Court File No. 36654

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

B E T W E E N:

ASTRAZENECA CANADA INC.,
ASTRAZENECA AKTIEBOLAG and ASTRAZENECA UK LIMITED

Appellants

– and –

APOTEX INC. and
APOTEX PHARMACHEM INC.

Respondents

– and –

INNOVATIVE MEDICINES CANADA AND BIOTECANADA and CENTRE FOR INTELLECTUAL PROPERTY POLICY and CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION and FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE and INTELLECTUAL PROPERTY OWNERS ASSOCIATION and INTELLECTUAL PROPERTY INSTITUTE OF CANADA

Interveners

FACTUM OF THE INTERVENER, CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION ("CGPA")

AITKEN KLEE LLP
Suite 3350, 181 Bay Street
Toronto, ON M5J 2T3

Jonathan Stainsby
Scott A. Beeser

Tel: 647-317-6868/6869
Fax: 613-695-5854
E-mail:
jstainsby@aitkenklee.com
sbeeser@aitkenklee.com

Counsel for the Intervener, Canadian Generic Pharmaceutical Association

AITKEN KLEE LLP
Suite 300, 100 Queen Street
Ottawa, ON K1P 1J9

Lesley Caswell

Tel: (613) 903-5033
Fax: 613-695-5854
E-mail: lcaswell@aitkenklee.com

Agents for the Intervener, Canadian Generic Pharmaceutical Association

ORIGINAL TO: **The Registrar**
Supreme Court of Canada
301 Wellington Street
Ottawa ON K1A 0J1

COPY TO:

Counsel for the Appellants

SMART & BIGGAR
Barristers and Solicitors
438 University Avenue, Suite 1500
Toronto, ON M5G 2K8

Gunars A. Gaikas
Yoon Kang
Y. Lynn Ing

Tel: 416-593-5514
Fax: 416-591-1690
Email:
ggaikis@smart-biggar.ca
ykang@smart-biggar.ca
yling@smart-biggar.ca

Agent for the Appellants

SMART & BIGGAR
Barristers and Solicitors
55 Metcalfe St., 10th Floor
Ottawa, Ontario
KIP 6L5

Colin B. Ingram

Tel: 613-232-2486
Fax: 613-238-8440
Email: cbingram@smart-biggar.ca

AND TO:

Counsel for the Respondents

GOODMANS LLP
3400 - 333 Bay Street
Toronto, Ontario
M5H 2S7

Counsel Harry B. Radomski
Richard Naiberg
Sandon Shogilev

Tel: 416-979-2211
Fax: 416-979-1234
Email: hradomski@goodmans.ca

Agent for the Respondents

NELLIGAN O'BRIEN PAYNE LLP
1500-50 O'Connor Street
Ottawa, Ontario
K1P 6L2

Christopher Rootham

Tel: 613-231-8311
Fax: 613-788-3667
Email: christopher.rootham@nelligan.ca

AND TO:

Counsel for the Intervener, Innovative Medicines Canada and BIOTECanada

NORTON ROSE FULBRIGHT CANADA LLP
Suite 3800, Royal Babnk Plaza, South Tower
200 Bay Steet
Toronto, Ontario M5J 2Z4

Patrick E. Kierans
Kristin Wall

Telephone: (416) 216-4000
Fax: (416) 216-3930
E-mail:
patrick.kierans@nortonrosefulbright.com
kristin.wall@nortonrosefulbright.com

Agents for the Intervener, Innovative Medicines Canada and BIOTECanada

NORTON ROSE FULBRIGHT CANADA LLP
45 O'Connor Street
Suite 1500
Ottawa, Ontario K1P 1A4

Jamie Macdonald

Telephone: (613) 780-8628
Fax: (613) 230-5459
E-mail:
jamie.macdonald@nortonrosefulbright.com

AND TO:

Counsel for the Intervener, Centre for Intellectual Property Policy (CIPP)

McGill University, Faculty of Law
3644 Peel Street
Montreal, Quebec H3A 1W9

Jeremy de Beer
E. Richard Gold

Telephone: (514) 398-6636

Agents for the Intervener Centre for Intellectual Property Policy

SAMUELSON-GLUSHKO CANADIAN INTERNET POLICY & PUBLIC INTEREST CLINIC (CIPPIC)
University of Ottawa, Faculty of Law
57 Louis Pasteur Street,
Ottawa, Ontario K1N 6N5

Tamir Israel

Telephone: (613) 562-5800 Ext: 2914
Fax: (613) 562-5417
E-mail: tisrael@cippic.ca

AND TO:

Counsel for the Intervener, Fédération internationale des conseils en propriété intellectuelle

FASKEN MARTINEAU DUMOULIN LLP
The Stock Exchange Tower, Suite 3700,
800 Victoria Square, P.O. Box 242
Montréal, Quebec H4Z 1E9

Julie Desrosiers
Kang Lee

Telephone: (514) 397-7516/5285
Fax: (514) 397-7600
E-mail: jdesrosiers@mtl.fasken.com
klee@fasken.com

Agents for the Intervener, Intervener, Fédération internationale des conseils en propriété intellectuelle

GOUDREAU GAGE DUBUC LLP
Suite 2200,
2000 McGill College Avenue
Montréal (Québec) H3A 3H3

Alain M. Leclerc

Telephone: (514) 397-7675
Fax: (514) 397-4382
E-mail: aleclerc@ggd.com

AND TO:

Counsel for the Intervener, Intellectual Property Owners Association

TORYS LLP
79 Wellington Street West, Suite 3000
TD South Tower
Toronto, Ontario M5K 1N2

Andrew E. Bernstein
Tel: (416) 865-7954
Email: abernstein@torys.com

Yael S. Bienenstock
Tel: (416) 865-7954
Email: ybienenstock@torys.com

Agent for the Intervener, Intellectual Property Owners Association

GOWLING WLG (CANADA) LLP
160 Elgin Street
Suite 2600
Ottawa, Ontario K1P 1C3

Jeffrey W. Beedell
Tel: (613) 786-0171
Email: jeff.beedell@gowlingwlg.com

AND TO:

