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 FACTUM OF THE APPELLANT

GOODMANS LLP
Barristers & Solicitors
Bay Adelaide Centre
333 Bay Street, Suite 3400
Toronto, ON M5H 2S7

H.B. Radomski
Richard Naiberg

Tel: 416.979.2211
Fax: 416.979.1234
hradomski@goodmans.ca

Solicitors for the Appellants, Apotex Inc.

NELLIGAN O'BRIEN PAYNE LLP
Barristers & Solicitors
Suite 1500, 50 O'Connor Street
Ottawa, ON K1P 6L2

Dougald E. Brown

Tel: 613.238.8080
Fax: 613.238.2098
dougald.brown@nelligan.ca

Agent for the Appellants, Apotex Inc.

ORIGINAL TO: **THE REGISTRAR**
Supreme Court of Canada
301 Wellington St.
Ottawa, Ontario
K1A 0J1

COPIES TO:

GOWLING LAFLEUR HENDERSON LLP Barristers & Solicitors 2600-160 Elgin Street Ottawa, Ontario KIP 1C3 Tel: 613-233-1781 Fax.:613-563-9869 Anthony G. Creber Marc Richard Livia Aumand Solicitors for the Respondents, Sanofi-Aventis and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership	
SMART & BIGGAR 55 Metcalfe Street, Suite 900 Ottawa, Ontario K1P 5Y6 Steven B. Garland Colin B. Ingram Tel: (613) 232-2486 Fax: (613) 232-8440 Solicitors for the Association Internationale pour la Protection de la Propriété Intellectuelle / International Association for the Protection of Intellectual Property	
BORDEN LADNER GERVAIS LLP World Exchange Plaza 100 Queen Street, Suite 1300 Ottawa, Ontario K1P 1J9	**BORDEN LADNER GERVAIS LLP** World Exchange Plaza 100 Queen Street, Suite 1300 Ottawa, Ontario K1P 1J9

Jamie Mills Chantal Saunders Tel: 613.369.4782/369.4783 Fax: 613.230.8842 Counsel for BIOTECanada	Nadia Effendi Tel: 613.237.5160 Fax: 613.230.8842 Agent for BIOTECanada
NORTON ROSE FULBRIGHT CANADA LLP Royal Bank Plaza, South Tower, Suite 3800 200 Bay Street, P.O. Box 84 Toronto, Ontario M5J 2Z4 Patrick E. Kierans Kristin Wall Tel: (416) 216-4000 Fax: (416) 216-3930 Email: kristin.wall@nortontosefulbright.com Counsel for Canada's Research-Based Pharmaceutical Companies	**NORTON ROSE FULBRIGHT CANADA LLP** Suite 1500 45 O'Connor Street Ottawa, Ontario K1P 1K4 Sally A. Gomery Tel: (613) 780-8604 Fax: (613) 230-5459 Email: sally.gomery®nortonrosefulbright.com Agents for Canada's Research-Based Pharmaceutical Companies
Jeremy de Beer Professional Corporation 676 Roosevelt Avenue Ottawa, Ontario K2A 2A7 Jeremy de Beer Tel: (613) 263-9155 Fax: (613) 562-5417 Email: Jeremy@JeremydeBeer.ca Counsel for the Centre for Intellectual Property Policy	**Samuelson-Glushko Canadian Internet Policy & Public Interest Clinic (CIPPIC)** University of Ottawa, Faculty of Law, CML 57 Louis Pasteur Street Ottawa, Ontario K1N 6N5 Tamir Israel Tel: (613) 562-5800 ext. 2914 Fax: (613) 562-5417 Email: tisrael@cippic.ca Agent for the Centre for Intellectual Property Policy

AITKEN KLEE LLP Suite 300, 100 Queen Street Ottawa, Ontario K1P 1J9 **David W. Aitken** **Jonathan Stainsby** Tel: 613-903-5099 647-317-6868 Fax: 613-695-5854 E-mail: daitken@aitkenklee.com jstainsby@aitkenklee.com Solicitors for Canadian Generic Pharmaceutical Association	
M^e^ Julie Desrosiers **M^e^ Kang Lee** **Fasken Martineau DuMoulin LLP** **Lawyers** Stock Exchange Tower, Suite 3700 800 Place Victoria Montréal, Québec H4Z 1E9 Tel: 514.397.7516 Fax: 514.397.7600 jdesrosiers@fasken.com klee@fasken.com and **M^e^ Alain Leclerc** **Goudreau Gage Dubuc LLP** **Lawyers** Suite 2200 2000 McGill College Avenue Montréal, Québec H3A 3H3 Tel: 514.397.7675 Fax: 514.397.4382 aleclerc@ggd.com **Counsel for Fédération Internationale des Conseils en Propriété Intellectuelle**	**M^e^ Jay Kerr-Wilson** **M^e^ J. Aidan O'Neill** **Fasken Martineau DuMoulin LLP** **Lawyers** Suite 1300 55 Metcalfe Street Ottawa, Ontario K1P 6L5 Tel: 613.696.6884 Fax: 613.230.6423 jkerrwilson@fasken.com aoneill@fasken.com **Agent for the Applicant/Proposed Intervener** **Fédération Internationale des Conseils en Propriété Intellectuelle**

PART I - OVERVIEW

1. Sanofi[1] seeks to uphold the judgment below with the incorrect assertions that the so-called "promise" and "heightened disclosure" doctrines are new, extra-statutory, unsupported by the case law, and should be ignored or changed. Sanofi further selects isolated passages from the evidentiary record to urge that this Court make findings that contradict those of the trial judge. The Court below did not rely upon these assertions and selections as grounds in its Reasons for Judgment and thus Apotex[2] now addresses these grounds in reply.[3]

2. In fact, the "promise doctrine" and "heightened disclosure" are not new but rather are properly understood as convenient short-hand for the specific requirements in the *Patent Act*[4] that a patent's invention be correctly and fully disclosed, and be useful. These are necessary doctrines, rooted in the *Act*, and carefully explained by this Court. Sanofi's proposals to abandon these doctrines would not only contradict the *Act* and reverse decades-old, unanimous precedents of this Court, but would also disregard this Court's reasoning as to how these doctrines serve patent law, reasoning which Sanofi's factum does not address much less overcome.

PART II - STATEMENT OF ARGUMENT

A. THE "PROMISE DOCTRINE" IS NOT NEW AND IS FIRMLY ROOTED IN CANADIAN LAW

3. Contrary to Sanofi's arguments,[5] the promise doctrine arises directly from sections 2 and 34(1) of the *Patent Act* and have been cited as such by this Court for decades.[6] Subsection 34(1)

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[1] The respondents, Sanofi-Aventis and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership.

