Court File No.: 35562

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

BETWEEN:

APOTEX INC. and APOTEX PHARMACHEM INC.

Appellants

-and-

SANOFI-AVENTIS and BRISTOL-MYERS SQUIBB SANOFI PHARMACEUTICALS HOLDING PARTNERSHIP

Respondents

REPLY TO THE INTERVENERS OF THE APPELLANTS, APOTEX INC.

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PART I – OVERVIEW

1. The patentee-side interveners[1] (the "interveners") propose that this Court reverse its unanimous and reasoned articulations of the law of utility and sound prediction and instead endorse a system in which a pharmaceutical company can obtain a full patent monopoly in return for writing down a research goal in a patent application. Under the interveners' proposal, the goal could be a mere speculative hope, the basis for the speculation could be kept secret from the public, and the speculation need never provide its promised benefit.

2. While such a system may be keenly desired by patent owners, this Court has specifically explained why such a system would be contrary to the *Patent Act* and undo the bargain that lies at its core. Free to distinguish their patents over the state of the art by making predictions of utility that need not be sound nor ever be justified, applicants would be encouraged to prospectively monopolize vast areas of future inquiry. The resulting patents would also discourage others from making the investments and doing the work necessary to actually determine if and how the end goal could be reached, stifling the very research the *Act* was designed to encourage. Free to keep confidential the bases for their predictions, applicants would be encouraged to deny the public any disclosure of what the inventors' pre-application work truly accomplished.

3. The doctrines of utility and sound prediction as defined in this Court prevent such speculative patenting. The law of utility insists that a patented invention do what the patent says it will do, discouraging an applicant from promising high and delivering low. The law of sound prediction understands that, if the utility asserted for a patent is not demonstrated prior to the filing date, then the invention is a prediction. To distinguish valuable predictions from mere speculations, and to ensure that the true invention made is fairly disclosed, the law insists that the inventor have and disclose in the patent a factual basis and line of reasoning for a sound prediction

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[1] Canada's Research-Based Pharmaceutical Companies ("Rx&D") and BIOTECanada are organization representing patent owners. Fédération Internationale Des Conseils En Propriété Intellectuelle ("FICPI") represents the interests of "inventors and patent applicants". [See Koster Affidavit, paras. 3-5,FICPI motion to intervene]. International Association for the Protection of Intellectual Property ("AIPPI") seeks to "promote the protection of intellectual property on a national and international basis." [< https://www.aippi.org/?sel=aims >]

that the invention will do what the patent says it will do.[2]

4. The interveners barely touch upon this Court's rationale for the law of utility and sound prediction and they do not explain how their proposed system of speculative patenting serves the goals of the *Patent Act*. Instead, the interveners argue that Canadian law is out-of-step with international law and is based on "inadvertent"[3] errors. These arguments are incorrect.

PART II - STATEMENT OF ARGUMENT

A. Canadian law does not violate any international standards or treaties

5. The interveners' argument that this Court ought to take the extraordinary step of reversing its precedents[4] on utility and sound prediction because of the state of foreign law is not supportable on the present record. Foreign law is a question of fact that must be pleaded, proven and explained in the evidence,[5] circumstances that are absent in this case. Even accepting the international surveys reported by AIPPI at face value, it is clear both that international law is not harmonized and that the Canadian law of utility and sound prediction is not an international outlier.[6]

6. The Canadian utility requirement is based upon the *Patent Act*'s definition that an invention be "useful"[7]. Many countries[8] do not consider "utility" but rather have a statutory "industrial applicability" requirement. Contrary to FICPI's and Rx&D's unsupported assertions,[9] AIPPI confirms that "industrial applicability" is not synonymous with "utility" but rather is a

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[2] *Apotex Inc. v. Wellcome Foundation Ltd.*, 2008 SCC 77, [2002] 4 S.C.R. 153 at para. 40.

[3] BIOTECanada Factum, para. 12.

[4] *Fraser v. Ontario (Attorney General)*, 2011 SCC 20 at paras. 60, 132.