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

BELMORE NEIDRAURE LLP
TD South Tower
79 Wellington Steet West, Suite 2401
Toronto, ON M5K 1A1

Jason Markwell
Marian Wolanski
Stefanie Di Giandomenico

Tel: (416) 863-1771
Fax: (416) 863-9171
Email: jmarkwell@belmorelaw.com
Marian.wolanski@belmorelaw.com
sdigiandomenico@belmorelaw.com

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

BORDEN LADNER GERVAIS LLP
World Exchange Plaza
100 Queen Street, Suite 1300
Ottawa, Ontario K1P 1J9

Nadia Effendi

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

PART I – STATEMENT OF FACTS

1. The appellant and certain of the interveners ask this Court to reverse and set aside a number of fundamental aspects of Canadian patent law that have long provided the balanced and predictable patent system so necessary to Canadians, including the generic pharmaceutical industry. They invite this Court to rewrite the law of utility and of patent construction, including seeking the reversal of this Court's decision in *AZT*,[1] drastically lowering the standard for utility to "not devoid of utility"[2], and rendering what the inventor says in the patent's disclosure inconsequential. One of the interveners (IPO) even argues that the language of the patent be disregarded in favour of examining the invention and asking, in a backwards, results-driven inquiry, "what must this new [thing] do to make it inventive?"[3]

2. These arguments fail to recognize that the patent system is not intended for the exclusive benefit of patentees, but for all stakeholders. The generic pharmaceutical industry makes enormous investments to bring affordable generic drugs to the Canadian market and thus to the ultimate benefit of the public, the other player in the patent bargain. Generic pharmaceutical companies rely, as they must, on the language of patents in making investment decisions. To do so rationally, there need to be clear and predictable rules in place. The public must also rely on the language of issued patents, as this language is the only official public notice and "timely disclosure" of what has been accomplished by the inventor and what has been claimed. The content of patent descriptions plays a critical role in the decisions made by generic manufacturers and others contemplating research projects. The radical changes being proposed are all intended to improve the lot of patentees, but come at significant cost to the public.

3. The assertion that underlies the arguments of the appellant and certain of the interveners is that there is a newly minted, extra-statutory, unpredictable and unfair 'promise doctrine', but this assertion is entirely unsustainable. The term 'promise doctrine' is merely a shorthand for one aspect of what has long been the law of utility in Canada.[4] This Court ought not import the proposed radical changes into Canadian patent law. Doing so will foster uncertainty and upset the existing balance. "There is a high economic cost attached to uncertainty and it is the proper

---

[1] *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77 ("*AZT*").
[2] Appellants' Factum at ¶51, 154.
[3] IPO's memorandum of fact and law on its motion for leave to intervene at ¶30.
[4] *Apotex Inc. v. Pfizer Canada Inc.*, 2014 FCA 250 at ¶65 ("*Apotex celecoxib"*); *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504 at ¶525-6 ("*Consolboard*").

policy of patent law to keep it to a minimum."[5]

PART II – STATEMENT OF ISSUES

4. The CGPA will address the following issues: (1) the current law of utility supports the patent bargain – ¶5; (2) purposive construction - ¶13; (3) section 53 - ¶19; (4) sound prediction - ¶21; (5) post-filing evidence - ¶27; and (6) harmonization - ¶29.

PART III – STATEMENT OF ARGUMENT

5. ***The current law of utility supports the patent bargain.*** The appellant and a number of the interveners assert that the modern use of the word 'promise' somehow amounts to the creation of a new "judicially imposed utility requirement".[6] In fact, no new judicial doctrine has been created. The courts have consistently applied the established principle, just as articulated in this Court's decisions, that a patentee must be able to show that the utility described in the specification had been demonstrated or soundly predicted as of the date the patent was filed.[7]

6. The patent bargain has two aspects: in return for correctly and fully disclosing the invention and its operation or use as contemplated by the inventor, the patentee is given an opportunity to obtain a time limited monopoly on its use.[8] The applicant's identification and description of the 'invention' (in words of the inventor's choosing) is the currency in the bargain between the public and the patentee.[9] If the invention does not do what the patent says it will do, the inventor's side of the bargain is unmet.[10]

7. Utility is a precondition for the very existence of an invention.[11] Patents are not granted for "almost-inventions".[12] If the utility of the 'invention' is not demonstrated or predicted as of

---

[5] *Free World Trust v. Électro Santé Inc*., 2000 SCC 66 at ¶42 ("*Free World Trust*").
[6] Appellant's Factum, ¶72.
[7] *Consolboard* at 525-6; *AZT* at ¶46; *Teva Canada Limited v. Pfizer Canada Inc.*, 2012 SCC 60 at ¶32 ("*Teva Viagra*").
[8] *AZT* at ¶37; *Teva Viagra* at ¶32.
[9] *Free World Trust* at ¶51; *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26 at ¶133 ("*Biolyse*"); *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67 ("*Whirlpool*") at ¶42; *Teva Viagra* at ¶31-35.
[10] *Patent Act,* ss. 2 and 27(3) ("*Act*"). For jurisprudence considering the 'promise' see: *Wandscheer v. Sicard,* [1948] S.C.R. 1 at 2, 5; *Consolboard* at 525-6; *Teva Viagra at* ¶38; *AZT at* ¶46, 55; *Monsanto Co. v. Commissioner of Patents,* [1979] 2 S.C.R. 1108 at 116-117; *New Process Screw Corporation v. P.L. Robertson Mfg. Co. Ltd.* (1961), 39 C.P.R. 31 at 33, 34; *Amfac Foods Inc. v. Irving Pulp & Paper Ltd.* (1986), 12 C.P.R. (3d) 193 (FCA) at 204; *Apotex celecoxib at* ¶65.
[11] *Act,* section 2 ("invention"); *AZT* at ¶46.
[12] *AZT* at ¶84.

the filing date, there is no invention to patent.[13]

8. Where the patentee chooses to describe a specific utility in the patent, the claimed invention must be able to do what the applicant has chosen to tell the public it will do.[14] At the date the application is filed, the patentee must know that any statements in the patent regarding demonstrated or predicted utility are justified.[15] It is entirely fair that patentees be called upon to defend the promises they make – the public can and must rely on what the patent says. What is unfair is for the patentee to shirk its responsibility to live up to the statements it voluntarily made in an effort to obtain the exceptional control of the marketplace consequent on the issuance of patent rights.

