Federal Court of Appeal  Cour d'appel fédérale

Date: 20180320

Docket: A-71-17

Citation: 2018 FCA 53

CORAM: **RENNIE J.A.**
GLEASON J.A.
LASKIN J.A.

BETWEEN:

ELI LILLY CANADA INC.

Appellant
(Respondent by Cross-Appeal)

and

TEVA CANADA LIMITED

Respondent
(Appellant by Cross-Appeal)

Heard at Toronto, Ontario, on November 22 and 23, 2017.

Judgment delivered at Ottawa, Ontario, on February 22, 2018.

REASONS FOR JUDGMENT BY: LASKIN J.A.

CONCURRED IN BY: RENNIE J.A.
GLEASON J.A.

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(Confidential Reasons for Judgment Issued February 22, 2018)

LASKIN J.A.

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I. Overview

[1] Eli Lilly Canada Inc. appeals from the judgment of Justice O'Reilly of the Federal Court (2017 FC 88) awarding damages to Teva Canada Limited under section 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, for loss suffered when it was kept out of the market for olanzapine by Lilly's unsuccessful prohibition application under the Regulations. Lilly raises a series of grounds of appeal. Some would, if accepted, require dismissal of Teva's claim in its entirety and return of the more than $70 million that Lilly has already paid towards the judgment, while others would reduce the amount payable. Teva has cross-appealed, on three grounds.

[2] For the reasons set out below, I would dismiss the appeal and allow the cross-appeal in part.

[3] Given the number of grounds of appeal and cross-appeal, I will start with a brief outline of the scheme of the Regulations and a summary of the litigation history. I will then provide any further factual context necessary to address each ground as I come to it. I will address the main grounds argued by the parties, and will do so largely in the categories and the sequence in which they were argued. For simplicity, I will refer throughout to the respondent and appellant by cross-appeal as Teva, though during the relevant period its corporate name was Novopharm Limited.

II. The Regulations

[4] In setting out the scheme of the Regulations, I borrow heavily from the outline that this Court recently provided in *Pfizer Canada Inc. v. Teva Canada Limited*, 2016 FCA 161, 483 N.R. 275 at paras. 13-18 (*Venlafaxine*). I also describe the Regulations as they existed at the relevant time. They were recently substantially amended by the *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2017-166.

[5] In order to market a new drug in Canada, an innovator drug manufacturer must, among other things, file a new drug submission and receive approval in the form of a notice of compliance from the Minister of Health. As part of that process, the Regulations permit the manufacturer to list in a patent register all of the patents relevant to the submission.

[6] A generic drug manufacturer wishing to make and market a generic version of the drug may submit an abbreviated new drug submission, using the results of clinical trials regarding safety and effectiveness undertaken by the innovator to demonstrate that the generic formulation is bioequivalent to the innovator's. This dispenses with the need for the generic manufacturer to undertake its own clinical trials.

[7] In its submission, the generic drug manufacturer must address any patent listed in the patent register concerning the innovator drug. It does so either by stating that it is not seeking the issuance of an NOC until the patent expires or by alleging that the patent is not valid or will not be infringed by the making, using or selling of the generic drug. If it takes the latter course, it

must serve a notice of allegation containing a detailed statement of the factual and legal bases for the allegation.

[8] An innovator who wishes to challenge the allegation of invalidity or non-infringement in the NOA must apply to the Federal Court within 45 days for an order prohibiting the Minister of Health from issuing an NOC for the generic product before the expiry of the patent or patents that are the subject of the NOA. The bringing of a prohibition application triggers what is sometimes referred to as a regulatory stay: the Minister may not issue an NOC to the generic drug company for 24 months or until the application is withdrawn, discontinued or dismissed.

[9] If a prohibition application is ultimately unsuccessful either at first instance or on appeal, or if it is discontinued or withdrawn, section 8 of the Regulations gives the generic company a right of action against the innovator for any loss suffered during a period that ordinarily runs from the date on which the Minister certified that an NOC would have been issued in the absence of the Regulations (often called the patent hold date) to the date of the withdrawal, discontinuance or dismissal. By clause 8(1)(a)(ii), the court hearing the section 8 claim may determine that some start date other than the certified date is appropriate.

[10] Subsection 8(5) requires the court, in assessing the amount of compensation, to "take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the [parties] which contributed to delay the disposition of the [prohibition] application." The assessment of whether the generic manufacturer suffered a loss and, if it did, the proper amount of damages entails comparing what happened in the "real world," where the

generic manufacturer was kept out of the market, with what would have happened in the "hypothetical world" or "but-for world" – a world in which the generic manufacturer was free to enter (*Venlafaxine*, above at paras. 45-46).

III. Litigation history

[11] The parties have been engaged in litigation concerning olanzapine, a drug primarily useful in the treatment of schizophrenia, since August 2004. At that time Teva, which was seeking to bring to market a generic version of olanzapine, served an NOA under the Regulations alleging that Lilly's patent for olanzapine was invalid on a variety of grounds. Lilly responded with an application for prohibition in the Federal Court.

[12] In June 2005, before the evidence in the application was complete, Teva served a further NOA and advised that it would be withdrawing the first one. The second NOA was similar to the first, but dropped certain allegations and added several new ones. Once Teva withdrew the first NOA, Lilly's application was discontinued. In response to the second NOA, Lilly brought a further application for prohibition. That application was dismissed by Justice Hughes in June 2007 (*Eli Lilly Canada Inc. v. Novopharm Limited*, 2007 FC 596, [2008] 2 F.C.R. 749). Teva then obtained its NOC and was free to enter the olanzapine market. Lilly's appeal from the dismissal of its prohibition application was dismissed as moot (*Eli Lilly Canada Inc. v. Novopharm Limited*, 2007 FCA 359, 370 N.R. 140).

[13] On the dismissal of the application, Lilly commenced an infringement action against Teva in the Federal Court. Teva counterclaimed for a declaration of invalidity and for damages

under section 8 of the Regulations for the loss that it suffered from being kept off the market until Lilly's prohibition application was dismissed. Lilly sought and obtained an order bifurcating liability and remedies.

[14] The liability proceeding was tried before Justice O'Reilly (*Eli Lilly Canada Inc. v. Novopharm Limited*, 2009 FC 1018, 353 F.T.R. 35). He found Lilly's patent invalid, primarily on the basis that it was not a valid selection patent. He also found it invalid for double patenting, anticipation, insufficiency of disclosure, and obviousness. He found Teva entitled to section 8 damages, and ordered that their amount, together with other related issues, be determined in a separate proceeding.

[15] Lilly's appeal to this Court was allowed (*Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197, [2012] 1 F.C.R. 349). This Court concluded that the patent was not invalid for anticipation, double patenting or obviousness, but remitted the issues of utility and sufficiency to the Federal Court. Teva sought leave to appeal this Court's decision to the Supreme Court of Canada. Its application for leave to appeal was dismissed (2011 CanLII 6307 (SCC)).

[16] The re-trial proceeded before Justice O'Reilly (*Eli Lilly Canada Inc. v. Novopharm Limited*, 2011 FC 1288, 100 C.P.R. (4th) 269). He found that there was no insufficiency of disclosure, but again concluded that the patent was invalid, based on lack of utility. An appeal to this Court was dismissed (*Eli Lilly Canada Inc. v. Novopharm Limited*, 2012 FCA 232). Lilly again sought leave to appeal to the Supreme Court of Canada. Following an oral hearing, its application was dismissed (2013 CanLII 26762 (SCC)).

[17] The parties then moved on to the remedies proceeding, to determine the amount, if any, of section 8 damages. This proceeding too was tried before Justice O'Reilly. After a 16-day trial, he concluded that Teva was entitled to damages, and made a series of findings, as the parties had requested, to permit them to calculate the amount. I discuss these findings later in these reasons to the extent necessary to address the grounds of appeal and cross-appeal.

IV. Grounds that Lilly argues require dismissal of the section 8 claim in its entirety

[18] There are two grounds in this category. Lilly asserts that (1) the trial judge erred in failing to find that Teva abandoned its section 8 claim when it withdrew its first NOA, and (2) as the result of the recent decision of the Supreme Court of Canada in *AstraZeneca Canada Inc. v. Apotex Inc*., 2017 SCC 36, 147 C.P.R. (4th) 79, Teva suffered no compensable loss.

(1) *Abandonment*

[19] Lilly's abandonment argument is based on written representations made by Teva in response to a motion brought by Lilly for solicitor-and-client costs of its first prohibition application, which became moot and was discontinued once Teva withdrew its first NOC. The representations included the following paragraph (Appeal Book, Vol. 4, p. 898, emphasis added):

> The evidence on the record is that [Teva] had to withdraw its first Notice of Allegation and file its second Notice of Allegation to incorporate the new evidence and arguments that came to light between August 2004 and March 2005, thereby ensuring that all relevant issues were before the Court. This was to the prejudice of [Teva]. [Teva] lost time, restarted the "draconian" 24-month stay imposed by the Regulations, abandoned its claim to s. 8 damages and lost its first to market position to its competitor Apotex.

[20] Lilly submits that the trial judge erred in failing to find this to be an unequivocal representation to Lilly and the Court that Teva had abandoned its section 8 claim, as it related not only to Lilly's first prohibition application but also to the second. It says that if there is any ambiguity about the scope of the abandonment, it should be resolved against the party that made the representation of abandonment. It also submits that to make out a claim of abandonment – unlike other similar types of claims, such as promissory estoppel – there is no need to show reliance by the party to whom the representation of abandonment was made. It asserts that whether and the extent to which there is abandonment is not a question of fact, but "a question of interpretation."

[21] The trial judge rejected Lilly's arguments on this issue (at paras. 27-28). He found that, read in context, the statement by Teva that it abandoned its claim for section 8 damages related solely to the first proceeding, that "Teva was simply pointing out that one of the consequences of the withdrawal of its first NOA was a relinquishment of a claim to damages within that proceeding," and that "Teva did not agree that it would not […] seek s 8 damages in the second proceeding or, indeed, in this action." He drew support for his conclusion from, among other things, his own determination in the first liability trial that the amount of damages would be decided in a separate proceeding.

[22] In my view the threshold question raised by this ground of appeal – whether Teva's representation that it had abandoned its section 8 damages claim encompassed its claim flowing from the second application for prohibition – is a question of fact (B. MacDougall, *Estoppel* (Markham, Ontario: LexisNexis Canada Inc., 2012) at pp. 576-577). It is therefore subject to

review on the "palpable and overriding error" standard of review. This is of course a stringent and highly deferential standard (*Benhaim v. St-Germain*, 2016 SCC 48, [2016] 2 S.C.R. 352 at paras. 38-39).

[23] I see no basis for concluding that the trial judge committed a palpable and overriding error in making the finding that he did. Apart from the factors to which he referred, which were sufficient support for his finding, there was also evidence from Barry Fishman, Teva's then-Executive Vice President, Commercial Development, to the effect that the abandonment related only to the first application (Appeal Book, Vol. 56, p. 14497). There is therefore no need to consider the legal question whether Lilly is correct in its submission that it did not have to establish reliance on its part to make out the abandonment claim.

(2) *Impact of* AstraZeneca

[24] Lilly argues that the decision in *AstraZeneca* rendered legally untenable the sole basis on which its patent for olanzapine was ultimately found invalid. It relies heavily on the decision of the Supreme Court of the United Kingdom in *Virgin Atlantic Airways Limited v. Zodiac Seats UK Limited*, [2013] UKSC 46, [2014] 1 A.C. 160, in submitting that the Court must take into account a change of circumstances as to the validity of the patent – here, the change resulting from *AstraZeneca* – that arises between the finding of liability and the quantification of damages, even where the liability decision is *res judicata*. It points out that recovery of section 8 damages requires proof of a loss (*Venlafaxine*, above at paras. 44-45), and that damages are not recoverable for sales that in the hypothetical world would likely have been infringing and illegal (*Apotex Inc. v. Merck & Co., Inc.*, 2012 FC 620, 411 F.T.R. 284 at paras. 26, 37-40).