[2] The appellant, Apotex Inc.

[3] Rules 29(3) and 35(4), *Rules of the Supreme Court of Canada*, SOR/2002-156, *as amended.*

[4] *Patent Act*, R.S.C., 1985, c. P-4.

[5] Sanofi factum, paras. 2, 4, 46, 58, 59, 95.

[6] *Patent Act*, R.S.C., 1985, c. P-4, s.2; *Wandscheer v. Sicard Ltd.*, [1948] S.C.R. 1 at 15; *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 at 525-526; *Teva Canada ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 SCR 625 at para. 38. For reference to the promise doctrine in the context of a sound prediction case, *see Apotex Inc. v. Wellcome Foundation Ltd.*, 2008 SCC 77, [2002] 4 S.C.R. 153 at para. 62, citing

mandates that an applicant for a patent "shall in the specification ...correctly and fully describe the invention and its operation or use as contemplated by the inventor." The applicant chooses a definition of its "invention" and this definition becomes the currency in the notional bargain between the public and the patentee that underlies the patent grant.[7] Section 2 provides the further requirement that this "invention" be "useful", that is, that the invention must do what the patentee says that it will do.

4. Sanofi's observation that the word "promise" does not appear in the *Patent Act* is not illuminating. Much of patent law finds no explicit expression in the *Act*, including the settled law relating to selection patents, obviousness, double patenting, disclosure/enablement, inducing infringement, punitive damages, and patent dedications.[8] The *Act* recognizes that factors that may render a patent void arise from both the *Act* and "by law."[9] It is the role of the court to clarify the abstract generalities of the patent statute.[10]

5. Finally, and even as Sanofi argues that "promise" and "heightened disclosure" are not explicitly referenced in the *Patent Act*, Sanofi urges the adoption of a series of different legal standards that too are absent from the *Act*. For example, under the *Patent Act*, there is no "statutory scintilla standard," no "paramountcy" of the claims, no deferred demonstrations of utility, no results/applications distinction, no "explicit promise of specific result", no definition of

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Monsanto Co. v. Commissioner of Patents, [1979] 2 S.C.R. 1108 at p. 1116-1117. As such, Sanofi and Professor Siebrasse are incorrect that the promise doctrine arose in the last 10 years. [See Sanofi factum, paras. 59, 61, 63, ft. 160]

[7] For example, the "invention" as defined will be patentable only if is neither old nor obvious, and the scope of the claims may not exceed the scope of the "invention". [*Patent Act*, R.S.C., 1985, c. P-4, s.27(1); *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at para. 13; *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533 at para. 133; *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 at para. 37; *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60 at paras. 31-35]

[8] *Apotex v. Sanofi-Synthelabo Canada*, [2008] 3 S.C.R. 265 at paras. 5, 8-12, 17, 23-50, 5593, 97; *Aventis Pharma Inc. v. Pharmascience Inc.*, 2006 FCA 229, 53 CPR (4th) 453 at para. 67; *Merck & Co. v. Apotex Inc.*, 2006 FC 524, 53 CPR (4th) 1 at para. 206; *Merck & Co. v. Canada (Minister of Health)*, 2010 FC 1043, 88 CPR (4th) 81 at para. 17; *Dableh v. Ontario Hydro* (1996), 68 CPR (3d) 129, [1996] 3 F.C. 751 at 148-149 (FCA); Kelly Gill, *Fox on Canadian Law of Trademarks and Unfair Competition*, 4th ed. (Toronto: Carswell, 2014) at 13-59, footnote 299.

[9] *Patent Act*, R.S.C., 1985, c. P-4, s. 59.

[10] *Apotex v. Sanofi-Synthelabo Canada*, [2008] 3 S.C.R. 265 at para. 12, quoting *Synthon B.V. v. SmithKline Beecham plc*, [2006] 1 All E.R. 685, [2005] UKHL 59, at paras. 57-58.

"materiality", no "*prima facie* reasonable inference", and no deference to foreign law or treaties.[11]

B. PROMISE DOCTRINE DOES NOT DEPEND ON A REPEALED UK STATUTE

6. Sanofi's argument on the origins of the promise doctrine in Canada is built on several faulty premises.[12] First, Sanofi is incorrect that the promise doctrine arose in *Consolboard.*[13] Sections 2 and 34 have long been present in the *Patent Act* and this Court (and others), have required that an invention do what the patent says it will do, irrespective of the presence of other residual utility, more than 30 years before *Consolboard.*[14]

7. Second, Sanofi is incorrect that *Consolboard* took any section of the U.K. patent statute as its source. The analysis in *Consolboard* was based upon sections 2 and 34 of the *Patent Act* and judicial commentary on these sections.[15] While it is correct that *Consolboard* referenced "a helpful discussion…on the meaning of not useful" from Halsbury's Laws of England, this Court immediately then stated that "Canadian law is to the same effect" and affirmed the principle adopted earlier in Canada that "[i]f…the promised results are obtained, the invention is useful in the sense in which that term is used in patent law."[16] Nowhere did this Court state that it had any intention of importing provisions of any U.K. statute into Canadian law.[17] In any event, in 2012, this Court reiterated, without any reservation, that the promise doctrine is the Canadian standard for utility.[18]

8. Third, what Sanofi calls the "false promise" doctrine did not originate from the U.K.

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[11] Sanofi factum, paras. 2, 82, 84, 88-90, 94, 96-99, 102, 113, 114, 118.

[12] Sanofi Factum, paras. 65-81.

[13] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.,* [1981] 1 S.C.R. 504 at 518-519.

[14] *Wandscheer v. Sicard Ltd.,* [1948] S.C.R. 1 at 5, 24; Gold, E.R and Shortt, M., "The promise of the patent in Canada and around the world", (2014), 30 C.I.P.R. 35 at 52-56; *New Process Screw Corporation v. P.L. Robertson Mfg. Co. Limited* (1961), 39 C.P.R. 31 at p. 45 - 46; *Amfac Foods Inc. et al. v. Irving Pulp & Paper, Ltd.* (1986), 12 C.P.R. (3d) 193 (FCA) at p. 197-205

[15] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.,* [1981] 1 S.C.R. 504 at 514-516, 517-527.

[16] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.,* [1981] 1 S.C.R. 504 at 525-526, citing *Rodi & Wienenberger A.G. v. Metalliflex Limited* (1959), 19 Fox Pat. C. 49 at para 17, aff'd, [1961] S.C.R. 117.

