Court File Number: 33951

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

BETWEEN:

TEVA CANADA LIMITED

Appellant
(Appellant)

- and –

PFIZER CANADA INC., PFIZER INC.,
PFIZER IRELAND PHARMACEUTICALS,
PFIZER RESEARCH AND DEVELOPMENT COMPANY N.V./S.A. and
THE MINISTER OF HEALTH

Respondents
(Respondents)

REPLY FACTUM OF THE APPELLANT
Teva Canada Limited
(Pursuant to the Order of Justice Rothstein dated March 7, 2012)

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REPLY FACTUM

1. This Reply Factum is filed pursuant to the Order of Justice Rothstein dated March 7, 2012, granting the appellant permission to address the issues of foreign law, harmonization and Canada's international treaty obligations raised in the factum of the intervener, Canada's Research-Based Pharmaceutical Companies ("Rx&D").

The sound prediction disclosure requirement is not "non-statutory" or "retroactive"

2. Rx&D opens its argument with two diagrams ostensibly representing alternative filing routes for Canadian patent applications (Figure 1) and the "general validity scheme of the *Patent Act*" (Figure 2). With reference to Figure 2, Rx&D advances the proposition that the "general validity scheme of the *Patent Act* is divided into three main categories" and that "[t]he Commissioner of Patents considers these categories in deciding whether to grant a patent".[1] Both the proposition and Figure 2 are inaccurate or incomplete.

3. Rx&D's "Category 2" is described in Figure 2 as relating to the adequacy of the specification. Figure 2 cites Section 27(3) of the *Patent Act* and suggests that the inquiry into adequacy of the disclosure is limited to whether it "allows person skilled in the art to make and use invention". While this reasonably paraphrases Section 27(3)(b), it avoids entirely the wording of Section 27(3)(a) which requires the specification to "correctly and fully describe the invention and its operation as contemplated by the inventor".

4. Rx&D's "Category 3" relates to material representations under Section 53 of the *Patent Act*. However, Section 53 provides for the voiding by the Court of an *issued* patent on the basis of material untrue allegations in the petition, or misleading omissions or additions in the specification and drawings. Contrary to Rx&D's submission, Section 53 has no application to a pending application and is not invoked by the Commissioner in deciding whether to grant a patent.

5. Rx&D goes on to argue that "[r]elying on *AZT*[2], lower courts have superimposed an additional disclosure/utility framework onto the statutory scheme shown in Figure 2", asserts that

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[1] Rx&D factum ¶ 5

[2] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 ("*AZT*"), Teva BOA, Vol. I, Tab 2

"[t]he case under appeal is part of the evolution of this non-statutory framework"[3], and impugns what it characterizes as the "FCA's untethering of the patent validity framework from the statutory scheme".[4] Rx&D's submissions are wrong on all points.

6. Rx&D cites *Evista*[5] and alleges that "the FCA held that if an invention's utility is based upon sound prediction, an 'enhanced' and non-statutory retroactive disclosure obligation arises".[6] The FCA made no such holding. The expressions "enhanced" and "non-statutory" do not appear anywhere in the *Evista* decision. The FCA in fact expressly rejected the argument that *AZT* imposes non-statutory disclosure requirements and confirmed that the holding of this Court in *AZT* was made with "obvious reference" to the statutory framework imposed by Section 27(3):

> The appellant argues that in requiring the complete disclosure of the factual basis underlying the sound prediction (i.e. requiring data to substantiate the invention), the Federal Court Judge has changed the disclosure requirements as set out in subsection 27(3) of the *Patent Act*, R.S.C. 1985, c. P-4. I respectfully disagree. In *AZT*, the Supreme Court, with obvious reference to subsection 34(1) of the *Patent Act* (the predecessor to subsection 27(3)), held that where the claimed invention had not yet actually been reduced to practice, the patent must provide a disclosure such that a person skilled in the art, given that disclosure, could have as the inventors did, soundly predicted that the invention would work once reduced to practice. ....[7]