[25] Lilly goes on to argue that even apart from *Virgin Atlantic*, *res judicata* and its related doctrines do not preclude taking into account the decision in *AstraZeneca*. It argues that the issue of causation under section 8 is still open and has not been finally decided, and that issue estoppel does not apply to a declaratory statement of the law like that made in *AstraZeneca*. It submits that in any event, issue estoppel is an equitable doctrine that is to be flexibly applied, to achieve fairness according to the circumstances of each case. It submits that it would be unfair, and contrary to the ends of justice, to require Lilly to pay $70 million in damages when its patent would not now be found, and should not have been found, to be invalid, and when it has already suffered from the loss of exclusivity in the market for olanzapine. This, it submits, would be "pouring salt on the wounds."

[26] The Supreme Court of Canada issued its decision in *AstraZeneca* in June 2017, five months after the trial judge rendered the decision now under appeal. The argument that Lilly now makes is not, therefore, one that was or could have been put to the trial judge before he gave judgment; nor did Lilly seek leave to reopen the trial so that it could advance it before him. However, Lilly sought and was granted leave to amend its notice of appeal to add the argument to its grounds of appeal, without of course any determination of the merits of the argument or whether it could properly be made on appeal.

[27] In my view, the doctrine of issue estoppel bars Lilly from succeeding on this ground of appeal. While the doctrine of issue estoppel contemplates a discretion on the part of a court not to apply it where its application would work an injustice, I do not see a sufficient basis to exercise the discretion in Lilly's favour here. In argument, there was some discussion of other

doctrines within the umbrella of *res judicata*, but it is not necessary to go beyond issue estoppel in the circumstances here.

[28] Before setting out the elements of the doctrine of issue estoppel and discussing its application in the face of Lilly's submissions in support of this ground of appeal, I will review first the decision in *AstraZeneca* and how it affects the basis on which Lilly's patent was determined to be invalid, and then the decision in *Virgin Atlantic*. I will also consider why it is at a minimum problematic for Lilly to raise this new ground on appeal.

(a) The *AstraZeneca* decision

[29] The main issue in *AstraZeneca* was whether the "promise of the patent" doctrine is the correct approach for determining whether a patent has sufficient utility. The doctrine had grown out of observations by the Supreme Court and had been developed and applied by the Federal Court and this Court in a series of cases. One of these was this Court's decision on Lilly's appeal from the trial judge's first determination of invalidity. This Court set out the doctrine in that case as follows (2010 FCA 197 at para. 76):

> Where the specification does not promise a specific result, no particular level of utility is required; a "mere scintilla" of utility will suffice. However, where the specification sets out an explicit "promise", utility will be measured against that promise […]. The question is whether the invention does what the patent promises it will do.

In allowing the appeal and remitting the matter to the Federal Court, this Court held that the trial judge had erred in failing properly to apply the promise doctrine.

[30] The trial judge applied the doctrine in his second invalidity decision. He found that while the invention had some utility, it failed to meet the explicit promise that the patent set out. The patent was therefore invalid for want of utility (2011 FC 1288 at paras. 209, 267-268). This was the sole ground of invalidity on which Teva succeeded; its sufficiency attack failed.

[31] When Lilly applied for leave to appeal to the Supreme Court from this Court's decision upholding the second invalidity decision, it was on the basis that the appropriateness of the promise doctrine was a matter of public importance that the Supreme Court should consider. However, its application was dismissed. Some three years later, the Supreme Court granted leave to appeal to address this issue in *AstraZeneca*.

[32] The Supreme Court concluded in *AstraZeneca* that the promise doctrine is not the correct approach to determine whether a patent has sufficient utility. The doctrine, it stated, is "unsound," "not good law," and incongruent with both the language and the scheme of the *Patent Act* (at paras. 36, 51). The Court characterized the doctrine as excessively onerous. It also saw it as conflating the statutory requirements of utility and disclosure (at paras. 37-38), and stated that the mischief of overpromising could be dealt with through other requirements for a valid patent, including that of sufficient disclosure. It held that to meet the utility requirement, "a scintilla of utility will do" (at para. 55).

(b) The *Virgin Atlantic* decision

[33] In *Virgin Atlantic*, the U.K. Supreme Court dealt with a claim by Virgin against Zodiac for damages for infringement of a European patent for airplane passenger seats. U.K. law, in

conjunction with the European Patent Convention, establishes what the Court described as a "system of parallel jurisdiction for determining the validity of European patents" (at para. 3).

[34] Under this system the English courts have the same jurisdiction to determine validity and infringement of a European patent as they have for domestic patents. However, the European Patent Office has concurrent jurisdiction over questions of validity (at para. 7). A determination of invalidity by either an English court or the EPO is a decision *in rem*, which extends beyond the immediate parties. But the effect of an English decision is territorially limited to the U.K., while an EPO decision is effective in all states for which the patent was granted.

[35] Virgin brought infringement proceedings against Zodiac in the English High Court, claiming an injunction and damages. Zodiac defended on the basis that its seats did not infringe, and that in the alternative the patent was invalid. It also brought opposition proceedings in the EPO.

[36] Virgin's claim in the High Court was initially dismissed, but the Court of Appeal reversed, held the patent valid and infringed, granted an injunction, and directed an inquiry as to damages. In the meantime a division of the EPO upheld the validity of the patent. Zodiac appealed that decision to the EPO's Technical Board of Appeal. The TBA held that all of the claims that the Court of Appeal had found infringed were invalid, and amended the patent to remove them. Under the applicable law, its decision was retrospective, with effect from the priority date of the patent.

[37] By this time the Supreme Court had refused permission to appeal the decision of the Court of Appeal upholding the validity of the patent. However, Zodiac applied to the Court of Appeal for an order, among other things, discharging the order for an inquiry as to damages. The Court of Appeal upheld the order, based on *res judicata*. The question before the Supreme Court was whether Zodiac was entitled to argue at the inquiry as to damages – or alternatively precluded from arguing by *res judicata* – that there were no damages because the patent had been retrospectively amended to remove the claims held infringed.

[38] The Supreme Court was unanimous in holding that Zodiac was entitled to argue that there were no damages. The leading judgment was given by Lord Sumption; Lord Neuberger wrote a supporting judgment with which the other three members of the panel also concurred.

[39] Lord Sumption began with the observation that the appeal "perfectly [illustrated] the problems arising from the system of parallel jurisdiction for determining the validity of European patents" (at para. 3). He held that there were two reasons why, despite the principles of *res judicata*, Zodiac could not be precluded from making the argument that there were no damages. First, Zodiac would be relying not on the patent as upheld by the Court of Appeal, but "on the more limited terms of a different patent which, by virtue of the decision of the TBA, must at the time of the enquiry be treated as the only one which ever existed." Second, Zodiac was not seeking to reopen the question of validity determined by the Court of Appeal: "[t]he invalidity of the patent may be the reason why the TBA amended the patent, but the defendant is relying on the mere fact of amendment, not on the reasons why it happened" (at para. 27).

[40] In reviewing the English authorities on the principles flowing from *res judicata*, Lord Sumption had quoted from a decision of the House of Lords stating that the "underlying public interest is […] that there should be finality in litigation and that a party should not be twice vexed in the same matter" (at para. 24). He observed that "[t]he 'vexation' associated with the pursuit of two proceedings challenging the validity of the patent was an inescapable feature of the statutory scheme which [confers] concurrent jurisdiction on questions of validity on both the English court and the EPO" (at para. 33).

[41] In his reasons, Lord Neuberger was critical of the Court of Appeal for failing to "have appropriate regard to the statutory provisions relating to patents, which reflect the nature of a patent and the effect of its revocation" (at para. 48). The effect of revocation, he stated, "was that everyone was entitled to conduct their affairs as if the patent had never existed" (at para. 49). He added that "an issue of res judicata in connection with a patent case cannot be considered correctly without proper regard to the effect of [the Patents Act] and the [European Patent Convention]" (at para. 50). He described the fact that "the patent in issue" had been revoked as "a new, centrally important, uncontroversial fact" which could not have been raised in the English proceedings because the revocation had not yet occurred; "to deny the alleged infringer the ability to raise it would be to give effect to a monopoly right which the patentee never should have had" (at para. 52).

[42] Lord Neuberger went on to note that Zodiac was not seeking to challenge any of the conclusions reached by the Court of Appeal in the English proceedings. He added (at para. 53) that

> [a]ll that Zodiac are seeking to do is to contend that the damages on the assessment should be assessed at nil (or, perhaps, a nominal figure), because, as the Patent has been amended in the course of the EPO proceedings, it is now retrospectively to be treated as amended, so that Zodiac's product does not infringe, and so Virgin have suffered no damage.

[43] He stated that "it would be positively unjust, as between the parties, for a (former) patentee to recover damages for infringement of a patent after the patent has been irrevocably and retrospectively revoked (or, as in this case, relevantly amended)." He also saw "no public interest in such an outcome" (para. 62).

(c) Appropriateness of raising the argument on appeal

[44] I have serious doubt as to whether it is appropriate for Lilly to raise its new argument based on *AstraZeneca* and *Virgin Atlantic*, one that was not considered by the trial judge, on appeal. Ordinarily, an appellate court should not consider an issue that was not raised at trial, particularly where it calls for consideration of facts. In those circumstances "there is always the very real danger that the appellate record will not contain all of the relevant facts, or the trial judge's view on some critical factual issue, or that an explanation that might have been offered in testimony by a party or one or more of its witnesses was never elicited" (*Performance Industries Ltd. v. Sylvan Lake Golf & Tennis Club Ltd.*, 2002 SCC 19, [2002] 1 S.C.R. 678 at para. 32).

[45] An appellate court may depart from this ordinary rule and entertain a new issue "where the interests of justice require it and where the court has a sufficient evidentiary record and findings of fact to do so" (*Quan v. Cusson*, 2009 SCC 62, [2009] 3 S.C.R. 712 at paras. 36-37). As a matter of fairness, the party seeking to raise a new issue on appeal bears the onus of

establishing that "all relevant facts were adduced at trial and that no satisfactory response could have been offered by the opposite party" (*Keus v. Canada*, 2010 FCA 303, 410 N.R. 150 at paras. 10-11).

[46] Lilly's position as I understand it is that given the clarity of the decisions in *AstraZeneca* and *Virgin Atlantic,* the concerns ordinarily associated with deciding a new issue on appeal do not arise in this case: since the only ground on the Lilly's patent was invalidated has now been conclusively held to have been wrong in law, this Court need look no further than *AstraZeneca* in treating the patent as valid for purposes of Lilly's section 8 claim. *Virgin Atlantic*, it argues, then applies to reduce the damages to nil.

[47] In my view things are not so simple. For one thing, in this case, unlike in *Virgin Atlantic,* the subsequent decision related to a patent different from the patent in question. For another, it does not follow from the decision in *AstraZeneca* that Lilly's patent would necessarily have been found to be valid if validity had been litigated after the decision was rendered. Parties shape their trial evidence and argument to the law as it exists at the time of trial. The evidence and argument before the trial judge in this case would inevitably have been different if *AstraZeneca* had been the governing law. That is all the more likely given the Supreme Court's indication in *AstraZeneca* that at least some of the concerns that animated the promise doctrine can better be dealt with as issues of sufficiency of disclosure. Following *AstraZeneca,* generic drug companies have, not surprisingly, sought to recast arguments that were initially made as utility arguments as arguments going to sufficiency and other grounds of invalidity (*Pfizer Canada Inc. v. Teva*

Canada Limited, 2017 FC 777, [2017] F.C.J. No. 944 at paras. 313 and 315; *Apotex Inc. v. Shire LLC*, 2017 FC 831, [2017] F.C.J. No. 906 (Proth.) at paras. 5-6).