[17] In addition, the U.K. statute had been repealed several years prior to the decision in *Consolboard* and thus cannot be presumed to have influenced this Court in its deliberations.

[18] *Teva Canada Limited v. Pfizer Canada Inc.*, 2012 SCC 60 at para. 38.

statute, but rather in *Arthur Legat's Case* (1612), a decision which predates even the 1623 Statute of Monopolies.[19] The repeal of that U.K. statute does not remove the older concept from our law.

9. Fourth, the circumstances targeted by the former U.K. statute and the present Canadian promise doctrine are not the same. For instance, for many years, the U.K. false promise doctrine was designed to protect against deception of the Crown. As the Crown had the discretion to grant patents, U.K. Courts were reluctant to speculate as to whether the Crown would have exercised this discretion had it known the invention achieved less than what was promised in the specification. This is a concern that falls outside the ambit of the Canadian promise doctrine and provides an explanation about why the respective promise doctrines differ in the two jurisdictions.[20] In any case, the concerns embodied by the Canadian promise doctrine – namely, the need to protect the public from misrepresentations and the need to hold inventors to account for the claims they make in their patents – are also present in U.K. case law.[21]

10. Finally, the specific contours of obsolete U.K. jurisprudence and their relative merits are not raised on this appeal nor is an autopsy of the specific circumstances in which the U.K. doctrine was invoked now helpful. Canadian patent law is a unified collection of interacting doctrine whose provisions cannot sensibly be compared, one-for-one, with those of another country without an extensive and nuanced analysis of how each of the various provisions affects each of the other provisions in both countries.

C. FOREIGN UTILITY REQUIREMENTS DO NOT DEFINE CANADIAN LAW

11. This last point underscores why Sanofi is incorrect in suggesting that Canada's approach to

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[19] Siebrasse, N. "The False Doctrine of False Promise" (2013) 29 C.I.P.R. 3 at p.6.

[20] Gold, E.R and Shortt, M., "The promise of the patent in Canada and around the world", (2014), 30 C.I.P.R. 35 at p. 48.

[21] Gold, E.R and Shortt, M., "The promise of the patent in Canada and around the world", (2014), 30 C.I.P.R. 35 at p. 50-51. As explained in *Hatmaker v. Joseph Nathan & Co.* (1919), 36 RPC 231 (HL) at p. 237: "In other words, [patent] protection is purchased by the promise of results. It does not and ought not to, survive the proved failure of the promise to produce the results." Indeed, this language embodies the idea in Canadian law that a patent is not a hunting licence - the ingenuity of the patent lies not in the identification of a desirable result that is worth searching for but rather in teaching the means to achieve it. See, e.g., *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at para. 32.

utility ought to be "consistent with U.S. and European law".[22] A single doctrine, such as utility, cannot be used as a proxy for comparing the Canadian patent system with that of foreign jurisdictions. It is the interaction between the various Canadian patent doctrines which shapes the notional bargain that animates the *Patent Act*. Comparative law analyses must be undertaken on a holistic basis rather than by selecting individual elements of the law in isolation from the legal and policy matrix in which they are embedded.[23]

12. Canadian Courts have been reluctant to give effect to the decisions of foreign Courts, even where related patents are considered.[24] There are doctrinal differences among even Canada's closest trading partners that prevent direct comparison.[25] These include differences in the determination of when an invention has been made,[26] in patentable subject matter,[27] in the availability of selection patents,[28] in the approach taken in patent construction,[29] in the definition of

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[22] Sanofi factum, para. 83

[23] Gold, E.R and Shortt, M., "The promise of the patent in Canada and around the world", (2014), 30 C.I.P.R. 35 at p. 58-60

[24] *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at para. 40; *Johnson & Johnson Inc. v. Boston Scientific Ltd.*, 2008 FC 552 at paras. 257–270; *Bayer Inc. v. Cobalt Pharmaceuticals Co.*, 2013 FC 1061 at paras. 20-21; *Pfizer Canada Inc. v. Apotex Inc.*, 2009 FCA 8 at paras. 28–29.

[25] *Lubrizol Corp. v. Imperial Oil Ltd.* (1992), 45 CPR (3d) 449 at 459 (FCA); *Canada (Attorney General) v. Amazon.com*, 2011 FCA 328, 97 CPR (4th) 171 at para. 16; Gold, E.R and Shortt, M., "The promise of the patent in Canada and around the world" (2014) 30 C.I.P.R. 35 at p. 59; World Health Organization, World Intellectual Property Organization, World Trade Organization, Promoting Access to Medical Innovation and Technology: Intersections between
health, intellectual property and trade (Geneva: World Trade Organization, 2012) at 57.

[26] *Lubrizol Corp. v. Imperial Oil Ltd.* (1992), 45 CPR (3d) 449 at 459 (FCA) ; *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at paras. 40 and 53.

[27] In the US, it is permissible to claim a "method of medical treatment", whereas in Canada it is not. *Visx Inc. v. Nidek Co.,* (1997), 77 C.P.R. (3d) 532 at 535; *Tennessee Eastman Co. et al v. Commissioner of Patents*, [1974] S.CR. 111 at p. 118–119.

[28] *Dr. Reddy's Laboratories (UK) Ltd. v. Eli Lilly & company Ltd.*, 2008 EWHC 2345 at paras. 95-109, aff'd [2009] EWCA Civ. 1362 at paras. 35-40.

[29] The United States does not apply purposive construction. Gold, E.R and Shortt, M., "The promise of the patent in Canada and around the world" (2014) 30 C.I.P.R. 35 at p. 66

utility and how and when it is established,[30] in the effect of statements made to the patent office in the course of prosecution,[31] and in the articulation of the obviousness test.[32]

13. Different countries also have different utility standards. Australia and New Zealand have embraced a Canadian-style promise doctrine.[33] The World Intellectual Property Organization recognizes that "for the purposes of full harmonization of substantive patent law, the industrial applicability/utility requirement cannot be considered separately from other requirements."[34]

14. Finally, the fact that foreign law is different does not mean it ought to be emulated. Optimal harmonization may require the Canadian promise doctrine to be embraced more widely. [35]

D. PARLIAMENT HAS NOT ADOPTED THE EUROPEAN STANDARD OF UTILITY

15. Sanofi argues that Parliament has given a "clear direction" that utility in Canada ought to be interpreted in accordance with what it calls a "European standard" that excludes the promise doctrine.[36] In fact, Parliament has taken the opposite approach, choosing not to amend the *Patent Act* to match European law.