7. Rx&D argues that the FCA "recognized" in *Strattera*[8] that Justice Binnie in *AZT* "may not have definitively decided" that the factual basis and line of reasoning for the sound prediction needs to be disclosed.[9] Rx&D fails to mention that the FCA in *Strattera* went out of its way to leave no doubt that, based on *AZT*, "a patentee must disclose in the patent a study that provides the factual basis of the sound prediction".[10] Contrary to Rx&D's submission, *AZT* specifically addressed and definitively decided the disclosure obligation in sound prediction cases. Justice Binnie expressly stated that "there must be proper disclosure". The patent-in-suit in *AZT* disclosed both the factual basis and the line of reasoning upon which the prediction of utility in treating HIV

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[3] Rx&D factum ¶ 6
[4] Rx&D factum ¶ 7
[5] *Eli Lilly Canada Inc. v. Apotex Inc.* 2009 FCA 97 ("*Evista*"), Pfizer BOA, Tab 7
[6] Rx&D factum ¶ 7
[7] *Evista* ¶ 18, Pfizer BOA, Tab 7
[8] *Eli Lilly and Company v. Teva Canada Limited* 2011 FCA 220 ("*Strattera*") ¶ 47 (citing *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406, aff'd. 2009 FCA 97, 78 C.P.R. (4th) 388), Pfizer BOA, Tab 11
[9] Rx&D factum, ¶ 8
[10] *Strattera* ¶ 47, Pfizer BOA, Tab 11

was based and thus needed to "say no more about it."[11]

8. Subsection 27(3) of the *Patent Act* requires that the inventor fully and correctly disclose the invention, regardless of the type of invention involved. *AZT* merely confirmed that when the invention is a prediction, the prediction itself (*i.e.* the factual basis and sound line of reasoning) constitutes part of the *quid pro quo* and must be disclosed. There is simply no merit to Rx&D's argument that the expression of the sound prediction doctrine in *AZT* imposed a retroactive or non-statutory disclosure obligation. In this case, the patent-in-suit does not even let readers "know that it does work", which Justice Binnie observed is a disclosure requirement for all patents.[12] In the words of the Applications Judge, it "left the skilled reader guessing."[13]

9. Rx&D's arguments have nothing to do with the need to correct the interpretation of *AZT* in the FC and the FCA. Rather, Rx&D is trying to exploit what it sees as an opportunity overturn the unanimous holding in *AZT* that the sound prediction (*i.e.* the factual basis and line of reasoning) forms part of the *quid pro quo* where utility has not been demonstrated, and must be disclosed.

The sound prediction disclosure requirement does not conflict with the *PCT* or *TRIPS*

10. Having set up the straw man that the disclosure requirements for patents based on sound prediction expressed by this Court in *AZT* have been articulated by the FCA and the FC to add a "non-statutory retroactive disclosure obligation"[14], Rx&D then argues that such a disclosure obligation does not comply with Canada's obligations under the *PCT*[15] and *TRIPS*[16].

11. The law governing the validity of the patent-in-suit in this proceeding is the Canadian *Patent Act*. The *PCT* has no effect in Canada. The *PCT* is an international treaty that contains provisions each signatory pledges to enact in their domestic legislation. International treaties do not have the force of an act of Parliament.[17] It is for Parliament to choose what provisions of any treaty

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[11] *AZT* ¶ 70, Teva BOA, Vol. I, Tab 2
[12] *AZT* ¶ 70, Teva BOA, Vol. I, Tab 2
[13] FC Judgment ¶ 136, AR, Vol. I, Tab 2, Page 51; Teva BOA, Vol. II, Tab 29
[14] Rx&D factum ¶ 7
[15] *Patent Cooperation Treaty* ("*PCT*"), June 19, 1970, 28 U.F.T. 7647, as amended
[16] *Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco, 15 April 1994* ("*TRIPS*"), 1867 U.N.T.S. 3
[17] *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.*, 2002 FCA 158 ¶ 25, Teva Supplemental Book of Authorities ("Teva SBOA"), Tab 1

to enact into Canadian law and it is Parliament who must answer to any accusation of failing to correctly implement Canada's treaty obligations.

