent Acts is relevant to the Canadian law relating to promises, developments since 1977 are not.

The law surrounding a patent's promise in the United Kingdom emerged as an outgrowth of the rule that the patentee could not receive a patent on the basis of false representations.[60] The importance of the patentee's representations (as contained in the specification) related to the discretionary nature of patent grants in early British patent law.[61] Because the Crown exercised its discretion to grant a patent on the basis of the representations contained in the patent itself, any patent that issued on the basis of misrepresentations was void because the Crown had been deceived in the exercise of its discretion.[62] A single material misrepresentation (that is, a single failed promise) would suffice to invalidate a patent, because British courts refused to second-guess whether the Crown would have exercised its discretion to grant a patent that achieved less than the applicant had promised in the specification.[63]

According to Siebrasse's analysis, because the requirement that a patent fulfill its promise derives from the deception of the Crown, it is rooted in the discretionary prerogative power on which the British patent system depended at the time. Given that Canada's patent law does not depend on discretion, Siebrasse argues that the promise cases should not have been applied by Canadian courts. Siebrasse's history of the promissory approach to utility suggests that it amounts to no more than a technical legal rule with little, if any, policy justification.

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58 (UK), c 37.

59 *Convention on the Grant of European Patents*, 1065 UNTS 199 (5 October 1973), subsequently revised in 1991 (*Act revising the Convention on the Grant of European Patents*, reprinted in (1992) OJEPO 1) and 2000 (*European Patent Convention (2000)*, reprinted in (2007) OJEPO Special Edition 3) [collectively, the EPC].

60 Siebrasse, *supra* note 3 at 9-13.

61 *Ibid* at 14-17.

62 *Ibid* at 11-12.

63 *Ibid* at 16-17.

Our review of the British authorities reveals a broader legal policy justification for the law surrounding a patent's promise: avoidance of restraint of trade and deception of the *public*, rather than simply deception of the *Crown*. One of the oldest promise cases is *Turner v Winter*, a case that concerned a process patent for the production of "white lead" and two other compounds.[64] The Court of King's Bench found that the patented process failed to produce white lead and also that the patentee had included unnecessary steps and ingredients in the disclosure of the process.

Justice Ashurst delivered the first judgment of the case, and focused on the interplay between the promise of the patent, deception of the public, and the doctrine of restraint of trade:

> I think that, as every patent is calculated to give a monopoly to the patentee, it is so far against the principles of law, and would be a reason against it, were it not for the advantages which the public derive from the communication of the invention after the expiration of the time for which the patent is granted. It is therefore incumbent on the patentee to give a specification of the invention in the clearest and most unequivocal terms of which the subject is capable. And if it appears that there is any unnecessary ambiguity affectedly introduced into the specification or *any thing which tends to mislead the public, in that case the patent is void*. …
>
> But in truth the patent is for making white lead and two other things by one process. Therefore, if the process, as directed by the specification, *does not produce that which the patent professes to do, the patent itself is void*.[65]

According to Justice Ashurst, all patents are presumptively void at common law as restraints of trade, and they are saved only by the benefit that they confer on the public through the disclosure of a useful invention. Thus, a flawed and misleading disclosure, including one that contains false promises, will negate the benefit to the public and lead to the invalidity of the patent as a whole. This is a policy-driven justification for the promise theory that does not depend on deception of the *Crown*, but rather on deception of the *public*. The patent at issue was invalidated for failure to fulfill the promise of making white lead, even though it could be used to produce the other substances claimed.

Justice Buller concurred in *Winter*, and similarly delivered a judgment based in part on deception of the public and restraint of trade, although his reasons focused on the inclusion of unnecessary materials and superfluous steps in the disclosure.[66]

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[64] (1787), 99 ER 1274, 1 TR 602 (KB) [*Winter* cited to ER]. *Winter* appears to be the oldest case that invalidated a patent on the basis of an unfulfilled promise. Siebrasse identifies *Morgan v Seaward* (1836), 1 WPC 187 (Ex Ct) as the first promise case (*Siebrasse*, *supra* note 3 at 12). While *Seaward* is a clear example of courts enforcing the patent's promise, *Winter* seems to be an older authority for the rule. Another case that predates *Seaward* is *Bloxam v Elsee*, [1827] EngR 269, 172 ER 293 [*Bloxam*], where failure to fulfill a promise was the sole ground on which a patent for a paper-making machine was invalidated.

[65] *Winter*, *supra* note 64 at 1276, Ashurst J (emphasis added).

[66] *Ibid* at 1277, Buller J.

Justice Buller also discussed the failure of the invention to produce white lead under the classic deception of the Crown theory.[67]

Winter shows that a doctrinal concern over deception of the Crown was not the sole justification offered to support the legal requirement that a patent fulfill its promise in early British patent law. *Winter* also demonstrates a concern for policy, in particular the need to protect the public from misrepresentations contained in the patent, and the need to hold patentees to account for the claims they make in their patents. These are broad public policy concerns the relevance of which is universal and not limited to the fact that, at that time, Britain had a discretionary patent system.

Despite *Winter*'s focus on restraint of trade and deception of the public, deception of the Crown remained the predominant explanation for the promise theory in British law for many years. The leading case of *Re Alsop's Patent*, in particular, justified the promissory approach on this basis.[68] However, *Hatmaker*, which is the earliest House of Lords decision on the promissory approach, did not rely on deception of the Crown. Instead, the House of Lords treated the promise of the patent as a freestanding legal rule.[69] Indeed, Lord Parmoor's concurrence explicitly stated that there had been no deception of the Crown, but he nonetheless invalidated the patent for failure to fulfill its promise.[70]

That the House of Lords did not rely on deception of the Crown is unsurprising, because the theoretical justification for the deception theory was the discretionary nature of patent grants and the United Kingdom had switched to a non-discretionary patent system in mid-19th century. After the adoption of the *Patent Law Amendment Act, 1852*,[71] and, certainly, the *Patents, Designs, and Trade Marks Act, 1883*,[72] patents became available as of right. Thus the deception of the Crown theory, based as it was on the discretionary nature of pre-1852 patent grants, could no longer

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[67] *Ibid*.

[68] *Alsop*, *supra* note 24.

[69] *Hatmaker*, *supra* note 8 at 236-37, Lord Birkenhead (for himself and three other judges), 239, Lord Parmoor (concurring).

[70] *Ibid* at 239, lines 27-34 (setting out the deception of the Crown approach and stating that it does not apply), lines 35-47 (invalidating the patent for failure to fulfill its promise).

[71] (UK), 15 & 16 Vict, c 83, ss 8-9, 16 (although s 16 preserved the prerogative power of the Crown to grant or deny letters patent, this power was no longer the source of patent rights; the Crown could merely use its prerogative in reaction to administrative decisions by the Patent Commissioners to issue or not issue patents). See also Brad Sherman & Lionel Bently, *The Making of Modern Intellectual Property Law* (Cambridge: Cambridge University Press, 2002) at 134.

[72] (UK), 46 & 47 Vict, c 57, s 116. This Act removed any residual discretion from British patent law. Although both this Act and the subsequent revision in 1907 (*Patents and Designs Act, 1907* (UK) 7 Edw 7, c 29) stated that the Act not abridge the prerogative of the Crown in relation to the granting of letters patent, this applied to the grant of letters patent outside the field of patent law. This was made most explicit in the 1907 Act, where the savings provision in s 97 related to "letters patent," but the Act as a whole related to the "patents," which were defined in s 93 as "letters patent for an invention." Letters patent have applications, of course, far beyond patent law (see generally Siebrasse, *supra* note 3).

serve as the primary justification for the promissory approach. This reality was recognized by the House of Lords in *Hatmaker* and the line of cases that followed it under the post-1852 Patent Acts.

Although some confusion over the origins of the promissory approach persisted in British jurisprudence,[73] it is incorrect to say that the promise of the patent depends on the exercise of Crown discretion. In *Hatmaker*, the House of Lords applied the promise theory as a freestanding and self-justifying legal rule. In sum, not only does the promise doctrine achieve cogent policy goals, but it also has legal justifications that go beyond those peculiar to the British patent system in the 18th and 19th centuries.

The promise of the patent is routinely enforced in Commonwealth countries whose patent systems are derived from the United Kingdom. Australian case law recognizes that utility is determined by reference to the promise of the patent: " 'Inutility' means that the invention as claimed in the patent does not attain the result promised for it by the patentee."[74] Although Australian law also invalidates patents based on deception of the Crown, this is considered a separate ground of invalidity from lack of utility owing to a failed promise.[75] Accordingly, Australian courts have invalidated patents over inventions that fail to achieve their promise despite having some level of utility.[76] New Zealand case law is to similar effect: "So where the patentee promises (expressly or impliedly) the attainment of a certain result and this is not obtained, or what is stated as the main object of the invention is not obtained, the patent will be invalid."[77] Recent amendments to Australia's *Patent Act* (and similar proposed changes in New Zealand) have shifted it toward a US-style approach to utility,[78] but these changes are unlikely to affect the promise of the patent.

4.2 Canadian Origins

The Supreme Court of Canada's most cited endorsement of the promissory approach to utility is *Consolboard v MacMillan Bloedel (Saskatchewan) Ltd*,[79] in which Justice Dickson wrote for a unanimous court:

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[73] See e.g. *American Cyanamid v Ethicon Ltd*, [1979] RPC 215 (Ch D); *IG Farbenindustrie*, *supra* note 9.

[74] *Décor Corporation Pty Ltd v Dart Industries Inc* (1988), 13 IPR 385 at 394 (FC (Gen Div) (Austl)); *Rehm Pty Ltd v Webster's Security Systems (International) Pty Ltd* (1988), 11 IPR 289 (FC (Austl)).

[75] *Nesbit Evan Group Australia Pty Ltd v Impro Ltd* (1997), 39 IPR 56 at 96-99 (FC (Gen Div) (Austl)).

[76] *Pracdes*, *supra* note 51 (patent for improved control circuit for gas discharge lamps invalidated because the circuit fulfilled only five of six promised improvements over the prior art).

[77] *Hammar Maskin AB v Steelbro New Zealand Limited* [2010] NZCA 83 at para 76 (citation omitted).

[78] *Patents Act 1990*, 1990 No 83, s 7A, as amended by *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*, 2012, No 35. The *Raising the Bar Act* implements the *US–Australia Free Trade Agreement*, 43 ILM 1248, art 17.9(13) (18 May 2004).

[79] [1981] 1 SCR 504, 1981 CanLII 15 [*Consolboard*].

> In my respectful opinion the Federal Court of Appeal erred also in holding that s. 36(1) requires distinct indication of the real utility of the invention in question. There is a helpful discussion in Halsbury's Laws of England (3rd ed.), vol. 29, at p. 59, on the meaning of "not useful" in patent law. *It means "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do.*" There is no suggestion here that the invention will not give the result promised. The discussion in Halsbury's Laws of England, ibid., continues:
>
> > … the practical usefulness of the invention does not matter, nor does its commercial utility, unless the specification promises commercial utility, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested. [Footnotes omitted.]
>
> and concludes:
>
> > … it is sufficient utility to support a patent that the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice. [Footnotes omitted.]
>
> Canadian law is to the same effect.[80]

Relying on the emphasized passage above, most Canadian courts cite *Consolboard* for the definition of utility in Canadian patent law. This definition has two components. First, where the patent document itself makes no promise of utility, a mere "scintilla of utility" will suffice; this requirement has normally been interpreted as merely requiring that the invention produce some minimally useful result. Second, where the patentee makes a promise, the patent will have utility only if it fulfills that promise, and regardless of whether it does possess a scintilla of utility. Understanding this bifurcated structure is crucial: writers who characterize the *Consolboard* standard as a "very low threshold"[81] overlook its endorsement of the promise of the patent.

Despite its frequent citation, *Consolboard* was not the first time the Supreme Court considered a patent's promise. In *Wandscheer v Sicard Ltd*, a majority of the court explicitly defined "utility" from a promissory perspective. Justice Taschereau, for two of the three judges in the majority, wrote: "[The invention] had no usefulness and was not workable. It could not do what it was intended to do, and *could not serve the purposes mentioned in the patent*."[82] *Wandscheer* concerned a snow blower with a tendency to "choke" on heavy snow. The promissory approach was crucial in the court's determination of invalidity, because there was some evidence that the machine was useful in light snow conditions even though it did not meet its promise of working in all winter conditions. Indeed, Justice Estey's dissent was

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[80] *Ibid* at 525 (emphasis added).

[81] Legere, *supra* note 4 at 61.

[82] *Wandscheer*, *supra* note 32 at 5.

based primarily on the machine's operability in light, dry snow conditions (in other words, that it possessed a scintilla of utility).[83]

The case that introduced the precise phrase "the promise of the patent" into Canadian law is the 1961 decision of *New Process Screw Corp v PL Robertson Manufacturing Co* rendered by President Thorson of the Exchequer Court.[84] In addition to the distinguished President Thorson, Harold Fox acted successfully for the defendant, relying in part on the promise theory of utility. The patent in *New Process Screw Corp* concerned improvements to the methods and machines used in the making of screws.[85] In particular, the patent promised that the process it disclosed could manufacture many sizes of screw depending on the "pitch angle" used in the machine, ranging from a No 2 double-threaded screw at 12 degrees, to a No 18 double-threaded screw at 22 degrees.[86]

However, cross-examinations revealed that the plaintiff's employees never actually used the angles disclosed in the patent. The inventor even admitted that if someone attempted to produce a No 18 screw using a pitch angle of 22 degrees, the resulting screw would be "rough and not a good commercial product."[87] For President Thorson, the admission was conclusive: "This statement was enough in itself to destroy the patent … *there was a failure of the promise of the patent which was fatal to it*."[88] But the admission was not the only evidence before President Thorson: more damning still was an experiment by the defendant showing that a 12-degree pitch would roll a *single*-threaded screw, and that a 22-degree pitch would roll a *triple*-threaded screw, rather than the promised double-threaded screw in each case.[89] Thus even though the machine was capable of producing workable screws, it

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83 *Ibid* at 24, Estey J, dissenting.

84 39 CPR 31, 1961 CarswellNat 40 (Ex Ct) [*New Process Screw* cited to CarswellNat].

85 Claim 1 of patent 477,665 reads in relevant part:

> A pair of relatively movable screw thread rolling dies capable of only rolling double threads … extending obliquely thereof at a pitch angle varying from substantially 12° for a No. 2 screw to substantially 22° for a No. 18 screw of progressively decreasing depth and width along the length thereof and with successive groove means of progressively decreasing relative depth and width throughout the length of the cavity, … so that their entire faces remain at a spaced distance from each other with their groove means oppositely inclined to roll by axial and radial extrusion double screw threads on a screw blank rolled between them with similar portions of similar grooves in each die continuously opposite similar portions of respective oppositely inclined grooves in the opposite die along the respective successive lines of contact of said dies with said screw blank.

86 The promise was also contained in the description, *ibid* at para 38.

87 *Ibid* at para 39.

88 *Ibid*.

89 *Ibid* ("Only a further brief comment need be made. In *claims 1 and 3* there was a specific reference to the use of dies with a 12° pitch angle for a No. 2 screw and a 22° pitch angle for a No. 18 screw. The screws produced by the use of such dies would not be operative for the purpose for which they were intended and the claims would be invalid for lack of utility in the invention purported to be defined by them." By contrast, claims 2, 4, and 5 were invalid owing to insufficient disclosure.)

failed to create the types of screws promised in the patent.[90] Although this might seem to raise a sufficient description issue, President Thorson discussed sufficient disclosure issues separately, and only after invalidating the patent for lack of utility.[91] The promissory reasoning in *New Process Screw Corp* is thus entirely utility-based, without any appeal to sufficient disclosure or misleading the Patent Office.

Siebrasse reads *New Process Screw* very differently. In his view, the utility standard applied by the court was the scintilla standard, and the promissory language was mere verbiage.[92] We do not see how the promissory aspects of the judgment can be dismissed so easily. The apparatus in *New Process Screw* could make screws, which would normally qualify as the scintilla of utility necessary to support a patent, because commercial utility is not the required standard in patent law. Nor would the screw rolled at a 12-degree pitch lack utility simply by virtue of being single-threaded. The fact that the patented machine could operate as a screw-making device makes it difficult to understand how the invention could lack utility without taking seriously President Thorson's invocation of the "promise of the patent." The better reading of *New Process Screw* is that it fully embraced the importance of promise contained in the patent specification.

Another important promise case was *Amfac Foods v Irving Pulp and Paper*, a 1986 decision by the Federal Court of Appeal.[93] The patent litigated in *Amfac* concerned a machine that sliced the centre of a potato into french fries, while diverting the outside sections of the potato to other uses. The Court of Appeal began by noting that the specification must be construed as a whole when determining the promise of the patent.[94] After undertaking purposive construction of the patent, the Federal Court of Appeal determined that the promise of the patent was to "maximize the long uniform center cuts and eliminate or minimize the presence of outside cuts of potatoes in the processing of frozen french fried potatoes."[95] Claim 16, the crucial claim of the patent,[96] was held invalid for failure to fulfill the promise:

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[90] *Ibid* at paras 12, 39. In this respect the patent resembles the paper-making machine in *Bloxam*, *supra* note 64.

[91] *Ibid* at para 39.

[92] Siebrasse, *supra* note 3 at 8-9.

[93] *Amfac Foods*, *supra* note 25.

[94] *Ibid* at paras 12, 17.

[95] *Ibid* at para 20.

[96] Claim 16 read as follows:

> In a system for the cutting of vegetable products into sections, a hydraulic food pump, a product cutter, said pump being arranged to continuously and sequentially feed said products through said product cutter at relatively high speed, said cutter comprising a plurality of cutter blades arranged in spaced relation with their cutting edges lying in planes normal to the longitudinal axis of said cutters, said cutter blades being arranged in two sets, the cutting edges in the one set being at right angles to the cutting edges in the other set, each of said sets being disposed symmetrically with respect to said axis, the outer faces of said blades being inclined outwardly with respect to said axis in the direction of product feed,

> *The device claimed in Claim 16 will not produce the promised result* since no reference is made to the essential outer slabbing blades and the separation of such outer slabs at the cutter. Therefore, applying the principles derived from the foregoing jurisprudence, it is clear that Claim 16 is broader than the invention disclosed and was properly held to be invalid by Strayer J.[97]

The Federal Court of Appeal's reasoning is explicable only via the promissory approach to utility, because the device claimed by Claim 16 could still slice french fries, and thus possessed a scintilla of utility. It was the failure of the device to go beyond a mere scintilla of utility and to actually fulfill the promise of the patent that rendered Claim 16 invalid.

The cases above demonstrate that the promise of the patent was present in Canadian law as early as 1947 at the Supreme Court level. Clear applications of the doctrine can be seen in *New Process Screw* and *Amfac Foods*, by federal court judges with considerable expertise in intellectual property law. But these are by no means the only cases that invoked or relied on promises.[98]

At this point it is useful to revisit *Consolboard* and assess its authority in light of the decided cases. Siebrasse argues that *Consolboard* is "very weak authority" because the promise of the patent was "not a live issue" in the litigation.[99] This interpretation is not in line with the Supreme Court's explanation that lower courts should apply a previous Supreme Court precedent that might technically be considered *obiter* if it was "obviously intended for guidance."[100] Although it is true that the main issue in *Consolboard* concerned the *disclosure* of utility, this does not mean that lower courts are free to ignore or trivialize the *definition* of utility underlying the Supreme Court's analysis in the case. The definition of utility is obviously closely related to the issue of whether utility must be disclosed in the patent. In fact, until one has decided what "utility" is, it is difficult to see how one can decide whether it needs to be disclosed in the patent. Thus, even if lack of utility was not a pleaded ground of invalidity in *Consolboard*, the definition of utility nonetheless constituted a fundamental aspect of the Supreme Court's ruling.

Based on our review of the 20th-century patent jurisprudence, we conclude that, for at least the past 60 years, Canadian law has held a patent invalid if the skilled

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> and the inner faces of said blades being substantially parallel to said axis. ("Vegetable Slicing Apparatus" Can Patent No 773,884 (19 December 1967)).

97 *Amfac Foods*, *supra* note 25 at para 35.

98 See also *Wellcome Foundation v Apotex*, 60 CPR (3d) 135, [1995] FCJ 226 at para 46 (CA); *Mobil Oil Corp v Hercules Canada*, 57 CPR (3d) 488, [1994] FCJ 1391 (TD), rev'd on other grounds [1995] FCJ 1243 (CA); *Corning Glass Works v Canada Wire & Cable*, [1984] FCJ 353 (TD) (interestingly, the promise standard was mentioned, but the result seems to have been dictated by the scintilla standard); *Wandscheer v Sicard Ltd* (1944), [1946] Ex CR 112 at para 24, aff'd *Wandscheer*, *supra* note 32.

99 Siebrasse, *supra* note 3 at 23, 26.

100 *R v Henry*, 2005 SCC 76 at para 57, [2005] 3 SCR 609.

reader, looking at the specification as a whole, would find that the patent promised a certain utility that the patentee did not possess on the filing date.

5.0 LACK OF INTERNATIONAL STANDARDS ON UTILITY OR INDUSTRIAL APPLICABILITY

The previous two sections of this article have established that the promise of the patent is not a new idea in any of Canadian (pre-1977), British, or Australian law. This section and the sections that follow demonstrate that promises are not unique to this patent tradition. In fact, promises are an integral part of US and European patent law. This does not mean that all jurisdictions come to the same outcomes on particular cases involving litigation of the same patent: differences in evidence, procedure, the skill of counsel, and the appreciation of the evidence by the trial judge often result in different outcomes across jurisdictions. Nevertheless, the general trend across Canada, the United States, and Europe is to take promises seriously and to hold patentees to them.

5.1 International Trade Agreements Do Not Specify Substantive Patent Content

Article 27.1 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS)[101] mandates that every state impose either a utility or an industrial applicability requirement. However, neither TRIPS nor any other agreement attempts to set out the *substantive content* of these requirements.

Given the lack of explicit substantive rules for the utility requirement, it becomes impossible to argue that TRIPS also contains an implicit or indirect regulation of the utility standard. The basic rule for interpreting TRIPS is established in article 1.1, which states:

> Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. *Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.*[102]

This hands-off attitude to the rights of member states to implement TRIPS as they deem best is reinforced by article 19.2 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (DSU), which states that "in their findings

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[101] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, being Annex 1C of the *Marrakesh Agreement Establishing the World Trade Organization*, 1869 UNTS 299, 33 ILM 1197, art 27.1 [TRIPS].

[102] *Ibid*, art 1.1 (emphasis added).

and recommendations, the panel and Appellate Body cannot add to or diminish the rights and obligations provided in the covered agreements."[103]

The narrow approach to understanding the impact of TRIPS on substantive patent law was confirmed by the WTO's Appellate Body in the *India Mailbox Case* in which it chastised the original panel for reading in obligations not clearly specified in TRIPS regarding patents. The Appellate Body stated that TRIPS article 1.1 and the DSU article 19.2 "speak for themselves" and it was inappropriate for either the panel or the Appellate Body to broaden TRIPS protection in order to take into account "the legitimate expectations of Members *and* private rights holders."[104] Subsequent decisions of dispute resolution panels have similarly pointed to the freedom of WTO member states outside the *explicit* obligations within TRIPS.[105]

Moreover, the use of two legal concepts (utility and industrial applicability) drawn from two very different legal traditions is strong evidence that TRIPS did not intend to legislate a global standard for patentable utility:

> From their inclusion as alternatives in TRIPS, it may be supposed that the two concepts are related, but not necessarily that they are … identical. All that can be deduced with certainty is that the deliberate inclusion of these two alternatives precludes any inference that the draftsmen of TRIPS intended to incorporate by reference or implication any single existing standard of patentability, whether national or regional.[106]

Thus, beyond the requirement that a state's patent laws must contain a utility or industrial applicability requirement, the existing global intellectual property regime does not impose a uniform standard as to the substantive content of the two requirements.

5.2 Absence of International Norms Relating to Substantive Patent Content

Beyond the absence of formal law requiring any level of harmonization of the substantive contents of the novelty, non-obviousness/inventive step and utility/industrial applicability requirements, there are similarly no informal norms as to those contents. In fact, there are at least two competing systems to patent law: (1) the novelty,

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[103] *Understanding on Rules and Procedures Governing the Settlement of Disputes*, 15 April 1994, being Annex 2 of the *Marrakesh Agreement Establishing the World Trade Organization*, 1869 UNTS 299, 33 ILM 1197, reprinted in *The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations* (Cambridge: Cambridge University Press, 1999) [DSU].

[104] Appellate Body, *India: Patent Protection for Pharmaceutical and Agricultural Chemical Products* (1997) WT/DS50/AB/R at paras 47-48 (emphasis in original).

[105] See e.g. Panel Report, *China: Measures Affecting the Protection and Enforcement of Intellectual Property Rights* (2009) WT/DS362/R at para 7.513.

[106] Christopher Wadlow, "Utility and Industrial Applicability" in Toshiko Takenaka, ed, *Patent Law and Theory: A Handbook of Contemporary Research* (Cheltenham, UK: Edward Elgar, 2008).

non-obviounsess, and utility approach used in Anglo-Canadian-American law (although only to 1977 in Britain); and (2) the technical problem, novelty, inventive step, and industrial applicability approach in most of the rest of the world. Although, in their totality, both approaches address fundamentally the same issues, they do so differently and under different guises. Thus, notwithstanding the fact that trade agreements may suggest the similarity of industrial application and utility, for example, problems and issues addressed in one system may actually be dealt with through one of the other criteria in the other system.

The World Trade Organization, the World Intellectual Property Organization, and the World Health Organization recently concluded in a joint report that "*there is no agreed international understanding about the definition and interpretation of these [including utility/industrial applicability] criteria*."[107] Scholars of international trade and intellectual property law have echoed this conclusion.[108]

In fact, it was the very lack of uniform rules on substantive patent law (including utility and industrial applicability) that led states to begin negotiation of the *Substantive Patent Law Treaty* (SPLT). As Reichman and Cooper Dreyfus note, there had been hope that the SPLT could lead to the type of harmonization that previous instruments had not: "Ideally, member states would agree to adopt identical rules concerning what constitutes a novel and useful invention, when a technical advance meets the requirement for an 'inventive step' (non-obviousness), and how much information must be revealed by the patent disclosure."[109] Because of discordant views among participating states, the attempt at harmonization through the SPLT was ultimately shelved in 2006.[110]

Thus, not only do international agreements, including TRIPS, *not* establish any international norm on the substantive criteria of patent law, but the sole attempt to create such norms failed owing to divergent views on the contents of those criteria.

5.3 The Need for Holistic Comparative Law Analysis

The literature reveals relatively little rigorous comparative analysis of patent law.[111] It is therefore useful to briefly review how such an analysis would proceed. First,

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[107] World Health Organization, World Intellectual Property Organization & World Trade Organization, *Promoting Access to Medical Innovation and Technology: Intersections Between Health, Intellectual Property and Trade* (Geneva: World Trade Organization, 2012) at 57 [emphasis added].

[108] See e.g. Jerome H Reichman & Rochelle Cooper Dreyfuss, "Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty" (2007) 57 Duke LJ 85 at 89; Michael N Meller, "Principles of Patentability and Some Other Basics for a Global Patent System" (2001) 83 JPTOS 359 at 359.

[109] Reichman & Dreyfuss, *supra* note 108 at 89-90.

[110] See World Intellectual Property Organization, "Draft Substantive Patent Law Treaty," online: WIPO <http://www.wipo.int/patent-law/en/draft_splt.htm>.

[111] One of the few exceptions is the oft-cited Kelvin W Willoughby, "How Much Does Technology Really Matter in Patent Law? A Comparative Analysis of Doctrines of Appropriate Patentable Subject Matter in American and European Patent Law" (2009) 18 Fed Cir BJ 63 at 121.

one must be careful not to examine legal rules in isolation from the broader system in which they operate because one would miss the subtle compromises and countervailing forces that exist in every legal system. Any comparative discussion of the common law requirement that a contract be supported by consideration would be incomplete unless it also addressed promissory estoppel and sealed documents (for the Anglo-Canadian legal systems), detrimental reliance (for the United States), as well as various equitable doctrines applicable to a failure of consideration (for example, equitable estoppel and resulting and constructive trusts). In other words, one must take a holistic approach to comparing law in order to avoid distorting one's analysis.[112] One must not simply look at whether a given system uses the word "promise" or how it employs a concept called "utility," because different legal systems may achieve similar results using different legal concepts, or the same concept under a different label. The key to a rigorous comparative patent law analysis is an investigation of functionally equivalent legal rules.

This holistic and functional approach can be seen in the Supreme Court of Canada's jurisprudence dealing with the application of common law rules in Quebec. In *Globe and Mail v Canada (Attorney General)*,[113] the court carefully considered how the common and civil law rules of evidence are intertwined in Quebec in order to determine the applicability of the Wigmore doctrine in that province. Similarly, in *Prud'homme v Prud'homme*,[114] the court was careful to note the differences between the civil and common law with respect to defamation, and opted for an approach that reconciled public-law common-law defences to defamation with a foundation of private-law civil-law liability rules. The Supreme Court's jurisprudence on comparative civil and common law issues demonstrates the importance of comparing legal systems as a whole, rather than isolating and transplanting individual legal rules.

Similarly, one must also be careful to compare *rules*, and not merely the *result of litigation* involving the same (or similar) patents in different jurisdictions. The Federal Court of Appeal stated in *Re Amazon.com Inc* that "it would not be helpful in the disposition of this appeal to attempt to explain the results of Amazon's patent applications in other jurisdictions. It is enough to say that every jurisdiction has its own patent laws and administrative practices, and they are inconsistent with one another in important respects."[115] Beyond differences in patent law, it is particularly dangerous to compare the results of trials decided under different procedures and with different facts and witnesses. This was noted by Lord Hoffmann in *Conor*

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[112] Catherine Valcke, "Comparative History and the Internal View of French, German, and English Private Law" (2006) 19 Can JL & Juris 133; Ralf Michaels, "The Functional Method of Comparative Law" in *The Oxford Handbook of Comparative Law*, Mathias Reimann & Reinhard Zimmermann, eds (Oxford: Oxford University Press, 2006) 339.

[113] 2010 SCC 41, [2010] 2 SCR 592.

[114] 2002 SCC 85, [2002] 4 SCR 663.

[115] 2011 FCA 328 at para 16. See also *Apotex v H Lundebeck A/S*, 2013 FC 192 at para 65.

Medsystems v Angiotech Pharmaceuticals when he concluded: "It is therefore inevitable that [different courts] will occasionally give inconsistent decisions about the same patent. Sometimes this is because the evidence is different."[116]

Taking a holistic approach when comparing national laws is particularly important with respect to the substantive criteria of patentability, which are well-known to be deeply interconnected. The WIPO Standing Committee on the Law of Patents explicitly recognized this in 2001: "Therefore, for the purposes of full harmonization of substantive patent law, the industrial applicability/utility requirement cannot be considered separately from other requirements."[117] Indeed, as US law illustrates, there are deep links between utility and other patent law concepts.

6.0 THE AMERICAN LAW OF PROMISES

6.1 Utility in US Patent Law

This section begins by setting out some general propositions about the US law of utility, in order to provide the necessary context for a discussion of promises in US patent law.[118] These general propositions are: (1) the utility analysis in the United States can be conceptually divided into two steps, which we can call utility and operativeness, respectively; (2) despite the constitutional status of utility in US patent law, several evidentiary doctrines discourage US litigants from raising inutility arguments; and (3) in order to avoid those difficulties, many litigants prefer to reframe utility issues and plead them as failures of "enablement," with the result that the doctrine of enablement does much of the work handled by utility in Canada.[119]

6.1.1 A Bifurcated Concept of Utility

Both in theory and in practice,[120] the US concept of utility can be subdivided into two distinct concepts or stages of analysis. This bifurcated structure is important to un-

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116 [2008] UKHL 49 at para 3.

117 WIPO Standing Committee on the Law of Patents, "The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws" (2001) SPC5/Inf at para 24.

118 We leave aside other rules in US patent law that may generally serve some of the same functions as does the Canadian promise of the patent, such as ensuring that patent applicants fully possess the invention on the date of filing. The development of the non-obviousness criterion following the decision of the US Supreme Court in *KSR International v Teleflex*, 550 US 398 (2007) in relation to mechanical patents is a case in point. If the more recent decision applying that criterion in relation to the pharmaceutical sector is upheld in an eventual appeal of *Bristol-Myers Squibb Company v Teva Pharmaceuticals USA*, 2013 WL 509152 (D Del), it would represent a significant change to existing practice.

119 Our review of US jurisprudence includes cases from both the Court of Customs and Patent Appeals (CCPA) and its successor, the Federal Circuit. The Federal Circuit explicitly adopted all precedents rendered by the CCPA in *South Corp v United States*, 690 F 2d 1368 at 1369, 1370-71 (Fed Cir 1982) (en banc hearing).

120 *Process Control Corporation v Hydreclaim Corporation*, 190 F 3d 1350 at 1358 (CAFC 1999) [*Hydreclaim*], rehearing denied 1999 US App LEXIS 31878, cert denied 2000 US LEXIS 2216.

derstand, because each concept fulfills different purposes and requires judges to ask different questions. Reflecting the usage of the jurisprudence, we call these stages "utility" and "operativeness," respectively.

The utility concept is used to ask the question "does the invention have a use" or "what can you do with the invention?" Any purported use must meet the threshold test imposed by US patent law. An invention has utility if it offers "a significant and presently available benefit to the public."[121] Classic examples of patents lacking utility are patents over inventions that are physically impossible,[122] patents for substances with no known use,[123] and inventions that, without being physically impossible, are highly implausible in light of current scientific knowledge.[124]

However, it would be a mistake to think that lack of utility is confined to the extreme cases listed above. All patentees are required to include an assertion—functionally equivalent to a mandatory promise—of utility in their patent, unless the use of the patent is self-evident.[125] Additionally, US patent law imposes requirements on the content of the assertion of utility (in contrast to Canadian law, which leaves the content of the promise up to patentees). For example, failure to assert a sufficiently specific and substantial utility voids the patent.[126] Famously, the Court of Customs and Patent Appeals struck down a patent for polypropylene—one of the most widely used plastics of the 20th century—because the patent's assertion that polypropylene was "plastic-like" did not convey a sufficiently specific utility.[127] It is important to emphasize that the concept of "utility" is confined to "having a use"; the question whether an invention actually fulfills that use is analyzed under the separate concept of operativeness.

The "operativeness" inquiry asks, "does the invention achieve its asserted utility?" The standard for operativeness is low: an invention will be inoperative only if

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121 *In re Fisher*, 421 F 3d 1365 at 1371 (Fed Cir 2005) [*Fisher*]. Accord *Brenner*, *supra* note 7 at 534 ("The basic *quid pro quo* contemplated by the Constitution and Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility … [and] a specific benefit exists in a currently available form").

122 See e.g. *Raytheon Company v Roper Corporation*, 724 F 2d 951 (Fed Cir 1983) [*Raytheon*] (patent over a microwave oven with physically impossible claim limitation); *Hydreclaim*, *supra* note 120 at 1359 (invention violated principle of conservation of mass).

123 *Brenner*, *supra* note 7.

124 See e.g. *In re Houghton*, 433 F 2d 820 (a flying machine that operated by wing flapping); *In re Eltgroth*, 419 F 2d 918 (control over the aging process); *In re Ferens*, 417 F 2d 1072 (cure for baldness).

125 *In re Bremner*, 182 F 2d 216 at 216 (CCPA 1950) [*Bremner*]; *Cross v Iizuka*, 753 F 2d 1040 at 1044 (Fed Cir 1985); Manual of Patent Examining Procedure 2017(II)(A)-(B).

126 *Brenner*, *supra* note 7; *Fisher*, *supra* note 121; *Anderson v Natta*, 480 F 2d 1392 (CCPA 1973) [*Andersson*]; *In re Zeigler*, 992 F 2d 1197 (Fed Cir 1993) [*Ziegler*]; *Petrocarbon Ltd v Watson*, 247 F 2d 800 (DC App 1957); *In re '318 Patent Infringement Litigation*, 583 F 3d 1317 at 1327 (Fed Cir 2009) [*'318 Litigation*].

127 *Anderson*, *supra* note 126; *Zeigler*, *supra* note 126.

it is "totally incapable of achieving a useful result."[128] To give a simple analogy: a lawn mower that works poorly can still be used as a lawnmower, and it is only when it stops working entirely (that is, becomes totally inoperative) that it ceases to have a use as a lawnmower. The requirement of proving total inoperability often renders it difficult to prove that a US patent is not useful. However, as section 6.1.3, below, demonstrates, defendants face a much more stringent test when they plead inoperativeness issues through the lens of enablement rather than utility.

6.1.2 Evidentiary Barriers to Pleading Inutility

From its earliest patent statute[129] to the current day,[130] the United States has required inventions to be "useful" in order to be patentable. This language can be traced to the US Constitution, which authorizes Congress to grant patents that promote "the Sciences and useful Arts."[131] As a result, many judges see the utility standard as a constitutional one.[132] Yet despite this, lack of utility is not a commonly invoked ground of invalidity. It would be a mistake to conclude that the reasons for this are substantive, and that the utility requirement is a "toothless doctrine."[133] Rather, there are two evidentiary and procedural reasons why utility arguments are unattractive to litigants.

First, many US courts apply a rule that, once infringement is proved, the infringer is estopped from denying the utility of the invention.[134] This rule is not always applied

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128 *Brooktree Corp v Advanced Micro Devices*, 977 F 2d 1555 at 1557 (Fed Cir 1992). See also *EMI Group North America v Cypress Semiconductor Corp*, 268 F 3d 1342 at 1349 (Fed Cir 2001) [*EMI Group*]; *EI du Pont de Nemours & Co v Berkley & Co Inc*, 620 F 2d 1247 at 1260 n 17 (8th Cir 1980) [*EI du Pont de Nemours & Co*]; *Atlas Powder Co v EI du Pont de Nemours & Co*, 750 F 2d 1569 at 1576 (CAFC 1984) [*Atlas*].

129 *Patent Act of 1790*, c 7, § 1, 1 Stat 109.

130 35 USC § 101 (1952). Between 1790 and 1793, and again between 1836 and 1952, the US *Patent Act* would require inventions to be "*sufficiently* useful and important" to merit a patent, rather than merely "useful." In practice the "sufficient" component of the utility requirement was rarely invoked (Michael Risch, "Reinventing Usefulness" (2010) BYUL Rev 1195 at 1236 [Risch]).

131 US Const, art 1, § 8, cl 8. On the "intellectual property clause" of the US Constitution, see generally Edward C Walterscheid, "To Promote the Progress of Science and the Useful Arts: The Background and Origin of the Intellectual Property Clause of the United States Constitution" (1994) 2 J Intell Prop L 1.

132 See e.g. *Great Atlantic and Pacific Tea Co v Supermarket Equipment Corp*, 340 US 147 at 154-55 per Douglas and Black JJ, concurring (1950); *Brenner*, *supra* note 7 at 534; *Graham v John Deere Co*, 383 US 1 at 5-6 (1966).

133 Risch, *supra* note 130 at 1195.

134 *EI du Pont de Nemours & Co*, *supra* note 128 at 128 (accepting as "axiomatic" that infringers are estopped from denying utility). See also *Westinghouse Electric and Manufacturing Co v Wagner Electric and Manufacturing Co*, 225 US 604 at 616 (1912); *Balban v Polyfoto Corp*, 47 F Supp 472 at 478 (D Del 1942); *Panduit Corp v Stahlin Brothers Fibre Works*, 575 F 2d 1152 at 1160 (6th Cir 1978); *Raytheon*, *supra* note 122; *Otsuka Pharamceutical Co v Sandoz Inc*, 2010 US Dist LEXIS 132595 at 92 n 22 (DNJ 2010), aff'd 678 F 3d 1280 (Fed Cir 2012).

consistently,[135] and has been heavily criticized by academic writers,[136] but it has had a chilling effect on invalidity litigation strategies. This "infringement estoppel" has resulted in largely confining inutility arguments to patent prosecution and interference proceedings.

Second, US patentees may prove utility using post-filing evidence.[137] This contrasts with the Canadian position that (at least when utility is proved via sound prediction) such "after the fact" evidence is inadmissible.[138] Similarly to Canada, European law also prohibits proof of utility solely on the basis of post-filing evidence.[139] Because US law lacks a rule excluding post-filing evidence of utility, the incentive to raise such challenges diminishes because it is relatively easier for patentees to generate proof of utility by the time of litigation.

The result of the rules above has been that, for strategic reasons, utility arguments are not a preferred defence in US infringement litigation, although they remain viable in prosecution and interference contexts. Additionally, these rules create incentives to reframe issues that may have been dealt with in Canada as problems of utility and plead them as an argument based on a failure to enable the invention.[140]

6.1.3 Overlap Between Enablement and Utility

Enablement (together with the "written description" requirement[141]) is the US counterpart to Canada's sufficient description requirement. The source of the enablement requirement is statutory: 35 USC § 112 mandates that the patent specification contain "a written description … of the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains … to make and use the same." In other words, "[t]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'"[142]

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135 Defendants have successfully pled disutility in e.g. *Raytheon*, *supra* note 122; *Hydreclaim*, *supra* note 120.

136 John R Thomas, *Pharmaceutical Patent Law*, 2d ed (Bethesda, Md: BNA Books, 2010) at 95; Donald S Chisum, *Chisum on Patents*, looseleaf (New York: Matthew Bender, 1997) ch 4 at 106-8.

137 *Eli Lilly v Actavis Elizabeth LLC*, 435 Fed Appx 917 (Fed Cir 2011) [*Actavis*] (although this is the strongest recent authority on the issue, it was issued on a non-precedential basis); *In re Brana*, F 3d 1560 at 1567 n 19 (Fed Cir 1995).

138 *Apotex v Wellcome Foundation Ltd*, 2002 SCC 77 at paras 46, 78-85, [2002] 4 SCR 153.

139 See cases *infra* note 195.

140 Indeed, in *'318 Litigation*, *supra* note 126, the defendant pleaded lack of enablement *due to lack of utility*. Even though utility was at the core of the defendant's argument, enablement was still the preferred vector of attack.

141 *Ariad Pharamceuticals v Eli Lilly & Co*, 598 F 3d 1336 (Fed Cir 2010) (holding that § 112 contains distinct enablement and written description requirements), rehearing en banc of 560 F 3d 1366 (Fed Cir 2009).

142 *In re Wright*, 999 F 2d 1557 at 1561 [*Wright*]. See also *In re Vaeck*, 947 F 2d 488 at 495-96 (Fed Cir 1991) (discussing necessity of a "reasonable correlation" between scope of disclosure and scope of claims).

Beginning in the second half of the 20th century, US courts began to recognize an important conceptual overlap between utility and enablement. This recognition was sparked by the simple insight that an invention that does not work cannot be enabled.[143] By 1993, the Federal Circuit would declare:

> [T]he how to use prong of section 112 [that is, enablement] incorporates as a matter of law the requirement of 35 U.S.C. §101 that the specification disclose as a matter of fact a practical utility for the invention … If the application fails as a matter of fact to satisfy 35 U.S.C. §101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. §112.[144]

Indeed, the distinction between the two concepts is arguably metaphysical. It is difficult to see a practical distinction between alleging, on the one hand, that "your invention does not work" and, on the other, that "your invention, *as described in the patent*, does not work."

The conceptual overlap between enablement and utility in US patent law allows issues that would be litigated as utility attacks in Canada to be brought under the heading of enablement in the United States. Thus a patent for a medicine that fails to treat its target disease can be invalidated under enablement, because following the teachings of the specification will not result in a medicine that treats the target disease.[145] Likewise, a process claim that is missing a crucial step and cannot achieve its stated goals is invalid under enablement,[146] as are claims reading over large numbers of inoperative embodiments, because following the specification will not guarantee an operative version of the invention without unreasonable experimentation.[147]

Despite their conceptual overlap, in practice the courts treat enablement and utility differently, and do so in ways that allow enablement to serve as a stronger means of attacking a patent than utility.

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[143] *In re Fouche*, 439 F 2d 1237 at 1243 (CCPA 1971) ("While this position could have led to a rejection under § 101, it also leads to a rejection under the how-to-use provision of § 112, since if such compositions are in fact useless, appellant's specification cannot have taught how to use them"). See also *Raytheon*, *supra* note 122 at 957; *Hydreclaim*, *supra* note 120; *In re Swartz*, 232 F 2d 862 at 863 (Fed Cir 2000); *Rasmusson v Smithkline Beecham Corp*, 413 F 3d 1318 (Fed Cir 2005) [*Rasmusson*].

[144] *Ziegler*, *supra* note 126 at 1200-1. For a more recent statement of this overlap, see *'318 Litigation*, *supra* note 126 at 1327 ("The '318 patent's description of using galantamine to treat Alzheimer's disease thus does not satisfy the enablement requirement because the '318 patent's application did not establish utility").

[145] *In re Sichert*, 566 F 2d 1154 at 1162 (CCPA 1970) [*Sichert*].

[146] *United Pacific Resources Co v Chesapeake Energy Corp*, 236 F 3d 684 at 690-91 (Fed Cir 2001); *National Recovery Technologies v Magnetic Separation Systems*, 166 F 3d 1190 at 1196 (Fed Cir 1999) [*National Recovery Technologies*].

[147] *In re Corkill*, 771 F 2d 1495 at 1501 (Fed Cir 1985). See also *EMI Group*, *supra* note 128 at 1348 (impossible inventions "may" lack utility but "certainly" lack enablement).

First, a patent must be enabling as of its filing date, which generally precludes the patentee from relying on post-filing evidence of any kind.[148] This strict evidence regime for enablement contrasts with the more lenient rules for proving utility using post-filing evidence. In fact, the US position on the use of evidence in an enablement analysis closely resembles the Canadian rules concerning evidence of utility within the doctrine of sound prediction. Thus, by framing an argument in terms of enablement rather than utility, a defendant can limit the evidence base on which the patentee may rely. Obviously, any restriction on the evidence base available to the patentee will render enablement a more effective ground on which to attack a patent.

Second, the test for enablement is relatively strict: the patent must allow the skilled addressee to practice the "full scope"[149] of the invention without undue experimentation.[150] The importance of this standard can be illustrated by comparing how inoperative embodiments within a claim are treated under the utility and enablement approaches. Pleading inoperativeness through the lens of utility requires the defendant to prove that every single embodiment of the invention is inoperative.[151] On the other hand, pleading inoperativeness through enablement merely requires the defendant to show that there are enough inoperative elements to require undue experimentation before the invention can be practised. US courts have been coy about the exact proportion of inoperative elements that render a claim invalid under enablement, but one court suggested perhaps half.[152] In any case, whatever the proportion of inoperative elements, if undue experimentation is required to sort operative from inoperative embodiments, the patent will fail for lack of enablement, even though there are some operative embodiments.[153]

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148 *'318 Litigation*, *supra* note 126 at 1325 (Fed Cir 2009); *Rasmusson*, *supra* note 143 at 1324; *In re Glass*, 492 F 2d 1228 at 1232 (CCPA 1974).

149 *Wright*, *supra* note 142 at 1561.

150 The leading case on undue experimentation and the factors to be considered is *In re Wands*, 858 F 2d 731 (Fed Cir 1988) [*Wands*]. For examples of cases finding undue experimentation, see *White Consolidated Industries v Vega Servo-Control*, 713 F 2d 788 at 790-92 (Fed Cir 1983) (18 months to 2 years work was undue); *In re Ghiron*, 442 F 2d 985 at 992 (CCPA 1971) ("many months or years" is not routine but, rather, undue).

151 *EMI Group*, *supra* note 128 at 1349 ("[T]he party alleging invalidity has the burden to show that all disclosed alternative embodiments are inoperative"); *EI du Pont de Nemours & Co*, *supra* note 128 at 1260 n 17 ("In short, the defense of non-utility cannot be sustained without proof of total incapacity"); *Technical Tape Corporation v Minnesota Mining and Manufacturing Co*, 143 F Supp 429 at 437-38, US Dist LEXIS 2975 (SDNY 1956) ("Absent proof of total incapacity the defense of non-operativeness or non-utility is not available").

152 *In re Brimonidine Patent Litigation*, 2009 US Dist LEXIS 10329 at para 105 (D Del 2009).

153 See e.g. *Sichert*, *supra* note 145 at 1162; *Atlas*, *supra* note 128 at 1576; *AK Steel Corp v Sollac*, 344 F 3d 1234 at1244 (Fed Cir 2003).

6.2 Promises in US Patent Law

Armed with the above contextual knowledge, we can now turn to the issue of how US patent law deals with promises. The first point to note is that the United States does not have an explicitly recognized and distinct legal rule known as the "promise of the patent." However, this section demonstrates that, much like Molière's bourgeois gentleman—who spoke prose for decades without even knowing it—US patent law applies many of the same techniques, and reaches most of the same results, as does the Canadian law of promises, even without explicit acknowledgment of the promissory approach. Second, the United States does not follow the Anglo-Canadian approach of purposive construction (in which the nature of the invention and scope of the claims are determined by how a skilled reader would understand the whole of the patent specification). Rather, US law relies on a complex and sometimes contradictory set of rules of construction that places attention squarely on the claims and on file-wrapper estoppel, according much less significance to the description than would a purposive construction.[154]

The remainder of this section demonstrates that (1) US patent law recognizes and enforces "promises" in patents; (2) the requirement that patents include an "assertion of utility" is functionally equivalent to a mandatory promise; (3) US law goes beyond the Canadian law of promises by imposing minimum standards on the nature of promises made; and (4) if a patent contains multiple promises, only one need be true for the patent to be valid.