[48] However, it is also not apparent that it would have been possible for Lilly to go back to the trial judge to raise this issue. While this Court has held that motions to vary a judgment of the Federal Court that this Court has affirmed should be made to the Federal Court (*AstraZeneca Canada Inc. v. Apotex Inc.*, 2016 FCA 194, [2016] F.C.J. No. 759 at paras. 15-20), under the *Federal Courts Rules*, SOR/98-106, the grounds on which a judgment may be set aside or varied are very limited. Paragraph 399(2)(*a*) of the Rules provides that the Court may on motion set aside or vary an order "by reason of a matter that arose or was discovered subsequent to the making of the order." But this Court has repeatedly held, consistent with the finality principle referred to below, that subsequent decisions of a higher court do not constitute a "matter" within this provision (*Metro Can Construction Ltd. v. The Queen*, 2001 FCA 227, 273 N.R. 273 at paras. 4-6; *Siddiqui v. Canada (Citizenship and Immigration)*, 2016 FCA 237, [2017] 1 F.C.R. 69 at paras. 13-17).

[49] Because, in my view, Lilly's argument fails in substance as explained below, it appears to me to be unnecessary to decide the propriety of the manner in which it was raised in this case.

(d) Issue estoppel

[50] Issue estoppel is one manifestation of the doctrine of *res judicata*, the doctrine that precludes parties from relitigating an issue in respect of which a final determination has been made as between them (*Régie des rentes du Québec v. Canada Bread Company Ltd.*, 2013 SCC

46, [2013] 3 S.C.R. 125 at para. 24). *Res judicata* is a fundamental doctrine in the Canadian justice system. It is grounded on the two considerations of public policy referred to in *Virgin Atlantic*: that it is in the public interest that there be finality in litigation and that no one should be "twice vexed in the same cause" (D.J. Lange, *The Doctrine of Res Judicata in Canada*, 4th ed. (Markham, Ontario: LexisNexis Canada Inc., 2015) at pp. 4, 6). As the Supreme Court has put it, "[t]he stability and finality of judgments are fundamental objectives and are requisite conditions for ensuring that judicial action is effective and that effect is given to the rights of interested parties" (*Boucher v. Stelco Inc*., 2005 SCC 64, [2005] 3 S.C.R. 279 at para. 35).

[51] Issue estoppel aims to promote finality, in the interests of justice. It generally precludes a party from relitigating a question decided in a prior proceeding where three conditions are met: (1) the same question has been decided; (2) the judicial decision which is said to create the estoppel was final; and (3) the parties to the judicial decision or those who stand in their place were the same as those in the proceedings in which the estoppel is raised (*Danyluk v. Ainsworth Technologies Inc*., 2001 SCC 44, [2001] 2 S.C.R. 460 at para. 25).

[52] Where these three conditions are met, the court nonetheless retains a discretion not to apply the doctrine. As the Supreme Court stated in *Penner v. Niagara (Regional Police Services Board)*, 2013 SCC 19, [2013] 2 S.C.R. 125 at para. 30, "[t]he principle underpinning this discretion is that '[a] judicial doctrine developed to serve the ends of justice should not be applied mechanically to work an injustice' […]."

[53] While the discretion has been said to be limited to "special circumstances" (*Minott v. O'Shanter Development Company Ltd.*, 1999 CanLII 3686, 42 O.R. (3d) 321 at para. 51 (C.A.)), there is no definitive list of factors for determining whether special circumstances are made out (*Penner* at para. 38). The Supreme Court has stated that unfairness warranting the exercise of discretion may arise from the unfairness of the prior proceedings, or the unfairness of their result, or both (*Penner* at para. 39). It has also suggested that the discretion will be more limited where the prior decision is that of a court rather than an administrative tribunal. It has stated that "[a]s a final and most important factor, the Court should stand back and, taking into account the entirety of the circumstances, consider whether application in the particular case would work an injustice" (*Danyluk* at paras. 62, 80).

[54] There has been some controversy as to whether a change in the law can be regarded as creating an injustice sufficient to call for the exercise of the discretion not to apply the doctrine (Lange, *The Doctrine of Res Judicata in Canada*, above at pp. 260-273). However, this Court has at least on one occasion exercised the discretion based on a change in the law resulting from a Supreme Court decision (*Oberlander v. Canada (Attorney General)*, 2016 FCA 52, [2016] 4 F.C.R. 55 at para. 22; leave to appeal refused, 2016 CanLII 41772 (SCC)). Accepting that a change in the law like that in *Oberlander* may suffice for this purpose, that does not, as the Court of Appeal for Ontario has stated, mean that it necessarily will. As that Court has explained (*Smith Estate v. National Money Mart Company*, 2008 ONCA 746, 92 O.R. (3rd) 641 at para. 42), there is no "guarantee that a litigant who has fought an issue and lost will always be accorded the benefit of a change in the law":

> A litigant has no automatic or presumptive right to relitigate an issue on account of a change in the law: the matter rests upon the discretion of the court to ensure that the finality principle is applied in a manner consistent with the interests of justice.

(e) Application of issue estoppel

[55] In my view all of the three conditions for the operation of issue estoppel are met.

[56] First, the same question has been decided. At issue in the liability proceeding that resulted from the bifurcation order was the validity of Lilly's patent. Lilly seeks to raise the same issue now as a defence to Teva's section 8 damages claim.

[57] Lilly argues that the issue now is different – that it is not really raising an issue of validity but rather an issue of causation, and that all that it is seeking is a determination that, in the words of Lord Neuberger in *Virgin Atlantic* (at para. 53), "the damages […] should be assessed at nil."

[58] I disagree. The reason Lilly argues the damages should be assessed at nil is that any sales by Teva during the currency of the patent would have been unlawful. The reason they would have been unlawful, according to Lilly, is they would have infringed the patent. But they could have infringed Lilly's patent only if the patent was valid. At bottom, Lilly's argument depends on a finding of invalidity. That is an issue already decided.

[59] The second condition, that the judicial decision said to create the estoppel was final, is also met. The trial judge determined in the second validity trial that Lilly's patent was invalid.

His decision was affirmed by this Court on appeal, and leave to appeal to the Supreme Court was denied. That is as final as it gets in the Canadian justice and patent systems.

[60] Here lies the central reason why *Virgin Atlantic* does not apply in this case. The governing legislation in *Virgin Atlantic* gave the English courts and the European Patent Office concurrent jurisdiction to determine validity of a European patent. Even though permission to appeal the decision of the Court of Appeal upholding the validity of the patent was refused by the Supreme Court, the Court of Appeal's determination of validity was not in substance final; it was subject to being displaced by a decision of the EPO. That is what in fact occurred.

[61] In my view, therefore, *Virgin Atlantic* is very much an artifact of the UK patent system and the concurrent jurisdiction for which it provides. The Federal Court of Appeal of Australia has expressed the same view (*Jones Tulloch Pty Ltd v. Commissioner of Patents*, [2016] FCA 1108 at para. 25). That is why Lord Sumption was able to say in *Virgin Atlantic* that the case "perfectly illustrates the problems arising from the system of parallel jurisdiction for determining the validity of European patents" (at para. 3), and to describe "[t]he 'vexation' associated with the pursuit of two proceedings challenging the validity of the patent" as "an inescapable feature of the statutory scheme" (at para. 33).

[62] The third condition for the operation of issue estoppel is plainly met: the parties to the proceeding in which invalidity was determined and the parties here are the same.

[63] The question then is whether this Court should exercise its discretion not to apply issue estoppel. As already noted, according to *Danyluk* answering this question requires that the Court "stand back and, taking into account the entirety of the circumstances, consider whether application […] would work an injustice."

[64] As I perceive it, the basis on which Lilly submits that the Court should exercise its discretion not to apply issue estoppel to prevent Lilly from relitigating the validity of its patent is that it would be unfair not to give it the benefit of the change in the law made in *AstraZeneca*. It sees this as particularly unfair when it was unsuccessful itself in attempting to bring the promise doctrine before the Supreme Court, only to have the Court decide to deal with the doctrine just a few years later in response to another innovator company's leave application. (I appreciate that part of Lilly's position is that *AstraZeneca* did not really change but rather restored the law, but that is a distinction without a difference in this context.) Lilly sees the sheer amount of the damages Teva is seeking as a further factor aggravating the unfairness, especially when combined with the financial consequences that it has already suffered from Teva's entry into the olanzapine market.

[65] There are other factors that, in my view, also call for consideration. The first is the nature of the interests at stake. Here they are entirely commercial in nature. While I do not depreciate the importance of commercial interests, they are not of the same order as, for example, those at stake in *Oberlander*, above. There the discretion was exercised to enable an individual who faced revocation of his citizenship to relitigate the question of his complicity in war crimes based on the Supreme Court's rearticulation of the test for complicity.

[66] The consequences for the other party comprise, it seems to me, a further relevant factor. Here Teva can rightly complain about the prospect of being "twice vexed" on the issue of validity, when it fought and won on that issue, up to the Supreme Court of Canada, based on the law as it stood at the time.

[67] In addition, this is a case in which the prior decision is that of a court rather than an administrative tribunal. On the authorities, the discretion should be exercised less readily in this situation.

[68] Standing back and taking into account the entirety of the circumstances, I conclude that it would not work an injustice to apply issue estoppel in this case. As noted above, there is no presumptive right to relitigate an issue on account of a change in the law. If the discretion were exercised in this case, it would be difficult to resist its exercise in any case in which there was a change in the law on the basis of which a substantial judgment had been granted or refused. That would turn a "special circumstances" exception into a general rule, and seriously impair the principle of finality. The Ontario Superior Court has recently come to a similar conclusion in analogous circumstances (*Apotex v. Schering Corporation*, 2018 ONSC 903 at para. 64). I conclude, therefore, that issue estoppel applies, and that it bars Lilly from succeeding in its attempt to use *AstraZeneca* to eliminate its liability for section 8 damages.

V. Grounds relating to the application of subsection 8(5) of the Regulations

[69] There are also two grounds of appeal in this category. Lilly asserts that the trial judge erred in the assessment of damages by (1) ignoring the 11½ month delay caused by Teva

withdrawing its first NOA and serving a second, and (2) failing to find that serving two NOAs was an abuse of process, when subsection 8(5) of the Regulations required that both of these factors be considered.

[70] As set out above, subsection 8(5) requires the court, in assessing the amount of compensation, to "take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the [parties] which contributed to delay the disposition of the prohibition application" (emphasis added). The provision confers on the court a broad discretion to determine whether, and to what extent, a claim for compensation should be reduced or eliminated (*Apotex Inc. v Merck & Co., Inc*., 2011 FCA 364, 430 N.R. 74 at paras. 37-38, leave to appeal refused, 2012 CanLII 32663 (SCC)).

[71] The Federal Court has stated that this discretion is to be exercised "with due regard to all of the circumstances bearing on the claim" (*AstraZeneca Canada Inc. v. Apotex Inc*., 2017 FC 726 at para. 202). However, there is no reason why the exercise of the discretion under subsection 8(5) as to what "matters" to consider and the extent to which they should be taken into account should not be reviewable – like other discretionary determinations by the Federal Court – only on the *Housen* standard of palpable and overriding error or error on an extricable question of law or legal principle (*Hospira Healthcare Corporation v. Kennedy Institute of Rheumatology*, 2016 FCA 215, [2017] 1 F.C.R. 331 at paras. 28, 66-68, 71-73, 79; *Mahjoub v. Canada (Citizenship and Immigration)*, 2017 FCA 157 at paras. 71-74). Applying this standard, I see no reviewable error in the trial judge's disposition of the delay and abuse of process issues. I will now deal with each of these issues in turn, and explain the basis for my conclusion.

