

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

and

INTELLECTUAL PROPERTY INSTITUTE OF CANADA / INSTITUT DE LA PROPRIÉTÉ
INTELLECTUELLE DU CANADA

Proposed Intervener

MOTION FOR LEAVE TO INTERVENE

(Filed by the Proposed Intervener Intellectual Property Institute of Canada / Institut de la
Propriété Intellectuelle du Canada)

(Pursuant to Rules 47, 55-59 of the *Rules of Supreme Court of Canada*)

BELMORE NEIDRAUER LLP
TD South Tower
79 Wellington Street West, Suite 2401
TD Centre
Toronto, ON M5K 1A1

Jason Markwell
Marian Wolanski
Stefanie Di Giandomenico

Tel: (416) 863-1771
Fax: (416) 863-9171
E-mail: jmarkwell@belmorelaw.com
marian.wolanski@belmorelaw.com
sdigiandomenico@belmorelaw.com

Solicitors for the Proposed Intervener
Intellectual Property Institute of
Canada / Institut de la Propriété
Intellectuelle du Canada

BORDEN LADNER GERVAIS LLP
World Exchange Plaza
100 Queen St., Suite 1300
Ottawa, ON K1P 1J9

Nadia Effendi

Tel: (613) 787-3562
Fax: (613) 230-8842
Email: neffendi@blg.com

Ottawa Agent for the Proposed Intervener,
Intellectual Property Institute of Canada /
Institut de la Propriété Intellectuelle du
Canada

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 SUPREME COURT OF CANADA**

COPIES TO:

<p>SMART & BIGGAR Barristers & Solicitors 438 University Ave., Suite 1500 Toronto, ON M6G 2K8</p> <p>Gunars A. Gaikis Yoon Kang Y. Ling Ing</p> <p>Tel: (416) 593-5514 Fax: (416) 591-1690 E-mail: ggaikis@smart-biggar.ca ykang@smart-biggar.ca yling@smart-biggar.ca</p> <p>Counsel for the Appellants, Astrazeneca Canada Inc., Astrazeneca Aktiebolag and Astrazeneca UK Limited</p>	<p>SMART & BIGGAR Barristers & Solicitors 55 Metcalfe St., 10th Floor Ottawa, ON K1P 6L5</p> <p>Colin B. Ingram</p> <p>Tel: (613) 232-2486 Fax: (613) 232-8440 E-mail: cbingram@smart-biggar.ca</p> <p>Ottawa Agent for the Appellants, Astrazeneca Canada Inc., Astrazeneca Aktiebolag and Astrazeneca UK Limited</p>
<p>GOODMANS LLP Barristers & Solicitors Suite 3400, 333 Bay St. Bay Adelaide Centre Toronto, ON M5H 2S7</p> <p>H.B. Radomski Richard Naiberg Sandon Shogilev</p> <p>Tel: (416) 979-2211 Fax: (416) 979-1234 E-mail: hradomski@goodmans.ca sshogilev@goodmans.ca</p> <p>Counsel for the Respondents, Apotex Inc. and Apotex Pharmachem Inc.</p>	<p>NELLIGAN O'BRIEN PAYNE LLP Barristers & Solicitors Suite 1600 66 Slater St. Ottawa, ON K1P 5H1</p> <p>Christopher Rootham</p> <p>Tel: (613) 238-808 Fax (613) 238-2098 E-mail: christopher.rootham@nelligan.ca</p> <p>Ottawa Agent for the Respondents, Apotex Inc. and Apotex Pharmachem Inc.</p>

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TAB 1

IN THE SUPREME COURT OF CANADA
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BETWEEN:

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Respondents

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INTELLECTUAL PROPERTY INSTITUTE OF CANADA / INSTITUT DE LA PROPRIÉTÉ
INTELLECTUELLE DU CANADA

Proposed Intervener

NOTICE OF MOTION FOR INTERVENTION

(by the proposed intervenor Intellectual Property Institute of Canada / Institut de la
Propriété Intellectuelle du Canada

Pursuant to Rules 47 and 55-59 of the *Rules of the Supreme Court of Canada*)

TAKE NOTICE that the Proposed Intervener, Intellectual Property Institute of Canada / Institut de la Propriété Intellectuelle du Canada ("IPIC"), applies to a judge or the Registrar under Rules 47 and 55-59 of the *Rules of the Supreme Court of Canada* for an Order:

1. Granting IPIC leave to intervene on this appeal, subject to the following terms and conditions:
 - (a) that IPIC be permitted to file a factum not exceeding 15 pages;
 - (b) that IPIC be permitted to make oral argument at the hearing of this appeal, not exceeding 10 minutes; and
2. Such further and other Order that the Court may deem appropriate.

AND FURTHER TAKE NOTICE that the following documents will be referred to in support of the motion:

1. The affidavit of Peter Wilcox sworn July 26, 2016; and
2. Such further or other material as counsel may advise and the Court may permit.

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

1. IPIC is a Canadian association of patent agents, trademark agents, and lawyers practising in the field of intellectual property ("IP"). IPIC was founded in 1926 and is a not-for-profit corporation. As of 2016, IPIC has approximately 1,700 members, including approximately 1,000 lawyers and 700 patent and trademark agents.
2. IPIC is widely regarded as the association that is most closely connected with patent practitioners in Canada. IPIC has five stated objectives:
 - (a) Represent the interests of Canadian IP practitioners;
 - (b) Influence the development of laws to the extent they impact IP matters in Canada;
 - (c) Be the recognized and visible authority on Canadian IP law and practice;
 - (d) Ensure high levels of knowledge, training and ethics in Canadian IP practitioners;
and
 - (e) Increase the level of IP business in the Canadian economy.
3. IPIC believes that it is necessary for this Court to set out a clear and broadly applicable framework for assessing utility under the Canadian *Patent Act* to address the current uncertainty in the law. If IPIC is granted leave to intervene, it will propose a utility framework that is consistent with the *Patent Act* as a whole, reflects the object and purpose of Parliament, is aligned with the jurisprudence of this Court over the past thirty years, and can be applied to patents in all areas of technology, not just pharmaceuticals.

4. IPIC has an interest in this appeal for the following reasons:

- (a) IPIC has an interest in achieving greater certainty regarding the requirement that an invention be “useful” under the *Patent Act*;
- (b) IPIC has been involved in the development of IP laws in Canada for several decades. IPIC: consults with the Canadian Intellectual Property Office (“CIPO”) and other government departments and agencies; promotes changes to the legislative and regulatory scheme, as necessary; participates in joint committees with CIPO and the Federal Court; and seeks leave to intervene in appropriate judicial proceedings;
- (c) IPIC makes submissions to the government on various IP issues. As a result of these efforts, IPIC has influenced important changes to IP statutes in Canada. For example, IPIC was recently instrumental in Parliament’s decision to amend the *Patent Act* and *Trade-marks Act* to include statutory privilege for IP advisor-client communications (pursuant to Bill C-59);
- (d) IPIC has made recommendations to the government to address the utility requirement under the *Patent Act*, identifying it as a “critical issue warranting immediate attention”. IPIC noted that the “promise of the patent” doctrine has left patentees with increasing uncertainty as to the validity of their patents. IPIC recommended that if Parliament intended to create a “promise of the patent” doctrine, then it should be stated clearly in the *Patent Act*;
- (e) IPIC has intervened in judicial proceedings to present a unique and different perspective on important IP matters, including in *Dutch Industries Ltd v Barton No-Till Disk Inc*, 2003 FCA 121 (a case involving the payment of maintenance fees by patentees), *Weatherford Canada Ltd v Corlac Inc*, 2011 FCA 228 (a case involving section 73 of the *Patent Act* and whether patentees are subject to a general duty of good faith), and *Brown v Canada*, 2016 FCA 37 (a case involving section 53 of the *Patent Act* and its interplay with the *Public Servants Inventions Act*);

- (f) IPIC members advise clients on the patentability, commercialization, and enforcement of patents. IPIC members have first-hand experience with the patent utility requirement in Canada and its implications for inventors, patent owners, and the public;
- (g) IPIC provides regular training and education to IP practitioners, including patent practitioners and those interested in becoming patent agents; and
- (h) IPIC contributes to the dissemination of knowledge and the growth of IP law and policy in Canada by publishing a newsletter and a professional journal that has featured numerous articles on patent utility from different points of view.

5. If IPIC is granted leave to intervene, it will propose a framework for assessing patent utility that can be applied to all inventions, not just pharmaceuticals. This framework will be consistent with the *Patent Act* as a whole, the object and purpose of the *Act* as intended by Parliament, and long-established principles of patent law, including many decisions of this Court over the last thirty years. IPIC's proposed framework will be contextual and internally coherent, considering both the French and English versions of the statute.

6. At a high level, IPIC's proposed framework will have the following components:

- (a) Construction: In each and every case, the Court must construe the claims of the patent purposively from the perspective of a person skilled in the art, as stated in *Free World Trust v Électro Santé Inc*, [2000] 2 SCR 1024 and in *Whirlpool Corp v Camco Inc*, [2000] 2 SCR 1067, *inter alia*.
- (b) Patentability: Once the claims have been construed, the Court must determine whether the subject-matter defined by each claim is patentable and meets the statutory requirements prescribed by the *Patent Act* (*viz.*, statutory subject-matter, new, useful, inventive).
- (c) Utility (Standard): The utility of the subject-matter defined by each claim must then be assessed objectively through the eyes of a person skilled in the art on a

claim-by-claim basis. Utility should not be addressed in a different manner than other grounds of validity (*e.g.*, inventiveness, novelty).

- (d) Utility (Level): The subject-matter defined by each claim, as construed in part (a), must be “useful for the purpose claimed”, as stated in *Apotex Inc v Wellcome Foundation Limited*, [2002] 4 SCR 153, at paragraphs 54 and 80. If a patent makes a specific statement of utility in the claim, as construed, then this should be the yardstick. By contrast, if no utility is expressly stated in the claim, as construed, then the Court must decide if the subject-matter defined by the claim has a scintilla of utility. This determination should be made by the Court objectively, through the eyes of a person skilled in the art, in light of the common general knowledge and the patent specification as a whole. Excessive literalism and subjectivity should be avoided.
- (e) Utility (Policy): The *Patent Act* must be read and understood in its entirety. The concept of utility should not be used to deal with issues that can and should be addressed by other aspects of the *Act* (*e.g.*, inventiveness, novelty, sufficiency, fraud, etc.). There is no need for a “promise of the patent” doctrine to achieve the aims of patent law and the object and purpose intended by Parliament.

7. IPIC’s proposed submissions will be useful and different from those of the parties to the appeal for the following reasons:

- (a) IPIC has a wealth of experience and expertise in Canadian patent law and policy. IPIC is uniquely well-placed to help the Court understand the utility requirement, how the requirement fits into the overall statutory scheme, and how it can be applied in light of the relevant jurisprudence;
- (b) IPIC has no interest or stake in the outcome of this appeal. IPIC will not express a point of view on the validity of the specific patent at issue;
- (c) IPIC members represent clients in a wide-range of industries. While some IPIC members represent pharmaceutical companies, IPIC itself has no declared interest

or position on either side of the brand/generic debate. IPIC will provide an objective perspective to the issues before the Court; and

(d) IPIC is a domestic association. It will take no position on how the patent utility requirement in Canada compares to the law in other jurisdictions, or whether the law is presently aligned with Canada's treaty obligations.

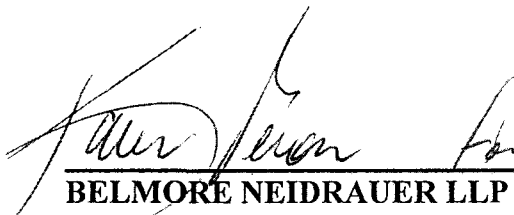
8. IPIC does not seek to file evidence on the appeal or to raise new issues. Rather, IPIC's main objective is to help this Court establish certainty and predictability in the law of utility.

9. IPIC does not seek costs and asks that no costs be awarded against it.

10. Rules 47 and 55-59 of the *Rules of the Supreme Court of Canada*.

11. Such further and other grounds as counsel may advise and the Court may permit.

Dated at Toronto, Ontario, this 29 day of July, 2016.


BELMORE NEIDRAUER LLP
 TD-South Tower
 79 Wellington Street West, Suite 2401
 TD Centre
 Toronto, ON M5K 1A1

Jason Markwell
Marian Wolanski
Stefanie Di Giandomenico

Tel: (416) 863-1771
 Fax: (416) 863-9171
 E-mail: jmarkwell@belmorelaw.com
marian.wolanski@belmorelaw.com
sdigiandomenico@belmorelaw.com

**Solicitors for the Proposed Intervener,
 Intellectual Property Institute of Canada /
 Institut de la Propriété Intellectuelle du
 Canada**


BORDEN LADNER GERVAIS
 World Exchange Plaza
 100 Queen St., Suite 1300
 Ottawa, ON K1P 1J9

Nadia Effendi

Tel: (613) 787-3562
 Fax: (613) 230-8842
 E-mail: neffendi@blg.com

**Ottawa Agent for the Proposed Intervener,
 Intellectual Property Institute of Canada /
 Institut de la Propriété Intellectuelle du
 Canada**

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<p>SMART & BIGGAR Barristers & Solicitors 438 University Ave., Suite 1500 Toronto, ON M6G 2K8</p> <p>Gunars A. Gaikis Yoon Kang Y. Ling Ing</p> <p>Tel: (416) 593-5514 Fax: (416) 591-1690 E-mail: ggaikis@smart-biggar.ca ykang@smart-biggar.ca yling@smart-biggar.ca</p> <p>Counsel for the Appellants</p>	<p>SMART & BIGGAR Barristers & Solicitors 55 Metcalfe St., 10th Floor Ottawa, ON K1P 6L5</p> <p>Colin B. Ingram</p> <p>Tel: (613) 232-2486 Fax: (613) 232-8440 E-mail: cbingram@smart-biggar.ca</p> <p>Ottawa Agent for the Appellants</p>
<p>GOODMANS LLP Barristers & Solicitors Suite 3400, 333 Bay St. Bay Adelaide Centre Toronto, ON M5H 2S7</p> <p>H.B. Radomski Richard Naiberg Sandon Shogilev</p> <p>Tel: (416) 979-2211 Fax: (416) 979-1234 E-mail: hradomski@goodmans.ca sshogilev@goodmans.ca</p> <p>Counsel for the Respondents, Apotex Inc. and Apotex Pharmachem Inc.</p>	<p>NELLIGAN O'BRIEN PAYNE LLP Barristers & Solicitors Suite 1600 66 Slater St. Ottawa, ON K1P 5H1</p> <p>Christopher Rootham</p> <p>Tel: (613) 238-808 Fax (613) 238-2098 E-mail: christopher.rootham@nelligan.ca</p> <p>Ottawa Agent for the Respondents, Apotex Inc. and Apotex Pharmachem Inc.</p>

NOTICE TO THE RESPONDENT TO THE MOTION: A respondent to the motion may serve and file a response to this motion within 10 days after service of the motion. If no response is filed within that time, the motion will be submitted for consideration to a judge or the Registrar, as the case may be.

TAB 2

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

B E T W E E N:

ASTRAZENECA CANADA INC.
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INTELLECTUAL PROPERTY INSTITUTE OF CANADA / INSTITUT DE LA PROPRIÉTÉ
INTELLECTUELLE DU CANADA

Proposed Intervener

AFFIDAVIT OF PETER WILCOX
Sworn July 26, 2016

I, Peter Wilcox, of the City of Toronto, Province of Ontario, MAKE OATH AND
SAY AS FOLLOWS:

1. I am the President of the Intellectual Property Institute of Canada / Institut de la Propriété Intellectuelle du Canada ("IPIC"), a proposed intervener in this proceeding. As such, I have personal knowledge of the facts contained in this affidavit. Where I have received information from others, I have disclosed the source of that information and believe it to be true.

A. Background

2. I am a lawyer, patent agent, and trademark agent in Canada. I am also a partner at the intellectual property ("IP") firm Belmore Neidrauer LLP in Toronto, Ontario.¹ I was called to the Ontario Bar in 1994 and admitted to the California Bar in 1997.

3. I have practiced exclusively in the IP field since 1994. I have represented clients in different areas of IP, including medical devices, pharmaceuticals, biotechnology, oil and gas, food supplements, consumer goods, and computer hardware and software.

4. I have held multiple volunteer positions within IPIC over the past fifteen years. I was Chair of the IPIC Litigation Committee from 2001 to 2008 and of the IPIC Intervention Committee from 2007 to 2011. I was also a Member of Executive Council from 2007 to 2009 and again from 2012 to the present. I have been President of IPIC since October 2015 and will remain in this position until the expiry of my one-year term.

B. IPIC's Mandate and Background

5. IPIC is the Canadian professional association of patent agents, trademark agents, and lawyers practicing in the field of IP. It was founded in 1926 and is headquartered in Ottawa, Ontario as a not-for-profit corporation.

6. IPIC has five stated objectives:

- (a) Represent the interests of Canadian IP practitioners;
- (b) Influence the development of IP laws to the extent that they impact IP matters in Canada;
- (c) Be the recognized and visible authority on Canadian IP law and practice;
- (d) Ensure high levels of knowledge, training, and ethics in Canadian IP practitioners; and

¹ Belmore Neidrauer LLP is counsel for IPIC in this proceeding; however, I am not acting or appearing as counsel in this intervention. I am making this affidavit solely in my capacity as IPIC President.

(e) Increase the level of IP business in the Canadian economy.

7. IPIC is governed by an Executive Council, including a President, Past President, Vice-President, Secretary, Treasurer and four Councilors, who are elected by IPIC's members. IPIC's Executive Council is dedicated to carrying out IPIC's objectives. This is accomplished by drawing upon the assistance and expertise of its members to achieve a fair representation of their interests.

8. IPIC's members include lawyers, patent agents, trademark agents, academics, and others interested in IPIC's objectives. Member IP practitioners work in law firms, government agencies, corporations, universities, and as sole practitioners. As of 2016, IPIC has approximately 1,700 members, including approximately 1,000 lawyers and 700 patent and trademark agents.

9. IPIC is the primary public association which represents the interests of patent agents and other patent practitioners in Canada. As such, it is uniquely positioned to represent their interests on this appeal. Our members' clients include virtually all Canadian businesses, universities and other institutions that have an interest in IP in Canada or elsewhere, as well as foreign companies who hold IP rights in Canada.

10. Over 400 IPIC members volunteer to take part in more than 35 specialized Committees. Examples of these Committees include the following: IP Trade Policy Committee; Litigation Committee; Patent Agent Examination Standards Committee; Patent Agent Training Course Committee; Life Science Committee; Patent Legislation Committee; and Patent Practice Committee. These Committees play a role in replying to consultations by the Canadian Intellectual Property Office ("CIPO"), advocating for IPIC initiatives, and offering professional development courses to members and the public, among other things.

11. Further information on IPIC may be found on the Internet at IPIC's website: <<http://www.ipic.ca>>. Copies of relevant excerpts from the IPIC website are attached as **Exhibit "A"**.

C. IPIC's Activities and Expertise

12. IPIC is involved in various activities that shape the IP landscape in Canada. At a high level, these fall into three broad categories:

- (a) promoting the competitiveness of the Canadian IP system;
- (b) providing professional development opportunities; and
- (c) producing IP-related publications.

13. IPIC consults with CIPO and other government departments/agencies, promotes changes to the legislative and regulatory framework, participates in joint committees with CIPO and the Federal Court, and seeks leave to intervene in appropriate judicial proceedings.

14. IPIC makes submissions to the government on various IP topics. It has prepared submissions to CIPO, Industry Canada (now Innovation, Science and Economic Development Canada), the Federal Courts, Canadian Heritage, the Department of Foreign Affairs and International Trade, the Standing Committee on Industry, Science and Technology, and the Canadian Internet Registration Authority. These submissions have included technical and policy recommendations, as well as educational materials to assist officials with studies or to prepare for international meetings. From 2013-2015, IPIC made nearly thirty submissions to government.

15. IPIC was influential in Parliament's recent decision to amend the *Patent Act* and *Trade-marks Act* to include statutory privilege for IP advisor-client communications (pursuant to Bill C-59).² IPIC actively advocated for legislation to confer such a privilege for more than 15 years and took part in the consultation process regarding Bill C-59. A copy of IPIC's recommendations to the House of Commons Standing Committee on Finance and the Standing Senate Committee on National Finance regarding certain aspects of Bill C-59 is attached as **Exhibit "B"**.

16. IPIC maintains an active Intervention Committee that meets on a regular basis. IPIC's policy is to intervene only when it can make a significant contribution to the issue(s) involved

² Bill C-59 received Royal Assent on June 23, 2015 and the privilege provisions came into force on June 24, 2016.

and only when the position sought to be advanced is a matter of compelling public interest or a matter of special significance to the IP profession. IPIC has intervened in patent cases such as:

- (a) *Dutch Industries Ltd v Barton No-Till Disk Inc*, 2003 FCA 121 – this case dealt with the payment of maintenance fees by patentees;
- (b) *Weatherford Canada Ltd v Corlac Inc*, 2011 FCA 228 – this case dealt with section 73 of the *Patent Act* and whether patentees are subject to a general duty of good faith; and
- (c) *Brown v Canada*, 2016 FCA 37 – this case dealt with section 53 of the *Patent Act* and its interplay with the *Public Servants Inventions Act*, and more particularly whether the applicant's failure to disclose his public servant status constituted a material untrue allegation that would affect the validity of a patent.