6.2.1 Recognition and Enforcement of Promises

US patent law is replete with promissory language. Although it is universally acknowledged that the amount of utility required to support a patent is small,[155] US judges and commentators never refer to an isolated "scintilla"-type standard. Instead, utility is invariably defined by reference to the purpose and objective of the invention—that is, to its promise. The invention must "be capable of doing the things claimed,"[156] fulfill "its intended purpose,"[157] and "exhibit the characteristics claimed."[158] As a general rule, utility is always "measured against the patent's objectives."[159] Although these decisions do not use the word "promise," the doctrinal

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[154] See *Warner-Jenkinson Co v Hilton Davis Chemical Co* (1997), 520 US 17; *Festo Corporation v Shoketsu Kinzoku Kogyo Kabushiki Ltd*, 535 US 722 (2002).

[155] See e.g. *In re Oberwerger*, 115 F 2d 826 at 826 (CCPA 1940) [*Oberwerger*]; *National Slug Rejectors v ABT Manufacturing Co*, 164 F 2d 333 (7th Cir 1947); *Atlas*, *supra* note 128 at 1260 n 17.

[156] *In re Perrigo*, 48 F 2d 965 at 965 (1931); *Oberwerger*, *supra* note 155 at 826.

[157] *Conner v Joris*, 241 F 2d 944 at 947 (CCPA 1957) [*Conner*].

[158] *Harris Corp v Ixys Corp*, 114 F 2d 1149 at 1155-56 (Fed Cir 1997) [*Harris Corp*].

[159] *Wesley Jessen Corp v Bausch & Lomb Inc*, 209 F Supp 2d 348 at 398 (D Del 2002), aff'd 56 Fed Appx 503 (Fed Cir 2003) [*Bausch & Lomb Inc*] (non-precedential endorsement of trial judge's reasons).

position is the same: a patentee cannot claim to have provided a "scintilla of utility" despite having failed to fulfill the purpose of the invention. Instead, the invention's utility and enablement will be judged against the objectives set out in the patent itself. Of course, given the emphasis placed on the claims in US patent law, promises are generally, but not always, found in the claims rather than in the description.

Promissory reasoning can also be seen in how US courts have treated asserted utilities. For example, in *In re Hartop*, a case concerning an anaesthetic, the patentees attempted to argue that they had no burden of demonstrating that their medicine was effective in humans, because such use was not explicitly expressed in the patent. The Court of Customs and Patent Appeals (CCPA) (predecessor to the United States Court of Appeals for the Federal Circuit) was unimpressed by this argument, noting that the use of the word "doctors" and the phrase "large institutional users" in the patent were incompatible with a promise of mere veterinary applications for the invention.[160] The court also pointed out that the reference works cited in the patent were standard pharmaceutical reference texts, again suggesting human rather than animal treatment.[161] This chain of reasoning is very close to the kind followed by Canadian courts when they identify the appropriate skilled reader and purposefully construe a patent's promise.

But is this promissory language and reasoning matched by promissory results—that is, by cases in which a patent with at least some usefulness is struck down because it fails to meet a promise? The following three examples are illustrative: in each case a patent over an invention that clearly possessed *some* utility was invalidated because the invention failed to achieve a promise set out in the patent itself.

In re Harwoord[162] concerned a patent over a method of sterilizing "insects" for extermination and pest-control purposes. This process operated by killing symbionts, the presence of which in the host insect was necessary for reproduction. By killing the symbiont, the host was rendered sterile. The patent was rejected for lack of utility because not all insects depend on symbionts for their reproduction. Thus, although the process was unquestionably useful for at least a subset of all insects (those that relied on symbionts for their reproduction), it failed to achieve its promise of sterilizing "insects" in a general, unqualified sense; failure to fulfill the promise was fatal to its utility.

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160 *Ibid* at 352.

161 *Ibid.*

162 390 F 2d 985 (CCPA 1968). Several claims of the patent were in issue; claim 32 was described by the court as representative and read as follows: "A method of causing sexual sterility in insects which comprises administering to the insect a 2-nitrofuran."

Harris Corp v Ixys Corp[163] concerned a patent over an electronic circuit that the patent asserted would avoid undesirable "latching" behaviour.[164] The patent contained a statement that the circuit would avoid latching "at all times" when, in fact, it was prone to latching under normal operating conditions and represented no particular improvement over the prior art in this respect. Thus, although the circuit was perfectly functional at a practically useful level as a standard electronic circuit, the patent's failure to teach how to avoid latching behaviour was a fatal lack of enablement.

Finally, in *National Recovery Technologies v Magnetic Separation Systems*,[165] the plaintiff had developed a process for automatically sorting recyclables. In particular, the patent claimed that the invention could address the long-standing issue

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[163] *Supra* note 158. The sole independent claim of the patent read as follows: "A vertical MOSFET device, comprising:

- a semiconductor substrate, including in series, adjacent source, body, drain and anode regions of alternate conductivity type;
- the body region being adjacent to a surface of the substrate;
- the source and drain regions being spaced so as to define a channel portion in the body region at said surface;
- the source, body and drain regions having a first forward current gain *alpha* [1] and the anode, drain and body regions having a second forward current gain *alpha* [2], such that the sum *alpha* [1] + *alpha* [2] is less than unity, and no thyristor action occurs under any device operating conditions."

[164] A circuit that "latches" cannot be closed until the flow of power to the entire electronic system is reduced below a certain threshold.

[165] *Supra* note 146. The claim at issue read as follows: "A method of distinguishing and separating material items having different levels of absorption of penetrating electromagnetic radiation, comprising the steps of:

(a) conveying a plurality of said material items in a random manner simultaneously and longitudinally along an elongated feed path;

(b) establishing a transverse region across said feed path irradiated by a sheet of penetrating electromagnetic radiation;

(c) irradiating said plurality of material items in said transverse region with said penetrating electromagnetic radiation;

(d) simultaneously measuring the amount of penetrating electromagnetic radiation passing through each material item in said transverse region at any instant of time as said items are continuously conveyed longitudinally through said transverse region to generate process signals; wherein more than one process signal is generated for each of said material items, each process signal being commensurate with the amount of penetrating electromagnetic radiation passing through a portion of each material item which is different from any other portion of said material item, and selecting for processing those of said process signals which do not pass through irregularities in the bodies of said material items; and

(e) simultaneously analyzing said process signals to cause said process signals to actuate means for directing said items to a different destination commensurate with the amount of said penetrating electromagnetic radiation passing through each of said corresponding material items.

of "misclassification due to irregularities in container thickness" that plagued automated sorting mechanisms. Unfortunately for the patentee, although the process contained innovative elements, it did not provide an automated solution to sorting irregularly shaped containers. The Federal Circuit used explicitly promissory language in its invalidation of the patent for lack of enablement:

> While the written description [of the patent] does enable one of ordinary skill in the art to approximate the claimed function, this is not the same as enabling one of ordinary skill in the art to perform the actual selection step of claim 1 for which NRT claims patent protection. The written description does not at all purport to enable one of ordinary skill in the art to determine where irregularities exist in the containers … . *The most that NRT can be credited with is promising the ideal result in claim 1, even though the specification does not completely deliver on this promise.*[166]

As the three above examples illustrate, promises are recognized and enforced in US patent law. Sometimes this is done under the heading of utility, but more frequently under enablement. The remainder of this section shows that US analogues to Canada's promise doctrine can, in some ways, be even stricter.

6.2.2 The Assertion of Utility as a Mandatory Promise

Recall that US patent applications must assert a utility unless the utility is self-evident.[167] In practice, utility will almost never be "self-evident" for chemical or pharmaceutical inventions, so in those fields utility will virtually always be expressly asserted. This is functionally equivalent to a mandatory promise for pharmaceutical and chemical inventions because, as discussed above in section 6.2.1, enablement and utility are measured against the asserted utility of the patent. Canadian law also requires disclosure of utility where it would not be self-evident (for example, when a new chemical compound has been discovered),[168] but this disclosure is not automatically treated as a promise, because promises are the result of purposive construction. As the difference in terminology suggests, the "disclosure" of utility in Canada does not carry with it the same legal consequences as the US "assertion" of utility. In the final analysis, "assertions of utility" are similar to promises, because the utility and enablement of a patent are measured against the assertion, and assertions are mandatory in all patents without self-evident utility. This contrasts with the Canadian position, which does not require patentees to make a promise.

6.2.3 Minimum Requirements for Assertions

In addition to requiring patentees to make promises in a broad array of circumstances, US law will invalidate patents if those promises are not *specific* and *substantial*. We saw an example of this above, when the Federal Circuit and its

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166 *Ibid* at 1196-97.

167 See cases cited *supra* note 125.

168 *Shell Oil*, *supra* note 27; *Janssen-Ortho*, *supra* note 27 at para 74, aff'd 2007 FCA 217.

predecessor court invalidated the polypropylene patent on the ground that "plastic-like" was not a specific enough assertion of utility.[169] More recently, the Federal Circuit struck down a patent over expressed sequence tags (ESTs), a genetic invention aimed at identifying the expression of certain genes in an organism's DNA.[170] In *Fisher*, the Federal Circuit found that the seven asserted utilities for the ESTs in question were neither specific nor substantial enough to satisfy the statutory utility requirement.[171] Thus, the problem with the ESTs in *Fisher* was not that they failed to achieve their asserted purpose, but that the assertion of utility was not sufficiently useful.

This approach is stricter than that required by Canadian law, which so far does not impose a minimum level of specificity or quality of utility on promises (apart from promises contained in selection patents): as a general rule, a Canadian patentee is free to make (or not make) any promise in the patent. While those promises will influence the utility analysis if the patent is litigated, Canadian courts do not investigate the "sufficiency" of the promise in their utility analyses, nor can a patent be invalidated on the ground that its promise does not meet a legal threshold.

6.2.4 Only One Promise Need Be Fulfilled

It is well settled in US law that if a patent makes multiple promises, only one needs to be fulfilled in order for the patent to have utility.[172] For example, a chemical patent that asserts that the disclosed compound can be used as a fungicide for crops, as an anti-fungal skin cream for humans, and as an abortion-inducing chemical for cows will have utility upon proof of any one of the three uses.[173] It need not fulfill all three. This approach to multiple promises is far more generous than the traditional English approach, which required that all promises made in a patent be met. The US position flows from the American definition of utility as "having a use," and as long as at least one promise is fulfilled, the invention does indeed have a use.

7.0 THE EUROPEAN LAW OF PROMISES

This section examines the role that promises play in the patent law of the EPC (collective term for the *Convention on the Grant of European Patents* (1973), the *Act revising the Convention on the Grant of European Patents* (1991 revision), and the *European Patent Convention (2000)* (2000 revision)). The focus is on the European

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169 *Anderson*, *supra* note 126; *Zeigler*, *supra* note 126.

170 *Fisher*, *supra* note 121.

171 *Ibid* at 1373-74.

172 *Conner*, *supra* note 157 at 947; *In re Gottlieb*, 328 F 2d 1016 at 1071 (CCPA 1964) [*Gottlieb*]; *Standard Oil Co (Indiana) v Montedison SpA*, 664 F 2d 356 at 375 (3rd Cir 1981); *Bausch & Lomb Inc*, *supra* note 159 at 398.

173 *Gottlieb*, *supra* note 172.

Patent Office (EPO), with some attention to member states—in particular, the United Kingdom post-1977. Just as the Canadian law of promises is related to two US patent law concepts (utility and enablement), so too do we find that European patent law deals with promises under two headings: "industrial applicability" and "inventive step." The European industrial application criterion requires that an invention contain a promise (often called a "function"), but does not require that the promise be a high one. On the other hand, the inventive step requirement holds that inventions must have a technical effect (which is functionally equivalent to a promise) that must be in the possession of the patent applicant. We investigate each in turn.

7.1 Promises and Industrial Applicability

The EPC requires that an invention be "susceptible to industrial application."[174] The concept of "industrial application" is further defined at article 57, which states: "An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture."[175]

While industrial applicability ought not to be equated with the utility requirement—the two constitute substantively different standards—both achieve many of the same *functional* goals. Thus, physically impossible inventions are neither industrially applicable nor useful;[176] similarly, substances without a known use fail both standards.[177] In addition, the industrial applicability requirement has been used to exclude inventions that are believed by the examiner to be inoperable as disclosed in the patent.[178]

Industrial applicability requires that the patent disclose how the invention can be used in industry if that function would not otherwise be obvious.[179] This has similar effect to the US requirement that patents contain an assertion of utility, although the

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174 EPC, *supra* note 59, art 52(1). For a general review of patentability requirements under the EPC, especially the technicality requirement, see T0154/04 (method of estimating product distribution) (2006), [2008] OJ 46 at 60-61.

175 *Ibid*, art 57.

176 *Thompson's Application*, [2005] EWHC 3065 (a "flying saucer" that violated Newton's third law of motion and the first law of thermodynamics); *Duckett v Comptroller*, [2005] EWHC 3140 (a perpetual motion machine); "Perpetual Motion," T0005/86, [1988] EPOR 301 (another perpetual motion machine).

177 *Chiron Corp v Murex Diagnostics Ltd*, [1995] RPC 535 (CA). This result is identical to that arrived at by the US Supreme Court applying the law of utility in *Brenner*, *supra* note 7.

178 *Eastman Kodak Co v American Photo Booths Inc* (BL no O/457/02), online: Intellectual Property Office <http://www.ipo.gov.uk/pro-types/pro-patent/pro-p-os/p-challenge-decision-results-bl?BL_Number=O/457/02>. See also T 0451/89 (power generator) (1993), [1998] EPOR 333.

179 EPC, *supra* note 59, r 27(1)(f); T0898/05 (hematopoietic receptor) (2006), unpublished at para 6 [hematopoietic receptor]; T0870/04 (BDP1 phosphatase) (2005), unpublished at para 21 [BDP1 phosphatase]; T0604/04 (PF4A receptors) (2006) [unpublished] at paras 14-15 (concurring with BDP1 phosphatase) [PF4A receptors].

EPC does not subject this assertion to the "specific, substantial, and credible" standard that applies in the United States.[180] The degree of function is unimportant to industrial applicability, as long as there is a "practical application,"[181] "some financial or commercial benefit,"[182] or an "immediate concrete benefit."[183] As in the United States, this is tantamount to a mandatory promise for all inventions without a self-evident industrial application. However, in contrast to the United States, there is no minimum threshold of industrial applicability that must be achieved.

Although industrial applicability establishes a low bar to patentability in Europe,[184] it is not a trivial requirement. Patentees whose promises of industrial applicability are not credible at the date of patent filing will see their patents rejected as lacking industrial applicability.[185] In particular, if a patent's proposed industrial application is merely "speculative"[186] at the date of patent filing, or if it would require the skilled person to undertake a "research programme,"[187] then the invention will lack industrial applicability. Overall, then, the EPC approach to industrial applicability has significant functional overlaps with the Canadian promise theory of utility.

7.2 Promises and Inventive Step Under the EPC

Promises take on greater importance within the European "inventive step" analysis. Inventive step is roughly, but not equivalent to, the US and Canadian non-obviousness requirement.[188]

The EPO approach to inventive step is the so-called problem-and-solution approach,[189] which consists of the following three steps:

1. Identify the closest prior art to the invention disclosed in the patent, with "closest prior art" defined as the prior art that would be the most promising starting point for an obvious development leading to the invention.

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180 Sivaramjani Thambisetty, "Legal Transplants in Patent Law: Why 'Utility' Is the New 'Industrial Applicability'" (2009) 48 Jurimetrics 155, argues that the European industrial applicability standard is, at least in respect of biotechnology, increasingly moving toward "specific, substantial and credible" standard.

181 BDP1 phosphatase, *supra* note 179 at para 4.

182 Hematopoietic receptor, *supra* note 179 at para 4.

183 *Ibid* at para 6; *Eli Lilly v Human Genome Sciences*, [2011] UKSC 51 at para 121.

184 See e.g. Julia Powles, "Industrial Applicability of Bioscience Inventions in the Supreme Court" (2012) 71 Cambridge LJ 50 at 51.

185 BDP1 phosphatase, *supra* note 179 at para 21; hematopoietic receptor, *supra* note 179 at paras 6, 20-22.

186 BDP1 phosphatase, *supra* note 179 at para 21.

187 PF4A receptors, *supra* note 179 at para 22.

188 UK law continues to follow the traditional common law non-obviousness approach: *Ranbaxy UK Ltd v Warner-Lambert Co*, [2005] EWHC 2142 (Pat) at paras 66-69, [2005] All ER (D) 124.

189 *Guidelines for Examination in the European Patent Office* (Munich: EPO, 2012) part G, ch 7 [EPO Guidelines].

2. Identify the "objective technical problem" that the patent aims to solve. This may or may not be the objective of the invention that is set out in the patent itself.

3. Ask whether the skilled person, starting from the closest prior art, would have seen the patented invention as an obvious means to solve the objective technical problem. If not, then the invention involves an inventive step and is non-obvious.[190]

Promises appear in step 2 of the problem-and-solution approach, in that all inventions must promise a solution to an "objective technical problem" for the purpose of the inventive step analysis. The promise used in step 2 of the problem-and-solution approach can be different from the disclosure of function necessary to satisfy the industrial application requirement. In fact, and in contrast to Canada and the United States, EPO examiners can identify promises for the purpose of inventive step based on materials outside the patent itself, such as prior art or statements made by the patentee during prosecution.[191]

The promise used in step 2 of the problem-and-solution approach is enforced by the EPO because patentees must actually fulfill the promise identified by the problem-and-solution approach. An invention that fails to offer at least a plausible solution to the objective technical problem will be held to lack an inventive step.[192] For example, in the factor-9 decision, the EPO Board of Appeals stated that a patent for a growth differentiation factor lacked an inventive step because, at the time the patent was filed, there was no evidence that it solved the technical problem.[193] Similarly, in the triazoles decision, the Board of Appeals held that a chemical that did not solve a technical problem required no inventive activity and thus did not contain an inventive step.[194] This evidence must be available as of the filing date, although a party challenging the validity of the patent may submit post-filing evidence to disprove the existence of an inventive step.[195] Thus, under the EPO problem-and-solution approach, promises are recognized and enforced as aspects of inventive step, in addition to their role in industrial application.

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190 This is a paraphrase of the description of the problem-and-solution approach presented in the EPO Guidelines, *ibid* at 5.

191 *Ibid* at 5.2.

192 T1329/04 (factor-9) (2005) [unpublished] at paras 4-6, 9, 11-12, 15; T0939/92 (triazoles) (1992), [1996] OJEPO 309 at paras 2.4-2.4.1, 2.5-2.5.1, 2.5.3-2.5.4, [1996] EPOR 171 [triazoles]; *Actavis v Norvartis*, [2010] EWCA Civ 82 at paras 36-37; *Generics (UK) Ltd v Yeda Research and Development*, [2013] EWCA Civ 925 at para 55 [*Generics (UK)*].

193 Factor-9, *supra* note 192. The board also stated that the presence of an inventive step is to be assessed using pre-filing evidence, and that post-filing evidence may not serve as the sole basis for the inventive step (*ibid* at para 12).

194 Triazoles, *supra* note 192.

195 *Generics (UK)*, *supra* note 192 at paras 64-65.

8.0 CONCLUSION

As our comparative law analysis demonstrates, the promise of the patent is not a concept unique to Canada.[196] In this conclusion, however, we return to Canada in order to examine some of the unanswered questions within the promise rules in operation.

Perhaps the most fundamental unanswered question is that of the continued relevance of the scintilla standard of utility in Canada. To put it bluntly, does every patent have a promise? The traditional position endorsed by the Supreme Court in *Consolboard* is a bifurcated standard: if a patent contains a promise, then the promise must be met; but absent a promise, the patented invention need only display a "scintilla" of utility.[197] The Federal Court of Appeal recently reaffirmed this position, stating that not every patent has a promise.[198] But, in practice, the number of cases decided on the scintilla standard in the last few years is vanishingly small.[199] Indeed, there are several Federal Court judgments in which any discussion of the scintilla standard is studiously avoided and the promise of the patent is treated as if it were the sole measure of utility.[200] For its part, the CIPO *Manual of Patent Office Practice* makes no mention of the scintilla standard, instead speaking only of self-evident utilities, on the one hand, and promises on the other.[201]

In part, the reason for the near disappearance of the scintilla standard in recent years may be that the freedom to abstain from making a promise is largely illusory for chemical and pharmaceutical patents, and these patents make up the majority of modern Canadian case law. The utility of chemical or pharmaceutical compounds will rarely be self-evident and will thus need to be disclosed in the patent specification. Any such disclosure will, in turn, give litigants an opening to argue that it is a promise. Given the reassertion of the *Consolboard* bifurcated approach to utility in *Plavix Impeachment*, only time will tell how this tension is resolved.

A second important question that remains unresolved in Canadian law is how to treat a patent that contains multiple promises. As mentioned previously, the *Manual of Patent Office Practice* requires that all promises be met,[202] but no Canadian court has ruled on the issue. When discussing multipromise patents, it is important to

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196 We are not alone in reaching this conclusion: see Jennifer L Wilkie & Jay Zakaib, "Canada: Utility, Sound Prediction and Promise of the Patent" (2013) Life Sciences and Law: Current Issues 33 (2013-14) at 34, online: Gowlings <http://www.gowlings.com/KnowledgeCentre/PDFs/LSIG-Current-Issues_Broch-2013.pdf> ("However, where one promises more than one's claimed invention can deliver, a *patentee may face jeopardy in numerous jurisdictions*, not just Canada" (emphasis added)).

197 *Consolboard*, *supra* note 79 at 525.

198 *Plavix Impeachment*, *supra* note 12.

199 See e.g. *Allergan v Canada (Health)*, 2011 FC 1316 at para 209; *Lundebeck Canada v Ratiopharm*, 2009 FC 1102 at para 212.

200 See e.g. *Eurocopter*, *supra* note 30 at paras 58-59.

201 MPOP, *supra* note 57 at 12.08.01.

202 *Ibid*.

distinguish a "true" situation of multiple promises (in which the subject matter covered by a single claim is subject to more than one promise[203]) from a "false" situation of multiple promises (in which different promises apply to different claims in the patent, with no single claim being subject to the multiple promises[204]). Only when a patent involves a true situation of multiple promises will a single claim be subject to two or more promises simultaneously.

A true situation of multiple promises naturally raises the question what should happen if a claim fulfills some, but not all, of its promises. As mentioned above, there are two possible approaches to the issue. The US position is that as long as at least one promise is satisfied, the invention possesses utility. The British position is that all promises must be satisfied; otherwise, the invention lacks utility. Although Canadian cases often cite *Alsop* and *Hatmaker*, two British multipromise cases, the issue has yet to be decided in Canada.

Arguments can be made in favour of both approaches. The British position has the weight of authority on its side, including authority seminal to the promissory approach as a whole. The British position also imposes discipline on patent applicants by invalidating patents that contain a mixture of true and false representations as to what the invention can accomplish. By contrast, the US position avoids the seemingly harsh results of the British rule, which can invalidate a patent over an invention that successfully achieves one or more useful results simply because it falls short of fulfilling every promise. Under the American view, where an inventor has actual possession of the invention and its utility—and not simply a hoped-for or after-confirmed utility—at the filing date, the inventor has satisfied the bargain of providing the public with tangible knowledge and thus, arguably, should receive the exclusive rights that the patent system pays in return.

A third area that requires further development is the role of the skilled reader in the interpretation of promises. Prior to the *Plavix Impeachment* decision, when the skilled reader of a pharmaceutical patent included a clinician, the patent would normally be interpreted as promising clinical or therapeutical effectiveness.[205] Similarly, when the skilled reader is a pharmaceutical industry professional, the promise may be found to be either clinical and therapeutical effectiveness or mere pharmacological activity.[206] This rule would be unproblematic if each patent had only one skilled reader. But in all of the clinical skilled reader cases, the clinician was a skilled reader in addition to the traditional pharmacological reader(s). This begs the question why the clinician's interpretation of the promise is automatically preferred to that of the pharmacologist. *Plavix Impeachment* reverses the dominant approach and accords

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[203] See e.g. *Allergan*, *supra* note 49.

[204] The "false" situation can arise, for example, where a patent includes both a process claim and a product claim, because the differences between the two claims will necessitate different promises. See e.g. *Novartis AG*, *supra* note 23.

[205] See above section 3.2.2.

[206] *Ibid*.

primacy to the interpretation of skilled readers with expertise in pharmaceutical formulation.[207] However, Canadian courts have thus far not explained how one should decide between conflicting interpretations of the promise when the reason for the conflict lies in the professional identity and training of the skilled readers. This issue is likely to grow in importance given the increasing tendency to identify multiple skilled readers or to characterize the "skilled reader" as a team.[208]

Fourth, the cases in which courts will rely on an implicit promise derived from the nature of the invention remain to be systematized and placed on a principled foundation. *Plavix Impeachment* appears to repudiate any reliance on "implicit" promises.[209] Unfortunately, this decision fails to cite, let alone reconcile, several previous decisions by the Federal Court of Appeal itself that found and enforced implicit promises.[210] *Plavix Impeachment* has thus introduced conflicting case law at the appellate level, creating considerable uncertainty in the law of promises. This uncertainty is compounded because that decision does not explain how trial judges should differentiate between an "explicit" and "implicit" promise. One approach, which is perhaps most consistent with the law prior to *Plavix Impeachment*, is to simply ignore differences between explicit and implicit promises and leave it to purposive construction and the skilled reader to determine which promises have been made.

That there are unanswered questions and unresolved tensions within the law relating to promise of the patent is not unusual, because the common law advances incrementally, and progress on a given question often depends on whether litigants are interested in debating it. Nor is it unusual that progress takes the form of judicial interpretation of the *Patent Act*. Many commentators take issue with the allegedly unprecedented judicial activism that lies behind the promise of the patent.[211] What these commentators overlook is that there is a long history of judicially created patent law. The non-obviousness requirement—one of the most fundamental requirements for patentability—owes its existence entirely to case law.[212] As such, it was once considered quite controversial by many members of the patent bar. For example, Harold Fox attacked the non-obviousness requirement as little more than

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207 *Plavix Impeachment*, *supra* note 12 at paras 55-66.

208 See e.g. *Sanofi-Aventis*, *supra* note 29 at para 77; *Novartis AG*, *supra* note 23 at para 82.

209 *Plavix Impeachment*, *supra* note 12 at para 49.

210 E.g. *Apotex*, *supra* note 33 at paras 24-28; *Teva Canada*, *supra* note 33 at paras 18-27. In both cases, the Federal Court of Appeal found an implicit promise of long-term treatment of a chronic disease.

211 Siebrasse, *supra* note 3; Legere, *supra* note 4. The Federal Court of Appeal in *Plavix Impeachment*, *supra* note 12 at paras 35-37, found a statutory basis for the promise of the patent in s 27(3) of the *Patent Act*, RSC 1985, c P-4.

212 The non-obviousness requirement was codified only in 1993: *Patent Act*, *supra* note 211, s 33.

a "value judgment" by judges lacking scientific expertise,[213] and concluded that "from this doctrine much evil has resulted … . If it had never found its way into the law, we should have had a much more satisfactory and workable system."[214] Yet within a few decades, the non-obviousness requirement became a settled part of Canadian patent law, and few would today argue that patents should be granted for obvious inventions. It is arguable that the promise of the patent is going through the same cycle of innovation, criticism, and response that led to the codification of the non-obviousness requirement in 1993.

[213] Harold G Fox, *Monopolies and Patents: A Study of the History and Future of the Patent Monopoly* (Toronto: University of Toronto Press, 1947) at 253.

[214] *Ibid* at 212.

This is **Exhibit "C"** to the Affidavit of Anna Hucman
sworn before me on this 27th day of July, 2016

Commissioner for taking affidavits

Reworked remarks for University of Toronto 2nd Patent Law Colloquium, Nov 22 2013

Is Canada's Patent Law Out of Step?

-- David Vaver
Professor of IP Law, Osgoode Hall Law School
Emeritus Professor of IP & IT Law, University of Oxford

My short answer to the question put to the Panel – is Canada's patent law out of step? – is that it may be out of step with some countries' laws ... but so what? The problem is more that it's out of step with other Canada's other intellectual property laws, and with the goal of having a patent law that is clear and accessible to the public that it should be serving. That's where it should get into step.

The question put is of course a provocation – it begs the real question, what tune is Canada out of step with, and who's calling it?

The tune is presumably the old Coca-Cola jingle, suitably rephrased: "I'd like to teach the world to sing in patent harmony".

As to who's calling the tune, it doesn't seem to be the Canadian government, Canadian SMEs, the Canadian public, or Canadian NGOs. Rather, it is the firms that patent worldwide, and their proxies in their national governments, which would like the standardized rules that benefit them, and which they've lobbied for and managed to get included in some of their national patent legislation, become globally entrenched.

The key players here are of course the US, the European Union, and Japan, which were behind the partial harmonization of patent law in the TRIPs Agreement in 1994. Their efforts for greater worldwide harmonization continue, despite the stalled WIPO negotiations for a treaty on substantive patent law. Greater harmonization of the rules that the would-be harmonizers want would mean more opportunities for royalties from licensing and generally more exporting at higher prices free of domestic competition. Good for the exporter's economy, certainly – but whether it's as good for the importer's is more debatable.

Canada is of course "in step" with the international patent obligations it has ratified under the Paris Convention, the PCT, NAFTA, and the WTO Agreement. And where it hasn't occasionally been in step in the past, people have not been particularly shy in telling it so publicly or suing it, as Europe did, successfully, for its pharmaceutical industry over pre-patent-expiry stockpiling and, unsuccessfully, for the *Bolar* exemption for regulatory testing.

Is harmonization a good thing in itself? Only if the harmonized rules themselves are good and advance a country's patent policy. Harmonizing bad rules makes no sense at all. And whether a rule is good or bad often depends on one's perspective.

The model of harmonization the US and EU are currently pushing in negotiations for TRIPs-plus trade treaties is one which simply increases the rights of patent holders and treats public rights of access and use as narrow exceptions, to be only grudgingly conceded.

There is another more realistic model which considers patent law as a balance of rights between owners and users, i.e., the consuming public and potential competitors. Under this model, user rights are as fundamental as owner rights: e.g., the right to research is as basic a right as the right to patent; indeed without research, the capacity to invent is a mere shadow.

The Canadian Supreme Court has accepted this balanced model of IP rights, with its human rights undertones, for copyright and, with a suitable case and argument, the Court may expressly accept that model for patents system too.

Balance is not however what harmonizers seek. The rules they would like harmonized are a carefully chosen few. They do not include rules that would impose duties on rights holders, broad user rights, cheap compulsory licensing or protection for traditional knowledge – provisions that developing countries or indigenous peoples seek – however justifiable such provisions might be in public policy terms or however much they might appeal to the general public if only it had a say in the harmonization debate – which it doesn't, as the current secret negotiations of the current Trans-Pacific Partnership Agreement makes clear.

So what is Canada out of step with?

If we set aside global harmonization aside for a moment, we could ask: is there some best practice Canada should be in step with? The short answer is: no. There is no common consensus beyond some core issues on what a universally acceptable patent law should look like. That's why the attempts at WIPO to establish a substantive Patent Law Treaty failed. One country's best practice turns out to be another's worst.

Should then Canada be "in step" with the patent law of its main trading partners? This is a typically Canadian question. It would of course be quite un-Canadian to ask whether Canada's trading partners should be "in step" with Canada, however objectively wonderful Canada's law might be. Fortunately, we need not pursue that point because even its most ardent supporter would not present Canada's law as wonderful enough for someone else to emulate.

It is easy to say Canada should be "in step" with someone else's law, but whose law would that be? And is the idea to accept all that law, parts of it, or just isolated rules? For example, should it get in step with US rules which exclude any third party right to do research on patented inventions, or that allow inventors who file only locally to opt out of publicly disclosing their application until grant? Who's out of step with whom here?

The problem is, of course, that the great proponents of harmonization – Europe and the US – have patent laws that differ radically from each other, once one moves past the basics of 20-year protection for a new, useful, and unobvious invention that is fully disclosed on a public register.

Here are some random examples where it's unclear who's out of step with whom, or whom one should get in step with:

- **Subject-matter**

The US allows patents on business methods and medical treatments, Europe does not; nor are computer programs that are patentable in the US necessarily patentable in Europe. Biotechnological inventions are treated very differently in

principle and practice. What can be patented is defined differently between the two jurisdictions, despite TRIPs' attempt to paper over the cracks.

Canada's law here is in flux. Some business methods, medical treatments, computer programs, and biotech inventions are patentable, and some are not, depending on the facts and the claims applied for. On this, Canada's law probably lies somewhere between European and US law.

The formal differences are the definitions and interpretations of invention among nations, but the real cause is probably equivocation and scepticism about whether the causes of consumer welfare and innovation are better served by competition rather than patenting particular classes of invention.

So it's not easy to give an answer about whom should Canada get in step with here.

- **Grace periods**

Canada, the US, and Australia are among the few countries with a 1-year grace period during which an inventor can publish or promote her invention without losing the right to file for a patent. Should Canada get in step with the rest of the world by eliminating its grace period? Doing so might actually help those Canadian inventors who think the grace period doesn't count against them if they later decide to file in grace-less jurisdictions such as Europe, where prior art published anywhere makes the invention unpatentable for lack of novelty.

- **Employee Sharing**

In some jurisdictions where employers get to own the rights in inventions their employees create on the job, there are schemes entitling employees to a reasonable share in the benefits the employer gets from patenting. Japan has such a scheme and so do some European states. The US and Canada have nothing.

A study conducted a couple of years ago by a former student of mine, Alex Gloor ((2011) 23 IPJ 37), showed that the top 5 nations that tied patent number to population – Switzerland, Japan, Sweden, Germany and the Netherlands – all

have such employee compensation schemes. Gloor argued that these correlations were not accidents and that, if the theory that patents stimulate invention means anything, Canada should seek to improve its poor innovation rate by legislating for such a mandatory compensation scheme. Getting in step here may in fact be getting ahead.

- **Enforcement**

Canada is out of step with others when it comes to civil enforcement. Just a couple of examples:

It's out of step with the US because Canadian courts let a plaintiff choose between recovering what it's lost from infringement or what the defendant has gained from it – an "account of profits" – although a Canadian court can withhold the account in its discretion for reasons such as the plaintiff's misbehaviour or because the remedy would otherwise be less just than an award of damages. The US lacks the accounts remedy except for design patents. The Canadian rules seem more consistent with the twin goals of preventing unjust enrichment and deterring infringement.

Canadian law is also out of step with British law because Canadian courts can award punitive damages against very bad infringers, and British courts don't; and Canadian courts make the innocent infringer as liable as the deliberate infringer to compensate a plaintiff, and British courts don't: no monetary award (other than costs) is made against an infringer who did not know and had no reasonable grounds to suppose a patent existed.

With ever more patenting and broader claiming, plausible assertions of infringement are more prevalent, and with them the ranks of innocent infringers, for whom having to shut down and hand over existing stock may be a big enough shock in itself.

So again, who is out of step with whom here? Who should get "in step"?

What to Do?

Being out of step with other laws is not necessarily bad. Getting in step with the goal of a good patent law – one that encourages innovation and distribution in ways that appeal to those of inventive turns of mind, and that is clear, coherent, and worthy of public support – seems a better proposition.

I make two suggestions:

•Canada's patent law needs to be completely rewritten to make it clear, coherent, and understandable to those who are regulated by it. Currently it is none of those. It is the incoherent and unclear result of 150 years of patching and tinkering, a result that cause judges and lawyers no end of trouble and produces a high error rate in decision-making.

Let me give just one of many possible examples. Four years ago, the Federal Court of Canada decided for the first time that an inventor need disclose the best method of working the invention only when the patent applied for was for a machine (*Sanofi v Apotex*, 2009). For everything else, any method that worked – the second, third, or tenth best – was all that was legally needed. The result was crazy, as the judge who wrote the first judgment recognized; but that is how the statute read to her, and that was that. A couple of years later the Federal Court of Appeal agreed with the decision (*Viagra*, 2010, revd on other grounds *Teva v Pfizer,* SCC 2012).

Now the initial judge hadn't misread the paragraph she relied on (s 27(3)(c)), but she had overlooked another paragraph in the same subsection that required inventors to correctly and fully describe their invention and its contemplated use and operation (s 27(3)(a)) A little historical digging – well, actually a lot – and it becomes clear that Canada is not in fact out of step with every other country in the world that has a best method disclosure requirement: the general duty to correctly and fully describe the invention and its operation is the provision, with ancient historical roots, that imposes a specific duty to disclose the best method of working every kind of invention. A meandering stream of British, American, and even Canadian case law and commentary from the late 18th century on establishes that. The special provision on machines was simply a tautology that did not detract from that universal obligation (Vaver (2013) 25:3 IPJ).

Too many provisions in the Canadian Patent Act are tautologous, overlapping, or just badly drafted by 21st century standards. They shouldn't be. The whole Act offends the Rule of Law principle that laws should be clearly accessible to those whose conduct they seek to regulate. That does not mean just the patent law expert, but actual or would-be inventors, SMEs, non-specialist lawyers – in fact the public at large for whom laws are ultimately written.

•Patent law is just part of a whole set of IP laws that includes copyright, trade-marks, industrial designs, plant breeder rights. The whole field needs to be codified to create a coherent innovation and distribution policy. Here Canadian law is out of step with itself. Provisions on ownership, defences, enforcement, and management (e.g., transfer, licensing, and registration) in the various IP statutes read differently simply because they were written by different drafters in different styles over the years. They, as well as overlapping subject-matter, need to be rationalized across the board, so the whole IP scheme hangs together coherently and comprehensibly.

So it is high time for the Patent Act to be comprehensively reviewed as part of Canada's IP system. We have had inconclusive reviews in the past, including even a royal commission in 1960 (Ilsley). But we have the model of a successful review, that of the trade-mark law in the early 1950s by a committee under Harold Fox. It recommended tossing out the then hopeless trade-mark statute – a patchwork affair just like our current Patent Act – and replacing it with a modern, coherent, well-drafted statute that would stand the test of time. Not everything in the 1953 Trade-marks Act that Fox's committee drafted has passed that test, but overall the statute put Canada's trade-mark law a step ahead of other similar laws of the time.

A "Thought de Jour" on the front page of the *The Globe and Mail* a few years ago (Oct 29 2002) said: "A step backwards is a step in the right direction if you are facing the wrong way to begin with." Exactly.

This is **Exhibit "D"** to the Affidavit of Anna Hucman
sworn before me on this 27th day of July, 2016

Commissioner for taking affidavits

HARMONIZATION WITHOUT CONSENSUS: CRITICAL REFLECTIONS ON DRAFTING A SUBSTANTIVE PATENT LAW TREATY

JEROME H. REICHMAN†

ROCHELLE COOPER DREYFUSS††

ABSTRACT

In this Article, we contend that the World Intellectual Property Organization's proposed Substantive Patent Law Treaty (SPLT) is premature. Developing countries are struggling to adjust to the heightened standards of intellectual property protection required by the TRIPS Agreement of 1994. With TRIPS, at least, these countries obtained side payments (in the form of trade concessions) to offset the rising costs of knowledge products. A free-standing instrument, such as the SPLT, would shrink the remaining flexibilities in the TRIPS Agreement with no side payments and no concessions to the catch-up strategies of developing countries at different stages of technological advancement.

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† Bunyan S. Womble Professor of Law, Duke University School of Law. The author presented an early version of this Article at the World Intellectual Property Organization's Open Forum on the Draft Substantive Patent Law Treaty (SPLT), International Conference Center (ICC), Geneva, Switzerland, March 1–3, 2006, and at the Intellectual Property & Communications Law Conference, Michigan State University College of Law, April 8, 2006. He would like to thank Professor Peter Yu and the participants at the latter conference for their comments and suggestions, as well as his research assistants, Dr. Emanuela Arezzo, S.J.D. Candidate, Duke University School of Law, and Samantha Jameson, J.D., Duke University School of Law, 2006. The author gratefully acknowledges the support of the National Human Genome Research Institute and the Department of Energy (CEER Grant P50 HG003391, Duke University, Center of Excellence for ELSI Research).

†† Pauline Newman Professor of Law, New York University School of Law. The author wishes to thank the Filomen D'Agostino and Max E. Greenberg Research Fund for its financial support.

More controversially, we argue that a deep harmonization would boomerang against even its developed country promoters by creating more problems than it would solve. There is no vision of a properly functioning patent system for the developed world that commands even the appearance of a consensus. The evidence shows, instead, that the worldwide intellectual property system has entered a brave new scientific epoch, in which experts have only tentative, divergent ideas about how best to treat a daunting array of new technologies. The proposals for reconciling the needs of different sectors, such as information technology and biotechnology, pose hard, unresolved issues at a time when the costs of litigation are rising at the expense of profits from innovation. These difficulties are compounded by the tendency of universities to push patenting up stream, generating new rights to core methodologies and research tools. As new approaches to new technologies emerge in different jurisdictions, there is a need to gather empirical evidence to determine which, if any, of these still experimental solutions are preferable over time.

Our argument need not foreclose other less intrusive options and measures surveyed in the Article that can reduce the costs of delaying harmonization. However, the international community should not rush to freeze legal obligations regarding the protection of intellectual property. It should wait until economists and policymakers better understand the dynamics of innovation and the role that patent rights play in promoting progress and until there are mechanisms in place to keep international obligations responsive to developments in science, technology, and the organization of the creative community.

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INTRODUCTION

Proposals to further harmonize domestic patent laws at the international level[1] have understandably attracted considerable attention.[2] As intellectual property continues to grow as a component of global trade, the costs of worldwide protection and enforcement have soared.[3] Patent holders accordingly seek ways to acquire and maintain their exclusive rights more efficiently in an integrated world marketplace.[4] They are also increasingly frustrated by the need to pursue multiple actions for infringement in cross-border disputes.[5] Under the bedrock principle of territoriality, successive litigations can trigger different applications of domestic and international patent norms to the same set of facts and can lead to conflicting judgments and arguably irreconcilable outcomes.[6]

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1. *See* World Intellectual Prop. Org. (WIPO), Standing Comm. on the Law of Patents, Report, at 1–2, WIPO Doc. SCP/10/11 (June 1, 2005); WIPO, Standing Comm. on the Law of Patents, *Information on Certain Recent Developments in Relation to the Draft Substantive Patent Law Treaty (SPLT)*, at 2–3, WIPO Doc. SCP/10/8 (Mar. 17, 2004); WIPO, Standing Comm. on the Law of Patents, *Draft Substantive Patent Law Treaty (SPLT)*, at 2, WIPO Doc. SCP/10/2 (Sept. 30, 2003).

2. *See generally* WIPO, Open Forum on the Draft Substantive Patent Law Treaty (SPLT), Geneva, Switz., Mar. 1–3, 2006 [hereinafter WIPO Open Forum], *available at* http://www.wipo.int/meetings/en/2006/scp_of_ge_06/scp_of_ge_06_inf1.html (hosting the presentation of papers, lectures, and speeches on the international harmonization of patent law).

3. *See* Gretchen Ann Bender, *Clash of the Titans: The Territoriality of Patent Law vs. The European Union*, 40 IDEA 49, 53 (2000); Erwin F. Berrier, Jr., *Global Patent Costs Must Be Reduced*, 36 IDEA 473, 473 (1996).

4. *See infra* notes 8–19 and accompanying text.

5. *See, e.g.*, Int'l Ass'n for the Prot. of Intellectual Prop. (AIPPI), Question Q174—Jurisdiction and Applicable Law in the Case of Cross-border Infringement of Intellectual Property Rights, 2003/I Y.B. 827–28, Oct. 25–28, 2003, *available at* http://www.aippi.org/reports/resolutions/Q174_E.pdf (recognizing the need for a fairer and more efficient method of resolving cross-border controversies); European Max-Planck Group for Conflict of Laws in Intellectual Prop., *Exclusive Jurisdiction and Cross-Border IP (Patent) Infringement: Suggestions for Amendment of the Brussels I Regulation*, *in* 29(5) EUR. INTELL. PROP. REV. 195, 195–96 (2007) (suggesting the need to amend the Brussels Regulation on Jurisdiction and Enforcement of Judgments in Civil and Commercial Matters, EC Regulation No 44/2001, to improve the efficiency of transnational dispute resolution).

6. *See, e.g.*, David Perkins & Garry Mills, *Patent Infringement and Forum Shopping in the European Union*, 20 FORDHAM INT'L L.J. 549, 550 (1996) (observing that "the English and German courts reached opposite conclusions in parallel litigation in the two countries" (citing Improver Corp. v. Remington Prods. Inc., 21 IIC 572 (1990), 24 IIC 838 (1993), [1993] GRUR Int. 242 (F.R.G.), and Improver Corp. v. Remington Consumer Prods. Ltd., [1990] F.S.R. 181 (Eng. Ch. 1989))). On the validity and infringement of the patent protecting Fosamax, see *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005), holding that the patent is invalid because it was obvious, and *Merck & Co. Inc.'s Patents*, [2003] EWCA (Civ) 1545, [1]–[73] (Eng.), holding that the patent is invalid because it was both

Governments have responded to the upswing in patent applications by searching for techniques that would allow them to share examination responsibilities and costs.[7] The Patent Cooperation Treaty[8] and various regional agreements, such as the Convention on the Grant of European Patents, embody many important procedural advances.[9] These instruments, however, are seldom the product of true harmonization exercises, in part because the outcome of examinations conducted within these frameworks is typically a set of individual national patents that remain separately enforceable under local laws.[10] In 1994, the Agreement on Trade-Related Aspects of

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obvious and lacked novelty. On the importance of allocating a jurisdiction for a patent dispute, see generally Rochelle C. Dreyfuss & Jane C. Ginsburg, *Draft Convention on Jurisdiction and Recognition of Judgments in Intellectual Property Matters*, 77 CHI.-KENT L. REV. 1065 (2002), and Mariano Municoy, Symposium, *Allocation of Jurisdiction on Patent Disputes in the Models Developed by the Hague Conference in Private International Law: Asymmetric Countries and the Relationship of Private Parties*, 4 CHI.-KENT J. INTELL. PROP. 342 (2005), and see also Case C-593/03, Roche Nederland BV v. Primus, [2007] F.S.R. 5 (E.C.J. 2006) (questioning whether conflicting national judgments of validity or infringement should be considered "irreconcilable").

In the United States, the Court of Appeals for the Federal Circuit seems torn by the tension between territoriality and the global exercise of patent rights. *Compare, e.g.*, Voda v. Cordis Corp., 476 F.3d 887, 898 (Fed. Cir. 2007) (holding that "considerations of comity, judicial economy, convenience, fairness, and other exceptional circumstances constitute compelling reasons to decline [supplemental] jurisdiction under [28 U.S.C.] § 1367(c)" over foreign patents), *with* AT&T Corp. v. Microsoft Corp., 414 F.3d 1366, 1370–71 (Fed. Cir. 2005) (endorsing de facto extraterritorial application of domestic software patents to conduct occurring in countries that reject software patents), *rev'd*, 127 S. Ct. 1746 (2007).

7. Bruce A. Lehman, *Addressing the Crisis of the Global Patent System*, JAPAN ECON. CURRENTS, Jan. 2005, at 5, 5–6, *available at* http://www.keidanren-usa.org/publications/currents/docs/JEC_Jan05_132K.pdf.

8. Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231.

9. Convention on the Grant of European Patents, Oct. 5 1973, 1065 U.N.T.S. 255. In addition, the European Community (EC) is considering the development of a region-wide community patent. *See* John H. Barton, *Issues Posed by a World Patent System*, 7 J. INT'L ECON. L. 341, 343 (2004); Hanns Ullrich, *National, European and Community Patent Protection: Time for Reconsideration* 14–22 (European Univ. Inst., Dep't of Law, EUI Working Papers, LAW No. 2006/41, 2006), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=963759. Other nations are contemplating or have enacted similar measures. *See* Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization, tit. I, Feb. 24, 1999, *available at* http://www.oapi.wipo.net/doc/en/bangui_agreement.pdf; Protocol on Patents and Industrial Designs within the Framework of the African Regional Intellectual Property Organization (ARIPO), 2, § 1, Dec. 10, 1982, *available at* http://www.aripo.org/Documents/Protocols/harare_agreement.pdf (last amended Aug. 13, 2004); Marcelo J. Vernengo, Kees de Joncheere & Enrique Fefer, *Advances in Pharmaceutical Market Integration in Mercosur and Other Latin American Countries*, 32 DRUG INFO. J. 831, 834–35 (1998).

10. *See, e.g.*, Convention on the Grant of European Patents, *supra* note 9. The Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual

Intellectual Property Rights (TRIPS Agreement or TRIPS),[11] which incorporated the 1967 text of the Paris Convention for the Protection of Industrial Property,[12] took a major step toward substantive patent law harmonization. It established a set of minimum international standards of protection for some 150 participating countries.[13] Yet the Agreement, which did not attempt to create a uniform or deeply harmonized global patent regime, left ample room for national variations and approaches, which are often collectively deemed "the TRIPS flexibilities."[14]

The effort by the World Intellectual Property Organization (WIPO) to organize a thorough exploration of the possibilities for further harmonization is therefore a welcome development to much of the patent community.[15] Under the aegis of WIPO's Standing Committee on the Law of Patents (SCP), the Draft Substantive

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Property Organization, *supra* note 9, however, does grant a regional patent. A draft European Patent Litigation Agreement is also under consideration. Draft Agreement on the Establishment of a European Patent Litigation System, Feb. 16, 2004, *available at* http://www.european-patent-office.org/epo/epla/pdf/agreement_draft.pdf.

11. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

12. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 (as revised at Stockholm on July 14, 1967); TRIPS Agreement, *supra* note 11, art. 2.1.

13. *See* TRIPS Agreement, *supra* note 11, arts. 27–34.

14. *See id.*, art. 1.1; *see also* John Sulston, Presentation Before the WIPO, Open Forum on the Draft Substantive Patent Law Treaty (SPLT): International Patent Law Harmonization, Development and Policy Space for Flexibility (Mar. 3, 2006), *available at* http://www.wipo.int/meetings/en/2006/scp_of_ge_06/scp_of_ge_06_inf1.html (discussing the TRIPS flexibilities). *See generally* CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT (2007); UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT (2005) [hereinafter UNCTAD-ICTSD, RESOURCE BOOK] (providing background and technical information on the TRIPS Agreement); J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement*, *in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT (C. M. Correa & A. A. Yusuf eds., 1998).

15. *See, e.g.*, Daeshik Jeh, Director, Patent Examination Policy Team, Korean Intellectual Property Office, Presentation Before the WIPO, Open Forum on the Draft Substantive Patent Law Treaty (SPLT): International Patent Law Harmonization and Development: The Experience of the Republic of Korea (Mar. 1, 2006), *available at* http://www.wipo.int/meetings/en/2006/scp_of_ge_06/scp_of_ge_06_inf1.html (discussing the benefits and desirability of harmonization); Kenji Kamata, Japan Intellectual Property Association, Presentation Before the WIPO, Open Forum on the Draft Substantive Patent Law Treaty (SPLT): The Rationale and Benefits of Patent Law Harmonization (Mar. 1, 2006), *available at* http://www.wipo.int/meetings/en/2006/scp_of_ge_06/scp_of_ge_06_inf1.html (same).

Patent Law Treaty (SPLT)[16] represents an attempt "to pursue a 'deep harmonization' of both the law and practice" concerning not just the drafting, filing, and examination of patent applications, but also the cornerstone requirements of patentability.[17] Ideally, member states would agree to adopt identical rules concerning what constitutes a novel and useful invention, when a technical advance meets the requirement for an "inventive step" (nonobviousness), and how much information must be revealed by the patent disclosure. "Deep harmonization" would also entail agreement on priority of inventorship (whether a patent is awarded to the first to invent or the first to file) and whether inventors will be accorded a grace period permitting publication for some period prior to filing.[18] Notably, through the efforts of the so-called Group of Friends of Development,[19] this initiative is being tested against the drive for a more development-friendly agenda at WIPO, with a view to ensuring

16. WIPO, Standing Comm. on the Law of Patents, *Draft Substantive Patent Law Treaty (SPLT)*, *supra* note 1.

17. Karen M. Hauda, *The Role of the United States in World-Wide Protection of Industrial Property*, *in* THE FUTURE OF INTELLECTUAL PROPERTY IN THE GLOBAL MARKET OF THE INFORMATION SOCIETY 89, 97 (Frank Gotzen ed., 2003).

18. *Id.* ("This approach was adopted in an attempt to avoid the controversial hurdles to agreement that were found in the past."); *see also* Philippe Baechtold, *The Future Role of WIPO in the Area of Industrial Property*, *in* THE FUTURE OF INTELLECTUAL PROPERTY IN THE GLOBAL MARKET OF THE INFORMATION SOCIETY, *supra* note 17, at 139, 143 ("[T]here are other issues that require further reflection . . . [including] the question of patentable subject matter, . . . the requirement of technical character of the invention, the exceptions from patentability, the introduction of some form of grace period and the issue of equivalents.").

19. In the Fall of 2004, the General Assembly of the World Intellectual Property Organization invited comment on a proposal presented by the Group of Friends of Development (led by Argentina and Brazil) for the establishment of a Development Agenda for WIPO. WIPO, Gen. Assembly, *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WO/GA/31/11 (Aug. 27, 2004), *available at* http://www.wipo.int/documents/en/document/govbody/wo_gb_ga/pdf/wo_ga_31_11.pdf. Since then, many other proposals have been presented and discussed. *E.g.*, WIPO, Provisional Comm. on Proposals Related to a WIPO Development Agenda, *Report of the Third Session*, at 1, PCDA/3/3 (June 11, 2007), *available at* http://www.wipo.int/edocs/mdocs/mdocs/en/pcda_3/pcda_3_3.pdf; WIPO, Provisional Comm. on Proposals Related to a WIPO Development Agenda, *Proposal for a Decision of the PCDA on the Establishment of a WIPO Development Agenda*, PCDA/2/2 (June 23, 2006), *available at* http://www.wipo.int/edocs/mdocs/mdocs/en/pcda_2/pcda_2_2.pdf; *see also* James Boyle, *A Manifesto on WIPO and the Future of Intellectual Property*, 2004 DUKE L. & TECH. REV. 9, at 3–4 (2004), *available at* http://www.law.duke.edu/journals/dltr/articles/pdf/2004DLTR0009.pdf (criticizing the "one size fits all" approach of WIPO and the TRIPS agreement).

consideration of the needs of all nations, whatever their technological capacities may be.[20]

Despite the promise such an effort holds, we believe that it is unwise to move to deep substantive harmonization so quickly after the TRIPS Agreement elevated patent standards universally.[21] These standards challenged the technological catch-up strategies of all the developing countries and saddled them with social costs they are struggling to absorb.[22] As the endless controversies surrounding pharmaceutical patents demonstrate,[23] higher standards of global protection—whatever their incentive effects[24]—also generate severe and unintended distributional consequences for the developing

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20. WIPO, Provisional Comm. on Proposals Related to a WIPO Development Agenda, *Proposal for a Decision of the PCDA on the Establishment of a WIPO Development Agenda*, *supra* note 19; WIPO, Provisional Comm. on Proposals Related to a WIPO Development Agenda, *Report of the Third Session*, *supra* note 19, at 1.

21. For developing countries, the patent standards (articles 27–34) of the TRIPS Agreement became generally operational on January 1, 2000. TRIPS Agreement, *supra* note 11, art. 65.2; J.H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 CASE W. RES. J. INT'L L. 441, 444 (2000). Developing countries, however, that did not previously allow product patents on pharmaceutical and agricultural chemical products were given another five years to cover them, subject to a "mail-box" provision for patents arising in the meantime. TRIPS Agreement, *supra* note 11, arts 65.4, 70.8–70.9 (mailbox and minimum exclusive marketing rights).

22. *See* COMM'N ON INTELLECTUAL PROP. RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 159–62 (2002), *available at* http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf [hereinafter CIPR]; CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 5–44 (2000); Reichman, *supra* note 14, at 77–92.

23. *See, e.g.*, Janice M. Mueller, *Taking TRIPS to India—Novartis, Patent Law, and Access to Medicines*, 356 NEW ENG. J. MED. 541, 541 (2007) (discussing Novartis's effort to patent Gleevec); Robert Steinbrook, *Thailand and the Compulsory Licensing of Efavirenz*, 356 NEW ENG. J. MED. 544–46 (2007) (noting Merck's objection to Thailand's compulsory licensing of an antiretroviral medication). *See generally* Frederick M. Abbott, *Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 394, 408–10 (Keith Maskus & Jerome H. Reichman eds., 2005) (discussing how patents function as obstacles both to prevent generic products from entering the market and to prevent competition that may lower costs).

24. *See, e.g.*, Ashish Arora, Andrea Fosfuri & Alphonso Gambardella, *Markets for Technology, Intellectual Property Rights and Development*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 321, 325–26 ("Strong patent protection provides incentives to codify and organize new knowledge in ways that are meaningful and useful to others."); Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 48 (2002) ("The ultimate wisdom of measures that relax intellectual property protection for pharmaceuticals in developing countries turns on complex matters, including empirical issues about which one can only hazard an educated guess.").

world.[25] A further round of harmonization will likely aggravate these and other unresolved problems without producing any offsetting user rights or concessions for these countries. On the contrary, the dynamics of TRIPS and the post-TRIPS trade agreements teach that even a development-sensitive negotiation process is likely to produce an instrument that furthers the interests of developed countries at the expense of poorer, less powerful participants.[26]

More controversially, we contend that higher levels of harmonization will harm even the developed countries, including those that are most aggressively pressing for yet another round of multilateral intellectual property negotiations. The domestic patent laws as currently practiced were largely formulated for the inventions of the Industrial Revolution,[27] and these laws still reflect the technological premises and concepts of the creative sectors as they were then structured. Yet in this postindustrial information age, with knowledge-intensive inventions emerging from new kinds of research institutions, creative entities are organized nonhierarchically and along continuously changing lines.[28] New players, such as universities and scientific research organizations, routinely patent their output, and whole new sectors, including biotechnology and information

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25. *See, e.g.*, Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2832 (2006) ("Over-reliance on utility maximization ignores distributional consequences . . . but intellectual property globalization has made these aspects of the provision of basic knowledge goods increasingly difficult to ignore."); Peter M. Gerhart, *Distributive Values and Institutional Design in the Provision of Global Public Goods*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 69, 72 ("[A]lthough institutions like the World Trade Organization (WTO) and World Intellectual Property Organization (WIPO) promote an efficient system of global trade and investment, we have found no way to tax those who benefit from the efficiency of the global system in order to support those who do not."); Joseph E. Stiglitz, Lecture, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. (forthcoming 2007), *available at* http://www.law.duke.edu/webcast.

26. *See, e.g.*, Peter K. Yu, *Five Disharmonizing Trends in the International Intellectual Property Regime*, *in* 4 INTELLECTUAL PROPERTY AND INFORMATION WEALTH 73, 73–74 (Peter K. Yu ed., 2007) (discussing the tensions between developed and less-developed countries with respect to the TRIPS Agreement).

27. *See generally* CHRISTOPHER MAY & SUSAN K. SELL, INTELLECTUAL PROPERTY RIGHTS: A CRITICAL HISTORY (2006).

28. *See* Yochai Benkler, *An Unhurried View of Private Ordering in Information Transactions*, 53 VAND. L. REV. 2063, 2077–78 (2000); James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 LAW & CONTEMP. PROBS. 33, 39–40, 44–46 (Winter/Spring 2003); Charlotte Hess & Elinor Ostrum, *Ideas, Artifacts, and Facilities: Information as a Common-Pool Resource*, 66 LAW & CONTEMP. PROBS. 111, 133–34 (Winter/Spring 2003).

technology, have emerged.[29] Until the operations of these and other new technical communities are better understood, there is a greater need for legal experimentation at the substantive level than for harmonization. In the absence of any international governance infrastructure capable of interpreting and amending the law (rather than freezing it prematurely), a compelling case can be made for delaying deep harmonization until other methods for improving the efficiency of a global patent system have been fully explored.[30]

Part I of this Article surveys the implications of deep harmonization for developing countries, and Part II does likewise for developed countries. Part III suggests that the appropriate goal for the progressive development of world intellectual property law after TRIPS is to nurture an "incipient transnational system of innovation,"[31] which can, in turn, provide the appropriate template for validating global patent norms over time.

I. THE LIKELY ADVERSE IMPACT ON DEVELOPING COUNTRIES

Before moving to the more controversial claim that harmonization could boomerang against its developed-country advocates, we stress that even a cursory look at the results of the TRIPS Agreement reveals the problems harmonization of the type envisioned by the SPLT pose for the developing world. Although TRIPS specifically leaves room for nations to tailor their laws to their internal needs and pace of intellectual advancement,[32] experience shows that emerging economies are, in fact, greatly challenged by the costs and hardship associated with adjusting their development

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29. *See* Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *International Intellectual Property Law and the Public Domain of Science*, 7 J. INT'L ECON. L. 431, 433 (2004); Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 291 (Winter/Spring 2003).

30. *See* Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 3, 17–20.

31. *Id.* at 44.

32. TRIPS Agreement, *supra* note 11, art. 1.1 (leaving Members "free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice"); *id.* at arts. 7–8 (stressing objectives of promoting innovation and transfer of technology "to the mutual advantage of producers and users of technological knowledge" and "the public interest in sectors of vital importance to [Members'] socio-economic and technological development"). *See generally* UNCTAD-ICTSD, RESOURCE BOOK, *supra* note 14 (discussing "flexibilities" within the TRIPS regime).

strategies to new legal realities and that successive rounds of negotiations tend to reduce the flexibilities available for nations to tailor intellectual property law to their own needs.[33]

A. The Social Costs of the TRIPS Patent Standards

In principle, higher standards of patent protection under the TRIPS Agreement will provide needed incentives to invest in the innovative sectors of some developing economies,[34] to make high-technology products available to local industries, and to promote new licensing agreements and direct foreign investments.[35] In practice, however, their different national and regional capabilities, institutions, and endowments limit the developing countries' absorptive capacities and reduce the potential benefits of open markets for knowledge goods. This "technology divide" is further widened by the high rents exacted by technology exporters.[36]

Whether they fall into the high-, medium-, or low-income brackets, all the developing countries—except for a small group of Least Developed Countries (LDCs)—that seek to become suppliers of knowledge goods must compete on roughly the same normative terms and conditions that govern advanced industrialized countries.[37]

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33. *See, e.g.*, CIPR, *supra* note 22, at 8–9, 21–27; Maskus & Reichman, *supra* note 30, at 4–15; Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT'L L. REV. 819, 839–42 (2003). For a more optimistic view, see Joseph Straus, *The Impact of the New World Order on Economic Development: The Role of Intellectual Property Rights System*, 6 J. MARSHALL REV. INTELL. PROP. 1, 3 (2006).

34. *See* Straus, *supra* note 33, at 4.

35. *See, e.g.*, KEITH E. MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY 109–42 (2000); Keith E. Maskus, Kamal Saggi & Thitima Puttitanun, *Patent Rights and International Technology Transfer Through Direct Investment and Licensing*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 265, 265. *But see* Daniel C.K. Chow, *The Role of Intellectual Property in Promoting International Trade and Foreign Direct Investment*, *in* 4 INTELLECTUAL PROPERTY AND INFORMATION WEALTH, *supra* note 26, at 187, 187 (stressing China's ability to attract foreign direct investment despite weak intellectual property rights).

36. *See, e.g.*, Carlos M. Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 227, 229–32 [hereinafter Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?*]; Carlos M. Correa, *Trends in Technology Transfer: Implications for Developing Countries*, 21 SCI. & PUB. POL'Y 369, 377–79 (1994) [hereinafter Correa, *Trends in Technology Transfer*]; *see also* KEITH E. MASKUS, UNCTAD-ICTSD, ENCOURAGING INTERNATIONAL TECHNOLOGY TRANSFER 2 (2004).

37. *See, e.g.*, TRIPS Agreement, *supra* note 11, art. 27.1 (requiring that "patents shall be available for any inventions, whether products or processes, in all fields of technology" if they

Although some developing countries have demonstrated considerable capacity in certain technological sectors,[38] all are struggling to cope with the limits TRIPS places on their ability to reverse engineer up-to-date foreign technologies that were previously unpatented in their territories. For example (and especially problematical), the ability to produce generic drugs without regard to pharmaceutical patents was completely eliminated in 2005.[39] For an economy like that of India, where the generic drug industry is a significant source of income and a key locus of technological development, "fair following" by honest means of reverse engineering had been an important strategic option.[40]

Whether they engage in the production of knowledge goods for local consumption or for export purposes, developing countries must internalize the TRIPS-mandated intellectual property standards in ways that stimulate potentially innovative industrial sectors without legally discriminating against foreign competitors.[41] They must also avoid undermining those less-advanced sectors of their own economies that meet local needs for knowledge goods at affordable prices. India's new patent law, for example, reflects the tensions between efforts to stimulate the nation's research-based

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meet specified eligibility criteria); *id.* arts. 65–66. As regards pharmaceutical products in particular, see World Trade Organization, Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001) [hereinafter Doha Declaration]; Decision by the Council for TRIPS of 27 June 2002, *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WT/IP/C/25 (July 1, 2005).

LDCs may postpone implementation of other TRIPS obligations, including the duty to provide patent protection for products other than pharmaceuticals, until 2013. *See* Decision of the Council for TRIPS of 29 November 2005, *Extension of the Transition Period under Article 66.1 for Least-Developed Country Members*, WT/IP/C/40 (Nov. 30, 2005). During these transition periods, LDCs must continue to respect national treatment and Most Favored Nation (MFN) obligations under articles 3–4 of the TRIPS Agreement. *See id.* para. 5.

38. *See* Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. (forthcoming 2007) (manuscript at 3), *available at* http://ssrn.com/abstract=923538 ("India became a world leader in high-quality generic drug manufacturing."); Straus, *supra* note 33, at 6–8.

39. *See* sources cited *supra* note 37.

40. *See* Mueller, *supra* note 38, at 4, 28, 55. *See generally* J.H. Reichman, *From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11 (1997) (evaluating "the impact of the TRIPS Agreement on [developing countries'] capacity to acquire the knowledge and skills they need to compete on the market for technologically advanced products and processes").

41. TRIPS Agreement, *supra* note 11, arts. 3–4.

pharmaceutical sector and efforts to preserve its well-developed capacity to supply low-cost drugs for the needy in both domestic and foreign markets.[42]

At the same time, the foreign technology suppliers' demands for increased rent extraction—combined with refusals to work, refusals to deal, and various forms of unchecked anticompetitive conduct—hamper the efforts of developing-country entrepreneurs to acquire high-technology goods on open markets at prices that preserve their own comparative advantages.[43] These practices also frustrate their governments' ability to attract foreign direct investment and to build the infrastructure needed to move to a more competitive position on the technological frontier.[44] Although the full extent of these barriers has been insufficiently studied, it seems that high-tech manufacturers in developed countries prefer selling to wholly owned foreign subsidiaries rather than to potential competitors in developing countries. When sales are made to third parties, the net welfare gains from technology installation may be offset by the costs of increased rent extraction.[45]

Moreover, all the developing countries, even those not engaged in the production of knowledge goods, must maintain patent offices and create mechanisms that enable foreign patent owners to enforce their rights—a costly and burdensome operation.[46] How they accomplish this task will seriously affect their internal development

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42. *See* Mueller, *supra* note 23, at 541–43; Mueller, *supra* note 38, at 55–61.

43. *See* John Barton, *Integrating IPR Policies in Development Strategies*, *in* TRADING IN KNOWLEDGE 57, 61 (Christophe Bellmann et al. eds., 2003) (stressing the difficulties of entry—"compounded by the international IP system"—into markets "dominated by multinational oligopolies"); Paul Champ & Amir Attaran, *Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 369–70 (2002) (discussing differing opinions on local work requirements between developed and developing countries); *cf.* Ruth L. Okediji, *Sustainable Access to Copyrighted Digital Information Works in Developing Countries*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 142, 145 (suggesting that similar problems arise in connection with copyrighted scientific and educational works).

44. *See* MASKUS, *supra* note 35, at 119–35; Barton, *supra* note 43, at 373–74; Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?*, *supra* note 36, at 229–32; Correa, *Trends in Technology Transfer*, *supra* note 36, at 371–72.

45. *See, e.g.*, Lee G. Branstetter, *Do Stronger Patents Induce More Local Innovation?*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 309, 317–20 (finding increased rent extraction following patent strengthening).

46. CIPR, *supra* note 22, at 114.

strategies along with their ability to supply such essential public goods as education, public health, environmental safety, scientific advancement, and a soundly competitive marketplace for goods and services.[47]

These tensions are linked with, but not necessarily determined by, problems of wealth distribution. For example, the TRIPS Agreement made assumptions about technological self-sufficiency that proved inaccurate and contributed directly to a health crisis over much of the globe.[48] Although the subsequent Doha Round remedied the problem by permitting countries to issue compulsory licenses to meet the health needs of nations unable to produce locally needed medicines, the Doha Agreement took several years to negotiate and its efficacy is yet to be demonstrated.[49]

Admittedly, TRIPS gives its Members some leeway to tailor their laws to local needs. For example, states can presumably supply their own definitions of "inventive step" and determine for themselves the technological scope of patent protection.[50] They can refuse to patent diagnostic, surgical, and therapeutic methods;[51] they can exclude from

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47. Maskus & Reichman, *supra* note 30, at 33–35; *cf.* Chon, *supra* note 25, at 28–49 (describing the nation-state as the "best guardian of the domestic welfare bargain" upon which the international trading system should not unduly intrude); Peter K. Yu, *Reconceptualizing Intellectual Property Interests in a Human Rights Framework*, 40 U.C. DAVIS L. REV. 1039, 1090 (2007) (comparing material interests in intellectual creations and protections to human rights interests, such as health, education and free expression).

48. *See* Doha Declaration, *supra* note 37, para. 6; TRIPS Agreement, *supra* note 11, art. 31(f). The TRIPS Agreement allowed compulsory licensing of patented products in the domestic market. TRIPS Agreement, *supra* note 11, art. 31. Members lacking the capacity to manufacture pharmaceuticals locally, however, could not effectively use compulsory licensing or obtain exports under a double compulsory licensing regime. *Id.*, art. 31(f); Doha Declaration, *supra* note 35, para. 6. For a description of the difficulties in providing access to essential medicines, see generally Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317 (2005).

49. *See* FREDERICK M. ABBOTT & JEROME H. REICHMAN, EUROPEAN PARLIAMENT COMMITTEE ON INTERNATIONAL TRADE, ACCESS TO ESSENTIAL MEDICINES: LESSONS LEARNED SINCE THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, AND POLICY OPTIONS FOR THE EUROPEAN UNION 13 (2007); Abbott, *supra* note 48, at 317 ("Nongovernmental organizations (NGOs) concerned about access to medicines were disappointed by the complexity of the [Doha Declaration's implementation], arguing that it would be unworkable in practice.").

50. *See* TRIPS Agreement, *supra* note 11, arts. 27(1), 28. Article 27(1) lists an "inventive step" as one of the requirements for patentable subject matter but does not define the term. *Id.* art. 27(1). Article 28 defines scope in terms of the nature of the rights conferred, but the Agreement does not set out the breadth of technological terrain a patent right must cover. *Id.* art. 28.

51. *Id.* art. 27(3)(a).

patentability inventions required to protect *ordre public*, morality, and human health;[52] and they can grant limited exceptions to the exclusive rights conferred.[53] They also have increasing power to order compulsory licenses.[54] These flexibilities allow developing countries considerable policy space in which to maximize the benefits and minimize the social costs of adopting the international minimum standards. But addressing these flexibilities is expensive and requires a sophisticated legal infrastructure. Taken together with the costs of complying with the obligations TRIPS mandates, the burden on developing countries is formidable.[55] To make matters worse, these same countries must increasingly also deal with pressures to provide the higher, TRIPS-plus levels of intellectual property protection embodied in bilateral or regional trade agreements.[56]

B. Shrinking the TRIPS Flexibilities

Against this background, any form of deep harmonization through the SPLT that is likely to win the support of the developed countries seems certain to erode whatever flexibilities the developing countries still retain under the TRIPS Agreement and under subsequently negotiated TRIPS-plus Free Trade Agreements (including their Most Favored Nation implications[57]). Consider, for example, the eligibility requirement of an inventive step (nonobviousness).[58] The standard of inventiveness is intimately tied to a nation's economic goals, and especially to its citizens' technological

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52. *Id.* art. 27(2).

53. *Id.* art. 30.

54. *See id.* art. 31; *see also* ABBOTT & REICHMAN, *supra* note 49, at 13 (noting that the proposed amendment to the TRIPS agreement, already accepted by WTO members on December 6, 2005, would permit expansion of compulsory licensing for pharmaceutical products).

55. *See, e.g.*, UNCTAD-ICTSD, RESOURCE BOOK, *supra* note 14, at 135–214, 358–61 (describing flexibilities in the TRIPS Agreement); SISULE F. MUSUNGU, SUSAN VILLANUEVA & ROXANA BLASETTI, UTILIZING TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PROTECTION THROUGH SOUTH-SOUTH REGIONAL FRAMEWORKS 23–34 (2004); Reichman, *supra* note 40, at 28–29.

56. *See* Frederick M. Abbott, *Intellectual Property Rights in a Global Trade Framework: IP Trends in Developing Countries*, 98 AM. SOC'Y INT'L L. PROC. 95, 97–98 (2004).

57. *See* TRIPS Agreement, *supra* note 11, art. 4 (establishing MFN treatment).

58. *Id.* art. 27.1 (requiring patents to be made available for inventions that are "new, involve an inventive step and are capable of industrial application"). Footnote 5 equates the terms "inventive step" and "capable of industrial application" with "nonobvious" and "useful." *Id.* n.5.

potential and to the types of creativity it can hope to foster.[59] Even within one nation, determining the right standard can be difficult. In the United States, for example, the threshold of nonobviousness has varied widely at different periods,[60] and it remains a contentious issue.[61]

Perhaps for these reasons, TRIPS leaves the height of the inventive step to national law. Presumably, deep harmonization requires convergence on a single standard. Yet finding one that would suit countries at different levels of technological sophistication and for all kinds of intellectual advances could easily prove impossible.[62] Whatever standard is chosen will, at best, represent a mediate position—one that will differ from the optimum for many developing countries.

More generally, there is a risk that virtually every procompetitive option still left open to developing countries under their domestic patent laws—from exceptions to patentability to limitations on exclusive rights and the possibility of imposing compulsory licenses[63]—would shrink or disappear in the SPLT. After all, if experience is any guide, on virtually all of these issues, the advanced industrialized countries will tend to demand higher protectionist standards than those favored by policymakers in developing countries. The United States, for example, has shown little willingness to limit the scope of patentable subject matter by adopting the "technical effect" requirement found in other countries' patent statutes.[64] The United States—indeed developed countries

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59. Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 300–01 (1997); *see* CIPR, *supra* note 22, at 7.

60. *See* ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS 35 (2004).

61. *See id.*; John H. Barton, *Non-Obviousness*, 43 IDEA 475, 508 (2003); Rebecca S. Eisenberg, *Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA*, 19 BERKELEY TECH. L.J. 885, 887 (2004). Indeed, despite more than two-hundred years of experience with a patent system, the standard of nonobviousness was just the subject of another Supreme Court case, *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007). *KSR*'s effect on patent issuances remains to be seen, but it appears to have once again raised the standard of nonobviousness.

62. For example, although the standard in the United States is currently low, *see, e.g.*, JAFFE & LERNER, *supra* note 60, at 34–35, the standard in India is high, *see* Mueller, *supra* note 38, at 86–89.

63. *See* UNCTAD-ICTSD, RESOURCE BOOK, *supra* note 14, at 351–57.

64. *Compare* Convention on the Grant of European Patents, *supra* note 9, arts. 52–53, 57 (requiring patents to be capable of having an "industrial application," defined by the EPO as requiring the ability to be used in any kind of industry), *and* European Patent Office,

generally—has resisted the inclusion of exceptions to patentability for health, the environment, or the protection of genetic resources and traditional knowledge.[65] In fact, the United States appears to be taking the position that any agreement reached must reflect the standards of protection found in U.S. law.[66] Such intransigence does not bode well for the kind of compromising required to produce an instrument that truly accommodates diverse needs.

Of course, the TRIPS Agreement adopted some relatively high standards, and various bilateral and regional free trade agreements impose even higher ones.[67] But in those negotiations, there is, at least theoretically, the prospect that advanced industrialized countries will exchange higher intellectual property standards for trade concessions in other areas which fosters some degree of equity. The rents to be extracted from a highly protectionist intellectual property regime would thus be offset (to some extent) by new market access opportunities. In the context of a free-standing patent agreement, such as the SPLT, no such compensation is possible. There is little in the way of offsetting doctrinal concessions that private stakeholders would permit developed-country negotiators to offer developing countries in return for adopting a patent regime that the latter regard as suboptimal. Such a bargaining stalemate, indeed, is precisely what caused the failure of the Diplomatic Conference to Revise the Paris Convention in 1985 and led the technology-exporting countries to

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Computer-Implemented Inventions, http://www.epo.org/focus/issues/computer-implemented-inventions.html (last visited Oct. 4, 2007) (requiring patents for computer-implemented inventions to make a technical contribution), *with* State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998) (requiring only that mathematical inventions have a "useful, concrete and tangible result"(quoting *In re* Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994))).

65. DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 228–34 (2d ed. 2003); *cf.* Dawson Chem. Co. v. Rohm and Haas Co., 448 U.S. 176, 215 & n.21 (1980) (noting resistance to the adoption of compulsory licensing provisions in U.S. patent law).

66. *See generally* Hauda, *supra* note 17.

67. *See, e.g.*, Australia-United States Free Trade Agreement, U.S.-Austl., art. 17.4.7(e)(i), May 18, 2004, 118 Stat. 919, *available at* http://www.dfat.gov.au/trade/negotiations/us_fta/final-text/index.html (prohibiting parallel importation, even though the issue is left open by article 6 of the TRIPS Agreement). *See generally* Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 80 (2004) (elaborating "on the bilateralism in [intellectual property rights] standard setting, using as an example the substantial elevation of [intellectual property rights] standards in the Central American Free Trade Agreement . . . in relation to pharmaceutical test data . . . and the new requirement . . . linking patent protection to the registration of a pharmaceutical product").

bring intellectual property within the Uruguay Round of Multilateral Trade Negotiations in 1986.[68]

The counterargument is that the benefits of a smoothly working worldwide patent system will ultimately trickle down to developing countries and help them climb the technological innovation ladder.[69] Such a system would, in theory, lower transaction costs, produce greater legal certainty, and permit emerging economies to invest in building the technological skills of their population, secure in the knowledge that technology transfer and foreign direct investment will follow.[70]

However, the counterargument has many defects. One is that no one knows the exact contours of a system that would produce these results, and a good case can be made for quite divergent approaches. For example, one of us has taken the Indian example to heart and argued that developing countries would benefit from a patent system that makes it easy to acquire protection.[71] The theory is that such a regime would encourage innovation at the level at which it can be realistically elicited, and that the resulting patents would produce "buy in" in the form of an appreciation for the wealth that intellectual property protection creates.[72] Conversely, the other author has suggested exactly the opposite: that the need to build competitive markets mandates that the acquisition of full patent rights should be

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68. *See* World Trade Organization, Ministerial Declaration of 20 September 1986, MIN(86)/W/19, 25 I.L.M. 1623 (1986), *available at* http://www.sice.oas.org/trade/Punta_e.asp; *see also* SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 96–120 (2003) ("In effect, twelve corporations made public law for the world."). *See generally* Frederick M. Abbott, *Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework*, 22 VAND. J. TRANSNAT'L L. 689 (1989) (addressing "industrialized countries' growing concerns over technology transfer and their efforts to obtain protection of intellectual property rights under the General Agreement on Tariffs and Trade"); Peter K. Yu, Symposium, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOY. L.A. L. REV. 323 (2004) (demonstrating "that the international intellectual property regime is an ongoing project that provides opportunities and crises for both developed and less developed countries, as well as for rights holders and individual end users").

69. *See* Maskus et al., *supra* note 35, at 265 (noting that developing countries rely on foreign technology to spark economic growth).

70. John H. Barton, *Issues Posed by a World Patent System*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 617, 622 (proposing ways to limit the costs of a global patent system for developing countries).

71. Dreyfuss & Lowenfeld, *supra* note 59, at 300.

72. *Id.*

made relatively difficult.[73] On this view, governments should rely on second-tier regimes—such as utility model laws or "compensatory liability regimes" (liability rules)—to stimulate investment in locally attainable adaptations or improvements of foreign technology, and in "cumulative and sequential innovation" generally.[74] In the absence of empirical evidence either way, experimentation makes more sense than freezing the law prematurely.

Trumping all of these substantive and strategic considerations, moreover, is the fact that what developing countries most need is a period of calm and stability in which to devise intellectual property strategies consistent with both the TRIPS Agreement and the needs of their own emerging national and regional systems of innovation. This is a lengthy and arduous task in its own right. It is difficult for governments and civil society to interact in devising innovation policies that will maximize the use of local assets, minimize the social costs of high international minimum standards of intellectual property protection, and preserve an optimal supply of public goods that are as essential to long-term development prospects as legal incentives to innovate.[75] Developing countries cannot succeed if, at the international level, a new round of multilateral intellectual property negotiations threatens to raise the technological ladder once again, before these countries even get a solid foothold on it.[76]

II. THE LIKELY ADVERSE IMPACT ON DEVELOPED COUNTRIES

However cogent the concerns of developing countries might be, one must nonetheless weigh them against the supposed benefits of deep harmonization.[77] If lower transaction costs, increased legal certainty, and greater economies of scale and scope prove as remunerative as the advocates of harmonization contend, one could

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73. Reichman, *supra* note 40, at 31.

74. Maskus & Reichman, *supra* note 30, at 3, 39–41; *see also* Jerome H. Reichman & Tracy Lewis, *Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 337, 340–42 (arguing that a liability rule which promotes small-scale innovation in the developing world would stimulate investment by local entrepreneurs).

75. Margaret Chon, for example, highlights the problem of providing school children with affordable textbooks. Chon, *supra* note 25, at 2894–95.

76. *See* Maskus & Reichman, *supra* note 30, at 37–39.

77. *See* Baechtold, *supra* note 18, at 142–43. *See generally* Hauda, *supra* note 17; Jeh, *supra* note 15.

envision a compromise scheme that achieves these ends on behalf of developed economies, but permits developing countries to reject such changes if, on balance, they are not as helpful to them as pursuing a slower track. Developing countries could be further placated with selected concessions[78] and compensatory side payments.[79]

The sad truth, however, is that no one has managed to put forward a vision of a properly functioning patent system for the *developed* world that commands even the appearance of a consensus. There are as many different proposals on the table as there are thinkers and investigators. With its relatively experienced patent office, excellent trial courts, specialized appellate court, and a Supreme Court poised to add a generalist perspective, the United States uniquely possesses the kind of institutional infrastructure needed to build and maintain a strong patent law system.[80] Even so, all that the proponents for change in that country can agree on is that the patent law badly needs reform. The risk and cost of litigation is rising rapidly, which creates a drag on innovation and imposes disincentives to invest in creative production.[81] Two studies by the National Academies[82] and another by the Federal Trade

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78. Concessions might include greater harmonization of international patent law with the Convention on Biological Diversity, with imposition of certificates of origin and prior consent for inventions making use of developing country resources and with some recognition of traditional knowledge in international intellectual property law. *See* Thomas Cottier & Marion Panizzon, *Legal Perspectives on Traditional Knowledge: The Case for Intellectual Property Protection*, 7 J. INT'L ECON. L. 371, 372, 376 (2004); Graham Dutfield, *Legal and Economic Aspects of Traditional Knowledge*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 495, 505–06.

79. Robert O. Keohane, *Comment: Norms, Institutions, and Cooperation*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 65, 67.

80. *See* Rochelle C. Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. Rev. 1 (1989).

81. *See* James Bessen & Michael J. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (Sept. 19, 2007) (unpublished manuscript at 14, on file with the *Duke Law Journal*) (suggesting that the costs of litigation are beginning to overtake the monetary rewards of the patent system, at least in certain technological sectors); Michael J. Meurer & James Bessen, *The Patent Litigation Explosion* 1 (Am. L. & Econ. Ass'n 15th Annual Meeting, Working Paper No. 57, 2005), *available at* http://law.bepress.com/alea/15th/art57; Scott Stern & Fiona Murray, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis* 9–10 (Nat'l Bureau of Econ. Research, Working Paper No. 11465, 2005), *available at* http://ssrn.com/abstract=755701.

82. NAT'L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH (2006) (considering the effects of patenting and licensing practices in the fields of genomics and

Commission,[83] and criticism from numerous legal and economics scholars[84] and a variety of judges[85] have offered various diagnoses of the problems and assorted, often contradictory, prescriptions for change. Indeed, even the goals of the patent system are the subject of debate: although patents may still protect inventors from free riders, scholars have suggested that in many new industries, patents serve signaling, financing, and allocating functions,[86] which arguably could be performed in ways that have fewer adverse effects on the public interest.[87]

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protemics and steps that the NIH can take to promote productivity and innovation); NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY (2004) (offering seven criteria for evaluating the present patent system and seven recommendations for designing a more effective patent system).

83. FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf (recommending policies for maintaining the proper balance between patent law and competition law and policy).

84. *See, e.g.*, JAFFE & LERNER, *supra* note 60, at 35 (contending that patents are now available "to pretty much anyone who ask[s] for one, despite the legal tests or novelty and non-obviousness," arguing that the trend "now undermines rather than fosters the crucial process of innovation"); Rochelle Dreyfuss, *Pathological Patenting: The PTO as Cause or Cure*, 104 MICH. L. REV. 1559, 1578 (2006) ("[A] strong argument can be made that the observed problems are not caused merely by the *implementation* of the law, but also by its *articulation*: by an institutional failure to keep patent law and policy abreast with developments at the technological frontier."); Maskus & Reichman, *supra* note 30, at 24 nn.85–88 (citing critical articles by Professors Rai, Kesan, Merges, Lemley, Heller & Eisenberg, Barton and others); Robert P. Merges, *As Many as Six Impossible Patents before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 615 (1999) (proposing "common-sense starting points to deal with the problem of business concept patents"). In reality, Professors Jaffe and Lerner are more optimistic than they sound, because they think the problems stem from how the patent law is applied and not from what it provides. JAFFE & LERNER, *supra* note 60, at 5–6.

85. *See, e.g.*, *In re* Fisher, 421 F.3d 1365, 1379–80 (Fed. Cir. 2005) (Rader, J., dissenting) (disagreeing with the majority's position on utility standards); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 919–30 (Fed. Cir. 2004) (considering and rejecting Rochester's position on the written description requirement); Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 863–64 n.2 (Fed. Cir. 2003) (disagreeing with the dissent's position on the scope of infringement liability), *vacated*, 545 U.S. 193 (2005).

86. *See generally* Bronwyn H. Hall & Rosemary Ham Ziedonis, *The Patent Paradox: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979–1995*, 32 RAND J. ECON. 101, 102 (2001) (examining the "'patent paradox' in the semiconductor industry, where the gap between the relative ineffectiveness of patents . . . and their widespread use is particularly striking"); Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 627 (2002) ("The ability to convey information credibly to observers at low cost is a highly valuable role of patents that has been completely overlooked."); Ronald J. Mann, *Do Patents Facilitate Financing in the Software Industry?*, 83 TEX. L. REV. 961 (2005) (analyzing the role patents play in fostering investments).

87. For example, Dirk Czarnitzki and his coauthors demonstrate a positive correlation between patenting rate and publication rate, which suggests that publications could serve as

In Europe, similar uncertainty exists. In a publication entitled *Scenarios for the Future*,[88] the European Patent Office (EPO)[89] has frankly recognized the uncertain future of the worldwide patent system. It has outlined four different scenarios that could emerge in response to different interest groups seeking to influence domestic and international policymaking forums.

The first scenario envisions the tightening of worldwide patent standards under an international treaty, such as the SPLT, a position championed by many multinational corporations.[90] A second scenario envisions the evolution of a variegated system in which developing countries—especially emerging economies—gradually reshape the existing patent system to suit their own comparative advantages.[91] A third scenario envisions a shift toward second-tier regimes, possibly sounding in liability rules rather than exclusive rights, which would specifically address the problems posed by cumulative and sequential innovation.[92] The fourth scenario envisions a re-elaboration of the

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signals of technological competence. Dirk Czarnitzki, Wolfgang Glänzel & Katrin Hussinger, *An Empirical Assessment of Co-Activity Among German Professors* 17 (ZEW Ctr. for European Econ. Research, Discussion Paper No. 06-080, 2006), *available at* ftp://ftp.zew.de/pub/zew-docs/dp/dp06080.pdf. Eric Brousseau and coauthors have investigated the use of contracts to govern relationships among innovators in the high-tech sector. Eric Brousseau, Régis Coeurderoy & Camille Chaserant, *The Governance of Contracts: Empirical Evidence on Technology Licensing Agreements*, 163 J. INSTITUTIONAL & THEORETICAL ECON. 205, 205 (2007). Paul David's work looks at the role of publication rates in allocating research resources in science. Paul A. David, *Positive Feedbacks and Research Productivity in Science: Reopening Another Black Box*, *in* ECONOMICS OF TECHNOLOGY 65, 69–70 (O. Granstrand ed., 1994).

88. EUROPEAN PATENT OFFICE (EPO), SCENARIOS FOR THE FUTURE—HOW MIGHT IP REGIMES EVOLVE BY 2025? WHAT GLOBAL LEGITIMACY MIGHT SUCH REGIMES HAVE? (2007) [hereinafter SCENARIOS FOR THE FUTURE].

89. The EPO is not an organ of the European Communities. Rather, it was established by the Convention on the Grant of European Patents (EPC). *Id.* at inside cover. The EPO, which acts as a regional patent office for the member states, is the executive body of the treaty members. There is also an administrative council, which operates as a de facto legislative body. Revisions of the EPC are undertaken by an intergovernmental diplomatic conference for the contracting states. *Id.*

90. *See id.* at 30–47. With "[b]usiness as the dominant driver," this scenario tells "[t]he story of consolidation in the face of a system that has been so successful that it is collapsing under its own weight; Power and Global Jungle are the major driving forces." *Id.* at 29.

91. *See id.* at 48–65. With "[g]eopolitics as dominant driver," this scenario tells "the story of conflict in the face of changing geopolitical balances and competing ambitions, where Power and Global Jungle are the major driving forces, but in contrast to the business-led scenario, the states are the key players." *Id.* at 29.

92. *See id.* at 95–96. With "[t]echnology as dominant driver," this scenario tells "[t]he story of differentiation in the face of global systemic crises, where Pace of Change, Systemic Risks and Knowledge Paradox (as the nature of knowledge changes) are the major driving forces." *Id.* at 29; *see also* J.H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in*

basic patent paradigm that would give much greater weight to the provision of public goods and "access to knowledge" in general, at the expense of private incentives to innovate.[93] Although the EPO takes no position on which of these scenarios it favors, its publication demonstrates that policymakers responsible for the future evolution of the patent system will be constrained to take account of the divergent interests underlying each of these remarkably prescient scenarios.

It should, indeed, surprise no one that routine tinkering with a patent paradigm launched in Venice in the fifteenth century and refined by the United Kingdom in the seventeenth century cannot answer the hard questions raised by new technologies and the new modes of producing them.[94] There are major challenges for which past experiences give only untested and untrustworthy hypotheses, with no convincing empirical studies on the horizon to resolve the doubts. These problems affect all aspects of patent protection. Not only are there discordant views on how high the inventive step should be, there are also disagreements on virtually every substantive topic under discussion in connection with the SPLT: novelty and utility standards, the research exemption, compulsory licenses—along with standards for analyzing infringement and awarding relief.[95]

Subpatentable Innovation, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 23, 24 (Rochelle Dreyfuss et al. eds., 2001) [hereinafter Reichman, *Of Green Tulips and Legal Kudzu*] (proposing a "compensatory liability regime" for incremental innovation); J.H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 COLUM. L. REV. 2432, 2447 (1994) [hereinafter Reichman, *Legal Hybrids between the Patent and Copyright Paradigms*] (suggesting that a liability regime would increase investment in cumulative and sequential technologies while avoiding market failure with fewer anticompetitive effects).

93. *See* SCENARIOS FOR THE FUTURE, *supra* note 88, at 72. With "[s]ociety as the dominant driver," this scenario tells, "[t]he story of erosion [of patent law] in the face of diminishing societal trust, where Power (from the bottom up) and societal fear of Pace of Change and Systemic Risks—and Knowledge Paradox (in terms of access and control)—are the major driving forces." *Id.* at 29; *see also* Amy Kapczynski, *The Access to Knowledge Movement*, 117 YALE L.J. (forthcoming 2008) (describing the development of groups opposing restrictive rights and promoting greater public access).

94. *See* MAY & SELL, *supra* note 27, at 203–18 ("Only by understanding the long history of intellectual property can the problems of its contemporary global governance be properly assessed."). *See generally* John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685 (2002) (discussing the diversity of patent law and the potential costs of harmonization).

95. *See, e.g.*, Request for Comments on the International Effort to Harmonize the Substantive Requirements of Patent Law, 66 Fed. Reg. 15,409, 15,409–11 (Mar. 19, 2001) (listing seventeen differences between U.S. patent law and the law of other developed countries); *see*

Furthermore, there are a multitude of open procedural questions—including questions about the level of scrutiny that patent offices give to applications,[96] the standards for reexamining issued patents, as well as the availability of avenues to challenge patents administratively (through opposition procedures)[97] and judicially (through, for instance, declaratory judgment actions).[98] The National Academies' Report criticized the reluctance of the Court of Appeals for the Federal Circuit to defer to the examination guidelines that the U.S. Patent Office applies to new technologies, while applying unrealistic standards of its own that ignore what those skilled in the art actually know.[99] Others have questioned vesting powers over patent law in a single specialized court, pointing to the Federal Circuit's penchant for *de novo* review,[100] its apparent lack of interest in economics or patent policy,[101] and its insulation from criticism.[102]

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also James Gleick, *Patently Absurd*, N.Y. TIMES MAG., Mar. 12, 2000, at 44, 44 (describing the proliferation of patent infringement claims in e-commerce).

96. *See* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1495–96 (2001).

97. *See* JAFFE & LERNER, *supra* note 60, at 181, 192 (discussing opposition procedures and standards of proof).

98. For U.S. examples, see the various proposals for patent reform, including the Patent Reform Act of 2007, H.R. 1908, S. 1145, 110th Cong. (2007); the Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005), which proposed opposition procedures, including varying standards of proof on the question of validity; and the ruling in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 775–76 (2007), in favor of standing to challenge patent validity in a declaratory judgment action. *Cf.* Paul Edward Geller, *An International Patent Utopia?*, 25 EUR. INTELL. PROP. REV. 515, 516 (2003) (advocating instant disclosure of all patent applications via the Internet).

99. *See* NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY, *supra* note 82, at 87–95.

100. *See, e.g.*, Samantha A. Jameson, Note, *The Problems of the Utility Analysis in Fisher and its Associated Policy Implications and Flaws*, 56 DUKE L.J. 311, 311 (2006) (questioning whether the PTO is equipped to deal with policy and criticizing the decision in *Fisher*).

101. *Cf. In re* Fisher, 421 F.3d 1365, 1378 (Fed. Cir. 2005) ("[W]e observe that the government and its amici express concern that allowing EST patents without proof of utility would discourage research, delay scientific discovery, and thwart progress in the 'useful Arts' and 'Science.'... [These] are public policy considerations which are more appropriately directed to Congress as the legislative branch of government, rather than this court as a judicial body responsible simply for interpreting and applying statutory law."). *See generally* Rochelle C. Dreyfuss, *The Federal Circuit: A Continuing Experiment in Specialization*, 54 CASE W. RES. L. REV. 769 (2004) (surveying the effects of "specializing the adjudication of patent disputes by channeling patent appeals to a single court").

102. *See, e.g.*, Dreyfuss, *supra* note 84, at 1567–70; Arti K. Rai, *Allocating Power over Fact-Finding in the Patent System*, 19 BERKELEY TECH. L.J. 907, 913 (2004); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1035 (2003); Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity*

This Article cannot explore all of the problems with which the system is grappling. Our purpose is to demonstrate how promulgating substantive law in the absence of either a normative consensus or an authority competent (in both the cognitive and juridic sense) to administer and revise it will interfere with the emergence of new industries, with scientific advancement, and with the development of new approaches to encouraging and supporting innovation.

A. Emerging Industries

Although there is broad dissatisfaction with domestic patent systems, many of the complaints—at least in the United States—are based on law developed for emerging sectors, principally information technology and biotechnology.[103] These issues merit a deeper look.

1. *Information Technology (IT).* With regard to the IT sector, there is considerable debate about the need for exclusive rights to promote development of software and business methods and whether patent protection is the appropriate regime to use. Unlike copyrights and contractual rights, patents create claims that are good even against independent inventors. For cumulative technologies or in instances where interoperability is an important goal, the need to sift through prior patents and negotiate rights arguably creates a high tax on innovation and a drag on development.[104]

Other untoward consequences may flow from the decision to permit patenting in this area. For example, the risk of debilitating suits motivates participants to acquire multiple patents, hoping that with enough potential counterclaims, they can fend off or negotiate their way out of difficulty. The result is a vicious cycle: thickets of rights that are expensive (or nearly impossible) to clear, requiring an ever-larger arsenal of defensive protection.[105] Furthermore, many IT products involve multiple inventions and, accordingly, multiple

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Principle 5 (George Washington Univ. Legal Studies Research Paper No. 225), *available at* http://ssrn.com/abstract=928498.

103. *See, e.g.*, Dan Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1155–56 (2002).

104. *See* Pamela Samuelson, Randall Davis, Mitchell D. Kapor & J.H. Reichman, *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 COLUM. L. REV. 2308, 2422 (1994). Many of these problems were identified well before patents on software were issued. *Id.* at 2361.

105. *See* JAFFE & LERNER, *supra* note 60, at 59.

licenses.[106] In that environment, holdout possibilities are numerous and, as the Blackberry case[107] nearly demonstrated, can potentially undermine the investments of producers, other patentees, and the public.[108] All of this patenting activity fosters so many potential lawsuits that, as economists James Bessen and Michael Meurer have concluded, the cost of litigation has begun to exceed the profits from patents by all measures in this sector.[109]

In addition, some IT products are characterized by strong network effects and standard setting, which may make switching costs high and lock consumers into inferior products.[110] Those holding patent rights in products toward which a market has tipped receive awards out of proportion to the technical contributions of the inventors. When these patents also dominate their fields, they allow right holders to prevent entry by competitors.[111]

Commentators further criticize the way the law has been administered. To some, the European approach, which looks for a technical effect, is superior because it greatly limits the kinds of information technology that can be protected.[112] Others note that, because courts assume the level of skill in the art to be high, they relieve patentees of the obligation to disclose the underlying code.