[5] *Allen v. Hay*, 1922 CarswellBC 74 at para. 24, 64 S.C.R. 1976; Stephen G.A. Pitel & Nicholas S. Rafferty, *Conflict of Laws* (Toronto: Irwin Law, 2010) at 237.

[6] AIPPI questionnaire, section 1.

[7] *Patent Act*, section 2, 34 (now section 27).

[8] AIPPI National Group Reports online: AIPPI < https://www.aippi.org/?sel&cf=aippiPlavixSubmissions> "AIPPI Reports": Argentina (q.1-2), Belgium (q.1-2), Brazil (q.1-2); Czech Republic (q.2); Denmark (q.1-2); Finland (q.2); France (q.1-2); Germany (q.1-2); Greece (q.1-2); Hungary (q.2); Italy (q.1-2); Mexico (q.1-2); Netherlands (q.1-2); Poland (q.1-2); Slovenia (q.1); Sweden (q.1-2); Switzerland (q.1); Turkey (q.1), United Kingdom (q.1-2); Ukraine (q. 1-2).

[9] FICPI factum, para. 26; Rx&D factum, para. 11.

"fundamentally different concept".[10] International efforts to harmonize the utility requirement have foundered on this difference, among others.[11]

7. Most of the countries having a "utility" requirement[12] do indeed require the invention to have the utility promised, or, in U.S. parlance, "be capable of being used to effect the object proposed."[13] Those with industrial applicability requirements typically require patents to have this applicability. As AIPPI notes, "most countries exclude the patentability of...inventions which do not provide the effects or results disclosed in the patent".[14]

8. Because the Canadian sound prediction doctrine addresses what the inventor had accomplished by the date of the patent application, knowledge developed after the filing date cannot retroactively nourish the patentability of a speculation in Canada.[15] Many of the surveyed countries[16] are in agreement with this and provide that a prediction cannot be justified on the basis of knowledge that arose after a material date, typically the priority or filing date.[17]

9. Canada's sound prediction disclosure requirements are also echoed in many surveyed countries[18] where the patent must disclose a sound and concrete technical basis, including test data,

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[10] AIPPI Summary Report, Q.180, Conclusions, s. 4(d), online: AIPPI < https://www.aippi.org/download/commitees/180/SR180English.pdf >; Resolution, See also, Denmark (q.2).

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

[12] AIPPI Reports Australia (q.2, 3); Hungary (q.3); Israel (q. 2); Singapore (q. 2). See also: Australian government explanatory memorandum, item 6, cited at AIPPI factum, footnote 26.

[13] Chisum on Patents, section 4.04, cited in AIPPI factum, ft. 22.

[14] AIPPI Resolution, Q.180, p. 1, online: <https://www.aippi.org/download/commitees/180/RS180English.pdf>; Note that AIPPI is incorrect in asserting that, in Australia, the promised utility need only be met by one embodiment of the claims. The cited case, *Martin Engineering Co. v. Trison Holdings Pty* (1989), 14 IPR 330 at 336-337, stands for the opposite proposition.

[15] *Apotex Inc. v. Wellcome Foundation Ltd.,* 2008 SCC 77, [2002] 4 S.C.R. 153 at para. 40.

[16] AIPPI Reports: Argentina (q.12); Australia (q.8); China (q.8,12); Germany (q.12); Israel (q.7,11); Japan (q.8,12); Netherlands (q.8); United States (q.3,7,8).

[17] AIPPI Reports: Argentina (q.3); Australia (q.2) at the "grant date"; Belgium (q.7); China (q.7); Denmark (q.11); France (q.11); Germany (q.7); Hungary (q.7); Israel (q.7,11); Italy (q.7,11); Japan (q.7,11); Netherlands (q.7,11); Poland (q.7); Slovenia; Switzerland (q.7); United Kingdom (q.7); Ukraine (q.7,11).