16. Contrary to paragraph 84 of Sanofi's factum, Article 1709(1) of NAFTA only provides that "a party may deem the terms inventive step, and capable of industrial application to be

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[30] Gold, E.R and Shortt, M., "The promise of the patent in Canada and around the world" (2014) 30 C.I.P.R. 35 at p. 60 – 62 and 71

[31] *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at paras. 63-67.

[32] In the UK, courts apply a "worth a try" test for obviousness, while Canadian courts do not. [*Pfizer Canada Inc. v. Apotex Inc.*, 2009 FCA 8 at paras. 28 – 29] In Canada, subsequently recognized advantages are not considered in determining obviousness. In the United States, post-patent findings are considered relevant. [*Janssen-Ortho Inc. v. Novopharm Ltd.*, 2006 FC 1234, 57 CPR (4th) 6 at para. 113(8) (FC), aff'd 2007 FCA 217, 59 CPR (4th) 116 at paras. 25-28 (FCA), leave to appeal to S.C.C. denied, [2007] S.C.C.A. No. 442; *In re Zenitz*, 52 C.C.P.A. 746 at 748 (C.C.P.A. 1964)].

[33] Gold, E. R. and Shortt, M. "The Promise of the Patent in Canada and Around the World". (2014) 30 C.I.P.R. 35 at p. 51

[34] 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.

[35] The asserted absence of a "promise doctrine" in Europe and the U.S. may be more apparent than real. See: Gold, Gold, E.R and Shortt, M., "The promise of the patent in Canada and around the world" (2014) 30 C.I.P.R. 35 at p. 60 -72.

[36] Sanofi factum, para. 84

synonymous with the terms non-obvious and useful, respectively. " Parliament has not undertaken any legislative actions to introduce these definitions into the *Patent Act*. Further, Canada's position on the meaning of utility has recently been articulated as supporting the present promise doctrine.[37]

E. SANOFI'S PROPOSED REVISIONS TO THE PROMISE DOCTRINE ARE INCONSISTENT WITH THE *PATENT ACT* AND ITS GOALS

17. Sanofi also proposes modifications to the promise doctrine. These proposals are inconsistent with the *Patent Act* and its goals, as well as inconsistent with the jurisprudence.

1. The 'scintilla' proposal

18. Sanofi's argument that a scintilla of utility[38] is always sufficient to meet the utility requirement is incorrect. The 777 patent, like any selection patent, requires an invention having a special advantage over other members of its genus, and that this advantage be disclosed.[39] The argument also directly contradicts the promise doctrine as articulated repeatedly by this Court.

19. Sanofi's statement that, for a compound, "some utility, such as having biological activity in an animal model or Petri dish" will, by definition, meet the statutory requirement of utility in the *Patent Act* is similarly incorrect.[40] This 'one-size-fits-all' approach ignores that, as discussed above, the invention in any particular patent depends upon what the inventor in that patent has described to be the invention. Every patent is different and there can be no general articulation of what constitutes utility in every case.[41]

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[37] Government of Canada Statement of Defence in The Matter of an Arbitration Under Chapter Eleven of the North American Free Trade Agreement and the Uncitral Arbitration Rules (1976), paras. 16, 21-30.

[38] Sanofi factum, paras. 2, 44, 55, 57, 82, 88, 90. Sanofi's use of the word "scintilla" is confusing. A "scintilla" is a quantity, not a description of the nature or definition of a given patent's utility. A demonstration that a compound has particular (or even encouraging) *in vitro* biological properties does not mean it has a scintilla of utility as a medicine. They are different questions.

[39] *Apotex v. Sanofi-Synthelabo Canada*, [2008] 3 S.C.R. 265 at paras. 9-10, 114

[40] Sanofi factum, para. 55

[41] *Electrolytic Zinc Process Co. v. French's Complex Ore Reduction Co. of Canada Ltd.*, [1930] S.C.R. 462, 4 D.L.R. 902 at 466

20. All compounds have properties, biological or otherwise, and the *Patent Act* does not suggest that an inventor can, during litigation, highlight one such property and declare that this property is its utility. The task in every case will be to construe the invention as it is described by the inventor and determine whether that invention does what the patent says it will do. Construction will determine if the patent is for a laboratory property or for a medical use.

21. In the present case, Apotex and Sanofi agree that the invention is directed to clopidogrel and its improved therapeutic properties as compared to PCR 4099 and the other compounds of the 875 patent. This utility will match the inventive concept of the patent.[42] This is so because a single patent (including its various claims) is addressed to a single invention. The inventive concept, and thus the utility, is construed purposively once and for all purposes on the basis of both the claim language and the advantages discussed in the disclosure.[43]

2. The 'result/application' proposal

22. Sanofi also proposes that the Court distinguish between promises of a specific result (which promises would need to be met) and promises related to potential applications (which promises could be ignored).[44] This is a distinction without a difference and is but another way of articulating Sanofi's 'scintilla' argument. Whether a statement of the application of a patent's subject matter is part of the invention or not will depend upon a construction of the patent. There would be no statutory justification or policy rationale for ignoring any aspect of what the patentee describes as the invention when the utility of the invention is challenged in litigation.

23. Sanofi argues that "[r]equiring the invention to satisfy every statement as to potential

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[42] Sanofi factum, para. 32; Bernstein, A. *et al.*, "Unpacking the promise of the patent", 28 C.I.P.R. 245 at pp. 245, 258; *Hoffmann-La Roche Limited v. Apotex Inc.*, 2011 FC 875 at para. 22; *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915, aff'd 2011 FCA 220. Paragraph 8 of Sanofi's factum incorrectly asserts that Apotex has applied a different or "inconsistent" approach to its inventive concept.]

[43] *Allergan Inc. v. Canada (Minister of Health)*, 2012 FCA 308, 105 CPR (4th) 371 at paras. 23-26, 55-58, 74, leave den'd2013] S.C.C.A. No. 3; [*Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 at paras. 43, 49(b); *Hoffmann-La Roche Limited v. Apotex Inc.*, 2011 FC 875, 104 CPR (4th) 233 at para. 22; *AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023, 96 CPR (4th) 159 at para. 82, aff'd 2012 FCA 109, 101 CPR (4th) 275 at paras. 19-20; *Alcon Canada Inc. v. Cobalt Pharmaceuticals Co.*, 2014 FC 149, 117 CPR (4th) 323 at paras. 60, 63, 65-66; *Novopharm Limited v. Eli Lilly and Company*, 2010 FC 915, 87 CPR (4th) 301 at paras. 32, 93.