9. The appellant asserts that, in compelling the inventor to disclose the use contemplated, the *Act* requires that the inventor describe every potential use for the invention as a certain and specific promised result. This is not what the *Act* says. It is up to the inventor to express the invention in terms that "correctly and fully" describe the use as contemplated, but the *Act* does not require that the inventor contemplate potential uses as certainties.[16] If the applicant is fair in describing what it has actually accomplished, be it a demonstration or a sound prediction, the utility requirement will be satisfied.[17] Using the word 'promise' does not change the substantive law of utility: the fact remains that the invention must do what the patent says it will do.[18]

10. The assertion that the courts' determination or construction of the promise of the patent is 'unpredictable' has no foundation. Courts have been careful to avoid reading-in promises where none were made.[19] Further, the assertion that Canadian courts invalidate patents for a lack of utility more frequently than occurs in other countries or that there has been a recent increase in the number of invalidations on this ground is contrary to the evidence.[20]

11. Any suggestion that clear statements of utility in the specification can be ignored would

---

[13] *Act,* section 2.
[14] *AZT* at ¶37 and 46, 52, 69.
[15] *AZT* at ¶70; *Teva Viagra* at ¶8.
[16] *Act, subsection* 27(3).
[17] Appellant's factum at ¶104.
[18] *Teva Viagra,* at ¶60.
[19] *Apotex Celecoxib at* ¶70-72; *Novartis Pharmaceuticals Canada Inc. v. Teva Canada Ltd*., 2015 FC 770 at ¶30-33; *Actavis Pharma Co. v. Alcon Canada Inc.,,* 2015 FCA 192 at ¶16; *Eli Lilly Canada Inc. v. Apotex Inc.,* 2015 FC 1016 at ¶133-137; *Gilead Sciences, Inc. v. Idenix Pharmaceuticals Inc*., 2015 FC 1156 ("*Gilead*") at ¶241.
[20] Appellant's factum ¶134; "Patent Litigation: Putting Assumptions to the Empirical Test": CIPP (July 28, 2016) http://www.cippmcgill.ca/news/2016/07/28/patent-litigation-putting-assumptions-to-the-empirical-test/.

relieve patentees of their obligation to correctly and fully describe their invention and should be rejected. Were it otherwise, patentees would be encouraged to describe their inventions and how they work so as to prophylactically avoid novelty and obviousness objections, secure in the knowledge that they will never have to defend or support any assertions of what the invention will do.[21] Indeed, patent applicants routinely include assertions of particular utility (a "promise of a specific result") when they perceive it to be required to impart patentability to otherwise obvious subject matter.[22] As stated by Thurlow J.:

> The invention as claimed in claim 18 is one for a process which includes the reacting of certain known chemical substances with certain other known chemical substances in a well-known type of chemical reaction for the purpose of producing a result which any skilled chemist would have expected. … it follows, notwithstanding the further fact that no one had previously carried out the reaction using the particular starting substances, that there could have been no invention in the process, unless it had been found to produce substances possessing utility which on the basis of previous knowledge could not have been expected of them.[23]

12. Patents promising speculative utilities are a public nuisance[24] and undermine the patent system's goal of advancing research and development. It is neither fair nor reasonable to require the public, having upheld its side of the bargain by awarding a time-limited monopoly, to verify the utility described by the inventor in order to separate the truly inventive wheat from the speculative chaff. Any resources diverted by the public in order to confirm or refute a speculative utility promised by an inventor cannot be used to advance research and development.

13. ***Purposive construction.*** The argument has been advanced that construing the patent to determine what the skilled reader would understand the inventors to have said leads to unfair, arbitrary and even subjective results. Construing a patent purposively to ascertain whether it discloses a particular utility of the claimed invention (*i.e.*, whether a 'promise' has been made) is neither unfair nor arbitrary. Construction is an objective, not a subjective, exercise. The canons

---

[21] See, for example, *Eli Lilly Canada Inc. v. Novopharm Limited*, 2011 FC 1288 at ¶208-209, aff'd 2012 FCA 232. In this case, having relied on the advantages in the patent to overcome obviousness and anticipation challenges (see 2010 FCA 197), the patentee argued on a rehearing before the trial judge (where the Court was called upon to consider a utility challenge) that the patent merely set forth advantages, not promises. This was not accepted by the Court.

[22] *Allergan Inc. v. Canada (Minister of Health*), 2012 FCA 308 at ¶36, leave ref'd [2013] S.C.C.A No. 31, where the patentee admitted the asserted claim was obvious if the inventive concept did not include the increased safety profile specifically disclosed in the patent.

[23] *Société des Usines Chimiques Rhone-Poulenc v. Jules R. Gilbert Ltd*. (1968), 55 C.P.R. 207 (Ex Ct) at 227 aff'd [1968] S.C.R. 950.

[24] *Free World* at ¶42.

of patent construction are well-established.[25] The construction of documents, statutes and regulations is a central aspect of the judicial role; it is what courts do, day in and day out.[26]

14. It is central to the appellant's and certain of the interveners' arguments that the focus in patent construction ought only be on the claims ('primacy of the claims').[27] This is not the statutory role of patent claims. The claims define the monopoly (they set the 'fences'), not the invention.[28] The invention is described in the specification as a whole.[29]

15. Construction is informed by knowledge of what the skilled reader would understand the inventor's chosen language to mean. The Court of Appeal has said: "the promise should be properly defined, within the context of the patent as a whole, through the eyes of the [skilled reader], in relation to the science and information available at the time of filing."[30] This approach has been applied in numerous decisions from the Federal Courts,[31] and by this Court.[32]