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106. Hall & Ziedonis, *supra* note 86, at 109–10 (discussing semiconductors).

107. NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282 (Fed. Cir. 2005).

108. *See* Jeremiah Chan & Matthew Fawcett, *Footsteps of the Patent Troll*, 10 INTELL. PROP. L. BULL. 1, 5 (2005).

109. Bessen & Meurer, *supra* note 81 (manuscript at 13, on file with the *Duke Law Journal*) (noting that "annual worldwide profits from software patents are only $0.69 billion, far less than litigation costs").

110. *See* Michael L. Katz & Carl Shapiro, *Network Externalities, Competition, and Compatibility*, 75 AM. ECON. REV. 424, 424 (1985); Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101, 124 (2006).

111. *See, e.g.*, Rochelle Dreyfuss, *Unique Works/Unique Challenges at the Intellectual Property/Competition Law Interface*, *in* EUROPEAN COMPETITION LAW ANNUAL 119, 121–23 (2005) (noting that the dominance factor exists especially in fields such as biotechnology); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, 1 INNOVATION POL'Y & ECON. 119, 119 (2001) ("In several key industries, including semiconductors, biotechnology, computer software, and the Internet, our patent system is creating a *patent thicket:* an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees.").

112. *See* Rochelle Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263, 278–79 (2000) (advocating an approach that asks whether "a patent incentive is actually required to promote investment in innovation"); John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139, 1179–84 (1999) (stating that "the European Patent Convention presents the most fulsome articulation of the industrial applicability standard").

These patents can be very broad and, because they fail to enable, they deprive the public of disclosure, which is one of the significant benefits of the patent system.[113] Moreover, because monetary damages are calculated based on the value of the product and not of the patent that has been infringed, this sector attracts "trolls," who are in the business of making money though litigation rather than through product development.[114]

2. *Biotechnology.* The burgeoning field of biotechnology is experiencing a different set of problems. Here, courts and the PTO consider the level of skill quite low,[115] which leads to narrow patents and the danger of an "anticommons effect."[116] When that occurs, property rights cannot be aggregated efficiently to create, for example, effective methods for assembling and screening new molecules or to realize the ambitions of personalized medicine, which would require whole-genome sequencing.

Because U.S. courts tend to conceptualize DNA as molecules rather than information products,[117] manufacturers and researchers can easily evade patent rights in some cases by—essentially—paraphrasing the information covered by the patent.[118] As a result, the patent may yield insufficient incentives to support research in a given area.[119] Paradoxically, there is also a growing number of patents in this

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113. *See* 35 U.S.C. § 112 (2000) (requiring a "written description of the . . . manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to *enable* any person skilled in the art . . . to make and use the same" (emphasis added)); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1689 (2003).

114. *See* Amy L. Landers, *Let the Games Begin: Incentives to Innovation in the New Economy of Intellectual Property Law*, 46 SANTA CLARA L. REV. 307, 307 (2006); *cf.* Patent Reform Act of 2007, S. 1145, 110th Cong., § 5(a)(2) (2007) (proposing a change in damages calculation based upon "the patent's specific contribution").

115. *See, e.g.*, *In re* Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995) (refusing to find the subject of a patent "obvious" despite the fact the "the claimed molecules, their functions, and their general chemical nature may have been obvious from" prior research); *In re* Bell, 991 F.2d 781, 785 (Fed. Cir. 1993) ("[T]he combination of prior art references does not render the claimed invention obvious . . . .").

116. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 699 (1998).

117. *See* Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 833 (1999).

118. *See* Helen M. Berman & Rochelle C. Dreyfuss, *Reflections on the Science and Law of Structural Biology, Genomics, & Drug Development*, 53 UCLA L. REV. 871, 876 (2006) (noting that manufacturers could alter "protected nucleotide sequences" while generating a functionally similar product).

119. *See* Burk & Lemley, *supra* note 113, at 1676–80.

field—particularly patents on genes and certain proteins that are, at least for research purposes, so broad[120] that it is unlikely a patent holder could efficiently exploit the entire breadth of the claims. Meanwhile, the potential blocking effects appear increasingly serious.

3. *Reconciling the Needs of Different Sectors.* It is not clear that these problems will be easy to resolve. First, these quick sketches of two emerging sectors demonstrate that there is disagreement concerning the existence, scope, and nature of the problem. For example, despite the strong and persistent complaints about patents in the software industry, there is some empirical evidence that the patent system is not hurting—and may be helping—the development of this sector.[121] Patent reform is thus stalling at least in part because domestic stakeholders cannot even agree that reform will be worth the dislocations it will entail.

Second, there are disputes about how to handle the problems. For example, some economists claim that reengineering the law is not necessary. They argue that the system could be restored to order by simply improving the quality of the patents that issue (that is, by creating a mechanism for ensuring that patents issue only for inventions that are truly nonobvious).[122]

Third, it is proving so difficult to find common ground among the various patent industries that some have suggested sector-specific legislation.[123] If heeded, this approach could take patent law down untested pathways culminating in a set of clumsy, *sui generis* regimes.[124] Moreover, even if such an approach proved politically

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120. *See* Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239, 239 (2005) (suggesting that sometimes a single gene can be associated with as many as twenty patents); Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 711–12 & n.19 (2004); *see also* Andrew Chin, *Artful Prior Art and the Quality of DNA Patents*, 57 ALA. L. REV. 975, 977 (2006) (describing the shortcomings of the U.S. Patent Office registry approach in documenting prior art of genetic research, thus leading to "low-quality patents . . . issued on inventions that are already known or represent only an obvious advance in the field").

121. Mann, *supra* note 86, at 985–1012; Robert P. Merges, Patents, Entry and Growth in the Software Industry (Aug. 1, 2006) (unpublished manuscript, *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=926204).

122. JAFFE & LERNER, *supra* note 60, at 197–207.

123. Burk & Lemley, *supra* note 103, at 1202 (suggesting that industry-specific tailoring is "desirable").

124. *Cf.* Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, *supra* note 92, at 2445 (examining "proliferating legal hybrids . . . [that] represent both a consequence of . . .

feasible in a domestic setting, it could elicit objections sounding in the TRIPS Agreement, which requires that "patents . . . be available and patent rights enjoyable without discrimination as to . . . the field of technology."[125] But TRIPS is only a minimum standard regime. Were the United States bound by an instrument that required complete substantive harmonization, resolving the issues that exist within emerging industries would not be feasible without endless rounds of entangling negotiations—and, if the system includes enforceable obligations, unsettling appeals.[126]

Moreover, the technology sectors are hardly the end of the line: science is sure to generate new and equally daunting innovation opportunities in the future. Synthetic biology represents one such development.[127] Because it utilizes both software and biotechnological advances, this field potentially suffers from the combined impact of

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growing incoherence and a cause of the incipient breakdown that is weakening the international intellectual property system from within").

125. TRIPS Agreement, *supra* note 11, art. 27(1); *see also* Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000) (distinguishing between permissible reconcilable "differentiation" attributable to needs of different product sectors and impermissible "discrimination"). *But see* Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *Diversifying Without Discriminating: Complying with the Mandates of the TRIPS Agreement*, 13 MICH. TELECOMM. & TECH. L. REV. 445, 450 (2007) (arguing that "[d]iscrimination is not the same as differential treatment" and suggesting that some types of differentiating should withstand challenge).

126. The TRIPS dispute resolution experience is not an entirely happy one in this respect because WTO Settlement Panels have been ill equipped to deal with technical legal issues. *See, e.g.*, Dinwoodie & Dreyfuss, *supra* note 29, at 413 (identifying "interpretive approaches" to the TRIPS Agreement and raising "questions regarding the level of formalism" of the WTO dispute settlement process); Joost Pauwelyn, *WTO Dispute Settlement: Of Sovereign Interests, Private Rights and Public Goods*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 817, 829 (examining "the tension between sovereign/government interests, private rights, and public goods" in the WTO dispute settlement process); Gregory Shaffer, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 884, 884 (focusing on disputes related to pharmaceutical patents and concerns about public goods including "the generation of new knowledge, the provision of public health, and the maintenance of rules fostering trade and competition").

127. Synthetic biology is an engineering field that utilizes artificially constructed DNA to construct/program useful "machines" (such as plants that produce fuel). *See generally* Philip Ball, *Starting from Scratch*, 431 NATURE 624 (2004) (describing synthetic biology and concerns about risks associated with the field).

patenting problems in both sectors.[128] Were the SPLT to be implemented, its adherents would have diminished capacity to adapt the legal order so that such new opportunities could flourish.

B. *Scientific Advancement*

The prospects for the future could become even more troubling. As patenting moves upstream to cover fundamental advances, existing dysfunctionalities within the system could impede scientific progress and reduce the chances of generating future opportunities for innovation. Drawing once again on the situation in the United States as an example, a reorganization underway within the scientific community has begun to pose hard and unresolved problems for patent law.

A major development was, undoubtedly, the wholesale entry of universities into the patent system. Since the passage of the Bayh-Dole Act in 1980,[129] which permits universities to patent the fruits of federally funded research, filings by the university sector have significantly increased.[130] Although the statute aimed mainly to encourage technology transfer, universities increasingly understand it as a funding mechanism, with many untoward consequences for science and education. Most obviously, work that once would have gone into the public domain for general and free use becomes privatized.[131]

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128. *See* Arti K. Rai & Sapna Kumar, *Synthetic Biology: The Intellectual Property Puzzle*, 85 TEX. L. REV. 1745, 1747 (2007) ("The manner in which the law has handled software on the one hand and biotechnology on the other may not bode well for synthetic biology.").

129. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–212 (2000)).

130. The issue of cause and effect is itself a subject of dispute. Some claim that the Bayh-Dole Act created the university patenting phenomenon, whereas others contend that universities' desire to patent gave rise to the Act. *See* Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL'Y 99, 100 (2001).

131. *See, e.g.*, Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1666 (1998) ("Only in exceptional circumstances does the statute acknowledge that there may be an affirmative case for putting a discovery in the public domain for the greater good."); Rai & Eisenberg, *supra* note 29, at 303 (discussing how increased patent opportunities may reduce the chance that technology will end up in the public domain); *see also* J.H. Reichman & Paul F. Uhlir, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 LAW & CONTEMP. PROBS. 315, 342–43 (Winter/Spring 2003) (discussing the impact of the Bayh-Dole Act on university research and the public domain).

Moreover, because academia engages in fundamental research, university patenting tends to push upstream, which creates broad rights over core methodologies and research tools—rights that can dominate diverse research agendas.[132] Although there is some empirical evidence indicating that universities have begun to patent more selectively and license these opportunities more wisely,[133] horror stories abound in which universities reportedly signed over rights without any guarantee that their licensees would bring products to market. Indeed, sometimes universities appear to have licensed rights to institutions that had private reasons to stifle research and access.[134] Perhaps to counter this problem, the courts have begun to deploy various patent law theories to narrow the ambit of broad claims.[135] But overly narrow rights in "slivers of innovation" create problems of their own.[136]

Even if the universities' behavior were to improve, problems with their patenting practices could persist. Courts have decided that because universities are behaving as commercial actors, patent law should treat them as such. Accordingly, courts do not afford academic researchers special privileges to delay work on patentable subject matter, even when the delay arises from attempts to preserve

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132. *See, e.g.*, Rebecca S. Eisenberg, *Bargaining Over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?*, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY, *supra* note 92, at 223, 225 ("[T]here seems to be a widely-shared perception that negotiations over the transfer of proprietary research tools present a considerable and growing obstacle to progress in biomedical research and product development."). *See generally* Rebecca S. Eisenberg, *Reaching Through the Genome*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT at 209 (F. Scott Kieff ed., 2003) (discussing reach-through strategies, remedies, and mechanisms).

133. *See* David C. Mowery, Bhaven N. Sampat & Arvids A. Ziedonis, *Learning to Patent: Institutional Experience, Learning, and the Characteristics of U.S. University Patents after the Bayh-Dole Act, 1981–1992*, 48 MGMT. SCI. 73, 85–86 (2002).

134. *See* Avital Bar-Shalom & Robert Cook-Deegan, *Patents and Innovation in Cancer Therapeutics: Lessons from CellPro*, 80 MILBANK Q. 637, 661 (2002); Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1417–27 (2007).

135. *See, e.g.*, Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 929 (Fed. Cir. 2004) (finding that the University's patent was invalid for lack of an adequate description and stating that the Bayh-Dole Act "was not intended to relax the statutory requirements for patentability" for universities).

136. J.H. Reichman, *Saving the Patent Law from Itself*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT, *supra* note 132, at 289, 297; *see also supra* text accompanying note 116.

pedagogic opportunities for students.[137] This creates one of a series of new conflicts between a university's educational mission and its commercial goals; between a faculty member's research and teaching commitments; and between the academy's duties as honest brokers in science policy debates and its proprietary self-interest.

Far more worrisome is the judicial trend to deny academics engaged in scholarly inquiry any further research exemptions from infringement liability.[138] Fortunately, few infringement suits have been filed against universities to date, but if such cases were to proliferate unchecked, the cost of basic science would soar. Even in the absence of suits against scientists, an empirical study has uncovered evidence that university research is beginning to suffer from an anticommons effect.[139] Although some studies also claim that patents have little direct impact on university work, scholarship has documented the erosion of the Mertonian norms, with increased secrecy and a growing reluctance to share research materials.[140] Furthermore, patenting could easily come to affect scholarly agendas, shifting attention from the basic work that opens whole new fields of knowledge to applied research aimed narrowly at exploiting particular commercial markets. Again, the empirical evidence is mixed, but the effects of an increasing interest in patenting (and commerce) on the part of university faculty is alarming.[141]

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137. *See, e.g.*, Griffith v. Kanamaru, 816 F.2d 624, 626 (Fed. Cir. 1987) (finding no excuse for a university professor-inventor's inactivity when he claimed that his delay was due in part to the fact that he was waiting for a particular graduate student to begin work).

138. *See, e.g.*, Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) ("[O]ur precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.").

139. Stern & Murray, *supra* note 81, at 5.

140. Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1092 (2006); Wesley M. Cohen & John P. Walsh, *Real Impediments to Academic Biomedical Research*, *in* 8 INNOVATION POL'Y & ECON. (Adam B. Jaffe, Joshua Lerner & Scott Stern eds., forthcoming 2007); Wesley M. Cohen, John P. Walsh & Charlene Cho, *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002 (2005). For an introduction to Mertonian norms, see ROBERT K. MERTON, *The Normative Structure of Science*, *in* THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS 267 (Norman W. Storer ed., 1973).

141. *See, e.g.*, Pierre Azoulay, Waverly Ding & Toby Stuart, *The Determinants of Faculty Patenting Behavior: Demographics or Opportunities?*, 63 J. ECON. BEHAV. & ORG. 599, 601

In theory, of course, legislation might remedy some of these problems. For example, Congress could enact a codified research exemption.[142] Patent applications from academics could be examined differently, and the scope of patents could be adjusted to deal with the anticommons effect. When necessary, compulsory licenses to unblock dependent patents and enable improvers to reach the market could also be enacted, a solution that remains fully consistent with the TRIPS Agreement.[143]

Yet, as Section A showed, there is substantial disagreement concerning the very existence of the problems and the wisdom of proposed legislative solutions.[144] Were the laws in question subject to substantive international obligations, it would compound these problems. Some economies may rely on the spillover benefits of basic research; others may see commercializing university work as an important source of funding. Another complicating factor is that universities do not participate equally in all commercial sectors. Consequently, arguments about technological neutrality would arise

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(2007) (suggesting that mid-career faculty, faculty associated with patent holders, and faculty employed by institutions holding many patents are more likely to patent); Mario Calderini, Chiara Fanzoni & Andrea Vezzulli, *If Star Scientists Do Not Patent: The Effect of Productivity, Basicness and Impact on the Decision to Patent in the Academic World*, 36 RES. POL'Y 303, 317 (2007) (suggesting that scientists engaged in applied research are more likely to patent than scientists engaged in basic research); Richard R. Nelson, *Observations on the Post Bayh-Dole Rise of Patenting at American Universities*, 26 J. TECH. TRANSFER 13, 15 (2001) (arguing that the rising number of patents suggests trouble down the road); Jerry G. Thursby & Marie C. Thursby, *Who Is Selling the Ivory Tower? Sources of Growth in University Licensing*, 48 MGMT. SCI. 90, 102 (2002) (showing that research agendas are not changing significantly, but instead universities are patenting discoveries that they would previously have made publicly available).

142. *See generally* Rochelle C. Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 463 (2004) (calling for a broad, statutory experimental use exception).

143. *See* TRIPS Agreement, *supra* note 11, art. 31(*l*); JEROME H. REICHMAN WITH CATHERINE HASENZAHL, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS: HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS, AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE USA 1–2 (June 2003), *available at* http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf.

144. *Compare, e.g.*, Richard A. Epstein, *Steady the Course: Property Rights in Genetic Material*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT, *supra* note 132, at 153, 168, 168 (suggesting the current system of genomic patent filings is preferable to alternatives), *with* Rochelle Cooper Dreyfuss, *Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT, *supra* note 132, at 196, 195–96 (examining the assumptions underlying arguments for and against legislative stability); *see also* Reichman, *supra* note 136, at 289 (contesting Epstein's "all or nothing" premise and proposing greater reliance on liability rules).

in any attempt to alter the patent system to protect core scientific progress.

C. New Approaches

When faced with the problems of new technologies and new players, countries have adopted very different strategies. In particular, the U.S. approach differs significantly from developments in Europe. With regard to patents in biotechnology, for example, the EPO, following the European Directive on Biotechnology,[145] seems to be breaking away from the "chemical compound" analogy that typifies U.S. law. Instead, it has begun to treat DNA patents as information products, whose eligibility tests should turn on the quality and industrial applicability of the information revealed.[146]

The EC Biotechnology Directive also added a new compulsory license to facilitate interaction between infringing plant breeders and biotech patents.[147] When implementing the Biotechnology Directive, moreover, a number of European governments have embarked on new directions of their own at the expense of a uniform law. Although some nations were initially unwilling to fully implement the Biotechnology Directive,[148] others, such as Germany, have attempted to limit gene patents to the use or purpose recited in the application.[149]

The EPO also seems to have handled the information technology sector more cautiously than the United States by insisting on a demonstrable "technical contribution" palpably beyond the state of

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145. Council Directive 98/44, Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13 (EC).

146. *See* Rob J. Aerts, *The Industrial Applicability and Utility Requirements for the Patenting of Genomic Inventions: A Comparison between European and US Law*, 26 EUR. INTELL. PROP. REV. 349, 351–52 (2004); Samantha A. Jameson, *A Comparison of the Patentability and Patent Scope of Biotechnological Inventions in the United States and the European Union*, 35 AIPLA Q.J. 193, 217–24 (2007).

147. *See* Council Directive 98/44, *supra* note 145, art. 12.

148. The recalcitrant EU Member States all implemented the Directive by the end of 2006. *See* STATE OF PLAY OF THE IMPLEMENTATION OF DIRECTIVE 98/44/EC (2007), http://www.europa.eu.int/comm/internal_market/indprop/docs/invent/state-of-play_en.pdf (last visited Oct. 4, 2007).

149. German Patent Statute, PatG § 1a(4). The provision is controversial. *See, e.g.*, Christoph Ann, *Patents on Human Gene Sequences in Germany: On Bad Lawmaking and Ways to Deal With It*, 7 GERMAN L. J. 279, 280, *available at* http://www.germanlawjournal.com/pdf/Vol07/pdf_Vol_07_No_03.pdf.

the art.[150] How the EPO proceeds in this area following the European Parliament's rejection of a proposed Community Directive on the Patenting of Software deserves careful scrutiny.[151] Furthermore, even if patents on software were eventually to produce the kind of blocking effects experienced in the United States, many European countries formally recognize the possibility of compulsory licenses for dependent patents on improvements.[152] Although these provisions are seldom invoked, they likely exert *in terrorem* effects that stimulate efficient licensing practices, and they provide patent authorities with a codified antiblocking measure when needed.

Moreover, the patent system is not the only mechanism for encouraging technological progress. A strong argument can be made for supplementing patents with new kinds of intermediate or second-tier protection systems that are more attuned to present-day technological realities. Although robust property-like regimes, such as patent law, presuppose clear boundaries between different rights holders, the actual boundaries between products of the new technologies are often ill-defined. The problem of cumulative innovation is thus aggravated by the ways in which new contributions are dependent on, and intermingled with, earlier innovations. Patents increasingly breed high litigation and transaction costs because they artificially divide that which is inherently indivisible, a practice that needlessly slows the rate of innovation by chilling the ability of second comers to build on earlier contributions for both scientific and commercial purposes.[153]

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150. Thomas Hoeren, *The European Union Commission and Recent Trends in European Information Law*, 29 RUTGERS COMPUTER & TECH. L.J. 1, 10 (2003); E. Panagiotidou, *The Patentability of Computer Programs, according to the Commission's New Proposal for a Directive and to EPO Boards of Appeal Decisions*, 9 COMPUTER & TELECOMM. L. REV. 126, 129 (2003); Wolfgang Tauchert, *Patent Protection for Computer Programs—Current Status and New Developments*, 31 IIC 812, 818 (2000).

151. *See, e.g.*, Andreas Grosche, *Software Patents—Boon or Bane for Europe?*, 14 INT'L J.L. & INFO. TECH. 257, 259–60 (2006) (providing analysis of a wide scope of patent laws and policies beyond the proposed provisions before the European Parliament).

152. *See, e.g.*, Patents Act, 1977, c. 37, § 48A(1)(b)(i) (Eng.); 2 J.W. Baxter, World Patent Law and Practice § 8.02 (2001); *see also* Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 104 (1994) ("[S]tatutes [that] provide, in varying ways, for a liability rule in the case of an improvement invention that infringes on a dominant patent . . . have no discernable effect on the incentives for European firms to invent."); REICHMAN WITH HASENZAHL, *supra* note 143, at 12 (discussing the presence of blocking patents on improvements to prior inventions in many countries).

153. *See* Reichman, *Of Green Tulips and Legal Kudzu*, *supra* note 92, at 23, 26–29.

In sectors where these conditions prevail, a different kind of regime may be superior. To give one example, compensatory liability regimes—liability rules—may be a good solution for cumulative technologies. They would protect first comers against wholesale duplication while enabling improvers to build on their work, subject to an obligation to return a healthy share of the potential gains to the earlier innovator.[154] These entitlements could be voluntarily adopted by industrial sectors or mandated by law or regulation to resolve blocking effects.[155] Other ideas—open source models, collaborative modes of production, clearinghouse models—have also attracted growing attention,[156] although their dependence on exclusive property rights is often overlooked.[157]

Of course, not all the advocates of deep harmonization claim to know all the answers; rather, some suggest codifying basic aspects of domestic patent law—so-called "best practices"—that would provide a solid foundation for transnational harmonization.[158] But this approach is premised on several fallacies. First, even for countries at similar levels of technological sophistication, "best practices" are not likely to be the same. Moreover, what any given country views as "best practices" in patent law may reflect other practices in other laws—including copyright, trade secret, utility model laws, and, above all, competition laws—that may vary widely from one country to another.[159] The advocates of a "best practices" approach to

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154. *See, e.g., id.*, at 48–52; Reichman & Lewis, *supra* note 74, at 337, 348–65.

155. *See generally* Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, *supra* note 92 (showing breakdown of trade secret law under present-day conditions and advocating use of liability rules not premised on secrecy to deal with market failures affecting incremental innovation).

156. *See, e.g.*, YOCHAI BENKLER, THE WEALTH OF NETWORKS: HOW SOCIAL PRODUCTION TRANSFORMS MARKETS AND FREEDOM 463–66, 471–73 (2006); Ian Ayres & J.M. Balkin, *Legal Entitlements as Auctions: Property Rules, Liability Rules, and Beyond*, 106 YALE L.J. 703, 706–07 (1996); Janet Hope, Open Source Biotechnology (Dec. 23, 2004) (unpublished Ph.D. thesis, The Australian National University), *available at* http://rsss.anu.edu.au/~janeth/OpenSourceBiotechnology27July2005.pdf; Geertui Van Overwalle et al., *Models for Facilitating Access to Patents on Genetic Inventions*, 7 NATURE REVIEWS: GENETICS 143 (2006)Esther van Zimmeren et al., *A Clearing House for Diagnostic Testing: The Solution to Ensure Access to and Use of Patented Genetic Inventions?*, 84 BULL. WORLD HEALTH ORG. 352, 353–56 (2006).

157. *See* Boyle, *supra* note 28, at 67–69.

158. *See* Hauda, *supra* note 17, at 97.

159. *See* Mark D. Janis, *Second Tier Patent Protection*, 40 HARV. INT'L L.J. 151, 177–99 (1999) (critiquing the harmonization of second tier patent regimes); Jonathan Zuck, President, Ass'n for Competitive Tech., Comments to the Antitrust Modernization Comm'n (Feb. 7, 2006), *available at* http://www.amc.gov/public_studies_fr28902/international_pdf/060207_ACT_Intl.pdf (noting the importance of consistent treatment of small businesses in the information

harmonization do not explain how to identify which practices are genuinely the best, or explain how international lawmakers will keep the practices they choose responsive to changing needs.

Another more subtle effect of premature legal harmonization is that it could unhelpfully homogenize creative development. The diverging approaches observed in national innovation laws may not solely depend on differing perceptions of how to cure the same set of problems. Some of these differences may emerge from differing problems, differences that arise because each society values its own specific kinds of creativity and prioritizes its technological requirements in its own way. The TRIPS Agreement still leaves countries some room to exclude developments from patentability on grounds such as public policy and lack of inventiveness, or because the work is not considered within a field of "technology" and therefore not within the subject matter of patent law.[160] As a result, a country that excels in certain kinds of work has some flexibility to put the tools for accomplishing that work into the public domain; other countries skilled in producing the tools may prefer to make them patentable.[161]

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technology sector). The debate outlined in the text accompanying this footnote suggests that, at a minimum, the level of intellectual property protection in any given country may depend on whether that country has enacted and implemented antitrust law to deal with competitive excesses. Yet, the SPLT (like TRIPS) does not mandate protection outside the intellectual property field, and antitrust law is only one of the many related issues that might influence the appropriate level of protection. *See* Josef Drexl, *The Critical Role of Competition Law in Preserving Public Goods in Conflict with Intellectual Property Rights*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 709, 716–24; Eleanor M. Fox, *Can Antitrust Policy Protect the Global Commons from the Excesses of IPRs?*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 758, 758–69; Maskus & Reichman, *supra* note 30, at 33–41; Hanns Ullrich, *Expansionist Intellectual Property Protection and Reductionist Competition Rules: A TRIPS Perspective*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 726, 737, 752.

160. *See* TRIPS Agreement, *supra* note 11, art. 27.

161. For example, the United States and Canada have taken divergent positions on whether higher-order life forms can be patented, leading to different treatment of mice bred as research tools in the life sciences. *Compare* Harvard Coll. v. Canada (Comm'r of Patents), File 28155, 2002 S.C.C. 76 (Dec. 5, 2002), *available at* http://scc.lexum.umontreal.ca/en/2002/2002scc76/2002scc76.html (holding the oncomouse unpatentable), *with* Transgenic Non-Human Mammals, U.S. Patent No. 4,736,866 (filed June 22, 1984) (issued Apr. 12, 1988), *available at*, http://patft.uspto.gov/netahtml/PTO/search-bool.html (search for "4,736,866" in "Field1: Patent Number"), *and* Hibberd, 227 U.S.P.Q. 443, 445 (B.P.A.I. 1985) (holding certain living organisms patentable).

Because the information necessary to match particular approaches to specific types of innovation opportunities is lacking, allowing nations to experiment would be highly beneficial. Some will use legislative solutions; the Supreme Court's foray into patent law suggests that the U.S. approach may be judicially based;[162] and in some places, voluntary schemes will emerge. Over time, experts can compare and evaluate these experiments, and when one or another solution appears to yield positive results, nations can emulate that approach. Harmonization would, in that event, be achieved voluntarily and on the basis of actual empirical data and experience, not simply backroom wrangling and special-interest lobbying.[163]

Allowing nations to shape their laws also gives rise to comparative advantages by enabling each nation to foster what its technological community does best. So long as trade remains relatively free, the flexibility to experiment enhances social welfare worldwide. Accommodations between national and regional systems of innovation can then evolve over time on the basis of bottom-up preferences. Without an agreed-upon legitimate governance process (through administrative agencies, courts, and legislatures), it is difficult to see how these kinds of continual accommodations can occur. A politically skewed re-regulation of the world market,

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162. Between the summer of 2005 and the summer of 2007, the Supreme Court considered seven patent cases. *See* Microsoft Corp. v. AT&T Corp., 127 S. Ct. 1746 (2007); KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007); MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007); Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (per curiam) (dismissing writ of certiorari as improvidently granted); eBay, Inc. v. MercExchange, LLC, 126 S. Ct. 1837 (2006); Ill. Tool Works Inc. v. Indep. Ink, Inc., 126 S. Ct. 1281 (2006); Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372 (2005).

163. To be sure, special-interest politics will play out in domestic arenas as well. But in the international context, the problems are particularly severe: well-heeled groups may be better at attracting international attention, and differences in the ways in which international and domestic instruments are reviewed tend to systematically unravel carefully negotiated deals in a direction that favors right holders. *See* Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *TRIPS and the Dynamics of International Property Lawmaking*, 36 CASE W. RES. J. INT'L L. 95, 119–21 (2004). *See generally* Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 6 (2004) ("In the case of intellectual property rights, developing countries and their allies are shifting negotiations to international regimes whose institutions, actors, and subject matter mandates are more closely aligned with these countries' interests . . . challenging established legal prescriptions and generating new principles, norms, and rules of intellectual property protection . . . .").

coupled with excessive privatization of global public goods, could instead make both competition and innovation more difficult.[164]

To put this another way, patent law's *raison d'être* is to encourage the production of novelty and inventiveness. Its success means that there will always be new problems to solve. It makes little sense to preclude the U.S. Supreme Court, the European Court of Justice, and their equivalents elsewhere, along with national agencies and legislatures—all of which have shown themselves capable of creating law responsive to new circumstances—from offering their contributions to the evolution of the future patent system.

III. NURTURING AN INCIPIENT TRANSNATIONAL SYSTEM OF INNOVATION

Of course, if trade is relatively free and creativity flourishes, some international coordination of the patent system becomes a necessity. But instead of premature substantive harmonization, what an integrated world economy needs is a method for lowering the costs that discrepancies in national laws impose on international actors and a system that will gradually enable innovators in all countries to reach the world market by means that are geared to their different national and regional capabilities and endowments.[165] The trick, then, is to decide which laws actually need some modest degree of harmonization and to find a mechanism for revising the law as new coordination problems crop up.

New measures are urgently needed at the prosecution stage. The priority rules of the Paris Convention, coupled with the Patent Cooperation Treaty and other procedural advances,[166] move the

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164. *See* Maskus & Reichman, *supra* note 30, at 19 (suggesting that a "knowledge cartel" pushes "governments to regulate the global market in ways that lock in temporary competitive advantages without necessarily advancing the global public interest in innovation, competition, or the provision of complementary public goods" and reasoning that "representatives of the global public interest are unlikely to be seated at the table where hard-law negotiations take place").

165. *See id.* at 33 ("All countries could benefit from a functionally efficient transnational system of innovation if low barriers to entry enabled entrepreneurs anywhere to invest in the production and distribution of knowledge goods."); *see also* KEITH E. MASKUS, COUNCIL ON FOREIGN RELATIONS, REFORMING U.S. PATENT POLICY: GETTING THE INCENTIVES RIGHT 8, 38 (2006) ("The needs of innovation will be better served by a more flexible—and better enforced—global regime than by the harmonization agenda being pushed by U.S. trade negotiators.").

166. Paris Convention for the Protection of Industrial Property, *supra* note 12, art. 4; *see supra* text accompanying notes 7–9.

system in a direction that makes serial applications easier to accomplish. Nonetheless, modest harmonization of the standards of patentability could dramatically lower private costs and make work sharing among national patent offices feasible.[167] It is not, however, necessary to rely on top-down negotiation at WIPO; beneficial moves toward a more unified approach could be made even in the face of a moratorium on new international lawmaking.[168] After all, when the advantages of a particular rule become evident, nations often tend to voluntarily conform their law to that rule. For example, with the exception of the United States, every country has acquiesced in awarding priority on a first-to-file basis;[169] the United States is considering the absolute novelty standard in use elsewhere;[170] and there is discussion (and some action) outside the United States to introduce a grace period similar to that found in American law.[171]

Cooperation at the level of government agencies and courts can achieve significant moves toward coordination.[172] These mechanisms are well known in international law generally and are taking hold in transnational patent law as well. For example, the European, Japanese, and U.S. patent offices regularly hold trilateral meetings to discuss sets of representative cases and to identify differences in examination practice. When law permits, the offices iron out their differences, so that they can examine applications using the same

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167. *See* John G. Mills III, *A Transnational Patent Convention for the Acquisition and Enforcement of International Patent Rights*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 958, 963 (2006) ("This article revisits the long known problem of the doctrine of territoriality" and "proposes an alternative transnational model using as a basis the *de facto* regional approach of Europe.").

168. *See* Maskus & Reichman, *supra* note 30, at 36–39 (calling for such a moratorium).

169. Request for Comments on the International Effort to Harmonize the Substantive Requirements of Patent Law, 66 Fed. Reg. 15,409, 15,410 (Mar. 19, 2001).

170. For an example of proposed legislation that would move the United States to first-to-file and an absolute novelty standard, see *supra* note 98.

171. *See* Kate H. Murashige, *Harmonization of Patent Laws*, 16 HOUS. J. INT'L L. 591, 610–11 (1994) (describing limited grace periods available in Japanese, Australian, and Canadian law); Toshiko Takenaka, *Rethinking the United States First-To-Invent Principle From a Comparative Law Perspective: A Proposal to Restructure § 102 Novelty and Priority Provisions*, 39 HOUS. L. REV. 621, 626–29, 663 (2002); *see also infra* note 187 and accompanying text.

172. *See* Robert O. Keohane & Joseph S. Nye, *Transgovernmental Relations and International Organizations*, 27 WORLD POL. 39, 42–43 (1974); Anne-Marie Slaughter, *Global Government Networks, Global Information Agencies, and Disaggregated Democracy*, 24 MICH. J. INT'L L. 1041, 1043 (2003); Anne-Marie Slaughter, *A Global Community of Courts*, 44 HARV. INT'L L.J. 191, 191 (2003). *See generally* GOVERNANCE WITHOUT GOVERNMENT: ORDER AND CHANGE IN WORLD POLITICS (James N. Rosenau & Ernst-Otto Czempiel eds., 1992) (compiling works discussing governance on a worldwide scale).

standards.[173] Further coordination is achieved through examiner exchange programs[174] and regular judicial forums at which patent-law judges can discuss common challenges that arise in their respective national jurisdictions.[175]

Many post-grant issues could benefit from comprehensive international attention. For example, because patentees operate on a global scale, costly infringement suits on parallel patents have become common.[176] Although different results remain technically possible (in that national patents are independent of one another[177]), inconsistent outcomes (in that different parties win in different locations) can complicate global marketing efforts. Some of these transnational cases have tempted courts to give extraterritorial effect to their own laws, a practice that can lead to multiple liabilities for the same harm and damage claims for acts that were legal in the territory where they were performed.[178]

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173. *See, e.g.*, Japan Patent Office, http://www.jpo.go.jp/index.htm (last visited Oct. 4, 2007) (showing examples of cooperative efforts by Japan and partner countries).

174. *See, e.g.*, The Website of the Trilateral Co-operation, Projects, Use of Work Results, Exchange of Examiners, and Comparative Studies, http://www.trilateral.net/projects/use_of_work_results (last visited Oct. 4, 2007).

175. *See, e.g.*, Invitation to the Fourth International Judges Conference on Intellectual Property Law, Intellectual Prop. Owners Educ. Found., *available at* http://www.ipo.org/AM/Template.cfm?Section=Past_Meetings_and_Events&Template=/CM/ContentDisplay.cfm&ContentFileID=6462 (announcing the schedule of conference events).

176. *See* John R. Thomas, *Litigation beyond the Technological Frontier: Comparative Approaches to Multinational Patent Enforcement*, 27 LAW & POL'Y INT'L BUS. 277, 291 (1996); *see also* Mills, *supra* note 167, at 989–96 (discussing a variety of disputes involving parallel patents). *See generally* European Max-Planck Group for Conflict of Laws in Intellectual Prop., *supra* note 5, at 196–97, 202 (proposing amendments to Regulation EC 44/2001 to ensure efficient enforcement of parallel intellectual property rights); sources cited *supra* note 6.

177. Paris Convention for the Protection of Industrial Property, *supra* note 12, art. 4*bis*(1).

178. The Federal Circuit was particularly drawn to this tactic. *See, e.g.*, AT&T Corp. v. Microsoft Corp., 414 F.3d 1366, 1367–72 (Fed. Cir. 2005), *rev'd*, 127 S. Ct. 1746 (2007) (applying U.S. patent law to the transfer of software onto foreign-assembled computers from "golden master" disks or electronic transmissions originating in the United States); Eolas Techs. Inc. v. Microsoft Corp., 399 F.3d 1325, 1938–41 (Fed. Cir. 2005) (same). The Supreme Court has presumably ended this practice by reversing the *AT&T* case. *AT&T Corp.*, 127 S. Ct. at 1759. *Cf.* Soc'y of Composers, Authors & Music Publishers of Can. v. Canadian Ass'n of Internet Providers, File 29286, 2004 S.C.C. 45 (June 30, 2004), *available at* http://scc.lexum.umontreal.ca/en/2004/2004scc45/2004scc45.html (noting that the decision to find jurisdiction over an Internet service provider "raises the spectre of imposition of copyright duties on a single telecommunication in both the State of transmission and the State of reception," and also noting that "as with other fields of overlapping liability . . . the answer lies in the making of international or bilateral agreements").

Globalization has also created new opportunities for sharp practices. Examples include harassment of lawful users with successive suits[179] and so-called "torpedo actions" that prevent the patentee from obtaining timely relief.[180] In addition, because patents are territorial, infringers can spread their activities across several states and leave the patent holder with no single place where a court can find the patent to have been infringed.[181]

Once again, top-down solutions are not necessarily the right approach. Another less radical response would permit parties in transnational cases to consolidate all their claims before a single tribunal or to coordinate multiple lawsuits through cooperation among the courts in which actions are pending. This would reduce costs, conserve court resources, reduce opportunities for harassment, and hopefully mitigate the extraterritorial impulse. Furthermore, as Professor Graeme Dinwoodie has suggested, courts hearing multijurisdictional cases may be positioned to find middle ground among disparate rules—that is, to further harmonization efforts through common-law adjudication.[182] Although adjudicators have proved reluctant to forge new procedural approaches on their own,[183] several organizations are in the process of proposing guidelines and procedures that courts (or national governments) could adopt. Some apply to transnational litigation generally;[184] others to intellectual

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179. *See, e.g.*, Computer Assocs. Int'l, Inc. v. Altai, Inc., 126 F.3d 365, 367, 371 (2d Cir. 1997) (successive suits for infringing trade secrets brought in the United States and France not barred by res judicata).

180. Paul A. Coletti, *No Relief in Sight: Difficulties in Obtaining Judgments in Europe Using EPO Issued Patents*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 351, 367 & n.89 (1999); Robin Jacob, *International Intellectual Property Litigation in the Next Millennium*, 32 CASE W. RES. J. INT'L L. 507, 511 (1999).

181. Mark A. Lemley et al., *Divided Infringement Claims*, 6 SEDONA CONF. J. 117, 120–21 (2005); Melissa Feeney Wasserman, *Divided Infringement: Expanding the Extraterritorial Scope of Patent Law*, 82 N.Y.U. L. REV. 281, 281–82 (2007).

182. Graeme B. Dinwoodie, *A New Copyright Order: Why National Courts Should Create Global Norms*, 149 U. PA. L. REV. 469, 542–43 (2000).

183. *See, e.g.*, Voda v. Cordis Corp., 476 F.3d 887, 890 (Fed. Cir. 2007) (rejecting attempt to consolidate U.S. and foreign patent claims); Case C-4/03, Gesellschaft für Antriebstechnik mbH & Co KG v Lamellen und Kupplungsbau Beteiligungs KG, [2006] F.S.R. 45 (E.C.J. 2006) (refusing to permit a German court to determine the consequences of allegedly patent-infringing activity in France when the case required the determination of the validity of the French patent); *cf.* Case C-593/03, Roche Nederland BV v. Primus, Goldenberg, [2007] F.S.R. 5 (E.C.J. 2006) (refusing to permit a Dutch court to join foreign defendants to a patent infringement suit involving a resident defendant).

184. *See, e.g.*, F. K. Juenger, *The ILA Principles on Provisional and Protective Measures*, 45 AM. J. COMP. L. 941, 941 (1997); Int'l Law Ass'n [ILA], *International Civil and Commercial*

property cases specifically.[185] If one of these projects were to succeed, the experience generated would provide future advocates of harmonized patent law with data of extraordinary value.

Even when a more centralized approach becomes propitious, questions will remain about the level at which harmonization should take place. Thus, the European Community has long been debating the merits of instituting a Community Patent and other regions are considering similar projects.[186] The United States, Europe, Japan, and other industrialized countries have discussed the possibility of creating a "limited package" instrument.[187] These initiatives differ from the SPLT negotiations in a significant way. Because they involve nations that are similar economically and technologically, there is no need to compromise on rules that are, in fact, optimum for no one. If such arrangements were to move forward, broader harmonization might eventually trickle down, as nations reaching the technological frontier decided to voluntarily join an existing regime.

Finally, there are advantages to giving the system established under the TRIPS Agreement more time to evolve.[188] The

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Litigation, ILA Res. No. 1/2000 (July 25–29, 2000), *available at* http://www.ila-hq.org/pdf/Civil%20&%20Commercial%20Litigation/RESlitigation.pdf; Hague Conf. on Private Int'l Law, *Draft Convention on Jurisdiction and Foreign Judgments in Civil and Commercial Matters*, Oct. 30, 1999, *available at* http://www.hcch.net/upload/wop/jdgmpd11.pdf; Hague Conf. on Private Int'l Law, *Convention on Choice of Court Agreements*, June 30, 2005, *available at* http://pub.bna.com/eclr/hagueconvention063005.pdf.

185. AM. LAW INST., INTELLECTUAL PROPERTY: PRINCIPLES GOVERNING JURISDICTION, CHOICE OF LAW, AND JUDGMENTS IN TRANSNATIONAL DISPUTES, approved May 14, 2007 (forthcoming 2008); Dreyfuss & Ginsburg, *supra* note 6, at 1065–66. The Max Planck Institute is also working on an International Convention on Jurisdiction and Enforcement of Judgments. Annette Kur, *Applicable Law: An Alternative Proposal for International Regulation—The Max-Planck Project on International Jurisdiction and Choice of Law*, 30 BROOK. J. INT'L L. 951 (2005); *see also* Int'l Ass'n for the Prot. of Intellectual Prop. [AIPPI], *supra* note 5, at 827 (resolving that "courts of a given country should be allowed to make a ruling over infringing acts regarding certain intellectual property rights, which have taken place in any other country"); Yoav Oestreicher, Recognition and Enforcement of Foreign Intellectual Property Judgments: Analysis and Guidelines for a New International Convention 10 (2004) (unpublished S.J.D. dissertation, Duke University School of Law), *available at* http://ssrn.com/abstract=939093 (proposing a minimalist international intellectual property convention to solve the world community's continuing inability to regulate the field). The European Union has also had a European Patent Litigation Agreement under consideration. Draft Agreement on the Establishment of a European Patent Litigation System, *supra* note 10.

186. *See supra* note 9.

187. *Industrialized Countries to Seek Deal on Global Patent Treaty Outside WIPO*, 72 Pat. Trademark & Copyright J. (BNA) No. 1788, at 606 (Oct. 6, 2006).

188. The Council for TRIPS bears responsibility for monitoring TRIPS implementation issues. *See* TRIPS Agreement, *supra* note 11, art. 68. There are also nongovernmental

international intellectual property community would learn a great deal from examining how well emerging economies adapt to the minimum standards TRIPS sets out, from scrutinizing the decisions of the WTO's dispute-settlement apparatus,[189] and from observing how WTO Members cope with TRIPS mistakes, such as the one solved in the Doha round.[190]

As drafted, TRIPS has some of the features that a responsive harmonized law needs. It has a dispute resolution system that could be used to keep the law current and, as the Doha Ministerial Declaration on TRIPS and Public Health demonstrated, a quasi-legislative body able to make larger corrections.[191] It is worth waiting to see how well these existing mechanisms deal with the problems challenging the international patent community.

As it stands, however, the TRIPS Agreement is not a final answer to the problem of harmonizing global patent law. The regime lacks a solid legislative basis for adjusting intellectual property law to changing needs. Despite precatory statements about the need for balance,[192] the Agreement focuses solely on the producer end of the equation and does not establish user rights. Thus, it includes no way for the parties to strike, at the international level, the balance between proprietary and access interests that good patent law

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organizations that follow international intellectual property policy making. *See, e.g.*, Intellectual Property Watch, http://ip-watch.org/index.php?res=1024&print=0 (last visited Oct. 4, 2007); Médecins Sans Frontiéres (MSF), Campaign for Access to Essential Medicines, http://www.accessmed-msf.org/index.asp (last visited Oct. 4, 2007); Knowledge Ecology International (KEI), http://www.keionline.org/index.php?option=com_frontpage&Itemid=1 (last visited Oct. 4, 2007).

189. Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 22, Apr. 15 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1126 (1994).

190. *See supra* notes 48–49 and accompanying text; *see also* MASKUS, *supra* note 165, at 7 (recommending "a formal complaint at the WTO that specific countries have failed to meet their enforcement obligations under TRIPS."); Marianne Levin & Annette Kur, Special Session at the Annual Meeting of the International Association for the Advancement of Teaching and Research in Intellectual Property: Towards More Balanced, User-Friendly Paradigms in IP Law: A Project Reform of TRIPS (Sept. 5, 2006) (spearheading a proposal to amend the TRIPS Agreement).

191. *See, e.g.*, Doha Declaration, *supra* note 37 (mandating further negotiations). *See generally* GAIL E. EVANS, LAWMAKING UNDER THE TRADE CONSTITUTION: A STUDY IN LEGISLATING BY THE WORLD TRADE ORGANIZATION (2000); Abbott, *supra* note 48 (commenting on the implementation of the Doha Declaration).

192. TRIPS Agreement, *supra* note 11, art. 7; *see id.*, pmbl. & art. 8(1).

requires.[193] Although dispute resolution panels have hinted that their charge includes making normative assessments of the legitimate expectations of patentees—a procedure that could, in theory, develop a series of user rights—these panels have looked no further than a narrow reading of *existing* rules protecting user interests.[194] They articulate nothing like the normative vision required of a dynamic system, capable of responding to new situations.

Arguably, a properly functioning patent law also requires competition law safeguards. The TRIPS Agreement permits Members to control anticompetitive abuse, but it does not mandate such control.[195] If WIPO intends to proceed with the SPLT, it would do well to consider what sorts of user safeguards are needed, to determine whether it is viable to separate the regime that creates exclusive rights from the regime that controls monopolies, and to develop experience and consensus regarding the delicate intersection

193. *See* Graeme B. Dinwoodie, *The International Intellectual Property Law System: New Actors, New Institutions, New Sources*, 10 MARQ. INTELL. PROP. L. REV. 205, 214 (2006) (advocating the inclusion of "substantive maxima" in the TRIPS Agreement to provide balance to the international intellectual property system). *See generally* Rochelle Cooper Dreyfuss, *TRIPS—Round II: Should Users Strike Back?*, 71 U. CHI. L. REV. 21 (2004) ("The TRIPS Agreement . . . is structured to directly protect the rights of intellectual property holders . . . [but] does little . . . to explicitly safeguard the interests of those who seek to use protected works.").

194. *See, e.g.*, Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, *supra* note 125, ¶ 7.56 (finding an exemption permitting the testing of patented pharmaceuticals for regulatory review purposes to be normatively appropriate (without stockpiling) but only because many members already had experimental use exceptions in their patent laws); Dinwoodie & Dreyfuss, *supra* note 29, at 435 ("WTO panels tend to hew closely to text when resolving disputes."); Jane C. Ginsburg, *Toward Supranational Copyright Law? The WTO Panel Decision and the "Three Step Test" for Copyright Exemptions*, 187 REVUE INTERNATIONALE DU DROIT D'AUTEUR 3, 49 (2001) (arguing that the United States–Section 110(5) of the US Copyright Act, WTR/DS/160/R (WTO Dispute Settlement Panel 2000) case sought only to "anticipate what the empirical situation [would] be, [rather] than [provide] an explanation of what the right holder's markets *should* cover").

195. TRIPS Agreement, *supra* note 11, art. 31(k); *see id.* art. 8(2); Mark D. Janis, *"Minimal" Standards for Patent-Related Antitrust Law Under TRIPS*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 774, 776–78; Ullrich, *supra* note 159, at 731–35.

between these two bodies of law,[196] with due regard to the needs of countries at different levels of development.[197]

CONCLUSION

This Article demonstrates that any efforts to achieve deep harmonization of world patent law at the present time, such as those contemplated by the SPLT, are both premature and counterproductive. The evidence shows, instead, that the worldwide intellectual property system has entered a brave new scientific epoch, in which experts have only tentative, divergent ideas about how best to treat a daunting array of emerging new technologies. The existing system has become increasingly dysfunctional because it operates with a set of rudimentary working hypotheses that have not kept pace with technical change. As different countries put these hypotheses to the test, the focus of international lawmakers—whether at WIPO, the WTO, or in a trilateral coalition—should be on gaining experience and data from living within the parameters set out by the TRIPS Agreement during a prolonged period of open-minded experimentation.