[44] Sanofi factum, paras. 76, 96-98.

application or use upon pain of invalidity...would discourage patentees from disclosing such applications." However, the *Patent Act* is directed to encouraging the disclosure of completed inventions, not to encouraging the disclosure of speculative ideas for possible applications which themselves do not constitute proper consideration for the patent grant.[45] As for the "pain of invalidity," it is the only tool by which the *Patent Act* ensures that the public is not short changed by receiving only an 'almost' invention.

24. Sanofi's argument in this regard is erroneously based upon its incomplete quotation from *Alsop's Patent.*[46] The full passage begins with the statement that "[t]he well-known rule is that the utility of an invention depends upon whether, by following the directions of the patentee, the result which the patentee professed to produce can in fact be produced." This articulation is consistent with the Canadian requirement that all promises must be kept. The case further establishes that, in addition to promises of results, representations as to ancillary "useful purposes" may provide a basis for invalidating a patent where the representation was sufficiently material to have deceived the Crown. [47]

25. Finally, Sanofi's 'result/application' proposal does not apply in any event to the present case. As the trial judge held, the 777 patent is a selection patent and its invention is in its advantageous application to humans. The trial judge did not accept, as Sanofi now asserts, that the "gravamen of the invention" as described in the 777 patent was some lower utility, or that its performance in studies in laboratory rats represented a useful result.

3. The 'consider only the literal words' proposal

26. Sanofi argues that the promised utility of a patent ought to be exempted from the principles of purposive construction.[48] Otherwise, Sanofi suggests, "an infringer...[will] twist the words of

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[45] *Apotex Inc. v. Wellcome Foundation Ltd.*, 2008 SCC 77, [2002] 4 S.C.R. 153 at para. 69.

[46] Sanofi factum, para. 96.

[47] The case does, however, provide that a patent can be invalidated for failure to deliver on an a '"useful purpose" where "the Crown has been deceived" in issuing the grant, a point ignored by Sanofi. *Re Alsop's Patent* (1907) 24 RPC 733, at 753.

[48] Sanofi factum, paras. 2, 4, 99-101.

the patent", in a "hair-splitting" exercise to hold applicant will be to a promise he never made.[49]

27. Sanofi's argument fails to appreciate that purposive construction was adopted in patent cases precisely to avoid such result-oriented analyses. Purposive construction ensures that the words of a patent are given a meaning consistent with the purposes of the inventor as those purposes are revealed by the words chosen in the patent.[50]

28. Sanofi also argues that the principles of purposive construction are applied only to claims, and not the disclosure. In fact, purposive construction has been applied to all aspects of the patent, including the inventive concept and the promise of utility.[51] As this Court has observed, patents are in the nature of regulations and, like all regulations, are construed purposively.[52] The goals of purposive construction apply with equal force to all aspects of the patent.

29. Sanofi also argues that the only statements that are material to the patent grant will attract the promise doctrine.[53] This too is a restatement of Sanofi's 'scintilla' and 'result/application' proposals discussed above. The argument is also contrary to this Court's direction that purposive construction can lead to invalidity when the inventor unnecessarily misspeaks.[54] The contours of the invention in any particular patent will be construed in light of the context and purpose of the inventor. There can be no separate, *a priori*, evaluation of whether a particular statement was or was not material to the patent grant. However, in the case of the 777 patent, the unexpected therapeutic advantages are indeed the "gravamen" of the invention and, as Sanofi concedes, in such circumstances the advantages are material.[55]

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[49] Sanofi factum, paras. 89, 100, 101.

[50] *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at para. 51; *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 at para. 49(c).

[51] *Apotex v. Sanofi-Synthelabo Canada*, [2008] 3 S.C.R. 265 at paras. 76-78; *Apotex Inc. v. Pfizer Inc.*, 2011 FCA 236 at paras. 5, 23-28; *Allergan Inc. v. Canada (Minister of Health)*, 2012 FCA 308, 105 CPR (4th) 371 at paras. 23-26, 55-58, 74.

[52] *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 at para. 49(e).

[53] Sanofi factum, para. 102.

[54] *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at para. 51.

[55] Sanofi factum, para. 73.

4. The 'only-in-the-claims' proposal

30. Sanofi states that the "promise doctrine ought to be applied on a claim-by-claim basis"[56] but the statute and the jurisprudence of this Court direct the opposite approach.

31. There is no statutory requirement that the invention be described in the claims. Subsection 34(2) of the *Patent Act* states that claims need only state "distinctly and in explicit terms the things or combinations of things that the applicant regards as new and in which he claims exclusive property or privilege". As this Court has explained, the claims of the patent are not separate inventions, but rather aspects of the singular invention that underlies the patent.[57]

32. Accordingly, that patent claims are severable does not mean a common utility does not inform them all. A unified conception of utility does not "defeat the purposes of having claims".[58] Having multiple claims of varying scope serves as a hedge against unanticipated rulings by the Court as to the scope of particular prior art.

33. This Court's articulation of the promise doctrine has always addressed the promised utility as a singular concept that pervades the entire patent, including all of the claims. Utility means that the invention will do what the patent as a whole, and not just its claims, says that it will do.[59] This is also the approach directed of patent examiners in the Manual of Patent Office Practice and of lower courts.[60]

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[56] Sanofi factum, paras. 89-92.

[57] *Teva Canada ltd. v. Pfizer Canada Inc.,* 2012 SCC 60, [2012] 3 SCR 625 at paras. 54-60.

[58] Sanofi Factum, para. 89.

[59] *Wandscheer v. Sicard Ltd.,* [1948] S.C.R. 1 at 15; *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.,* [1981] 1 S.C.R. 504 at 525-526; *Teva Canada ltd. v. Pfizer Canada Inc.,* 2012 SCC 60, [2012] 3 SCR 625 at para. 38; *Feherguard Products Ltd. v. Rocky's of B.C. Leisure Ltd.* (1995), 60 C.P.R. (3d) 512 at p. 517-518; *New Process Screw Corporation v. P.L. Robertson Mfg. Co. Limited* (1961), 39 C.P.R. 31 at p. 45 -46; *Amfac Foods Inc. et al. v. Irving Pulp & Paper, Ltd.* (1986), 12 C.P.R. (3d) 193 (FCA) at p. 197-205.