16. The proposition that purposively construing the patentee's own words is unfair to the patentee completely ignores the public's interest in ensuring that patent applicants disclose useful inventions, rather than hypotheses or almost inventions. Readers of the application and issued patent are entitled to rely on what it says; it is required to provide solid and meaningful teaching.[33]

17. The appellant accuses courts of "search[ing] for a clear and unequivocal promise"[34] in a

---

[25] See, e.g., *Free World Trust at* ¶31; *Whirlpool at* ¶48, 49.
[26] *Whirlpool* at ¶49(d) citing *Williams v. Box* (1910), 44 S.C.R. 1 at p. 10.
[27] Appellant's factum at, among other places, ¶52-3, 69, 99, 106 and 120-2.
[28] A patentee is not obliged to claim everything that is new and useful disclosed in the specification. See *Whirlpool* at ¶42; *Free World Trust* at ¶14, 15.
[29] *Teva Viagra* at ¶49-52.
[30] *Eli Lilly and Co. v. Novopharm Limited*, 2010 FCA 197 at ¶80 ("*Olanzapine FCA*"). The appellant's argument (factum ¶125) that this should apply exclusively to selection patents ignores the fact that selection patents are not different from any other patents – see *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.,* 2008 SCC 61 ("*Sanofi")* at ¶9 and *Olanzapine FCA* at ¶30.
[31] *Eli Lilly and Co. v. Teva Canada Ltd.*, 2011 FCA 220 at ¶22; *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236 at ¶24; *Apotex Inc. v. Sanofi-Aventis*, 2011 FC 1486 at ¶141; *Hoffmann-La Roche Ltd. v. Apotex Inc.*, 2011 FC 875 at ¶19; *AstraZeneca Canada Inc. v. Pharmascience Inc.*, 2012 FC 1189 at ¶182; *Apotex Inc. et al v. ADIR et al*, 2009 FCA 222 at ¶101; *Sanofi-Aventis Canada v. Apotex Inc.*, 2009 FC 676 at ¶119-133; *Eurocopter v. Bell Helicopter Textron Canada Limitée*, 2012 FC 113 at ¶59; *Fournier Pharma Inc. v. Canada (Minister of Health)*, 2012 FC 741 at ¶128; *Mylan Pharmaceuticals ULC v. Pfizer Canada Inc.*, 2012 FCA 103 at ¶48; *Bristol-Myers Squibb Canada Co. v. Canada (Minister of Health)*, 2012 FC 1142 at ¶65; *Mylan Pharmaceuticals ULC v. AstraZeneca Canada Inc.*, 2012 FCA 109 at ¶16-19.
[32] *Consolboard* at 523-4.
[33] *AZT*, ¶69 and 83.
[34] Appellant's factum at ¶77.

pejorative attempt to insinuate that even though the patentee may not have made any promise(s), challengers and the courts will nonetheless embark on an effort to create one from stray phrases or an overly zealous interpretation in order to invalidate a patent. This does not, in fact, occur. The determination of the utility asserted is simply the exercise of purposive construction. There is no "search" and courts do not "hunt" for promises. If the court reading the patent as a whole sees that a specific utility has been promised, then that utility is the utility the patent must meet.

18. The suggestion that patents ought to be construed in favour of patentees, with a view to finding validity, improperly adopts a results driven perspective. Moreover, it is an overstatement. Purposive construction is to be done on an objective basis, without consideration of the validity and infringement issues at play.[35] As recently noted by the Court of Appeal, this suggestion "does not mean that in all cases [the court] must adopt 'any arguable interpretation that would uphold the patent.'"[36]

19. ***Section 53.*** The appellant and the interveners argue that courts should only examine what the patentee has said in the patent where there has been an "omission or addition willfully made for the purpose of misleading" as expressed in section 53.[37] This argument confuses the utility requirement with the additional strictures of section 53. Moreover, section 53 mandates a subjective analysis of what the patentee knew and intended, whereas construction is an objective exercise to determine what the patent means to the skilled addressee.

20. One of the intervenors (FICPI) suggests that the promise doctrine is, in effect, a disguised application of subsection 53(1), but one that allows the challenger to avoid the burden of showing willful deceit. A similar argument was rejected by this Court in *Teva Viagra*, which held that section 53 can operate independently of other requirements of validity.[38] Where an invention lacks the utility described in the specification, it is not necessary to show any willful intent to deceive.

21. ***Sound prediction*** is patentee friendly. It allows the early filing of patents before the utility of the invention has been demonstrated. In the pharmaceutical context, sound prediction

[35] *Whirlpool* at ¶42, 43 and 49(b); *Free World Trust* at ¶51; *ABB Technology AG, ABB Inc. v. Hyundai Heavy Industries Co., Ltd*, 2015 FCA 181 ("*ABB*") at ¶37, aff'g 2013 FC 946.
[36] *ABB* at ¶45.
[37] *Act,* section 53.
[38] *Teva Viagra* at ¶87.

recognizes that the development of drug products can take time, and permits pharmaceutical companies to protect their inventions before that has been accomplished, provided that the extrapolated utility is soundly based.[39]

22. Certain of the interveners argue that the disclosure mandated by the *Act* should not be applied where utility is based on a sound prediction. This should be rejected. The requirement that a patent based on sound prediction disclose both the inventor's factual basis and sound line of reasoning has been repeatedly applied, without difficulty, in the courts.[40]

23. The argument that the disclosure element of sound prediction should be discarded seeks to take the benefit of the sound prediction doctrine – obtaining patents early on the basis of predicted, rather than demonstrated, utility – but resists the burden of the disclosure of that prediction to the public. Such an approach is inequitable and inimical to the patent regime because it fails to provide the public with the hard coinage of a truly useful disclosure.[41] Patent law does not exist merely to benefit patentees, but to advance research and development by balancing the interests of patentees with those of their competitors and the general public.