If international policymakers rise above sectarian interests and power politics to concentrate on nurturing the incipient transnational system of innovation that the TRIPS Agreement brought into being, they can stimulate research and innovation on a grander scale than ever before. But they must take the time and invest the effort to get it right. Locking in the fleeting, competitive advantages of one group of stakeholders or another at the expense of real innovators and dynamic entrepreneurs everywhere is a bad strategy that will compromise the world's aggregate innovative capacity in the long run. Instead of moving forward with harmonization for its own sake, the

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196. GUSTAVO GHIDINI, INTELLECTUAL PROPERTY AND COMPETITION LAW: THE INNOVATION NEXUS 99–115 (2007); *see* Emanuella Arezzo, *Intellectual Property Rights at the Crossroad between Monopolization and Abuse of a Dominant Position: American and European Approaches Compared*, 24 J. MARSHALL J. COMPUTER & INFO. L. 455, 477–94 (2006).

197. *See* Drexl, *supra* note 159, at 709, 720 ("[R]elevant product markets usually have a limited geographical scope. Whereas intangible goods protected by IPRs may be exploited worldwide, the geographical market for products based on such IPRs is not necessarily a global one.... For instance, in poorer countries that are net importers of agricultural goods, small farmers will not compete with farmers on foreign markets."); Ullrich, *supra* note 159, at 40 ("Community and national protection must be seen as complimentary parts of an overall system of protection, where unification and harmonization allow to balance uniformity with specificity and stability with flexibility of protection.").

international intellectual property community must first identify and test trustworthy, empirically supportable solutions likely to benefit humanity at large.

This is **Exhibit "E"** to the Affidavit of Anna Hucman
sworn before me on this 27th day of July, 2016

Commissioner for taking affidavits

ANNEX 1C

AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

Members,

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;

Recognizing, to this end, the need for new rules and disciplines concerning:

(a) the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions;

(b) the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;

(c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;

(d) the provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments; and

(e) transitional arrangements aiming at the fullest participation in the results of the negotiations;

Recognizing the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods;

Recognizing that intellectual property rights are private rights;

Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base;

Emphasizing the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures;

Desiring to establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (referred to in this Agreement as "WIPO") as well as other relevant international organizations;

Hereby agree as follows:

PART I

GENERAL PROVISIONS AND BASIC PRINCIPLES

Article 1

Nature and Scope of Obligations

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

2. For the purposes of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.

3. Members shall accord the treatment provided for in this Agreement to the nationals of other Members.[1] In respect of the relevant intellectual property right, the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the WTO members of those conventions.[2] Any Member availing itself of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights (the "Council for TRIPS").

Article 2

Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

Article 3

National Treatment

1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection[3] of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this

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[1]When "nationals" are referred to in this Agreement, they shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

[2]In this Agreement, "Paris Convention" refers to the Paris Convention for the Protection of Industrial Property; "Paris Convention (1967)" refers to the Stockholm Act of this Convention of 14 July 1967. "Berne Convention" refers to the Berne Convention for the Protection of Literary and Artistic Works; "Berne Convention (1971)" refers to the Paris Act of this Convention of 24 July 1971. "Rome Convention" refers to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome on 26 October 1961. "Treaty on Intellectual Property in Respect of Integrated Circuits" (IPIC Treaty) refers to the Treaty on Intellectual Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989. "WTO Agreement" refers to the Agreement Establishing the WTO.

[3]For the purposes of Articles 3 and 4, "protection" shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement.

Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

Article 4

Most-Favoured-Nation Treatment

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:

(a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;

(b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;

(c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;

(d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

Article 5

Multilateral Agreements on Acquisition or Maintenance of Protection

The obligations under Articles 3 and 4 do not apply to procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of intellectual property rights.

Article 6

Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

PART II

STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS

SECTION 1: COPYRIGHT AND RELATED RIGHTS

Article 9

Relation to the Berne Convention

1. Members shall comply with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto. However, Members shall not have rights or obligations under this Agreement in respect of the rights conferred under Article 6*bis* of that Convention or of the rights derived therefrom.

2. Copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such.

Article 10

Computer Programs and Compilations of Data

1. Computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971).

2. Compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself.

Article 11

Rental Rights

In respect of at least computer programs and cinematographic works, a Member shall provide authors and their successors in title the right to authorize or to prohibit the commercial rental to the public of originals or copies of their copyright works. A Member shall be excepted from this obligation

in respect of cinematographic works unless such rental has led to widespread copying of such works which is materially impairing the exclusive right of reproduction conferred in that Member on authors and their successors in title. In respect of computer programs, this obligation does not apply to rentals where the program itself is not the essential object of the rental.

Article 12

Term of Protection

Whenever the term of protection of a work, other than a photographic work or a work of applied art, is calculated on a basis other than the life of a natural person, such term shall be no less than 50 years from the end of the calendar year of authorized publication, or, failing such authorized publication within 50 years from the making of the work, 50 years from the end of the calendar year of making.

Article 13

Limitations and Exceptions

Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.

Article 14

Protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations

1. In respect of a fixation of their performance on a phonogram, performers shall have the possibility of preventing the following acts when undertaken without their authorization: the fixation of their unfixed performance and the reproduction of such fixation. Performers shall also have the possibility of preventing the following acts when undertaken without their authorization: the broadcasting by wireless means and the communication to the public of their live performance.

2. Producers of phonograms shall enjoy the right to authorize or prohibit the direct or indirect reproduction of their phonograms.

3. Broadcasting organizations shall have the right to prohibit the following acts when undertaken without their authorization: the fixation, the reproduction of fixations, and the rebroadcasting by wireless means of broadcasts, as well as the communication to the public of television broadcasts of the same. Where Members do not grant such rights to broadcasting organizations, they shall provide owners of copyright in the subject matter of broadcasts with the possibility of preventing the above acts, subject to the provisions of the Berne Convention (1971).

4. The provisions of Article 11 in respect of computer programs shall apply *mutatis mutandis* to producers of phonograms and any other right holders in phonograms as determined in a Member's law. If on 15 April 1994 a Member has in force a system of equitable remuneration of right holders in respect of the rental of phonograms, it may maintain such system provided that the commercial rental of phonograms is not giving rise to the material impairment of the exclusive rights of reproduction of right holders.

5. The term of the protection available under this Agreement to performers and producers of phonograms shall last at least until the end of a period of 50 years computed from the end of the calendar

year in which the fixation was made or the performance took place. The term of protection granted pursuant to paragraph 3 shall last for at least 20 years from the end of the calendar year in which the broadcast took place.

6. Any Member may, in relation to the rights conferred under paragraphs 1, 2 and 3, provide for conditions, limitations, exceptions and reservations to the extent permitted by the Rome Convention. However, the provisions of Article 18 of the Berne Convention (1971) shall also apply, *mutatis mutandis*, to the rights of performers and producers of phonograms in phonograms.

SECTION 2: TRADEMARKS

Article 15

Protectable Subject Matter

1. Any sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark. Such signs, in particular words including personal names, letters, numerals, figurative elements and combinations of colours as well as any combination of such signs, shall be eligible for registration as trademarks. Where signs are not inherently capable of distinguishing the relevant goods or services, Members may make registrability depend on distinctiveness acquired through use. Members may require, as a condition of registration, that signs be visually perceptible.

2. Paragraph 1 shall not be understood to prevent a Member from denying registration of a trademark on other grounds, provided that they do not derogate from the provisions of the Paris Convention (1967).

3. Members may make registrability depend on use. However, actual use of a trademark shall not be a condition for filing an application for registration. An application shall not be refused solely on the ground that intended use has not taken place before the expiry of a period of three years from the date of application.

4. The nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to registration of the trademark.

5. Members shall publish each trademark either before it is registered or promptly after it is registered and shall afford a reasonable opportunity for petitions to cancel the registration. In addition, Members may afford an opportunity for the registration of a trademark to be opposed.

Article 16

Rights Conferred

1. The owner of a registered trademark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed. The rights described above shall not prejudice any existing prior rights, nor shall they affect the possibility of Members making rights available on the basis of use.

2. Article 6*bis* of the Paris Convention (1967) shall apply, *mutatis mutandis*, to services. In determining whether a trademark is well-known, Members shall take account of the knowledge of the

trademark in the relevant sector of the public, including knowledge in the Member concerned which has been obtained as a result of the promotion of the trademark.

3. Article 6*bis* of the Paris Convention (1967) shall apply, *mutatis mutandis*, to goods or services which are not similar to those in respect of which a trademark is registered, provided that use of that trademark in relation to those goods or services would indicate a connection between those goods or services and the owner of the registered trademark and provided that the interests of the owner of the registered trademark are likely to be damaged by such use.

Article 17

Exceptions

Members may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interests of the owner of the trademark and of third parties.

Article 18

Term of Protection

Initial registration, and each renewal of registration, of a trademark shall be for a term of no less than seven years. The registration of a trademark shall be renewable indefinitely.

Article 19

Requirement of Use

1. If use is required to maintain a registration, the registration may be cancelled only after an uninterrupted period of at least three years of non-use, unless valid reasons based on the existence of obstacles to such use are shown by the trademark owner. Circumstances arising independently of the will of the owner of the trademark which constitute an obstacle to the use of the trademark, such as import restrictions on or other government requirements for goods or services protected by the trademark, shall be recognized as valid reasons for non-use.

2. When subject to the control of its owner, use of a trademark by another person shall be recognized as use of the trademark for the purpose of maintaining the registration.

Article 20

Other Requirements

The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings. This will not preclude a requirement prescribing the use of the trademark identifying the undertaking producing the goods or services along with, but without linking it to, the trademark distinguishing the specific goods or services in question of that undertaking.

Article 21

Licensing and Assignment

Members may determine conditions on the licensing and assignment of trademarks, it being understood that the compulsory licensing of trademarks shall not be permitted and that the owner of a registered trademark shall have the right to assign the trademark with or without the transfer of the business to which the trademark belongs.

SECTION 3: GEOGRAPHICAL INDICATIONS

Article 22

Protection of Geographical Indications

1. Geographical indications are, for the purposes of this Agreement, indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.

2. In respect of geographical indications, Members shall provide the legal means for interested parties to prevent:

(a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good;

(b) any use which constitutes an act of unfair competition within the meaning of Article 10*bis* of the Paris Convention (1967).

3. A Member shall, *ex officio* if its legislation so permits or at the request of an interested party, refuse or invalidate the registration of a trademark which contains or consists of a geographical indication with respect to goods not originating in the territory indicated, if use of the indication in the trademark for such goods in that Member is of such a nature as to mislead the public as to the true place of origin.

4. The protection under paragraphs 1, 2 and 3 shall be applicable against a geographical indication which, although literally true as to the territory, region or locality in which the goods originate, falsely represents to the public that the goods originate in another territory.

Article 23

Additional Protection for Geographical Indications for Wines and Spirits

1. Each Member shall provide the legal means for interested parties to prevent use of a geographical indication identifying wines for wines not originating in the place indicated by the geographical indication in question or identifying spirits for spirits not originating in the place indicated by the geographical indication in question, even where the true origin of the goods is indicated or the geographical indication is used in translation or accompanied by expressions such as "kind", "type", "style", "imitation" or the like.[4]

[4]Notwithstanding the first sentence of Article 42, Members may, with respect to these obligations, instead provide for enforcement by administrative action.

2. The registration of a trademark for wines which contains or consists of a geographical indication identifying wines or for spirits which contains or consists of a geographical indication identifying spirits shall be refused or invalidated, *ex officio* if a Member's legislation so permits or at the request of an interested party, with respect to such wines or spirits not having this origin.

3. In the case of homonymous geographical indications for wines, protection shall be accorded to each indication, subject to the provisions of paragraph 4 of Article 22. Each Member shall determine the practical conditions under which the homonymous indications in question will be differentiated from each other, taking into account the need to ensure equitable treatment of the producers concerned and that consumers are not misled.

4. In order to facilitate the protection of geographical indications for wines, negotiations shall be undertaken in the Council for TRIPS concerning the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those Members participating in the system.

Article 24

International Negotiations; Exceptions

1. Members agree to enter into negotiations aimed at increasing the protection of individual geographical indications under Article 23. The provisions of paragraphs 4 through 8 below shall not be used by a Member to refuse to conduct negotiations or to conclude bilateral or multilateral agreements. In the context of such negotiations, Members shall be willing to consider the continued applicability of these provisions to individual geographical indications whose use was the subject of such negotiations.

2. The Council for TRIPS shall keep under review the application of the provisions of this Section; the first such review shall take place within two years of the entry into force of the WTO Agreement. Any matter affecting the compliance with the obligations under these provisions may be drawn to the attention of the Council, which, at the request of a Member, shall consult with any Member or Members in respect of such matter in respect of which it has not been possible to find a satisfactory solution through bilateral or plurilateral consultations between the Members concerned. The Council shall take such action as may be agreed to facilitate the operation and further the objectives of this Section.

3. In implementing this Section, a Member shall not diminish the protection of geographical indications that existed in that Member immediately prior to the date of entry into force of the WTO Agreement.

4. Nothing in this Section shall require a Member to prevent continued and similar use of a particular geographical indication of another Member identifying wines or spirits in connection with goods or services by any of its nationals or domiciliaries who have used that geographical indication in a continuous manner with regard to the same or related goods or services in the territory of that Member either (*a*) for at least 10 years preceding 15 April 1994 or (*b*) in good faith preceding that date.

5. Where a trademark has been applied for or registered in good faith, or where rights to a trademark have been acquired through use in good faith either:

(a) before the date of application of these provisions in that Member as defined in Part VI; or

(b) before the geographical indication is protected in its country of origin;

measures adopted to implement this Section shall not prejudice eligibility for or the validity of the registration of a trademark, or the right to use a trademark, on the basis that such a trademark is identical with, or similar to, a geographical indication.

6. Nothing in this Section shall require a Member to apply its provisions in respect of a geographical indication of any other Member with respect to goods or services for which the relevant indication is identical with the term customary in common language as the common name for such goods or services in the territory of that Member. Nothing in this Section shall require a Member to apply its provisions in respect of a geographical indication of any other Member with respect to products of the vine for which the relevant indication is identical with the customary name of a grape variety existing in the territory of that Member as of the date of entry into force of the WTO Agreement.

7. A Member may provide that any request made under this Section in connection with the use or registration of a trademark must be presented within five years after the adverse use of the protected indication has become generally known in that Member or after the date of registration of the trademark in that Member provided that the trademark has been published by that date, if such date is earlier than the date on which the adverse use became generally known in that Member, provided that the geographical indication is not used or registered in bad faith.

8. The provisions of this Section shall in no way prejudice the right of any person to use, in the course of trade, that person's name or the name of that person's predecessor in business, except where such name is used in such a manner as to mislead the public.

9. There shall be no obligation under this Agreement to protect geographical indications which are not or cease to be protected in their country of origin, or which have fallen into disuse in that country.

SECTION 4: INDUSTRIAL DESIGNS

Article 25

Requirements for Protection

1. Members shall provide for the protection of independently created industrial designs that are new or original. Members may provide that designs are not new or original if they do not significantly differ from known designs or combinations of known design features. Members may provide that such protection shall not extend to designs dictated essentially by technical or functional considerations.

2. Each Member shall ensure that requirements for securing protection for textile designs, in particular in regard to any cost, examination or publication, do not unreasonably impair the opportunity to seek and obtain such protection. Members shall be free to meet this obligation through industrial design law or through copyright law.

Article 26

Protection

1. The owner of a protected industrial design shall have the right to prevent third parties not having the owner's consent from making, selling or importing articles bearing or embodying a design which is a copy, or substantially a copy, of the protected design, when such acts are undertaken for commercial purposes.

2. Members may provide limited exceptions to the protection of industrial designs, provided that such exceptions do not unreasonably conflict with the normal exploitation of protected industrial designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking account of the legitimate interests of third parties.

3. The duration of protection available shall amount to at least 10 years.

SECTION 5: PATENTS

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[5] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing[6] for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

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[5]For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

[6]This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[7] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

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[7] "Other use" refers to use other than that allowed under Article 30.

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 32

Revocation/Forfeiture

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Article 33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.[8]

[8]It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

Article 34

Process Patents: Burden of Proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

SECTION 6: LAYOUT-DESIGNS (TOPOGRAPHIES) OF INTEGRATED CIRCUITS

Article 35

Relation to the IPIC Treaty

Members agree to provide protection to the layout-designs (topographies) of integrated circuits (referred to in this Agreement as "layout-designs") in accordance with Articles 2 through 7 (other than paragraph 3 of Article 6), Article 12 and paragraph 3 of Article 16 of the Treaty on Intellectual Property in Respect of Integrated Circuits and, in addition, to comply with the following provisions.

Article 36

Scope of the Protection

Subject to the provisions of paragraph 1 of Article 37, Members shall consider unlawful the following acts if performed without the authorization of the right holder:[9] importing, selling, or otherwise distributing for commercial purposes a protected layout-design, an integrated circuit in which a protected layout-design is incorporated, or an article incorporating such an integrated circuit only in so far as it continues to contain an unlawfully reproduced layout-design.

Article 37

Acts Not Requiring the Authorization of the Right Holder

1. Notwithstanding Article 36, no Member shall consider unlawful the performance of any of the acts referred to in that Article in respect of an integrated circuit incorporating an unlawfully

[9]The term "right holder" in this Section shall be understood as having the same meaning as the term "holder of the right" in the IPIC Treaty.

reproduced layout-design or any article incorporating such an integrated circuit where the person performing or ordering such acts did not know and had no reasonable ground to know, when acquiring the integrated circuit or article incorporating such an integrated circuit, that it incorporated an unlawfully reproduced layout-design. Members shall provide that, after the time that such person has received sufficient notice that the layout-design was unlawfully reproduced, that person may perform any of the acts with respect to the stock on hand or ordered before such time, but shall be liable to pay to the right holder a sum equivalent to a reasonable royalty such as would be payable under a freely negotiated licence in respect of such a layout-design.

2. The conditions set out in subparagraphs (a) through (k) of Article 31 shall apply *mutatis mutandis* in the event of any non-voluntary licensing of a layout-design or of its use by or for the government without the authorization of the right holder.

Article 38

Term of Protection

1. In Members requiring registration as a condition of protection, the term of protection of layout-designs shall not end before the expiration of a period of 10 years counted from the date of filing an application for registration or from the first commercial exploitation wherever in the world it occurs.

2. In Members not requiring registration as a condition for protection, layout-designs shall be protected for a term of no less than 10 years from the date of the first commercial exploitation wherever in the world it occurs.

3. Notwithstanding paragraphs 1 and 2, a Member may provide that protection shall lapse 15 years after the creation of the layout-design.

SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices[10] so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

[10]For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

3. Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member to which the request for consultations has been addressed is undertaking practices in violation of the requesting Member's laws and regulations on the subject matter of this Section, and which wishes to secure compliance with such legislation, without prejudice to any action under the law and to the full freedom of an ultimate decision of either Member. The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.

4. A Member whose nationals or domiciliaries are subject to proceedings in another Member concerning alleged violation of that other Member's laws and regulations on the subject matter of this Section shall, upon request, be granted an opportunity for consultations by the other Member under the same conditions as those foreseen in paragraph 3.

PART III

ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

SECTION 1: GENERAL OBLIGATIONS

Article 41

1. Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which

constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

2. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.

4. Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there shall be no obligation to provide an opportunity for review of acquittals in criminal cases.

5. It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

SECTION 2: CIVIL AND ADMINISTRATIVE PROCEDURES AND REMEDIES

Article 42

Fair and Equitable Procedures

Members shall make available to right holders[11] civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice which is timely and contains sufficient detail, including the basis of the claims. Parties shall be allowed to be represented by independent legal counsel, and procedures shall not impose overly burdensome requirements concerning mandatory personal appearances. All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence. The procedure shall provide a means to identify and protect confidential information, unless this would be contrary to existing constitutional requirements.

Article 43

Evidence

1. The judicial authorities shall have the authority, where a party has presented reasonably available evidence sufficient to support its claims and has specified evidence relevant to substantiation of its claims which lies in the control of the opposing party, to order that this evidence be produced by the opposing party, subject in appropriate cases to conditions which ensure the protection of confidential information.

2. In cases in which a party to a proceeding voluntarily and without good reason refuses access to, or otherwise does not provide necessary information within a reasonable period, or significantly

[11] For the purpose of this Part, the term "right holder" includes federations and associations having legal standing to assert such rights.

impedes a procedure relating to an enforcement action, a Member may accord judicial authorities the authority to make preliminary and final determinations, affirmative or negative, on the basis of the information presented to them, including the complaint or the allegation presented by the party adversely affected by the denial of access to information, subject to providing the parties an opportunity to be heard on the allegations or evidence.

Article 44

Injunctions

1. The judicial authorities shall have the authority to order a party to desist from an infringement, *inter alia* to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

Article 45

Damages

1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

2. The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.

Article 46

Other Remedies

In order to create an effective deterrent to infringement, the judicial authorities shall have the authority to order that goods that they have found to be infringing be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to avoid any harm caused to the right holder, or, unless this would be contrary to existing constitutional requirements, destroyed. The judicial authorities shall also have the authority to order that materials and implements the predominant use of which has been in the creation of the infringing goods be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements. In considering such requests, the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties shall be taken into account. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.

Article 47

Right of Information

Members may provide that the judicial authorities shall have the authority, unless this would be out of proportion to the seriousness of the infringement, to order the infringer to inform the right holder of the identity of third persons involved in the production and distribution of the infringing goods or services and of their channels of distribution.

Article 48

Indemnification of the Defendant

1. The judicial authorities shall have the authority to order a party at whose request measures were taken and who has abused enforcement procedures to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees.

2. In respect of the administration of any law pertaining to the protection or enforcement of intellectual property rights, Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith in the course of the administration of that law.

Article 49

Administrative Procedures

To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, such procedures shall conform to principles equivalent in substance to those set forth in this Section.

SECTION 3: PROVISIONAL MEASURES

Article 50

1. The judicial authorities shall have the authority to order prompt and effective provisional measures:

(a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance;

(b) to preserve relevant evidence in regard to the alleged infringement.

2. The judicial authorities shall have the authority to adopt provisional measures *inaudita altera parte* where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.

3. The judicial authorities shall have the authority to require the applicant to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant is the right holder and that the applicant's right is being infringed or that such infringement is imminent,

and to order the applicant to provide a security or equivalent assurance sufficient to protect the defendant and to prevent abuse.

4. Where provisional measures have been adopted *inaudita altera parte*, the parties affected shall be given notice, without delay after the execution of the measures at the latest. A review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period after the notification of the measures, whether these measures shall be modified, revoked or confirmed.

5. The applicant may be required to supply other information necessary for the identification of the goods concerned by the authority that will execute the provisional measures.

6. Without prejudice to paragraph 4, provisional measures taken on the basis of paragraphs 1 and 2 shall, upon request by the defendant, be revoked or otherwise cease to have effect, if proceedings leading to a decision on the merits of the case are not initiated within a reasonable period, to be determined by the judicial authority ordering the measures where a Member's law so permits or, in the absence of such a determination, not to exceed 20 working days or 31 calendar days, whichever is the longer.

7. Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.

8. To the extent that any provisional measure can be ordered as a result of administrative procedures, such procedures shall conform to principles equivalent in substance to those set forth in this Section.

SECTION 4: SPECIAL REQUIREMENTS RELATED TO BORDER MEASURES[12]

Article 51

Suspension of Release by Customs Authorities

Members shall, in conformity with the provisions set out below, adopt procedures[13] to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods[14] may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are

[12]Where a Member has dismantled substantially all controls over movement of goods across its border with another Member with which it forms part of a customs union, it shall not be required to apply the provisions of this Section at that border.

[13]It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.

[14]For the purposes of this Agreement:

(a) "counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;

(b) "pirated copyright goods" shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.

Article 52

Application

Any right holder initiating the procedures under Article 51 shall be required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is *prima facie* an infringement of the right holder's intellectual property right and to supply a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities. The competent authorities shall inform the applicant within a reasonable period whether they have accepted the application and, where determined by the competent authorities, the period for which the customs authorities will take action.

Article 53

Security or Equivalent Assurance

1. The competent authorities shall have the authority to require an applicant to provide a security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to these procedures.

2. Where pursuant to an application under this Section the release of goods involving industrial designs, patents, layout-designs or undisclosed information into free circulation has been suspended by customs authorities on the basis of a decision other than by a judicial or other independent authority, and the period provided for in Article 55 has expired without the granting of provisional relief by the duly empowered authority, and provided that all other conditions for importation have been complied with, the owner, importer, or consignee of such goods shall be entitled to their release on the posting of a security in an amount sufficient to protect the right holder for any infringement. Payment of such security shall not prejudice any other remedy available to the right holder, it being understood that the security shall be released if the right holder fails to pursue the right of action within a reasonable period of time.

Article 54

Notice of Suspension

The importer and the applicant shall be promptly notified of the suspension of the release of goods according to Article 51.

Article 55

Duration of Suspension

If, within a period not exceeding 10 working days after the applicant has been served notice of the suspension, the customs authorities have not been informed that proceedings leading to a decision on the merits of the case have been initiated by a party other than the defendant, or that the duly empowered authority has taken provisional measures prolonging the suspension of the release of the goods, the goods shall be released, provided that all other conditions for importation or exportation have been complied with; in appropriate cases, this time-limit may be extended by another 10 working days. If proceedings leading to a decision on the merits of the case have been initiated, a review, including a right to be heard, shall take place upon request of the defendant with a view to deciding,

within a reasonable period, whether these measures shall be modified, revoked or confirmed. Notwithstanding the above, where the suspension of the release of goods is carried out or continued in accordance with a provisional judicial measure, the provisions of paragraph 6 of Article 50 shall apply.

Article 56

Indemnification of the Importer and of the Owner of the Goods

Relevant authorities shall have the authority to order the applicant to pay the importer, the consignee and the owner of the goods appropriate compensation for any injury caused to them through the wrongful detention of goods or through the detention of goods released pursuant to Article 55.

Article 57

Right of Inspection and Information

Without prejudice to the protection of confidential information, Members shall provide the competent authorities the authority to give the right holder sufficient opportunity to have any goods detained by the customs authorities inspected in order to substantiate the right holder's claims. The competent authorities shall also have authority to give the importer an equivalent opportunity to have any such goods inspected. Where a positive determination has been made on the merits of a case, Members may provide the competent authorities the authority to inform the right holder of the names and addresses of the consignor, the importer and the consignee and of the quantity of the goods in question.

Article 58

Ex Officio Action

Where Members require competent authorities to act upon their own initiative and to suspend the release of goods in respect of which they have acquired *prima facie* evidence that an intellectual property right is being infringed:

(a) the competent authorities may at any time seek from the right holder any information that may assist them to exercise these powers;

(b) the importer and the right holder shall be promptly notified of the suspension. Where the importer has lodged an appeal against the suspension with the competent authorities, the suspension shall be subject to the conditions, *mutatis mutandis*, set out at Article 55;

(c) Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith.

Article 59

Remedies

Without prejudice to other rights of action open to the right holder and subject to the right of the defendant to seek review by a judicial authority, competent authorities shall have the authority to order the destruction or disposal of infringing goods in accordance with the principles set out in Article 46. In regard to counterfeit trademark goods, the authorities shall not allow the re-exportation

of the infringing goods in an unaltered state or subject them to a different customs procedure, other than in exceptional circumstances.

Article 60

De Minimis Imports

Members may exclude from the application of the above provisions small quantities of goods of a non-commercial nature contained in travellers' personal luggage or sent in small consignments.

SECTION 5: CRIMINAL PROCEDURES

Article 61

Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.

PART IV

ACQUISITION AND MAINTENANCE OF INTELLECTUAL PROPERTY RIGHTS AND RELATED *INTER-PARTES* PROCEDURES

Article 62

1. Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II, compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement.

2. Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

3. Article 4 of the Paris Convention (1967) shall apply *mutatis mutandis* to service marks.

4. Procedures concerning the acquisition or maintenance of intellectual property rights and, where a Member's law provides for such procedures, administrative revocation and *inter partes* procedures such as opposition, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of Article 41.

5. Final administrative decisions in any of the procedures referred to under paragraph 4 shall be subject to review by a judicial or quasi-judicial authority. However, there shall be no obligation to provide an opportunity for such review of decisions in cases of unsuccessful opposition or administrative revocation, provided that the grounds for such procedures can be the subject of invalidation procedures.

PART V

DISPUTE PREVENTION AND SETTLEMENT

Article 63

Transparency

1. Laws and regulations, and final judicial decisions and administrative rulings of general application, made effective by a Member pertaining to the subject matter of this Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights) shall be published, or where such publication is not practicable made publicly available, in a national language, in such a manner as to enable governments and right holders to become acquainted with them. Agreements concerning the subject matter of this Agreement which are in force between the government or a governmental agency of a Member and the government or a governmental agency of another Member shall also be published.

2. Members shall notify the laws and regulations referred to in paragraph 1 to the Council for TRIPS in order to assist that Council in its review of the operation of this Agreement. The Council shall attempt to minimize the burden on Members in carrying out this obligation and may decide to waive the obligation to notify such laws and regulations directly to the Council if consultations with WIPO on the establishment of a common register containing these laws and regulations are successful. The Council shall also consider in this connection any action required regarding notifications pursuant to the obligations under this Agreement stemming from the provisions of Article 6*ter* of the Paris Convention (1967).

3. Each Member shall be prepared to supply, in response to a written request from another Member, information of the sort referred to in paragraph 1. A Member, having reason to believe that a specific judicial decision or administrative ruling or bilateral agreement in the area of intellectual property rights affects its rights under this Agreement, may also request in writing to be given access to or be informed in sufficient detail of such specific judicial decisions or administrative rulings or bilateral agreements.

4. Nothing in paragraphs 1, 2 and 3 shall require Members to disclose confidential information which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private.

Article 64

Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement except as otherwise specifically provided herein.

2. Subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement.

3. During the time period referred to in paragraph 2, the Council for TRIPS shall examine the scope and modalities for complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 made pursuant to this Agreement, and submit its recommendations to the Ministerial Conference for approval. Any decision of the Ministerial Conference to approve such recommendations or to extend the period in paragraph 2 shall be made only by consensus, and approved recommendations shall be effective for all Members without further formal acceptance process.

PART VI

TRANSITIONAL ARRANGEMENTS

Article 65

Transitional Arrangements

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66

Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

Article 67

Technical Cooperation

In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance

in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

PART VII

INSTITUTIONAL ARRANGEMENTS; FINAL PROVISIONS

Article 68

Council for Trade-Related Aspects of Intellectual Property Rights

The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights. It shall carry out such other responsibilities as assigned to it by the Members, and it shall, in particular, provide any assistance requested by them in the context of dispute settlement procedures. In carrying out its functions, the Council for TRIPS may consult with and seek information from any source it deems appropriate. In consultation with WIPO, the Council shall seek to establish, within one year of its first meeting, appropriate arrangements for cooperation with bodies of that Organization.

Article 69

International Cooperation

Members agree to cooperate with each other with a view to eliminating international trade in goods infringing intellectual property rights. For this purpose, they shall establish and notify contact points in their administrations and be ready to exchange information on trade in infringing goods. They shall, in particular, promote the exchange of information and cooperation between customs authorities with regard to trade in counterfeit trademark goods and pirated copyright goods.

Article 70

Protection of Existing Subject Matter

1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. In respect of this paragraph and paragraphs 3 and 4, copyright obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention (1971), and obligations with respect to the rights of producers of phonograms and performers in existing phonograms shall be determined solely under Article 18 of the Berne Convention (1971) as made applicable under paragraph 6 of Article 14 of this Agreement.

3. There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain.

4. In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.

5. A Member is not obliged to apply the provisions of Article 11 and of paragraph 4 of Article 14 with respect to originals or copies purchased prior to the date of application of this Agreement for that Member.

6. Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

Article 71

Review and Amendment

1. The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.

2. Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS.

Article 72

Reservations

Reservations may not be entered in respect of any of the provisions of this Agreement without the consent of the other Members.

Article 73

Security Exceptions

Nothing in this Agreement shall be construed:

(a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or

(b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;

(i) relating to fissionable materials or the materials from which they are derived;

(ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;

(iii) taken in time of war or other emergency in international relations; or

(c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.

This is **Exhibit "F"** to the Affidavit of Anna Hucman
sworn before me on this 27th day of July, 2016

Commissioner for taking affidavits

North American Free Trade Agreement

Skip to Section >>

Chapter Seventeen: Intellectual Property

PART SIX: INTELLECTUAL PROPERTY

Article 1701: Nature and Scope of Obligations

1. Each Party shall provide in its territory to the nationals of another Party adequate and effective protection and enforcement of intellectual property rights, while ensuring that measures to enforce intellectual property rights do not themselves become barriers to legitimate trade.

2. To provide adequate and effective protection and enforcement of intellectual property rights, each Party shall, at a minimum, give effect to this Chapter and to the substantive provisions of:

(a) the *Geneva Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of their Phonograms* , 1971 (Geneva Convention);

(b) the *Berne Convention for the Protection of Literary and Artistic Works* , 1971 (Berne Convention);

(c) the *Paris Convention for the Protection of Industrial Property* , 1967 (Paris Convention); and

(d) the *International Convention for the Protection of New Varieties of Plants* , 1978 (UPOV Convention), or the *International Convention for the Protection of New Varieties of Plants* , 1991 (UPOV Convention).

If a Party has not acceded to the specified text of any such Conventions on or before the date of entry into force of this Agreement, it shall make every effort to accede.

3. Annex 1701.3 applies to the Parties specified in that Annex.

Article 1702: More Extensive Protection

A Party may implement in its domestic law more extensive protection of intellectual property rights than is required under this Agreement, provided that such protection is not inconsistent with this Agreement.

Article 1703: National Treatment

1. Each Party shall accord to nationals of another Party treatment no less favorable than that it accords to its own nationals with regard to the protection and enforcement of all intellectual property rights. In respect of sound recordings, each Party shall provide such treatment to producers and performers of another Party, except that a Party may limit rights of performers of another Party in respect of secondary uses of sound recordings to those rights its nationals are accorded in the territory of such other Party.

2. No Party may, as a condition of according national treatment under this Article, require right holders to comply with any formalities or conditions in order to acquire rights in respect of copyright and related rights.

3. A Party may derogate from paragraph 1 in relation to its judicial and administrative procedures for the protection or enforcement of intellectual property rights, including any procedure requiring a national of another Party to designate for service of process an address in the Party's territory or to appoint an agent in the Party's territory, if the derogation is consistent with the relevant Convention listed in Article 1701(2), provided that such derogation:

(a) is necessary to secure compliance with measures that are not inconsistent with this Chapter; and

(b) is not applied in a manner that would constitute a disguised restriction on trade.

4. No Party shall have any obligation under this Article with respect to procedures provided in multilateral agreements concluded under the auspices of the World Intellectual Property Organization relating to the acquisition or maintenance of intellectual property rights.

Article 1704: Control of Abusive or Anticompetitive Practices or Conditions

Nothing in this Chapter shall prevent a Party from specifying in its domestic law licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. A Party may adopt or maintain, consistent with the other provisions of this Agreement, appropriate measures to prevent or control such practices or conditions.

Article 1705: Copyright

1. Each Party shall protect the works covered by Article 2 of the Berne Convention, including any other works that embody original expression within the meaning of that Convention. In particular:

(a) all types of computer programs are literary works within the meaning of the Berne Convention and each Party shall protect them as such; and

(b) compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations, shall be protected as such.

The protection a Party provides under subparagraph (b) shall not extend to the data or material itself, or prejudice any copyright subsisting in that data or material.

2. Each Party shall provide to authors and their successors in interest those rights enumerated in the Berne Convention in respect of works covered by paragraph 1, including the right to authorize or prohibit:

(a) the importation into the Party's territory of copies of the work made without the right holder's authorization;

(b) the first public distribution of the original and each copy of the work by sale, rental or otherwise;

(c) the communication of a work to the public; and

(d) the commercial rental of the original or a copy of a computer program.

Subparagraph (d) shall not apply where the copy of the computer program is not itself an essential object of the rental. Each Party shall provide that putting the original or a copy of a computer program on the market with the right holder's consent shall not exhaust the rental right.

3. Each Party shall provide that for copyright and related rights:

(a) any person acquiring or holding economic rights may freely and separately transfer such rights by contract for purposes of their exploitation and enjoyment by the transferee; and

(b) any person acquiring or holding such economic rights by virtue of a contract, including contracts of employment underlying the creation of works and sound recordings, shall be able to exercise those rights in its own name and enjoy fully the benefits derived from those rights.

4. Each Party shall provide that, where the term of protection of a work, other than a photographic work or a work of applied art, is to be calculated on a basis other than the life of a natural person, the term shall be not less than 50 years from the end of the calendar year of the first authorized publication of the work or, failing such authorized publication within 50 years from the making of the work, 50 years from the end of the calendar year of making.

5. Each Party shall confine limitations or exceptions to the rights provided for in this Article to certain special cases that do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.

6. No Party may grant translation and reproduction licenses permitted under the Appendix to the Berne Convention where legitimate needs in that Party's territory for copies or translations of the work could be met by the right holder's voluntary actions but for obstacles created by the Party's measures.

7. Annex 1705.7 applies to the Parties specified in that Annex.

Article 1706: Sound Recordings

1. Each Party shall provide to the producer of a sound recording the right to authorize or prohibit:

(a) the direct or indirect reproduction of the sound recording;

(b) the importation into the Party's territory of copies of the sound recording made without the producer's authorization;

(c) the first public distribution of the original and each copy of the sound recording by sale, rental or otherwise; and

(d) the commercial rental of the original or a copy of the sound recording, except where expressly otherwise provided in a contract between the producer of the sound recording and the authors of the works fixed therein.

Each Party shall provide that putting the original or a copy of a sound recording on the market with the right holder's consent shall not exhaust the rental right.

2. Each Party shall provide a term of protection for sound recordings of at least 50 years from the end of the calendar year in which the fixation was made.

3. Each Party shall confine limitations or exceptions to the rights provided for in this Article to certain special cases that do not conflict with a normal exploitation of the sound recording and do not unreasonably prejudice the legitimate interests of the right holder.

Article 1707: Protection of Encrypted ProgramCarrying Satellite Signals

Within one year from the date of entry into force of this Agreement, each Party shall make it:

(a) a criminal offense to manufacture, import, sell, lease or otherwise make available a device or system that is primarily of assistance in decoding an encrypted program carrying satellite signal without the authorization of the lawful distributor of such signal; and

(b) a civil offense to receive, in connection with commercial activities, or further distribute, an encrypted program carrying satellite signal that has been decoded without the authorization of the lawful distributor of the signal or to engage in any activity prohibited under subparagraph (a).

Each Party shall provide that any civil offense established under subparagraph (b) shall be actionable by any person that holds an interest in the content of such signal.

Article 1708: Trademarks

1. For purposes of this Agreement, a trademark consists of any sign, or any combination of signs, capable of distinguishing the goods or services of one person from those of another, including personal names, designs, letters, numerals, colors, figurative elements, or the shape of goods or of their packaging. Trademarks shall include service marks and collective marks, and may include certification marks. A Party may require, as a condition for registration, that a sign be visually perceptible.

2. Each Party shall provide to the owner of a registered trademark the right to prevent all persons not having the owner's consent from using in commerce identical or similar signs for goods or services that are identical or similar to those goods or services in respect of which the owner's trademark is registered, where such use would result in a likelihood of confusion. In the case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed. The rights described above shall not prejudice any prior rights, nor shall they affect the possibility of a Party making rights available on the basis of use.

3. A Party may make registrability depend on use. However, actual use of a trademark shall not be a condition for filing an application for registration. No Party may refuse an application solely on the ground that intended use has not taken place before the expiry of a period of three years from the date of application for registration.

4. Each Party shall provide a system for the registration of trademarks, which shall include:

(a) examination of applications;

(b) notice to be given to an applicant of the reasons for the refusal to register a trademark;

(c) a reasonable opportunity for the applicant to respond to the notice;

(d) publication of each trademark either before or promptly after it is registered; and

(e) a reasonable opportunity for interested persons to petition to cancel the registration of a trademark.

A Party may provide for a reasonable opportunity for interested persons to oppose the registration of a trademark.

5. The nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to the registration of the trademark.

6. Article 6bis of the Paris Convention shall apply, with such modifications as may be necessary, to services. In determining whether a trademark is wellknown, account shall be taken of the knowledge of the trademark in the relevant sector of the public, including knowledge in the Party's territory obtained as a result of the promotion of the trademark. No Party may require that the reputation of the trademark extend beyond the sector of the public that normally deals with the relevant goods or services.

7. Each Party shall provide that the initial registration of a trademark be for a term of at least 10 years and that the registration be indefinitely renewable for terms of not less than 10 years when conditions for renewal have been met.

8. Each Party shall require the use of a trademark to maintain a registration. The registration may be canceled for the reason of non-use only after an uninterrupted period of at least two years of non-use, unless valid reasons based on the existence of obstacles to such use are shown by the trademark owner. Each Party shall recognize, as valid reasons for non- use, circumstances arising independently of the will of the trademark owner that constitute an obstacle to the use of the trademark, such as import restrictions on, or other government requirements for, goods or services identified by the trademark.

9. Each Party shall recognize use of a trademark by a person other than the trademark owner, where such use is subject to the owner's control, as use of the trademark for purposes of maintaining the registration.

10. No Party may encumber the use of a trademark in commerce by special requirements, such as a use that reduces the trademark's function as an indication of source or a use with another trademark.

11. A Party may determine conditions on the licensing and assignment of trademarks, it being understood that the compulsory licensing of trademarks shall not be permitted and that the owner of a registered trademark shall have the right to assign its trademark with or without the transfer of the business to which the trademark belongs.

12. A Party may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take into account the legitimate interests of the trademark owner and of other persons.

13. Each Party shall prohibit the registration as a trademark of words, at least in English, French or Spanish, that generically designate goods or services or types of goods or services to which the trademark applies.

14. Each Party shall refuse to register trademarks that consist of or comprise immoral, deceptive or scandalous matter, or matter that may disparage or falsely suggest a connection with persons, living or dead, institutions, beliefs or any Party's national symbols, or bring them into contempt or disrepute.

Article 1709: Patents

1. Subject to paragraphs 2 and 3, each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For purposes of this Article, a Party may deem the terms "inventive step" and "capable of industrial application" to be synonymous with the terms "non-obvious" and "useful", respectively.

2. A Party may exclude from patentability inventions if preventing in its territory the commercial exploitation of the inventions is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that the exclusion is not based solely on the ground that the Party prohibits commercial exploitation in its territory of the subject matter of the patent.

3. A Party may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than microorganisms; and

(c) essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production.

Notwithstanding subparagraph (b), each Party shall provide for the protection of plant varieties through patents, an effective scheme of *sui generis* protection, or both.

4. If a Party has not made available product patent protection for pharmaceutical or agricultural chemicals commensurate with paragraph 1:

(a) as of January 1, 1992, for subject matter that relates to naturally occurring substances prepared or produced by, or significantly derived from, microbiological processes and intended for food or medicine, and

(b) as of July 1, 1991, for any other subject matter,

that Party shall provide to the inventor of any such product or its assignee the means to obtain product patent protection for such product for the unexpired term of the patent for such product granted in another Party, as long as the product has not been marketed in the Party providing protection under this paragraph and the person seeking such protection makes a timely request.

5. Each Party shall provide that:

(a) where the subject matter of a patent is a product, the patent shall confer on the patent owner the right to prevent other persons from making, using or selling the subject matter of the patent, without the patent owner's consent; and

(b) where the subject matter of a patent is a process, the patent shall confer on the patent owner the right to prevent other persons from using that process and from using, selling, or importing at least the product obtained directly by that process, without the patent owner's consent.

6. A Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of other persons.

7. Subject to paragraphs 2 and 3, patents shall be available and patent rights enjoyable without discrimination as to the field of technology, the territory of

the Party where the invention was made and whether products are imported or locally produced.

8. A Party may revoke a patent only when:

(a) grounds exist that would have justified a refusal to grant the patent; or

(b) the grant of a compulsory license has not remedied the lack of exploitation of the patent.

9. Each Party shall permit patent owners to assign and transfer by succession their patents, and to conclude licensing contracts.

10. Where the law of a Party allows for use of the subject matter of a patent, other than that use allowed under paragraph 6, without the authorization of the right holder, including use by the government or other persons authorized by the government, the Party shall respect the following provisions:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and such efforts have not been successful within a reasonable period of time. The requirement to make such efforts may be waived by a Party in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill that enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the Party's domestic market;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances that led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, on motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization shall be subject to judicial or other independent review by a distinct higher authority;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial or other independent review by a distinct higher authority;

(k) the Party shall not be obliged to apply the conditions set out in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anticompetitive. The need to correct anticompetitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions that led to such authorization are likely to recur;

(l) the Party shall not authorize the use of the subject matter of a patent to permit the exploitation of another patent except as a remedy for an adjudicated violation of domestic laws regarding anticompetitive practices.

11. Where the subject matter of a patent is a process for obtaining a product, each Party shall, in any infringement proceeding, place on the defendant the burden of establishing that the allegedly infringing product was made by a process other than the patented process in one of the following situations:

(a) the product obtained by the patented process is new; or

(b) a substantial likelihood exists that the allegedly infringing product was made by the process and the patent owner has been unable through reasonable efforts to determine the process actually used.

In the gathering and evaluation of evidence, the legitimate interests of the defendant in protecting its trade secrets shall be taken into account.

12. Each Party shall provide a term of protection for patents of at least 20 years from the date of filing or 17 years from the date of grant. A Party may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes.

Article 1710: Layout Designs of Semiconductor Integrated Circuits

1. Each Party shall protect layout designs (topographies) of integrated circuits ("layout designs") in accordance with Articles 2 through 7, 12 and 16(3), other than Article 6(3), of the *Treaty on Intellectual Property in Respect of Integrated Circuits* as opened for signature on May 26, 1989.

2. Subject to paragraph 3, each Party shall make it unlawful for any person without the right holder's authorization to import, sell or otherwise distribute for commercial purposes any of the following:

(a) a protected layout design;

(b) an integrated circuit in which a protected layout design is incorporated; or

(c) an article incorporating such an integrated circuit, only insofar as it continues to contain an unlawfully reproduced layout design.

3. No Party may make unlawful any of the acts referred to in paragraph 2 performed in respect of an integrated circuit that incorporates an unlawfully reproduced layout design, or any article that incorporates such an integrated circuit, where the person performing those acts or ordering those acts to be done did not know and had no reasonable ground to know, when it acquired the integrated circuit or article incorporating such an integrated circuit, that it incorporated an unlawfully reproduced layout design.

4. Each Party shall provide that, after the person referred to in paragraph 3 has received sufficient notice that the layout design was unlawfully reproduced, such person may perform any of the acts with respect to the stock on hand or ordered before such notice, but shall be liable to pay the right holder for doing so an amount equivalent to a reasonable royalty such as would be payable under a freely negotiated license in respect of such a layout design.

5. No Party may permit the compulsory licensing of layout designs of integrated circuits.

6. Any Party that requires registration as a condition for protection of a layout design shall provide that the term of protection shall not end before the expiration of a period of 10 years counted from the date of:

(a) filing of the application for registration; or

(b) the first commercial exploitation of the layout design, wherever in the world it occurs.

7. Where a Party does not require registration as a condition for protection of a layout design, the Party shall provide a term of protection of not less than 10 years from the date of the first commercial exploitation of the layout design, wherever in the world it occurs.

8. Notwithstanding paragraphs 6 and 7, a Party may provide that the protection shall lapse 15 years after the creation of the layout design.

9. Annex 1710.9 applies to the Parties specified in that Annex.

Article 1711: Trade Secrets

1. Each Party shall provide the legal means for any person to prevent trade secrets from being disclosed to, acquired by, or used by others without the consent of the person lawfully in control of the information in a manner contrary to honest commercial practices, in so far as:

(a) the information is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons that normally deal with the kind of information in question;

(b) the information has actual or potential commercial value because it is secret; and

(c) the person lawfully in control of the information has taken reasonable steps under the circumstances to keep it secret.

2. A Party may require that to qualify for protection a trade secret must be evidenced in documents, electronic or magnetic means, optical discs, microfilms, films or other similar instruments.

3. No Party may limit the duration of protection for trade secrets, so long as the conditions in paragraph 1 exist.

4. No Party may discourage or impede the voluntary licensing of trade secrets by imposing excessive or discriminatory conditions on such licenses or conditions that dilute the value of the trade secrets.

5. If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

7. Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.

Article 1712: Geographical Indications

1. Each Party shall provide, in respect of geographical indications, the legal means for interested persons to prevent:

> (a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a territory, region or locality other than the true place of origin, in a manner that misleads the public as to the geographical origin of the good;
>
> (b) any use that constitutes an act of unfair competition within the meaning of Article 10bis of the Paris Convention.

2. Each Party shall, on its own initiative if its domestic law so permits or at the request of an interested person, refuse to register, or invalidate the registration of, a trademark containing or consisting of a geographical indication with respect to goods that do not originate in the indicated territory, region or locality, if use of the indication in the trademark for such goods is of such a nature as to mislead the public as to the geographical origin of the good.

3. Each Party shall also apply paragraphs 1 and 2 to a geographical indication that, although correctly indicating the territory, region or locality in which the goods originate, falsely represents to the public that the goods originate in another territory, region or locality.