17. IPIC trains potential and current IP professionals on various substantive and procedural issues. IPIC assists CIPO with the professional registration exams and offers training courses for patent agent candidates. In doing so, IPIC teaches members of the association how to draft patents in accordance with the *Patent Act*, including the utility requirement.

18. IPIC contributes to the dissemination of knowledge and the growth of IP law and policy in Canada by publishing a professional, peer-reviewed journal featuring articles on the latest IP issues and research (known as the *Canadian Intellectual Property Review* or "CIPR"), as well as a newsletter with case summaries, member and committee profiles, and informational articles. The CIPR has contained numerous articles on patent utility over the past several years reflecting different points of view.

D. The Present Appeal

19. This appeal arises from an action to impeach Canadian Patent No. 2,139,653 (the "653 Patent") involving the drug esomeprazole. A central issue at trial in the Federal Court was whether the '653 Patent was invalid for inutility. Much of the utility analysis at trial centered on defining the "promises" of the '653 Patent. Ultimately, the trial judge held that the '653 Patent was invalid for lack of utility.

20. On appeal to the Federal Court of Appeal, the patentee asserted that the Federal Court erred by: failing to consider utility, and any promise of utility, on a claim-by-claim basis; construing the utility of the claims in issue in a manner that was inconsistent with their inventive concept; and failing to apply a purposive construction to the promise of utility. The Federal Court of Appeal dismissed the appeal, concluding that the patentee had not demonstrated any legal error in the Federal Court's construction of the promise of the relevant claims and had not demonstrated any palpable and overriding error in its appreciation of the evidence.

21. In this Court, the appellant raises two main issues: (i) does a "promise of the patent" utility doctrine exist; and (ii) what is the correct and applicable standard for patent utility in Canada?

E. IPIC's Interest in the Appeal

22. The concept of "patent utility" is of significant importance to IPIC and its members. IPIC has an overarching interest in achieving greater certainty and predictability in this area of the law. IPIC's interest in this appeal flows directly from its objectives.

23. Any decision rendered in this proceeding will have wide-ranging and significant effects on the prosecution and enforcement of patents in Canada. It will also have a direct bearing on how IPIC trains its members, how patent agents draft patents, and how Canadian patent practitioners advise clients and conduct patent litigation. Since these are important issues for IPIC and its members, IPIC wishes to intervene in this appeal.

The Decision Affects IPIC as an Educator

24. As an educator, IPIC requires certainty in the law of utility. IPIC trains individuals planning to take their patent agent exams and provides continuing education courses for IP practitioners. In order to properly train its members, IPIC must be able to understand and describe the current state of the law. IPIC requires certainty to provide useful and accurate guidance to Canadian patent agents and practitioners.

The Decision Affects Patent Agents

25. In order to meaningfully advise clients and draft patents that comply with the *Patent Act*, patent agents require clarity and certainty in the law of utility. They must understand how the words they use in the patents they draft will be construed by the courts and what effect they may have on patent validity. Without a clear framework for assessing utility, patent agents cannot avoid so-called “self-inflicted wounds” in patent drafting.

The Decision Affects Patent Applicants and Owners

26. Patent applicants require certainty in the law of utility in order to properly instruct patent agents during the patent prosecution process. Due to the current uncertainty in the law, applicants may not know how much information to disclose within their patent applications. For instance, if applicants say too much about the utility of the subject-matter defined by their claims or express the utility using certain verbs (*e.g.*, “will”) as opposed to others (*e.g.*, “may”), they run the risk of being held to a “promise” that is not codified in the *Patent Act*.

27. The outcome of this appeal may have serious consequences for patent owners. For example, if a new or different utility standard is adopted by this Court, then patents that were drafted and issued prior to this Court’s decision may be exposed to challenge without any means of narrowing the so-called “promise”.

The Decision Affects Patent Litigators and Litigants

28. Utility is often asserted as a ground of invalidity in impeachment actions, as a defence to infringement actions, and as an invalidity allegation under the *Patented Medicines (Notice of Compliance) Regulations*. With uncertainty in the law, it can be difficult for counsel to provide clients with strategic guidance when challenging or defending a patent on the basis of alleged inutility. Conversely, litigants are not able to properly instruct counsel about whether or how to assert or defend a challenge of inutility.

The Decision Affects the Public and Economic Growth in Canada

29. The Canadian public has a direct interest in the outcome of this appeal. Uncertainty in the law of utility may hinder innovation and investment in research and development in Canada.

Investors may be wary of developing and/or selling technology in Canada if they do not know how, or if, their inventions will be protected. On the other hand, if the law of utility is clarified, then inventors may be encouraged to invest and innovate in Canada. IPIC believes that promoting innovation stimulates economic growth and leads to far-reaching public benefits.

F. IPIC's Proposed Submissions and History Considering the Utility Requirement and the "Promise of the Patent"

30. IPIC believes that its intervention will assist this Court by offering a unique perspective to the issues arising on this appeal. IPIC is well-suited to intervene because it has previously considered and made recommendations to the government regarding the utility requirement and the "promise of the patent" doctrine in Canada. In October 2013, IPIC submitted to Industry Canada a list of possible amendments to the *Patent Act* and *Patent Rules* for consideration. A copy of these submissions is attached at **Exhibit "C"**.³ This document was approved by IPIC's governing Council and specifically prepared by the following IPIC Committees: Patent Legislation Committee; Information, Communication and Technology Committee; Biotechnology Patents Committee (now the Life Science Committee); and International Patent Issues Committee. IPIC members of the Joint Liaison Committee – Patents also contributed to the submissions.

31. In its submission to the government, IPIC identified utility as a "critical issue warranting immediate attention". It noted that the requirement that "the claimed invention is useful beyond a basic level of industrial applicability" and the requirement that "this elevated utility be evidenced in the patent specification" are not clearly specified in the *Patent Act*. IPIC recommended that if the government believes that these principles are part of Canadian law, then they ought to be stated clearly in the *Patent Act*.

32. IPIC noted that the "promise of the patent" doctrine has caused litigants to argue over seemingly innocuous statements within the disclosure to determine whether a promise was made, the scope of the promise (if any), and whether the promise was fulfilled. IPIC concluded that the "promise of the patent" doctrine has left patentees with increasing uncertainty as to the validity

³ This document also contains submissions on other issues and possible amendments for consideration in a broader context. IPIC is currently in the process of gathering input on these submissions to update the list for potential resubmission to the government.

of their patents. Therefore, it suggested that Canada's utility requirements be codified within the *Patent Act* in a way that ensures certainty.

33. If IPIC is granted leave to intervene, it will make submissions about why a universally applicable framework for assessing utility is warranted and should be set out by this Court. IPIC will also provide a proposed framework that can be used to assess utility in all patent cases. In brief, this proposed framework will have the following components:

- (a) Construction: In each and every case, the Court must construe the claims of the patent purposively from the perspective of a person skilled in the art, as stated in *Free World Trust v Électro Santé Inc*, [2000] 2 SCR 1024 and in *Whirlpool Corp v Camco Inc*, [2000] 2 SCR 1067, *inter alia*.
- (b) Patentability: Once the claims have been construed, the Court must determine whether the subject-matter defined by each claim is patentable and meets the statutory requirements prescribed by the *Patent Act* (*viz.*, statutory subject-matter, new, useful, inventive).
- (c) Utility (Standard): The utility of the subject-matter defined by each claim must then be assessed objectively through the eyes of a person skilled in the art on a claim-by-claim basis. Utility should not be addressed in a different manner than other grounds of validity (*e.g.*, inventiveness, novelty).
- (d) Utility (Level): The subject-matter defined by each claim, as construed in part (a), must be "useful for the purpose claimed", as stated in *Apotex Inc v Wellcome Foundation Limited*, [2002] 4 SCR 153, at paragraphs 54 and 80. If a patent makes a specific statement of utility in the claim, then this should be the yardstick. By contrast, if no utility is expressly stated in the claim, then the Court must decide if the subject-matter defined by the claim has a scintilla of utility. This determination should be made by the Court objectively, through the eyes of a person skilled in the art, in light of the common general knowledge and the patent specification as a whole. Excessive literalism and subjectivity should be avoided.

- (e) Utility (Policy): The *Patent Act* must be read and understood in its entirety. The concept of utility should not be used to deal with issues that can and should be addressed by other aspects of the *Act* (e.g., inventiveness, novelty, sufficiency, fraud, etc.). There is no need for a “promise of the patent” doctrine to achieve the aims of patent law and the object and purpose intended by Parliament.

H. IPIC Has a Useful and Different Perspective

34. IPIC’s submissions will be useful to this Court because IPIC is a well-recognized and respected authority on Canadian IP law. IPIC makes recommendations to government departments and agencies in relation to IP matters, promotes changes to the legislative and regulatory IP framework, participates in joint committees with CIPO and the Federal Court, and intervenes in appropriate judicial proceedings. IPIC also has experience with the utility requirement, as described above. IPIC will assist this Court in understanding the utility requirement, how the requirement fits into the overall statutory scheme of the *Patent Act*, and how it can be applied in light of the relevant jurisprudence.

35. IPIC possesses a unique awareness and understanding of the concerns and interests of Canadian patent agents and lawyers practicing in all areas of industry. If granted leave to intervene, IPIC will assist this Court in developing a utility framework that is objective, workable, and predictable.

36. IPIC’s perspective is unique from those of the parties to this appeal as IPIC’s members represent brand name and generic drug companies, as well as clients outside of the pharmaceutical sphere altogether. By contrast, the parties to this appeal are drug companies with particular goals and interests in respect of the subject-matter claimed in the ‘653 Patent.

37. IPIC has no stake or interest in the particular outcome of this case. Rather, it seeks to provide this Court with a unique and unbiased perspective on how to achieve certainty and predictability in the law of utility in all areas of industry and technology, using the tools provided in the *Patent Act* and the jurisprudence.

38. IPIC will take no position on how the Canadian utility requirement compares to the law in other jurisdictions, or whether the law is aligned with Canada’s treaty obligations. If granted

leave to intervene, IPIC will offer a Canadian framework to bring predictability to an uncertain area of Canadian patent law.

39. In the absence of IPIC's intervention, this Court may be left without a truly objective Canadian perspective on the issues which would be prejudicial to IPIC given the importance of the issues to its members.

SWORN BEFORE ME at the City of
Toronto, in the Province of Ontario
this 26th day of July, 2016



A Commissioner, etc.

LINDSAY NEIDRAUER



PETER WILCOX

THIS IS **EXHIBIT A** MENTIONED AND
REFERRED TO IN THE AFFIDAVIT OF
PETER WILCOX SWORN BEFORE ME
THIS 26th DAY OF JULY 2016

A handwritten signature in black ink, appearing to read 'Lindsay Neidrauer', written over a horizontal line.

A COMMISSIONER, *ETC.*

LINDSAY NEIDRAUER

- Objectives
- Activities
- Council
- Committees
- Staff
- Code of Ethics
- Contact Us



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Activities

IPIC is the Canadian professional association of patent agents, trademark agents and lawyers practising in intellectual property (IP).

Provide Professional Development Opportunities:

- assist CIPPO with the professional admission exams
- offer training courses for those who want to become patent or trademark agents
- provide courses and webinars throughout the year on various topics (levels ranging from beginner to advanced)
- provide leadership and networking opportunities within more than 35 committees

Promote the Competitiveness of the Canadian IP System:

- respond to all consultations by the Canadian Intellectual Property Office (CIPO) (view submissions)
- respond to consultations by other departments and agencies as appropriate (view submissions)
- make formal submissions to parliamentary committees
- promote changes to the legislative and regulatory framework
- participate in joint committees with CIPO and with the Federal Court
- seek leave to intervene in appeals if IPIC can bring a unique perspective to an issue

Produce Information:

- publish a professional journal featuring articles on the latest IP issues and research
- publish a newsletter with case summaries, member and committee profiles, informational articles, job offers and upcoming events
- raise awareness among small and medium enterprises (SMEs) about IP by offering with CIPO a bank of speakers
- provide a members-only section of ipic.ca with member-specific news, a directory of members, all IPIC publications and information on advocacy efforts

• Objectives

• Activities

• Council

• Committees

• Staff

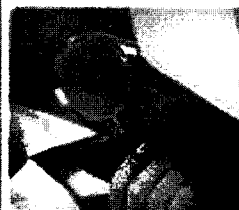
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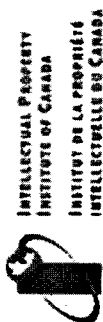


Objectives

IPIC's objectives:

1. Represent the interests of Canadian intellectual property practitioners;
2. Influence the development of intellectual property laws to the extent they impact intellectual property matters in Canada;
3. Be the recognized and visible authority on Canadian intellectual property law and practice;
4. Ensure high levels of knowledge, training, and ethics in Canadian intellectual property practitioners; and
5. Increase the level of intellectual property business in the Canadian economy.

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Current Initiatives

IPIC, Canada's association of intellectual property (IP) professionals, provides opportunities for entrepreneurs, owners and managers of SMEs, and other interested parties to learn about patents, trademarks, copyright, and other types of IP through its courses and speaking engagements. IPIC also informs policy through its many advocacy submissions. Some highlights of IPIC's activities include:

Providing IP Training and Professional Development

IPIC offers many educational opportunities for owners and managers of all sizes of businesses, students and other interested parties, including:

- Courses on the basics of patents, trademarks, copyright, and managing trademark disputes offered by IPIC and McGill University
- In collaboration with CIPQ, nearly 100 presentations a year on the basics of IP are given to more than 2,500 participants as part of the Bank of Speakers program
- Annual writing competition with IP Osgoode (York University)
 - Categories for law students, graduate students, and professionals

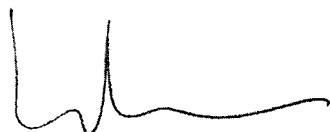
Advocating for a competitive IP system

The competitiveness of the IP system in Canada is a key requirement for economic growth and innovation. Some simple ways of improving Canada's competitiveness include:

- Protecting confidential communications between clients and their patent or trademark agents to put Canada on a level playing field with other countries
- Implementing provisions in case of emergency or exceptional circumstances to prevent the needless loss of valuable rights and increase confidence in the system

IPIC prepares approximately 20 submissions/year to the government on these and many other topics. In some submissions, IPIC makes specific technical (e.g. legal wording) or policy recommendations, while in other cases, IPIC

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THIS 26th DAY OF JULY 2016



A COMMISSIONER, *ETC.*

LINDSAY NEIDRAUER

**Review of Part 3, Division 3, Clauses 44-72 of Bill C-59,
*An Act to implement certain provisions of the budget
tabled in Parliament on April 21, 2015 and other
measures***

Submission to the House of Commons Standing Committee on Finance
& the Standing Senate Committee on National Finance

June 8, 2015



INTELLECTUAL PROPERTY INSTITUTE OF CANADA
INSTITUT DE LA PROPRIÉTÉ INTELLECTUELLE DU CANADA

Bill C-59 — Brief of the Intellectual Property Institute of Canada

The Intellectual Property Institute of Canada (IPIC) welcomes the opportunity to submit a brief to the Senate Standing Committee on National Finance and the House of Commons Standing Committee on Finance on Bill C-59.

Confidential communications and *force majeure*

IPIC is pleased that the Bill protects confidential communications between Canadian innovators and their patent agents and trademark agents, and that the Bill gives the Canadian Intellectual Property Office (CIPO) the power to extend deadlines in cases of *force majeure* events, such as floods and ice storms.

These are welcome improvements to Canada's intellectual property laws, and IPIC commends the Government's initiative in making them.

Other provisions of Bill C-59 relating to intellectual property

Brief comments on particular intellectual property aspects of the Bill follow. Headings refer to section numbers of C-59.

Section 52

Section 11 of the *Patent Act* is repealed. This provision permits the public to enquire whether a Canadian patent application corresponding to a foreign patent remains pending.

The provision is useful with respect to "old Act" applications filed before October 1, 1989, and which are not published until grant. Although few old Act applications are believed to remain pending, it is not clear that it is beneficial to repeal section 11 at present.

The rationale for repealing section 11 of the Act is not clear to IPIC. Perhaps it is merely a "housekeeping" initiative. However, we have not studied whether e.g. international obligations mandate repeal of section 11.

Section 59

The amendments to subparagraph 55.11(1)(a)(iii) of the *Patent Act* appear possibly to have the effect of permitting the "intervening rights" provisions of Bill C-43 to apply in the case of an application abandoned for non-payment of the final fee under current paragraph 73(1)(f) of the Act—i.e. to have retroactive effect. For example, would intervening rights potentially apply in the case of a patent granted on an application abandoned in 2010 for non-payment of the final fee and subsequently reinstated?

IPIC would expect that intervening rights should only potentially arise in the case of an application abandoned *after* the coming in force of Bill C-43.

The coordinating and coming into force provisions are complex and perhaps we have misunderstood. But IPIC recommends that section 59 be reviewed to ensure it is correct.

Section 60

Section 62 of the *Patent Act* is repealed. This section concerns registration of judgments voiding patents in CIPO's records.

While IPIC does not object *per se* (e.g. most patent actions are in the Federal Court, whose records are searchable on the internet), the rationale for repealing this provision is not understood.

Section 62

Paragraph 73(1)(f) of the *Patent Act* is repealed. This provision provides that an application is deemed to be abandoned if the final fee is not paid.

It is common that a patent application must be amended after it has been allowed, often as a result of a foreign applicant's lack of understanding of unique aspects of Canadian practice, such as double patenting.

Under the current system, substantial amendments (e.g. those requiring a further search of the prior art) may only be made if the application is permitted to become abandoned by non-payment of the final fee. On subsequent reinstatement, the application is subject to amendment and further examination.

It appears that repeal of paragraph 73(1)(f) may remove this important procedural mechanism for amending patents post-allowance.

IPIC recommends that provision be made in the *Patent Act* and/or *Patent Rules* to permit prosecution to be re-opened after allowance (possibly on payment of a fee), so that further amendments may be made and examined.

IPIC comments made at the Standing Committees

To clarify our comments made at the Standing Committees regarding the responses to Industry Canada's consultations in the past, we are aware of the following submissions:

1. Regarding the Industry Canada consultation in 2004, the Federation of Law Societies of Canada submitted a response and the National Intellectual Property Law Section of the Canadian Bar Association submitted a response.
2. Regarding the Industry Canada consultation in 2013, the National Intellectual Property Law Section of the Canadian Bar Association submitted a response.

Further information on these submissions may be obtained from the Federation of Law Societies of Canada and the National Intellectual Property Law Section of the Canadian Bar Association.

Summary of Recommendations

Section 59

IPIC would expect that intervening rights should only potentially arise in the case of an application abandoned *after* the coming in force of Bill C-43.

The coordinating and coming into force provisions are complex and perhaps we have misunderstood. But IPIC recommends that section 59 be reviewed to ensure it is correct.

Section 62

IPIC recommends that provision be made in the *Patent Act* and/or *Patent Rules* to permit prosecution to be re-opened after allowance (possibly on payment of a fee), so that further amendments may be made and examined.

IPIC is the professional association of lawyers, patent agents, and trademark agents practicing in all areas of intellectual property law. Our membership totals over 1,700 individuals, consisting of practitioners in law firms and agencies of all sizes, sole practitioners, in-house corporate intellectual property professionals, government personnel, and academics. Our members' clients include virtually all Canadian businesses, universities and other institutions that have an interest in intellectual property in Canada or elsewhere, and also foreign companies who hold intellectual property rights in Canada.

THIS IS **EXHIBIT C** MENTIONED AND
REFERRED TO IN THE AFFIDAVIT OF
PETER WILCOX SWORN BEFORE ME
THIS 26th DAY OF JULY 2016

A handwritten signature in black ink, appearing to read 'Lindsay Netrauer', written over a horizontal line.

A COMMISSIONER, *ETC.*

LINDSAY NETRAUER

Possible Amendments to the *Patent Act* and *Patent Rules*

Prepared by the Intellectual Property Institute of Canada

October 2013



INTELLECTUAL PROPERTY INSTITUTE OF CANADA
INSTITUT DE LA PROPRIÉTÉ INTELLECTUELLE DU CANADA

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Introduction

The Intellectual Property Institute of Canada (IPIC) is the professional association of patent agents, trade-mark agents and lawyers practising in all areas of intellectual property law. Our membership totals over 1,700 individuals, consisting of practitioners in law firms and agencies of all sizes, sole practitioners, in-house corporate intellectual property professionals, government personnel, and academics. Our members' clients include virtually all Canadian businesses, universities and other institutions that have an interest in intellectual property in Canada or elsewhere, and also foreign companies who hold intellectual property rights in Canada.