24. The *Act* requires that the inventor "correctly and fully" disclose the invention, as contemplated by the inventor, regardless of the type of invention involved.[42] When the invention is a prediction, that prediction constitutes part of the *quid pro quo* and must be disclosed.[43] "When utility is based on sound prediction, disclosure of its factual foundation goes to the

---

[39] *AZT* at ¶69, 77 and 83-4.
[40] *AZT* at ¶3, 70; *Eli Lilly Canada Inc. v. Apotex Inc*., 2009 FCA 97 ("*Raloxifene FCA*") at ¶13-19, aff'g, 2008 FC 142 at ¶159-178, leave ref'd, [2009] S.C.C.A. No. 219; *Novopharm Ltd. v. Eli Lilly and Co*., 2011 FCA 220 ("*Atomoxetine FCA*"), aff'g 2010 FC 915 at ¶114-120, leave ref'd, [2011] S.C.C.A. No. 362; *Bell Helicopter Canada Limitée v. Eurocopter,* 2013 FCA 219 at ¶153 ("*Bell Helicopter*"); *Allergan Inc. v. Canada (Minister of Health)*, 2011 FC 1316 at ¶216, 220, 222, 223; *Sanofi-Aventis Canada Inc. v. Apotex Inc*., 2009 FC 676 at ¶142-147, 214-217, aff'd, 2011 FCA 300; *AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023 at ¶188; *Apotex Inc. v. Pfizer Canada Inc*., 2011 FCA 236 at ¶30-34, 41-52; *Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 547 at ¶240; *GlaxoSmithKline Inc. v. Pharmascience Inc*., 2011 FC 239 at ¶95; *Merck & Co. v. Apotex Inc*., 2010 FC 1265 at ¶520-530; *Olanzapine FCA* at ¶83, leave ref'd, [2010] S.C.C.A. No. 377; *AstraZeneca Canada Inc. v. Apotex Inc*., 2010 FC 714 at ¶92-93; *Pfizer Canada Inc. v. Ratiopharm Inc*., 2010 FC 612 at ¶94-95, 112-113; *Sanofi-Aventis Canada Inc. v. Ratiopharm Inc*., 2010 FC 230 at ¶73-77; *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2009 FC 1294 at ¶150-154, aff'd, 2011 FCA 102; *Lundbeck Canada Inc. v. Ratiopharm Inc*., 2009 FC 1102 at ¶200-215; *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 235 at ¶101-102, 108-109; *GlaxoSmithKline Inc. v. Pharmascience Inc*., 2008 FC 593 at ¶71; *Pfizer Canada Inc. v. Apotex Inc*., 2007 FC 26 at ¶61-71, aff'd, 2007 FCA 195, leave ref'd, [2007] S.C.C.A. No. 371.
[41] *AZT* at ¶37.
[42] *Act,* subsection 27(3).
[43] *AZT* at ¶49.

essence of the bargain with the public underlying patentability."[44]

25. *AZT* did not "leave open" the requirement to disclose the factual basis and line of reasoning. It concluded that a specification must disclose the rational basis for the prediction of utility and observed several times that the patent met this threshold. Removing this disclosure requirement would require the Court to ignore the requirements of s. 27(3) and overturn *AZT*.

26. ***Post-filing evidence of utility is irrelevant.*** As held by this Court, the patent system is not a lottery to be gamed by deep-pocketed corporations employing patent agents to engage in strategic patent drafting to convert an "almost-invention" into a statutory monopoly, thereby excluding all others from entire areas of research.[45] Recently, a pharmaceutical patentee asserted a patent claiming an entire class of antiviral compounds, even though the inventors had never made a single member of the class[46] and the entire class lacked a specific functional group believed by the inventors to be essential for anti-viral activity.[47]

27. It is not at all anomalous that a patentee's product turns out to be useful and yet its patent fails because it was filed before the patentee had actually made the invention. Patent applications are not place-holders or hunting licences.[48] The invention must be complete before the application is filed.[49]

28. Even if the appellant's assertion that esomeprazole was later determined to provide reduced interindividual variation were true, it is no answer to the invalidity of the patent.[50] The danger inherent in permitting patentees to rely on post-filing or post-patent proof was addressed by this Court in *AZT*.[51] Allowing post-patent proof would permit the granting of patents and awarding of monopoly rights where the applicant had neither demonstrated nor soundly

---

[44] *Atomoxetine FCA* at ¶51. While there is conflicting judicial views at the trial level of whether the disclosure requirement of sound prediction applies only to "new use" claims (compare *AstraZeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638 at ¶141, 142, and *Gilead* at ¶379 with *Eli Lilly Canada Inc. v. Hospira Healthcare Corporation*, 2016 FC 47 at ¶48, 49 and *Allergan Inc. v. Apotex Inc*., 2016 FC 344 at ¶57), the Court of Appeal, after the decision of this Court in *Teva Viagra*, has required disclosure where the utility of a claimed helicopter landing gear assembly, a manufacture, was predicted. See *Bell Helicopter* at ¶153.
[45] *AZT* at ¶80 - 84.
[46] Notably, the patentee tried to make members of the claimed class for more than two years without success. See *Gilead* at ¶29 and 448.
[47] *Gilead* at ¶221, 283.
[48] *Brenner v. Manson*, 383 U.S. 519 (1966).
[49] *AZT* at ¶46.
[50] Appellant's factum at ¶81, 176.
[51] *AZT* at ¶46.

predicted utility as of the filing date. The reason for rejecting this is simple – the public should not suffer a monopoly where the applicant has no invention.

29. ***Harmonization.*** The "harmonization" of Canadian patent law with the laws of other jurisdictions would require this Court to investigate foreign patent laws and the developmental history of statutory provisions governing patent utility, as well as the interconnected provisions governing patent validity, such as anticipation, obviousness and disclosure, leaving aside approaches to patent construction. No evidence on these questions is before the Court, and none of the interveners is entitled to lead such evidence in this appeal.

30. The concept of "harmonization" raises important and related threshold questions involving matters of patent policy. Parliament alone has the responsibility and authority to make policy decisions respecting the content of Canadian statutory law.