4. Nothing in this Article shall be construed to require a Party to prevent continued and similar use of a particular geographical indication of another Party in connection with goods or services by any of its nationals or domiciliaries who have used that geographical indication in a continuous manner with regard to the same or related goods or services in that Party's territory, either:

(a) for at least 10 years, or

(b) in good faith,

before the date of signature of this Agreement.

5. Where a trademark has been applied for or registered in good faith, or where rights to a trademark have been acquired through use in good faith, either:

(a) before the date of application of these provisions in that Party, or

(b) before the geographical indication is protected in its Party of origin,

no Party may adopt any measure to implement this Article that prejudices eligibility for, or the validity of, the registration of a trademark, or the right to use a trademark, on the basis that such a trademark is identical with, or similar to, a geographical indication.

6. No Party shall be required to apply this Article to a geographical indication if it is identical to the customary term in common language in that Party's territory for the goods or services to which the indication applies.

7. A Party may provide that any request made under this Article in connection with the use or registration of a trademark must be presented within five years after the adverse use of the protected indication has become generally known in that Party or after the date of registration of the trademark in that Party, provided that the trademark has been published by that date, if such date is earlier than the date on which the adverse use became generally known in that Party, provided that the geographical indication is not used or registered in bad faith.

8. No Party shall adopt any measure implementing this Article that would prejudice any person's right to use, in the course of trade, its name or the name of its predecessor in business, except where such name forms all or part of a valid trademark in existence before the geographical indication became protected and with which there is a likelihood of confusion, or such name is used in such a manner as to mislead the public.

9. Nothing in this Chapter shall be construed to require a Party to protect a geographical indication that is not protected, or has fallen into disuse, in the Party of origin.

Article 1713: Industrial Designs

1. Each Party shall provide for the protection of independently created industrial designs that are new or original. A Party may provide that:

(a) designs are not new or original if they do not significantly differ from known designs or combinations of known design features; and

(b) such protection shall not extend to designs dictated essentially by technical or functional considerations.

2. Each Party shall ensure that the requirements for securing protection for textile designs, in particular in regard to any cost, examination or publication, do not unreasonably impair a person's opportunity to seek and obtain such protection. A Party may comply with this obligation through industrial design law or copyright law.

3. Each Party shall provide the owner of a protected industrial design the right to prevent other persons not having the owner's consent from making or selling articles bearing or embodying a design that is a copy, or substantially a copy, of the protected design, when such acts are undertaken for commercial purposes.

4. A Party may provide limited exceptions to the protection of industrial designs, provided that such exceptions do not unreasonably conflict with the normal exploitation of protected industrial designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking into account the legitimate interests of other persons.

5. Each Party shall provide a term of protection for industrial designs of at least 10 years.

Article 1714: Enforcement of Intellectual Property Rights: General Provisions

1. Each Party shall ensure that enforcement procedures, as specified in this Article and Articles 1715 through 1718, are available under its domestic law so as to permit effective action to be taken against any act of infringement of intellectual property rights covered by this Chapter, including expeditious remedies to prevent infringements and remedies to deter further infringements. Such enforcement procedures shall be applied so as to avoid the creation of barriers to legitimate trade and to provide for safeguards against abuse of the procedures.

2. Each Party shall ensure that its procedures for the enforcement of intellectual property rights are fair and equitable, are not unnecessarily complicated or costly, and do not entail unreasonable timelimits or unwarranted delays.

3. Each Party shall provide that decisions on the merits of a case in judicial and administrative enforcement proceedings shall:

(a) preferably be in writing and preferably state the reasons on which the decisions are based;

(b) be made available at least to the parties in a proceeding without undue delay; and

(c) be based only on evidence in respect of which such parties were offered the opportunity to be heard.

4. Each Party shall ensure that parties in a proceeding have an opportunity to have final administrative decisions reviewed by a judicial authority of that Party and, subject to jurisdictional provisions in its domestic laws concerning the importance of a case, to have reviewed at least the legal aspects of initial judicial decisions on the merits of a case. Notwithstanding the above, no Party shall be required to provide for judicial review of acquittals in criminal cases.

5. Nothing in this Article or Articles 1715 through 1718 shall be construed to require a Party to establish a judicial system for the enforcement of intellectual property rights distinct from that Party's system for the enforcement of laws in general.

6. For the purposes of Articles 1715 through 1718, the term "right holder" includes federations and associations having legal standing to assert such rights.

Article 1715: Specific Procedural and Remedial Aspects of Civil and Administrative Procedures

1. Each Party shall make available to right holders civil judicial procedures for the enforcement of any intellectual property right provided in this Chapter. Each Party shall provide that:

(a) defendants have the right to written notice that is timely and contains sufficient detail, including the basis of the claims;

(b) parties in a proceeding are allowed to be represented by independent legal counsel;

(c) the procedures do not include imposition of overly burdensome requirements concerning mandatory personal appearances;

(d) all parties in a proceeding are duly entitled to substantiate their claims and to present relevant evidence; and

(e) the procedures include a means to identify and protect confidential information.

2. Each Party shall provide that its judicial authorities shall have the authority:

(a) where a party in a proceeding has presented reasonably available evidence sufficient to support its claims and has specified evidence relevant to the substantiation of its claims that is within the control of the opposing party, to order the opposing party to produce such evidence, subject in appropriate cases to conditions that ensure the protection of confidential information;

(b) where a party in a proceeding voluntarily and without good reason refuses access to, or otherwise does not provide relevant evidence under that party's control within a reasonable period, or significantly impedes a proceeding relating to an enforcement action, to make preliminary and final determinations, affirmative or negative, on the basis of the evidence presented, including the complaint or the allegation presented by the party adversely affected by the denial of access to evidence, subject to providing the parties an opportunity to be heard on the allegations or evidence;

(c) to order a party in a proceeding to desist from an infringement, including to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, which order shall be enforceable at least immediately after customs clearance of such goods;

(d) to order the infringer of an intellectual property right to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of the infringement where the infringer knew or had reasonable grounds to know that it was engaged in an infringing activity;

(e) to order an infringer of an intellectual property right to pay the right holder's expenses, which may include appropriate attorney's fees; and

(f) to order a party in a proceeding at whose request measures were taken and who has abused enforcement procedures to provide adequate compensation to any party wrongfully enjoined or restrained in the proceeding for the injury suffered because of such abuse and to pay that party's expenses, which may include appropriate attorney's fees.

3. With respect to the authority referred to in subparagraph 2(c), no Party shall be obliged to provide such authority in respect of protected subject matter that is acquired or ordered by a person before that person knew or had reasonable grounds to know that dealing in that subject matter would entail the infringement of an intellectual property right.

4. With respect to the authority referred to in subparagraph 2(d), a Party may, at least with respect to copyrighted works and sound recordings, authorize the judicial authorities to order recovery of profits or payment of pre-established damages, or both, even where the infringer did not know or had no reasonable grounds to know that it was engaged in an infringing activity.

5. Each Party shall provide that, in order to create an effective deterrent to infringement, its judicial authorities shall have the authority to order that:

(a) goods that they have found to be infringing be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to avoid any injury caused to the right holder or, unless this would be contrary to existing constitutional requirements, destroyed; and

(b) materials and implements the predominant use of which has been in the creation of the infringing goods be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements.

In considering whether to issue such an order, judicial authorities shall take into account the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of other persons. In regard to counterfeit goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.

6. In respect of the administration of any law pertaining to the protection or enforcement of intellectual property rights, each Party shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith in the course of the administration of such laws.

7. Notwithstanding the other provisions of Articles 1714 through 1718, where a Party is sued with respect to an infringement of an intellectual property right as a result of its use of that right or use on its behalf, that Party may limit the remedies available against it to the payment to the right holder of adequate remuneration in the circumstances of each case, taking into account the economic value of the use.

8. Each Party shall provide that, where a civil remedy can be ordered as a result of administrative procedures on the merits of a case, such procedures shall conform to principles equivalent in substance to those set out in this Article.

Article 1716: Provisional Measures

1. Each Party shall provide that its judicial authorities shall have the authority to order prompt and effective provisional measures:

(a) to prevent an infringement of any intellectual property right, and in particular to prevent the entry into the channels of commerce in their jurisdiction of allegedly infringing goods, including measures to prevent the entry of imported goods at least immediately after customs clearance; and

(b) to preserve relevant evidence in regard to the alleged infringement.

2. Each Party shall provide that its judicial authorities shall have the authority to require any applicant for provisional measures to provide to the judicial authorities any evidence reasonably available to that applicant that the judicial authorities consider necessary to enable them to determine with a sufficient degree of certainty whether:

(a) the applicant is the right holder;

(b) the applicant's right is being infringed or such infringement is imminent; and

(c) any delay in the issuance of such measures is likely to cause irreparable harm to the right holder, or there is a demonstrable risk of evidence being destroyed.

Each Party shall provide that its judicial authorities shall have the authority to require the applicant to provide a security or equivalent assurance sufficient to protect the interests of the defendant and to prevent abuse.

3. Each Party shall provide that its judicial authorities shall have the authority to require an applicant for provisional measures to provide other information necessary for the identification of the relevant goods by the authority that will execute the provisional measures.

4. Each Party shall provide that its judicial authorities shall have the authority to order provisional measures on an *ex parte basis* , in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.

5. Each Party shall provide that where provisional measures are adopted by that Party's judicial authorities on an *ex parte basis* :

(a) a person affected shall be given notice of those measures without delay but in any event no later than immediately after the execution of the measures;

(b) a defendant shall, on request, have those measures reviewed by that Party's judicial authorities for the purpose of deciding, within a reasonable period after notice of those measures is given, whether the measures shall be modified, revoked or confirmed, and shall be given an opportunity to be heard in the review proceedings.

6. Without prejudice to paragraph 5, each Party shall provide that, on the request of the defendant, the Party's judicial authorities shall revoke or otherwise cease to apply the provisional measures taken on the basis of paragraphs 1 and 4 if proceedings leading to a decision on the merits are not initiated:

(a) within a reasonable period as determined by the judicial authority ordering the measures where the Party's domestic law so permits; or

(b) in the absence of such a determination, within a period of no more than 20 working days or 31 calendar days, whichever is longer.

7. Each Party shall provide that, where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where the judicial authorities subsequently find that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, on request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.

8. Each Party shall provide that, where a provisional measure can be ordered as a result of administrative procedures, such procedures shall conform to principles equivalent in substance to those set out in this Article.

Article 1717: Criminal Procedures and Penalties

1. Each Party shall provide criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. Each Party shall provide that penalties available include imprisonment or monetary fines, or both, sufficient to provide a deterrent, consistent with the level of penalties applied for crimes of a corresponding gravity.

2. Each Party shall provide that, in appropriate cases, its judicial authorities may order the seizure, forfeiture and destruction of infringing goods and of any materials and implements the predominant use of which has been in the commission of the offense.

3. A Party may provide criminal procedures and penalties to be applied in cases of infringement of intellectual property rights, other than those in paragraph 1, where they are committed wilfully and on a commercial scale.

Article 1718: Enforcement of Intellectual Property Rights at the Border

1. Each Party shall, in conformity with this Article, adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark goods or pirated copyright goods may take place, to lodge an application in writing with its competent authorities, whether

administrative or judicial, for the suspension by the customs administration of the release of such goods into free circulation. No Party shall be obligated to apply such procedures to goods in transit. A Party may permit such an application to be made in respect of goods that involve other infringements of intellectual property rights, provided that the requirements of this Article are met. A Party may also provide for corresponding procedures concerning the suspension by the customs administration of the release of infringing goods destined for exportation from its territory.

2. Each Party shall require any applicant who initiates procedures under paragraph 1 to provide adequate evidence:

(a) to satisfy that Party's competent authorities that, under the domestic laws of the country of importation, there is *prima facie* an infringement of its intellectual property right; and

(b) to supply a sufficiently detailed description of the goods to make them readily recognizable by the customs administration.

The competent authorities shall inform the applicant within a reasonable period whether they have accepted the application and, if so, the period for which the customs administration will take action.

3. Each Party shall provide that its competent authorities shall have the authority to require an applicant under paragraph 1 to provide a security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to these procedures.

4. Each Party shall provide that, where pursuant to an application under procedures adopted pursuant to this Article, its customs administration suspends the release of goods involving industrial designs, patents, integrated circuits or trade secrets into free circulation on the basis of a decision other than by a judicial or other independent authority, and the period provided for in paragraphs 6 through 8 has expired without the granting of provisional relief by the duly empowered authority, and provided that all other conditions for importation have been complied with, the owner, importer or consignee of such goods shall be entitled to their release on the posting of a security in an amount sufficient to protect the right holder against any infringement. Payment of such security shall not prejudice any other remedy available to the right holder, it being understood that the security shall be released if the right holder fails to pursue its right of action within a reasonable period of time.

5. Each Party shall provide that its customs administration shall promptly notify the importer and the applicant when the customs administration suspends the release of goods pursuant to paragraph 1.

6. Each Party shall provide that its customs administration shall release goods from suspension if within a period not exceeding 10 working days after the applicant under paragraph 1 has been served notice of the suspension the customs administration has not been informed that:

(a) a party other than the defendant has initiated proceedings leading to a decision on the merits of the case, or

(b) a competent authority has taken provisional measures prolonging the suspension,

provided that all other conditions for importation or exportation have been met. Each Party shall provide that, in appropriate cases, the customs administration may extend the suspension by another 10 working days.

7. Each Party shall provide that if proceedings leading to a decision on the merits of the case have been initiated, a review, including a right to be heard, shall take place on request of the defendant with a view to deciding, within a reasonable period, whether these measures shall be modified, revoked or confirmed.

8. Notwithstanding paragraphs 6 and 7, where the suspension of the release of goods is carried out or continued in accordance with a provisional judicial measure, Article 1716(6) shall apply.

9. Each Party shall provide that its competent authorities shall have the authority to order the applicant under paragraph 1 to pay the importer, the consignee and the owner of the goods appropriate compensation for any injury caused to them through the wrongful detention of goods or through the detention of goods released pursuant to paragraph 6.

10. Without prejudice to the protection of confidential information, each Party shall provide that its competent authorities shall have the authority to give the right holder sufficient opportunity to have any goods detained by the customs administration inspected in order to substantiate the right holder's claims. Each Party shall also provide that its competent authorities have the authority to give the importer an equivalent opportunity to have any such goods inspected. Where the competent authorities have made a positive determination on the merits of a case, a Party may provide the competent authorities the authority to inform the right holder of the names and addresses of the consignor, the importer and the consignee, and of the quantity of the goods in question.

11. Where a Party requires its competent authorities to act on their own initiative and to suspend the release of goods in respect of which they have acquired prima facie evidence that an intellectual property right is being infringed:

(a) the competent authorities may at any time seek from the right holder any information that may assist them to exercise these powers;

(b) the importer and the right holder shall be promptly notified of the suspension by the Party's competent authorities, and where the importer lodges an appeal against the suspension with competent authorities, the suspension shall be subject to the conditions, with such modifications as may be necessary, set out in paragraphs 6 through 8; and

(c) the Party shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith.

12. Without prejudice to other rights of action open to the right holder and subject to the defendant's right to seek judicial review, each Party shall provide that its competent authorities shall have the authority to order the destruction or disposal of infringing goods in accordance with the principles set out in Article 1715(5). In regard to counterfeit goods, the authorities shall not allow the re exportation of the infringing goods in an unaltered state or subject them to a different customs procedure, other than in exceptional circumstances.

13. A Party may exclude from the application of paragraphs 1 through 12 small quantities of goods of a non-commercial nature contained in travellers' personal luggage or sent in small consignments that are not repetitive.

14. Annex 1718.14 applies to the Parties specified in that Annex.

Article 1719: Cooperation and Technical Assistance

1. The Parties shall provide each other on mutually agreed terms with technical assistance and shall promote cooperation between their competent authorities. Such cooperation shall include the training of personnel.

2. The Parties shall cooperate with a view to eliminating trade in goods that infringe intellectual property rights. For this purpose, each Party shall establish and notify the other Parties by January 1, 1994 of contact points in its federal government and shall exchange information concerning trade in infringing goods.

Article 1720: Protection of Existing Subject Matter

1. Except as required under Article 1705(7), this Agreement does not give rise to obligations in respect of acts that occurred before the date of application of the relevant provisions of this Agreement for the Party in question.

2. Except as otherwise provided for in this Agreement, each Party shall apply this Agreement to all subject matter existing on the date of application of the relevant provisions of this Agreement for the Party in question and that is protected in a Party on such date, or that meets or subsequently meets the criteria for protection under the terms of this Chapter. In respect of this paragraph and paragraphs 3 and 4, a Party's obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention and with respect to the rights of producers of sound recordings in existing sound recordings shall be determined solely under Article 18 of that Convention, as made applicable under this Agreement.

3. Except as required under Article 1705(7), and notwithstanding the first sentence of paragraph 2, no Party may be required to restore protection to subject matter that, on the date of application of the relevant provisions of this Agreement for the Party in question, has fallen into the public domain in its territory.

4. In respect of any acts relating to specific objects embodying protected subject matter that become infringing under the terms of laws in conformity with this Agreement, and that were begun or in respect of which a significant investment was made, before the date of entry into force of this Agreement for that Party, any Party may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Party. In such cases, the Party shall, however, at least provide for payment of equitable remuneration.

5. No Party shall be obliged to apply Article 1705(2)(d) or 1706(1)(d) with respect to originals or copies purchased prior to the date of application of the relevant provisions of this Agreement for that Party.

6. No Party shall be required to apply Article 1709(10), or the requirement in Article 1709(7) that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the

text of the Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations became known.

7. In the case of intellectual property rights for which protection is conditional on registration, applications for protection that are pending on the date of application of the relevant provisions of this Agreement for the Party in question shall be permitted to be amended to claim any enhanced protection provided under this Agreement. Such amendments shall not include new matter.

Article 1721: Definitions

1. For purposes of this Chapter:

confidential information includes trade secrets, privileged information and other materials exempted from disclosure under the Party's domestic law.

2. For purposes of this Agreement:

encrypted program-carrying satellite signal means a program-carrying satellite signal that is transmitted in a form whereby the aural or visual characteristics, or both, are modified or altered for the purpose of preventing the unauthorized reception, by persons without the authorized equipment that is designed to eliminate the effects of such modification or alteration, of a program carried in that signal;

geographical indication means any indication that identifies a good as originating in the territory of a Party, or a region or locality in that territory, where a particular quality, reputation or other characteristic of the good is essentially attributable to its geographical origin;

in a manner contrary to honest commercial practices means at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by other persons who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition;

intellectual property rights refers to copyright and related rights, trademark rights, patent rights, rights in layout designs of semiconductor integrated circuits, trade secret rights, plant breeders' rights, rights in geographical indications and industrial design rights;

nationals of another Party means, in respect of the relevant intellectual property right, persons who would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Geneva Convention (1971), the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (1961), the UPOV Convention (1978), the UPOV Convention (1991) or the *Treaty on Intellectual Property in Respect of Integrated Circuits* , as if each Party were a party to those Conventions, and with respect to intellectual property rights that are not the subject of these Conventions, "nationals of another Party" shall be understood to be at least individuals who are citizens or permanent residents of that Party and also includes any other natural person referred to in Annex 201.1 (CountrySpecific Definitions);

public includes, with respect to rights of communication and performance of works provided for under Articles 11, 11bis(1) and 14(1)(ii) of the Berne Convention, with respect to dramatic, dramatico-musical, musical and

cinematographic works, at least, any aggregation of individuals intended to be the object of, and capable of perceiving, communications or performances of works, regardless of whether they can do so at the same or different times or in the same or different places, provided that such an aggregation is larger than a family and its immediate circle of acquaintances or is not a group comprising a limited number of individuals having similarly close ties that has not been formed for the principal purpose of receiving such performances and communications of works; and

secondary uses of sound recordings means the use directly for broadcasting or for any other public communication of a sound recording.

Annex 1701.3

Intellectual Property Conventions

1. Mexico shall:

(a) make every effort to comply with the substantive provisions of the 1978 or 1991 UPOV Convention as soon as possible and shall do so no later than two years after the date of signature of this Agreement; and

(b) accept from the date of entry into force of this Agreement applications from plant breeders for varieties in all plant genera and species and grant protection, in accordance with such substantive provisions, promptly after complying with subparagraph (a).

2. Notwithstanding Article 1701(2)(b), this Agreement confers no rights and imposes no obligations on the United States with respect to Article 6bis of the Berne Convention, or the rights derived from that Article.

Annex 1705.7

Copyright

The United States shall provide protection to motion pictures produced in another Party's territory that have been declared to be in the public domain pursuant to 17 U.S.C. section 405. This obligation shall apply to the extent that it is consistent with the Constitution of the United States, and is subject to budgetary considerations.

Annex 1710.9

Layout Designs

Mexico shall make every effort to implement the requirements of Article 1710 as soon as possible, and shall do so no later than four years after the date of entry into force of this Agreement.

Annex 1718.14

Enforcement of Intellectual Property Rights

Mexico shall make every effort to comply with the requirements of Article 1718 as soon as possible and shall do so no later than three years after the date of signature of this Agreement.

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Court File No. 36654

IN THE SUPREME COURT OF CANADA
(ON APPEAL FROM THE FEDERAL COURT OF APPEAL)

B E T W E E N:

ASTRAZENECA CANADA INC.
ASTRAZENECA AKTIEBOLAG and
ASTRAZENECA UK LIMITED

Appellants

– and –

APOTEX INC. and
APOTEX PHARMACHEM INC.

Respondents

MEMORANDUM OF ARGUMENT OF CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION ("CGPA") (Proposed Intervener)

PART I – STATEMENT OF FACTS

Overview

1. On this appeal, the Court is asked by the Appellants to change Canadian patent law by overturning long-standing jurisprudence and fundamentally altering the approach to utility, a core concept in Canadian patent law.

2. Overturning this long-standing jurisprudence would upset the balance that Canadian patent law establishes between the rights of patentees and the Canadian public, and the "bargain" that lies at the heart of the patent system. In considering the potentially serious consequences to Canadian patent law as a whole, this Court should have the benefit of a perspective beyond the specific interests of the parties to the appeal. The CGPA seeks leave to intervene in this appeal to provide the Court with a broader perspective.

The CGPA

3. The CGPA is an industry association that represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of active

pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry.[1]

4. The members of the CGPA provide substantial cost savings to Canadian governments and private payers of prescription medications, by introducing lower-cost versions of drugs to the Canadian market. In 2015, savings resulting from the sale of generic pharmaceuticals totaled about $15 billion.[2]

5. The availability of generic drugs is essential to the health of Canadian citizens, both because lower-cost drugs means greater access for all, and also because for many important drugs in Canada, only generic versions are now available. For those important drugs, the "brand" companies have stopped selling them, rather than competing on price.[3]

6. In order for members of the CGPA to bring generic drugs to market in Canada, they must comply with both the requirements of the *Food and Drugs Act* and the *Patented Medicines (Notice of Compliance) Regulations* (the "*Regulations*"), enacted under the *Patent Act*.[4] The *Regulations* provide unique and substantial protection to pharmaceutical patentees, beyond the protection available to other patentees.[5] The *Regulations* also indicate that one of their stated purposes is to ensure the timely entry of generic pharmaceuticals into the Canadian market.[6]

7. Members of the CGPA appear regularly as parties to applications under the *Regulations* and to patent impeachment and infringement actions. Approximately 986 applications relating to patents for pharmaceutical products have been commenced since the *Regulations* were promulgated in 1993 and approximately 155 actions involving pharmaceutical patents have been commenced in Canada since 2000. Most have involved

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[1] Affidavit of James Keon, sworn July 28, 2016 ("Keon Affidavit"), ¶2, CGPA Record, Tab 2, p. 8.

[2] Keon Affidavit, ¶3, CGPA Record, Tab 2, p. 9.

[3] Keon Affidavit, ¶4, CGPA Record, Tab 2, p. 9.

[4] Keon Affidavit, ¶5-6, CGPA Record, Tab 2, pp. 9-10.

[5] Keon Affidavit, ¶7, CGPA Record, Tab 2, p. 10.

[6] RIAS dated March 12, 1998, Canada Gazette Part II, p. 1057-8, CGPA Record, Tab 5; RIAS dated October 18, 2006, Canada Gazette Part II, p. 1510, CGPA Record, Tab 6.

members of the CGPA.[7] This appeal arises from the judgment of the Federal Court of Appeal upholding the trial court's judgment that had invalidated the patent-in-suit.

8. This Court has recognized CGPA's interest in the development of patent law, in particular as it relates to pharmaceutical patents, by granting the CGPA leave to intervene in the last six Supreme Court of Canada cases involving pharmaceutical patents: *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*., 2008 SCC 61, *Teva Canada Limited v. Pfizer Canada Inc*., 2012 SCC 60, *Apotex Inc., et al. v. Sanofi-Aventis, et al*. Supreme Court Docket 35562 (appeal discontinued prior to the hearing), and *Sanofi-Aventis v. Apotex Inc.*, 2015 SCC 20.[8]

PART II – QUESTIONS IN ISSUE

9. The question to be decided on this motion is whether the CGPA be granted leave to intervene on this appeal.

PART III – STATEMENT OF ARGUMENT

Test for Intervener status

10. To obtain leave to intervene, the CGPA must show that (1) it has an interest in the appeal; and (2) that its submissions will be useful and different from those of the parties.[9] The CGPA submits that it meets both criteria.

The CGPA has an interest in this appeal

11. Patents are of central importance to the pharmaceutical industry. In Canada, patents covering finished pharmaceutical products and active pharmaceutical chemicals are the subject of constant and repeated litigation in the Federal Court and Federal Court of Appeal. The CGPA's members are parties to almost all of those cases. It is vital to the generic

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[7] Keon Affidavit, ¶8-10, CGPA Record, Tab 2, pp. 10-11.

[8] Keon Affidavit, ¶18, CGPA Record, Tab 2, p. 12.

[9] *R. v. Finta*, [1993] 1 S.C.R. 1138 at 1142, CGPA Book of Authorities ("CGPA BA"), Tab 1.

pharmaceutical industry that its voice, though its industry organization, the CGPA, be heard on the issues being considered on this appeal.[10]

12. The CGPA has no specific interest in the validity of the patent-in-suit. However, the CGPA is vitally interested in ensuring that the Canadian law relating to fundamental requirements of patent validity, including utility, are given appropriate direction that maintains the delicate balance between, on one hand, the rights of patentees, and on the other hand, the rights of the CGPA's members and ultimately, the Canadian public.

13. The pursuit of marketing approval for a generic version of a branded drug is a costly and time consuming endeavour. The decision to do so engages the *Regulations.* Where patent invalidity is asserted, the generic manufacturer is required to serve a Notice of Allegation setting out the detailed factual and legal basis of any ground of patent invalidity that it may wish to rely on. In order to do that, the generic manufacturer has first to engage in a detailed analysis of the validity of the patent.

14. The members of the CGPA, generic pharmaceutical manufacturers, are routinely and continually engaged in evaluating the validity of patents and litigating them in applications under the *Regulations* and in patent infringement or impeachment actions.[11] No industry in Canada follows patent jurisprudence more closely than the pharmaceutical industry and there is no industry whose members are more affected by changes to, or uncertainty in, patent law. Simply put, there is no industry association in Canada that has a greater interest in the development of patent law than the CGPA.[12] Accordingly, from the perspective of the CGPA and its members, it is essential that the requirements for a valid patent receive a fair and consistent treatment in the jurisprudence.

The CGPA's submissions will be useful and different

15. The Appellants' submissions are directed to the appropriateness of the so-called "promise doctrine" as a matter of law and the application of the doctrine to the patent in suit. The CGPA's submissions will be different because they will deal with the broader

[10] Keon Affidavit, ¶8-11, 14-16, CGPA Record, Tab 2, pp. 10-11.
[11] Keon Affidavit, ¶8-11, CGPA Record, Tab 2, pp. 10-11.
[12] Keon Affidavit, ¶11, CGPA Record, Tab 2, p. 11.

implications of the approach to utility in Canadian patent law to the Canadian generic pharmaceutical industry and to the members of the Canadian public.

16. If leave is granted, the CGPA will make the following submissions:

A. Uncertainty, the bargain and the balance

17. Existing Canadian patent jurisprudence respects and promotes the balance between the rights of patentees and the public through enforcement of the "bargain" that lies at the heart of Canadian patent law. The judgment that the Appellants seek would place a heavy finger on the scale of justice and would upset this fundamental balance.

18. Utility is a core requirement in Canadian patent law. As of the filing date, the patentee must have either demonstrated or soundly predicted that the invention will do what the patent has chosen to say that the patented invention will do. The so-called "promise doctrine" is no more than a reference to the need to construe the patent to ascertain that patented invention will do what the patentee has in fact chosen to say it will do.

19. Canadian patent law has long held that where a patentee promises that a patented invention will have a particular utility, that the invention will do a certain thing, the failure to achieve that result will render the patent invalid. This concept dates back at least to the decision in *New Process Screw* in 1961[13], and found expression (without the use of the word "promise") much earlier in the 1947 decision of this Court in *Wandscheer v. Sicard*.[14]

20. In 1981, this Court made it clear in *Consolboard* that an invention is not useful and lacks utility where "the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do."[15] This Court further made it clear in its 2002 decision in *AZT* that where the promised utility of an invention was neither demonstrated nor soundly predicted, the patent will be invalid. Where the utility is based on prediction, the factual basis and the

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[13] *New Process Screw Corp v. PL Robertson Manufacturing Co.*, (1961), 39 C.P.R. 31, CGPA BA, Tab 2.

[14] *Wandscheer v. Sicard Ltd*, [1948] S.C.R. 1 at p. 5, CGPA BA, Tab 3.

[15] *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504 at p. 525, CGPA BA, Tab 4.

sound line of reasoning must be disclosed in the patent.[16] The disclosure requirement is part of the "*quid pro quo*" for the patent monopoly. Its purpose is to enable the skilled person to make the same successful use as the inventor could at the time of his patent application.[17]

21. The legal framework that this Court ultimately adopts will have significant and lasting ramifications for the Canadian pharmaceutical industry as a whole. The issues for determination could tip the delicate balance between the entitlement of a patentee to obtain a monopoly and prevent the entry of generic pharmaceutical products into to the Canadian market. Changing the long-standing approach to utility will not only tip the delicate balance inherent in the patent bargain, it will also inject uncertainty and arbitrariness into the framework for assessing patent validity.

22. The CGPA will provide this Court with its perspective on the broader effects of the Appellants' proposed changes to Canadian patent law on the pharmaceutical industry. The CGPA will submit that the decision below is properly grounded in Canadian patent law and helps to foster and promote the fundamental balance that Parliament sought to achieve.

B. Comparative international law

23. The CGPA will submit that there is no universal law of patents and that there is no single guiding set of patent law principles, other than at a high level of abstraction. Recent efforts to arrive at a uniform global law were abandoned when the goal was seen to be unattainable.[18]

24. Different results can be reached in different countries on counterpart patents.[19] Different outcomes can arise due to different arguments, evidence, procedural

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[16] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153, 2002 SCC 77 ("*AZT*"), at ¶70, CGPA BA, Tab 5.

[17] *Teva Canada Limited v. Pfizer Canada Inc.*, 2012 SCC 60, [2013] 3 S.C.R. 625, at ¶70, 75, 79 and 80, CGPA BA, Tab 6.

[18] World Intellectual Property Organization, *Draft Substantive Patent Law Treaty* online: http://www.wipo.int/patent-law/en/draft_splt.htm, Affidavit of Anna Hucman sworn July 27, 2016 ("Hucman Affidavit") Exhibit "A", CGPA Record, Tab 3(A), p. 20.

[19] For example, the patent-in-suit in *Teva v. Pfizer* (2012 SCC 60) was found invalid in Canada (for inadequate disclosure under section 27(3) of the *Patent Act*); the UK

frameworks, statutory regimes and jurisprudence. It is not possible to extrapolate from the fact of differing results in different jurisdictions to a conclusion that the laws are not the same, let alone inconsistent.[20]

25. The CGPA will submit that the Canadian law of utility is neither precisely the same as nor radically different from the laws of other jurisdictions. Most jurisdictions seek to balance the interests of patentees and the public, by providing incentives to disclose new inventions and also protecting the legitimate interests of those making such disclosures. While this may be achieved in different ways in different jurisdictions, the ultimate goal is the same.

26. The CGPA will submit that the judgment below and the existing approach to utility do not place Canada out-of-step with international jurisprudence or international obligations.[21] The CGPA will further submit that pharmaceutical patents are not more frequently invalidated in Canada than elsewhere.

27. The CGPA will submit that focusing on utility as a stand-alone consideration, and asking only whether the patent laws in selected foreign jurisdictions consider utility (or industrial applicability) differently is inconsistent with the accepted approach to comparative law analysis.[22] Comparative legal analysis cannot be approached piecemeal, but must be undertaken holistically and must proceed on the basis of an examination and consideration of the entire corpus of the patent laws of each of the jurisdictions under

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counterpart patent was found invalid (for obviousness) and the United States counterpart was held valid (despite arguments of obviousness, double patenting and inequitable conduct). The patents-in-suit related to quetiapine extended release and alendronate were upheld as valid in the US (first instance and Court of Appeal); the counterpart patents for quetiapine ER and alendronate were held invalid in the UK (first instance and C.A.). The patent covering drospirenone/estradiol was held invalid in the US (first instance and C.A.) but was upheld in the UK at both levels.

[20] *Re Amazon.com Inc.*, 2011 FCA 328 at ¶16, CGPA BA, Tab 7; see also *Conor Medsystems v. Angiotech Pharmaceuticals* [2008] UKHL 49 at ¶3, CGPA BA, Tab 8.

[21] See, e.g., Gold, R., and Shortt, M., "The Promise of the Patent In Canada and Around the World", 30 CIPR 36, Hucman Affidavit, Exhibit "B", CGPA Record, Tab 3(B), pp. 22-64; and Vaver, D., "Is Canada's Patent Law Out of Step?", Reworked Remarks for University of Toronto 2nd Patent Law Colloquium, November 22, 2013, Hucman Affidavit, Exhibit "C", CGPA Record, Tab 3(C), pp. 67-73.

[22] Gold and Shortt, *supra* note 21 at 58-60, CGPA Record, Tab 3(B), pp. 45-47.

consideration.[23]

Undue weight should not be given to international patent law harmonization

28. The question of "harmonization" raises at least two important and related threshold questions, both of which involve matters of patent policy.

29. First, Parliament alone has the responsibility and authority to make policy decisions respecting the content of Canadian statutory law.

30. Second, there is no overarching requirement that the patent laws of different countries be harmonized, nor is there any informal international norms directing that this should be pursued.[24] International treaties do not compel or even promote harmonization. Rather, they expressly provide for the fact that the laws of the signatory states will differ (expressly so as regards "utility" and "industrial applicability").[25]

31. The patent laws of the US, the UK, the European Union (which follows the European Patent Convention) and Japan, to name but a few, differ in significant respects. Even if one were one to accept that "harmonization" might be worth pursuing, this Court should not be asked, in an evidentiary vacuum, to select and identify the target jurisdiction(s) for harmonization. As Professor Vaver has said:[26]

> Is harmonization a good thing? Only if the harmonized rules themselves are good and advance a country's patent policy. Harmonizing bad rules makes no sense at all. And whether a rule is good or bad often depends on one's perspective.

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[23] Gold and Shortt, *supra* note 21, CGPA Record, Tab 3(B).

[24] Gold, and Shortt, *supra* note 21, at 56-58, CGPA Record, Tab 3(B), pp. 43-45, citing to Reichman, H. & Cooper Dreyfuss, R., "Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty" (2007) 57 Duke LJ 85 at 89, Hucman Affidavit, Exhibits "B" and "D", CGPA Record, Tabs 3(B), pp. 22-64 and (D), pp. 75-120.

[25] *Marrakesh Agreement Establishing the World Trade Organization, Annex 1C*, 15 April 1994, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (*TRIPs*), Article 1 and 27(1); *North American Free Trade Agreement*, 32 I.L.M. 289 and 605, Article 1709, Hucman Affidavit, Exhibits "E" and "F", CGPA Record Tabs 3(E), pp. 122-150 and (F), pp. 152-174.

[26] Vaver, *supra*, note 21, at 2. Hucman Affidavit, Exhibit "C", CGPA Record, Tab 3(C), p. 68.

32. Given that there is no particular consistency, and certainly no uniformity in the patent laws of various countries, the CGPA will submit that undue weight should not be given to considerations of international patent law harmonization.

33. Moreover, as the issue of "harmonization" was not developed in the Courts below, there is no record on which this Court could undertake the requested analysis.

Summary

34. The CGPA seeks leave to intervene so that it can address and explain the broader issues that arise on this appeal. The CGPA will make submissions that are different from those of the parties, which will be of assistance to the Court.

PART IV – COSTS

35. The CGPA asks that there be no costs of this motion.

PART V – ORDER SOUGHT

36. The CGPA seeks an Order granting it leave to intervene in this appeal, to file a factum not to exceed 20 pages in length and to present oral argument at the hearing of the appeal for not more than 20 minutes.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 28th day of July, 2016.

Jonathan Stainsby

Marcus Klee

Devin Doyle

Counsel to the Proposed Intervener,
Canadian Generic Pharmaceutical Association

PART VI – TABLE OF AUTHORITIES

TAB	AUTHORITY	REFERENCE
1.	*R. v. Finta*, [1993] 1 S.C.R. 1138 at 1142.	Fn 9
2.	*New Process Screw Corp v PL Robertson Manufacturing Co.*, (1961), 39 CPR 31.	Fn 13
3.	*Wandscheer v Sicard Ltd*, [1948] SCR 1 at 5.	Fn 14
4.	*Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd*., [1981] 1 SCR 504 at 525.	Fn 15
5.	*Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153, 2002 SCC 77 ("AZT"), at ¶70.	Fn 16
6.	*Teva Canada Limited v. Pfizer Canada Inc.*, 2012 SCC 60, [2013] 3 S.C.R. 625, at ¶70, 75, 79 and 80.	Fn 17
7.	*Re Amazon.com Inc*., 2011 FCA 328 at ¶16	Fn 20
8.	*Conor Medsystems Incorporated v. Angiotech Pharmaceuticals Incorporated and others*, [2008] UKHL 49 at ¶3.	Fn 20

PART VII – STATUTORY PROVISIONS

DOCUMENT	REFERENCE
Regulatory Impact Analysis Statement to the Regulations Amending the *Patented Medicines (Notice of Compliance) Regulations*, March 12, 1998, Canada Gazette Part II, p. 1057-1058.	Fn 6
Regulatory Impact Analysis Statement to the Regulations Amending the *Patented Medicines (Notice of Compliance) Regulations*, October 18, 2006, Canada Gazette Part II, p. 1510.	Fn 6

(*b*) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.

(2) A second person may, by action against a first person, apply to the court for an order requiring the first person to compensate the second person for the loss referred to in subsection (1).

(3) The court may make an order under this section without regard to whether the first person has commenced an action for the infringement of a patent that is the subject matter of the application.

(4) The court may make such order for relief by way of damages or profits as the circumstances require in respect of any loss referred to in subsection (1).

(5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).

TRANSITIONAL PROVISIONS

9. (1) Subsection 4(4) does not apply to an allegation if, before the coming into force of these Regulations, it was served on the first person, if proof of that service was served on the Minister and if the first person has commenced a proceeding under subsection 6(1).

(2) Subsections 6(5) and (9) and paragraphs 6(10)(*a*) and (*b*) of the Regulations, as enacted by section 5, apply to an application pending on the coming into force of these Regulations.

(3) Subsections 6(6) to (8) and paragraph 6(10)(*c*) of the Regulations, as enacted by section 5, apply to an application commenced on or after the coming into force of these Regulations.

(4) Paragraph 7(1)(*e*) of the Regulations, as enacted by subsection 6(2), applies to an application made on or after the coming into force of these Regulations. Paragraph 7(1)(*e*) of the Regulations as it read before the coming into force of these Regulations, continues to apply to an application pending at the time of that coming into force.

(5) Subsection 7(5) of the Regulations, as enacted by subsection 6(3), applies to an application pending on the coming into force of these Regulations.

(6) Section 8 of the Regulations, as enacted by section 8, applies to an application pending on the coming into force of these Regulations.

COMING INTO FORCE

10. These Regulations come into force on March 11, 1998.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Description

The *Patented Medicines (Notice of Compliance) Regulations* were introduced to allow patent issues to be dealt with at the

b) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance.

(2) La seconde personne peut, par voie d'action contre la première personne, demander au tribunal de rendre une ordonnance enjoignant à cette dernière de lui verser une indemnité pour la perte visée au paragraphe (1).

(3) Le tribunal peut rendre une ordonnance aux termes du présent article sans tenir compte du fait que la première personne a institué ou non une action pour contrefaçon du brevet visé par la demande.

(4) Le tribunal peut rendre l'ordonnance qu'il juge indiquée pour accorder réparation par recouvrement de dommages-intérêts ou de profits à l'égard de la perte visée au paragraphe (1).

(5) Pour déterminer le montant de l'indemnité à accorder, le tribunal tient compte des facteurs qu'il juge pertinents à cette fin, y compris, le cas échéant, la conduite de la première personne ou de la seconde personne qui a contribué à retarder le règlement de la demande visée au paragraphe 6(1).

DISPOSITIONS TRANSITOIRES

9. (1) Le paragraphe 4(4) ne s'applique pas aux allégations si, avant l'entrée en vigueur du présent règlement, elles ont été signifiées à la première personne, si la preuve de leur signification a été signifiée au ministre et si la première personne a présenté une demande aux termes du paragraphe 6(1).

(2) Les paragraphes 6(5) et (9) et les alinéas 6(10)*a*) et *b*) du même règlement, édictés par l'article 5, s'appliquent aux demandes qui sont pendantes à la date d'entrée en vigueur du présent règlement.

(3) Les paragraphes 6(6) à (8) et l'alinéa 6(10)*c*) du même règlement, édictés par l'article 5, s'appliquent aux demandes présentées à la date d'entrée en vigueur du présent règlement ou après cette date.

(4) L'alinéa 7(1)*e*) du même règlement, édicté par le paragraphe 6(2), s'applique aux demandes présentées à la date d'entrée en vigueur du présent règlement ou après cette date. L'alinéa 7(1)*e*) du même règlement, dans sa version antérieure à la date d'entrée en vigueur du présent règlement, continue de s'appliquer aux demandes qui sont pendantes à cette date.

(5) Le paragraphe 7(5) du même règlement, édicté par le paragraphe 6(3), s'applique aux demandes qui sont pendantes à la date d'entrée en vigueur du présent règlement.

(6) L'article 8 du même règlement, édicté par l'article 8, s'applique aux demandes qui sont pendantes à la date d'entrée en vigueur du présent règlement.

ENTRÉE EN VIGUEUR

10. Le présent règlement entre en vigueur le 11 mars 1998.

RÉSUMÉ DE L'ÉTUDE D'IMPACT DE LA RÉGLEMENTATION

(*Ce résumé ne fait pas partie du règlement.*)

Description

Le *Règlement sur les médicaments brevetés (avis de conformité)* a été pris pour permettre de régler les problèmes relatifs aux

same time as the Minister of Health assesses the safety and efficacy of a generic version of a patented drug. A list of patents relating to the brand name version of the drug, filed by the patentee, is maintained by the Minister of Health. A generic manufacturer may wish to make reference to a patentee's drug that is already marketed in Canada in applying for approval (the NOC) to market a generic version of that patented drug. In such circumstances, the generic manufacturer must either agree to await patent expiry for its NOC to issue, or file a notice of allegation (the NOA) explaining why its product would not infringe the patents listed for the drug. The patentee, if it disagrees with the generic's allegation, may seek a court order prohibiting the Minister of Health from granting the NOC until patents listed for the drug have expired. If such an application is commenced, there is a stay preventing the Minister from issuing the NOC for a specified period. If the patent issues are decided by the court in favour of the generic manufacturer, the Minister of Health may issue the NOC for the generic as soon as it is ready. If the patent issues are decided in favour of the patentee, the NOC cannot issue until expiry of all relevant listed patents.

The following improvements to the NOC Regulations are enacted:

Reducing length of stay: The stay preventing the Minister from issuing an NOC while patent issues are resolved is reduced to 24 months from the 30 months currently provided. The government is committed to ensuring that the length of the stay continues to be appropriate, taking into account the time it takes the court to decide patent issues, given the expected impact of the Federal Court Rules, and the time it takes Health Canada to assess a drug's safety and efficacy.

Lengthening or shortening stay: The lengthening or shortening of the stay is allowed on consent of both parties. Also, the court's discretion to lengthen or shorten the stay is modified such that delay at any time during the proceeding would be taken into account.

Specifying circumstances in which damages or costs can be awarded: A clearer indication is given to the court as to the circumstances in which damages could be awarded to a generic manufacturer to compensate for loss suffered by reason of delayed market entry of its drug, and the factors that may be taken into account in calculating damages. The court may also award costs to either a generic manufacturer or a patentee, including solicitor and client costs, as appropriate, consistent with Federal Court Rules.

Ensuring a product-specific patent list: Patentees are required to certify that the patents submitted on the list for a drug are relevant to that particular version of the drug. This will ensure that patents that do not apply to the particular version of the drug will not impede the generic's market entry.

brevets pendant que le ministre de la Santé évalue l'innocuité et l'efficacité de la version générique d'un médicament breveté. Le ministre de la Santé conserve une liste des brevets se rapportant à la version générique du médicament, liste remise par le titulaire de brevet. Lorsqu'un fabricant de médicaments génériques demande l'autorisation de commercialiser une version générique d'un médicament breveté, il se peut qu'il veuille faire référence à un médicament du titulaire du brevet qui a déjà été mis en marché au Canada. En pareilles circonstances, il doit soit accepter d'attendre l'expiration des brevets pour obtenir l'avis de conformité, soit déposer un avis d'allégation affirmant que son produit ne constituera pas une contrefaçon des brevets répertoriés sur la liste correspondant au médicament d'origine. Si le titulaire du brevet conteste l'allégation du fabricant de médicaments génériques, il peut demander à un tribunal de rendre une ordonnance interdisant au ministre de la Santé de délivrer un avis de conformité jusqu'à l'expiration des brevets répertoriés sur la liste des brevets protégeant le médicament. Si une telle procédure est engagée, une prohibition empêche le Ministre de délivrer un avis de conformité pendant un laps de temps dont la durée est précisée. Si les problèmes relatifs aux brevets sont réglés à l'avantage du fabricant de médicaments génériques, le ministre de la Santé peut émettre l'avis de conformité dès qu'il est prêt. Si, au contraire, le litige est tranché en faveur du titulaire de brevet, l'avis de conformité ne peut être délivré avant l'expiration de tous les brevets répertoriés pertinents.

Les améliorations suivantes apportées au *Règlement sur les médicaments brevetés (avis de conformité)* sont promulguées :

Réduire la durée de la prohibition : La prohibition qui empêche le Ministre de délivrer un avis de conformité tant que les problèmes relatifs aux brevets ne sont pas réglés est ramenée à 24 mois. Elle est actuellement de 30 mois. Le gouvernement est résolu à faire en sorte que la durée de la prohibition soit toujours appropriée, compte tenu du temps qu'il faut au tribunal pour statuer sur les questions relatives aux brevets, et vu les conséquences prévues qu'auront les Règles de la Cour fédérale et le temps qu'il faut à Santé Canada pour évaluer l'innocuité et l'efficacité d'un médicament.

Proroger ou écourter la prohibition : Il sera possible de proroger ou d'écourter la durée de la prohibition si les deux parties sont d'accord là-dessus. En outre, on modifie le pouvoir discrétionnaire que le tribunal a de proroger ou d'écourter la prohibition, de manière que tout délai intervenant dans la procédure soit pris en compte.

Préciser les circonstances où des dommages-intérêts peuvent être accordés : De plus grandes précisions sont données aux tribunaux en ce qui concerne les circonstances où des dommages-intérêts pourront être accordés à un fabricant afin de le dédommager des pertes subies à cause du report de la mise en marché de son médicament générique; par ailleurs, des précisions sont aussi données sur les facteurs dont on peut tenir compte pour calculer les dommages-intérêts. Les tribunaux peuvent également accorder les dépens à l'une ou l'autre des parties (fabricant de médicaments génériques ou titulaire de brevet), y compris les honoraires professionnels, le cas échéant, conformément aux Règles de la Cour fédérale.

Exiger une liste de brevets par médicament : Les titulaires de brevet doivent certifier que les brevets répertoriés sur la liste correspondant à un médicament se rapportent au médicament en question, afin d'éviter que des brevets visant d'autres versions du médicament empêchent de commercialiser la version générique.

Expressly confirming the authority of the Minister of Health to audit the patent list: The Minister of Health's authority to audit the patent list and to refuse to add and to remove ineligible patents from the patent list is expressly confirmed.

Fuller disclosure: The court has the explicit capacity to order disclosure to the patentee of portions of a generic manufacturer's NOC submission where it is relevant to resolving issues in the proceeding. The Regulations provide that the disclosed information must be treated confidentially, under the same terms as would apply to similar disclosure orders made under the authority of the Federal Court Rules.

More specificity with an NOA: When an allegation relating to non-infringement (NOA) is submitted, a generic manufacturer is required to indicate to the patentee the specific version of the medicine it intends to market.

No premature NOA: An NOA relating to non-infringement may only be served on a patentee by a generic manufacturer when or after it has filed a submission for an NOC with the Minister of Health.

Burden of proof: A generic manufacturer seeking to make a version of the patentee's drug and alleging non-infringement of a product-by-process patent on the patent list has the onus of proving that the patent would not be infringed.