[18] AIPPI Reports: Australia (q.3); Belgium (q.2); Brazil (q.3); (China, q.3); Denmark (q.3); Germany (q.3); Hungary (q.3); Israel (q.3); Japan (q.3); Mexico (q.3,8,12); Poland (q.3,8); Ukraine (q.3,7), United States (q.3,4); AIPPI factum, paras. 20, 26; Australian government explanatory memorandum, item 6, cited at AIPPI factum, footnote 26;

that allows the skilled person to predict the promised use without further research. In the U.K., a technical solution must be 'plausible or reasonably credible' and, while "there is no equivalent of the 'sound prediction' test,... insofar as this may be equated with 'plausibility' then that would need to be in the application as filed."[19] Many surveyed countries[20] also require that the industrial applicability or utility be disclosed in the specification if not otherwise obvious.

10. Canadian law is also not in "breach" of TRIPS, PCT or NAFTA.[21] NAFTA and TRIPS provide that Canada "may deem" the terms "useful" and "industrially applicable" to be synonymous but Parliament has not acted to do so. PCT contains no provision that precludes a signatory either from defining utility in terms of what the patent says the invention will do, or from requiring the disclosure of the factual basis and sound line of reasoning for a patented prediction. Further, PCT expressly provides that signatories are free to prescribe any "substantive conditions of patentability."[22] In Canada, disclosure at the heart of the whole patent system.[23] It is also notable that virtually all the AIPPI surveyed countries are signatories to PCT and TRIPS and yet have laws that often mirror Canada's as discussed above.

11. Even if there were an international consensus with which to harmonize, it would still be foremost[24] that the definition of "invention" as used throughout the *Patent Act* and jurisprudence remains consistent. It is the making of an "invention" (not an almost-invention) that entitles an

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Manual IP on Kluwer IP law, Japan entry, cited at AIPPI factum, footnote 31;. AIPPI is incorrect in asserting that, in Japan, a mere statement of utility "may" suffice in the present circumstances: the utility for therapeutic applications,such as at bar, requires disclosure in the specification of pharmacological data (*Astellas &Fujisawa v Commissioner Japan Patent Office*, Heisei 17 (gyo-ke) 10312 dated 30 Aug 2005, cited in AIPPI factum, ft. 35.

[19] AIPPI Reports: United Kingdom (q.3,7,8).

[20] AIPPI Reports: Argentina (q.3); Australia (q.3-4,7), Belgium (q.2,3); Brazil (q.3); China (q.3); Czech Republic (q.3); Denmark (q.3); Finland (q.3); France (q.3); Germany (q.3); Greece (q.1); Hungary (q.7); Italy (q.3); Netherlands (q.3); Singapore (q.3); Slovenia (q.3,7); United Kingdom (q.3); United States (q.2-3); Venezuela (q.3).

[21] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA 197, 85 C.P.R. (4th) 413 at paras. 48-50; *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 78, 78 CPR (4th) 388 at para. 19.

[22] *Patent Cooperation Treaty*, June 19, 1970, 28 U.S.T. 7647, as amended, Arts. 5, 27(5)(6); Regulations under the PCT, June 19, 1970, 28 U.S.T. 7647, as amended, r. 5.1(a)(iii).

[23] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* (1981), 56 C.P.R. (2d) 145 at 154 (S.C.C.); *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142 at para. 46; *Apotex Inc. v. Wellcome Foundation Ltd.* (2002), 21 C.P.R. (4th) 499 at para. 37 (S.C.C.).

[24] *Galerie d'art du Petit Champlain inc v Théberge*, 2002 SCC 34, [2002] 2 S.C.R. 336 at paras. 70-75.

inventor to a patent; it is this same "invention" (not only part of it) that the specification must disclose; it is this same "invention" (not some lesser invention) that must be useful; and it is this same invention that is compared to the prior art for purposes of assessing the patent's inventiveness. The major doctrines of patent law, as systemically addressed by this Court over the last 15 years, have depended upon a unitary definition of "invention" in a given patent.[25]