31. Further, there is no single patent law with which Canada could be harmonized. Recent efforts to arrive at a uniform global patent law were abandoned when the goal was seen to be unattainable.[52] Canada's utility requirements do, in any event, have parallels around the world. Even if "harmonization" were worth pursuing, this Court would have no basis for choosing which jurisdiction(s) ought to be emulated. The patent laws of the US, the UK, the European Union (which follows the European Patent Convention) and Japan, to name but a few, such as they are, differ in significant respects.[53]

32. International treaties do not compel or even promote harmonization, but, rather, accept that the laws of the signatory states will differ (expressly so as regards "utility" and "industrial applicability").[54] The *PCT* provides that nothing in it shall be construed as limiting the

---

[52]World Intellectual Property Organization, *Draft Substantive Patent Law Treaty* online: http://www.wipo.int/patent-law/en/draft_splt.htm.

[53] The UK employs the "worth a try" test for obviousness, while Canadian courts do not (*Pfizer Canada Inc. v. Apotex Inc.,* 2009 FCA 8 at ¶28-9); the US permits reliance on post-filing proof, but Canada does not (*Janssen-Ortho Inc. v. Novopharm Limited,* 2006 FC 1234 at ¶113(8), aff'd 2007 FCA 217, leave denied [2007] SCCA No. 442, *In re Zenitz* (1964), 52 C.P.P.A. 746 at ¶2); selection patents are no longer part of UK law (*Dr. Reddy's Laboratories v. Eli Lilly & Company Ltd.*, 2008 EWHC 2345 at ¶95-109, aff'd [2009] EWCA 1362 at ¶35-40); methods of medical treatment are not patentable in Canada, but are in the USA (*Visx Inc. v. Nidek Co.*, (1997), 77 C.P.R. (3d) 532 at ¶6 and *Tennessee Eastman Co. v. Commissioner of Patents,* [1974] S.C.R. 111 at 117-9); the differences in utility and construction are discussed in Gold, R., and Shortt, M., "The Promise of the Patent In Canada and Around the World", 30 CIPR 36, generally, and at 60-2, 66, 71 and 74 ("Gold and Shortt").

[54] *Marrakesh Agreement Establishing the World Trade Organization, Annex 1C*, 15 April 1994, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (*TRIPs*), Article 1 and 27(1); *North American Free Trade Agreement*, 32 I.L.M. 289 and 605, Article 1709. *Patent Cooperation Treaty,* June 19, 1970, 28 U.S.T. as amended, ("*PCT*") Articles 5, 27(5) and (6) ("*PCT*").

"Contracting States'" freedom to prescribe the substantive conditions of patentability.[55]

33. One of the interveners (IMC/BTC) asserts that Canada's current approach to utility undermines the goal of the *PCT* to provide a single international application that may be simultaneously filed in multiple jurisdictions. This argument ignores the fact that all patent applications may be amended at any time prior to issuance provided they do not introduce new matter.[56] Should a *PCT* application initially promise an entirely speculative utility, nothing prevents the application from subsequently being amended by removing that speculation.

34. There is no overarching requirement that the patent laws of different countries be harmonized, nor are there any informal international norms directing that this should be pursued.[57] International treaties do not compel or even promote harmonization. In any event, the *Act* must be followed even if it is inconsistent with international treaties.[58] As to whether harmonization might be worth pursuing, Professor Vaver has said:

> Is harmonization a good thing? Only if the harmonized rules themselves are good and advance a country's patent policy. Harmonizing bad rules makes no sense at all. And whether a rule is good or bad often depends on one's perspective. [59]

PART IV - COSTS

35. The CGPA does not seek costs and asks that costs not be awarded against it.

PART V – ORDER SOUGHT

36. The CGPA requests leave to present oral argument at the hearing of this appeal.

All of which is respectfully submitted this 18th day of October 2016.

---

[55] *PCT,* Articles 27(5) and (6) - this has been recognized by the Federal Courts – see, e.g., *Atomoxetine FCA* at ¶48-50 and *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97 at ¶19. The patent systems of different jurisdictions achieve their goals in different ways, and comparative legal analysis must be undertaken holistically – see Gold and Shortt.

[56] *Act*, s. 38.2(1) and (2).

[57] Gold and Shortt at 56-58, citing to Reichman, H. & Cooper Dreyfuss, R., "Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty" (2007) 57 Duke LJ 85 at 89.

[58] *Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.*, 2002 FCA 158 at ¶25; *Schreiber v. Canada (Attorney General)*, [2002] 3 S.C.R. 269 at ¶50-51; *Daniels v. White*, [1968] S.C.R. 517 at 541; *Raloxifene FCA* at ¶19, aff'g 2008 FC 142 at ¶165-173; *Atomoxetine FCA* at ¶48-51.

[59] Vaver, D., "Is Canada's Patent Law Out of Step?", Reworked Remarks for University of Toronto 2nd Patent Law Colloquium, November 22, 2013, at 2.

PART VI – TABLE OF AUTHORITIES

Appellants' Book of Authorities = ABA
Respondents' Book of Authorities = RBA
Intervener's (CGPA) Book of Authorities = IBA

NO.	CONTENTS	PARAGRAPH REFERENCE IN CGPA'S FACTUM	BOOK OF AUTHORITIES REFERENCE
1.	*ABB Technology AG, ABB Inc. v. Hyundai Heavy Industries Co., Ltd*, 2015 FCA 181, 132 C.P.R. (4th) 405 ("*ABB*") at ¶37, 45, aff'g 2013 FC 946	18	RBA, Tab 13
2.	*Actavis Pharma Co. v. Alcon Canada Inc.,* 2015 FCA 192 at ¶16	10	IBA, Tab 1
3.	*Allergan Inc. v. Apotex Inc*., 2016 FC 344 at ¶57	24	RBA, Tab 15
4.	*Allergan Inc. v. Canada (Minister of Health)*, 2011 FC 1316 at ¶216, 220, 222, 223	22	IBA, Tab 2
5.	*Allergan Inc. v. Canada (Minister of Health)*, 2012 FCA 308 at ¶36, leave ref'd, [2013] S.C.C.A. No. 31	11	IBA, Tab 3
6.	*Amfac Foods Inc. v. Irving Pulp & Paper Ltd.* (1986), 12 C.P.R. (3d) 193 (FCA) at 204	6	RBA, Tab 17
7.	*Apotex Inc. et al v. ADIR et al*, 2009 FCA 222 at ¶101	15	IBA, Tab 4
8.	*Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236 at ¶24, 30-34, 41-52	15, 22	IBA, Tab 5
9.	*Apotex Inc. v. Pfizer Canada Inc.*, 2014 FCA 250 at ¶65, 70-72 [*Apotex celecoxib*]	3, 6, 10	IBA, Tab 6
10.	*Apotex Inc. v. Sanofi-Aventis*, 2011 FC 1486 at ¶141	15	IBA, Tab 7
11.	*Apotex Inc. v. Sanofi-Synthelabo Canada Inc.,* 2008 SCC 61, [2008] 3 S.C.R. 265 [*Sanofi*] at ¶9	15	IBA, Tab 8
12.	*Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77 [*AZT*] at ¶3, 37, 46, 49, 52, 55, 69, 70, 77, 80-84	1, 5, 6, 7, 8, 16, 21, 22, 23, 24, 26, 27, 28	IBA, Tab 9
13.	*AstraZeneca Canada Inc. v. Apotex Inc*., 2010	22	RBA, Tab 24