(1) *Delay*

[72] The sequence of events on which this ground of appeal rests can be recapitulated as follows. Teva served its first NOA on August 5, 2004. In response, on September 24, 2004, Lilly commenced an application for prohibition. On April 21, 2005, Teva withdrew its first NOA. On July 20, 2005, 11½ months after it had served its first NOA, Teva served its second. Lilly then commenced a second application for prohibition, on September 8, 2005. The Federal Court granted leave to discontinue the first application on June 19, 2006. The trial judge found that the liability period ran from March 3, 2006 to June 5, 2007 (at para. 24). This was the period from the date on which the Minister certified that an NOC would have been issued in the absence of the Regulations to the date of the dismissal of the second prohibition application.

[73] Lilly argues that it was an error of law for the trial judge not to accept its submission that the liability period should be reduced by the 11½ months that elapsed between service of the first and service of the second NOA, and should therefore start to run from March 22, 2007 rather than March 3, 2006. It further argues that the trial judge erred in law by ignoring this issue.

[74] In my view, the trial judge committed no error of law in his treatment of Lilly's submission on the start date of the liability period. First, the trial judge did not ignore the issue. He expressly stated at paragraph 24 of his reasons that he was "not persuaded by Lilly's arguments relating to abandonment or an alternate start date."

[75] Second, the trial judge went on to state that in fixing the start date he was adopting the date on which, according to the evidence, Teva would have received its NOC. This is the

presumptive start date, which by paragraph 8(1)(*a*) of the Regulations applies "unless the court concludes that […] a date other than the certified date is more appropriate." The trial judge did not explain why he was not persuaded by Lilly's arguments that another date was more appropriate, and it would no doubt have been helpful for him to do so. However, the failure of trial judges to show how they arrived at their conclusions is not by itself reviewable error, and reasons must be read in their overall context (*Hennessey v. Canada*, 2016 FCA 180, 484 N.R. at paras. 9-11). This Court has held that the Regulations impose no deadline by which the generic company must serve its NOA, and that as much time as it deems necessary for this purpose is available to it (*AB Hassle v. Canada (Minister of National Health and Welfare)*, 2000 CanLII 15586 (FCA), 256 N.R. 172 at para. 19). In this context it is understandable why the trial judge declined to exercise his discretion to depart from the presumptive start date.

(2) *Abuse of process*

[76] Lilly argues that for Teva to send two NOAs was an abuse of process. It says that this is a factor that should have led the trial judge to find that Teva was not entitled to any section 8 damages, or at a minimum to reduce Teva's claim, but that the trial judge ignored it in his decision.

[77] I do not see the trial judge as having ignored Lilly's submission on this point. On a fair reading of his reasons, I see the trial judge's statement that he was not persuaded by Lilly's alternative start date arguments as encompassing this argument. In any event I do not agree that the sending of two NOAs was in the circumstances here an abuse of process. Even if I were inclined to agree with this proposition, Justice Hughes rejected Lilly's abuse of process

contention in his decision dismissing Lilly's second prohibition application. Contrary to Lilly's position, this was a final determination, so that issue estoppel bars Lilly from relitigating this issue.

[78] In submitting that the trial judge erred in failing to find that the sending of two NOAs was an abuse of process, Lilly relies on the decisions of this Court in *Pharmascience Inc. v. Canada (Health)*, 2007 FCA 140, 362 N.R. 91, and *AB Hassle v. Apotex Inc*., 2006 FCA 51, [2006] 4 F.C.R. 513. In *Pharmascience*, this Court stated that "multiple NOAs from the same generic relating to a particular pharmaceutical and alleging invalidity of a particular patent will generally not be permitted, even if different grounds for establishing invalidity are put forward in each" (at para. 41). In *AB Hassle*, this Court stated that "if a [generic company] submits a second or subsequent notice of allegation relating to the same proposed product and the same patent, the [innovator company] may commence prohibition proceedings and argue that the second or subsequent notice of allegation is an abuse of process" (at para. 24).

[79] However, both of these cases involved attempts by a generic to raise in a second NOA and to litigate questions that it had failed to raise in previously decided litigation between the same parties in relation to the same patent. The position here is different: here the withdrawal of the first NOA and the discontinuance of the first prohibition application meant that the issues raised by Teva would be litigated only once.

[80] In finding that Teva's service of a second NOA was not in the circumstances an abuse of process, Justice Hughes first noted that the Regulations provide no procedure for amending an

NOA, at least once the matter reaches the courts (2007 FC 596 at para. 16). He then reviewed both this Court's decision in *Pharmascience* and other cases in which courts had considered whether the sending of multiple NOAs was abusive.

[81] Justice Hughes accepted Teva's argument that in the absence of an amendment procedure, the withdrawal of an NOA and service of a new NOA was the only way a generic company could amend its NOA. He characterized this process as "clumsy," but stated that, "given the arcane and often illogical procedure offered in NOA proceedings, this is the only way to do it" (at para. 26). He noted that a generic company that adopted this method might suffer from an award of costs against it in the withdrawn proceeding and would have to face a fresh 24-month stay if its new NOA triggered a new prohibition application. But, he concluded, if a generic company was willing to accept these possible consequences, "[t]he generic should not be driven from its day in Court for amending its NOA in the only way practically possible" (at paras. 26-27). Only if the court process had proceeded to a hearing or a decision would the generic company lose the possibility of serving a new, amended NOA (at para. 28).

[82] I agree with this analysis of the abuse of process issue. But even if there were grounds to disagree, Lilly would be barred by issue estoppel from challenging now the determination by Justice Hughes that there was no abuse of process. This Court has held that issue estoppel may apply to bar relitigation of subsidiary issues (issues other than infringement and validity) decided in prohibition proceedings under the Regulations (*Apotex Inc. v. Pfizer Ireland Pharmaceuticals*, 2011 FCA 77, 419 N.R. 189 at paras. 24-27). The three conditions for applying issue estoppel,

set out above in paragraph 51, are all plainly met, and I see no special circumstances in this context that would justify its non-application.

[83] Lilly suggests that the decision of Justice Hughes on this issue does not meet the finality condition because Lilly was unable to appeal it; as noted above, its appeal from Justice Hughes's dismissal of its prohibition application was dismissed as moot. This suggestion misconceives what finality for issue estoppel purposes entails. A decision is final and binding on the parties "when all available reviews have been exhausted or abandoned" (*Toronto (City) v. C.U.P.E., Local 79*, 2003 SCC 63, [2003] 3 S.C.R. 77 at para. 46 per Justice Arbour). The fact that no appeal from the decision was available does not render the decision any less final. I would therefore not give effect to Lilly's abuse of process argument.

VI. Grounds relating to the finding that Teva could and would have come to market in March 2006

[84] There are three grounds and four sub-grounds in this category. Lilly submits that the trial judge erred in (1) putting the burden on Lilly to show that Teva could not and would not have come to market with its generic version of olanzapine in March 2006, rather than on Teva to show that it could have and would have done so; (2) ignoring uncontradicted evidence on four key elements of his finding that Teva could and would have come to market; and (3) relying on inadmissible hearsay and lay opinion evidence to support a March 2006 entry date. Lilly argues that as a consequence of these errors, the trial judge effectively asked only that Teva prove the date on which the Minister certified that it would have obtained its NOC in the absence of the

Regulations, and thus failed to hold Teva to proving that it could and would have entered the market on that date.

(1) *Burden of proof*

[85] This Court reviewed in *Venlafaxine*, above, the principles governing proof of damages in section 8 claims. It pointed out that section 8 makes compensation available for "any loss suffered" during the relevant period. The generic company suing for damages under section 8 must therefore show that it actually suffered a loss caused by the innovator company's unsuccessful prohibition application (2016 FCA 161 at para. 44). "If [it] cannot prove a loss caused by the failed proceedings under the [Regulations] during that period, it cannot recover section 8 damages."

[86] As the Court went on to explain, "[t]ypically most of the [generic company's] loss will be its inability to sell its version of a drug during that period, in other words, the financial impact of lost sales" (at para. 45). To assess the existence and amount of any loss, the Court stated, the trial court must examine what would have happened had the innovator not brought the unsuccessful prohibition application. "In effect," therefore, "the court is examining a hypothetical world. What would have happened in that hypothetical world must be proven by admissible evidence and any permissible inferences from that evidence" (at para. 46).

[87] Showing that sales were lost requires the generic company to show that in the hypothetical world it both could have and would have made the lost sales (at paras. 48-51):

> [50] Both "would have" and "could have" are key. Compensatory damages are to place plaintiffs in the position they would have been in had a wrong not been committed. Proof of that first requires demonstration that nothing made it impossible for them to be in that position – i.e., they could have been in that position. And proof that plaintiffs would have been in a particular position also requires demonstration that events would transpire in such a way as to put them in that position–i.e., they would have been in that position.
>
> [51] Both elements have to be present. "Could have" does not prove "would have"; "would have" does not prove "could have" [...].

[88] The Court confirmed that the party claiming section 8 damages bears the burden of proving, on a balance of probabilities, the hypothetical world in which it would have made the sales that it claims it lost (at para. 54). It observed that this allocation of the burden was consistent with that in other contexts, such as claims for breach of contract or for damages in tort: there too the party claiming damages ordinarily bears the burden to prove what would have happened but for the commission of the breach or wrong (at para. 55).

[89] The Court proceeded to add a corollary, by reference to the Supreme Court's decision in *Rainbow Industrial Caterers Ltd. v. Canadian National Railway Co*., 1991 CanLII 27 (SCC), [1991] 3 S.C.R. 3. Where the party defending the claim seeks to establish a different hypothetical world than that put forward by the claimant, and thus to set up a new issue or a positive defence, the party defending the claim bears the burden of proving it (*Venlafaxine*, at paras. 58-65). The claimant, "having proved its version of the hypothetical world, does not have to disprove other speculative hypotheses" (at para. 63).

[90] In directing himself on the burden of proof, the trial judge referred expressly to this Court's decision in *Venlafaxine*, which was rendered shortly after final argument at trial (2017

FC 88 at paras. 9-10). He stated, “Teva shoulders the legal burden of establishing all of the elements of its claim for damages: this includes showing that its alleged losses were a product of the operation of the regulations” (at para. 9). He added that “Lilly has an evidentiary burden to respond to Teva’s evidence, and bears the legal burden in respect of its defences” (at para. 10). He gave the following example: “For example, in its defence Lilly maintains that Teva had earlier abandoned its claim for damages and that the start date for the period of liability is much later than the date certified by the Minister. Lilly bears the burden of proof on those issues” (at para. 10; citation to *Venlafaxine* omitted). Later in his reasons, he stated that “[t]he question of whether Teva could have and would have launched [in the hypothetical world that it put forward] can be answered only after considering all of the relevant evidence; it is my responsibility to answer it based on all of the evidence before me” (at para. 15). I see no reviewable error in the trial judge’s statement of the burden of proof.

[91] Lilly argues in particular that the sentence, “Lilly has an evidentiary burden to respond to Teva’s evidence, and bears the legal burden in respect of its defences,” reflects an improper shifting of the burden of proof to Lilly. I do not agree. The phrase “evidentiary burden” (and the similar phrase “evidential burden”) can be confusing, in part because “to satisfy an evidential burden a party is not required to prove anything”; see the discussion in S.N. Lederman, A.W. Bryant and M.K. Fuerst, *The Law of Evidence in Canada*, 4th ed. (Markham, Ontario: LexisNexis Canada Inc., 2014 at pp. 87-90, 99-101. But here in my view the trial judge used the phrase simply to indicate that evidence adduced by Teva might result in the drawing of an inference adverse to Lilly, and that Lilly ran the risk of an adverse inference unless it led or pointed to evidence to the contrary (*Snell v. Farrell*, [1990] 2 S.C.R. 311 at pp. 329-330, 1990

CanLII 70 (SCC)). As for the second part of the sentence, the example given by the trial judge makes it apparent that he was merely restating, innocuously, the corollary derived from *Rainbow Industrial Caterers* discussed above in paragraph 89.