[60] Manual of Patent Office Practice(Ottawa-Gatineau: Canadian Intellectual Property Office, 1998), Ch. 12.08.01, c. 17.03 2 *Apotex Inc. v. Pfizer Canada Inc.,* 2011 FCA 236 at paras. 24-28; *Sanofi -Aventis Canada Inc. v. Apotex Inc.*, 2009 FC 676 at paras. 119-137; *Hoffmann-La Roche Ltd. v. Apotex Inc.*, 2011 FC 875 at 12-31; *AstraZeneca Canada Inc. v. Pharmascience Inc.*, 2012 FC 1189 at para. 194; *Apotex Inc. et al. v. ADIR et al.*, 2009 FCA 222 at paras. 39, 100-103, 106-110; *Pfizer Limited v. Ratiopharm Inc.*, 2009 FC 711 at paras. 108-112, aff'd 2010 FCA 204; *Sanofi-Aventis Canada v. Apotex Inc.*, 2009 FC 676 at paras. 119-137, aff'd 2011 FCA 300; *Eurocopter v. Bell Helicopter Textron Canada Limitee*, 2012 FC 113 at paras. 215-216, aff'd 2013 FCA 219.

34. Contrary to Sanofi's argument, even the applicable U.K. law did not require the Court to find a false promise in the claims. In *Hatmaker*, the House of Lords invalidated a patent on the basis of promises made, not in the claims, but in the disclosure.[61]

35. Finally, Sanofi's 'only-in-the claims' proposal does not apply to the present case. This Court has already determined that the invention that clopidogrel will have improved therapeutic properties over PCR 4099 and the other compounds of the 875 patent, while not explicit in the claims themselves, nevertheless underlies each one. It was on the basis of this construction that the claims were held not to be anticipated by the 875 patent or obvious in the state of the art.

5. The 'section 53 standard' proposal

36. Sanofi proposes that the failure of a patent to deliver its promised utility ought to be judged on the same terms as section 53 of the *Patent Act*.[62] Sanofi's proposal is simply to remove the promise doctrine from Canadian law. To say that the promise doctrine is to be determined based on the criteria of section 53 is to say that only section 53 is operable to invalidate a patent on the basis of statements made within it.

37. The promise doctrine and section 53 of the *Patent Act* address unrelated concerns and ought not to be tied together. The promise doctrine is addressed to ensuring that the invention as defined by a patent works across its scope and can be relied on as such by the public as a useful teaching. Section 53 is directed to fraudulent statements or omissions "wilfully made for the purpose of misleading".

6. The 'after the fact' utility proposal

38. Sanofi proposes that, if a patent's promises of utility, though unknown on the filing date, are eventually realized, there ought to be no cause to invalidate the patent for inutility.[63]

39. This proposal is incorrectly premised on the notion that the promise is a *sui generis*

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[61] *Hatmaker v. Joseph Nathan & Co.* (1919), 36 RPC 231 (HL) at p. 236-237.

[62] Sanofi factum, paras. 103-105.

[63] Sanofi factum, paras. 94-95.

doctrine, rather than an aspect of the statutory requirement of utility. Since *Wellcome*, it has been the settled law in Canada that the inventor of a patent must have demonstrated or soundly predicted the utility of his invention before the Canadian filing date. This Court was not only unanimous in reversing the lower Court on this point, but also provided a lengthy explanation that this rule was necessary to provide the public with the hard coinage of a useful disclosure in return for the patent grant and was a reasonable cost to extract from a patentee who was seeking protection for an invention that was not yet known to work.

40. Sanofi cites the statement in *Teva* that "evidence as to utility may be found in the reception of the invention by the public" as if this statement was intended to reverse the *Wellcome* approach. It was not. The two cases are directed to different issues. *Teva* speaks only to the type of evidence that may be used to demonstrate utility and does not suggest that ultimate commercial acceptance can be used support the promise of utility of a patent filed years before. *Teva* cited *Wellcome* but did not discuss, criticize or overrule its approach to 'after-the-fact' evidence of utility.

F. THE "HEIGHTENED DISCLOSURE" REQUIREMENT ARISES DIRECTLY FROM SECTION 34 OF THE *PATENT ACT*

41. Sanofi's mistaken description of "heightened disclosure" as an obligation on an applicant to "prove the utility in a patent" or to "extol the effect or advantage of"[64] obscures that this requirement is not "extra-statutory"[65] and was specifically mandated by this Court in *Wellcome*.[66]

42. In the context of an invention that is only a prediction at the filing date, the full and correct disclosure of the invention pursuant to subsection 34(1) of the *Patent Act* requires disclosure of that prediction, the factual basis and line of reasoning. This disclosure is what has been termed the "heightened disclosure."

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[64] Sanofi factum, paras. 34, 35, 116-117.

[65] Sanofi factum, paras. 60, 127.

[66] *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at para. 70.

43. Contrary to Sanofi's argument, [67] this approach to disclosure does not conflict with the *Consolboard* or *Teva* cases because those cases did not involve predictions – the utility of invention has been demonstrated before the filing date and no part of the invention involved a prediction. In a prediction case, the public needs to understand the factual basis and line of reasoning to comprehend what the inventor has truly achieved. Disclosure of the factual basis and line of reasoning for a prediction, by definition, is not disclosure of a "proof" of utility, nor is it an extolling of the invention's advantages. [68]

G. APOTEX PROVIDED PROPER NOTICE OF THE DEFICIENCIES IN THE DISCLOSURE OF THE 777 PATENT

44. Sanofi says that it is "problematic" that Apotex's pleading did not specifically reference section 34 of the *Patent Act*, but does not allege any prejudice or surprise. Presumably, Sanofi recognizes that its observation is an irrelevancy.

45. Apotex specifically pleaded that the 777 patent was invalid because a factual basis and a sound and articulable line of reasoning was missing from the patent.[69] The insufficiency of the patentee's disclosure was thus squarely raised between the parties. There was no requirement to detail the source of the obligation of disclosure for pleading purposes.[70]

46. When Sanofi challenged the statutory basis for the heightened disclosure argument in the Court below, Apotex specifically relied upon subsection 34 of the *Patent Act* (as it has been renumbered to section 27(3)).[71] Sanofi took no objection to this. The concurring reasons in the Court below specifically commented that neither "the description of the invention (as per s. 34 of the *Act*) nor the policy reasons discussed in the AZT decision …are at issue".[72] Apotex is entitled

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[67] Sanofi factum, paras. 2, 117. In *Teva*, this Court stated that it was not deciding the question of whether there is a heightened disclosure in sound prediction cases and the present discussion regarding the statutory source for this obligation were not considered. *Teva Canada Limited v. Pfizer Canada Inc.*, 2012 SCC 60 at para. 43.

[68] See initial Apotex factum, paras. 69-75.

[69] Second Amended Statement of Defence and Counterclaim dated December 14, 2010, para. 98.

[70] *Harmony Consulting Ltd. v. G.A. Foss Transport Ltd.*, 2012 FCA 226 at paras. 41, 42.