NO.	CONTENTS	PARAGRAPH REFERENCE IN CGPA'S FACTUM	BOOK OF AUTHORITIES REFERENCE
	FC 714, 88 C.P.R. (4th) 28 at ¶92-93		
14.	*AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 1023 at ¶188	22	IBA, Tab 10
15.	*AstraZeneca Canada Inc. v. Pharmascience Inc.*, 2012 FC 1189 at ¶182	15	IBA, Tab 11
16.	*AstraZeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638 at ¶141-142	24	Appellants' Record, Tab 1
17.	*Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd*., 2002 FCA 158 at ¶25	34	IBA, Tab 12
18.	*Brenner v. Manson*, 383 U.S. 519 (1966)	27	ABA, Tab 15
19.	*Bristol-Myers Squibb Canada Co. v. Canada (Minister of Health)*, 2012 FC 1142 at ¶65	15	IBA, Tab 13
20.	*Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26 at ¶133 [*Biolyse*]	6	IBA, Tab 14
21.	*Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504 at ¶523-6 [*Consolboard*]	3, 5, 6, 15	ABA, Tab 17
22.	*Daniels v. White*, [1968] S.C.R. 517 at p. 541	34	IBA, Tab 15
23.	*Dr. Reddy's Laboratories v. Eli Lilly & Company Ltd.*, 2008 EWHC 2345 at ¶95-109, aff'd, [2009] EWCA 1362 at ¶35-40	31	IBA, Tab 16
24.	*Eli Lilly and Co. v. Novopharm Limited*, 2010 FCA 197 at ¶30, 80, 83 [*Olanzapine FCA*], leave ref'd, [2010] S.C.C.A. No. 377	11, 15, 22	IBA, Tab 17
25.	*Eli Lilly and Co. v. Teva Canada Ltd.*, 2011 FCA 220, 94 C.P.R. (4th) 95 at ¶22	15	RBA, Tab 37
26.	*Eli Lilly Canada Inc. v. Apotex Inc*., 2009 FCA 97, 78 C.P.R. (4th) 388 [*Raloxifene FCA*] at ¶13-19, aff'g, 2008 FC 142 at ¶159-178, leave ref'd, [2009] S.C.C.A. No. 219	22, 24, 32, 34	RBA, Tab 34 (FCA) IBA, Tab 18 (FC)
27.	*Eli Lilly Canada Inc. v. Apotex Inc.,* 2015 FC 1016 at ¶133-137	10	IBA, Tab 19
28.	*Eli Lilly Canada Inc. v. Novopharm Limited*, 2011 FC 1288 at ¶208-209, aff'd 2012 FCA 232	11	IBA, Tab 20

NO.	CONTENTS	PARAGRAPH REFERENCE IN CGPA'S FACTUM	BOOK OF AUTHORITIES REFERENCE
29.	*Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 235 at ¶101-102, 108-109	22	IBA, Tab 21
30.	*Eli Lilly Canada Inc. v. Hospira Healthcare Corporation*, 2016 FC 47 at ¶ 48, 49	24	RBA, Tab 35
31.	*Eurocopter v. Bell Helicopter Textron Canada Limitée*, 2012 FC 113 at ¶59, aff'd 2013 FCA 219, 120 C.P.R. (4th) 394 at ¶153 [*Bell Helicopter*]	15, 22, 24	IBA, Tab 22 (FC) RBA, Tab 29 (FCA)
32.	*Fournier Pharma Inc. v. Canada (Minister of Health)*, 2012 FC 741 at ¶128	15	IBA, Tab 23
33.	*Free World Trust v. Électro Santé Inc*., 2000 SCC 66 at ¶14, 15, 31, 42, 51 [*Free World Trust*]	5, 6, 12, 13, 14, 18	RBA, Tab 38
34.	*Gilead Sciences, Inc. v. Idenix Pharmaceuticals Inc*., 2015 FC 1156 [*Gilead*] at ¶29, 221, 241, 283, 379, 448	10, 24, 26	IBA, Tab 24
35.	*GlaxoSmithKline Inc. v. Pharmascience Inc*., 2008 FC 593 at ¶71	22	IBA, Tab 25
36.	*GlaxoSmithKline Inc. v. Pharmascience Inc*., 2011 FC 239 at ¶95	22	IBA, Tab 26
37.	*Hoffmann-La Roche Ltd. v. Apotex Inc.*, 2011 FC 875 at ¶19	15	IBA, Tab 27
38.	*Janssen-Ortho Inc. v. Novopharm Limited,* 2006 FC 1234 at ¶113(8), aff'd 2007 FCA 217, leave ref'd, [2007] SCCA No. 442	31	IBA, Tab 28
39.	*Lundbeck Canada Inc. v. Ratiopharm Inc*., 2009 FC 1102 at ¶200-215	22	IBA, Tab 29
40.	*Merck & Co. v. Apotex Inc*., 2010 FC 1265 at ¶520-530	22	IBA, Tab 30
41.	*Monsanto Co. v. Commissioner of Patents,* [1979] 2 S.C.R. 1108 at 116-117	6	IBA, Tab 31
42.	*Mylan Pharmaceuticals ULC v. AstraZeneca Canada Inc.*, 2012 FCA 109 at ¶16-19	15	IBA, Tab 32
43.	*Mylan Pharmaceuticals ULC v. Pfizer Canada Inc.*, 2012 FCA 103 at ¶48	15	IBA, Tab 33