[92] Lilly also submits that paragraphs 30 to 43 of the trial judge's reasons support its position that the trial judge shifted the burden to Lilly once the patent hold date was proved. In this portion of his reasons the trial judge addressed Lilly's contention that the start date of the liability period should be March 2007 rather than the patent hold date in March 2006.

[93] It is true that the discussion in these paragraphs focuses on Lilly's evidence aimed at showing that Teva could not have come to market in March 2006, rather than Teva's evidence that it could. But the trial judge had already concluded, in paragraph 24 of his reasons, that "the evidence demonstrates that Teva would have been able to put its product on the market upon receiving its NOC on March 3, 2006." This was a finding that Teva had met its burden on the "could have" issue.

(2) *Ignoring uncontradicted evidence*

[94] Lilly argues that the trial judge erred by ignoring uncontradicted evidence on key elements of Teva's claim – evidence that (1) Teva did not have access to the necessary active pharmaceutical ingredient, olanzapine, as of March 2006, when the trial judge determined the liability period began, but only began to receive API, in small quantities, in September 2006; (2) Teva did not complete its validation and approval process until March 2007, and could not begin the process until it received the API; (3) Teva had decided to wait before launching its generic

olanzapine products until it obtained regulatory approval for API made through [redacted] [an alternate] process, and this did not occur until March 2007; and (4) [redacted].

[95] Lilly asserts that these are all errors of law, subject to the correctness standard. In making this submission, it relies first on the proposition that it is an error of law to make a finding of fact for which there is no support in the evidence (citing *R. v. J.M.H.*, 2011 SCC 45, [2011] 3 S.C.R. 197 at paras. 25-28; *Aubrey* v. *Teck Highland Valley Copper Partnership*, 2017 BCCA 144), and second on the proposition that a trial judge's failure to address relevant evidence may constitute a material error justifying appellate intervention "if the omission gives rise to the reasoned belief that the trial judge must have forgotten, ignored or misconceived the evidence in a way that affected his or her conclusion" (*Merck Frosst Canada Ltd. v. Canada (Health)*, 2012 SCC 3, [2012] 1 S.C.R. 23 at para. 125).

[96] However these alleged errors are characterized, in my view they are not made out on the record before the trial judge. There was at a minimum some evidence to support the findings of the trial judge on the first three points that Lilly raises. On the fourth point, there was insufficient evidence to establish Lilly's proposition, and therefore nothing that called for evidence in response. This ground of appeal accordingly provides no basis on which this Court may interfere with the trial judge's decision (*Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235 at para. 1). For the Court to interfere would be to retry the case, something that it is not of course appropriate for an appellate court to do.

[97] I now consider each of the four points in turn. In doing so I keep in mind the further statement in *Merck Frosst Canada Ltd.*, above, that "the failure of a judge at first instance to discuss a relevant factor in depth, or even at all, is not itself a sufficient basis for an appellate court to reconsider the evidence" (at para. 125, citing *Housen*).

[98] I also note the manner in which the trial judge limited the evidence that Teva could call. Teva sought to meet its burden by, among other things, leading evidence from witnesses who at the relevant time were employees or officers of Teva as to what they thought would or would not have happened in a hypothetical world in which Teva was free to enter the market. The trial judge agreed with Lilly that evidence of this kind was inadmissible as improper lay opinion evidence. He proposed to the parties that the best way to provide the relevant evidence would be to explore with fact witnesses what they did in the real world, and then ask them whether they knew of any reason why they would have acted differently in the hypothetical world. This approach, he stated, would confine fact witnesses to their own knowledge and experience (at paras. 11, 13). On this basis, he stated, he did not consider the testimony of fact witnesses in which they offered opinions about what would or would not have happened in the hypothetical world, but relied solely on the opinions of experts and his own inferences drawn from the evidence (at para. 16).

[99] In my view, the trial judge erred in restricting in this manner the evidence that Teva was entitled to call to establish that it could have and would have entered the market in March 2006. This Court held in *Venlafaxine* that evidence of this kind from a former executive of a generic company was admissible: that he "[had] the expertise having been employed there for a number

of years to say, this is what we […] would have done [in the hypothetical world] or this is what I believe we would have done" (at para. 106). This Court has also faulted a generic company for failing to call evidence of what it would have done in the hypothetical world (*Apotex Inc. v. Merck & Co., Inc*., 2015 FCA 171, [2016] 2 F.C.R. 202 at para. 93 (*Lovastatin*)).

[100] The trial judge here referred to the very passage from this Court's reasons in *Venlafaxine* referred to in the paragraph above. But based on this Court's observation in *Venlafaxine* that "[t]he Federal Court considered that sort of evidence admissible on the issue of [the generic company's] general intentions in the hypothetical world and evidence of the general steps it took to prepare itself for entry into the market," he drew a distinction between evidence as to "general intentions or preparatory steps" – which he acknowledged was admissible – and evidence as to "what they actually would have done or what would have actually happened in the but-for world" – which he determined was not (at para. 14).

[101] In my respectful view, this is neither a workable nor a principled distinction. It is not workable because there can be no bright line between "general intentions" and "what they actually would have done." It is not principled because it does not reflect the rationales for admitting opinion evidence from lay witnesses, which include that the witness has the necessary experiential capacity to draw the inferences (Lederman, Bryant and Fuerst, *The Law of Evidence in Canada*, above at p. 774).

[102] However, the trial judge did not have the benefit of this Court's recent decision on this point in *Toronto Real Estate Board v. Commissioner of Competition*, 2017 FCA 236. There the

Court drew a different distinction in the analogous context of considering what evidence is admissible to demonstrate the hypothetical world that would have unfolded in the absence of anti-competitive restrictions (at para. 81, emphasis in original):

> [L]ay witnesses cannot testify on matters beyond *their own conduct* and that of *their businesses* in the "but for" world. Lay witnesses are not in a better position than the trier of fact to form conclusions about the greater economic consequences of the "but for" world, nor do they have the experiential competence. While questions pertaining to how their particular business might have responded to the hypothetical world are permissible provided the requisite evidentiary foundation is established, any witness testimony regarding the impact of the […] restrictions on competition generally strays into the realm of inappropriate opinion evidence.

[103] Based on this distinction, which I would reiterate and apply here, the trial judge incorrectly stopped witnesses called by Teva on the question of what it could and would have done in the hypothetical world from giving admissible evidence on "their own conduct and that of their businesses in the 'but-for' world." But despite the limits that the trial judge imposed there was in my view evidence to support the findings made by the trial judge on the three points for which Lilly submits evidence was lacking. Considering the evidence improperly excluded makes this even clearer.

(a) Access to API

[104] Lilly argues that there was undisputed evidence that Teva did not have access to API as of March 2006. It points to evidence that it says showed that Teva placed its first purchase order for API with its supplier, Dr. Reddy's Laboratories in India, in March 2006 for delivery in April 2006, and that delivery was delayed several times, so that API ordered in March and April 2006 was not delivered until September and October 2006. It says that no explanation for the delay

was provided by the witness Teva called from Dr. Reddy's, Rajesh Sadanandan, and that Teva provided no other evidence to explain its real world inability to obtain API during the period from March to September 2006. This is a "could have" issue.

[105] I would not accept Lilly's submission on this point. There was evidence to support the inference drawn by the trial judge that API would have been available to Teva to enable it to launch in March 2006.

[106] In initially seeking regulatory approval from Health Canada for its generic olanzapine products, Teva used API obtained from Dr. Reddy's. This API was manufactured by a first process, developed in 2002. Dr. Reddy's began to sell this process 1 API in the period 2002-2003. It later developed a second process for manufacturing olanzapine API in response to requests from customers in Europe, [redacted]. It began selling process 2 API to the commercial market in 2007. Teva made a notifiable change submission to Health Canada for process 2 olanzapine, and received regulatory approval for process 2 on March 22, 2007.

[107] There was evidence from two Teva witnesses – Dr. Brian Des Islet, the head of Teva's Regulatory Affairs Department in 2006, and Mr. Fishman – that in the hypothetical world Teva would have launched with process 1 API in March 2006. Dr. Des Islet testified among other things that Teva would have used process 1 because it was the only process for which, at that time, Teva had regulatory approval (Appeal Book, Vol. 56, p. 14373).

[108] While it appears from paragraph 37 of his reasons that the trial judge considered at least some of this evidence to be inadmissible, in my view he was fully entitled to admit and rely on it. Moreover, the transcript indicates that no objection was made to the evidence when it was given; this is another reason why it can be considered admissible (*Pfizer Canada Inc. v. Apotex Inc*., 2014 FCA 54, 117 C.P.R. (4th) 401 at para. 9). Dr. Des Islet also testified that in the real world, Dr. Reddy's has been Teva's source of supply for olanzapine API throughout, from the regulatory approval process through commercial launch to ongoing commercial supply (Appeal Book, Vol. 56, p. 14368).

[109] Mr. Fishman, whose evidence consisted in part of responses to questions recast to follow the trial judge's guidance as to what he considered permissible, testified that it would have been highly unusual for Teva not to launch when it had an NOC for an available product (process 1 olanzapine) and a potential single-source market opportunity (Appeal Book, Vol. 56, pp. 14490-14491).

[110] Mr. Sadanandan worked at the Dr. Reddy's plant that manufactured both process 1 and process 2 API, and had responsibilities for sales of olanzapine API since 2003. He testified that Teva was "a global key account" for Dr. Reddy's, and that the plant had the capacity from 2005 on to manufacture 1800 kilograms of process 1 API. It is common ground that that this was sufficient capacity to supply Canadian demand. Dr. Reddy's continues to supply both process 1 and process 2 API to the commercial market in a variety of countries (Appeal Book, Vol. 56, pp. 14553-14554). It has been one of Teva's substantial suppliers, of multiple products (Appeal Book, Vol. 57, pp. 14776-14777).

[111] Counsel for Lilly put to Mr. Sadanandan documents from Teva's records that appeared to show a six-month delay in the delivery of API ordered by Teva in March 2006. Mr. Sadanandan had no knowledge of the reasons for any delay, but suggested that it could have been associated with the delivery date requested by the customer (Appeal Book, Vol. 56, p. 14564). Dr. Gordon Munro, an expert witness called by Lilly, agreed that the delivery date shown on a purchase order could be the requested delivery date (Appeal Book, Vol. 58, 14902). In the end there was no definitive evidence on this question, though the parties agreed that any delay was with respect to process 2 rather than process 1 material.

[112] Lilly made before the trial judge the same submission now made to this Court – that this unexplained delay meant that Teva would have been unable to obtain sufficient supplies of API to launch in March 2006, so that Teva failed to meet its "could have" burden. However, the trial judge rejected this submission, in part because he recognized that Lilly's arguments were directed to process 2 API, while Teva's "would have" case was that it would have launched with process 1. He stated (at para. 35):

> I disagree with Lilly's position. While the evidence shows that Teva could not have marketed its product with Process 2 API prior to March 22, 2007, it equally demonstrates that Teva could have sold olanzapine tablets containing Process 1 API as of March 3, 2006. Dr Reddy's was in a position to supply it. Mr Rajesh Sadanandan, an employee of Dr Reddy's who was responsible for European sales of Dr Reddy's API products at the relevant time, explained that Process 1 was developed in 2002. During the 2005 to 2007 period, Dr Reddy's was capable of producing about 1800 kg a year.

[113] In essence, Lilly is now asking this Court to find that the absence of a definitive explanation for the possible delay in supplying process 2 API bars the trial judge from drawing the inference that Teva could have obtained sufficient process 1 API to launch in March 2006.

But there was evidence, including the evidence summarized above, to support drawing that inference. Contrary to Lilly's submission, this evidence went beyond evidence merely of capacity to supply, which this Court has held is not sufficient (*Venlafaxine*, above at paras. 165-168); it included evidence of the business relationship between Teva and Dr. Reddy's and evidence of the supply of API by Dr. Reddy's in the real world. I do not, therefore, accept Lilly's argument on this point.