Dismissal of the case at an early stage: A generic manufacturer will be able to seek dismissal of the patentee's case, at an early stage, in certain circumstances.

Coming into Force

Changes to the Regulations came into force on March 12, 1998. Specific transitional rules deal with how the amended Regulations will apply to existing and new proceedings.

Alternatives

The changes to the Regulations respond to the April, 1997 report of the Standing Committee on Industry reviewing the *Patent Act Amendment Act, 1992*, which called for changes to the regulatory framework to address stakeholder concerns regarding fairness, effectiveness, and reduction of unnecessary litigation. They also address issues raised during consultations with stakeholders relating to proposed changes pre-published in the *Canada Gazette* Part I on January 24, 1998.

Benefits and Costs

The link between the patent status of a drug and approval for a generic version of the drug is being maintained, to provide effective enforcement of patent rights, while at the same time ensuring that generic drugs can enter the market as soon as possible; either as soon as it is determined that they are not covered by a patent, or, where they are covered by a patent, immediately after the expiry of the patent. Overall, since the amendments are designed to make the Regulations fairer and more effective, and reduce unnecessary litigation, compliance costs to private sector parties should be reduced. The amendments will not significantly alter

Confirmer expressément que le ministre de la Santé est habilité à vérifier la liste de brevets : Il est confirmé expressément que le ministre de la Santé est habilité à vérifier la liste de brevets, à refuser d'y ajouter des brevets inadmissibles et à en retirer de tels brevets.

Divulgation accrue : Les tribunaux sont expressément habilités à ordonner la divulgation au titulaire de brevet d'éléments de la demande d'avis de conformité déposée par un fabricant de médicaments génériques, si cela favorise le règlement du litige. Le Règlement exige que les renseignements ainsi divulgués soient traités confidentiellement, tout comme dans le cas d'ordonnances de divulgation semblables établies aux termes des Règles de la Cour fédérale.

Plus de précisions dans les avis d'allégation : Lorsqu'il soumet un avis d'allégation affirmant l'absence de contrefaçon, le fabricant de médicaments génériques doit aussi indiquer précisément au titulaire de brevet quelle version du médicament il entend commercialiser.

Pas d'avis d'allégation prématuré : Le fabricant de médicaments génériques ne peut pas signifier au titulaire de brevet un avis d'allégation relatif à une absence de contrefaçon s'il n'a pas d'abord déposé une demande d'approbation d'avis de conformité auprès du ministre de la Santé.

Fardeau de la preuve : Il incombe au fabricant qui souhaite produire une version générique d'un médicament protégé par un brevet et qui affirme ne pas contrefaire un brevet portant sur un produit par procédé, de prouver qu'il n'y a pas contrefaçon de brevet.

Rejet de la cause au stade initial : Le fabricant de médicaments génériques pourra demander le rejet de la cause du titulaire de brevet à un stade initial, dans certaines circonstances.

Entrée en vigueur

Les changements apportés au Règlement sont entrés en vigueur le 12 mars 1998. Des règles particulières de transition concernent la façon dont le Règlement modifié s'appliquera aux procès en cours et aux nouveaux procès.

Autres solutions envisagées

Les changements apportés au Règlement font suite au rapport remis en avril 1997 par le Comité permanent de l'industrie, qui était chargé d'examiner la *Loi de 1992 modifiant la Loi sur les brevets*. Dans ce rapport, le Comité recommandait de modifier le cadre de réglementation afin de répondre aux préoccupations des intervenants par rapport à l'équité, à l'efficacité et à la réduction du nombre des litiges inutiles. Ces changements concernent aussi les questions soulevées pendant les consultations avec les intervenants au sujet des changements proposés qui avaient été publiés dans la *Gazette du Canada* Partie I le 24 janvier 1998.

Avantages et coûts

Le lien entre le statut du brevet protégeant un médicament et l'approbation d'une version générique de ce médicament est maintenu afin de faire respecter véritablement les droits conférés par les brevets, tout en assurant que les médicaments génériques puissent être commercialisés aussitôt que possible, soit dès qu'il est déterminé qu'ils ne sont couverts par aucun brevet, soit, s'ils sont couverts par un brevet, immédiatement après l'expiration de celui-ci. Dans l'ensemble, les modifications visant à rendre le Règlement plus équitable et plus efficace, et à réduire le nombre des litiges inutiles devraient faire en sorte que l'observation du

the costs of administering, or adjudicating cases under the Regulations.

The amendments reinforce the balance between providing a mechanism for the effective enforcement of patent rights and ensuring that generic drug products enter the market as soon as possible.

Consistent with maintaining this balance, certain changes will further facilitate market entry of generic drugs: for example, reducing the length of the stay, clarifying the court's discretion to shorten the stay, and providing a mechanism for early dismissal of a case. The government intends to ensure that the length of the stay continues to be appropriate, taking into account the time it takes the Minister of Health to approve generic drugs and the time it takes the court to decide patent issues, and how this latter time may be affected by the *Federal Court Rules, 1998*, that will come into effect on April 25, 1998.

Certain changes would make the system for protecting patent rights more effective: for example, clarifying the court's discretion to lengthen the stay.

Other changes are designed to reduce unnecessary litigation and streamline the litigation process: specifying the circumstances in which parties can be awarded damages and factors that may be taken into account in calculating damages; specifying some of the circumstances in which costs may be awarded; ensuring a product-specific patent list; expressly confirming the authority of the Minister of Health to audit patent lists; placing the burden of proof on manufacturers seeking to produce a generic version of a drug covered by a product-by-process patent; permitting the court to order disclosure portions of a generic manufacturer's Notice of Compliance submission if it is relevant to resolving the issues by the court (the information must be treated confidentially); requiring more specificity with a Notice of Allegation and allowing early dismissal of a patentee's case in circumstances where listed patents are irrelevant or ineligible for inclusion on the patent register.

Consultation

Extensive consultations were undertaken with stakeholders. In particular, comments on proposed changes to the Regulations prepublished in the *Canada Gazette* Part I were received from the Canadian Drug Manufacturers Association (CDMA), the Pharmaceutical Manufacturers Association of Canada (PMAC), the industrial biotechnology association (BIOTECanada), consumer groups, various sectors of the health care industry, and provincial governments. Issues raised during the course of these consultations have been taken into account in the final amendments, which improve the balance and effectiveness of the Regulations.

Compliance and Enforcement

The courts and the Minister of Health will continue to exercise jurisdiction over these matters to ensure compliance, since they relate to various aspects of the regulatory framework for granting

Règlement devrait coûter moins cher aux parties du secteur privé. Les modifications ne changeront guère les frais d'administration ou d'adjudication des causes en vertu du Règlement.

Les modifications envisagées renforceront l'équilibre entre l'assurance d'un mécanisme qui permet de faire véritablement respecter les droits conférés par les brevets et la garantie que les médicaments génériques soient commercialisés aussitôt que possible.

Afin de préserver cet équilibre, certaines des modifications faciliteront davantage encore la mise en marché des médicaments génériques, par exemple, en raccourcissant la durée de la prohibition, en clarifiant le pouvoir discrétionnaire qu'a le tribunal de la raccourcir, et en prévoyant un mécanisme de rejet de la cause tôt dans la procédure. Le gouvernement entend s'assurer que la durée de la prohibition demeure adéquate, compte tenu du temps qu'il faut à Santé Canada pour approuver les médicaments génériques, des délais dont les tribunaux ont besoin pour statuer sur les questions relatives aux brevets, et de la façon dont les *Règles de la Cour fédérale (1998)* influeront sur ces délais, elles qui doivent entrer en vigueur le 25 avril 1998.

Certaines modifications envisagées accroîtront l'efficacité du système de protection des droits conférés par les brevets, par exemple, en clarifiant le pouvoir discrétionnaire que les tribunaux ont de proroger la prohibition.

D'autres changements visent à réduire le nombre des litiges inutiles et à rationaliser le processus judiciaire, en précisant les circonstances où les parties peuvent obtenir des dommages-intérêts et les facteurs pouvant être pris en compte dans le calcul de ces dommages; en définissant certaines des circonstances où les parties peuvent se faire rembourser leurs dépens; en exigeant une liste des brevets par produit; en confirmant expressément que le ministre de la Santé est habilité à vérifier les listes de brevets; en plaçant le fardeau de la preuve sur les fabricants qui souhaitent produire une version générique d'un médicament protégé par un brevet portant sur un produit par procédé; en permettant la divulgation d'éléments de la demande d'avis de conformité déposée par le fabricant de médicaments génériques, si cela peut aider le tribunal à trancher le litige (les renseignements doivent être traités confidentiellement); en exigeant plus de précisions dans l'avis d'allégation et en autorisant le rejet de la cause du titulaire de brevet tôt au cours de la procédure, dans les cas où les brevets figurant sur la liste ne sont pas pertinents ou y sont inscrits à tort.

Consultations

Le gouvernement a largement consulté les intervenants. Plus particulièrement, l'Association canadienne des fabricants de produits pharmaceutiques (ACFPP), l'Association canadienne de l'industrie du médicament (ACIM), l'Association canadienne de l'industrie de la biotechnologie (BIOTECanada), des groupes de consommateurs, divers secteurs de l'industrie des soins de santé et des gouvernements provinciaux ont exprimé leurs points de vue sur les changements que l'on proposait d'apporter au Règlement et qui avaient été publiés dans la *Gazette du Canada* Partie I. Les questions soulevées pendant ces consultations ont été prises en compte dans la rédaction des modifications finales, ce qui a permis d'améliorer l'équilibre et l'efficacité du Règlement.

Conformité et mise en application

Les tribunaux et le ministre de la Santé resteront compétents pour ces questions afin d'assurer la conformité. En effet, celles-ci se rapportent à divers aspects du cadre de réglementation visant

marketing approval to generic versions of drugs and disputes involving patent rights.

Contact

Vinita Watson
Director General
Corporate Governance Branch
Industry Canada
5th Floor, West Tower
235 Queen Street
Ottawa, Ontario
K1A 0H5

l'autorisation de commercialiser des versions génériques de médicaments et le règlement des litiges relatifs aux droits conférés par les brevets.

Personne-ressource

Vinita Watson
Directrice générale
Direction générale de la régie d'entreprise
Industrie Canada
5^{e} étage, tour Ouest
235, rue Queen
Ottawa (Ontario)
K1A 0H5

8. Subsection 8(4) of the *Patented Medicines (Notice of Compliance) Regulations*, as enacted by subsection 5(2) of these Regulations, does not apply to an action commenced under section 8 of the *Patented Medicines (Notice of Compliance) Regulations* prior to the coming into force of these Regulations.

COMING INTO FORCE

9. These Regulations come into force on the day on which they are registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Description

These amendments are intended to restore the balanced policy underlying the *Patented Medicines (Notice of Compliance) Regulations* ("PM(NOC) Regulations") by reaffirming the rules for listing patents on the register and clarifying when listed patents must be addressed.

Background

The Government's pharmaceutical patent policy seeks to balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower priced generic competitors. The current manner in which that balance is realized was established in 1993, with the enactment of Bill C-91, the *Patent Act Amendment Act, 1992*, S.C. 1993, c. 2.

On the one end of the balance lies subsection 55.2(1) of the *Patent Act*, better known as the "early-working" exception. In the pharmaceutical industry, early-working allows second and subsequent entry drug manufacturers (typically generic drug companies) to use a patented, innovative drug for the purpose of seeking approval to market a competing version of that drug. Normally, conduct of this kind would constitute patent infringement but an exception has been made so that generic drug companies can complete Health Canada's regulatory approval process while the equivalent innovative drug is still under patent, in order to be in a position to enter the market as soon as possible after patent expiry. The generic pharmaceutical industry estimates that early-working can accelerate the market entry of its products in Canada by some three to five years.

The PM(NOC) Regulations represent the other half of the balance. As explained in the original Regulatory Impact Analysis Statement (RIAS) which accompanied their passage in 1993, in creating the early-working exception, Bill C-91 removed an exclusive right otherwise available to patentees and the PM(NOC) Regulations are therefore required "... to ensure that this new exception to patent infringement is not abused by generic drug applicants seeking to sell their products during the term of the competitor's patent...". The PM(NOC) Regulations do this by linking Health Canada's ability to approve a generic drug to the patent status of the equivalent innovative product the generic seeks to copy. Under the current scheme, a generic drug company which compares its product directly or indirectly with a patented, innovative drug in

8. Le paragraphe 8(4) du *Règlement sur les médicaments brevetés (avis de conformité)*, édicté par le paragraphe 5(2) du présent règlement, ne s'applique pas à l'action intentée en vertu de l'article 8 du *Règlement sur les médicaments brevetés (avis de conformité)* avant la date d'entrée en vigueur du présent règlement.

ENTRÉE EN VIGUEUR

9. Le présent règlement entre en vigueur à la date de son enregistrement.

RÉSUMÉ DE L'ÉTUDE D'IMPACT DE LA RÉGLEMENTATION

(Ce résumé ne fait pas partie du règlement.)

Description

Ces modifications ont pour objectif de rétablir la politique équilibrée qui sous-tend le *Règlement sur les médicaments brevetés (avis de conformité)* (« règlement de liaison ») en réaffirmant les règles régissant l'inscription de brevets au registre et en éclaircissant les circonstances où ceux-ci doivent être respectés.

Contexte

La politique du gouvernement en matière de brevets pharmaceutiques cherche à atteindre un équilibre entre la mise en application efficace des droits conférés par les brevets protégeant les nouvelles drogues innovatrices et l'entrée sur le marché en temps opportun des produits génériques concurrents moins coûteux. La manière actuelle dont cet équilibre se réalise a été instaurée en 1993, avec l'adoption du projet de loi C-91, soit la *Loi de 1992 modifiant la Loi sur les brevets*, L.C. 1993, ch. 2.

Une part de cet équilibre réside dans le paragraphe 55.2(1) de la *Loi sur les brevets*, mieux connu sous l'appellation d'exception relative à la « fabrication anticipée ». Dans l'industrie pharmaceutique, la fabrication anticipée permet au deuxième fabricant et aux fabricants subséquents (généralement un fabricant de produits génériques) d'utiliser une drogue innovatrice brevetée afin d'obtenir l'approbation pour commercialiser un produit concurrent. Normalement, cette conduite constituerait une contrefaçon de brevet, mais cette exception a été conçue afin d'autoriser les fabricants de produits génériques d'entamer le processus d'approbation réglementaire de Santé Canada pendant que la drogue innovatrice équivalente est encore protégée par un brevet leur permettant ainsi de commercialiser leurs produits le plus tôt possible après l'expiration du brevet. Selon les membres de l'industrie des produits génériques, la fabrication anticipée peut accélérer de trois à cinq ans l'entrée de leurs produits sur le marché canadien.

L'autre part de cet équilibre réside dans l'application du règlement de liaison. Comme l'explique le premier Résumé de l'étude d'impact de la réglementation (RÉIR) ayant accompagné l'adoption de ce règlement en 1993, la création de l'exception relative à la fabrication anticipée par le projet de loi C-91 a eu pour effet d'éliminer un droit exclusif dont bénéficiaient par ailleurs les titulaires des brevets. Le règlement de liaison était donc nécessaire pour « ... éviter que cette nouvelle exception en matière de contrefaçon soit mal utilisée par les fabricants de médicaments génériques désireux de vendre leurs produits au Canada pendant que le brevet original est encore valide... ». Le règlement de liaison parvient à cet objectif en liant la capacité de Santé Canada d'approuver un produit générique au statut du brevet de la drogue

order to establish the former's safety and efficacy and secure marketing approval from Health Canada (which comes in the form of a "notice of compliance" or "NOC") must make one of two choices. It can either agree to await patent expiry before obtaining its NOC or make an allegation justifying immediate market entry that is either accepted by the innovator or upheld by the court.

Thus, while early-working is intended to promote the timely market entry of generic drugs by allowing them to undergo the regulatory approval process in advance of patent expiry, the PM(NOC) Regulations are intended to provide effective patent enforcement by ensuring the former does not result in the actual issuance of a generic NOC until patent expiry or such earlier time as the court or innovator considers justified having regard to the generic company's allegation. Despite their seemingly competing policy objectives, it is important that neither instrument be considered in isolation as the intended policy can only be achieved when the two operate in a balanced fashion.

Patent Listing Requirements

Considering the societal imperative of encouraging new and better medical therapies, and the difficulties associated with protecting pharmaceutical patent rights by way of conventional infringement litigation, the PM(NOC) Regulations are intended to operate as a very potent patent enforcement mechanism. The 24-month stay under the regulations serves that purpose by providing innovator companies with the means to pre-empt the market entry of suspected patent infringers. At the same time, it is this very potency which calls for moderation in the application of the PM(NOC) Regulations, lest their effect dominate that of early-working and defeat the overall purpose of the policy. As has been observed by the courts on numerous occasions, the PM(NOC) Regulations are a special enforcement remedy which exists in addition to, not in lieu of, the right to pursue an action for patent infringement.

Consistent with this understanding of the PM(NOC) Regulations is the fact that not every patent pertaining to an approved drug qualifies for enforcement under the scheme. Only those patents which meet the current timing, subject matter and relevance requirements set out in section 4 of the regulations are entitled to be added to Health Canada's patent register and to the concurrent protection of the 24-month stay. Embodied in each of these requirements are certain fundamental principles which must be respected if the PM(NOC) Regulations are to operate in balance with early-working. While the operation of some of these requirements is described in more detail below, a brief discussion of the principles they represent is warranted.

By stipulating that the application filing date of the patent precede the date of the corresponding drug submission, the timing requirement promotes a temporal connection between the invention sought to be protected and the product sought to be approved. This ensures that patents for inventions discovered after the existence of a product do not pre-empt generic competition on that

innovatrice équivalente. Suivant le régime actuel, un fabricant de produits génériques comparant son produit, directement ou indirectement, à un médicament novateur breveté afin d'établir l'innocuité et l'efficacité de son produit et d'obtenir l'approbation réglementaire de Santé Canada pour la mise en marché (qui prend la forme d'un « avis de conformité ») doit, soit consentir à attendre l'expiration du brevet avant d'obtenir son avis de conformité, soit formuler une allégation justifiant la mise en marché immédiate que la compagnie innovatrice accepte ou que le tribunal confirme.

Ainsi, bien que l'exception relative à la fabrication anticipée vise à promouvoir l'entrée sur le marché en temps opportun de produits génériques en permettant aux fabricants d'entamer le processus d'approbation réglementaire avant l'expiration du brevet, le règlement de liaison a pour but d'assurer la mise en application efficace des droits conférés par un brevet en veillant à ce que ledit processus ne donne pas lieu à la délivrance d'un avis de conformité pour un produit générique avant l'expiration du brevet ou avant toute date antérieure que le tribunal ou l'innovateur juge justifiée à l'égard de l'allégation du fabricant de produits génériques. Malgré ces objectifs stratégiques apparemment contradictoires, il est important qu'aucun de ces instruments ne soit examiné de façon isolée puisque la politique sous-jacente voulue ne peut être atteinte que si les deux fonctionnent de façon équilibrée.

Les exigences relatives à l'inscription des brevets

En considérant le besoin vital de la société d'encourager la création de nouveaux traitements médicaux améliorés, sans oublier les problèmes associés à la protection des droits conférés par les brevets pharmaceutiques au moyen d'une action en contrefaçon ordinaire, le règlement de liaison se veut un mécanisme très puissant dans l'application des droits conférés par un brevet. La suspension de 24 mois prévue par le règlement atteint cet objectif en permettant aux innovateurs d'empêcher l'entrée sur le marché des produits génériques concurrents dont ils soupçonnent de contrefaçon. En revanche, c'est ce même pouvoir qui doit être modéré dans l'application du règlement de liaison, faute de quoi les effets de celui-ci l'emporteraient sur ceux de la fabrication anticipée et empêcheraient l'atteinte du but général de la politique. Comme l'ont observé les tribunaux à maintes reprises, le règlement de liaison constitue un mécanisme d'application spécial supplétif et non substitut au droit d'intenter une action en contrefaçon.

Il s'ensuit que ce ne sont pas tous les brevets protégeant une drogue approuvée qui peuvent se prévaloir du mécanisme d'application prévu par le règlement de liaison. Seuls les brevets respectant les exigences énoncées à l'article 4 du règlement relatives au délai, à l'objet et à la pertinence, peuvent être inscrits au registre des brevets de Santé Canada et bénéficier de la protection correspondante de la suspension de 24 mois. Ces exigences reposent sur certains principes fondamentaux devant être respectés afin que le règlement de liaison fonctionne de manière équilibrée avec l'exception relative à la fabrication anticipée. Avant de passer à l'explication du fonctionnement de quelques-unes de ces exigences, les principes qui les sous-tendent seront d'abord décrits.

En stipulant que la date de dépôt de la demande de brevet doit précéder celle de la demande d'avis de conformité correspondante, l'exigence relative au délai procure un lien temporel entre l'invention que l'on cherche à protéger et le produit visé par la demande d'approbation. Ceci permet de faire en sorte que les brevets protégeant des inventions dont la découverte est postérieure à

product. Similarly, the relevance requirement limits the protection of the PM(NOC) Regulations to that which the innovator has invested time and money to test and have approved for sale. This prevents hypothetical innovation from impeding generic market entry and encourages innovators to bring their latest inventions to market. Finally, in only allowing patents to be listed which contain claims for the medicine or its use, the subject matter requirement makes it clear that innovations without direct therapeutic application, such as processes or intermediates, do not merit the special enforcement protection of the PM(NOC) Regulations.

It is recognized that there may be instances where a patent which does not qualify for the protection of the PM(NOC) Regulations is ultimately infringed by the fact of generic market entry. However, the Government's view is that where the patent fails to meet the listing requirements described above, policy considerations tip the balance in favour of immediate approval of the generic drug, and the matter is better left to the alternative judicial recourse of an infringement action. It follows that the continued viability of the regime greatly depends upon the fair and proper application of these listing requirements.

It has come to the Government's attention that an increasing number of court decisions interpreting the PM(NOC) Regulations have given rise to the need to clarify the patent listing requirements. These decisions, which turn on timing and relevance issues, are not the product of judicial error but rather of deficiency in the language of the PM(NOC) Regulations themselves. Of particular concern is the failure of the language to fully account for the range of submission types possible under the *Food and Drug Regulations*, the various pharmaceutical patent claims available under the *Patent Act* and, most importantly, the breadth of scenarios which can arise from the linkage between the two established by the PM(NOC) Regulations.

Timing and Relevance

As mentioned, in order for a patent to be added to the register and be protected under the PM(NOC) Regulations, its application must have been filed prior to the date of the corresponding drug submission. Under the *Food and Drug Regulations*, there are two principal types of drug submission an innovator company may file in order to obtain a NOC in respect of a new drug: a New Drug Submission (NDS) and a Supplement to a New Drug Submission (SNDS). A NDS is filed when approval is first sought for a new drug and contains all of the information necessary to prove that the drug is safe and effective. A SNDS is filed whenever a subsequent change is made to the drug which departs from the information in the NDS in a way that can impact on safety and efficacy.

l'existence d'une drogue n'empêchent pas l'arrivée sur le marché de versions génériques de cette même drogue. De la même façon, l'exigence relative à la pertinence vise à faire en sorte que le règlement de liaison protège uniquement ce pourquoi l'innovateur a investi temps et argent afin d'effectuer les études et l'approbation nécessaires en vue de l'entrée sur le marché. Ceci fait en sorte que l'innovation hypothétique n'entrave pas la mise en marché du produit générique et encourage les innovateurs à commercialiser leurs inventions les plus récentes. Enfin, en permettant uniquement l'inscription des brevets contenant des revendications à l'égard du médicament ou de son utilisation, l'exigence relative à l'objet signale clairement que les innovations ne comportant aucune application thérapeutique directe, comme les procédés ou les intermédiaires, ne méritent pas la protection spéciale prévue au règlement de liaison.

Bien entendu, il peut y avoir des cas où un brevet n'étant pas admissible à la protection conférée par le règlement de liaison soit finalement contrefait suite à l'arrivée d'un produit générique sur le marché. Toutefois, le gouvernement estime que dans le cas où le brevet ne respecterait pas les exigences susmentionnées, les intérêts de la politique sous jacente font pencher la balance en faveur de l'approbation immédiate du produit générique et qu'il est préférable que la question soit tranchée au moyen d'une action en contrefaçon ordinaire. Il s'ensuit que la viabilité du régime dépend en grande partie de l'application juste et équitable de ces exigences.

Le gouvernement a constaté qu'un nombre accru de décisions judiciaires portant sur l'interprétation du règlement de liaison ont donné lieu à la nécessité d'apporter des précisions quant aux exigences relatives à l'inscription des brevets décrites ci-dessus. Ces décisions, concernant les exigences relatives au délai et à la pertinence, ne sont pas le résultat d'erreurs de la part des tribunaux, mais plutôt d'une lacune dans le libellé du règlement lui-même. Plus précisément, le libellé du règlement de liaison ne tient pas pleinement compte de l'éventail de types de demandes d'avis de conformité possibles en vertu du *Règlement sur les aliments et drogues*, des différentes revendications relatives aux brevets pharmaceutiques pouvant être formulées en vertu de la *Loi sur les brevets* et, surtout, de la foule de scénarios pouvant découler du lien entre les deux lois résultant du règlement de liaison.

Délai et pertinence

Tel que mentionné précédemment, pour qu'un brevet puisse être inscrit au registre et bénéficier de la protection prévue au règlement de liaison, la demande de ce brevet doit avoir été déposée avant la date de la demande d'avis de conformité correspondante. En vertu du *Règlement sur les aliments et drogues*, il existe deux principaux types de demandes qu'un fabricant de médicaments novateurs peut déposer afin d'obtenir un avis de conformité lui permettant de commercialiser une nouvelle drogue : une présentation de drogue nouvelle (PDN) et un supplément à une présentation de drogue nouvelle (SPDN). Une PDN est déposée lorsque l'approbation est demandée pour la première fois à l'égard d'une nouvelle drogue et renferme tous les renseignements nécessaires pour prouver que la drogue en question est sécuritaire et efficace. Un SPDN est déposé pour chaque changement subséquent à la drogue s'écartant de l'information contenue dans le PDN d'une manière pouvant affecter l'innocuité et l'efficacité du produit.

The PM(NOC) Regulations speak only to the requirement that the patent filing date precede the date of the "submission for a notice of compliance" and do not specify whether this applies to the date of the NDS, the SNDS or both. Until relatively recently however, the timing requirement was treated as applying to the NDS only. This understanding of the provisions changed in 1999, when the Federal Court ruled that patents which were out of time in relation to the NDS could nevertheless be added to the register provided they met the timing requirement in relation to a subsequently filed SNDS[1].

Allowing patents to be listed in this manner is inherently problematic because a SNDS can be filed virtually any time for any number of reasons, ranging from the mundane, such as a change in drug name, to the substantive, such as a change in its indications or formulation. Accordingly, taken to the extreme, this practice has the potential to deprive the timing requirements of any meaningful effect.

In addition to ruling on this timing question, the same Federal Court decision also expressly sanctioned the listing of new formulation patents that do not claim the specific product the innovator is approved to sell. The latter finding was predicated on the court's view that the sole purpose of the PM(NOC) Regulations is the prevention of patent infringement.

Significantly, the ruling in question interpreted the PM(NOC) Regulations as they were prior to their substantial amendment in 1998[2]. That year, the Government introduced a number of changes to the PM(NOC) Regulations designed to improve their operation and reduce and streamline litigation. As further confirmation that the PM(NOC) Regulations were intended to effect a balanced policy objective, the RIAS to the 1998 amendments reiterated the point in the following passage:

> The amendments reinforce the balance between providing a mechanism for the effective enforcement of patent rights and ensuring that generic drugs enter the market as soon as possible.
>
> Consistent with maintaining this balance, certain changes will further facilitate the market entry of generic drugs [...]

Among the changes introduced by the 1998 amendments to "facilitate the market entry of generic drugs" were provisions designed to reinforce the patent listing requirements. In particular, the amended PM(NOC) Regulations reaffirm the application of strict time limitations for adding a patent to the register and contain an additional requirement that patents be relevant to the strength, dosage form and route of administration of the approved drug.

Since 1998, the Minister of Health ("Minister") has sought to apply the amendments on timing and relevance in order to place reasonable limits on the ability of innovator drug companies to list new patents on the basis of SNDS filings. The Minister has invoked the timing amendment in opposing attempts by certain innovator companies to add new patents to the register on the basis of a SNDS for a change in drug or company name. Similarly, the Minister has applied the relevance requirement in an effort to prevent innovators from adding formulation patents to

[1] *Apotex v. Minister of Health* (1999), 87 C.P.R. (3d) 271 (F.C.T.D.), affirmed 11 C.P.R. (4th) 538 (F.C.A.)

[2] SOR/98-166

Le règlement de liaison énonce que la date de dépôt du brevet doit précéder la date de la « demande d'avis de conformité » sans préciser si cette exigence s'applique à la date de la PDN, du SPDN ou des deux. Cependant, jusqu'à récemment, on considérait que l'exigence relative au délai s'appliquait uniquement à la PDN. Cette interprétation de ces dispositions fut changée officiellement en 1999, lorsque la Cour fédérale du Canada a statué que les brevets n'ayant pas été déposés dans les délais prescrits à l'égard de la PDN pouvaient néanmoins être ajoutés au registre, pourvu qu'ils respectent l'exigence relative au délai d'un SPDN déposé subséquemment[1].

Inscrire des brevets de cette manière pose problème puisqu'un SPDN peut être pratiquement déposé en tout temps et pour toutes sortes de raisons, qu'elles soient banales, telle une modification du nom de la drogue, ou majeures, tel un changement de ses indications ou de sa formulation. Ainsi, poussée à l'extrême, cette pratique pourrait enlever tout effet significatif aux exigences relatives au délai.

En plus de trancher sur cette question relative au délai, la Cour fédérale a expressément approuvé, dans cette même décision, l'inscription des brevets relatifs à une nouvelle formulation ne revendiquant pas le produit spécifique que l'innovateur est autorisé à vendre. Cette dernière conclusion était fondée sur l'opinion du tribunal selon laquelle le seul objectif du règlement de liaison était d'empêcher la contrefaçon de brevets.

La décision en question portait sur le règlement de liaison qui était en vigueur avant les modifications importantes dont il a fait l'objet en 1998[2]. Cette année-là, le gouvernement a adopté un certain nombre de changements visant à améliorer l'application du règlement ainsi qu'à réduire et à simplifier les litiges afférents. Le fait que le règlement de liaison vise un objectif équilibré est réitéré dans le passage suivant du RÉIR relatif aux modifications de 1998 :

> Les modifications envisagées renforceront l'équilibre entre la mise en place d'un mécanisme permettant véritablement de faire respecter les droits conférés par les brevets et l'assurance que les médicaments génériques soient commercialisés le plus tôt possible.
>
> Afin de préserver cet équilibre, certaines des modifications proposées faciliteront davantage la mise en marché des médicaments génériques [...]

Parmi les changements intégrés dans les modifications de 1998 ayant pour objet de « faciliter la mise en marché des médicaments génériques », on retrouve des dispositions visant à renforcer les exigences relatives à l'inscription des brevets. Plus précisément, le règlement de liaison modifié réaffirme l'application de délais stricts pour l'inscription d'un brevet au registre et exige également que les brevets soient pertinents quant à la concentration, à la forme posologique et à la voie d'administration de la drogue approuvée.

Depuis 1998, le ministre de la Santé (« ministre ») tente d'appliquer les modifications concernant les exigences relatives au délai et à la pertinence afin d'imposer des limites raisonnables à la capacité des innovateurs d'inscrire de nouveaux brevets sur le registre à l'égard des dépôts de SPDN. Le ministre a invoqué l'exigence relative au délai pour contester les tentatives faites par certains innovateurs en vue d'ajouter de nouveaux brevets au registre à l'égard d'un SPDN pour un changement du nom de la drogue ou du fabricant. De la même façon, le ministre a appliqué

[1] *Apotex c. Canada (ministre de la Santé)*, [1999] A.C.F. n° 458, confirmé [2001] A.C.F. n° 143

[2] DORS/98-166

the register which are not product-specific. The Minister also sought more general guidance on these questions through the filing of a reference with the Federal Court, but the matter was dismissed on procedural grounds following vigorous resistance from parties opposed to its terms[3].

Against the above background, in January 2003, the Federal Court of Appeal rendered a precedent-setting decision based on the amended PM(NOC) Regulations which reaffirmed the right of innovator companies to list formulation patents that do not claim the formulation approved for sale[4]. The court came to this view on the basis of what if felt to be the plain wording of the relevance provision and notwithstanding the explanatory language on product specificity in the 1998 RIAS. In so doing, the court appears to have reinvigorated the single purpose approach to interpreting patent listing requirements, as epitomized by the 1999 decision on SNDS filings discussed above. It has also accentuated a split in the jurisprudence as to the policy underlying the PM(NOC) Regulations.

The Government is concerned that the combined effect of the above described jurisprudence is a weakening of the listing requirements, potentially to the point of redundancy. Such was the reasoning of the Federal Court of Appeal in a more recent case involving a patent list submitted on the basis of a SNDS for a change in drug name[5]. In refusing to allow a patent to be listed in this manner, the court recognized that the change in name in that case was part of a strategy designed to overcome the time limitation for filing a patent list under section 4, which, if sanctioned, would render the time requirements embodied in that section meaningless. The Court of Appeal subsequently expanded on this line of reasoning to refuse a new patent listed on the basis of a SNDS for a change in manufacturing site[6]. The court recognized that both such changes (i.e. in name or manufacturing site) could not possibly be relevant to any potential claim for infringement of a patent for a medicine and were therefore outside the scope of section 4.

Although a change in drug or company name or a change in manufacturing site now appear to have been ruled out as an opportunity to add new patents to the register, the ambit of remaining changes in respect of which a SNDS can be filed is considerable, and the possible combinations of submission type and patent claims all the more so. Requiring the courts to rule on each of these piecemeal without adequate direction in the language of the PM(NOC) Regulations can only result in confusion, uncertainty and further unintended consequences.

To date, these unintended consequences include the possibility that an innovator company may delay generic market entry by listing new and sometimes irrelevant patents on the basis of minor

[3] *Patented Medicines (Notice of Compliance) Regulations (Ont.) (Re)*, 2002 FCT 1000
[4] *Eli Lilly Canada Inc. v. Canada (Minister of Health)*, 2003 FCA 24
[5] *Ferring Inc. v. Canada (Attorney General)*, 2003 FCA 274
[6] *Hoffmann-La Roche Ltd. v. Canada (Minister of Health)*, 2005 FCA 140

l'exigence relative à la pertinence afin d'empêcher certains innovateurs d'ajouter au registre des brevets relatifs à la formulation d'une drogue ne correspondant pas à la version de la drogue sur le marché. Le ministre a également demandé des lignes directrices plus générales concernant ces questions en déposant un renvoi auprès de la Cour fédérale, mais l'affaire a été rejetée pour des raisons de procédure à la suite d'une importante contestation de la part des parties qui s'y opposaient[3].

Dans ce contexte, la Cour d'appel fédérale a rendu une décision en janvier 2003 constituant un précédent au sujet du règlement de liaison modifié, puisqu'elle a réaffirmé le droit des innovateurs d'inscrire des brevets relatifs à la formulation ne revendiquant pas la même formulation approuvée pour la vente[4]. La Cour en est arrivée à cette conclusion en se fondant sur la disposition relative à la pertinence, dont le texte lui semblait clair, malgré les explications apparaissant au RÉIR de 1998 au sujet de la spécificité des produits. Ce faisant, la Cour semble avoir fait renaître l'approche fondée sur l'existence d'un seul objectif quant à l'interprétation des exigences relatives à l'inscription des brevets, approche qu'elle avait préconisée en 1999 dans la décision commentée plus haut au sujet des dépôts de SPDN. Elle a également accentué le clivage qui existe dans la jurisprudence en ce qui a trait aux objectifs de politique sous-tendant le règlement de liaison.

Le gouvernement craint que les décisions susmentionnées n'aient ensemble pour effet d'affaiblir les exigences relatives à l'inscription au point de les rendre redondantes. C'est d'ailleurs l'avis que la Cour d'appel fédérale du Canada a exprimé dans une plus récente affaire concernant une liste de brevets présentée à l'égard d'un SPDN se rapportant à un changement du nom d'une drogue[5]. Refusant de permettre que le brevet soit inscrit de cette façon, le tribunal a reconnu que le changement du nom dans ce contexte faisait partie d'une stratégie visant à contourner le délai fixé à l'article 4 pour le dépôt des listes de brevets, et a précisé que si cette stratégie était approuvée, les exigences énoncées dans cet article relatives au délai seraient sans effet pratique. Plus récemment, la Cour d'appel a élaboré sur ce raisonnement en refusant qu'un nouveau brevet soit inscrit à l'égard d'un SPDN pour un changement du lieu de fabrication[6]. La cour a reconnu que les deux changements (de nom ou de lieu de fabrication) ne pouvaient s'avérer pertinents à aucune revendication de contrefaçon de brevet portant sur une drogue et se situaient donc en dehors de la portée de l'article 4.

Même si le changement du nom d'une drogue ou d'un fabricant ou de lieu de fabrication semble maintenant avoir été définitivement écarté comme motif permettant d'ajouter de nouveaux brevets au registre, la portée des autres changements à l'égard desquels un SPDN peut être déposé demeure considérable et les combinaisons possibles de types de demandes d'avis de conformités et de revendications de brevet sont encore plus nombreuses. Obliger les tribunaux à se prononcer sur chacune de ces possibilités sans qu'ils puissent s'inspirer de directives satisfaisantes dans le règlement de liaison ne peut qu'entraîner confusion, incertitude et autres conséquences non désirables.

Jusqu'à présent, ces conséquences comprennent la possibilité qu'un innovateur retarde l'entrée de produits génériques sur le marché en inscrivant des nouveaux brevets parfois non pertinents

[3] *Règlement sur les médicaments brevetés (avis de conformité) (Ont.) (Re)*, 2002 CF 1000
[4] *Eli Lilly Canada Inc. c. Canada (ministre de la Santé)*, 2003 CAF 24
[5] *Ferring Inc. C. Canada (Procureur général)*, [2003] A.C.F. n° 49
[6] *Hoffmann-La Roche Ltd. c. Canada (ministre de la Santé)*, 2005 CAF 140

product revisions. The result is a blurring of the lines between the original product, as approved via the NDS, and the "changed" version, as approved via the SNDS, such that generic manufacturers may be prevented from entering the market with a competing version of the original innovator product even when the original patents have long since expired or been addressed.

In fact, the Government has observed instances of SNDS filings being used to list multiple new patents over time in a manner that results in repeat 24-month stays against the same generic competitor. While the possibility of repeat stays due to later listed patents is expressly contemplated under the PM(NOC) Regulations, their recurrence near and after expiry of the original product patents can only operate to delay generic competition in a manner that is inconsistent with the balanced policy objectives early-working and the PM(NOC) Regulations were intended to serve.

Although as matters stand, these instances are exceptional, they do involve drugs of significant commercial value. They also have the potential to serve as a model other innovator companies may be tempted to emulate. In this regard, the Minister has reported a significant increase in new patents being listed on the basis of SNDS filings recently[7]. In many of these cases, the SNDS does not materially change the original drug or is not directly relevant to the patent being submitted for listing.

Purpose of Amendments

The primary purpose of these amendments is to pre-empt further such behaviour by restoring the original policy intent of the PM(NOC) Regulations. This entails reaffirming the requirements innovators must meet to list patents on the register and clarifying when these patents must be addressed by their generic competitors. In addition, a number of ancillary amendments are being made with a view to reducing unnecessary litigation and improving the overall effectiveness of the regime. These were developed in response to specific concerns expressed by stakeholders following pre-publication of an earlier round of proposed amendments in the *Canada Gazette*, Part I, on December 11, 2004.

Changes to patent listing requirements

As mentioned, in order for a patent to qualify for protection under the PM(NOC) Regulations, it must be relevant to the drug product the innovator is approved to sell. This requirement serves certain policy objectives, outlined above, but also recognizes the practical limits of the Minister's role as administrator of the PM(NOC) Regulations.

To the extent that the efficient functioning of the regime depends upon a threshold determination of what patents can be

[7] Therapeutic Products Directorate Statistical Report 2005, *Patented Medicines (Notice of Compliance) Regulations*: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/patmrep_mbrevrap_2005_e.pdf

se fondant sur des changements mineurs apportés au produit. Par suite de cette mesure, les différences entre le produit original approuvé au moyen de la PDN et la version « modifiée » décrite dans le SPDN pourraient devenir floues au point d'empêcher les fabricants de produits génériques de lancer une version concurrente du produit original sur le marché même lorsque les brevets originaux sont expirés depuis longtemps ou ont été traités par le fabricant de produits génériques.

En effet, le gouvernement a observé des cas où des innovateurs se servent de dépôts de SPDN pour inscrire de nombreux brevets de façon à entraîner des suspensions successives de 24 mois à l'égard du même fabricant de produits génériques. Bien que la possibilité de suspensions répétées déclenchées par l'inscription de brevets subséquents soit expressément envisagée par le règlement de liaison, une conduite de ce genre se produisant peu avant et même après l'expiration des brevets relatifs au produit original ne peut qu'entraîner le retard de la concurrence des produits génériques d'une manière allant à l'encontre de l'équilibre visé au départ par la fabrication anticipée et le règlement de liaison.

Il convient de préciser que, même si ces cas sont exceptionnels jusqu'à présent, ils concernent des drogues de valeur commerciale importante. Ils pourraient également servir d'exemples que d'autres innovateurs seraient tentés d'imiter. À cet égard, le ministre a signalé une hausse significative du nombre de nouveaux brevets qui sont inscrits sur la base de SPDN déposés récemment[7]. Dans bon nombre de cas, le SPDN ne prévoit aucun changement important à la drogue originale ou n'est pas directement pertinent au brevet dont l'inscription est demandée.

Objectif des modifications

Les modifications ont pour objectif principal d'empêcher tout comportement similaire à l'avenir en rétablissant l'objectif stratégique initial du règlement de liaison. Il s'agit donc de réaffirmer les exigences auxquelles doivent satisfaire les innovateurs pour inscrire des brevets au registre et de préciser les circonstances dans lesquelles ces brevets doivent être respectés par leurs concurrents génériques. En outre, un certain nombre de modifications complémentaires sont en cours en vue de limiter les litiges inutiles et d'accroître l'efficacité globale du régime. Ces modifications ont été formulées en réponse aux préoccupations exprimées par des intervenants à la suite de la publication au préalable d'une série de modifications antérieures dans la *Gazette du Canada* Partie I le 11 décembre 2004.

Changements concernant les exigences relatives à l'inscription des brevets

Tel que mentionné précédemment, pour pouvoir bénéficier de la protection conférée par le règlement de liaison, un brevet doit être pertinent par rapport à la drogue pour laquelle l'innovateur a obtenu l'approbation de vente. Cette exigence répond à certains objectifs en matière de politique, expliqués ci-dessus, et elle tient également compte des limites pratiques du rôle du ministre en tant qu'administrateur du règlement de liaison.

Dans la mesure où le fonctionnement efficace du régime dépend d'une détermination préliminaire des brevets pouvant être

[7] Direction des produits thérapeutiques rapport statistique 2005, sur l'application du *Règlement sur les médicaments brevetés (avis de conformité)* : http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/patmrep_mbrevrap_2005_f.pdf

listed, in making that determination the Minister can only be called upon to assess the relationship between the patent and the drug described in the innovator's submission for a NOC. A broader inquiry into the relationship between the patent and any potentially equivalent generic drug is not relevant to the listing question.

The amendments reflect this by further entrenching the concept of product specificity as the key consideration required of the Minister in applying the listing requirements under section 4 of the PM(NOC) Regulations. They do so through more precise language respecting the intended link between the subject matter of a patent on a patent list and the content of the underlying submission for a NOC in relation to which it is submitted. In addition, under the amendments, only certain clearly defined submission types will provide an opportunity to submit a new patent list.

In terms of what may be listed in relation to the NDS, the amendments stipulate that only patents filed prior to the NDS and which claim certain subject matter described therein may be added to the register in relation to the original form of the drug. This will facilitate the market entry of generic versions of the original innovator product as soon as possible after expiry of the original patents. To meet these criteria, a patent with a filing date anterior to that of the NDS must contain at least one of the following four claims: (1) a claim for the approved medicinal ingredient, (2) a claim for the approved formulation containing that medicinal ingredient, (3) a claim for the approved dosage form, or (4) a claim for an approved use of the medicinal ingredient.

It will be noted that amended section 4 no longer contains an explicit requirement that a patent contain a "claim for the medicine itself". However, in keeping with well settled law on the scope of protection afforded by that phrase, the PM(NOC) Regulations will continue to allow the listing of patents containing either a claim for the approved formulation or a claim for the approved medicinal ingredient.

For the purposes of amended section 4, the terms "formulation" and "medicinal ingredient" are intended to bear their established meaning under the extensive body of case law interpreting a "claim for the medicine itself". The term "formulation" thus refers to the physical mixture of medicinal and non-medicinal ingredients administered to the patient by means of the approved drug. The term "medicinal ingredient", in turn, refers to the substance in the formulation which, once administered, is responsible for the drug's desired effect in the body.

In light of the greater specificity being brought to these concepts, these amendments repeal the existing definitions in section 2 of the PM(NOC) Regulations relating to the "medicine", and replace these with definitions for "claim for the medicinal ingredient", "claim for the use of the medicinal ingredient" and "claim for the formulation".

A definition for the first of these phrases is necessary to ensure that product-by-process patents continue to qualify for protection under the regulations, and to confirm that the same is true of patents for biologic drugs. It also serves to clarify, in so far as small molecule drugs are concerned, that patents claiming different crystalline, amorphous, hydrated and solvated forms of the approved medicinal ingredient (i.e. "polymorphs") are eligible for listing when submitted in relation to the NDS, but that different

inscrits, le ministre, à cette fin, ne peut être appelé qu'à évaluer le rapport entre le brevet et la drogue décrite dans la demande d'avis de conformité de l'innovateur. Une enquête plus vaste sur le rapport entre le brevet et tout produit générique bioéquivalent potentiel est non pertinente à la question d'admissibilité.

Les modifications mettent ce fait en évidence en enracinant davantage le concept de la spécificité des produits en tant que principale considération exigée du ministre dans l'application des exigences relatives à l'inscription, prévues à l'article 4 du règlement de liaison. Les modifications utilisent un libellé plus précis quant au lien entre l'objet d'un brevet inscrit sur une liste et le contenu de la demande d'avis de conformité à l'égard duquel elle est soumise. De plus, en vertu des modifications, une nouvelle liste de brevets ne peut être soumise que dans le cas de certains types de demandes bien précis.

Quant à ce qui peut être inscrit par rapport à la PDN, les modifications prévoient que seuls les brevets déposés avant la PDN et revendiquant un certain objet qui y est décrit peuvent être ajoutés au registre en relation avec la forme originale de la drogue. Ces modifications faciliteront l'entrée sur le marché de versions génériques de la drogue d'origine le plus tôt possible après l'expiration des brevets originaux. Pour satisfaire à ces critères, un brevet dont la date de dépôt est antérieure à celle de la PDN doit renfermer au moins une des quatre revendications suivantes : (1) une revendication de l'ingrédient médicinal approuvé, (2) une revendication de la formulation approuvée renfermant cet ingrédient médicinal, (3) une revendication de la forme posologique approuvée ou (4) une revendication de l'utilisation approuvée de l'ingrédient médicinal.

Il est à noter que l'article 4 modifié n'exigera plus explicitement qu'un brevet comprenne une « revendication du médicament en soi ». Cependant, conformément à une interprétation bien établie dans la jurisprudence relative à la portée de la protection conférée par cette phrase, le règlement de liaison continuerait de permettre l'inscription de brevets comportant soit une revendication de la formulation approuvée, soit une revendication de l'ingrédient médicinal approuvé.

Aux fins de l'article 4 modifié, les termes « formulation » et « ingrédient médicinal » tirent leur sens de l'interprétation donnée par la jurisprudence mentionnée ci-haut relative à « revendication du médicament en soi ». Le terme « formulation » renvoie donc au mélange d'ingrédients médicinaux et non médicinaux administré au patient au moyen de la drogue approuvée. Le terme « ingrédient médicinal », quant à lui, renvoie à la substance dans la formulation qui, une fois administrée, est responsable de l'effet désiré de la drogue dans l'organisme.

En raison de la spécificité accrue conférée à ces concepts, les modifications abrogent les définitions actuelles à l'article 2 du règlement de liaison concernant le terme « médicament » pour y substituer des définitions relatives à « revendication de l'ingrédient médicinal », « revendication de l'utilisation de l'ingrédient médicinal » et « revendication de la formulation ».

Il est nécessaire d'établir une définition de « revendication de l'ingrédient médicinal » pour que les brevets protégeant un produit par procédé continuent de pouvoir bénéficier de la protection du règlement et pour confirmer qu'il en est de même pour les brevets relatifs à des médicaments biologiques. Une telle définition sert également à préciser, concernant les médicaments à petites molécules, que les brevets revendiquant différentes formes cristallines, amorphes, hydratées et solvatées de l'ingrédient

chemical forms, such as salts and esters, are not. This accords with Health Canada policy on what constitutes an "identical medicinal ingredient" for the purposes of establishing pharmaceutical equivalence under section C08.001.1 of the *Food and Drug Regulations*. None of these changes is intended to disturb prior jurisprudence to the effect that patents claiming intermediates or metabolites of the medicinal ingredient are ineligible for listing.

médicinal approuvé (c.-à-d., des « formes polymorphiques ») peuvent être inscrits au registre lorsqu'ils sont soumis en relation avec la PDN, mais que les diverses formes chimiques comme les sels et les esters ne le sont pas. Ceci est conforme à la politique de Santé Canada, laquelle définit ce qui constitue un « ingrédient médicinal identique » aux fins de l'établissement d'une équivalence pharmaceutique aux termes de l'alinéa C08.001.1 du *Règlement sur les aliments et drogues*. Ces changements n'ont pas pour objet de modifier la jurisprudence antérieure selon laquelle les brevets dont les revendications portent seulement sur des intermédiaires ou des métabolites de l'ingrédient médicinal ne peuvent pas être inscrits au registre.