IPIC is pleased to present the following list of possible amendments to the *Patent Act* and *Patent Rules* for consideration. This document was prepared by IPIC's Patent Legislation Committee, Information, Communication and Technology Committee, Biotechnology Patents Committee, International Patent Issues Committee, and by the IPIC members of the Joint Liaison Committee—Patents. The submission was reviewed, edited and approved by IPIC's governing Council.

The table below identifies issues in Canadian patent law that IPIC believes warrant study, possibly leading to amendment of the *Patent Act* and *Patent Rules*. The issues are organized in three categories: (1) critical issues warranting immediate attention; (2) issues of intermediate importance; and (3) issues that are of lesser concern or are otherwise not pressing matters. These groupings are based upon patent agents' experiences with the Canadian and international IP systems, and the experiences of their clients. Within sections, issues are not ranked by order of importance.

Brief explanatory comments are provided. For certain involved issues, further analysis is provided in the annex. The recommendations herein are made in contemplation of amendments to the *Patent Act* and *Patent Rules*. In some instances, amendments to other intellectual property legislation or other connected legislation would be warranted.

For more information, please contact Michel Gérin, Executive Director of IPIC, at 613-234-0516 or mgerin@ipic.ca.

(b) Critical Issues Warranting Immediate Attention

Issue and/or Proposed Amendment	Comments
<p><u>Protection of Confidential Communications</u></p> <p>Amend the <i>Patent Act</i> to provide explicit protection from forced disclosure of the confidential communications between clients and their patent and trade-mark agents.</p>	<p>IPIC recommends that the <i>Patent Act</i> be amended to provide that confidential communications between clients (e.g. applicants) and their patent agents are protected from forced disclosure, e.g. during litigation. This is consistent with legislative initiatives taken or underway in other countries and with the principle that the administration of justice is advanced if full and frank discussions between clients and their IP advisors are fostered.</p> <p>This topic was addressed in detail in IPIC's submission to the House of Commons Standing Committee on Industry, Science and Technology in response to their study on the IP regime in Canada.</p> <p><i>See annex point #1 for further analysis.</i></p>
<p><u>Prevent Inadvertent Loss of Rights</u></p> <p>Amend the <i>Patent Act</i> and <i>Patent Rules</i> to implement procedures to prevent inadvertent loss of rights.</p>	<p>The <i>Patent Act</i> does not provide measures to protect innovators from loss of rights resulting from inadvertent or unavoidable errors or omissions—e.g. failure to make a required fee payment due to a miscalculation of the applicable government fee or inability to make payment due to a power failure. In contrast to other patent systems, the Canadian system is unnecessarily rigid. Patent rights should be determined on substantive questions of patentability, not formal defects or unintentional or unavoidable errors.</p> <p>Amendments to the <i>Patent Act</i> and <i>Rules</i>—including amendments for compliance with aspects of the <i>Patent Law Treaty</i>—could remedy these deficiencies.</p> <p>If rights are restored, the interests of those who have relied to their detriment on the apparent lapse of the rights (e.g. by making, using, or selling the claimed invention after CIPO's records show that the application is dead or the patent has lapsed) can be addressed by a system that recognizes intervening rights.</p> <p>This topic was addressed in detail in IPIC's submission to the House of Commons Standing Committee on Industry, Science and Technology in response to their study on the IP regime in Canada. <i>See annex point #2 for further analysis.</i></p>

Issue and/or Proposed Amendment	Comments
<p><u>Double Patenting</u></p> <p>Amend the <i>Patent Act</i> to provide for terminal disclaimers and continuation applications.</p>	<p>The judicially-developed doctrine of “double-patenting” prevents a patentee from obtaining a second patent with claims that are obvious over the claims of the patentee’s earlier patent, even if that patent is not prior art.</p> <p>The doctrine arose in the context of “voluntary” divisional applications under the old <i>Patent Act</i>—the patent term of 17 years from grant extended the term of the divisional patent, resulting in impermissible “evergreening.” Evergreening cannot occur for divisional applications filed under the current <i>Patent Act</i> because the patent term for both patents is 20 years from the original filing date—but the courts have nevertheless applied double patenting principles.</p> <p>Double patenting poses difficulties when filing divisional applications, whether or not an objection for lack of unity of invention has been made by CIPO. It also causes serious problems for independently-filed applications, leading to perverse outcomes that are inconsistent with the novelty requirements under the <i>Patent Act</i> and with the patent laws of other countries.</p> <p>These problems arise because Canadian courts have essentially adopted US double patenting principles, despite the lack of the corresponding safeguards in the patent statute—namely provisions for terminal disclaimers (an agreement that both patents expire on the same day and must be commonly owned) and a procedure for filing continuation applications.</p> <p>Amending the <i>Patent Act</i> to provide for terminal disclaimers and a continuation procedure would be a simple way to fix the problems caused by the judicially-developed doctrine of double patenting, a doctrine that is incompatible with the current <i>Patent Act</i>.</p> <p><i>See annex point #3 for further analysis.</i></p>
<p><u>Utility</u></p>	<p>Section 2 of the <i>Patent Act</i> provides that an invention must be “useful.” The judicially-developed doctrine of the “promise of the patent” can raise the required utility beyond a</p>

15. Critical Issues Warranting Further Attention	
Issue and/or Proposed Amendment	Comments
<p>Codify/clarify law of utility, including sound prediction, promise of the patent, sufficiency of disclosure and permissibility of post-filing evidence.</p>	<p>threshold level of industrial applicability.</p> <p>The Canadian courts have held that the promised utility must either be demonstrated or “soundly predicted” as of the filing date, and that the elements required for a sound prediction of utility must be found in the specification as filed.</p> <p>But the requirements for the content of the specification are set forth in subsection 27(3) of the <i>Patent Act</i>, which makes no mention of disclosure of utility. Rather s. 27(3) requires only that the specification must “correctly and fully describe the invention and its operation or use as contemplated by the inventor” and to describe the invention in “such full, clear, concise and exact terms” as to enable any person skilled in the art to make or use it.</p> <p>Requirements that the claimed invention is useful beyond a basic level of industrial applicability and that this elevated utility be evidenced in the patent specification as filed are not clearly specified in the <i>Patent Act</i>, and are inconsistent with requirements in other countries.</p> <p>IPIC recommends that the utility requirement be studied. For the purposes of clarity and certainty, should it be concluded that such requirements are appropriate and compatible with Canadian patent law and international treaty obligations, IPIC recommends that any requirement for utility beyond the basic requirement of industrial applicability or that the patent specification as filed contain evidence of utility, be clearly stated in the <i>Patent Act</i>.</p> <p><i>See annex point #4 for further analysis.</i></p>
<p><u>Patentable Subject Matter</u></p> <p>Clarify patentable subject matter (s. 2 of the <i>Act</i>), especially patentability of computer-implemented methods, business methods, higher life forms,</p>	<p>Section 2 of the <i>Patent Act</i> provides that an invention is “any new and useful art, process, machine, manufacture, or composition of matter” or improvement thereof.</p> <p>Despite this expansive definition, the courts have imposed many limitations as to the scope of eligible subject-matter, and CIPO imposes its own additional limitations.</p>

Critical Issues Warranting Immediate Attention	
Issue and/or Proposed Amendment	Comments
methods of medical treatment, methods of medical diagnostics, and clarify exclusion of mere scientific principles and abstract theorems under s. 27(8) of <i>Act</i> .	<p>Consideration may be given to modernizing section 2 of the <i>Act</i> to reflect Parliament's current intentions as to the scope of patentable subject matter. This can provide greater clarity, efficiency of patent prosecution, and business certainty for innovators.</p> <p><i>See annex point #5 for further analysis.</i></p>
<p><u>Section 58 after <i>Teva</i></u></p> <p>Clarify, post-<i>Teva</i>, that s. 58 of the <i>Patent Act</i> requires validity of each claim to be determined separately, including when assessing compliance with disclosure requirements.</p>	<p>Section 58 of the <i>Patent Act</i> provides that: "When, in any action or proceeding respecting a patent that contains two or more claims, one or more of those claims is or are held to be valid but another or others is or are held to be invalid or void, effect shall be given to the patent as if it contained only the valid claim or claims."</p> <p>The meaning of this provision would seem clear on its face—the validity of each claim in a patent is assessed separately. But <i>Teva v. Pfizer</i> 2012 SCC 60 indicates that section 58 is engaged only <i>after</i> the validity analysis—in <i>Teva</i>, compliance with subsection 27(3)—is carried out.</p> <p>If applied broadly, this reasoning could render section 58 of no practical force or effect. Moreover, it can lead to wholly nonsensical outcomes, because many aspects of validity—e.g. whether the invention is novel over a particular prior art reference—necessarily must be determined in the context of a particular claim. See <i>Canada (Attorney General) v. Amazon.com</i> 2011 FCA 328.</p> <p>In <i>Teva</i>, assessing whether the specification complied with subsection 27(3) in the context of the subject-matter defined in each claim might not have resulted in a different outcome, because claim 7, directed to the use of sildenafil citrate in the treatment of ED, specifically claimed the very subject-matter that the Court determined to be the invention. On these facts, if claim 7 was invalid as lacking sufficient disclosure, it would not appear that the subject-matter of any other claim in the patent would be found to be properly disclosed.</p> <p>But on slightly different facts, there could be wholly aberrant results. For instance, there could be sufficient disclosure of the subject-matter of some claims but not others. What then</p>

(1) Critical Issue: Warranting Immediate Attention

Issue and/or Proposed Amendment	Comments
	<p>is the “invention” against which the disclosure requirement under subsection 27(3) is measured? Surely it must be the case that the sufficiency of disclosure is assessed on the basis of the subject-matter of the invention <i>as claimed</i>, and the validity of each claim assessed independently. Otherwise, there is little value in having multiple claims of different scope (a universally accepted practice) or, indeed, in having claims at all.</p> <p>Ultimately, this may be an issue of the notice function of the claims. It is problematic if matters of patentability are determined based on a nebulous concept of what is the “invention” rather than based on the subject-matter of the claims. A broader solution may be to amend subsection 27(3) to clarify that it is the subject-matter defined by a claim that must be sufficiently disclosed in the specification.</p>

Issue and/or Proposed Amendment	Comments
<p><u>Unity</u></p> <p>Clarify unity of invention, including definition of “one invention” under s. 36 of <i>Act</i>.</p>	<p>Section 36 and/or associated provisions of the <i>Act</i> may be amended as discussed above to provide for terminal disclaimers and a continuation procedure.</p> <p>Moreover, consideration should be given to ensuring that the <i>Patent Act</i> and <i>Patent Rules</i> further the policy goals of the requirement for unity of invention—it is not a substantive requirement for patentability but instead ensures that CIPO receives fees that are proportional to the cost and effort involved in examining a patent application. Accordingly, a practical approach to unity of invention should be taken, and narrow, literal, or academic approaches should be avoided.</p> <p>This topic was addressed in detail in IPIC’s submission to CIPO of April 7, 2011 concerning proposed amendments to Chapter 14 of the Manual of Patent Office Practice.</p>
<p><u>Restriction in Amending Applications after Allowance</u></p> <p>Amend the <i>Patent Rules</i> to include provision for an applicant to request withdrawal of the allowance so as to enter substantive amendments to the application instead of having to go through the abandonment of the application.</p>	<p>Currently, an allowed application can only be amended to correct clerical errors or to enter amendments that would not necessitate a further search. More substantial amendments are permitted, but require purposeless and time-consuming abandonment and reinstatement of the application. A more efficient and rational approach to re-opening prosecution should be established.</p> <p><i>See annex point #6 for further analysis.</i></p>
<p><u>Disclosure</u></p> <p>Eliminate “best mode” requirement for all types of inventions in s. 27(3) of the <i>Patent Act</i>.</p>	<p>Subsection 27(3) of the <i>Patent Act</i> reflects an unwieldy amalgamation of unrelated concepts.</p> <p>One simple step for improving this provision would be to remove the requirement in paragraph 27(3)(c) to provide the “best mode” for applying the principle a machine. This requirement is inconsistent with other aspects of subsection 27(3), which do not specify a best</p>

Other Important Issues	
Issue and/or Proposed Amendment	Comments
	mode requirement for e.g. processes, manufactures, or compositions of matter. Moreover, the concept of a “best mode” is undesirably subjective in any context.
<u>Changing Applicants/Inventors</u> Clarify and simplify procedures under s. 31 of <i>Act</i> to change applicants/inventors.	The language of section 31 of the <i>Patent Act</i> is antiquated and confusing, and the section in its entirety is poorly adapted for correcting the accidental omission or inclusion of inventors or their assignees, or for resolving disputes that may arise regarding entitlement to prosecute a patent application. This section advantageously would be wholly modernized. For example, at present, CIPO believes that section 31 does not provide a mechanism to correct a patent application in which the applicant (assignee) was misidentified through error.
<u>Inventor vs. Applicant</u> Clarify differences between definitions of “inventor” and “applicant” under <i>Act</i> .	The definitions of “applicant” and “legal representative” are antiquated and circular. The <i>Patent Act</i> and <i>Patent Rules</i> could beneficially be amended to clarify: (1) the role of the inventor in the prosecution of a patent application; (2) the requirements for someone other than the inventor to be named as the applicant; and (3) the interplay between the requirements to be a legal representative of an inventor versus an owner (i.e. assignee).
<u>Disclaimer</u> Clarify s. 48(4) of <i>Act</i> , “No disclaimer affects any action pending at the time when it is made, unless there is unreasonable neglect or delay in making it.”	Consider reversing <i>HersHKovitz et al v Tyco Safety Products Canada Ltd.</i> , 2010 FCA 190, by clarifying that filing a disclaimer adding a limitation to an existing claim, whether inventive or not, does not broaden the claim.
<u>Claims Framed in the Alternative</u> Consider adding a reference to s. 58 in s. 27(5).	As it stands now, it is arguably unclear whether a multiple dependent claim falls whenever any one of the claims from which it depends falls. The <i>Act</i> could be amended to clarify the treatment of such claims. This could also affect Markush type claims.

(2) Other Important Issues	
Issue and/or Proposed Amendment	Comments
<u>Sequence Listings</u> Eliminate excess page fees for sequence listings.	The <i>Patent Rules</i> should be amended to specify that the issue fee surcharge of \$6.00 per page for each page of description/claims/drawings in excess of 100 does not apply to a sequence listing in electronic form.

(3) Issues addressed/Proposed Amendments	
Issue and/or Proposed Amendment	Comments
<p><u>Prior User Rights</u></p> <p>Section 56 of the <i>Patent Act</i> provides for “prior user rights”—i.e. there is an exception from infringement for the use and sale of specific articles that were acquired before the priority date of a patent application. The application of section 56 to patented processes could be clarified.</p>	<p>Current section 56 is silent as to its potential application to claimed processes practiced before the claim date or products acquired before the claim date that were made by a claimed process. Although this is not an issue that appears to arise often, potentially section 56 could be clarified.</p>
<p><u>Translations</u></p> <p>Remove requirement that an English or French description be filed to obtain a filing date for a non-PCT application; allow late translation.</p>	<p>Likely best addressed in <i>Rules</i>; removal required by <i>PLT</i>.</p> <p><i>See annex point #7 for further analysis.</i></p>
<p><u>Filing Fee</u></p> <p>Remove requirement that a fee be paid to obtain a filing date; allow late payment.</p>	<p>Likely best addressed in <i>Rules</i>; removal required by <i>PLT</i>.</p>
<p><u>Assignments/DLRs</u></p> <p>Clarify interplay between requirement under s. 50 of <i>Act</i> that every</p>	<p>Simplified recordal requirements are required by <i>PLT</i>.</p>

(3) Issues of Interest	
Issue and/or Proposed Amendment	Comments
assignment be filed and CIPO's practice of accepting Declarations of Legal Representative.	
<u>Registration of Licenses</u> Clarify whether non-exclusive licenses need to be registered, and clarify consequences, if any, of failure to register exclusive or non-exclusive licenses.	
<u>Registered Interests and Bankruptcy</u> Clarify interplay between registrations under the <i>Patent Act / Personal Property Security Act</i> and bankruptcy proceedings under the <i>Bankruptcy and Insolvency Act / Companies' Creditors Arrangement Act</i> .	May require amendments beyond <i>Patent Act</i> .
<u>Requirement for Attestation of Assignments</u> Amend Act to remove ss. 49(3) and 50(3).	S. 49(3) and s. 50(3) of the Act require an affidavit or "proof to the satisfaction of the Commissioner" of the execution of the assignment. This is unnecessarily formalistic, and anomalous in view of the practices in many other countries.

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(3) Issues of Lesser Importance	
Issue and/or Proposed Amendment	Comments
<u>Formal Mechanism to get to Appeal</u> Provide formal mechanism to get to appeal.	<p>Currently, Applicants can spend years going back and forth with an Examiner without making progress in prosecution before a Final Action issues, allowing the Applicant to be heard by the Patent Appeal Board.</p> <p>Delays to a final determination of patentability could be greatly reduced in some cases by allowing Applicants to request an appeal after a certain point (e.g. 2 rejections on the same basis).</p>

Annex: Further analysis of selected issues

Item #1 – Protection of Confidential Communications

Confidential communications between IP owners and their Canadian patent or trade-mark agents are not protected from forced disclosure in litigation. This places Canadian innovators at a disadvantage in litigation in Canada and other jurisdictions, such as in the U.S. where the courts can force the disclosure of the communications if the protection does not exist in the country of origin.

For the IP system to work well, Canadian innovators must be able to have full and frank discussions with their patent and trade-mark agents. The lack of protection for confidential communications places Canadian innovators, businesses and universities at a competitive disadvantage. Many countries, including Australia, the UK and France, have resolved the problem through simple legislative amendments.

Rectifying this problem would allow Canadian businesses to compete on a level playing field. IPIC recommends that the government amend the *Patent Act* to protect confidential communications between IP owners and their patent agents from forced disclosure in litigation.

Item #2 – Prevent Inadvertent Loss of Rights

In Canada, companies can permanently lose IP rights due to exceptional circumstances, such as power outages. Rights can also be lost due to innocent mistakes in following clerical procedures. Canada's IP system is unnecessarily unforgiving. These easily-solvable problems cause costs and uncertainty for innovators and place a burden on the system.

Many other jurisdictions, such as the U.S., have mechanisms to prevent inadvertent loss of rights. Canada lags behind. In some instances the courts are able to resolve the problem, but to have to go to court to resolve small mistakes is a significant red tape burden. A business that suddenly and unexpectedly loses a patent loses its competitive advantage. This can mean loss of jobs. Correcting this problem and reducing an unnecessary regulatory burden on innovators will help protect the investments of innovative businesses.

IPIC recommends amending the *Patent Act* and *Patent Rules* to implement procedures to prevent inadvertent loss of rights.

Item #3 - Double Patenting

Canadian courts have established a US-style “obviousness-type double patenting” prohibition. The doctrine of “double patenting” is intended to prevent patentees from “evergreening” an invention by extending the term of patent protection beyond the statutory limits. However, the case law from which this prohibition arises was based on the ‘old’ *Patent Act* (pre-1989), when patent terms were calculated based on the issue date rather than the filing date, as it is now. Accordingly, the “evergreening” rationale which underlies the doctrine of double-patenting has no application to “new act” patent applications that share the same filing date, such as a divisional application or other applications that are filed on the same date.

This prohibition has become a significant barrier to the filing of divisional applications in Canada and is a trap for the unwary applicant. The only ‘safe’ way to file a divisional application in Canada is in response to an objection by the Patent Office for lack of unity of invention. This may be difficult or impossible in some situations, may delay the prosecution of valuable claims, and is a waste of Patent Office resources.

The prohibition against obviousness-type double patenting is also inconsistent with the requirements for novelty and unobvious under sections 28.2 and 28.3 of the current *Patent Act*. For instance, a patentee’s claims may have to be unobvious over the claims of the patentee’s own earlier patent, but merely novel over the full text of another person’s earlier patent. It would seem that the novelty and obviousness provisions under the current *Patent Act* were not enacted in contemplation of double patenting principles developing in this way.

One solution is to codify the doctrine of double patenting in the *Patent Act* and include an exemption for applications having the same filing date. This would prevent divisional and applications filed on the same day from being cited against one another. This would make it safer to prosecute divisional applications in Canada.

A broader solution to the issue of double patenting would be to introduce a terminal disclaimer system similar to that used in the United States. Such a system would allow a patentee to avoid double patenting altogether, even where the filing dates are not the same, by voluntarily shortening the term of their patent to match that of an earlier application, and requiring common ownership.

In *GlaxoSmithKline Inc. v. Apotex Inc.* 2003 FCT 687, a case relied upon by CIPO to justify double patenting objections, the Federal Court held that double patenting principles apply to divisional applications under the current *Patent Act* in the absence of term extension, on the basis that the second patent permitted an unauthorized second attempt to list a patent on the Health Canada patent register. It could be studied whether consequential amendments to the *Patented Medicines (Notice of Compliance) Regulations* would

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Diagnostic methods may include steps that compare the concentration of a compound in a treated subject with the concentration of the compound in a control subject, and then base a course of action on this comparison. These claims may include a combination of physical and mental steps, and/or prior art and novel steps. The combination of steps in these claims should be considered together in a purposive construction of the claims yet CIPO's approach to claim constructions parses the claims and analyzes each step in isolation.