(b) Timing of validation and regulatory approval

[114] Lilly argues that Teva did not complete the validation of the manufacturing process for its olanzapine products and the regulatory approval process until March 2007, and that it could not begin the validation and regulatory approval process until it had its API. It says that Teva adduced no evidence that it could have completed the process any faster than the time it took in the real world – approximately six months after receipt of the API. This too is a "could have" argument.

[115] This argument can relate only to process 2 API, since it was for process 2 API that Teva obtained regulatory approval in March 2007; it had obtained approval for process 1 API earlier. The argument is therefore of little moment if it is accepted – as it was by the trial judge – that Teva would have launched with process 1.

[116] In any event there was also evidence that the validation process could have been accelerated had it been necessary. Teva led evidence from Gordon Boughner, who in 2006 was

Teva's director of marketing, with responsibility for the launch of new products. He was directly involved in the launch of olanzapine.

[117] Mr. Boughner explained that Teva planned its launch activities with a view to a projected launch date. This date was determined taking into account whether the new product is the subject of patent proceedings. For olanzapine a June 2007 launch date was estimated based on the expected completion date of the proceeding under the Regulations. Teva aimed to complete validation sufficiently in advance of projected launch to allow a buffer if something went wrong, but not so early that the product would not have sufficient remaining shelf life once delivered to customers. In general, it tried to carry out validation six months in advance of launch (Appeal Book, Vol. 57, pp. 14777-14778, 14782).

[118] Mr. Boughner testified, based on his 15 years of experience, that Teva was capable of carrying out validation more quickly if necessary – in as little as a month. While counsel for Lilly objected to this evidence as improper opinion, it seems to me to be entirely unobjectionable based on the criteria for lay opinion evidence discussed above (Appeal Book, Vol. 57, pp.14778-14779). In any event, in the hypothetical world there would have been no need for Teva to validate more quickly: it could have timed the start of the validation process to its estimate of when, absent the Regulations, it would have been in a position to launch.

[119] I would not give effect to Lilly's argument based on the timing of validation and approval.

(c) Waiting for regulatory approval for API made through a non-infringing process

[120] Lilly argues that there was uncontested evidence – evidence that bears on the "would have" question – that because of concerns that [redacted], Teva had decided to wait before coming to market until it obtained regulatory approval for process 2 API. As noted above, regulatory approval for process 2 API was not obtained until March 22, 2007. In making this argument Lilly relies on the proposition, accepted by this Court, that a party's conduct in the real world can be a proxy for what it would have done in the hypothetical world (*Lovastatin*, above at paras. 90, 92; *Teva Canada Limited v. Sanofi-Aventis Canada Inc*., 2014 FCA 67, 126 C.P.R. (4th) 1 at para. 83).

[121] There was certainly evidence, some of which has already been referred to, that process 2 had been developed by Dr. Reddy's [redacted]. There was also evidence that in the real world Teva launched using process 2, and that this course of action allayed the concerns [redacted] (Appeal Book, Vol. 56, p. 14379).

[122] However, there was also evidence that in the hypothetical world, Teva would have [redacted] launched with process 1, the only process for which it had approval in March 2006. As set out in paragraph 107, that was the evidence of Dr. Des Islet, to which no objection was taken when he gave it. In addition, Mr. Fishman testified that he could not recall any case in which Teva did not launch into a single-source product market. He was also asked whether his testimony as to what Teva would have done in March 2006 would change [redacted]. His answer was that it would not (Appeal Book, Vol. 56, pp. 14490-14491). The trial

judge allowed these questions in the face of objection from Lilly, subject to further consideration. In my view this was also admissible evidence, and was at minimum evidence from which a "would have" inference could be drawn. I therefore do not accept Lilly's argument on this point.

(d) Infringement of claim 20

[123] Lilly submits that there was uncontested evidence that [redacted] would infringe claim 20 of its patent, a claim that was never held invalid. In making this submission it relies on the evidence of Dr. Gordon Munro, a pharmacist and chemist called by Lilly as an expert. It argues, based on *Venlafaxine* (above at para. 50), that showing that it could and would have come to market required Teva to demonstrate that nothing made it impossible for it to do so, and that Teva could not meet this burden if it would have infringed.

[124] Dr. Munro stated in his supplemental expert report that he "would consider" [redacted]. But in cross-examination (Appeal Book, Vol. 58, pp. 14909-14910), he described this statement as "an observation," and stated that "the patent issue" did not figure in his assessment as to when Teva could have launched its olanzapine product, and was "not his main area of expertise." He confirmed that he had conducted no validity analysis of claim 20, and ultimately gave the following evidence when asked about his opinion on infringement:

> I haven't got a conclusion on infringement. I said, from a chemistry perspective, it looks to me as if that would fit. That is very different from saying whether it infringes or not because that requires a more detailed legal analysis and possibly a more detailed analysis of the chemistry, as well. That is not what I was here to do and not what I did.

[125] The trial judge was not prepared to find on this and the other evidence before him that [redacted] infringed claim 20 of Lilly's patent; he found "little or no evidence" of infringement. He was therefore unable to conclude that Teva would have been legally prevented from entering the market with process 1 in March 2006. He stated that "[t]he evidence shows that Teva might have been concerned about [redacted], but that is not proof of [redacted]" (at para. 38).

[126] I see no basis on which this Court could interfere with the trial judge's finding on this issue.

(3) *Hearsay and lay opinion evidence*

[127] Lilly argues that the trial judge's determination that Teva would have and could have come to market in March 2006 was based on inadmissible hearsay and lay opinion evidence. I have already dealt with the admissibility of lay opinion evidence. I have also discussed the evidentiary basis for the trial judge's findings on the four points that Lilly identifies as particularly problematic. In view of the admissible evidence that supports the trial judge's conclusions on the first three of these points, and the absence of evidence to support Lilly's position on the fourth point, I see little advantage in addressing further this element of the appeal.

[128] I will however address one additional point emphasized by Lilly in its argument under this heading, which though it does not involve either hearsay or lay opinion evidence arises from evidence that Lilly complains was hearsay. That is the impact of an injunction granted in the United States on Teva's access to API from Dr. Reddy's.

[129] In his examination in chief, Dr. Des Islet was asked what he would have to say in response to the argument that process 1 could not in fact be commercialized. His answer was as follows: “That is not my understanding. I don’t have direct information. From speaking with our procurement people and through our global sources, Dr. Reddy’s was capable of supplying process 1 and, in fact, did so for the U.S. market” (Appeal Book, Vol. 56, p. 14373).

[130] Lilly argues that the phrase “I don’t have direct information” makes this evidence blatant hearsay. However, Lilly did not object to the evidence at the time it was given. In any event the trial judge did not appear to rely on it, and I have already discussed the other evidence, including that of Mr. Sadanandan, that supports the trial judge’s finding on the ability of Dr. Reddy’s to supply process 1 API.

[131] But Lilly goes on to argue that it would have been impossible for Dr. Reddy’s to supply the U.S. market from 2006 through 2011, because Dr. Reddy’s was during this period subject to an injunction issued by the United States District Court for the Southern District of Indiana, Indianapolis Division, in May 2005 in a proceeding by two Lilly companies against defendants including Dr. Reddy’s Laboratories, Ltd. and Teva Pharmaceuticals USA, Inc. The injunction prohibited the defendants and related parties from infringing the United States patent for olanzapine by, among other things, importing it (Appeal Book, Vol. 5, pp. 1272-1274). Lilly also argues that packing slips and invoices entered into evidence show that Teva received bulk API via Dr. Reddy’s in the United States, and that this too would have been prohibited by the injunction.

[132] It is not apparent from Dr. Des Islet's evidence what time period he was referring to in speaking of the supply of the U.S. market. As the trial judge observed, it is also unclear whether, in suggesting that the injunction would have barred shipments of API to Teva through the United States, "the evidence on which Lilly relies shows the actual provenance of shipments of API to Teva in Canada, or whether they [sic] simply show where the documents originated or where the billing occurred." "On this evidence," he stated, "[he could not] conclude that the shipments of API were illegal" (at para. 39).

[133] I see no basis on which this Court could interfere with this finding. In any event, Lilly led no expert evidence to explain the reach and potential impact of the injunction. That is a further reason why the injunction provides in my view no basis to question the trial judge's finding on the "could have" issue.

VII. Grounds relating to the trial judge's finding as to Teva's trade-spend rate

[134] Quantifying Teva's entitlement to damages under section 8 required taking into account what its "trade-spend" would have been on olanzapine in the hypothetical world. As the trial judge noted, trade-spend "represents the after-sales amount paid by generic drug manufacturers to their purchasers, mainly pharmacies and other retailers. Trade-spend can take various forms: rebates, trade allowances, educational subsidies, purchasing incentives, etc." (at para. 104). Through trade-spend, generic companies seek to provide incentives to retailers to purchase their products. The higher the trade-spend rate, the lower would be Teva's recovery.

[135] At trial, Lilly sought a finding that Teva's trade-spend rate on olanzapine would have been in the range of [redacted]. The trial judge did not accept this position. He accepted instead Teva's position that the rate would have been 29.4%, the figure put forward by Errol Soriano, an accountant and business valuator called as an expert by Teva (at paras. 106, 118, 120):

> [106] […] I am satisfied that in the 2006-2007 time frame, Teva's trade-spend would have been lower for generic olanzapine than it would have been than for its other products. In particular, given that Teva would have been the sole generic on the market during the relevant period, I am satisfied that its trade-spend rate would have been relatively low. Teva says it should be no higher than 30%. I agree.

[136] This was a finding of fact, reviewable only for palpable and overriding error.

[137] In coming to this finding, the trial judge reviewed (at paras. 107-117) both the evidence of Ann Woods, a chartered financial analyst with some experience in the pharmaceutical industry, who was called as an expert by Lilly, and the evidence of the witnesses, both fact and expert, who testified for Teva on this issue: Mr. Soriano; Oksana Tressel, a former financial officer with Teva; Doug Somerville, Senior Vice-President and General Manager at Teva; Mr. Fishman; and Gordon Fahner of Apotex Inc. Mr. Somerville and Mr. Fishman were both involved in setting Teva's trade-spend policy. There was ample evidence to support the finding that in a sole-source market, Teva's trade-spend rate would have been relatively low.

[138] However, Lilly argues that the trial judge made three errors of law: (1) relying on the opinion given by Mr. Soriano, when it was based on inadmissible hearsay; (2) relying on a summary prepared by Ms. Tressel, which was inadmissible hearsay but which the trial judge

improperly concluded was a business record; and (3) relying on factual findings from other section 8 cases.

[139] I will consider first the hearsay arguments that Lilly advances, and then the asserted reliance on other section 8 cases. In my view, the trial judge made no error warranting interference with his finding on trade-spend.

(1) *The hearsay arguments*

[140] In his evidence, Mr. Soriano discussed at some length, as a proxy for the trade-spend on olanzapine in the hypothetical world, the actual trade-spend by Teva on another drug, venlafaxine, during the 2006-2007 period. Venlafaxine was the subject of a licensing agreement between Teva and an innovator pharmaceutical company. In deriving the actual trade-spend on venlafaxine, Mr. Soriano relied on data set out in a report prepared by Deloitte & Touche LLP for the innovator company tracking Teva's compliance with the licensing agreement. He also relied on a collection of Teva documents containing information about trade-spend on venlafaxine and on a summary prepared by Ms. Tressel (Appeal Book, Vol. 57, p. 14715).

[141] The starting point for his opinion on the trade-spend rate was Ms. Tressel's summary. He used the Deloitte report for confirmation, and then made two downward adjustments – the first reflecting the unique circumstances in which a payment was made to a larger customer and the second, an increase in trade-spend for venlafaxine in the period immediately preceding the market entry of other generic competition. The adjustments brought his calculation of the average trade-spend on venlafaxine from 33.9% to 29.4%. That was the figure that he adopted

for trade-spend on olanzapine in the hypothetical world (Soriano Report, Appeal Book, Vol. 48, pp. 12505-12509; Appeal Book, Vol. 57, pp. 14716-14717, 14721). The trial judge expressly found, based on the evidence of Mr. Somerville, that the two adjustments were appropriate (at para. 121).