B. The law of utility and sound prediction arises from and serves the *Patent Act*

1. The interveners' faulty proposals to reverse the doctrine of utility

12. FICPI is incorrect that the 'promise doctrine' is "more [exacting] than that provided"[26] in the *Patent Act.* The *Act* demands that an applicant describe its "invention" in its patent specification[27] and this "invention" be "useful".[28]

13. FICPI proposes that utility should mean "useful in any way,"[29] even if unrelated to the specific invention described in the patent. The facts at bar illustrate why this approach is unreasonable: Sanofi's prior 875 patent identified clopidogrel as having anti-platelet aggregation activity with low toxicity in humans. The justification for the issuance of the 777 patent was Sanofi's assertion that clopidogrel had therapeutic advantages over the remaining compounds of the 875 patent. To FICPI, the lesser utility disclosed for clopidogrel in the 875 patent supports the 777 patent and Sanofi need never predict nor deliver the very promised therapeutic advantages for clopidogrel that were the basis for the 777 patent in the first place. Even BIOTECanada and Rx&D recognize that FICPI is incorrect, asserting that a patent must have utility "for the use

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[25] *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024; *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067; *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153; *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265; ,*Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R 625; *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902; *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623.

[26] FICPI factum, paras.12, 28.

[27] Section 34(1) of the *Patent Act*, now Section 27.

[28] Section 2 of the *Patent Act.*

[29] FICPI factum, paras. 26, 28.

disclosed" and that promises be enforced when "necessary to support an inventive step".[30]

14. FICPI and Rx&D claim that there is uncertainty in the law of utility.[31] In fact, this law as stated by this Court simple and clear.[32] Apotex's application for leave to appeal did note the Court below's failure to defer to the trial judge's findings on construction, and to undertake a purposive construction consistent with the inventive concept, but these issues appear no longer to be very contentious. Sanofi has not meaningfully responded to Apotex's case on the standard of review and both Sanofi and Rx&D have indicated their agreement that the promised utility ought to be construed purposively.[33]

15. Rx&D's observation that patent construction is often contested and involves resolving the conflicting opinions of experts is not germane.[34] Disputes over the construction of a patent and its claims are a common feature of patent litigation routinely resolved by trial judges. Rx&D's proposal that applicants be held to their promises only when "explicitly stated in a patent claim, or necessary to support an inventive step" will not end debates over construction in patent cases.[35]

16. FICPI and BIOTECanada each assert that unfulfilled promises ought to be relevant only when they are demonstrated to have been "wilfully made for the purpose of misleading" within the meaning of section 53 of the *Patent Act*.[36] This submission confuses the distinct purposes served

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[30] BIOTECanada factum, paras. 30, 36; Rx&D factum, para. 9(c).

[31] FICPI factum, paras. 9, 10, 15, 26; Rx&D factum, paras. 4, 42.

[32] AIPPI articulated the law without difficulty in the introductory sections of its survey questionnaire. [See: AIPPI Reports, Denmark]

[33] Sanofi factum, para. 47 ; Rx&D factum, para. 4.

[34] Rx&D factum, paras. 6, 9(e), 15-16, 26.

[35] Rx&D's assertion that promises ought to be gleaned only from claims also ignores that (1) claims are intended to define the scope of the monopoly, not the invention [*Patent Act*, s. 34; *Windsurfing International Inc. v. Triantic Corporation* (1985), 8 C.P.R. (3d) 241 at 254-255 (F.C.A.), citing *Western Electric Co. v. Baldwin,* [1934] S.C.R. 94 at 100; *Bristol-Myers Squibb Co. v. Canada (Attorney General)* (2005), 52 C.P.R. (4th) 449 at para. 52 (S.C.C.); *Whirlpool Corp. v. Camco Inc.* (2000), 9 C.P.R. (4th) 129 at paras. 49(g), 52 (S.C.C.), citing *Noranda Mines Ltd. v. Minerals Separation North American Corp.* (1949), 12 C.P.R. 99 (S.C.C.)]; (2) claims are not separate inventions, but rather aspects of the singular invention that underlies the patent [*Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at paras. 54-60]; (3) the inventive concept of the claims is determined in the context of the patent as whole and is not restricted to the literal words of the claims. [*Apotex Inc. v. Sanofi-Synthelabo Canada*, [2008] 3 S.C.R. 265 at para. 77]