Whereas methods of medical treatment may not constitute patentable subject matter in Canada (*Tennessee Eastman v. Commissioner of Patents* [(1972), 8 C.P.R. (2nd), 203 (S.C.C.)]), medical use claims are accepted. Subsequent to recent Federal Court jurisprudence which provides that use claims that contain dosing ranges are unpatentable as embodying the exercise of professional skill, CIPO has published an Office Practice guideline indicating that claims will be rejected if the inventive concept is a dosage regimen, even if the claim has been converted to a medical use claim. There are two issues: first, the guideline is vague and arguably goes beyond the jurisprudence insofar as it seems to preclude claims that involve dosing or dosage regimens in respect of which no professional skill is to be exercised (e.g. fixed dosing or regimens); second, the jurisprudence leads to a hindrance to valuable research and development in an area of the pharmaceutical arts which leads to significant outcomes in drug therapy, including efficacy, safety and patient compliance. The distinction drawn in the recent jurisprudence, and the broader prohibition arguably set out in the CIPO Office Practice guideline is inconsistent with permitting medical use claims simpliciter, since all medical uses of prescription drugs involve the exercise of professional skill - that of the prescribing health professional.

Item #6 - Restriction in Amending Applications after Allowance

There are circumstances, after a patent application has been allowed, when an applicant may wish to withdraw the application from allowance for further examination. For example, the applicant may wish to make substantive amendments to the application in view of newly-discovered prior art, a newly-discovered infringing product in the marketplace, etc., but section 32 of the *Patent Rules* prohibits substantive amendments after an application has been allowed and section 33 of the *Patent Rules* prohibits any amendments at all after the issue fee has been paid.

Unlike in other countries, such as the U.S., the Canadian *Patent Act/Rules* do not provide a simple means of requesting continued examination of an application after an application has been allowed or a simple means of requesting that an application be withdrawn from issue after the issue fee has been paid. Rather, in cases where the application has been allowed but the issue fee not yet paid, the applicant is usually forced by subsection 73(4) of the *Patent Act* and section 33 of the *Patent Rules* to go through the pretense of allowing the application to go abandoned by deliberately failing to pay the issue fee and then reinstating the application (often unnecessarily waiting for up to 6 months until the due date for paying the issue fee has passed), so that the Notice of Allowance is

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deemed withdrawn and the application subject to further amendment and examination. After the issue fee has been paid, the applicant's options for getting an application withdrawn from issue are even more limited and potentially harmful – for example, filing prior art against one's own application under section 34.1 of the *Patent Act* to get the Commissioner to withdraw the application from issue under subsection 30(7) of the *Patent Rules*. The Canadian *Patent Act/Rules* should be amended to provide a simple means to request continued examination of an allowed application and to withdraw an application from issue

Item #7 - Translations

The *Patent Act* and *Patent Rules* require that a patent specification be filed in French or English in order to obtain a filing date. This puts patent applicants in Canada at a disadvantage relative to applicants in other countries that grant a filing date upon filing a patent specification in any language. The Canadian *Patent Act* and *Patent Rules* should be amended to grant a filing date upon filing a specification in any language, provided that a translation into English or French is filed within a short time. Such an amendment will be required in order for Canada to ratify the *Patent Law Treaty*, to which it is a signatory.

TAB 3

**MEMORANDUM OF ARGUMENT OF THE PROPOSED INTERVENER,
INTELLECTUAL PROPERTY INSTITUTE OF CANADA / INSTITUT DE LA
PROPRIÉTÉ INTELLECTUELLE DU CANADA**

PART I – OVERVIEW AND FACTS

A. Overview

1. The Intellectual Property Institute of Canada / Institut de la Propriété Intellectuelle du Canada (“IPIC”) seeks leave to intervene in this appeal. IPIC is a Canadian association of patent agents, trademark agents and lawyers practising in the field of intellectual property (“IP”).
2. The main issue on this appeal relates to the utility requirement under Canada’s *Patent Act*. This issue has become increasingly uncertain over the past several years with inconsistent appellate jurisprudence on point. IPIC has an interest in restoring the cardinal values of certainty and predictability into the law in a manner that is consistent with the object and purpose of the *Patent Act* as intended by Parliament.
3. As the domestic association most closely connected with patent practitioners in Canada, IPIC is intimately familiar with their interests. IPIC is able to provide useful submissions on the issues on this appeal from a perspective that is different from the other parties. IPIC has an interest in ensuring that this Court look beyond the parties, patent, and facts of this particular case, and set out a universal framework that restores certainty for assessing patent utility consistently across all areas of technology.
4. If IPIC is granted leave to intervene, it will draw upon its expertise in Canadian patent law to propose a utility framework that is objective, consistent with the overall scheme of the *Patent Act*, and consistent with seminal patent decisions of this Court over the past thirty years. IPIC’s proposed utility framework will be applicable to patents across all types of technologies.
5. IPIC has no direct interest in the outcome of this case on its merits. IPIC’s overarching interest in this appeal is to achieve greater certainty and predictability regarding the utility requirement under the *Patent Act*.

B. Statement of Facts

(i) The Intellectual Property Institute of Canada / Institut de la Propriété Intellectuelle du Canada ("IPIC")

6. IPIC was founded in 1926 and is headquartered in Ottawa, Ontario as a not-for-profit corporation. As of 2016, IPIC has approximately 1,700 members, including approximately 1,000 lawyers and 700 patent and trademark agents.

Affidavit of Peter Wilcox sworn on July 26, 2016, paras 5, 8, Tab 2

7. IPIC has five stated objectives:

- (a) Represent the interests of Canadian IP practitioners;
- (b) Influence the development of IP laws to the extent that they impact IP matters in Canada;
- (c) Be the recognized and visible authority on Canadian IP law and practice;
- (d) Ensure high levels of knowledge, training, and ethics in Canadian IP practitioners; and
- (e) Increase the level of IP business in the Canadian economy.

Affidavit of Peter Wilcox sworn on July 26, 2016, para 6, Tab 2

8. IPIC's activities are centered on advancing its objectives. Details of these activities are set out in the affidavit of Peter Wilcox, IPIC's current President, filed in support of this motion. IPIC trains members on various substantive and procedural IP issues, assists the Canadian Intellectual Property Office ("CIPO") with professional patent registration exams, offers training courses for patent agent candidates, and assists government and the courts with various IP-related matters.

Affidavit of Peter Wilcox sworn on July 26, 2016, paras 12-17, Exhibit "A", Tab 2, 2A

9. IPIC also publishes a professional peer-reviewed journal and newsletter that includes featured articles on the latest IP issues. IPIC's journal (known as the *Canadian Intellectual*

Property Review, or “CIPR”) has contained numerous articles on patent utility over the past several years reflecting a wide-variety of interests and points of view.

Affidavit of Peter Wilcox sworn on July 26, 2016, para 18, Tab 2

10. IPIC is widely regarded as the association that is most closely connected with patent practitioners in Canada. IPIC members advise clients on the patentability, commercialization, and enforcement of patents in Canada. IPIC consults with government departments and agencies to promote changes to the IP legislative and regulatory scheme, as necessary.

Affidavit of Peter Wilcox sworn on July 26, 2016, paras 9, 13 Tab 2

11. IPIC has made submissions to: CIPO; Industry Canada (now Innovation, Science and Economic Development Canada); Canadian Heritage; the Department of Foreign Affairs and International Trade; the Standing Committee on Industry, Science and Technology; and the Canadian Internet Registration Authority. These submissions have included technical and policy recommendations on IP issues, as well as educational materials to assist officials with studies or to prepare for international meetings. As a result of such submissions, for example, IPIC was instrumental in Parliament’s recent decision to amend the *Patent Act* and *Trade-marks Act* to include provisions to protect confidential communications between clients and their patent and trademark agents. From 2013 to 2015, IPIC made nearly thirty submissions to the government on IP issues.

Affidavit of Peter Wilcox sworn on July 26, 2016, paras 14, 15, Tab 2

12. In its submissions to the Minister of Industry in 2013, IPIC proposed a list of possible amendments to the *Patent Act* and *Patent Rules* and identified the utility requirement as a “critical issue warranting immediate attention”. IPIC noted that the “promise of the patent” doctrine has caused litigants to argue over seemingly innocuous statements within the disclosure to determine whether a promise was made, the scope of the promise (if any), and whether the promise was fulfilled. IPIC concluded that the “promise of the patent” doctrine has left patentees with increasing uncertainty as to the validity of their patents. IPIC’s recommendation was that if Parliament intended to create a “promise of the patent” doctrine, then it should be stated clearly in the *Act*.

Affidavit of Peter Wilcox sworn on July 26, 2016, paras 30-32 and Exhibit "C", Tab 2 and 2C

13. IPIC has intervened in judicial proceedings to present a unique and different perspective on important IP matters, including in *Dutch Industries Ltd v Barton No-Till Disk Inc*, 2003 FCA 121 (a case involving the payment of maintenance fees by patentees), *Weatherford Canada Ltd v Corlac Inc*, 2011 FCA 228 (a case involving section 73 of the *Patent Act* and whether patentees are subject to a general duty of good faith) and *Brown v Canada*, 2016 FCA 37 (a case involving section 53 of the *Patent Act* and its interplay with the *Public Servants Inventions Act*).

Affidavit of Peter Wilcox sworn on July 26, 2016, para 16, Tab 2

(ii) The Present Appeal

14. The main issue on this appeal relates to the utility requirement under Canada's *Patent Act*. The outcome of this case will have implications on the prosecution and enforcement of patents in Canada.

PART II – QUESTION IN ISSUE

15. The issue on this motion is whether IPIC should be granted leave to intervene and be permitted to:

- (a) file a factum not exceeding 15 pages; and
- (b) make oral argument at the hearing of this appeal, not exceeding 10 minutes.

PART III – STATEMENT OF ARGUMENT

A. The Law of Intervention

16. In order to be granted leave to intervene before this Court, an applicant must establish that: (1) it has an interest in the appeal; and (2) its submissions will be useful to the Court and different from those of other parties.

Rules of the Supreme Court of Canada, SOR/2002-156, Rule 57

Reference re Workers' Compensation Act, 1983 (Nfld) (Application to Intervene), [1989] 2 SCR 335 at 339

R v Finta, [1993] 1 SCR 1138 at 1142

17. The interest requirement should not be narrowly construed. This Court has held that, subject to its discretion, any interest is sufficient.

Norcan Ltd v Lebrock, [1969] SCR 665 at 666

Reference re Workers' Compensation Act, 1983 (Nfld) (Application to Intervene), [1989] 2 SCR 335 at 339

18. The useful and different requirement has been satisfied where an applicant has a history of involvement in the issue on appeal, giving it expertise which can shed light or provide new information. Intervention is welcomed if the applicant can provide a fresh perspective.

Reference re Workers' Compensation Act, 1983 (Nfld) (Application to Intervene), [1989] 2 SCR 335 at 340

B. IPIC Has an Interest in this Appeal

19. IPIC has an interest in attaining certainty in the utility requirement in Canadian patent law. IPIC's interest in this appeal flows directly from its objectives. IPIC's policy is to intervene in judicial proceedings only when the matter is of compelling public interest or of special significance to the IP profession, and only when IPIC believes that its intervention could make a significant contribution to the Court's consideration of the issues involved. IPIC believes that the present appeal warrants its intervention.

Affidavit of Peter Wilcox sworn on July 26, 2016, paras 16, 22, Tab 2

IPIC's Interest to Represent the Interests of Canadian IP Practitioners

20. IPIC represents IP practitioners across Canada. The outcome of this appeal will have a direct bearing on how IPIC's members advise clients, draft patents, and conduct patent litigation. Certainty in the law of utility is required for patent practitioners to meaningfully advise clients on how to protect and enforce their IP.

Affidavit of Peter Wilcox sworn on July 26, 2016, para 23, Tab 2

IPIC's Interest to Influence the Development of IP Laws

21. IPIC has been involved in the development of IP laws in Canada for decades. IPIC makes submissions to the government on behalf of the interests of IPIC members and their clients. IPIC

was instrumental in getting protection for clients of IP practitioners on privileged communications with their agents by lobbying for Parliament's recent enactment of amendments to the *Patent Act* and *Trade-marks Act*. IPIC's interest in this appeal is to achieve greater certainty and predictability on the law of patent utility in Canada.

Affidavit of Peter Wilcox sworn on July 26, 2016, paras 13-15, Tab 2

IPIC's Interest to Ensure High Levels of Knowledge, Training, and Ethics in Canadian IP Practitioners

22. IPIC has an interest in ensuring that the utility requirement is clarified by courts in a manner that leads to predictable applications. IPIC trains patent agent candidates, provides various continuing education courses to IP practitioners, and publishes a professional peer-reviewed journal and newsletter to disseminate knowledge about IP law and policy in Canada. IPIC relies on predictability and certainty to provide proper training and guidance to its members and the public.

Affidavit of Peter Wilcox sworn on July 26, 2016, paras 17, 18, 24, Tab 2

IPIC's Interest to Increase IP Business in the Canadian Economy

23. One of IPIC's objectives is increasing the level of IP business in the Canadian economy. IPIC believes that this objective is best achieved with a patent system that provides certainty for inventors, patent owners and the public. IPIC previously considered and made submissions to government regarding the patent utility requirement and recommended to the Minister of Industry that Canada's requirements for utility be codified within the *Patent Act* in a way that creates certainty. IPIC believes that a "promise of the patent" doctrine is not necessary to achieve the objectives of the *Patent Act*, as set out in more detail in IPIC's proposed utility framework below.

Affidavit of Peter Wilcox sworn on July 26, 2016, paras 6, 29-33 and Exhibit "C", Tab 2 and 2C

C. IPIC's Proposed Submissions

24. IPIC believes that it is necessary for this Court to set out a framework for assessing patent utility across all types of inventions, rather than only for the patent at issue on this appeal, in order to eliminate the uncertainty in the current state of the law. IPIC has an interest in

establishing a framework that is certain, predictable and is consistent with the object and purpose of the *Patent Act*.

Affidavit of Peter Wilcox sworn on July 26, 2016, para 33, Tab 2

25. If IPIC is granted leave to intervene, it will propose a framework for assessing utility that conforms to the statutory scheme and long-established principles of patent law in the jurisprudence. At a high level, IPIC's proposed framework will have the following components:

- (a) Construction: In each and every case, the Court must construe the claims of the patent purposively from the perspective of a person skilled in the art, as stated in *Free World Trust v Électro Santé Inc*, [2000] 2 SCR 1024 and in *Whirlpool Corp v Camco Inc*, [2000] 2 SCR 1067, *inter alia*.
- (b) Patentability: Once the claims have been construed, the Court must determine whether the subject-matter defined by each claim is patentable and meets the statutory requirements prescribed by the *Patent Act* (*viz.*, statutory subject-matter, new, useful, inventive).
- (c) Utility (Standard): The utility of the subject-matter defined by each claim must then be assessed objectively through the eyes of a person skilled in the art on a claim-by-claim basis. Utility should not be addressed in a different manner than other grounds of validity (*e.g.*, inventiveness, novelty).
- (d) Utility (Level): The subject-matter defined by each claim, as construed in part (a), must be "useful for the purpose claimed", as stated in *Apotex Inc v Wellcome Foundation Limited*, [2002] 4 SCR 153, at paragraphs 54 and 80. If a patent makes a specific statement of utility in the claim, as construed, then this should be the yardstick. By contrast, if no utility is expressly stated in the claim, as construed, then the Court must decide if the subject-matter defined by the claim has a scintilla of utility. This determination should be made by the Court objectively, through the eyes of a person skilled in the art, in light of the common general knowledge and the patent specification as a whole. Excessive literalism and subjectivity should be avoided.

- (e) Utility (Policy): The *Patent Act* must be read and understood in its entirety. The concept of utility should not be used to deal with issues that can and should be addressed by other aspects of the *Act* (e.g., inventiveness, novelty, sufficiency, fraud, etc.). There is no need for a “promise of the patent” doctrine to achieve the aims of patent law and the object and purpose intended by Parliament.

Affidavit of Peter Wilcox sworn on July 26, 2016, para 33, Tab 2

26. IPIC believes that its proposed framework will restore certainty to Canada’s patent system by focussing the utility requirement on the invention as claimed, rather than searching for statements of so-called “promised” utility in a patent’s disclosure. This approach is consistent with the object and purpose of the *Patent Act* and the jurisprudence of this Court over the last 15 years, which has consistently affirmed the importance of the claims to any assessment of validity and infringement.

Affidavit of Peter Wilcox sworn on July 26, 2016, paras 33, 35, 37, Tab 2

D. IPIC’s Proposed Submissions Are Useful and Different

27. IPIC can shed fresh light on the issues in this appeal. IPIC’s submissions will be useful as it is a well-recognized authority on Canadian IP law. IPIC makes recommendations to government departments and agencies regarding IP-related matters, promotes changes to the legislative and regulatory IP frameworks, participates in joint committees with CIPO and the Federal Court, and intervenes in appropriate judicial proceedings.

Affidavit of Peter Wilcox sworn on July 26, 2016, para 34, Tab 2

28. IPIC has the expertise and experience in Canadian patent law to assist this Court in understanding the utility requirement, how the requirement fits into the overall statutory scheme, and how it can and ought to be applied in light of the relevant jurisprudence. IPIC has been instrumental in shaping the framework of Canadian patent law and has the ability to bring this Court a truly different, informed and unbiased perspective. IPIC has made recommendations to government about the utility requirement in particular.

Affidavit of Peter Wilcox sworn on July 26, 2016, paras 34, 37, Tab 2

29. IPIC's proposed submissions will be useful because IPIC possesses a unique awareness and understanding of the concerns and interests of Canadian patent agents and patent lawyers practising in all areas of industry. If granted leave to intervene, IPIC will assist this Court in developing a utility framework that is objective, workable, consistent and predictable.

Affidavit of Peter Wilcox sworn on July 26, 2016, para 35, Tab 2

30. IPIC's submissions will be different from those of the current parties. IPIC will provide a fresh and objective perspective on the issues arising from its mandate to represent the interests of Canadian IP practitioners. The current parties to this appeal have a particular interest and position in regard to the validity of the patent in suit. On the other hand, IPIC has no interest in the outcome of this case. IPIC's submissions will be geared toward attaining certainty in this area of the law for patents in all areas of technology.

Affidavit of Peter Wilcox sworn on July 26, 2016, paras 35-38, Tab 2

31. The parties to this appeal are focused on the utility requirement as it relates to pharmaceutical patents. At the broadest level, their arguments represent the perspectives of brand name and generic pharmaceutical companies. On the other hand, IPIC represents IP practitioners who advise clients in a wide-range of industries. IPIC will help this Court understand the utility requirement, and will provide a unique and unbiased perspective about how to achieve certainty and predictability in the law for patents from all areas of industry and technology.

Affidavit of Peter Wilcox sworn on July 26, 2016, paras 35-36, Tab 2

32. IPIC will not take a position on how the Canadian utility requirement compares to the law in other jurisdictions and whether or not the law is aligned with Canada's treaty obligations.

Affidavit of Peter Wilcox sworn on July 26, 2016, para 38, Tab 2

33. In the absence of IPIC's intervention, this Court will be left without a truly objective Canadian perspective on the issues, which would be prejudicial to IPIC given the importance of the issues to its members.

Affidavit of Peter Wilcox sworn on July 26, 2016, para 39, Tab 2

PART IV – SUBMISSIONS ON COSTS

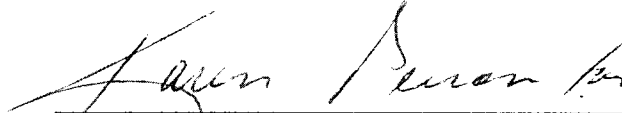
34. IPIC does not claim costs in respect of its motion for leave to intervene on the present appeal, and asks that no costs be awarded against it.

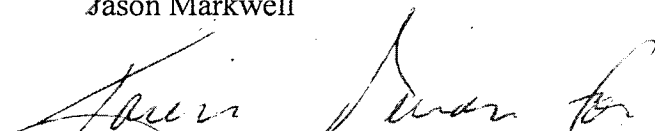
PART V – ORDER SOUGHT

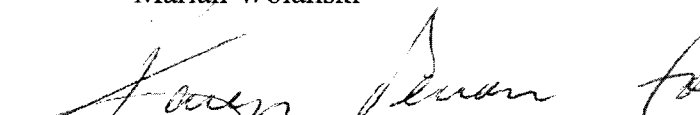
35. IPIC respectfully requests an Order granting it leave to intervene on the present appeal on the following terms:

- (a) that IPIC be permitted to file a factum not exceeding 15 pages; and
- (b) that IPIC be permitted to make oral argument at the hearing of this appeal, not exceeding 10 minutes.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 29 day of July, 2016.