[142] The trial judge ruled that the Deloitte report was inadmissible hearsay, and that it did not meet the test for the business records exception (at paras. 17-18). No one from Deloitte was called as a witness at trial. The trial judge noted that the author of the report and the details surrounding its preparation were unknown.

[143] He also ruled the Teva documents inadmissible (at paras. 19-20). He observed that they were not prepared contemporaneously with the transactions they were said to record, and that their authors were not called as witnesses. He stated that, even though there were some indications that the documents were reliable, the necessity criterion for the admission of hearsay was not met. This was because direct evidence relating to trade-spend was provided by Teva's fact witnesses, Ms. Tressel, Mr. Somerville and Mr. Fishman. It was therefore "not necessary to look to the Deloitte report or the other impugned documents to determine what Teva's trade-spend rate was for venlafaxine."

[144] However, the trial judge rejected Lilly's contention that Ms. Tressel's summary was inadmissible hearsay (at para. 114). He found the summary to meet the criteria for application of the business records exception to the hearsay rule: it reflected the underlying data captured in Teva's financial records system; it was Ms. Tressel's responsibility to assemble the data; she

personally verified the accuracy of the information that it set out; and it was prepared in the ordinary course of business for purposes of tracking trade-spend on venlafaxine.

[145] A trial judge's ruling on admissibility, including admissibility under the business records exception to the hearsay rule, is entitled to deference if informed by correct principles of law (*Boroumand v. Canada*, 2016 FCA 313 at paras. 3, 5). I see no departure from correct principles of law in the trial judge's analysis here, and his factual conclusions concerning the summary all had support in Ms. Tressel's evidence as to how and why the document was prepared and the source of the information that it contained (Appeal Book, Vol. 57, pp. 14678, 14683). The trial judge did not err in applying the business records exception and treating the summary as proof of its contents.

[146] Where then does this leave Lilly's hearsay arguments? There is no doubt that Mr. Soriano's opinion was based in part on inadmissible hearsay. However, this does not necessarily render the opinion itself inadmissible; rather, it ordinarily goes to the weight to be given to the opinion (*R. v. Lavallee*, [1990] 1 S.C.R. 852 at pp. 893-896, 1990 CanLII 95 (SCC)). Here Mr. Soriano started with admissible evidence – Ms. Tressel's summary – in formulating his opinion on the likely trade-spend rate. The adjustments that he made were also supported by admissible evidence, that of Mr. Somerville. In these circumstances I see no error of law on the part of the trial judge in relying on Mr. Soriano's opinion to the extent that he did.

(2) *Reliance on other section 8 cases*

[147] Lilly argues that the trial judge relied on the findings in other section 8 cases involving other drugs and parties as evidence going to the appropriate trade-spend rate in this case. It says that this amounted to making a finding based on evidence not before the court and not accessible to Lilly. I do not agree with this characterization.

[148] The reference by the trial judge to other cases followed his summary of evidence given by Lilly's expert Ms. Woods (at para. 107). As the trial judge pointed out, she testified that a single-source trade-spend rate was "a fiction" – that retailers look to recover an overall rebate percentage from drug manufacturers regardless of the molecules (that is, the drugs) they are selling, so that manufacturers do not set trade-spend rates molecule by molecule.

[149] The trial judge first observed that this opinion did not accord with the other evidence before him. He then went on to say this (at para. 108):

> Further, it does not correspond with findings in other s 8 damages cases where this Court has concluded that single-source trade-spend rates are very low, much lower even than percentage put forward by Teva in this case. For example, Justice Phelan found that the trade-spend rate on a single-source molecule in circumstances where there was a risk of an infringement action was 8.9% (*Apotex v Takeda*, above, at paras 161-162). Justice Zinn found that the trade-spend rate on venlafaxine in a single-source market would have been 15% (*Pfizer Canada Inc v Teva Canada Limited*, above, at para 217).

[150] In my view, this was not reliance on findings in other cases as evidence. The trial judge was merely using the conclusions in other cases to support his rejection of Ms. Woods' opinion

that single-source trade-spend rates were "a fiction." I see nothing in this point that would warrant interfering with the judgment.

VIII. Teva's grounds of cross-appeal

[151] In its cross-appeal, Teva takes issue with three aspects of the trial judgment. It argues that the trial judge (1) erred in law, or in the alternative made a palpable and overriding error of fact, in denying recovery for pipefill sales; (2) similarly erred in law or in fact in failing to provide for an adjustment to take into account systemic under-reporting of sales; and (3) made a palpable and overriding error of fact in determining the price at which Teva's olanzapine products would have been listed on the Ontario formulary as of January 1, 2007.

[152] As the manner in which Teva has framed its cross-appeal reflects, appellate courts must show considerable deference to trial judges before varying the quantum of damages. The *Housen* standard applies (*Richard v. Time Inc.*, 2012 SCC 8, [2012] 1 S.C.R. 265 at para. 189). The assessment of damages is ordinarily a question of mixed fact and law, reviewable only for palpable and overriding error or extricable error of law.

[153] For the reasons that follow, I would nonetheless allow the cross-appeal as it relates to recovery for pipefill sales and under-reporting. I would not disturb the trial judgment as it relates to Ontario pricing.

(1) *Pipefill*

[154] Teva sought at trial compensation for losses during the liability period that included lost pipefill sales – "that is, the quantity of sales Teva would have made to distributors in the but-for world […] that would not be captured by retail sales figures […]." It submitted that compensation for losses attributable to lost pipefill sales has been ordered in other section 8 cases (at para. 90).

[155] The trial judge rejected this element of Teva's claim. He stated that as he understood it, "pipefill represents the differential between retail sales and the quantity of product leaving the factory." He continued (at para. 92):

> That differential represents sales that would have been made outside the liability period. It is true that pipefill may represent some lost sales in the sense that in the but-for world Teva would have moved a certain amount of inventory into the distribution stream which, in due course, would be sold to customers. In the but-for world, those sales would have been made, but they would have been made outside the liability period. Accordingly, for present purposes, they should not be included in Teva's losses.

[156] The trial judge went on to express his agreement with the opinion of Dr. Iain Cockburn, an economist called by Lilly as an expert. Dr. Cockburn opined that the appropriate way to deal with the delay between manufacture and retail sale would be to award Teva interest representing the time value of the money tied up in inventory during the period of delay. In his view, to award compensation for inventory sold to distributors and not captured in retail data would be to count each tablet leaving the factory as a sale, and thus to provide over-compensation. "As he explained," the trial judge recounted, "the accumulation of product in wholesalers' warehouses will eventually be sold. Since it will be sold, it cannot constitute lost sales" (at para. 95).

[157] The trial judge then reviewed the other section 8 cases on which Teva relied – *Apotex Inc. v. Sanofi-Aventis*, 2012 FC 553 at paras. 221-226, affirmed 2014 FCA 68; *Teva Canada Limited v. Pfizer Canada Inc.*, 2014 FC 248 at paras. 186-190; and *Apotex Inc. v Takeda Canada Inc.*, 2013 FC 1237 at paras. 119-120. He described these decisions as "somewhat ambiguous on the issue of pipefill." He added that "[i]n none of them was the issue seriously contested or a quantum specifically calculated" (at para. 101).

[158] He then reiterated his conclusion (at paras. 102-103):

> [102] Within the liability period, where there is a differential between data on retail sales and figures on the amount of product leaving the manufacturer's factories, that difference represents future sales of the product, sales that will take place outside the liability period. […]
>
> [103] It is clear that it is only losses suffered during the liability period that are compensable under the Regulations. It follows, in my view, that where a generic company lost sales that would have been made after the end of the liability period, those losses are not compensable. Accordingly, with the greatest respect for the learned judges of this Court who may have acceded to representations to the contrary, I find that a figure representing pipefill should not be added to Teva's losses.

[159] He therefore included in setting out his findings to be followed in calculating Teva's damages the statement that "[n]o allowance for pipefill should be included in lost sales" (at subpara. 134(4)).

[160] The point of departure for analysis of this issue is that – as the trial judge recognized – liability under section 8, and the generic company's entitlement to compensation, extends to "any loss suffered during the [liability] period." This means that damages are recoverable for any "sales that can be shown to have been lost within the period" (*Apotex Inc. v. Merck & Co. Inc.*,

2009 FCA 187, [2010] 2 F.C.R. 389 at paras. 99-102). Correspondingly, there is no liability, and no entitlement to compensation, for sales lost or other damages caused by the innovator company's bringing of a prohibition application, even though they were actually suffered by the generic company, if they were suffered beyond the liability period (*Apotex Inc. v. Sanofi-Aventis*, 2014 FCA 68, [2015] 2 F.C.R. 828 at paras. 189-192).

[161] Determining what sales were lost within the liability period is complicated by two factors – the multiple channels through which sales are made and the limitations of the data through which sales are reported.

[162] Manufacturers like Teva distribute their products largely through distributors or wholesalers. They in turn sell the products to hospitals, pharmacies or other retailers. There may thus be three levels of sales: (1) by manufacturers to distributors or wholesalers, (2) by distributors or wholesalers to retailers, and (3) by retailers to retail customers. It is the lost sales during the liability period by the generic manufacturer – to distributors or wholesalers or (to the extent that the manufacturer bypasses distributors or wholesalers and sells directly to retailers) one level down the distribution stream – that are relevant in assessing damages under section 8.

[163] In this case the experts for both parties – Dr. Aidan Hollis for Teva and Dr. Cockburn for Lilly – relied in quantifying Teva's lost sales primarily on "CDH data." This is data from the Canadian Drug Stores & Hospitals Purchase Audit regularly carried out by IMS Health Canada Inc., an independent, third-party collector and provider of data on the pharmaceutical industry. As Dr. Cockburn testified, CDH data is "built from surveys or samples and some extrapolation

or estimation." It is also at the level not of transactions between manufacturers and wholesalers, distributors or others – termed "ex-factory sales" – but of transactions between distributors or wholesalers and retailers (Appeal Book, Vol. 57, p. 14840). For these and other reasons, both experts recognized that it would be appropriate to make an upwards adjustment to take account of possible under-reporting of sales in the CDH data (Appeal Book, Vol. 56, pp. 14419, 14442; Vol. 57, p. 14844).

[164] I will return to the question of under-reporting later in discussing Teva's second ground of cross-appeal. For present purposes, the important point is that the lost sales for which damages are recoverable by the generic company are sales that it would have made, not sales made by wholesalers or distributors or retailers.

[165] How then could the trial judge not accept that pipefill should be taken into account in his award of damages? As the passages from his reasons set out above at paragraphs 155 and 158 make clear, he appears to have treated the sales that are relevant in this context – and the only sales that are relevant – as the sales to retail customers. He reasoned that if those sales took place outside the liability period, no damages would be recoverable, even though "Teva would have moved a certain amount of inventory into the distribution stream which, in due course, would be sold to [those retail] customers," and even though that "movement" would have taken place within the liability period.

[166] In taking the approach that he did, the trial judge failed to recognize that "product leaving the manufacturer's factories" and "moved […] into the distribution stream" is product that the

manufacturer has sold. The fact that the sales were to distributors or wholesalers rather than directly to retail customers does not take them outside of section 8. Nor does the fact that sales of that product further down the distribution stream – sales to retail customers – would have taken place beyond the liability period.

[167] I appreciate that in coming to his view on the pipefill issue, the trial judge relied on the evidence of Dr. Cockburn. But Dr. Cockburn's opinion was coloured in my view by his premise that damages under section 8 should be calculated on a "make-whole" basis (Cockburn Report, Appeal Book, Vol. 9, p. 2329). As set out in paragraph 160 above, that is not the nature of the compensation for which, according to the decisions of this Court, section 8 provides.