12. Rx&D cites *PCT* Article 27 for the proposition that Canada is "precluded from making more onerous disclosure obligations".[18] This is wrong. *PCT* Article 27(1) deals only with "form and contents" of applications. *PCT* Articles 27(5) and 27(6) specifically recognize the supremacy of national law over the *PCT* in setting rules for substantive conditions of patentability. Article 27(5) provides that "[n]othing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires".[19]

13. The FCA has repeatedly held that the requirement to disclose the factual basis and line of reasoning underlying a prediction is a substantive and fundamental condition of patentability that does not engage the *PCT* obligations. In *Evista*, the FCA stated:

> [19] The appellant further argues that requiring the complete disclosure of the factual basis underlying the sound prediction is inconsistent with the *Patent Cooperation Treaty*, 1970, 28 U.F.T. 7647 (*Treaty*). However, this *Treaty* specifically contemplates the supremacy of national law in setting the rules for substantive conditions of patentability (see article 27(5) of the *Treaty*). We are concerned here with substantive conditions of patentability.[20]

14. Similarly, in *Strattera*, the FCA confirmed that disclosure of the factual foundation for the sound prediction goes to the essence of the patent bargain and constitutes a substantive ground of patentability which is not inconsistent with the *PCT*.[21]

15. In any event, Canadian disclosure requirements do not contradict the *PCT*. Rule 5.1(a)(iii) of the *Regulations* to the *PCT* states that a patent description must "disclose the invention, as claimed, in such terms that the technical problem…and its solution can be understood and state the advantageous effects, if any, of the invention with reference to the background art."[22] To understand any "solution" in the context of a prediction requires a recitation of the factual basis

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[18] Rx&D factum ¶ 11
[19] *PCT* Art. 27, Rx&D factum, Tab "C"
[20] *Evista*, ¶ 19, aff'g, 2008 FC 142 ¶ 165-178, leave to appeal to SCC ref'd, [2009] S.C.C.A. No. 219, Teva SBOA, Tab 2
[21] *Strattera* ¶ 48-49, Pfizer BOA, Tab 11
[22] *Regulations under the Patent Cooperation Treaty*, Rule 5.1(a)(iii), Teva SBOA, Tab 3

and line of reasoning for the prediction.

16. More fundamentally, the *PCT* does not allow a patentee to conceal the only compound actually shown to have utility in treating ED. Article 5 of the *PCT* requires, as a minimum standard, that the patentee clearly disclose the invention.[23] The only invention in the case before this Court is not clearly disclosed. As the Application Judge found, the patent in suit "plays games with the reader" who is "expected to look for the 'needle in the haystack' or the 'tree in the forest'". As a result of Pfizer's "conscious choice not to disclose the identity of the only compound found to work" the patent "left the skilled reader guessing" and "obfuscated the reader".[24] There can be no reasonable suggestion that such a disclosure complies with the *PCT*.

17. Nor do the provisions of *TRIPS* assist Rx&D. Rx&D does not argue that *TRIPS* forms part of domestic Canadian patent law but merely cites Article 29(1) to argue that *TRIPS* requires patent applicants "to only provide sufficient instruction to allow a person of skill to make and use the claimed invention"[25]. Article 29(1) does not limit what must be disclosed in a patent. As with the *PCT*, *TRIPS* Article 29(1) sets only *minimum* disclosure requirements.[26]

Dated: March 19, 2012 ALL OF WHICH IS RESPECTFULLY SUBMITTED

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[23] *PCT* Art. 5, Rx&D factum, Tab "C"
[24] FC Judgment, ¶ 118, 135, 136, 137, 148, AR, Vol. I, Tab 2, Pages 45,50-51,54; Teva BOA, Vol. II, Tab 29
[25] Rx&D factum, ¶ 12
[26] *TRIPS* Art. 29(1), Rx&D factum, Tab "D"

TABLE OF AUTHORITIES

	CASES	PARAGRAPH WHERE CITED
1.	*Apotex Inc. v. Wellcome Foundation Ltd.* [2002], 4 S.C.R. 153	5, 7, 8
2.	*Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.*, 2002 FCA 158	11
3.	*Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142	13
4.	*Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97	6, 13
5.	*Eli Lilly and Company v. Teva Canada Limited*, 2011 FCA 220	7, 14