Jason Markwell


Marian Wolanski


Stefanie Di Giandomenico

Belmore Neidrauer LLP

Counsel for the Proposed Intervener, Intellectual
Property Institute of Canada / Institut de la
Propriété Intellectuelle du Canada

PART VI – TABLE OF AUTHORITIES

NO	AUTHORITY	PARAGRAPH(S)
1.	<i>Apotex Inc. v Wellcome Foundation Limited</i> , [2002] 4 S.C.R. 153	25(d)
2.	<i>Brown v Canada</i> , 2016 FCA 37	13
3.	<i>Dutch Industries Ltd v Barton No-Till Disk Inc</i> , 2003 FCA 121	13
4.	<i>Free World Trust v Électro Santé Inc.</i> , [2000] 2 S.C.R. 1024	25(a)
5.	<i>Norcan Ltd v Lebrock</i> , [1969] SCR 665	17
6.	<i>Reference re Workers' Compensation Act, 1983 (Nfld)</i> , [1989] 2 SCR 335	16, 17, 18
7.	<i>R v Finta</i> , [1993] 1 SCR 1138	16
8.	<i>Weatherford Canada Ltd v Corlac Inc</i> , 2011 FCA 228	13
9.	<i>Whirlpool Corp. v Camco Inc.</i> , [2000] 2 SCR 1067	25(a)

PART VII – RELEVANT STATUTES

Rules of the Supreme Court of Canada, SOR/2002-156, Rule 57

<p>57 (1) The affidavit in support of a motion for intervention shall identify the person interested in the proceeding and describe that person's interest in the proceeding, including any prejudice that the person interested in the proceeding would suffer if the intervention were denied.</p>	<p>57 (1) L'affidavit à l'appui de la requête en intervention doit préciser l'identité de la personne ayant un intérêt dans la procédure et cet intérêt, y compris tout préjudice que subirait cette personne en cas de refus de l'autorisation d'intervenir.</p>
<p>(2) A motion for intervention shall</p> <p>(a) identify the position the person interested in the proceeding intends to take with respect to the questions on which they propose to intervene; and</p> <p>(b) set out the submissions to be advanced by the person interested in the proceeding with respect to the questions on which they propose to intervene, their relevance to the proceeding and the reasons for believing that the submissions will be useful to the Court and different from those of the other parties.</p> <p>SOR/2013-175, s. 38.</p>	<p>(2) La requête expose ce qui suit :</p> <p>a) la position que cette personne compte prendre relativement aux questions visées par son intervention;</p> <p>b) ses arguments relativement aux questions visées par son intervention, leur pertinence par rapport à la procédure et les raisons qu'elle a de croire qu'ils seront utiles à la Cour et différents de ceux des autres parties.</p> <p>DORS/2013-175, art. 38.</p>



CANADA

CONSOLIDATION

CODIFICATION

Patent Act

Loi sur les brevets

R.S.C., 1985, c. P-4

L.R.C. (1985), ch. P-4

Current to June 6, 2016

À jour au 6 juin 2016

Last amended on June 17, 2015

Dernière modification le 17 juin 2015

OFFICIAL STATUS OF CONSOLIDATIONS

Subsections 31(1) and (2) of the *Legislation Revision and Consolidation Act*, in force on June 1, 2009, provide as follows:

Published consolidation is evidence

31 (1) Every copy of a consolidated statute or consolidated regulation published by the Minister under this Act in either print or electronic form is evidence of that statute or regulation and of its contents and every copy purporting to be published by the Minister is deemed to be so published, unless the contrary is shown.

Inconsistencies in Acts

2) In the event of an inconsistency between a consolidated statute published by the Minister under this Act and the original statute or a subsequent amendment as certified by the Clerk of the Parliaments under the *Publication of Statutes Act*, the original statute or amendment prevails to the extent of the inconsistency.

NOTE

This consolidation is current to June 6, 2016. The last amendments came into force on June 17, 2015. Any amendments that were not in force as of June 6, 2016 are set out at the end of this document under the heading "Amendments Not in Force".

CARACTÈRE OFFICIEL DES CODIFICATIONS

Les paragraphes 31(1) et (2) de la *Loi sur la révision et la codification des textes législatifs*, en vigueur le 1^{er} juin 2009, prévoient ce qui suit :

Codifications comme élément de preuve

31 (1) Tout exemplaire d'une loi codifiée ou d'un règlement codifié, publié par le ministre en vertu de la présente loi sur support papier ou sur support électronique, fait foi de cette loi ou de ce règlement et de son contenu. Tout exemplaire donné comme publié par le ministre est réputé avoir été ainsi publié, sauf preuve contraire.

Incompatibilité — lois

(2) Les dispositions de la loi d'origine avec ses modifications subséquentes par le greffier des Parlements en vertu de la *Loi sur la publication des lois* l'emportent sur les dispositions incompatibles de la loi codifiée publiée par le ministre en vertu de la présente loi.

NOTE

Cette codification est à jour au 6 juin 2016. Les dernières modifications sont entrées en vigueur le 17 juin 2015. Toutes modifications qui n'étaient pas en vigueur au 6 juin 2016 sont énoncées à la fin de ce document sous le titre « Modifications non en vigueur ».

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R.S.C., 1985, c. P-4

L.R.C., 1985, ch. P-4

Patent Act respecting patents of invention

Loi concernant les brevets d'invention

Short Title

Titre abrégé

Short title

This Act may be cited as the *Patent Act*.

S., c. P-4, s. 1.

Titre abrégé

1 *Loi sur les brevets*.

S.R., ch. P-4, art. 1.

Interpretation

Définitions

Définitions

In this Act, except as otherwise provided,

Définitions

2 Sauf disposition contraire, les définitions qui suivent s'appliquent à la présente loi.

applicant includes an inventor and the legal representatives of an applicant or inventor; (*demandeur*)

brevet Lettres patentes couvrant une invention. (*patent*)

claim date means the date of a claim in an application for a patent in Canada, as determined in accordance with section 28.1;

breveté ou **titulaire d'un brevet** Le titulaire ayant pour le moment droit à l'avantage d'un brevet. (*patentee*)

Commissioner means the Commissioner of Patents; (*commissaire*)

commissaire Le commissaire aux brevets. (*Commissioner*)

country includes a Member of the World Trade Organization, as defined in subsection 2(1) of the *World Trade Organization Agreement Implementation Act*; (*pays*)

date de dépôt La date du dépôt d'une demande de brevet, déterminée conformément à l'article 28. (*filing date*)

filing date means, in relation to an application for a patent in Canada, the date on which the application is filed, as determined in accordance with section 28; (*date de dépôt*)

date de priorité [Abrogée, 1993, ch. 15, art. 26]

demande de priorité La demande visée à l'article 28.4. (*request for priority*)

invention means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter; (*invention*)

demandeur Sont assimilés à un demandeur un inventeur et les représentants légaux d'un demandeur ou d'un inventeur. (*applicant*)

legal representatives includes heirs, executors, administrators, guardians, curators, tutors, assigns and all other persons claiming through or under applicants for patents and patentees of inventions; (*représentants légaux*)

exploitation sur une échelle commerciale [Abrogée, 1993, ch. 44, art. 189]

invention Toute réalisation, tout procédé, toute machine, fabrication ou composition de matières, ainsi que tout perfectionnement de l'un d'eux, présentant le caractère de la nouveauté et de l'utilité. (*invention*)

Minister means the Minister of Industry or such other member of the Queen's Privy Council for Canada as is designated by the Governor in Council as the Minister for the purposes of this Act; (*ministre*)

patent means letters patent for an invention; (*brevet*)

patentee means the person for the time being entitled to the benefit of a patent; (*breveté ou titulaire d'un brevet*)

predecessor in title includes any person through whom an applicant for a patent in Canada claims the right to the patent; (*prédécesseur en droit*)

prescribed means prescribed by rules or regulations of the Governor in Council and, in the case of a fee, includes a fee determined in the manner prescribed; (*réglementaire*)

prescribed fee [Repealed, R.S., 1985, c. 33 (3rd Supp.), s. 1]

priority date [Repealed, 1993, c. 15, s. 26]

regulation and rule include rule, regulation and form; (*règlement et règle*)

request for priority means a request under section 28.4. (*demande de priorité*)

work on a commercial scale [Repealed, 1993, c. 44, s. 89]

S., 1985, c. P-4, s. 2; R.S., 1985, c. 33 (3rd Supp.), s. 1; 1992, c. 1, s. 145(F); 1993, c. 2, s. 15, s. 26, c. 44, s. 189; 1994, c. 47, s. 141; 1995, c. 1, s. 62.

Her Majesty

Binding on Her Majesty

2.1 This Act is binding on Her Majesty in right of Canada or a province.

1993, c. 44, s. 190.

Patent Office and Officers

Patent Office

There shall be attached to the Department of Industry, or to such other department of the Government of Canada as may be determined by the Governor in Council, an office called the Patent Office.

S., 1985, c. P-4, s. 3; 1992, c. 1, s. 145(F); 1995, c. 1, s. 63.

ministre Le ministre de l'Industrie ou tel autre membre du Conseil privé de la Reine pour le Canada chargé par le gouverneur en conseil de l'application de la présente loi. (*Minister*)

pays Notamment un membre de l'Organisation mondiale du commerce au sens du paragraphe 2(1) de la *Loi de mise en œuvre de l'Accord sur l'Organisation mondiale du commerce*. (*country*)

prédécesseur en droit Est assimilée à un prédécesseur en droit toute personne par l'intermédiaire de laquelle le demandeur de brevet réclame le droit à celui-ci. (*predecessor in title*)

règlement et règle S'entendent notamment d'une formule. (*regulation and rule*)

réglementaire Prescrit par règle ou règlement du gouverneur en conseil; dans le cas où le terme qualifie une taxe, s'entend en outre d'une taxe dont le montant est déterminé selon les modalités réglementaires. (*prescribed*)

représentants légaux Sont assimilés aux représentants légaux les héritiers, exécuteurs testamentaires, administrateurs, gardiens, curateurs, tuteurs, ayants droit, ainsi que toutes autres personnes réclamant par l'intermédiaire ou à la faveur de demandeurs et de titulaires de brevets. (*legal representatives*)

taxe réglementaire [Abrogée, L.R. (1985), ch. 33 (3^e suppl.), art. 1]

L.R. (1985), ch. P-4, art. 2; L.R. (1985), ch. 33 (3^e suppl.), art. 1; 1992, ch. 1, art. 145(F); 1993, ch. 2, art. 2, ch. 15, art. 26, ch. 44, art. 189; 1994, ch. 47, art. 141; 1995, ch. 1, art. 62.

Sa Majesté

Obligation de Sa Majesté

2.1 La présente loi lie Sa Majesté du chef du Canada ou d'une province.

1993, ch. 44, art. 190.

Bureau des brevets et fonctionnaires

Bureau des brevets

3 Est attaché au ministère de l'Industrie, ou à tout autre ministère fédéral que le gouverneur en conseil peut désigner, un bureau appelé le Bureau des brevets.

L.R. (1985), ch. P-4, art. 3; 1992, ch. 1, art. 145(F); 1995, ch. 1, art. 63.

Commissioner of Patents

(1) The Governor in Council may appoint a Commissioner of Patents who shall, under the direction of the Minister, exercise the powers and perform the duties conferred and imposed on that officer by or pursuant to this Act.

Duties of Commissioner

(1) The Commissioner shall receive all applications, fees, papers, documents and models for patents, shall perform and do all acts and things requisite for the granting and issuing of patents of invention, shall have the charge and custody of the books, records, papers, models, machines and other things belonging to the Patent Office and shall have, for the purposes of this Act, all the powers that are or may be given by the *Inquiries Act* to a commissioner appointed under Part II of that Act.

Term of office and salary

(1) The Commissioner holds office during pleasure and shall be paid such annual salary as may be determined by the Governor in Council.

Delegation

(1) The Commissioner may, after consultation with the Minister, delegate to any person he deems qualified any of his powers, duties and functions under this Act, except the power to delegate under this subsection.

Appeal

(1) Any decision under this Act of a person authorized to make the decision pursuant to subsection (4) may be appealed in the like manner and subject to the like conditions as a decision of the Commissioner under this Act.

S., c. P-4, s. 4; 1984, c. 40, s. 57.

Assistant Commissioner

(1) An Assistant Commissioner of Patents may be appointed in the manner authorized by law and shall be a technical officer experienced in the administration of the Patent Office.

Absence or inability to act

(2) When the Commissioner is absent or unable to act, the Assistant Commissioner, or, if he also is at the same time absent or unable to act, another officer designated by the Minister, may exercise the powers and shall perform the duties of the Commissioner.

S., c. P-4, s. 5.

Commissaire aux brevets

(1) Le gouverneur en conseil peut nommer un commissaire aux brevets. Sous la direction du ministre, celui-ci exerce les pouvoirs et fonctions qui lui sont attribués en conformité avec la présente loi.

Fonctions du commissaire

(2) Le commissaire reçoit les demandes, taxes, pièces écrites, documents et modèles pour brevets, fait et exécute tous les actes et choses nécessaires pour la concession et la délivrance des brevets; il assure la direction et la garde des livres, archives, pièces écrites, modèles, machines et autres choses appartenant au Bureau des brevets, et, pour l'application de la présente loi, est revêtu de tous les pouvoirs conférés ou qui peuvent être conférés par la *Loi sur les enquêtes* à un commissaire nommé en vertu de la partie II de cette loi.

Occupation de poste et traitement

(3) Le commissaire occupe son poste à titre amovible et reçoit le traitement annuel fixé par le gouverneur en conseil.

Délégation

(4) Le commissaire peut, après consultation avec le ministre, déléguer à toute personne qu'il estime compétente les pouvoirs et fonctions que lui confère la présente loi, sauf le pouvoir de déléguer prévu au présent paragraphe.

Appel

(5) Il peut être interjeté appel d'une décision prise en vertu de la présente loi par une personne autorisée conformément au paragraphe (4) de la façon dont il peut être interjeté appel d'une décision du commissaire prise en vertu de la présente loi, et aux mêmes conditions.

S.R., ch. P-4, art. 4; 1984, ch. 40, art. 57.

Sous-commissaire

(1) Un sous-commissaire aux brevets peut être nommé de la manière autorisée par la loi. Il doit être un fonctionnaire spécialiste possédant de l'expérience dans l'administration du Bureau des brevets.

Absence ou empêchement

(2) En cas d'absence ou d'empêchement du commissaire, le sous-commissaire, ou, en cas d'absence ou d'empêchement de celui-ci, un autre fonctionnaire désigné par le ministre, exerce les pouvoirs et fonctions du commissaire.

S.R., ch. P-4, art. 5.

Staff

There may be appointed in the manner authorized by law such principal examiners, examiners, associate examiners and assistant examiners, clerks, stenographers and other assistants as are necessary for the administration of this Act.

S., c. P-4, s. 6.

Officers of Patent Office not to deal in patents

(1) No officer or employee of the Patent Office shall buy, sell, acquire or traffic in any invention, patent or right to a patent, or any interest therein, and every purchase, sale, assignment, acquisition or transfer of any invention, patent or right to a patent, or any interest therein, made by or to any officer or employee is void.

Restriction

(2) Subsection (1) does not apply to a sale by an original inventor or to an acquisition under the last will, or by the testacy, of a deceased person.

S., c. P-4, s. 7.

Clerical errors

Clerical errors in any instrument of record in the Patent Office do not invalidate the instrument, but they may be corrected under the authority of the Commissioner.

S., 1985, c. P-4, s. 8; 1993, c. 15, s. 27.

Electronic or other submission of documents, information or fees

8.1 (1) Subject to the regulations, any document, information or fee that is authorized or required to be submitted to the Commissioner under this Act may be submitted in electronic or other form in any manner specified by the Commissioner.

Time of receipt

(2) For the purposes of this Act, any document, information or fee submitted in accordance with subsection (1) is deemed to be received by the Commissioner at the time provided by the regulations.

1993, c. 15, s. 27.

Storage of documents or information in electronic or other form

8.2 Subject to the regulations, any document or information received by the Commissioner under this Act in electronic or other form may be entered or recorded by any information storage device, including any system of mechanical or electronic data processing, that is capable

Personnel

6 Sont nommés, de la manière autorisée par la loi, les examinateurs principaux, les examinateurs, les examinateurs associés, les examinateurs adjoints et les autres personnes nécessaires à l'application de la présente loi.

S.R., ch. P-4, art. 6.

Le personnel du Bureau ne peut acheter ou vendre des brevets

7 (1) Il est interdit au personnel du Bureau des brevets d'acheter, de vendre ou d'acquérir une invention, un brevet ou un droit à un brevet, ou tout intérêt y afférent, ou d'en faire le commerce. Est nul tout achat, vente, cession, acquisition ou transport d'une invention, d'un brevet, d'un droit à un brevet, ou de tout intérêt y afférent, auquel est partie un membre du personnel du Bureau.

Restriction

(2) Le paragraphe (1) ne s'applique pas à une vente effectuée par l'auteur original d'une invention, ni à une acquisition par dernier testament ou par succession ab intestat d'une personne décédée.

S.R., ch. P-4, art. 7.

Erreurs d'écriture

8 Un document en dépôt au Bureau des brevets n'est pas invalide en raison d'erreurs d'écriture; elles peuvent être corrigées sous l'autorité du commissaire.

L.R. (1985), ch. P-4, art. 8; 1993, ch. 15, art. 27.

Transmission électronique

8.1 (1) Sous réserve des règlements, les documents, renseignements ou taxes dont la présente loi exige ou autorise la remise au commissaire peuvent lui être transmis sous forme électronique ou autre, de la manière qu'il précise.

Date de réception

(2) Pour l'application de la présente loi, les documents, renseignements ou taxes ainsi transmis sont réputés avoir été reçus par le commissaire au moment déterminé par règlement.

1993, ch. 15, art. 27.

Mise en mémoire

8.2 Sous réserve des règlements, les documents ou renseignements reçus par le commissaire, en application de la présente loi, sous forme électronique ou autre, peuvent

reproducing stored documents or information in intelligible form within a reasonable time.

33, c. 15, s. 27.

Destroyed or lost patents

If any patent is destroyed or lost, a certified copy may be issued in lieu thereof on payment of the prescribed fee.

S., c. P-4, s. 9.

Inspection by the public

10 (1) Subject to subsections (2) to (6) and section 20, all patents, applications for patents and documents filed in connection with patents or applications for patents shall be open to public inspection at the Patent Office, under such conditions as may be prescribed.

Confidentiality period

(2) Except with the approval of the applicant, an application for a patent, or a document filed in connection with the application, shall not be open to public inspection before a confidentiality period of eighteen months has expired.

Beginning of confidentiality period

(3) The confidentiality period begins on the filing date of the application or, where a request for priority has been made in respect of the application, it begins on the earliest filing date of any previously regularly filed application in which the request is based.

Withdrawal of request

(4) Where a request for priority is withdrawn on or before the prescribed date, it shall, for the purposes of subsection (3) and to the extent that it is withdrawn, be considered never to have been made.

Withdrawn applications

(5) An application shall not be open to public inspection if it is withdrawn in accordance with the regulations on or before the prescribed date.

Prescribed date

(6) A prescribed date referred to in subsection (4) or (5) must be no later than the date on which the confidentiality period expires.

S., 1985, c. P-4, s. 10; R.S., 1985, c. 33 (3rd Supp.), s. 2; 1993, c. 15, s. 28.

Patents issued out of Canada

11 Notwithstanding the exception in section 10, the Commissioner, on the request of any person who states

être mis en mémoire par tout procédé, notamment mécanographique ou informatique, susceptible de les restituer en clair dans un délai raisonnable.

1993, ch. 15, art. 27.

Perte ou destruction de brevets

9 En cas de destruction ou de perte d'un brevet, il peut en être délivré une copie certifiée, en remplacement du brevet qui aura été détruit ou perdu, sur paiement de la taxe réglementaire.

S.R., ch. P-4, art. 9.

Consultation des documents

10 (1) Sous réserve des paragraphes (2) à (6) et de l'article 20, les brevets, demandes de brevet et documents relatifs à ceux-ci, déposés au Bureau des brevets, peuvent y être consultés aux conditions réglementaires.

Période de non-consultation

(2) Sauf sur autorisation du demandeur, une demande de brevet et les documents relatifs à celle-ci ne peuvent être consultés avant l'expiration d'une période de dix-huit mois.

Calcul de la période

(3) La période se calcule à compter de la date de dépôt de la demande de brevet ou, si une demande de priorité a été présentée à l'égard de celle-ci, de la date de dépôt de la première demande antérieurement déposée de façon régulière sur laquelle la demande de priorité est fondée.

Demande de priorité retirée

(4) Pour l'application du paragraphe (3), le retrait total ou partiel d'une demande de priorité, au plus tard à la date réglementaire, vaut présomption de non-présentation de la demande.

Demande de brevet retirée

(5) La demande de brevet qui est retirée, conformément aux règlements, à la date réglementaire ou avant celle-ci ne peut être consultée.