Although the definition for "claim for the use of the medicinal ingredient" in these amendments is unchanged from the current definition for "claim for the use of the medicine", a point of clarification regarding the intention underlying this aspect of the PM(NOC) Regulations is in order. It is acknowledged that the regulatory language employed in the health and safety context to describe the use for which a medicinal ingredient in a drug is sometimes at odds with the manner in which claims are drafted in the many different kinds of so-called "use patents" which exist in the pharmaceutical realm. Examples of the latter include kit claims, "Swiss-type" claims and claims for dosing regimens. However, the combined effect of the definition under this part and the requirement that the claimed use be one described in the underlying NDS should be to limit the eligibility of use patents to those which contain a claim to an approved method of using the medicinal ingredient, for an approved indication. This link should be apparent from a comparison of the claims in the patent with the relevant portions of the product monograph and labelling for the approved drug.

Bien que la définition du terme « revendication de l'utilisation de l'ingrédient médicinal » visée par ces changements est la même que la définition actuelle du terme « revendication de l'utilisation du médicament », il y a lieu d'apporter des éclaircissements au sujet de l'intention sous-jacente de cet aspect du règlement de liaison. On reconnaît que les termes réglementaires employés dans le contexte de la santé et de la sécurité pour décrire l'utilisation pour laquelle un ingrédient médicinal dans un médicament est destinée vont parfois à l'encontre de la façon dont sont rédigées les revendications dans les différents types de brevets communément appelés « brevets d'utilisation » existant dans le domaine pharmaceutique. À titre d'exemples, mentionnons les revendications relatives à des trousses, celles dites de « type suisse » et celles à l'égard des schémas posologiques. Toutefois, l'effet combiné de cette définition dans ce contexte et de l'exigence selon laquelle l'utilisation revendiquée doit être décrite dans la PND devrait limiter l'admissibilité des « brevets d'utilisation » à ceux contenant une revendication pour une utilisation approuvée de l'ingrédient médicinal, pour une indication approuvée. Ce lien devrait être apparent en comparant les revendications du brevet avec les sections pertinentes de la monographie du produit et de l'étiquetage du médicament approuvé.

Whereas the above described amendments to section 4 are intended to clarify existing policy by reinforcing the link between the subject matter of a patent and the content of the NDS, other changes mark an expansion in that policy. In particular, the scope of eligible subject matter is being broadened to include patents for approved dosage forms.

Alors que les modifications relatives à l'article 4 décrites ci-dessus ont pour objet de préciser la politique actuelle en renforçant le lien entre l'objet d'un brevet et le contenu de la PDN, d'autres modifications envisagées entraîneraient un élargissement de cette politique. En particulier, la portée de l'objet admissible à la protection du règlement est élargie de façon à inclure les brevets relatifs aux formes posologiques approuvées.

When seized of the question, courts have consistently held that the current language "claim for the medicine itself" in section 4 is insufficient to support the listing of dosage form patents. However, in light of representations from the innovative industry regarding the significant therapeutic advantages afforded by novel dosage forms, the Government has come to the view that inventions in this area merit the special protection of the PM(NOC) Regulations. This is particularly true where biologic drugs are concerned, as effective administration of the medicinal ingredient is often dependent on the development of new and innovative delivery mechanisms. Amended section 4 thus contains new language necessary to implement this change, and a new definition for the phrase "claim for the dosage form" has been added to section 2 in order to clarify the scope of protection this change is intended to effect.

Les tribunaux, lorsque saisis de la question, s'entendent pour dire que le libellé actuel de l'article 4, à savoir « revendication du médicament en soi » est insuffisant pour permettre l'inscription des brevets relatifs à des formes posologiques. Toutefois, à la lumière des observations reçues de l'industrie innovatrice au sujet des avantages thérapeutiques considérables qu'offrent de nouvelles formes posologiques, le gouvernement est d'avis que les inventions à ce titre méritent la protection spéciale prévue par le règlement de liaison. Ceci est d'autant plus vrai dans le cas des médicaments biologiques dont l'administration efficace de l'ingrédient médicinal est souvent tributaire du développement de mécanismes d'administration nouveaux et novateurs. L'article 4 modifié offre ainsi un nouveau libellé nécessaire à la mise en œuvre de ce changement, et une nouvelle définition du terme « revendication de la forme posologique » a été ajoutée à l'article 2 afin de préciser la portée de la protection que ce changement est censé conférer.

Although amended section 2 defines the phrase "claim for the dosage form" in very general terms, in order to accommodate future advancements in this field, the intent is to provide protection for the novel delivery system by which the approved medicinal

Bien que l'article 2 modifié définisse le terme « revendication de la forme posologique » en termes très généraux pour tenir compte des progrès qui seront réalisés dans ce domaine, l'objectif consiste à conférer une protection au nouveau système par lequel

ingredient, or a formulation containing that ingredient, is administered to the patient. Examples include controlled-release tablets and capsules, implants and transdermal patches. As with other eligible subject matter, a dosage form patent must include a claim to the specific dosage form described in the NDS (typically as identified in the notification issued by the Minister pursuant to paragraph C08.004(1)(*a*)). In addition, it must contain a claim that includes within its scope the approved medicinal ingredient. This latter requirement is meant to ensure that a patent directed solely to a device, such as an intravenous stand or a syringe, does not meet the definition of "dosage form" and remains ineligible for listing.

The amendments to section 4 also formally confirm the right to list new patents on the basis of SNDS filings and introduce listing requirements governing that right. Under these requirements, a patent which had been applied for prior to the filing of an SNDS may be submitted in relation to that SNDS provided the purpose of the latter is to obtain approval for a change in use of the medicinal ingredient (i.e. a new method of use or new indication), a change in formulation or a change in dosage form and the patent contains a claim to the formulation, dosage form or use so changed. This will protect and encourage legitimate and substantive incremental innovation of direct therapeutic application. New patents claiming novel physical forms of the approved medicinal ingredient will not be eligible for listing in this manner.

In keeping with existing practice, the amendments to section 4 include a provision expressly allowing innovators to carry forward patent lists submitted in relation to a NDS by resubmitting them in relation to a supplement to that NDS. A finding of ineligibility in respect of one patent on a patent list should not prevent the carrying forward of the remaining patents on that list.

The amendments also eliminate the unnecessary and somewhat ambiguous distinction in current section 4 between an "existing" patent list and an "amendment" to such a list. Under the amendments, each time an innovator submits new patents to the Minister these shall be considered as comprising a unique and stand alone patent list. This will be the case regardless of which of subsections 4(5) or 4(6) is relied upon in submitting the list and notwithstanding the presence of any preexisting patents on the register for the same form of the drug described in the submission to which the list relates.

Lastly, in order to minimize any market disruption and investment uncertainty resulting from the above described changes to section 4, the amendments include a grandfathering provision which provides that patents submitted for listing prior to June 17, 2006, the date of pre-publication in the *Canada Gazette*, Part I, remain subject to the listing requirements as they were interpreted and applied prior to that date.

l'ingrédient médicinal approuvé ou une formulation contenant cet ingrédient est administré au patient. Parmi ces modes, mentionnons les comprimés et les capsules à libération contrôlée, les implants et les timbres transdermiques. Comme dans le cas d'autres contenus, un brevet relatif à une forme posologique doit contenir une revendication pour la forme posologique précise décrite dans la PDN [(généralement telle qu'identifiée dans l'avis émis par le ministre, conformément à l'alinéa C08.004(1)*a*)]. En outre, le brevet doit également contenir une revendication incluant dans sa portée l'ingrédient médicinal approuvé. Cette dernière exigence vise à faire en sorte qu'un brevet portant uniquement sur du matériel médical, par exemple un pied à perfusion ou une seringue, ne corresponde pas à la définition du terme « revendication de la forme posologique » et demeure inadmissible à l'inscription au registre.

De plus, les modifications relatives à l'article 4 confirment formellement le droit d'inscrire de nouveaux brevets en se fondant sur des dépôts de SPDN et instaurent des exigences régissant ce droit. Selon ces exigences, un brevet ayant une date de dépôt antérieure au dépôt d'un SPDN peut être soumis à l'égard de ce SPDN à condition que ce dernier ait pour objet l'approbation d'un changement relatif à l'utilisation de l'ingrédient médicinal (c.-à-d. un nouveau mode d'utilisation ou une nouvelle indication), d'un changement relatif à la formulation ou d'un changement relatif à la forme posologique et que le brevet comporte une revendication relative à la formulation, à la forme posologique ou à l'utilisation ainsi modifiée. Ces exigences auront pour effet de protéger et d'encourager l'innovation progressive légitime et substantielle ayant une application thérapeutique directe. Les nouveaux brevets revendiquant de nouvelles formes physiques de l'ingrédient médicinal approuvé ne pourront être inscrits suivant ces modalités.

Conformément à la pratique établie, les modifications relatives à l'article 4 comportent une disposition autorisant expressément les innovateurs à reporter les listes de brevets soumises se rattachant à une PDN en les soumettant à nouveau en relation avec un supplément à cette PDN. Une conclusion de non-admissibilité d'un brevet apparaissant sur une liste de brevets ne doit pas empêcher le report des autres brevets sur cette liste.

En outre, les modifications éliminent la distinction superflue et parfois ambiguë que l'on trouve à l'article 4, soit la distinction entre une liste de « brevets existants » et une « modification » apportée à cette liste. Suivant les modifications, à chaque fois que l'innovateur soumet de nouveaux brevets au ministre, ceux-ci seront considérés comme faisant partie d'une seule et unique liste, et ce, indépendamment du paragraphe, 4(5) ou 4(6), sur lequel la présentation de la liste est fondée et malgré la présence de brevets préexistants au registre à l'égard de la même forme de drogue décrite dans la demande d'avis à laquelle la liste a trait.

Enfin, en vue de limiter les perturbations sur le marché ainsi que l'incertitude pour les investisseurs qui pourraient résulter des changements à l'article 4 décrits plus haut, les modifications renferment une disposition relative aux droits acquis prévoyant que les brevets soumis pour inscription au registre avant le 17 juin 2006, date de la publication au préalable dans la *Gazette du Canada* Partie I demeurent assujettis aux exigences relatives à l'inscription telles qu'elles étaient interprétées et appliquées avant cette date.

Changes to the requirements governing when listed patents must be addressed

Under the amendments to section 5, a generic manufacturer that files a submission or supplement for a NOC in respect of a generic version of an innovative drug is only required to address the patents on the register in respect of the innovative drug as of that filing date. Patents added to the register thereafter will not give rise to any such requirement. The register will thus be "frozen" in respect of that generic manufacturer's regulatory submission. Subsequent submissions originating from additional generic manufacturers would each benefit from the same freezing mechanism, as of their respective dates of filing with the Minister. As a corollary to this frozen register concept, generic manufacturers will no longer be permitted to initiate the process for challenging a patent under the PM(NOC) Regulations (i.e. through the service of a notice of allegation – "NOA") until that same filing has occurred. The combined effect of these two new rules will significantly curtail the incidence of repeat cases, whether due to multiple NOAs on the part of generic manufacturers or multiple patent listings on the part of innovators.

Although freezing the register and eliminating early NOAs is thought to be the most expedient solution to the problem of multiple stays under the PM(NOC) Regulations, considerable confusion could result from the immediate application of these changes to preexisting facts. The transitional rules accompanying the amendments thus provide that, for those generic manufacturers that have already filed a submission or supplement for a NOC in respect of a generic version of an innovative drug with patents on the register, the filing date for the purposes of amended section 5 is deemed to be the date the amendments come into force.

While not a transitional matter, a similar deeming function will apply to generic drug submissions filed under C.07.003. of the *Food and Drug Regulations*, which escape the 6-year prohibition on filing under concurrent amendments to the data protection provisions in the *Food and Drug Regulations*. Where such a submission is for a generic version of an innovative drug and that innovative drug would otherwise benefit from the new data protection term, the filing date of the submission for the purposes of section 5, if it is less than six years from the day on which the first NOC was issued in respect of the innovative drug, will be deemed to be six years from that day.

The amendments also repeal subsection 5(1.1). That provision was introduced in 1999, when it became apparent that a generic company could avoid compliance with the PM(NOC) Regulations by making an indirect comparison to an innovator's drug with patents on the register. However, a subsequent ruling from the Federal Court of Appeal established that the pre-existing triggering provision, subsection 5(1), was sufficiently broad to capture avoidance strategies founded on indirect reliance[8]. Repeal of subsection 5(1.1) is also consistent with the Supreme Court of Canada's recent decision in the "Biolyse case"[9], which confirmed that the PM(NOC) Regulations do not apply to second and subsequent entry drug submissions where the sponsor of the submission

[8] *Merck & Co. v. Nu-Pharm Inc.* (2000), 5 C.P.R. (4th) 138
[9] *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26

Modification des exigences régissant le moment où les brevets inscrits doivent être pris en considération

Suivant les modifications à l'article 5, un fabricant de produits génériques déposant une demande ou un supplément en vue d'obtenir un avis de conformité pour une version générique d'un produit innovateur est seulement obligé de tenir compte des brevets inscrits au registre à l'égard du produit innovateur à la date de dépôt. Les brevets ajoutés au registre par la suite ne donneront plus lieu à une telle obligation. Le registre sera pour ainsi dire « gelé » en ce qui concerne la demande réglementaire de ce fabricant de produits génériques. Les demandes subséquentes soumises par d'autres fabricants de produits génériques seront assujetties à la même règle, à partir de la date de présentation de chacune d'elles au ministre. Comme corollaire de ce concept du « gel » du registre, les fabricants de produits génériques ne pourront plus contester un brevet en vertu du règlement de liaison (c.-à-d., en signifiant un avis d'allégation) tant que cette demande n'a pas été déposée. L'effet combiné de ces deux nouvelles règles limitera considérablement le nombre de cas de répétition, causés soit par de multiples avis d'allégation signifiés par des fabricants de produits génériques, soit par de multiples demandes d'inscription de brevets déposées par des fabricants innovateurs.

Même si l'on estime que le gel du registre et l'élimination des avis d'allégation anticipés sont les solutions les mieux indiquées au problème des suspensions multiples imposées en vertu du règlement de liaison, l'application immédiate de ces changements à des faits préexistants pourrait entraîner beaucoup de confusion. Ainsi, les règles transitoires dont les modifications sont assorties prévoient que dans le cas des fabricants de produits génériques ayant déjà déposé une demande d'avis de conformité ou un supplément pour la version générique d'un produit innovateur à l'égard duquel des brevets sont inscrits au registre, la date de dépôt aux fins de l'article 5 modifié est réputée être la date d'entrée en vigueur des modifications.

Bien qu'il ne s'agisse pas d'une question transitoire, une disposition de présomption analogue s'appliquera aux demandes d'avis de conformité déposées par les fabricants de produits génériques en vertu de l'article C.07.003 du *Règlement sur les aliments et drogues*, échappant à l'interdiction de six ans contre le dépôt de demandes aux termes de modifications concurrentes apportées aux dispositions du *Règlement sur les aliments et drogues* concernant la protection des données. Lorsqu'une telle demande vise une version générique d'une drogue innovatrice et que cette dernière bénéficierait autrement du nouveau délai de protection des données, la date de dépôt de la présentation aux fins de l'article 5, si elle survient moins de six ans après la délivrance du premier avis de conformité pour la drogue innovatrice, sera réputée être survenue six ans après cette date.

Les modifications entraînent également l'abrogation du paragraphe 5(1.1). Cette disposition a été instaurée en 1999, lorsqu'il a été constaté qu'un fabricant de produits génériques pouvait contourner le règlement de liaison en faisant une comparaison indirecte avec une drogue pour laquelle des brevets étaient inscrits au registre. Toutefois, la Cour d'appel fédérale a statué dans une décision subséquente que le mécanisme de déclenchement déjà prévu au paragraphe 5(1) était suffisamment large pour couvrir les stratégies d'évitement fondées sur une comparaison indirecte[8]. L'abrogation du paragraphe 5(1.1) concorde également avec l'arrêt récemment rendu par la Cour suprême du Canada dans l'affaire Biolyse[9], ayant confirmé que le règlement de liaison

[8] *Merck & Co. c. Nu Pharm Inc.*, [2000] A.C.F. n° 380
[9] *Bristol-Myers Squibb Co. c. Canada (Procureur général)*, 2005 CSC 26

is required by the Minister to conduct independent clinical studies to establish the safety and efficacy of its product.

Notwithstanding the repeal of subsection 5(1.1), amended section 5 will continue to feature two triggering provisions, in order to better mirror the structure of section 4. Subsection 5(1) will apply to a generic manufacturer that files an initial submission for a NOC for a generic version of an innovative drug. Subsection 5(2) will apply whenever the manufacturer files a supplement to that submission for a change in formulation, change in dosage form or a change in use of the medicinal ingredient. Distinguishing between the two types of submissions in this manner should also serve to accelerate the drug review process as the Minister will no longer be required to verify each and every supplement for compliance with the PM(NOC) Regulations.

It should be noted that while amended subsection 5(1) is geared towards abbreviated new drug submissions (ANDS), the provision speaks only of a "submission for a notice of compliance". The lack of precision on this point is purposeful in order that the PM(NOC) Regulations may catch "hybrid" or "paper" NDS type submissions when approved on the basis of a direct or indirect comparison or reference to an innovative drug in substantially the same fashion as an ANDS. Similarly, despite the Supreme Court's ruling in the Biolyse case, there is no mention of "bioequivalence" in either of the new triggering provisions, as the PM(NOC) Regulations are intended to apply equally to biologic drugs which, unlike small molecule pharmaceuticals, sometimes do not work through the bloodstream.

Amendments have also been made to section 5 to clarify the Government's intention with regard to the scope of protection afforded by the PM(NOC) Regulations to "use patents". The revised language in subparagraphs 5(1)(*b*)(iv) and (2)(*b*)(iv) makes it clear that in determining whether an allegation of non-infringement of a use patent is justified, the court should limit its inquiry to whether acts of infringement will occur by or at the behest of the generic manufacturer. This will resolve conflicting jurisprudence on this question[10] and facilitate the market entry of generic drugs where the facts as assumed or proven indicate that the manufacturer does not intend to market its product for the patented use.

Finally, in striving to keep litigation to a minimum, amended section 5 also imposes an obligation on the generic manufacturer to retract an NOA in the event that the submission or supplement to which it relates is either withdrawn by the Minister for non-compliance with the *Food and Drug Regulations* or cancelled by the manufacturer. However, that obligation is subject to a grace period of 90 days, in order to afford the sponsor of a submission found to be non-compliant a reasonable opportunity to have that finding overturned. Where a retracted NOA has already given rise to prohibition proceedings, the innovator, upon being informed of the retraction, is required to apply for a discontinuance of those proceedings in a timely fashion.

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[10] *Pharmascience Inc. V. Sanofi-Aventis Canada Inc.*, 2006 FCA 229. *Procter & Gamble Pharmaceuticals Canada, Inc. v. Canada (Minister of Health)*, 2002 FCA 290. *AB Hassle v. Canada (Minister of National Health and Welfare)*, 2002 FCA 421

ne s'applique pas au deuxième fabricant ou aux fabricants subséquents lorsque le ministre exige que le fabricant réalise des études cliniques indépendantes en vue de démontrer l'innocuité et l'efficacité de son produit.

Malgré l'abrogation du paragraphe 5(1.1), l'article 5 modifié contiendra toujours deux dispositions de déclenchement afin de mieux refléter la structure de l'article 4 modifié. Le paragraphe 5(1) s'appliquera donc aux fabricants de produits génériques présentant pour la première fois une demande d'avis de conformité pour une version générique d'une drogue innovatrice. Le paragraphe 5(2) s'appliquera toutes les fois où le fabricant présente un supplément à cette demande en vue de modifier la formulation, la forme posologique ou l'utilisation de l'ingrédient médicinal. Une telle distinction entre ces deux genres de demandes d'avis de conformité devrait aussi permettre d'accélérer le processus d'examen des drogues, car le ministre ne sera plus tenu de vérifier la conformité de chaque supplément au règlement de liaison.

Bien que le paragraphe 5(1) vise surtout les présentations abrégées de drogue nouvelle (PADN), il convient de noter que la disposition parle seulement de « demande d'avis de conformité ». Le manque de précision sur ce point est voulu. En effet, il permettra de repérer les PDNs dites « hybrides » ou « papier » pour qu'elles soient assujetties au règlement de liaison, lorsque leur approbation repose sur une comparaison ou renvoi direct ou indirect à une drogue innovatrice, de la même façon que pour une PADN. De même, malgré la décision de la Cour suprême dans l'affaire Biolyse, il n'y a aucune mention de « bioéquivalence » dans l'une ou l'autre des nouvelles dispositions de déclenchement, car la protection accordée par le règlement de liaison doit s'appliquer aussi aux drogues biologiques qui parfois, contrairement aux médicaments à petites molécules, n'agissent pas par voie sanguine.

Des modifications ont également été apportées à l'article 5 afin de préciser l'intention du gouvernement concernant l'étendue de la protection accordée par le règlement de liaison aux brevets revendiquant une utilisation. Grâce au texte révisé des sous-alinéas 5(1)*b*)(iv) et (2)*b*)(iv), il est maintenant clair que, en déterminant si une allégation de non-contrefaçon d'un brevet d'utilisation est justifiée, le tribunal devrait se limiter à se demander si des actes de contrefaçon seront commis ou incités par un fabricant de produits génériques. Cela permettra de régler le problème de jurisprudence contradictoire concernant cette question[10] et facilitera l'entrée sur le marché de produits génériques lorsque les faits supposés ou avérés indiqueront que le fabricant n'a pas l'intention de commercialiser son produit pour l'utilisation brevetée.

Enfin, dans l'objectif de minimiser le fardeau imposé par le règlement sur les tribunaux, l'article 5 modifié impose également au fabricant de produits génériques l'obligation de retirer un avis d'allégation si la présentation ou le supplément à celui-ci est soit retiré par le ministre pour non-conformité au *Règlement sur les aliments et drogues*, soit annulé par le fabricant. Toutefois, cette obligation est assujettie d'un délai de grâce de 90 jours afin de donner à la personne présentant une demande jugée non conforme un délai raisonnable pour faire annuler cette décision. Si un avis d'allégation retiré de cette façon a déjà fait l'objet d'une procédure d'interdiction, l'innovateur, une fois informé du retrait, est tenu de demander la cessation de la procédure de façon opportune.

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[10] *Pharmascience Inc. c. Sanofi-Aventis Canada Inc.*, 2006 CAF 229. *Procter & Gamble Pharmaceuticals Canada, Inc. c. le Canada (ministre de la Santé)*, 2002 CAF 290. *AB Hassle c. le Canada (ministre de la Santé nationale et du Bien-être social)*, 2002 CAF 421

Other changes

Sections 4 and 5 aside, the amendments also include a provision targeted at innovators who would seek to forestall generic competition by withdrawing the original form of the product from the market in order to deprive generic manufacturers of an immediate Canadian Reference Product. The provision in question would require the Minister to delete any patents on the register in respect of a drug which no longer has an active Drug Identification Number (DIN), thus resulting in the loss of protection under the PM(NOC) Regulations for that drug. However, this provision will not apply where the withdrawal of the DIN is due to a change in the manufacturer of the drug. As the reason for DIN withdrawal is not always immediately apparent, the Minister's duty to delete the patents is subject to a 90-day grace period. Reassignment of the DIN and resumption in the marketing of the drug by the manufacturer will result in the Minister re-listing earlier-deleted patents.

Last among the substantive changes proposed by these amendments are refinements to the section 8 damages provision. The first such change is to further specify the matters the court may take into account when calculating the period of delay for which an innovator may be held liable under that section. The second is to confirm that the Minister cannot be held liable for any delay under that section. The third is to remove the word "profits" from the provision prescribing the remedies available to a generic manufacturer seeking compensation for any loss arising from that delay.

On this last point, the Government is aware of a number of ongoing section 8 cases in which it is argued that in order for this provision to operate as a disincentive to improper use of the PM(NOC) Regulations by innovative companies, the term "profits" in this context must be understood to mean an accounting of the innovator's profits. While reserving comment on the proper interpretation of the term in these cases, which have been shielded from this change by transitional provisions, in light of the proposed tightening of the listing requirements under amended section 4, and of the introduction of the frozen register mechanism under amended section 5, the Government believes that this line of argument should no longer be open to generic companies that invoke section 8.

Finally, these amendments include a number of consequential changes in wording or numbering to reflect the substantive modifications discussed above.

Alternatives

As previously noted, the Government proposed an alternative set of amendments to those described above, which was pre-published in the *Canada Gazette*, Part I, on December 11, 2004. As will be explained below, the present proposals were conceived in response to the extensive representations received from interested parties following that earlier pre-publication.

Maintaining the status quo was not considered a viable option given the current imbalance in the PM(NOC) Regulations, as explained above.

Autres changements

Mis à part les articles 4 et 5, les modifications comprennent également une disposition visant les innovateurs qui chercheraient à retarder la concurrence des fabricants de produits génériques en retirant du marché la forme originale du produit afin de les priver d'un produit de référence canadien immédiat. La disposition en question obligerait le ministre à supprimer du registre tout brevet relatif à une drogue ne possédant plus d'identification numérique de drogue (DIN), ce qui entraînerait donc la perte de la protection accordée par le règlement de liaison pour cette drogue. Toutefois, cette disposition ne s'appliquera pas lorsque le retrait du DIN est attribuable à un changement du fabricant de la drogue. Comme la raison du retrait de la DIN n'est pas nécessairement immédiatement évidente, la responsabilité du ministre de supprimer le brevet est assujettie à un délai de grâce de 90 jours. La réattribution du DIN et la reprise de la commercialisation de la drogue par le fabricant entraîneront la réinscription par le ministre des brevets supprimés.

Figurant en dernier parmi les changements de fond proposés par ces modifications sont des améliorations de la disposition de l'article 8 concernant les dommages-intérêts. Le premier de ces changements vise à préciser davantage les éléments dont le tribunal peut tenir compte au moment de calculer la période de retard dont l'innovateur peut être tenu responsable en vertu de cet article. Le deuxième sert à confirmer que le ministre ne peut être tenu responsable pour tout retard en vertu de cet article. Le troisième consiste à supprimer le terme « profits » de la disposition relative aux mesures de réparation que le tribunal peut ordonner pour dédommager le fabricant de produits génériques pour les pertes encourues en raison de ce retard.

S'agissant de ce dernier changement, le gouvernement a pris connaissance d'un nombre d'affaires en cours relatives à l'article 8 dans lesquelles on avance qu'afin que cette disposition serve à décourager l'utilisation abusive du règlement de liaison par les fabricants innovateurs, le terme « profits » dans ce contexte doit s'entendre par reddition de compte de bénéfices de l'innovateur. Bien qu'il se réserve de commenter sur l'interprétation appropriée du terme dans ces affaires, ces dernières ayant été épargnées de ce changement en vertu des dispositions transitoires, à la lumière du resserrement proposé concernant les exigences relatives à l'inscription des brevets suivant l'article 4 modifié, et de l'introduction du mécanisme de « gel » du registre en vertu de l'article 5 modifié, le gouvernement est d'avis que ce genre d'argument ne devrait plus être admis pour les fabricants de médicaments génériques invoquant l'article 8.

Enfin, ces modifications comprennent plusieurs changements corrélatifs de libellé ou de numérotage de dispositions afin de tenir compte des changements de fond décrits ci-dessus.

Solutions envisagées

Tel que mentionné précédemment, le gouvernement a proposé un ensemble de modifications possibles autres que celles décrites ici, publié au préalable dans la *Gazette du Canada* Partie I le 11 décembre 2004. Comme il sera expliqué ci-dessous, les présentes propositions ont été formulées à la suite des observations approfondies reçues des parties intéressées après la publication au préalable, ayant eu lieu plus tôt.

Le maintien du statu quo n'a pas été considéré comme une option viable, étant donné le déséquilibre actuel dans le règlement de liaison, comme il a été expliqué ci-dessus.

Benefits and Costs

As mentioned, these amendments are being promulgated jointly with amendments to the data protection provisions in the *Food and Drug Regulations* and, together, are designed to bring a greater degree of stability and predictability to the pharmaceutical marketplace by establishing a firmer upper and lower boundary to the period during which innovative drugs enjoy market exclusivity.

The amendments to data protection will set the lower boundary by prohibiting generic companies from seeking an NOC until 6 years after the issuance of the NOC for the innovative drug and will prohibit actual issuance of the NOC until 8 years after that same date. Eligible innovative drugs (i.e. which contain a new chemical entity - "NCE") will thus receive an internationally competitive, guaranteed minimum period of market exclusivity. This is expected to have a minimal impact on the timing of generic market since in the majority of cases data protection runs concurrently and is eclipsed by the much longer term of protection available under a patent (i.e. 20 years). The amendments to the PM(NOC) Regulations will set the upper boundary by facilitating the market entry of generic versions of innovative drugs immediately following expiry of the relevant patents, as was originally intended.

In the course of conceiving the amendments, the Government conducted a retrospective assessment of the regulatory proposals for the period 1998 to 2002, and found that, with a data protection term of 8 years, the impact of the amendments on health care costs would have been very close to cost neutral. While it is not possible to definitively forecast future costs versus savings under the amended regimes, present trends suggest that the amendments could result in a significant net savings to the health care system in the years to come. This is due to the declining trend in drugs containing NCEs entering the market in the last few years and the corresponding increase in emphasis by some innovative companies on extending exclusivity over known best sellers through strategic patenting behaviour.

Consultation

Pre-publication of the earlier proposed amendments was followed by a 75-day period during which interested persons could submit written representations to the sponsoring departments. Industry Canada received representations on its proposed amendments from approximately 20 separate sources, including innovative and generic pharmaceutical companies, their respective trade associations, BIOTECanada, provincial governments, members of Parliament and consumer groups. Health Canada received a like number of submissions on its proposed amendments to data protection, from substantially the same sources. In addition, representatives from various quarters of both the innovative and generic pharmaceutical industries met with officials from the two departments on several occasions during the pre-publication period to elaborate orally on their written submissions.

Avantages et coûts

Tel que mentionné précédemment, ces modifications sont promulguées conjointement avec des modifications aux dispositions du *Règlement sur les aliments et drogues* portant sur la protection des données et, ensemble, visent à assurer un plus grand degré de stabilité et de prévisibilité au marché pharmaceutique en établissant des limites supérieure et inférieure fermes à la période durant laquelle les médicaments novateurs profitent de l'exclusivité commerciale.

Les modifications à la protection des données établiront la limite inférieure en interdisant aux fabricants de médicaments génériques de demander un avis de conformité pendant une période de 6 ans suivant la délivrance d'un avis de conformité pour un médicament novateur, et interdiraient également l'approbation même du produit générique pour une période de 8 ans suivant cette même date. Les médicaments novateurs admissibles (c.-à.-d., contenant une nouvelle entité chimique- « NEC ») bénéficieraient ainsi d'une période d'exclusivité commerciale minimale concurrentielle à l'échelle internationale. On s'attend à ce que ce changement ait un effet négligeable sur le moment d'entrée en marché des médicaments génériques puisque dans la plupart des cas, la protection des données est parallèle et se termine bien avant l'expiration du brevet (c.-à.d, 20 ans). Les modifications au règlement de liaison établiront la limite supérieure en facilitant l'entrée en marché des versions génériques de médicament novateurs immédiatement après l'expiration des brevets pertinents, tel que prévu initialement.

Dans le cadre de l'élaboration des modifications, le gouvernement a effectué une évaluation rétrospective des propositions réglementaires pour la période de 1998 à 2002 et a conclu qu'avec une période de protection des données de 8 ans, l'impact des modifications sur les coûts des soins de santé s'approche du point d'équilibre. Bien qu'il ne soit pas possible de prévoir définitivement les coûts et les économies engendrés par les modifications proposées aux régimes, les tendances actuelles permettent d'entrevoir des économies nettes importantes pour le système des soins de santé. Cela est dû au déclin enregistré, au cours des quelques dernières années, du nombre de médicaments contenant une NEC entrant sur le marché, et à augmentation corrélative du comportement stratégique de certains fabricants innovateurs visant à prolonger la période d'exclusivité de médicaments meilleurs vendeurs.

Consultations

La publication au préalable des modifications proposées antérieurement a été suivie d'une période de 75 jours au cours de laquelle les personnes intéressées pouvaient présenter des observations écrites aux ministères parrains. Industrie Canada a reçu des observations sur ses modifications proposées d'environ 20 sources distinctes, y compris les entreprises pharmaceutiques innovatrices et génériques, leurs associations commerciales, BIOTECanada, les gouvernements provinciaux, les députés et les groupes de défense des consommateurs. Santé Canada a reçu un nombre semblable d'observations relatives à ses modifications proposées aux dispositions sur la protection des données, provenant essentiellement des mêmes sources. De plus, les représentants de divers secteurs de l'industrie pharmaceutique innovatrice et de l'industrie pharmaceutique générique ont rencontré des fonctionnaires des deux ministères à plusieurs occasions au cours de la période de publication préalable afin de discuter des observations écrites qu'ils ont présentées.

While the views of individual stakeholders reflected their own unique perspective on the proposed amendments, some common ground did emerge during the pre-publication period. Most significant in this regard was a shared inclination that the Government should consider an alternative model of amendments which would see the Canadian system aligned more closely with that of the United States (US). Although there appeared to be agreement in principle on this point, stakeholders held varying views as to the particular features of the US system thought to be worthy of import. This can be attributed to an underlying divergence in opinion between the innovative and generic pharmaceutical industries as to the nature and scope of the multiple stay phenomenon the amendments should seek to redress.

From the generic industry's standpoint, multiple stays are a concern only in so far as they arise from multiple patents being listed sequentially over time by innovators, a practice they consider *ipso facto* "abusive". Because the amendments would continue to require a generic manufacturer to address patents listed after the date of its drug submission, the industry contends that abusive multiple stays will continue unabated. In advocating convergence with the US system, the generic industry is primarily seeking the adoption of the frozen register concept recently introduced in that country in response to similarly observed patent listing behaviour on the part of innovative drug companies there[11].

While sources on the innovative side of the industry recognize that the stated purpose of the amendments is to curb the occurrence of multiple stays, they observe that many such stays are due to the ability of generic manufacturers to serve multiple NOAs in respect of the same patents, and not to the listing behaviour of innovators. In their view, the former is the converse of the latter, and no less abusive in nature. Accordingly, the innovative industry asserts that any consideration of a frozen register option must also have regard for measures which would restrict the circumstances in which NOAs can be served upon them by generic manufacturers. To this end, they call for the introduction of a US-style "no-filing" term of data protection which would prohibit a generic manufacturer from seeking regulatory approval for an equivalent version of an innovative drug until a certain number of years after the latter's approval, during which time no NOAs could be advanced by the generic.

Despite stakeholders' competing emphasis on different aspects of US law, there appeared to be some degree of rapprochement between the two sides of the industry on the merits of moving toward a more US-style regime. In light of this and of the intense resistance manifested by stakeholders toward the amendments proposed on December 11, 2004, Industry Canada and Health Canada developed the framework for a US-style alternate set of amendments to the PM(NOC) Regulations and to the *Food and Drug Regulations*.

[11] *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, Sec. 1101

Bien que le point de vue de chaque intervenant reflète sa propre opinion sur les modifications proposées, des points communs sont ressortis au cours de la période de publication au préalable. Plus important encore à cet égard, les intervenants avaient la même conviction que le gouvernement devrait envisager un autre modèle de modifications qui permettrait de converger davantage le système canadien avec celui des États-Unis. Bien qu'ils semblaient s'entendre en principe sur ce point, les intervenants ont des opinions divergentes en ce qui a trait aux caractéristiques particulières du système américain qu'ils estimaient valoir la peine d'importer. Cela est dû à une divergence d'opinion fondamentale entre l'industrie pharmaceutique innovatrice et l'industrie pharmaceutique générique quant à la nature et la portée du phénomène des suspensions multiples que les modifications devraient viser à corriger.

Du point de vue de l'industrie générique, les suspensions multiples posent un problème seulement dans la mesure où elles découlent de brevets multiples inscrits à répétition au fil du temps par les innovateurs, une pratique qu'elle juge *ipso facto* « abusive ». Puisque les modifications proposées antérieurement exigeraient encore qu'un fabricant générique tienne compte des brevets inscrits après la date de la demande de l'avis de conformité, l'industrie soutient que les suspensions multiples abusives continueront sans fléchir. En prônant la convergence avec le système de liaison américain, l'industrie générique cherche principalement à faire adopter le concept de gel de registre, récemment introduit aux États-Unis en réponse à un comportement similaire observé chez les entreprises pharmaceutiques innovatrices concernant l'inscription de brevets[11].

Bien que des sources de l'industrie innovatrice reconnaissent que le but avoué des modifications est de réduire les cas de suspensions multiples, elles notent qu'un grand nombre de ces suspensions découlent de la capacité du fabricant de produits génériques de signifier plusieurs avis d'allégation pour les mêmes brevets, et non du comportement des personnes innovatrices concernant l'inscription de brevets. Selon ces sources, la première pratique est l'inverse de la deuxième, et n'est pas moins abusive de par sa nature. Par conséquent, l'industrie innovatrice a insisté pour que tout gel du registre qui serait envisagé prévoie également des mesures restreignant le nombre de cas où des avis d'allégation peuvent lui être signifiés par les fabricants des produits génériques. À cette fin, elle a demandé l'instauration d'un système de protection des données « sans dépôt », comme celui existant aux États-Unis, où il serait interdit à un fabricant de produits génériques de demander l'approbation réglementaire d'une version équivalente d'un produit novateur avant l'écoulement d'un certain nombre d'années après l'approbation de celui-ci, pendant lesquelles aucun avis d'allégation ne pourrait être signifié par le fabricant de produits génériques.

Malgré les accents divergents mis par les intervenants sur différents aspects de la loi américaine, les deux secteurs de l'industrie semblent s'entendre dans une certaine mesure sur les avantages de l'adoption d'un système ressemblant davantage à celui des États-Unis. Compte tenu de cette situation et de la forte résistance des intervenants aux modifications proposées le 11 décembre 2004, les ministères de l'industrie et de la santé ont élaboré le cadre d'un ensemble d'autres modifications possibles, semblable à celui des États-Unis, du règlement de liaison et du *Règlement sur les aliments et drogues*.

[11] *Medicare Prescription Drug, Improvement, and Modernization Act de 2003*, art. 1101

A document describing the above framework was circulated to industry stakeholders for another round of informal consultations between July and September 2005. Further written representations were received and further meetings were held between officials from both departments and representatives from the innovative, generic and biotech sectors of the pharmaceutical industry.

Based on the outcome of these informal consultations, the Government is proceeding with the present set of amendments to implement the no-filing data protection term sought by innovative companies, coupled with the frozen register mechanism sought by their generic counterparts. Other, lesser measures are also proposed, mainly with view to increased convergence with US law. As before, these amendments are expected to bring a greater degree of stability and predictability to the intellectual property environment for pharmaceuticals.

Pre-publication of the present amendments in the *Canada Gazette*, Part I, took place on June 17, 2006, and was followed by a 30-day consultation period during which Industry Canada and Health Canada received approximately thirty submissions, predominantly from the same industry stakeholders mentioned above, but also from a number of Provincial government authorities responsible for either health care or economic development portfolios. Whereas economic development authorities expressed strong support for the amendments, and urged the Government to proceed swiftly to final publication, health authorities requested an extension in the consultation period in order to allow for federal-provincial dialogue and to gain a better understanding of the impact of the amendments. In response to that request, on September 18, 2006, Health Canada and Industry Canada officials hosted an information session on the amendments attended by representatives of the Provincial and Territorial ministries of health.

In terms of stakeholder reaction to the June 17 pre-publication, the generic pharmaceutical industry endorsed the proposed "freezing" of the patent register but maintained its view that the amendments as a whole are weighted in favour of the innovative industry. The generic industry's key concerns were with the proposed increase in the data protection from 5 to 8 years, the proposed deletion of the term "profits" from the remedies provision in section 8 and the proposal to expand the eligibility requirements to allow for the listing of dosage form patents.

Reaction from the innovative industry was more equivocal, with the majority of companies supportive of the proposed increase in data protection but a minority strongly opposed to the proposed tightening of the patent eligibility requirements. As regards the "profits" issue, innovators were pleased with its proposed deletion, noting that there is no equivalent remedy under US law for a generic that has been delayed due to the operation of the automatic stay. For its part, BIOTECanada urged the Government to increase the proposed term of data protection to 10 years for biologics, in light of the longer development time required to bring these products to market.

Un document décrivant le cadre susmentionné a été distribué auprès des intervenants de l'industrie en vue d'une autre série de consultations informelles tenues entre juillet et septembre 2005. D'autres observations écrites ont été reçues et d'autres réunions ont été tenues entre les fonctionnaires des deux ministères et les représentants des secteurs innovateurs, génériques et biotechnologiques de l'industrie pharmaceutique.

Tenant compte du résultat de ces consultations informelles, le gouvernement s'appuie sur un ensemble révisé de modifications afin de mettre en œuvre le système de protection des données « sans dépôt » demandé par l'industrie innovatrice et d'introduire le concept de gel de registre que ses homologues génériques souhaitaient. D'autres mesures moins importantes sont également proposées, principalement dans le but d'accroître la convergence avec la loi américaine. Comme par le passé, les modifications visent à rendre le régime de protection de la propriété intellectuelle des produits pharmaceutiques plus stable et prévisible.

La publication au préalable des présentes modifications dans la *Gazette du Canada* Partie I a eu lieu le 17 juin 2006 et fut suivie d'une période de consultation de 30 jours, au cours de laquelle environ trente organismes ont présenté des observations sur la question à Industrie Canada et à Santé Canada; il s'agit essentiellement des mêmes intervenants de l'industrie dont il a été question plus haut, mais également d'instances des gouvernements provinciaux responsables des soins de santé ou du développement économique. Alors que les instances responsables du développement économique ont exprimé un appui solide à l'égard des modifications et ont fortement incité le gouvernement à procéder rapidement à la publication finale, les instances du domaine de la santé ont demandé que la période de consultations soit prolongée afin qu'il puisse y avoir des discussions au sujet des modifications entre les gouvernements fédéral et provinciaux et pour leur permettre de mieux comprendre l'incidence des modifications. Le 18 septembre 2006, en réponse à cette demande, Santé Canada et Industrie Canada ont organisé une séance d'information portant sur les modifications, à laquelle ont pris part des représentants des ministères provinciaux et territoriaux de la Santé.

Concernant la réaction des intervenants suite à la publication au préalable du 17 juin, l'industrie des médicaments génériques a exprimé son appui à l'égard du « gel » proposé en ce qui a trait à l'inscription des brevets mais maintient que les modifications, dans l'ensemble, sont plutôt favorables à l'industrie innovatrice. Les principales préoccupations de l'industrie des médicaments génériques ont trait à la prolongation proposée de la période de protection des données, qui passerait de 5 à 8 ans; à la suppression proposée du terme « profits » de la disposition relative aux mesures de réparation énoncées à l'article 8, et à la proposition relative à l'élargissement des exigences relatives à l'admissibilité pour permettre l'inscription des brevets ayant trait aux formes posologiques.

La réaction de l'industrie innovatrice a été plus équivoque, la majorité des entreprises appuyant la prolongation de la période de protection des données, mais une minorité étant fortement opposée au resserrement proposé des exigences relatives à l'admissibilité des brevets. En ce qui a trait à la question des « profits », les innovateurs se sont dits satisfaits de la suppression proposée, notant qu'il n'y aucun recours semblable aux États-Unis pour un fabricant de médicaments génériques ayant été retardé en raison du déclenchement de la suspension automatique. Pour sa part, BIOTECanada exhorta le gouvernement d'étendre la durée de protection des données proposée jusqu'à dix ans pour les produits biologiques, tenant compte du fait que ces derniers font l'objet d'une période de développement plus longue avant qu'ils puissent être commercialisés.

In addition to the above, each side of the industry expressed concern with competing aspects of the transitional provisions and both expressed a desire for greater clarity around the meaning of certain key terms such as "medicinal ingredient", "formulation" and "dosage form", although with diametrically opposed views as to how those terms should be defined. A number of technical adjustments to the amendments were made as a result of these submissions but no substantive revisions. Stakeholders also sought clarification on a number of lesser issues which have been addressed through changes in wording to the present impact analysis statement in order to better reflect the intent behind the amendments.

As a final note, certain generic drug companies also argued very forcefully that the Government should incorporate measures in these amendments to address what they perceive as diminishing market incentives in their industry. More specifically, they contend that innovators are increasingly entering into licencing arrangements with willing generic companies (so-called "authorized generics") in order to pre-empt genuine generic competitors and retain market share past patent expiry. This practice, which is also said to be prevalent in the US, is currently being studied by the US Federal Trade Commission. While the Government is of the view that there is insufficient information on the impact of this practice on market dynamics in the industry to support regulatory action at this time, it will be examining this practice more closely in response to these concerns.

Compliance and Enforcement

The courts and the Minister will continue to exercise jurisdiction over issues related to the administration of the PM(NOC) Regulations.

Contact

Susan Bincoletto
Director General
Marketplace Framework Policy Branch
Industry Canada
10th Floor, East Tower
235 Queen Street
Ottawa, Ontario
K1A 0H5
Telephone: (613) 952-0736
FAX: (613) 941-8151
E-mail: bincoletto.susan@ic.gc.ca

En outre, les tenants de ces deux points de vue dans l'industrie se sont dits préoccupés au sujet des aspects concurrents des dispositions transitoires et ont dit souhaiter que soit davantage précisé le sens de certains termes clés, dont « ingrédient médicinal », « formulation » et « forme posologique », bien que leurs points de vue soient diamétralement opposés en ce qui a trait à la façon dont ces termes devraient être définis. Un certain nombre de révisions de forme ont été apportées aux modifications par suite des commentaires reçus, mais aucune révision de fond. Les intervenants ont également demandé des éclaircissements au sujet d'un certain nombre de points mineurs; ces éclaircissements ont été apportés au moyen de changements au libellé de la présente analyse afin qu'elle reflète mieux l'intention sous-jacente aux modifications.

Enfin, certains fabricants de médicaments génériques ont fait valoir avec insistance que le gouvernement devrait introduire des mesures dans ces modifications afin de palier à ce qu'ils perçoivent comme une diminution des incitatifs à l'expansion du marché au sein de leur industrie. Plus précisément, ils craignent le fait que les innovateurs concluent un nombre croissant d'ententes d'octroi de licences avec des fabricants de médicaments génériques consentants (appelés « médicaments génériques autorisés ») dans le but de devancer leurs véritables concurrents fabriquant des médicaments génériques et conserver une part du marché après l'expiration des brevets. Cette pratique, que l'on dit de plus en plus courante aux États-Unis, fait actuellement l'objet d'une étude réalisée par le Federal Trade Commission américain (commission fédérale de la concurrence des États-Unis). Bien que le gouvernement soit d'avis qu'il n'y a pas suffisamment d'information concernant l'impact de cette pratique sur la dynamique des marchés afin d'appuyer une action réglementaire à l'heure actuelle, il étudiera cette question de plus près en réponse à ces préoccupations.

Respect et exécution

Les tribunaux et le ministre continueront d'exercer leur compétence sur les questions reliées à l'application du règlement de liaison.

Personne-ressource

Susan Bincoletto
Directrice générale
Politiques-cadres du marché
Industrie Canada
Tour Est, 10e étage
235, rue Queen
Ottawa (Ontario)
K1A 0H5
Téléphone : (613) 952-0736
TÉLÉCOPIEUR : (613) 941-8151
Courriel : bincoletto.susan@ic.gc.ca

Court File No. 36654

IN THE SUPREME COURT OF CANADA
(ON APPEAL FROM THE FEDERAL COURT OF APPEAL)

B E T W E E N:

ASTRAZENECA CANADA INC.
ASTRAZENECA AKTIEBOLAG and
ASTRAZENECA UK LIMITED

Appellants

– and –

APOTEX INC. and
APOTEX PHARMACHEM INC.

Respondents

MOTION RECORD OF THE PROPOSED INTERVENER CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

AITKEN KLEE LLP
Suite 300, 100 Queen Street
Ottawa, ON K1P 1J9

Jonathan Stainsby
Marcus Klee
Devin Doyle

Tel: 647-317-6868
613-903-5100
613-903-5105
Fax: 613-695-5854
E-mail:
jstainsby@aitkenklee.com
mklee@aitkenklee.com
ddoyle@aitkenklee.com

Solicitors for the Moving Party, Canadian Generic Pharmaceutical Association

AITKEN KLEE LLP
Suite 300, 100 Queen Street
Ottawa, ON K1P 1J9

Jonathan Stainsby
Marcus Klee
Devin Doyle

Tel: 647-317-6868
613-903-5100
613-903-5105
Fax: 613-695-5854
E-mail:
jstainsby@aitkenklee.com
mklee@aitkenklee.com
ddoyle@aitkenklee.com

Agents for Solicitors for the Moving Party, Canadian Generic Pharmaceutical Association