[71] Memorandum of Fact and Law of the Respondents, Apotex Inc. and Apotex Pharmachem Inc. in A-7-12, dated June 4, 2012, paras. 77-79.

[72] Concurring Appeal Reasons, para. 133

to submit the opposite on this appeal.[73]

H. *WELLCOME* IS CLEAR AUTHORITY FOR THE DISCLOSURE OBLIGATION IN CANADA

47. Sanofi cites a portion of this Court's decision in *Wellcome* to argue that this Court "suggested (without deciding) that perhaps the factual basis and line of reasoning should be in the disclosure".[74] In fact, a plain reading of entire passage reveals that this was not a mere "suggestion", but rather a statement of the rationale for why "proper disclosure" in a prediction case requires disclosure of the factual basis and line of reasoning.

48. Sanofi also states that this Court "made no determination with respect to the "nature" of the disclosure requirement as the issue did not arise on the facts of the case."[75] This is incorrect. The *nature* of the disclosure and "precise disclosure requirements" are different. This Court only indicated that the latter was not necessary to address because the patent there at issue did indeed disclose the *nature* of the prediction: "[I]t was sufficient that at that time the Glaxo/Wellcome scientists disclosed in the patent a rational basis for making a sound prediction that AZT would prove useful in the treatment and prophylaxis of AIDS, which it did...Precise disclosure requirements...do not arise for decision because both the underlying facts (the test data) and the line of reasoning (the chain terminator effect) were in fact disclosed."[76]

49. Sanofi's alternative explanation for the Court's comments as having to do with proof of the date of invention is neither sensible nor grounded in the words of the judgment. The Court does not suggest that there is any connection between the date of invention and that the date at which the inventor must comply with the requirements of sound prediction nor does its rationale for the

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[73] Sanofi's argument that "Apotex...did not challenge the trial judge's finding that the patent complied with section 34" refers to an argument on an unrelated point. Apotex had alleged insufficiency on the basis that the patent failed to disclose a substantial advantage for the subject matter of the 777 patent over that of the 875 patent (see paras. 117 to 121 of the Second Amended Statement of Defence and Counterclaim dated December 14, 2010). Sanofi does not and cannot suggest that it understood that the two issues are linked in any way.

[74] Sanofi factum, para. 121.

[75] Sanofi factum, para. 121.

[76] *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at paras. 3, 70. Contrary to the submissions of the respondents, the patent at issue in *Wellcome*, Canadian Letters Patent No. 1,238,277 did indeed contain the test data (see pp. 3-4, 14-17) and the chain terminator effect (see p. 4).

sound prediction disclosure requirement that "the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly" engage the date of invention.[77] Neither the *Patent Act*, nor any jurisprudence, requires the date of the invention to be disclosed in the patent.[78]

50. Finally, Sanofi is wrong that the Federal Court of Appeal "never considered the issue [of the requirement to disclose the factual basis and line of reasoning of a prediction cases] on first principles"[79] and also wrong that a later panel held the prior decision to be "incorrect".[80]

I. CANADA'S DISCLOSURE REQUIREMENTS DO NOT VIOLATE THE PCT

51. Sanofi further argues that the obligation to disclose the factual basis and line of reasoning in a patent is contrary to the Patent Cooperation Treaty ("PCT"). This assertion has been soundly rejected on clear rationale by the Federal Court of Appeal on several occasions.[81]

52. The PCT is not a statement of domestic Canadian law, but rather a treaty by which signatories pledge to enact certain provisions. The PCT has effect in Canada only to the extent that its provisions are adopted into the *Patent Act*. Even if Sanofi were to establish that Canadian law is somehow inconsistent with Canada's treaty obligations, this Court could grant Lilly no remedy. It is for Parliament to choose what provisions of any treaty to enact and it is Parliament who must answer to any accusation of failing to abide by a treaty.

53. In any event, the *Patent Act* is entirely compliant with the PCT. Article 5 of the PCT requires that "[t]he description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art". Rule 5.1(a)(iii) of the

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[77] *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at para. 70.

[78] At footnote 155 of its factum, Sanofi observes that a judge of the Federal Court described the disclosure requirement from *Wellcome* as being limited to use claims. Not only is this analysis inconsistent with *Wellcome* itself, but it is also inconsistent with Sanofi's present assertions that the *Wellcome* discussion of disclosure had to do with the date of invention, and that there is no heightened disclosure requirement at all.

[79] Sanofi factum, para. 125; *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 78, 78 CPR (4th) 388.

[80] Sanofi factum, para. 125; *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA, 85 CPR (4th) 413.

[81] See *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 FCA, 85 CPR (4th) 413 at paras. 48 to 50, and *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 78, 78 CPR (4th) 388 at para. 19.

PCT *Regulations* states that the 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." The PCT contains no provision that precludes a signatory from requiring the disclosure of the factual basis and sound line of reasoning in sound prediction cases.

54. Further, Articles 27(5) and 27(6) of the PCT provide that nothing in the Treaty or its *Regulations* shall be construed as limiting the Contracting States' freedom to prescribe substantive conditions of patentability.[82] This Court has repeatedly explained that the sufficiency of a patent's disclosure is a fundamental substantive condition of patentability because it comprises part of the *quid pro quo* for the patent monopoly.[83]

J. THE DISCLOSURE REQUIREMENT IS NOT UNFAIRLY APPLIED TO THE 777 PATENT

55. Contrary to Sanofi's argument, requiring the 777 patent to disclose the factual basis and line of reasoning for its invention is not an unfair, retroactive application of new law. As outlined above, the requirement to disclose one's invention arises directly from section 34 of the *Patent Act*, a provision whose language has not changed since 1923.[84] Further, the *Patent Rules* in effect at the filing date of the 777 patent specifically required an applicant to "disclose the inventive idea which the new article embodies and the way in which resort to it overcomes the difficulties and inconveniences of the previous practices or proposals."[85] Sanofi should have disclosed the factual basis and line of reasoning for its prediction since it was seeking a monopoly in respect of that prediction.

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[82] *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)

[83] *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 at 517; *Pioneer Hi Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 at paras. 23, 26; *Cadbury Schweppes Inc. v. FBI Foods Ltd.*, [1999] 1 S.C.R. 142 at para. 46; *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at para.13; *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at paras. 37, 70

[84] The requirement that the specification of a patent "correctly and fully disclose" the invention has been a part of the Canadian *Patent Act* for over 140 years, *Consolboard Inc, v, MacMillan Bloedel (Sask.) Ltd*, [1981] 1 S.C.R. 504 at 518.