Dates

(6) Les dates réglementaires visées aux paragraphes (4) et (5) ne peuvent être postérieures à la date de l'expiration de la période visée au paragraphe (2).

L.R. (1985), ch. P-4, art. 10; L.R. (1985), ch. 33 (3^e suppl.), art. 2; 1993, ch. 15, art. 28.

Brevets délivrés à l'étranger

11 Nonobstant l'exception que renferme l'article 10, le commissaire informe toute personne qui déclare par écrit

...writing the name of the inventor, if available, the title of the invention and the number and date of a patent said to have been granted in a named country other than Canada, and who pays or tenders the prescribed fee, shall inform that person whether an application for a patent of the same invention is or is not pending in Canada.

S., c. P-4, s. 11.

Rules and Regulations

Rules and regulations

2 (1) The Governor in Council may make rules or regulations

- (a) respecting the form and contents of applications for patents;
- (b) respecting the form of the Register of Patents and of the indexes thereto;
- (c) respecting the registration of assignments, transmissions, disclaimers, judgments or other documents relating to any patent;
- (d) respecting the form and contents of any certificate issued pursuant to this Act;
- (e) prescribing the fees or the manner of determining the fees that may be charged in respect of the filing of applications for patents or the taking of other proceedings under this Act or under any rule or regulation made pursuant to this Act, or in respect of any services or the use of any facilities provided thereunder by the Commissioner or any person employed in the Patent Office;
- (f) prescribing the fees or the manner of determining the fees that shall be paid to maintain in effect an application for a patent or to maintain the rights accorded by a patent;
- (g) respecting the payment of any prescribed fees including the time when and the manner in which such fees shall be paid, the additional fees that may be charged for the late payment of such fees and the circumstances in which any fees previously paid may be refunded in whole or in part;
- (h) for carrying into effect the terms of any treaty, convention, arrangement or engagement that subsists between Canada and any other country;
- (i) for carrying into effect, notwithstanding anything in this Act, the Patent Cooperation Treaty done at

le nom de l'inventeur, si ce nom est disponible, le titre de l'invention ainsi que le numéro et la date d'un brevet rapporté comme ayant été accordé dans un pays désigné autre que le Canada, et qui acquitte ou offre d'acquitter la taxe réglementaire, si une demande de brevet pour la même invention est en instance au Canada.

S.R., ch. P-4, art. 11.

Règles et règlements

Règles et règlements

12 (1) Le gouverneur en conseil peut, par règle ou règlement :

- a) prévoir la forme et le contenu des demandes de brevet;
- b) prévoir la forme du registre des brevets et de ses index;
- c) prévoir l'enregistrement de tous documents — cessions, transmissions, renonciations, jugements ou autres — relatifs à un brevet;
- d) prévoir la forme et le contenu des certificats délivrés sous le régime de la présente loi;
- e) prescrire les taxes qui peuvent être levées pour le dépôt des demandes de brevet ou les autres formalités d'application de la présente loi ou de ses règles ou règlements ou pour des services ou l'utilisation d'installations qui y sont prévus par le commissaire ou par tout fonctionnaire du Bureau des brevets ou prescrire les modalités de la détermination de ces taxes;
- f) prescrire les taxes à payer pour le maintien en état des demandes de brevet ainsi que des droits conférés par les brevets ou les modalités de leur détermination;
- g) prévoir le paiement des taxes réglementaires, y compris le moment et la manière selon laquelle ces taxes doivent être payées, les surtaxes qui peuvent être levées pour les paiements en souffrance, ainsi que les circonstances dans lesquelles les taxes peuvent être remboursées en tout ou en partie;
- h) rendre effectives les stipulations de tout traité, convention, accord ou entente qui subsiste entre le Canada et tout autre pays;
- i) par dérogation aux autres dispositions de la présente loi, mettre en œuvre le Traité de coopération en matière de brevets, conclu à Washington le 19 juin 1970, ainsi que les modifications et révisions éventuellement apportées à celui-ci et auxquelles le Canada est partie;

Washington on June 19, 1970, including any amendments, modifications and revisions made from time to time to which Canada is a party;

(j) respecting the entry on, the maintenance of and the removal from the register of patent agents of the names of persons and firms, including the qualifications that must be met and the conditions that must be fulfilled by a person or firm before the name of the person or firm is entered thereon and to maintain the name of the person or firm on the register;

(j.1) respecting the submission of documents, information or fees under section 8.1, including

(i) the documents, information or fees that may be submitted in electronic or other form under that section,

(ii) the persons or classes of persons by whom they may be submitted, and

(iii) the time at which they are deemed to be received by the Commissioner;

(j.2) respecting the entering or recording of any document or information under section 8.2;

(j.3) prescribing the manner in which an application for a patent may be withdrawn and, for the purposes of subsections 10(4) and (5), prescribing the date, or the manner of determining the date, on or before which a request for priority or an application for a patent must be withdrawn;

(j.4) respecting requests for priority, including

(i) the period within which priority must be requested,

(ii) the manner in which and period within which the Commissioner must be informed of the matters referred to in subsection 28.4(2),

(iii) the documentation that must be filed in support of requests for priority, and

(iv) the withdrawal of requests for priority;

(j.5) respecting the time within which requests for examination must be made and prescribed fees must be paid under subsection 35(1);

(j.6) respecting the deposit of biological material for the purposes of section 38.1;

j) prévoir l'inscription, le maintien et la suppression des noms de personne et d'entreprise dans le registre des agents de brevets, et notamment les conditions que doit remplir toute personne ou entreprise pour que son nom soit ainsi inscrit et maintenu;

j.1) régir la transmission des documents, renseignements et taxes visés à l'article 8.1, notamment en déterminant ceux qui peuvent être remis au titre du paragraphe 8.1(1), les personnes ou catégories de personnes habilitées à cet effet et les règles d'application du paragraphe 8.1(2);

j.2) régir la mise en mémoire des renseignements et documents visés à l'article 8.2;

j.3) déterminer les modalités de retrait des demandes de brevet et, pour l'application des paragraphes 10(4) et (5), préciser les dates, ou leur mode de détermination, de retrait des demandes de priorité et des demandes de brevet;

j.4) régir les demandes de priorité, notamment en ce qui a trait à leur délai de présentation, aux renseignements et documents à fournir à l'appui de celles-ci, au délai de transmission au commissaire de ces renseignements et documents ainsi qu'au retrait de ces demandes;

j.5) déterminer le délai de présentation des requêtes d'examen et fixer les taxes à payer aux termes du paragraphe 35(1);

j.6) régir le dépôt de matières biologiques visé à l'article 38.1;

j.7) déterminer les modalités de modification des mémoires descriptifs et des dessins faisant partie de la demande de brevet;

j.8) autoriser le commissaire, si celui-ci estime que les circonstances le justifient, à proroger, aux conditions réglementaires, tout délai fixé par la présente loi ou en vertu de celle-ci pour l'accomplissement d'un acte;

k) prendre toute autre mesure d'ordre réglementaire prévue par la présente loi;

l) prendre toute autre mesure d'application de la présente loi ou pour en assurer la mise en œuvre par le commissaire et le personnel du Bureau des brevets.

(j.7) respecting the manner in which amendments may be made to specifications or drawings furnished as part of an application for a patent;

(j.8) authorizing the Commissioner to extend, subject to any prescribed terms and conditions, the time fixed by or under this Act for doing anything where the Commissioner is satisfied that the circumstances justify the extension;

(k) prescribing any other matter that by any provision of this Act is to be prescribed; and

(l) generally, for carrying into effect the objects and purposes of this Act or for ensuring the due administration thereof by the Commissioner and other officers and employees of the Patent Office.

Effect

(1) Any rule or regulation made by the Governor in Council has the same force and effect as if it had been enacted herein.

S., 1985, c. P-4, s. 12; R.S., 1985, c. 33 (3rd Suppl.), s. 3; 1993, c. 15, s. 29.

Seal

Seal of office

3 (1) The Commissioner shall cause a seal to be made for the purposes of this Act and may cause to be sealed herewith every patent and other instrument and copy thereof issuing from the Patent Office.

Seal to be evidence

(1) Every court, judge and person shall take notice of the seal of the Patent Office, shall admit the impressions thereof in evidence in like manner as the impressions of the Great Seal are admitted in evidence and shall take notice of and admit in evidence, without further proof and without production of the originals, all copies or extracts certified under the seal of the Patent Office to be copies of or extracts from documents deposited in that office.

S., c. P-4, s. 13.

Proof of Patents

Certified copies of patents as evidence

4 In any action or proceeding respecting a patent authorized to be had or taken in Canada under this Act, a copy of any patent granted in any other country, or any official document connected therewith, purporting to be certified under the hand of the proper officer of the government of the country in which the patent has been

Effet

(2) Toute règle ou tout règlement pris par le gouverneur en conseil a la même force et le même effet que s'il avait été édicté aux présentes.

L.R. (1985), ch. P-4, art. 12; L.R. (1985), ch. 33 (3^e suppl.), art. 3; 1993, ch. 15, art. 29.

Sceau

Sceau du Bureau

13 (1) Le commissaire fait faire un sceau répondant aux fins de la présente loi, et peut le faire apposer sur tous les brevets et autres documents, et leurs copies, émanant du Bureau des brevets.

Le sceau fait foi

(2) Les tribunaux, juges et autres personnes admettent d'office le sceau du Bureau des brevets et en admettent les empreintes en preuve, au même titre que les empreintes du grand sceau. Il en va de même, sans autre justification et sans production des originaux, pour toutes les copies ou tous les extraits certifiés, sous le sceau du Bureau des brevets, être des copies ou des extraits conformes de documents déposés à ce Bureau.

S.R., ch. P-4, art. 13.

Preuve des brevets

Copies certifiées de brevets admises en preuve

14 Dans toute poursuite ou procédure relative à un brevet, autorisée à être prise ou exercée au Canada en vertu de la présente loi, une copie de tout brevet accordé dans un autre pays, ou de tout document officiel qui s'y rapporte, paraissant certifiée de la main du fonctionnaire compétent du gouvernement du pays dans lequel ce

obtained, may be produced before the court or a judge thereof, and the copy of the patent or document purporting to be so certified may be admitted in evidence without production of the original and without proof of the signature or official character of the person appearing to have signed it.

S., c. P-4, s. 14.

Patent Agents

Register of patent agents

5 A register of patent agents shall be kept in the Patent Office on which shall be entered the names of all persons and firms entitled to represent applicants in the presentation and prosecution of applications for patents or in their business before the Patent Office.

S., 1985, c. P-4, s. 15; R.S., 1985, c. 33 (3rd Suppl.), s. 4.

Misconduct

6 For gross misconduct or any other cause that he may deem sufficient, the Commissioner may refuse to recognize any person as a patent agent or attorney either generally or in any particular case.

S., c. P-4, s. 16.

Appeals

Practice on appeals

7 In all cases where an appeal is provided from the decision of the Commissioner to the Federal Court under this Act, the appeal shall be had and taken pursuant to the *Federal Courts Act* and the rules and practice of that court.

S., 1985, c. P-4, s. 17; 2002, c. 8, s. 182.

Notice on appeal

8 (1) Whenever an appeal to the Federal Court from the decision of the Commissioner is permitted under this Act, notice of the decision shall be mailed by the Commissioner by registered letter addressed to the interested parties or their respective agents.

Time for taking appeal

(2) The appeal shall be taken within three months after the date of mailing of the notice, unless otherwise provided by or under this Act.

S., 1985, c. P-4, s. 18; 1993, c. 15, s. 30.

brevet a été obtenu, peut être produite au tribunal, ou à un juge du tribunal, et la copie de ce brevet ou de ce document paraissant être ainsi certifiée peut être admise en preuve sans production de l'original et sans justification de la signature ou du caractère officiel de la personne qui paraît l'avoir signée.

S.R., ch. P-4, art. 14.

Agents de brevets

Registre des agents de brevets

15 Au Bureau des brevets est tenu un registre des agents de brevets sur lequel sont inscrits les noms de toutes les personnes et entreprises ayant le droit de représenter les demandeurs dans la présentation et la poursuite des demandes de brevet ou dans toute autre affaire devant le Bureau des brevets.

L.R. (1985), ch. P-4, art. 15; L.R. (1985), ch. 33 (3^e suppl.), art. 4.

Inconduite

16 Pour inconduite grossière, ou pour toute autre cause qu'il juge suffisante, le commissaire peut refuser de reconnaître une personne comme procureur ou agent de brevets, soit dans tous les cas en général, soit dans un cas particulier.

S.R., ch. P-4, art. 16.

Appels

Pratique d'appel

17 Dans tous les cas où appel est prévu de la décision du commissaire à la Cour fédérale en vertu de la présente loi, cet appel est interjeté conformément à la *Loi sur les Cours fédérales* et aux règles et à la pratique de ce tribunal.

L.R. (1985), ch. P-4, art. 17; 2002, ch. 8, art. 182.

Avis d'appel

18 (1) Lorsque, aux termes de la présente loi, il peut être fait appel de sa décision devant la Cour fédérale, le commissaire adresse, par courrier recommandé, un avis de sa décision aux parties intéressées ou à leurs agents respectifs.

Délai

(2) L'appel doit être interjeté dans un délai de trois mois à compter de la date de l'envoi de cet avis, à moins qu'un autre délai ne soit fixé sous le régime de la présente loi.

L.R. (1985), ch. P-4, art. 18; 1993, ch. 15, art. 30.

Use of Patents by Government

Government may apply to use patented invention

9 (1) Subject to section 19.1, the Commissioner may, on application by the Government of Canada or the government of a province, authorize the use of a patented invention by that government.

Terms of use

(1) Subject to section 19.1, the use of the patented invention may be authorized for such purpose, for such period and on such other terms as the Commissioner considers expedient but the Commissioner shall settle those terms in accordance with the following principles:

- (a)** the scope and duration of the use shall be limited to the purpose for which the use is authorized;
- (b)** the use authorized shall be non-exclusive; and
- (c)** any use shall be authorized predominantly to supply the domestic market.

Notice

(1) The Commissioner shall notify the patentee of any use of the patented invention that is authorized under this section.

Payment of remuneration

(1) Where the use of the patented invention is authorized, the authorized user shall pay to the patentee such amount as the Commissioner considers to be adequate remuneration in the circumstances, taking into account the economic value of the authorization.

Termination of authorization

(1) The Commissioner may, on application by the patentee and after giving all concerned parties an opportunity to be heard, terminate the authorization if the Commissioner is satisfied that the circumstances that led to the granting of the authorization have ceased to exist and are unlikely to recur, subject to such conditions as the Commissioner deems appropriate to protect the legitimate interests of the authorized user.

Authorization not transferable

(1) An authorization granted under this section is not transferable.

S., 1985, c. P-4, s. 19; 1993, c. 44, s. 191.

Usages de brevets par le gouvernement

Demande d'usage d'une invention brevetée par le gouvernement

19 (1) Sous réserve de l'article 19.1, le commissaire peut, sur demande du gouvernement du Canada ou d'une province, autoriser celui-ci à faire usage d'une invention brevetée.

Modalités

(2) Sous réserve de l'article 19.1, l'usage de l'invention brevetée peut être autorisé aux fins, pour la durée et selon les autres modalités que le commissaire estime convenables. Celui-ci fixe ces modalités en tenant compte des principes suivants :

- a)** la portée et la durée de l'usage doivent être limitées aux fins auxquelles celui-ci a été autorisé;
- b)** l'usage ne peut être exclusif;
- c)** l'usage doit être avant tout autorisé pour l'approvisionnement du marché intérieur.

Avis

(3) Le commissaire avise le breveté des usages de l'invention brevetée qui sont autorisés sous le régime du présent article.

Paiement d'une rémunération

(4) L'usager de l'invention brevetée paie au breveté la rémunération que le commissaire estime adéquate en l'espèce, compte tenu de la valeur économique de l'autorisation.

Fin de l'autorisation

(5) Le commissaire peut, sur demande du breveté et après avoir donné aux intéressés la possibilité de se faire entendre, mettre fin à l'autorisation s'il est convaincu que les circonstances qui y ont conduit ont cessé d'exister et ne se reproduiront vraisemblablement pas. Le cas échéant, il doit toutefois veiller à ce que les intérêts légitimes des personnes autorisées soient protégés de façon adéquate.

Incessibilité

(6) L'autorisation prévue au présent article est incessible.

L.R. (1985), ch. P-4, art. 19; 1993, ch. 44, art. 191.

Conditions for authorizing use

9.1 (1) The Commissioner may not authorize the use of a patented invention under section 19 unless the applicant establishes that

- (a) it has made efforts to obtain from the patentee on reasonable commercial terms and conditions the authority to use the patented invention; and
- (b) its efforts have not been successful within a reasonable period.

Exception

2) Subsection (1) does not apply in cases of national emergency or extreme urgency or where the use for which the authorization is sought is a public non-commercial use.

Prescribed uses

3) The Commissioner may not, under section 19, authorize any use that is a prescribed use unless the proposed user complies with the prescribed conditions.

Limitation on use of semi-conductor technology

4) The Commissioner may not, under section 19, authorize any use of semi-conductor technology other than a public non-commercial use.

1993, c. 44, s. 191; 1994, c. 47, s. 142.

Appeal

9.2 Any decision made by the Commissioner under section 19 or 19.1 is subject to appeal to the Federal Court.

1993, c. 44, s. 191.

Regulations

9.3 (1) The Governor in Council may make regulations for the purpose of implementing, in relation to patents, article 1720 of the Agreement.

Definition of Agreement

2) In subsection (1), *Agreement* has the same meaning as in subsection 2(1) of the *North American Free Trade Agreement Implementation Act*.

1993, c. 44, s. 191.

Conditions préalables

19.1 (1) Le commissaire ne peut donner l'autorisation visée à l'article 19 que si le demandeur lui démontre que :

- a) d'une part, il s'est efforcé d'obtenir l'autorisation auprès du breveté, à des conditions et modalités commerciales raisonnables;
- b) d'autre part, ses efforts n'ont pas abouti dans un délai raisonnable.

Exception

(2) Le paragraphe (1) ne s'applique pas dans les cas de situation nationale critique ou d'extrême urgence ou dans les cas où l'autorisation est demandée à des fins publiques non commerciales.

Usages prévus par règlement

(3) Le commissaire ne peut s'appuyer sur l'article 19 pour autoriser des usages prévus par règlement, à moins que l'utilisateur éventuel ne respecte les conditions réglementaires.

Limitation — semi-conducteurs

(4) Le commissaire ne peut s'appuyer sur l'article 19 pour autoriser l'usage de la technologie des semi-conducteurs, sauf dans les cas où l'autorisation est demandée à des fins publiques non commerciales.

1993, ch. 44, art. 191; 1994, ch. 47, art. 142.

Appel

19.2 Toute décision rendue par le commissaire dans le cadre des articles 19 ou 19.1 peut faire l'objet d'un appel devant la Cour fédérale.

1993, ch. 44, art. 191.

Règlements

19.3 (1) Le gouverneur en conseil peut prendre, concernant les brevets, des règlements pour la mise en œuvre de l'article 1720 de l'Accord.

Définition de Accord

(2) Au paragraphe (1), *Accord* s'entend au sens du paragraphe 2(1) de la *Loi de mise en œuvre de l'Accord de libre-échange nord-américain*.

1993, ch. 44, art. 191.

Government Owned Patents

Assignment to Minister of National Defence

0 (1) Any officer, servant or employee of the Crown or of a corporation that is an agent or servant of the Crown, who, acting within the scope of his duties and employment, invents any invention in instruments or munitions of war shall, if so required by the Minister of National Defence, assign to that Minister on behalf of Her Majesty all the benefits of the invention and of any patent obtained or to be obtained for the invention.

Idem

(2) Any person other than a person described in subsection (1) who invents an invention described in that subsection may assign to the Minister of National Defence on behalf of Her Majesty all the benefits of the invention and of any patent obtained or to be obtained for the invention.

Inventor entitled to compensation

(3) An inventor described in subsection (2) is entitled to compensation for an assignment to the Minister of National Defence under this Act and in the event that the consideration to be paid for the assignment is not agreed on, it is the duty of the Commissioner to determine the amount of the consideration, which decision is subject to appeal to the Federal Court.

Proceedings before Federal Court

(4) Proceedings before the Federal Court under subsection (3) shall be held in camera on request made to the court by any party to the proceedings.

Resting on assignment

(5) An assignment to the Minister of National Defence under this Act effectually vests the benefits of the invention and patent in the Minister of National Defence on behalf of Her Majesty, and all covenants and agreements herein contained for keeping the invention secret and otherwise are valid and effectual, notwithstanding any want of valuable consideration, and may be enforced accordingly by the Minister of National Defence.

Person making assignment and person having knowledge thereof

(6) Any person who has made an assignment to the Minister of National Defence under this section, in respect of any covenants and agreements contained in such assignment for keeping the invention secret and otherwise in respect of all matters relating to that invention, and any

Brevets appartenant au gouvernement

Cession au ministre de la Défense nationale

20 (1) Tout membre de l'administration publique fédérale ou du personnel d'une personne morale qui est un agent ou au service de la Couronne, qui, dans l'exercice de ses fonctions ou dans le cadre de son emploi, réalise une invention portant sur des instruments ou munitions de guerre, est tenu, s'il en est requis par le ministre de la Défense nationale, de céder à celui-ci, pour le compte de Sa Majesté, le plein bénéfice de l'invention et de tout brevet obtenu ou à obtenir pour celle-ci.