[36] FICPI factum, paras. 27-31; BIOTECanada factum, para. 40, 41.

by sections 2 and 53 of the *Act*. Section 53 does not address utility; it addresses fraud on the patent office.[37] By contrast, section 2 serves to preserve the bargain between the inventor and the public.[38] The public is short-changed by a patent that does not deliver its stated utility whether or not the assertion of this utility in the patent was "wilfully made for the purpose of misleading."[39]

2. The interveners' attempt to re-introduce speculative patenting

17. The law of sound prediction is also simple and clear and commonly applied in the lower courts.[40] The interveners do not question this Court's reasons for rejecting speculative patents.[41]

18. Rx&D and BIOTECanada seek to overturn the law of sound prediction by proposing that a patent be valid if "upon challenge" its utility "could have been proven to be useful in fact."[42] The interveners would not require the applicant to have done any work as of the application date or preclude an applicant from filing an application for a mere speculation or guess. Post-filing knowledge of utility in fact would be taken to nourish the soundness of the prediction when made.

19. This was the very point upon which this Court unanimously and unambiguously overruled the Federal Court of Appeal in *Wellcome*. As this Court there explained, such a rule confuses the distinct questions of whether an invention had been completed when its application was filed and whether the invention was eventually made to work. As Rx&D concedes, the former question is one of "invention" not "utility" and was the principal question determined in *Wellcome*.[43] Subsequently gained knowledge cannot, by definition, be imputed to the inventor at the application

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[37] *Corlac Inc. v. Weatherford Canada Inc.*, 2011 FCA 228 at para. 150.

[38] *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at para. 94.

[39] This Court explained that a patent can fail for insufficiency under section 27(3) without the requirements of section 53 having been met. [*Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 at para. 85-87]

[40] AIPPI articulated the law without difficulty in the introductory sections of its survey questionnaire. [See: AIPPI Reports, Denmark]

[41] Rx&D, BIOTECanada and FICPI acknowledge that patents ought not issue for speculations. [Rx&D factum, paras. 37, 40, 41; FICPI factum, paras. 26, 33; BIOTECanada, paras. 41] The fact that an inventor must disclose how he "contemplates" the invention will be used does not detract from this Court's long standing precedents that an invention is more than an idea. [*Christiani v. Rice*, [1930] S.C.R. 443 at 452-454]

[42] Rx&D factum, paras. 6, 9(a), 27-29; BIOTECanada factum, para.17.

[43] Rx&D factum, para. 39.

date.[44] Imagining an invention to have been made at the filing date because it was later shown to work would allow patent applicants to take the benefit of future advancements made by others and to force the public to pursue patent litigation before a patent disclosure could be credited as useful.

20. That sound prediction relates to "invention" also clarifies that the sound prediction disclosure requirement is directed to disclosure of the invention, not to disclosure of the utility.[45]

21. BIOTECanada argues that this Court made an "inadvertent error" in holding that speculations are not patentable.[46] Apotex submits that it is impossible to read *Wellcome* and fairly conclude that this unanimous decision was anything but deliberate. Further, BIOTECanada is incorrect that this Court's decision in *Monsanto* limited the doctrine of sound prediction to circumstances of actual inutility. In *Monsanto*, this Court stated that a patent claim would be invalid either if there was evidence of a lack of utility or if there was no sound prediction, [47] and explained the doctrine of sound prediction with reference to the same concerns about speculative claiming and paper inventions that animated this Court's discussion in *Wellcome*.[48]

22. Finally, none of the interveners' alternative ideas for protecting the public from speculative patents makes sense.[49] Even if there were a legal basis to impose increased damages or costs in a case involving a speculative patent, this would not address the chilling effect that such patents have on the public at large. Even if the Court could adopt the U.S. requirement of "good faith" without involving Parliament, the correlative right to rely on file wrapper estoppel would have to be provided.[50] European "industrial applicability" could not be adopted without Parliamentary action.