[85] *Patent Rules*, SOR/96-423, s. 21, Form 24, ss. 3 and 4

56. As Sanofi admits, *Wellcome* comprises a three-element test.[86] Sanofi's complaints regarding retroactivity constitute an attempt to maintain the benefit of a patent issued over subject matter not known to work at the filing date, while shirking the third, "disclosure" element of the test. If Sanofi is unwilling to explain to the public what it actually achieved (*i.e.,* a prediction), it ought not be able to maintain a patent for the subject matter of the prediction.

K. SANOFI'S ATTEMPT TO REVISIT THE FACTUAL FINDINGS

57. Sanofi has never asserted that any of the evidentiary findings of the trial judge were based on any palpable and overriding errors. As such, there is no basis for Sanofi's present invitation to this Court to review selected elements of the evidentiary record and draw new factual conclusions that conflict with the findings of the trial judge.

1. The invention of the 777 patent was not demonstrated by the filing date

58. Sanofi repeatedly argues that clopidogrel's beneficial properties had been demonstrated prior to the filing date of the 777 patent.[87] The trial judge's evidentiary finding was to the opposite:[88] Sanofi's clinical trial was not completed before the filing date, did not measure toxicity, and did not compare clopidogrel the other compounds of the 875 patent. Sanofi's animal studies were not a demonstration of human utility, let alone a demonstration that clopidogrel had any beneficial properties compared to PCR 4099 or the other compounds of the 875 patent.

2. The disclosure of the rat studies in the 777 patent was not disclosure of the prediction

59. Sanofi argues that the rat studies referenced in the 777 patent provide a sufficient factual basis and line of reasoning for the invention.[89] Sanofi actually made the opposite argument below when it asserted that, because the rat studies were obviously insufficient to ground a prediction in humans, no skilled person would understand the patent as making a prediction in humans.[90] The

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[86] Sanofi factum, para. 120.

[87] Sanofi factum, paras. 3, 4, 6, 28, 31, 33, 48, 56, 102, 107, 110, 128, 129 and 131.

[88] Trial Judgment, see paras. 339 to 356.

[89] Sanofi factum, paras. 131-133.

[90] Appeal Judgment, paras. 176 to 181.

concurring reasons even accepted Sanofi's argument.[91]

60. In any event, the trial judge held that the prediction in the 777 patent required reference to additional information and there is no basis to revisit this factual finding now.[92]

3. The trial judge did not require disclosure of the common general knowledge and every study Sanofi undertook

61. Contrary to Sanofi's argument, the trial judge did not require the 777 patent to disclose the common general knowledge and every study Sanofi undertook. Rather, the trial judge identified the factual bases and line of reasoning that were "critical", "crucial" and "essential elements" to Sanofi's sound prediction of utility and assessed the disclosure by reference to whether these essential facts were found in the 777 patent.[93]

4. The evidence did not establish that the promised utility was demonstrated even 'after the fact'

62. Sanofi's argument that the commercial acceptance of clopidogrel should be sufficient to meet any question with respect to utility ignores the nature of the 777 patent.[94] The 777 patent is addressed to the improved therapeutic properties of clopidogrel. There is no evidence that clopidogrel has improved therapeutic properties over PCR 4099 as well as the other compounds of the 875 patent. In fact, Sanofi attaches to its record the Investigator's Brochure for PCR 4099 which attests to the utility of PCR 4099 to treat humans.

5. Sanofi's request to lower the threshold for sound predictions is not consistent with this Court's jurisprudence and is irrelevant to this proceeding

63. Sanofi also states that the trial judge "required Sanofi to meet too high a standard for sound prediction" and should have sought only a *prima facie* reasonable inference. This complaint is misplaced because the trial judge considered the issue of sound prediction under a heading entitled

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[91] Appeal Judgment, paras. 127 to 130.

[92] Trial Judgment, paras. 406-584. The trial judge did not accept Sanofi's present assertion (Sanofi factum, paras. 24 and 131) that the patent's rat studies demonstrated any therapeutic advantage for clopidogrel.

[93] Trial Judgment, paras. 406, 561, 562, 571 to 573 and 581 to 584.

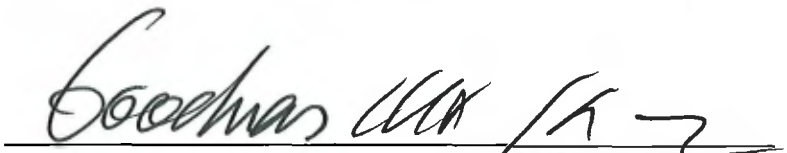
[94] Sanofi Factum, para. 135.

"*Prima Facie* Reasonable Inference of Utility".[95]

64. Sanofi's argument is that the trial judge required information concerning metabolism when such information was not required in *Wellcome*. This argument would take a factual aspect of what was required for the prediction of utility in the *Wellcome* case and elevate it to a legal principle, divorced from the relevant factual nexus surrounding the utility in question. The trial judge's finding that metabolism and pharmacokinetic information was relevant was specific to the 777 patent and based on the fact that clopidogrel is a pro drug and the substantial factual and expert evidence before him.[96] Sanofi identifies no palpable and overriding errors that would justify displacing these findings.

65. In any event, the trial judge found that the inventors possessed a sufficient factual basis and line of reasoning to meet the standard for sound prediction and thus Sanofi's complaint is moot. The failure of the 777 patent was that the inventors sought protection for a prediction while attempting to keep the constituents of the prediction secret from the public.

August 5, 2014 **ALL OF WHICH IS RESPECTFULLY SUBMITTED**



GOODMANS LLP,
LAWYERS FOR THE APPELLANTS

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[95] Trial Judgment, paras. 401 to 403. See also paras. 485, 489, 490, 539 to 541, 560 and 561.

[96] Trial Judgment, paras. 519 to 542.

PART III - TABLE OF AUTHORITIES, ARRANGED ALPHABETICALLY, PARAGRAPH NUMBER WHERE AUTHORITY IS CITED

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Publications
Bernstein, A. *et al.*, "Unpacking the promise of the patent", 28 C.I.P.R. 245
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Manual of Patent Office Practice(Ottawa-Gatineau: Canadian Intellectual Property Office, 1998), Ch. 12.08.01, c. 17.03 2
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World Health Organization, World Intellectual Property Organization, World Trade

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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 FACTUM OF THE APPELLANT

GOODMANS LLP
Barristers & Solicitors
Bay Adelaide Centre
333 Bay Street, Suite 3400
Toronto, ON M5H 2S7

H.B. Radomski
Richard Naiberg

Telephone: (416) 979-2211
Facsimile: (416) 979-1234
hradomski@goodmans.ca

Solicitors for the Appellants, Apotex Inc.