Idem

(2) Toute autre personne qui est l'auteur d'une telle invention peut céder au ministre de la Défense nationale, pour le compte de Sa Majesté, le plein bénéfice de l'invention et de tout brevet obtenu ou à obtenir pour celle-ci.

L'inventeur a droit à une indemnité

(3) L'inventeur visé au paragraphe (2) a droit à une indemnité pour une cession au ministre de la Défense nationale prévue dans la présente loi. S'il n'a pas été convenu de la considération à verser pour une telle cession, le commissaire en détermine le montant, mais il peut être interjeté appel de sa décision à la Cour fédérale.

Procédures devant la Cour fédérale

(4) Les procédures intentées devant la Cour fédérale sous le régime du paragraphe (3) ont lieu à huis clos, sur demande formulée au tribunal par une des parties.

La cession attribue les avantages

(5) La cession attribue efficacement au ministre de la Défense nationale, pour le compte de Sa Majesté, le bénéfice de l'invention et du brevet, et tous les engagements et conventions y contenus aux fins de garder, notamment, l'invention secrète sont valables et efficaces, nonobstant toute absence de contrepartie, et peuvent être exécutés en conséquence par le ministre de la Défense nationale.

Cédant et personne ayant connaissance de la cession

(6) Toute personne qui a fait au ministre de la Défense nationale une cession prévue au présent article, en ce qui concerne les engagements et conventions contenus dans cette cession aux fins de garder, notamment, l'invention secrète et en ce qui concerne toutes matières relatives à

her person who has knowledge of such assignment and of such covenants and agreements, shall be, for the purposes of the *Security of Information Act*, deemed to be persons having in their possession or control information respecting those matters that has been entrusted to them in confidence by any person holding office under Her Majesty, and the communication of any of that information by the first mentioned persons to any person other than one to whom they are authorized to communicate with, by or on behalf of the Minister of National Defence, shall be an offence under section 4 of the *Security of Information Act*.

Minister may submit application for patent

(7) Where any agreement for an assignment to the Minister of National Defence under this Act has been made, the Minister of National Defence may submit an application for patent for the invention to the Commissioner, with the request that it be examined for patentability, and if the application is found allowable may, before the grant of any patent thereon, certify to the Commissioner that, in the public interest, the particulars of the invention and of the manner in which it is to be worked are to be kept secret.

Secret application

(8) If the Minister of National Defence so certifies, the application and specification, with the drawing, if any, and any amendment of the application, and any copies of those documents and the drawing and the patent granted thereon shall be placed in a packet sealed by the Commissioner under authority of the Minister of National Defence.

Custody of secret application

(9) The packet described in subsection (8) shall, until the expiration of the term during which a patent for the invention may be in force, be kept sealed by the Commissioner, and shall not be opened except under the authority of an order of the Minister of National Defence.

Delivery of secret application

(10) The packet described in subsection (8) shall be delivered at any time during the continuance of the patent to any person authorized by the Minister of National Defence to receive it, and shall, if returned to the Commissioner, be kept sealed by him.

Delivery to Minister

(11) On the expiration of the term of the patent, the packet described in subsection (8) shall be delivered to the Minister of National Defence.

l'invention en question, et toute autre personne qui est au courant d'une telle cession et de ces engagements et conventions sont, pour l'application de la *Loi sur la protection de l'information*, réputées des personnes ayant en leur possession ou sous leur contrôle des renseignements sur ces matières qui leur ont été commis en toute confiance par une personne détenant un poste qui relève de Sa Majesté. La communication de l'un de ces renseignements par les personnes mentionnées en premier lieu à une personne autre que celle avec laquelle elles sont autorisées à communiquer par le ministre de la Défense nationale ou en son nom, constitue une infraction à l'article 4 de la *Loi sur la protection de l'information*.

Le ministre peut présenter une demande de brevet

(7) Lorsqu'une convention a été conclue pour une telle cession, le ministre de la Défense nationale peut présenter au commissaire une demande de brevet pour l'invention, accompagnée d'une requête pour étude en vue de déterminer si elle est brevetable, et si cette demande est jugée recevable, il peut, avant que soit accordé tout brevet en l'espèce, certifier au commissaire que, dans l'intérêt public, les détails de l'invention et de la manière dont elle sera exploitée doivent être tenus secrets.

Demande secrète

(8) Si le ministre de la Défense nationale le certifie, la demande et le mémoire descriptif, avec le dessin, le cas échéant, ainsi que toute modification de la demande et toutes copies de ces documents et dessin, de même que le brevet accordé en l'espèce, sont placés dans un paquet scellé par le commissaire sous l'autorité du ministre de la Défense nationale.

Garde de la demande secrète

(9) Jusqu'à l'expiration de la période durant laquelle un brevet pour l'invention peut être en vigueur, le paquet est gardé scellé par le commissaire, et il ne peut être ouvert que sous l'autorité d'un arrêté du ministre de la Défense nationale.

Transmission de la demande secrète

(10) Le paquet est remis pendant la durée du brevet à toute personne autorisée par le ministre de la Défense nationale à le recevoir, et, s'il est retourné au commissaire, ce dernier le garde scellé.

Transmission au ministre

(11) À l'expiration de la durée du brevet, le paquet est transmis au ministre de la Défense nationale.

Revocation

(12) No proceeding by petition or otherwise lies to have declared invalid or void a patent granted for an invention in relation to which a certificate has been given by the Minister of National Defence under subsection (7), except by permission of the Minister.

Prohibition of publication and inspection

(13) No copy of any specification or other document or drawing in respect of an invention and patent, by this section required to be placed in a sealed packet, shall in any manner whatever be published or open to the inspection of the public, but, except as otherwise provided in this section, this Act shall apply in respect of the invention and patent.

Waiver by Minister

(14) The Minister of National Defence may at any time waive the benefit of this section with respect to any particular invention, and the specification, documents and drawing relating thereto shall thereafter be kept and dealt with in the regular way.

Rights protected

(15) No claim shall be allowed in respect of any infringement of a patent that occurred in good faith during the time that the patent was kept secret under this section, and any person who, before the publication of the patent, had in good faith done any act that, but for this subsection would have given rise to a claim, is entitled, after the publication, to obtain a licence to manufacture, use and sell the patented invention on such terms as may, in the absence of agreement between the parties, be settled by the Commissioner or by the Federal Court on appeal from the Commissioner.

Communication to Minister

(16) The communication of any invention for any improvement in munitions of war to the Minister of National Defence, or to any person or persons authorized by the Minister of National Defence to investigate the invention or the merits thereof, shall not, nor shall anything done for the purposes of the investigation, be deemed use or publication of the invention so as to prejudice the grant or validity of any patent for the invention.

Order to keep non-assigned application secret

(17) The Governor in Council, if satisfied that an invention relating to any instrument or munition of war, described in any specified application for patent not assigned to the Minister of National Defence, is vital to the defence of Canada and that the publication of a patent

Révocation

(12) Nulle procédure par voie de pétition ou autrement n'est recevable en vue de faire déclarer invalide ou nul un brevet concédé pour une invention à l'égard de laquelle le ministre de la Défense nationale a donné un certificat aux termes du paragraphe (7), sauf sur permission de ce dernier.

Interdiction relative à la publication et l'inspection

(13) Aucune copie d'un mémoire descriptif ou autre document ou dessin à placer dans un paquet scellé, aux termes du présent article, ne peut de quelque manière que ce soit être publiée ni être accessible à l'inspection du public. Toutefois, sauf prescriptions contraires du présent article, la présente loi s'applique à l'égard d'une invention et d'un brevet qui y sont visés.

Renonciation par le ministre

(14) Le ministre de la Défense nationale peut renoncer aux avantages du présent article en ce qui concerne une invention particulière et, dès lors, le mémoire descriptif, les documents et le dessin sont gardés et traités de la manière régulière.

Droits sauvegardés

(15) Il ne peut être fait droit à une réclamation concernant une contrefaçon de brevet qui s'est produite de bonne foi pendant la période où le brevet a été tenu secret sous le régime du présent article. Quiconque, avant la publication de ce brevet, avait accompli de bonne foi un acte qui, sans le présent paragraphe, aurait donné lieu à une telle réclamation, a droit, après la publication en question, d'obtenir une licence pour fabriquer, utiliser et vendre l'invention brevetée aux termes qui, en l'absence de convention entre les parties, peuvent être arrêtés par le commissaire ou par la Cour fédérale sur appel de la décision du commissaire.

Communication au ministre

(16) La communication au ministre de la Défense nationale, ou à toute personne autorisée par ce dernier à en faire l'examen ou à en étudier les mérites, de toute invention destinée à un perfectionnement de munitions de guerre, n'est pas réputée, non plus qu'une chose faite aux fins de l'enquête, constituer un usage ou une publication de cette invention qui puisse nuire à l'octroi ou à la validité d'un brevet à cet égard.

Décret pour tenir secrète la demande non cédée

(17) Si le gouverneur en conseil est convaincu qu'une invention relative à tout instrument ou munition de guerre, décrite dans une demande spécifiée de brevet non cédée au ministre de la Défense nationale, est essentielle à la défense du Canada et que la publication d'un brevet en

herefor should be prevented in order to preserve the safety of the State, may order that the invention and application and all the documents relating thereto shall be treated for all purposes of this section as if the invention had been assigned or agreed to be assigned to the Minister of National Defence.

Règles

(18) The Governor in Council may make rules for the purpose of ensuring secrecy with respect to applications and patents to which this section applies and generally to give effect to the purpose and intent thereof.

S., 1985, c. P-4, s. 20; 2001, c. 41, s. 36.

Agreement between Canada and other government

1 Where by any agreement between the Government of Canada and any other government it is provided that the Government of Canada will apply section 20 to inventions disclosed in any application for a patent assigned or agreed to be assigned by the inventor to that other government, and the Commissioner is notified by any minister of the Crown that the agreement extends to an invention in a specified application, the application and all the documents relating thereto shall be dealt with as provided in section 20, except subsections (3) and (4), as if the invention had been assigned or agreed to be assigned to the Minister of National Defence.

S., c. P-4, s. 21.

Use of Patents for International Humanitarian Purposes to Address Public Health Problems

Purpose

21.01 The purpose of sections 21.02 to 21.2 is to give effect to Canada's and Jean Chrétien's pledge to Africa by facilitating access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2004, c. 23, s. 1.

Définitions

21.02 The definitions in this section apply in this section and in sections 21.03 to 21.19.

l'espèce devrait être empêchée afin de maintenir la sécurité de l'État, il peut ordonner que ces invention et demande ainsi que tous les documents s'y rattachant soient traités, pour l'application du présent article, comme si l'invention avait été cédée, ou comme s'il avait été convenu de céder l'invention, au ministre de la Défense nationale.

Règles

(18) Le gouverneur en conseil peut établir des règles pour assurer le secret en ce qui concerne les demandes et les brevets visés par le présent article et, d'une façon générale, pour son application.

L.R. (1985), ch. P-4, art. 20; 2001, ch. 41, art. 36.

Accord entre le Canada et un autre gouvernement

21 Si, aux termes d'un accord entre le gouvernement du Canada et tout autre gouvernement, il est prévu que le gouvernement du Canada appliquera l'article 20 aux inventions décrites dans une demande de brevet cédé par l'inventeur, ou que celui-ci convient de céder, à cet autre gouvernement, et si un ministre avise le commissaire que cet accord s'étend à l'invention dans une demande spécifiée, cette demande et tous les documents s'y rattachant sont traités de la manière prévue à l'article 20, sauf les paragraphes (3) et (4), comme si l'invention avait été cédée, ou qu'il avait été convenu de céder l'invention, au ministre de la Défense nationale.

S.R., ch. P-4, art. 21.

Usage de brevets à des fins humanitaires internationales en vue de remédier aux problèmes de santé publique

Objet

21.01 Les articles 21.02 à 21.2 ont pour objet de donner effet à l'engagement du Canada et de Jean Chrétien envers l'Afrique en facilitant l'accès aux produits pharmaceutiques nécessaires pour remédier aux problèmes de santé publique touchant de nombreux pays en voie de développement et pays les moins avancés, en particulier ceux résultant du VIH/SIDA, de la tuberculose, du paludisme et d'autres épidémies.

2004, ch. 23, art. 1.

Définitions

21.02 Les définitions qui suivent s'appliquent au présent article et aux articles 21.03 à 21.19.

Accord sur les ADPIC L'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce,

authorization means an authorization granted under subsection 21.04(1), and includes an authorization renewed under subsection 21.12(1). (*autorisation*)

General Council means the General Council of the WTO established by paragraph 2 of Article IV of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994. (*Conseil général*)

General Council Decision means the decision of the General Council of August 30, 2003 respecting Article 31 of the TRIPS Agreement, including the interpretation of that decision in the General Council Chairperson's statement of that date. (*décision du Conseil général*)

patented product means a product the making, constructing, using or selling of which in Canada would infringe a patent in the absence of the consent of the patentee. (*produit breveté*)

pharmaceutical product means any patented product listed in Schedule 1 in, if applicable, the dosage form, the strength and the route of administration specified in that schedule in relation to the product. (*produit pharmaceutique*)

TRIPS Agreement means the Agreement on Trade-Related Aspects of Intellectual Property Rights, being Annex 1C of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994. (*Accord sur les ADPIC*)

TRIPS Council means the council referred to in the TRIPS Agreement. (*Conseil des ADPIC*)

WTO means the World Trade Organization established by Article I of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994. (*OMC*)

2004, c. 23, s. 1.

Amending Schedules

21.03 (1) The Governor in Council may, by order,

(a) on the recommendation of the Minister and the Minister of Health, amend Schedule 1

(i) by adding the name of any patented product that may be used to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics and, if the Governor in Council considers it appropriate to do so, by adding one or more of the following in respect of the patented product, namely, a

figurant à l'annexe 1C de l'Accord instituant l'Organisation mondiale du commerce signé à Marrakech le 15 avril 1994. (*TRIPS Agreement*)

autorisation Autorisation accordée en vertu du paragraphe 21.04(1) ou renouvelée en vertu du paragraphe 21.12(1). (*authorization*)

Conseil des ADPIC Le conseil visé dans l'Accord sur les ADPIC. (*TRIPS Council*)

Conseil général Le Conseil général de l'OMC créé par le paragraphe 2 de l'article IV de l'Accord instituant l'Organisation mondiale du commerce, signé à Marrakech le 15 avril 1994. (*General Council*)

décision du Conseil général La décision rendue le 30 août 2003 par le Conseil général à l'égard de l'article 31 de l'Accord sur les ADPIC, y compris l'interprétation donnée de celle-ci dans la déclaration de son président faite le même jour. (*General Council Decision*)

OMC L'Organisation mondiale du commerce constituée par l'article I de l'Accord instituant l'Organisation mondiale du commerce, signé à Marrakech le 15 avril 1994. (*WTO*)

produit breveté Produit dont la fabrication, la construction, l'exploitation ou la vente au Canada sans le consentement du breveté constituerait une contrefaçon. (*patented product*)

produit pharmaceutique Produit breveté figurant à l'annexe 1, dans la forme posologique et selon la concentration et la voie d'administration indiquées, le cas échéant. (*pharmaceutical product*)

2004, ch. 23, art. 1.

Modification des annexes

21.03 (1) Le gouverneur en conseil peut, par décret :

a) sur recommandation du ministre et du ministre de la Santé, modifier l'annexe 1 :

(i) par adjonction du nom d'un produit breveté pouvant être utilisé pour remédier à des problèmes de santé publique touchant de nombreux pays en voie de développement et pays les moins avancés, en particulier ceux résultant du VIH/SIDA, de la tuberculose, du paludisme et d'autres épidémies, et de la mention de la forme posologique, de la concentration ou de la voie d'administration du produit, s'il le juge indiqué,

dosage form, a strength and a route of administration, and

(ii) by removing any entry listed in it;

(b) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Development, amend Schedule 2 by adding the name of any country recognized by the United Nations as being a least-developed country that has,

(i) if it is a WTO Member, provided the TRIPS Council with a notice in writing stating that the country intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, and

(ii) if it is not a WTO Member, provided the Government of Canada with a notice in writing through diplomatic channels stating that the country intends to import pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision, that it agrees that those products will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of that decision;

(c) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Development, amend Schedule 3 by adding the name of any WTO Member not listed in Schedule 2 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision; and

(d) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Development, amend Schedule 4 by adding the name of

(i) any WTO Member not listed in Schedule 2 or 3 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, or

(ii) any country that is not a WTO Member and that is named on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance and that has provided the Government of Canada

(ii) par suppression du nom d'un produit breveté ou d'une mention y figurant;

b) sur recommandation du ministre des Affaires étrangères, du ministre du Commerce international et du ministre du Développement international, modifier l'annexe 2, par adjonction du nom de tout pays qui, étant un pays moins avancé selon les Nations Unies, a transmis :

(i) s'il est membre de l'OMC, au Conseil des ADPIC un avis écrit de son intention d'importer, conformément à la décision du Conseil général, des produits pharmaceutiques au sens de l'alinéa 1a) de cette décision,

(ii) s'il n'est pas membre de l'OMC, au gouvernement du Canada, par la voie diplomatique, un avis écrit de son intention d'importer des produits pharmaceutiques au sens de l'alinéa 1a) de la décision du Conseil général, dans lequel il s'engage à ne pas utiliser les produits à des fins commerciales et à prendre les mesures visées à l'article 4 de cette décision;

c) sur recommandation du ministre des Affaires étrangères, du ministre du Commerce international et du ministre du Développement international, modifier l'annexe 3, par adjonction du nom de tout membre de l'OMC ne figurant pas à l'annexe 2 qui a transmis au Conseil des ADPIC un avis écrit de son intention d'importer, conformément à la décision du Conseil général, des produits pharmaceutiques au sens de l'alinéa 1a) de cette décision;

d) sur recommandation du ministre des Affaires étrangères, du ministre du Commerce international et du ministre du Développement international, modifier l'annexe 4, par adjonction :

(i) du nom de tout membre de l'OMC ne figurant pas à l'annexe 2 ou 3 qui a transmis au Conseil des ADPIC un avis écrit de son intention d'importer, conformément à la décision du Conseil général, des produits pharmaceutiques au sens de l'alinéa 1a) de cette décision,

(ii) du nom de tout pays non-membre de l'OMC qui figure sur la liste des pays admissibles à l'aide publique au développement établie par l'Organisation de coopération et de développement économiques, à la condition qu'il ait transmis au gouvernement du Canada, par la voie diplomatique, un avis écrit dans lequel il :

with a notice in writing through diplomatic channels

(A) stating that it is faced with a national emergency or other circumstances of extreme urgency,

(B) specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the country to deal with the emergency or other urgency,

(C) stating that it has no, or insufficient, pharmaceutical capacity to manufacture that product, and

(D) stating that it agrees that that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision.

Restriction - Schedule 3

2) The Governor in Council may not add to Schedule 3 the name of any WTO Member that has notified the TRIPS Council that it will import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, only if faced with a national emergency or other circumstances of extreme urgency.

Removal from Schedules 2 to 4

3) The Governor in Council may, by order, on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Development, amend any of Schedules 2 to 4 to remove the name of any country or WTO Member if

(a) in the case of a country or WTO Member listed in Schedule 2, the country or WTO Member has ceased to be recognized by the United Nations as being a least-developed country or, in the case of a country that is not a WTO Member, the country has permitted any product imported into that country under an authorization to be used for commercial purposes or has failed to adopt the measures referred to in Article 4 of the General Council Decision;

(b) in the case of a WTO Member listed in Schedule 3, the WTO Member has notified the TRIPS Council that it will import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, only if faced with a national emergency or other circumstances of extreme urgency;

(A) confirme qu'il fait face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence,

(B) précise le nom et la quantité du produit pharmaceutique, au sens de l'alinéa 1a) de la décision du Conseil général, dont il a besoin pour y faire face,

(C) confirme qu'il n'a pas la capacité de fabrication du produit pharmaceutique ou que cette capacité est insuffisante,

(D) s'engage à ne pas utiliser le produit à des fins commerciales et à prendre les mesures visées à l'article 4 de cette décision.

Réserve - annexe 3

(2) Le gouverneur en conseil ne peut ajouter à l'annexe 3 le nom d'un membre de l'OMC qui a avisé le Conseil des ADPIC de son intention de n'importer, conformément à la décision du Conseil général, des produits pharmaceutiques, au sens de l'alinéa 1a) de cette décision, que s'il fait face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence.