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[44] It is for this same reason that the fact that the Commissioner of Patents can request proof of utility during prosecution is not "anomalous" in the least.[44] [Rx&D factum, para. 30]

[45] Contrary to Rx&D's factum, para. 14, the sound prediction disclosure requirement does not characterize "utility as a disclosure requirement."

[46] BIOTECanada factum, para. 12.

[47] *Monsanto Company v. Commissioner of Patents*, [1979] 2 S.C.R. 1108 at 1117.

[48] *Monsanto Company v. Commissioner of Patents*, [1979] 2 S.C.R. 1108 at 1113-1117.

[49] BIOTECanada factum, paras. 8; Rx&D factum, paras. 38, 40; FICPI factum, para. 26.

[50] *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at paras. 63-66.

3. The law of utility and sound prediction serves the goals of the Patent Act

23. Contrary to the interveners' arguments, the Federal Court of Appeal's decisions in the latanoprost[51] and atomoxetine[52] cases are sensible and do not "treat[] useful inventions as useless". The latanoprost and atomoxetine patents were deemed invalid for prematurely staking a claim over an area that their respective inventors had yet to reach. The evidentiary findings in both cases were that the patents each addressed the use of the medicine to treat a disease which, unlike the common headache, was known to require repeated dosing. The knowledge of the inventors at the time of applying for these patents was not sufficient to predict that the drugs would address the specific diseases to which they were targeted. The threshold applied was one of sound prediction and did not seek, as the interveners assert, a "certainty" or "THE cure"[53].

24. Contrary to Rx&D,[54] the unbroken line of authority in Canada is that the disclosure of the invention in a patent must be at a level to enable the skilled addressee to understand it.[55] This same required level of disclosure in sound prediction cases serves this goal precisely.

25. The interveners also assert that the law of utility and sound prediction has or will discourage research or complicate patent filings in Canada. [56] Despite the many years these doctrines have been the law of Canada, there is no evidence that Canadian patent law has negatively affected the funding for any entity or complicated patent drafting for anyone.[57] There is

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[51] *Pfizer Canada Inc. v. Apotex Inc.*, 2011 FCA 236. Note that the latanaprost patent was also held invalid in the U.S. based on misstatements made regarding the experiments conducted. [*Pharmacia Corp. v. Par Pharm, Inc.*, 417 F.3d 1369 (Fed. Cir. 2005).

[52] *Novopharm Ltd. v. Eli Lilly & Co.*, 2011 FCA 220.

[53] FICPI factum, paras. 11, 13, 29; Rx&D factum, para. 13, 24. The law of sound. prediction does not demand clinical data be adduced in every circumstance, but rather depends upon the patent at issue. The conduct of clinical trials does not automatically destroy the novelty of an invention. [*Bayer Inc. et al. v. Apotex Inc.* et al., 2014 FC 436 at 121; *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008, 63 C.P.R. (4th) 406 at paras. 155-158, aff'd 2009 FCA 97]

[54] Rx&D factum, para. 18.

[55] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 at 524-525.

[56] BIOTECanada factum, paras. 2, 5-7, 25, 33, 39; FICPI factum, paras. 1, 2, 4, 7, 8.

[57]. FICPI factum, para. 4, 7, 23. The assertion that PCT standardizes patent applications such that they are drafted only once is overstated. Local laws regarding patent applications apply after a PCT application is nationalized. Professional, registered Canadian patent agents tailor foreign applications to Canadian requirements. [Patent Rules, s. 20(1), 21(1), 59, 60] The 777 patent was not filed under the PCT in any event.

also no evidence that a single patentee has located its research facilities outside of Canada in response to Canadian law, or that choosing a location for pharmaceutical research depends on the doctrines now in issue, opposed to labour costs, tax structure, regulatory compliance or the like.