[168] I also recognize that if adequate ex-factory data is available, the issue of compensation for pipefill (and the issue of under-reporting associated with the use of CDH data) should not arise. But in this case, both experts considered it appropriate to use CDH data as the primary source for their calculations. This choice made it necessary to consider whether lost pipefill sales should be accounted for in awarding Teva the compensation to which it was entitled under section 8.

[169] In my respectful view, the trial judge made an extricable error of law in excluding from Teva's recovery damages for lost pipefill sales –sales that would have been made by Teva to distributors or wholesalers or retailers within the liability period – on the basis that resale to retail customers would have taken place beyond the liability period. His doing so incorrectly limited the recoverable damages for which section 8 provides. I would therefore set aside paragraph 1 of

the judgment of the Federal Court insofar as it incorporates by reference the portion of subparagraph 134(4) of the reasons of the Federal Court that reads "No allowance for pipefill should be included in lost sales," and declare that Teva's damages be recalculated to account for any lost pipefill sales during the liability period.

[170] We have not been requested to quantify, or to set the methodology for quantifying, the additional damages that recognizing an entitlement to recover lost pipefill sales would entail. I would therefore proceed as the parties asked of the trial judge, and leave it to them in the first instance to attempt to work out the necessary calculations. If they are unable to do so within 30 days of their receipt of this Court's judgment, or any later date to which they may agree or that the trial judge may order, I would refer the quantification back to the trial judge to be determined based on the existing record.

(2) *Under-reporting*

[171] As noted above in paragraph 163, both parties' experts were of the opinion that it would be appropriate in calculating Teva's lost sales to make an adjustment to take account of possible under-reporting of sales in the CDH data. Dr. Hollis made a "pipeline adjustment" using Teva's ex-factory data. This adjustment was intended to account for both under-reporting and pipefill. He applied it equally to the figures for the first four months that Teva was assumed to be selling its olanzapine products in each province (Hollis Report, Appeal Book, Vol. 29, pp. 7304, 7322; Appeal Book, Vol. 56, p. 14419).

[172] Dr. Cockburn used data on Lilly's ex-factory sales in adjusting monthly sales figures for possible under-reporting. He was critical of Dr. Hollis for making his adjustment in the first four months of market entry, on the basis that this assumed that Teva would have immediately reached a steady state in sales (Cockburn Report, Appeal Book, Vol. 9, pp. 2331; Appeal Book, Vol. 57, pp. 14840, 14862).

[173] In his reasons, the trial judge addressed the question of under-reporting only briefly, in beginning his discussion of pipefill (at para. 90). He did not deal with the issue separately from his consideration of pipefill, even though on the evidence under-reporting is a phenomenon that also applies when goods have fully completed their movement down and through the distribution stream within the liability period. His list of findings to be followed in calculating Teva's damages is silent on the issue (at para. 134).

[174] In my view, the trial judge made a further extricable error of law in failing to include as an element in calculating Teva's damages an adjustment to take account of under-reporting. Section 8 confers an entitlement to compensation for any lost sales during the liability period. The evidence from both sides was that an adjustment for under-reporting was required to prevent under-compensation. The failure to provide for under-reporting deprived Teva of a portion of its legal entitlement.

[175] Teva asks us to order that Dr. Hollis's methodology be followed in providing for this adjustment. Lilly argues that Teva failed to adduce sufficient evidence at trial to permit the amount of the adjustment to be determined.

[176] While it is open to this Court both to decide how the adjustment should be determined and to determine it, given the nature of this issue it is in my view appropriate to leave its resolution to the parties and, if necessary, the trial judge, who is better placed to resolve it. No doubt the trial judge, if called upon to decide the issue, will do the best he can with the evidence before him (*Cadbury Schweppes Inc. v. FBI Foods Ltd*., [1999] 1 S.C.R. 142, 1999 CanLII 705 (SCC) at para. 99).

[177] I would therefore set aside the judgment of the Federal Court insofar as it fails to provide for an adjustment for under-reporting of sales in determining the compensation to which Teva is entitled, declare that an adjustment should be made, and refer the determination of the adjustment to the trial judge if the parties are unable to resolve it within 30 days of their receipt of this Court's judgment, or any later date to which they may agree or that the trial judge may order. For greater certainty, I would specify that the issue should be determined based on the existing record.

(3) *Pricing in Ontario*

[178] The findings of the trial judge to be followed in calculating Teva's damages included findings as to the date and the price at which Teva's olanzapine products would have been listed on the various provincial drug formularies (at subpara. 134(3)). In the case of Ontario, the parties agreed that, assuming that Teva received its NOC on March 3, 2006, listing would have occurred on May 19, 2006 (at para. 47). The trial judge found that the price in Ontario would initially have been 70% of the brand price, but that as of January 1, 2007, following the coming into force of

the *Transparent Drug System for Patients Act, 2006*, S.O. 2006, c. 14 (known as Bill 102), Teva would have had to reduce its price to 50% of the brand price.

[179] Teva argues that the trial judge made a palpable and overriding error of fact in finding that Teva would not have received an exemption from the 50% pricing established in Ontario under Bill 102 as of January 1, 2007, and that it would therefore have had to reduce its price as of that date. However, in my view, there was evidence to support the finding. I would therefore not give effect to this ground of Teva's cross-appeal.

[180] Teva led evidence from Brent Fraser, who was director of Ontario Public Drug Programs at the relevant time, and from Ian Hilley, a pharmaceutical pricing expert, concerning the Ontario pricing regime. Before the introduction of Bill 102, the first generic drug listed on the formulary would be priced at 70% of the brand price; generics subsequently listed would be priced at 63% of brand. There were no exceptions to this rule. Under Bill 102, Ontario fixed the pricing of generic drugs at 50% of the brand price. It also gave those administering the formulary discretion to allow exemptions from the 50% pricing in certain circumstances. Exemptions were available only for single-source generics.

[181] To obtain an exemption, a generic manufacturer would have to submit a business case, including information on operating and manufacturing costs, as to why its drug could not be priced at 50%. If an exemption was granted, the price would be negotiated, but would generally be around 70% of brand. In the period following implementation of the 50% rule, there were a large number of exemption requests, and in most cases they were granted. These included a

request by Teva for an exemption for its venlafaxine products (Appeal Book, Vol. 56, pp. 14508, 14538-14539).

[182] Mr. Fishman testified that, in the hypothetical world, Teva would have sought an exemption for olanzapine following the enactment of Bill 102, to be effective January 1, 2007. Its rationale for the request would have been that Teva had made a substantial investment in developing uniquely for the Canadian market a drug that was developed and manufactured in Ontario and that generated substantial savings (Appeal Book, Vol. 56, pp. 14492-14493).

[183] Teva did seek an exemption for olanzapine in the real world, in June 2007. The price it sought was 70% of brand. The rationale that it put forward was in essence the rationale that Mr. Fishman testified would have been put forward earlier in the hypothetical world. Its request triggered a series of written and oral exchanges with the Ontario government. During these exchanges Ontario's representatives expressed the view that Teva had not presented sufficient information to justify an exemption from 50% pricing. Ultimately, Ontario and Teva entered into a confidential arrangement under which Teva's olanzapine products would be listed on the Ontario formulary at 75% of brand, [redacted] (Appeal Book, Vol. 5, p. 1263; Appeal Book, Vol. 26, pp. 6612-6613; Appeal Book, Vol. 56, p. 14493).

[184] In substance, therefore, the exemption request was refused. However, Teva accepted the rebate arrangement because it wanted market access in Ontario and because it understood that Lilly had made an offer to Ontario to supply its branded olanzapine products at a similar price.

The 75% formulary listing also provided a benchmark that Teva could use in negotiations with other provinces (Appeal Book, Vol. 56, p. 14493).

[185] As Mr. Fraser's evidence confirmed, Teva was correct in its understanding that Lilly had made a competitive offer. He testified that in June 2007, Ontario would typically not have entered into a rebate arrangement with a generic company in the absence of a competitive offer from the innovator company. Rather, if during this period a generic company had a single-source product and was able to justify a higher price, Ontario would "in almost all cases" grant a price exemption. He also agreed that during the November-December 2006 period, when Ontario was negotiating exemptions from Bill 102 pricing, Ontario would also "generally" grant price exemptions if a generic company was able to satisfy "the single-source price exemption requirements" (Appeal Book, Vol. 56, pp. 14540-14541).

[186] The trial judge summarized the position and expressed his conclusion on pricing as follows (at paras. 49-50):

> [49] […] Teva sought, but was denied, an exemption for its olanzapine product. Teva was unable to justify a listing at [redacted] of the brand price. [redacted].
>
> [50] [redacted] Once Bill 102 came into effect, Teva would have sought, but would likely not have received, an exception to the rule. Therefore, as of January 1, 2007, Teva would have had to [redacted]

> [redacted]. In the but-for world, as in the real world, Teva would have had to set its effective price in Ontario at no more than [redacted] of Lilly's price.

[187] The trial judge's reasoning is not entirely easy to follow. He appears have proceeded on the understanding that in the hypothetical world, Teva's entitlement to an exemption effective January 1, 2007 would have depended in part on whether Lilly had offered Ontario a discount, that Lilly's offering of a discount would have helped Teva secure a [redacted] arrangement with Ontario, and that a [redacted] arrangement would have been beneficial to Teva. But the evidence as I understand it is to the effect that pricing effective January 1, 2007 (by contrast to the situation in June 2007) did not turn on whether the brand company had offered discounted pricing, that a [redacted] arrangement represented a failure by the generic to secure an exemption (though it could be helpful in negotiations with other provinces), and that exemptions were generally granted effective January 1, 2007 for sole-source generic products if exemption requirements were met.

[188] Nevertheless, the finding of the trial judge is clear: "Teva would not have obtained an exception to the 50% rule." And in my view there was evidence to support it: the evidence that, in the real world, Ontario was not persuaded by the rationale that Teva put forward in support of its request for an exemption, and that the exemption was refused. It was open to the trial judge, especially since conduct in the real world can be a proxy for conduct in the hypothetical world, to infer from that evidence that the exemption request would also have failed in the hypothetical world. It would accordingly be inappropriate to interfere with his finding on this issue.

IX. Proposed disposition

[189] For these reasons, I would dismiss the appeal with costs.

[190] I would allow the cross-appeal in part, and set aside paragraph 1 of the judgment of the Federal Court insofar as it (1) incorporates by reference the portion of subparagraph 134(4) of the reasons of the Federal Court that reads “No allowance for pipefill should be included in lost sales,” and (2) fails to provide for an adjustment for under-reporting of sales in determining the compensation to which Teva is entitled. I would declare that Teva’s damages should be recalculated to account for any lost pipefill sales during the liability period and for under-reporting of sales, and refer the pipefill and under-reporting adjustments back to the trial judge, to be determined on the existing record, if the parties are unable to agree on them within 30 days of their receipt of this Court’s judgment, or any later date to which they may agree or that the trial judge may order. Because success on the cross-appeal was divided, I would order that there be no costs of the cross-appeal.

"J.B. Laskin"
J.A.

“I agree.
Donald J. Rennie J.A.”

“I agree.
Mary J.L. Gleason J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-71-17
(APPEAL FROM A JUDGMENT OF THE HONOURABLE MR. JUSTICE O'REILLY DATED APRIL 4, 2017, DOCKET NO.: T-1048-07)	
STYLE OF CAUSE:	ELI LILLY CANADA INC. v. TEVA CANADA LIMITED
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	NOVEMBER 22 AND 23, 2017
PUBLIC REASONS FOR JUDGMENT BY:	LASKIN J.A.
CONCURRED IN BY:	RENNIE J.A. GLEASON J.A.
DATED:	MARCH 20, 2018

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