Suppression - annexes 2, 3 et 4

(3) Sur recommandation du ministre des Affaires étrangères, du ministre du Commerce international et du ministre du Développement international, le gouverneur en conseil peut, par décret, supprimer de l'annexe 2, 3 ou 4 le nom d'un pays ou d'un membre de l'OMC si :

a) dans le cas de l'annexe 2, le pays ou le membre de l'OMC n'est plus, selon les Nations Unies, un pays moins avancé ou, s'il n'est pas membre de l'OMC, le pays a permis que tout produit importé au titre d'une autorisation soit utilisé à des fins commerciales ou n'a pas pris les mesures visées à l'article 4 de la décision du Conseil général;

b) dans le cas de l'annexe 3, le membre de l'OMC a avisé le Conseil des ADPIC de son intention de n'importer des produits pharmaceutiques, au sens de l'alinéa 1a) de la décision du Conseil général et conformément à celle-ci, que s'il fait face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence;

c) dans le cas de l'annexe 4, le membre de l'OMC a révoqué l'avis donné au Conseil des ADPIC, selon lequel

(c) in the case of a WTO Member listed in Schedule 4, the WTO Member has revoked any notification it has given to the TRIPS Council that it will import pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision, only if faced with a national emergency or other circumstances of extreme urgency;

(d) in the case of a country listed in Schedule 4 that is not a WTO Member,

(i) the name of the country is no longer on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance,

(ii) the country no longer faces a national emergency or other circumstances of extreme urgency,

(iii) the country has permitted any product imported into that country under an authorization to be used for commercial purposes, or

(iv) the country has failed to adopt the measures referred to in Article 4 of the General Council Decision;

(e) in the case of any country or WTO Member listed in Schedule 3 or 4, the country or WTO Member has become recognized by the United Nations as a least-developed country; and

(f) in the case of any country or WTO Member listed in any of Schedules 2 to 4, the country has notified the Government of Canada, or the WTO Member has notified the TRIPS Council, that it will not import pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision.

Timeliness of orders

4) An order under this section shall be made in a timely manner.

2004, c. 23, s. 1; 2013, c. 33, s. 196.

Authorization

21.04 (1) Subject to subsection (3), the Commissioner shall, on the application of any person and on the payment of the prescribed fee, authorize the person to make, construct and use a patented invention solely for purposes directly related to the manufacture of the pharmaceutical product named in the application and to sell it for export to a country or WTO Member that is listed in any of Schedules 2 to 4 and that is named in the application.

il a l'intention de n'importer des produits pharmaceutiques au sens de l'alinéa 1a) de la décision du Conseil général que s'il fait face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence;

d) dans le cas de l'annexe 4, le pays non-membre de l'OMC, selon le cas :

(i) ne figure plus sur la liste des pays admissibles à l'aide publique au développement établie par l'Organisation de coopération et de développement économiques,

(ii) ne fait plus face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence,

(iii) a permis que tout produit importé au titre d'une autorisation soit utilisé à des fins commerciales,

(iv) n'a pas pris les mesures visées à l'article 4 de la décision du Conseil général;

e) dans le cas de l'annexe 3 ou 4, le pays ou le membre de l'OMC est devenu un pays moins avancé selon les Nations Unies;

f) dans le cas de l'annexe 2, 3 ou 4, le pays a avisé le gouvernement du Canada, ou le membre de l'OMC a avisé le Conseil des ADPIC, de son intention de ne pas importer de produits pharmaceutiques au sens de l'alinéa 1a) de la décision du Conseil général.

Célérité

(4) Tout décret visé au présent article doit être pris au moment opportun.

2004, ch. 23, art. 1; 2013, ch. 33, art. 196.

Autorisation

21.04 (1) Sous réserve du paragraphe (3) et du paiement des taxes réglementaires, le commissaire autorise quiconque en fait la demande à utiliser, fabriquer et construire l'invention brevetée, pourvu que ce soit dans un but directement lié à la fabrication du produit pharmaceutique mentionné dans la demande, et à vendre celui-ci aux fins d'exportation vers le pays ou le membre de l'OMC mentionné dans celle-ci dont le nom figure à l'une des annexes 2, 3 ou 4.

Contents of application

(1) The application must be in the prescribed form and set out

- (a) the name of the pharmaceutical product to be manufactured and sold for export under the authorization;
- (b) prescribed information in respect of the version of the pharmaceutical product to be manufactured and sold for export under the authorization;
- (c) the maximum quantity of the pharmaceutical product to be manufactured and sold for export under the authorization;
- (d) for each patented invention to which the application relates, the name of the patentee of the invention and the number, as recorded in the Patent Office, of the patent issued in respect of that invention;
- (e) the name of the country or WTO Member to which the pharmaceutical product is to be exported;
- (f) the name of the governmental person or entity, or the person or entity permitted by the government of the importing country, to which the product is to be sold, and prescribed information, if any, concerning that person or entity; and
- (g) any other information that may be prescribed.

Conditions for granting of authorization

(3) The Commissioner shall authorize the use of the patented invention only if

- (a) the applicant has complied with the prescribed requirements, if any;
- (b) the Minister of Health has notified the Commissioner that the version of the pharmaceutical product that is named in the application meets the requirements of the *Food and Drugs Act* and its regulations, including the requirements under those regulations relating to the marking, embossing, labelling and packaging that identify that version of the product as having been manufactured
 - (i) in Canada as permitted by the General Council Decision, and
 - (ii) in a manner that distinguishes it from the version of the pharmaceutical product sold in Canada by, or with the consent of, the patentee or patentees, as the case may be;

Demande

(2) La demande doit être en la forme réglementaire et contenir les renseignements suivants :

- a) le nom du produit pharmaceutique qui sera fabriqué et vendu aux fins d'exportation au titre de l'autorisation;
- b) les renseignements réglementaires concernant la version du produit pharmaceutique en cause;
- c) la quantité maximale prévue;
- d) en ce qui touche toute invention brevetée visée par la demande, le nom du breveté et le numéro d'enregistrement du brevet au Bureau des brevets;
- e) le nom du pays ou du membre de l'OMC vers lequel le produit sera exporté;
- f) le nom du représentant du gouvernement ou de l'entité gouvernementale, ou de la personne ou de l'entité permise par le gouvernement du pays importateur, à qui le produit sera vendu et tout autre renseignement éventuellement prévu par règlement à son égard;
- g) tout autre renseignement éventuellement prévu par règlement.

Conditions d'octroi de l'autorisation

(3) L'usage de l'invention brevetée ne peut être autorisé par le commissaire que si les conditions suivantes sont remplies :

- a) le demandeur s'est conformé aux éventuelles exigences réglementaires;
- b) le ministre de la Santé a notifié au commissaire le fait que la version du produit pharmaceutique mentionnée dans la demande satisfait aux exigences de la *Loi sur les aliments et drogues* et de ses règlements, notamment aux exigences réglementaires en matière de marquage, d'estampage, d'étiquetage et d'emballage qui indiquent que cette version du produit :
 - (i) est fabriquée au Canada au titre de la décision du Conseil général,
 - (ii) est différente de la version du produit pharmaceutique vendue au Canada par tout breveté ou avec son accord;

(c) the applicant provides the Commissioner with a solemn or statutory declaration in the prescribed form stating that the applicant had, at least thirty days before filing the application,

(i) sought from the patentee or, if there is more than one, from each of the patentees, by certified or registered mail, a licence to manufacture and sell the pharmaceutical product for export to the country or WTO Member named in the application on reasonable terms and conditions and that such efforts have not been successful, and

(ii) provided the patentee, or each of the patentees, as the case may be, by certified or registered mail, in the written request for a licence, with the information that is in all material respects identical to the information referred to in paragraphs (2)(a) to (g); and

(d) the applicant also provides the Commissioner with

(i) if the application relates to a WTO Member listed in Schedule 2, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and that the product is not patented in that WTO Member, or

(B) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(ii) if the application relates to a country listed in Schedule 2 that is not a WTO Member, a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels specifying the name of the pharmaceutical product, as defined in paragraph

c) le demandeur a fourni au commissaire une déclaration solennelle, en la forme réglementaire, selon laquelle, au moins trente jours avant le dépôt de la demande, il a :

(i) tenté d'obtenir une licence du breveté - ou de chacun des brevetés - par courrier certifié ou recommandé en vue de fabriquer et de vendre aux fins d'exportation le produit au pays ou au membre de l'OMC mentionné dans la demande, et ce à des conditions raisonnables et sans succès,

(ii) fourni au breveté - ou à chacun des brevetés - par courrier certifié ou recommandé, dans cette demande de licence, des renseignements qui sont, à tous égards importants, identiques à ceux énumérés aux alinéas (2)a) à g);

d) le demandeur a également fourni au commissaire :

(i) dans le cas d'une demande concernant un membre de l'OMC visé à l'annexe 2, d'une part, une copie certifiée de l'avis écrit transmis au Conseil des ADPIC dans lequel le membre précise le nom et la quantité du produit pharmaceutique, au sens de l'alinéa 1a) de la décision du Conseil général, dont il a besoin et, d'autre part :

(A) soit une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme que le produit mentionné dans sa demande est le produit précisé dans l'avis et n'est pas un produit breveté sur le territoire du membre,

(B) soit, d'une part, une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme que le produit mentionné dans sa demande est le produit précisé dans l'avis et, d'autre part, une copie certifiée de l'avis écrit transmis au Conseil des ADPIC dans lequel le membre confirme qu'il a accordé ou accordera, conformément à l'article 31 de l'Accord sur les ADPIC et aux dispositions de la décision du Conseil général, la licence obligatoire nécessaire à l'utilisation de l'invention relative au produit,

(ii) dans le cas d'une demande concernant un pays visé à l'annexe 2 qui n'est pas membre de l'OMC, d'une part, une copie certifiée de l'avis écrit transmis au gouvernement du Canada, par la voie diplomatique, dans lequel le pays précise le nom et la quantité du produit pharmaceutique, au sens de l'alinéa 1a) de la décision du Conseil général, dont il a besoin, et, d'autre part :

(A) soit une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme

1(a) of the General Council Decision, and the quantity of that product, needed by the country, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and that the product is not patented in that country, or

(B) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is the product specified in the notice and a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels confirming that the country has granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(iii) if the application relates to a WTO Member listed in Schedule 3, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and stating that the WTO Member has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that WTO Member, or

(B) a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product,

(iv) if the application relates to a WTO Member listed in Schedule 4, a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the WTO Member, and stating that the WTO Member is faced with a national emergency or other circumstances of extreme

que le produit mentionné dans sa demande est le produit précisé dans l'avis et n'est pas un produit breveté sur le territoire du pays,

(B) soit, d'une part, une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme que le produit mentionné dans sa demande est le produit précisé dans l'avis et, d'autre part, une copie certifiée de l'avis écrit transmis au gouvernement du Canada, par la voie diplomatique, dans lequel le pays confirme qu'il a accordé ou accordera la licence obligatoire nécessaire à l'utilisation de l'invention relative au produit,

(iii) dans le cas d'une demande concernant un membre de l'OMC visé à l'annexe 3, d'une part, une copie certifiée de l'avis écrit transmis au Conseil des ADPIC dans lequel le membre précise le nom et la quantité du produit pharmaceutique, au sens de l'alinéa 1a) de la décision du Conseil général, dont il a besoin et confirme qu'il n'a pas la capacité de fabrication du produit visé par la demande ou que cette capacité est insuffisante, et, d'autre part :

(A) soit une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme que le produit mentionné dans sa demande n'est pas un produit breveté sur le territoire du membre,

(B) soit une copie certifiée de l'avis écrit transmis au Conseil des ADPIC dans lequel le membre confirme qu'il a accordé ou accordera, conformément à l'article 31 de l'Accord sur les ADPIC et aux dispositions de la décision du Conseil général, la licence obligatoire nécessaire à l'utilisation de l'invention relative au produit,

(iv) dans le cas d'une demande concernant un membre de l'OMC visé à l'annexe 4, d'une part, une copie certifiée de l'avis écrit transmis au Conseil des ADPIC dans lequel le membre précise le nom et la quantité du produit pharmaceutique, au sens de l'alinéa 1a) de la décision du Conseil général, dont il a besoin et confirme qu'il fait face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence et qu'il n'a pas la capacité de fabrication du produit visé par la demande ou que cette capacité est insuffisante, et, d'autre part :

(A) soit une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme que le produit mentionné dans sa demande n'est pas un produit breveté sur le territoire du membre,

urgency and that it has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that WTO Member, or

(B) a certified copy of the notice in writing that the WTO Member has provided to the TRIPS Council confirming that the WTO Member has, in accordance with Article 31 of the TRIPS Agreement and the provisions of the General Council Decision, granted or intends to grant a compulsory licence to use the invention pertaining to the product, or

(v) if the application relates to a country listed in Schedule 4 that is not a WTO Member, a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the country, and stating that it is faced with a national emergency or other circumstances of extreme urgency, that it has insufficient or no pharmaceutical manufacturing capacity for the production of the product to which the application relates, that it agrees that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision, and

(A) a solemn or statutory declaration in the prescribed form by the person filing the application stating that the product to which the application relates is not patented in that country, or

(B) a certified copy of the notice in writing that the country has provided to the Government of Canada through diplomatic channels confirming that the country has granted or intends to grant a compulsory licence to use the invention pertaining to the product.

304, c. 23, s. 1.

Form and content of authorization

21.05 (1) The authorization must be in the prescribed form and, subject to subsection (2), contain the prescribed information.

(B) soit une copie certifiée de l'avis écrit transmis au Conseil des ADPIC dans lequel le membre confirme qu'il a accordé ou accordera, conformément à l'article 31 de l'Accord sur les ADPIC et aux dispositions de la décision du Conseil général, la licence obligatoire nécessaire à l'utilisation de l'invention relative au produit,

(v) dans le cas d'une demande concernant un pays visé à l'annexe 4 qui n'est pas membre de l'OMC, d'une part, une copie certifiée de l'avis écrit transmis au gouvernement du Canada, par la voie diplomatique, dans lequel le pays précise le nom et la quantité du produit pharmaceutique, au sens de l'alinéa 1a) de la décision du Conseil général, dont il a besoin, confirme qu'il fait face à une situation d'urgence nationale ou à d'autres circonstances d'extrême urgence et qu'il n'a pas la capacité de fabrication du produit visé par la demande ou que cette capacité est insuffisante et s'engage à ne pas utiliser le produit à des fins commerciales et à prendre les mesures visées à l'article 4 de cette décision et, d'autre part :

(A) soit une déclaration solennelle, en la forme réglementaire, dans laquelle lui-même affirme que le produit mentionné dans sa demande n'est pas un produit breveté sur le territoire du pays,

(B) soit une copie certifiée de l'avis écrit transmis au gouvernement du Canada, par la voie diplomatique, dans lequel le pays confirme qu'il a accordé ou accordera la licence obligatoire nécessaire à l'utilisation de l'invention relative au produit.

2004, ch. 23, art. 1.

Forme et contenu de l'autorisation

21.05 (1) L'autorisation doit être en la forme réglementaire et, sous réserve du paragraphe (2), contenir les renseignements prévus par règlement.

Quantity

(2) The quantity of the product authorized to be manufactured by an authorization may not be more than the lesser of

(a) the maximum quantity set out in the application for the authorization, and

(b) the quantity set out in the notice referred to in any of subparagraphs 21.04(3)(d)(i) to (v), whichever is applicable.

2004, c. 23, s. 1.

Disclosure of information on website

1.06 (1) Before exporting a product manufactured under an authorization, the holder of the authorization must establish a website on which is disclosed the prescribed information respecting the name of the product, the name of the country or WTO Member to which it is to be exported, the quantity that is authorized to be manufactured and sold for export and the distinguishing features of the product, and of its label and packaging, as required by regulations made under the *Food and Drugs Act*, as well as information identifying every known party that will be handling the product while it is in transit from Canada to the country or WTO Member to which it is to be exported.

Obligation to maintain

(2) The holder must maintain the website during the entire period during which the authorization is valid.

Links to other websites

(3) The Commissioner shall post and maintain on the website of the Canadian Intellectual Property Office a link to each website required to be maintained by the holder of an authorization under subsection (1).

Posting on the website

(4) The Commissioner shall, within seven days of receipt, post on the website of the Canadian Intellectual Property Office each application for authorization filed under subsection 21.04(1).

2004, c. 23, s. 1.

Export notice

21.07 Before each shipment of any quantity of a product manufactured under an authorization, the holder of the authorization must, within fifteen days before the product is exported, provide to each of the following a notice, by certified or registered mail, specifying the quantity to be exported, as well as every known party that will be handling the product while it is in transit from Canada to

Quantité

(2) La quantité de produit dont la fabrication est autorisée ne peut être supérieure à la plus petite des quantités suivantes :

a) la quantité maximale mentionnée dans la demande d'autorisation;

b) la quantité mentionnée dans l'avis prévu à l'un des sous-alinéas 21.04(3)d)(i) à (v), selon le cas.

2004, ch. 23, art. 1.

Affichage sur site Internet

21.06 (1) Avant d'exporter le produit fabriqué au titre de l'autorisation, le titulaire doit créer un site Internet et y afficher les renseignements réglementaires concernant le nom du produit, le nom du pays ou du membre de l'OMC vers lequel le produit sera exporté, la quantité qu'il est autorisé à fabriquer et à vendre aux fins d'exportation ainsi que les caractères distinctifs du produit et de son étiquetage et emballage, exigés par les règlements pris en vertu de la *Loi sur les aliments et drogues*, de même que le nom de tous les intervenants connus qui manutentionneront le produit dans le cadre de son transit entre le Canada et le pays ou le membre en question.

Obligation

(2) Le titulaire est tenu de conserver le site pendant toute la durée de l'autorisation.

Liens Internet

(3) Le commissaire affiche et conserve sur le site Internet de l'Office de la propriété intellectuelle du Canada un lien vers chaque site Internet devant être conservé par le titulaire d'une autorisation en vertu du paragraphe (1).

Affichage sur le site Internet

(4) Dans les sept jours de la réception de la demande déposée au titre du paragraphe 21.04(1), le commissaire affiche copie de celle-ci sur le site Internet de l'Office de la propriété intellectuelle du Canada.

2004, ch. 23, art. 1.

Avis d'exportation

21.07 Avant chaque expédition d'une quantité du produit fabriqué au titre de l'autorisation, le titulaire donne par courrier certifié ou recommandé, dans les quinze jours précédant l'exportation, avis de la quantité en cause et du nom de tous les intervenants connus qui manutentionneront le produit dans le cadre de son transit entre le Canada et le pays ou membre vers lequel il sera exporté :

the country or WTO Member to which it is to be exported:

- (a) the patentee or each of the patentees, as the case may be;
- (b) the country or WTO Member named in the authorization; and
- (c) the person or entity that purchased the product to which the authorization relates.

2004, c. 23, s. 1.

loyalty

21.08 (1) Subject to subsections (3) and (4), on the occurrence of a prescribed event, the holder of an authorization is required to pay to the patentee or each patentee, as the case may be, a royalty determined in the prescribed manner.

Factors to consider when making regulations

(2) In making regulations for the purposes of subsection (1), the Governor in Council must consider the humanitarian and non-commercial reasons underlying the issuance of authorizations under subsection 21.04(1).

Time for payment

(3) The royalties payable under this section must be paid within the prescribed time.

Federal Court may determine royalty

(4) The Federal Court may, in relation to any authorization, make an order providing for the payment of a royalty that is greater than the royalty that would otherwise be required to be paid under subsection (1).

Application and notice

(5) An order may be made only on the application of the patentee, or one of the patentees, as the case may be, and on notice of the application being given by the applicant to the holder of the authorization.

Contents of order

(6) An order may provide for a royalty of a fixed amount or for a royalty to be determined as specified in the order, and the order may be subject to any terms that the Federal Court considers appropriate.

a) au breveté ou à chacun des brevetés, selon le cas;

b) au pays ou au membre de l'OMC mentionné dans l'autorisation;

c) à la personne ou à l'entité qui a acheté le produit visé par celle-ci.

2004, ch. 23, art. 1.

Redevances

21.08 (1) Sous réserve des paragraphes (3) et (4), le titulaire de l'autorisation est tenu de verser, à la survenance de tout événement visé par règlement, au breveté – ou à chacun des brevetés – la redevance déterminée de la manière réglementaire.

Critère - règlements

(2) Pour la prise de tout règlement au titre du paragraphe (1), le gouverneur en conseil prend en considération le fait que l'octroi d'autorisations au titre du paragraphe 21.04(1) est fondé sur des motifs humanitaires et non commerciaux.

Modalités de temps

(3) Le titulaire est tenu de verser les redevances dans le délai réglementaire.

Fixation de la redevance par la Cour fédérale

(4) La Cour fédérale peut, par ordonnance, prévoir le versement d'une redevance dont le montant dépasse celui établi au titre du paragraphe (1).

Demande et avis

(5) L'ordonnance ne peut être rendue que sur demande présentée par le breveté, ou l'un des brevetés, et qu'après signification de celle-ci au titulaire de l'autorisation.

Contenu de l'ordonnance

(6) L'ordonnance peut soit préciser le montant de la redevance, soit en prévoir les modalités de détermination, et être assortie des conditions que le tribunal juge indiquées.