26. Finally, the necessity for a patent to disclose the factual basis and line of reasoning has been long known to patent drafters. Sanofi itself included reference to its rat studies on clopidogrel in the 777 patent itself. The 777 patent failed because Sanofi's prediction was not and could not be based on that work alone, and Sanofi chose not to disclose the information (*e.g.*, convulsions) that it actually used to predict the improved therapeutic utility of clopidogrel. Far from being "paradoxical," the need to invalidate a patent that does not disclose what the inventor actually accomplished has long been "at the heart" of the patent system in Canada.

PART III – SUBMISSIONS ON COSTS

27. Apotex seek costs associated with responding to the intervention from AIPPI, FICPI, BIOTECanada and Rx&D.

PART IV – ORDER SOUGHT

28. Apotex submits that, if the interveners are to make oral argument, the patentee industry groups, Rx&D and BIOTECanada, be collectively granted ten minutes; the generic industry group, Canadian Generic Pharmaceutical Association, be granted ten minutes; the patentee-side professional organizations, FICPI and AIPPI, collectively be granted ten minutes, and the Centre for Intellectual Property Policy be granted ten minutes. Following these submissions, Apotex submits that Sanofi and Apotex should each be granted ten minutes to respond.

SEPTEMBER 30, 2014

ALL OF WHICH IS RESPECTFULLY SUBMITTED

FOR

GOODMANS LLP,
LAWYERS FOR THE APPELLANTS

Legislature/Publications	
Chisum on Patents, section 4.04,	7
Patent Act, section 2, 34 (now section 27)	6
Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7647, as amended, Arts. 5, 27(5)(6); *Regulations* under the PCT, June 19, 1970, 28 U.S.T. 7647, as amended, r. 5.1(a)(iii)	10
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Stephen G.A. Pitel & Nicholas S. Rafferty, *Conflict of Laws* (Toronto: Irwin Law, 2010) at 237	5
WIPO Standing Committee on the Law of Patents, "The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws" (2001) SPC5/Inf at paragraph 24	6
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Corlac Inc. v. Weatherford Canada Inc., 2011 FCA 228 at para. 150	16
Eli Lilly Canada Inc. v. Apotex Inc., 2008, 63 C.P.R. (4th) 406 at paras. 155-158, aff'd 2009 FCA 97	23
Eli Lilly Canada Inc. v. Apotex Inc., 2009 FCA 78, 78 CPR (4th) 388 at para. 19.	10
Eli Lilly Canada Inc. v. Novopharm Ltd., 2010 FCA 197, 85 C.P.R. (4th) 413 at paras. 48-50	10
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Galerie d'art du Petit Champlain inc v Théberge, 2002 SCC 34, [2002] 2 S.C.R. 336 at paras. 70-75	11
Martin Engineering Co. v. Trison Holdings Pty (1989), 14 IPR 330 at 336-337	9
Monsanto Canada Inc. v. Schmeiser, 2004 SCC 34, [2004] 1 S.C.R. 902	11
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Novopharm Ltd. v. Eli Lilly & Co., 2011 FCA 220	23
Pfizer Canada Inc. v. Apotex Inc., 2011 FCA 236	23
Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents), [1989] 1 S.C.R. 1623	11
Teva Canada Ltd. v. Pfizer Canada Inc., 2012 SCC 60, [2012] 3 S.C.R. 625 at para. 54-60, 85-87	11, 15, 16
Western Electric Co. v. Baldwin, [1934] S.C.R. 94 at 100	15
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AIPPI National Group Reports	6, 8
AIPPI questionnaire, section 1	5, 14, 17
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Court File No.: 35562

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

B E T W E E N:

APOTEX INC. and
APOTEX PHARMACHEM INC.

Appellants

- and -

SANOFI-AVENTIS and BRISTOL-MYERS SQUIBB SANOFI PHARMACEUTICALS HOLDING PARTNERSHIP

Respondents

REPLY TO THE INTERVENERS OF THE APPELLANTS, APOTEX INC.

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