NO.	CONTENTS	PARAGRAPH REFERENCE IN CGPA'S FACTUM	BOOK OF AUTHORITIES REFERENCE
44.	*New Process Screw Corporation v. P.L. Robertson Mfg. Co. Ltd.* (1961), 39 C.P.R. 31 at 33-34	6	RBA, Tab 49
45.	*Novartis Pharmaceuticals Canada Inc. v. Teva Canada Ltd*., 2015 FC 770 at ¶30-33	10	IBA, Tab 34
46.	*Novopharm Ltd. v. Eli Lilly and Co*., 2011 FCA 220 [*Atomoxetine FCA*] at ¶48-50, 51, aff'g 2010 FC 915 at ¶114-120, leave ref'd, [2011] S.C.C.A. No. 362	22, 32, 34	IBA, Tab 35
47.	*Pfizer Canada Inc. v. Apotex Inc*., 2007 FC 26 at ¶61-71, aff'd, 2007 FCA 195, leave ref'd, [2007] S.C.C.A. No. 371	22	IBA, Tab 36
48.	*Pfizer Canada Inc. v. Apotex Inc.,* 2009 FCA 8 at ¶28-9	31	RBA, Tab 50
49.	*Pfizer Canada Inc. v. Canada (Minister of Health)*, 2009 FC 1294 at ¶150-154, aff'd 2011 FCA 102	22	IBA, Tab 37
50.	*Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC*, 2011 FC 547 at ¶240	22	IBA, Tab 38
51.	*Pfizer Canada Inc. v. Ratiopharm Inc*., 2010 FC 612 at ¶94-95, 112-113	22	IBA, Tab 39
52.	*Sanofi-Aventis Canada Inc. v. Ratiopharm Inc*., 2010 FC 230 at ¶73-77	22	IBA, Tab 40
53.	*Sanofi-Aventis Canada v. Apotex Inc.*, 2009 FC 676 at ¶119-133, 142-147, 214-217, aff'd 2011 FCA 300	15, 22	IBA, Tab 41
54.	*Schreiber v. Canada (Attorney General)*, [2002] 3 S.C.R. 269 at ¶50-51	34	IBA, Tab 42
55.	*Société des Usines Chimiques Rhone-Poulenc v. Jules R. Gilbert Ltd*. (1968), 55 C.P.R. 207 (Ex Ct) at 227 aff'd [1968] S.C.R. 950	11	IBA, Tab 43
56.	*Tennessee Eastman Co. v. Commissioner of Patents,* [1974] S.C.R. 111 at 117-9	31	IBA, Tab 44
57.	*Teva Canada Limited v. Pfizer Canada Inc.*, 2012 SCC 60 at ¶8, 31-35, 38, 49-52, 60, 87	5, 6, 8, 9, 14, 19	IBA, Tab 45

NO.	CONTENTS	PARAGRAPH REFERENCE IN CGPA'S FACTUM	BOOK OF AUTHORITIES REFERENCE
	[*Teva Viagra*]		
58.	*Visx Inc. v. Nidek Co.*, (1997), 77 C.P.R. (3d) 532 at ¶6	31	RBA, Tab 67
59.	*Wandscheer v. Sicard Ltd.,* [1948] S.C.R. 1 at p. 2, 5	6	IBA, Tab 46
60.	*Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67 [*Whirlpool*] at ¶42, 43, 48, 49(b) and (d)	6, 13, 14, 18	ABA, Tab 56
61.	*Williams v. Box* (1910), 44 S.C.R. 1 at 10	13	IBA, Tab 47
62.	*In re Zenitz* (1964), 52 C.P.P.A. 746 at ¶2	31	IBA, Tab 48

PART VII – STATUTORY PROVISIONS

NO.	CONTENTS	PARAGRAPH REFERENCE IN CGPA'S FACTUM	BOOK OF AUTHORITIES REFERENCE
63.	*Patent Act,* R.S.C. 1985, c P-4, ss. 2, 27(3), 38.2(1) and (2), 53	6, 7, 9, 19, 24, 33	IBA, Tab 49
64.	*North American Free Trade Agreement*, 32 I.L.M. 289 and 605, Article 1709	32	IBA, Tab 50
65.	*Patent Cooperation Treaty,* June 19, 1970, 28 U.S.T. as amended, ("*PCT*") Articles 5, 27(5) and (6)	32	IBA, Tab 51
66.	*Marrakesh Agreement Establishing the World Trade Organization, Annex 1C*, 15 April 1994, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (*TRIPs*), Article 1 and 27(1)	32	IBA, Tab 52
67.	World Intellectual Property Organization, *Draft Substantive Patent Law Treaty* online: http://www.wipo.int/patent-law/en/draft_splt.htm	31	IBA, Tab 53

PART VIII - OTHER SOURCES

NO.	CONTENTS	PARAGRAPH REFERENCE IN CGPA'S FACTUM	BOOK OF AUTHORITIES REFERENCE
68.	Gold, R., and Shortt, M., "The Promise of the Patent In Canada and Around the World", 30 CIPR 36 at p. 56-58, 60-2, 66, 71 and 74	31, 32, 34	RBA, Tab 3
69.	Vaver, D., "Is Canada's Patent Law Out of Step?", Reworked Remarks for University of Toronto 2nd Patent Law Colloquium, November 22, 2013 at p. 2	34	RBA, Tab 11
70.	"Patent Litigation: Putting Assumptions to the Empirical Test": CIPP (July 28, 2016) http://www.cippmcgill.ca/news/2016/07/28/patent-litigation-putting-assumptions-to-the-empirical-test/	10	IBA, Tab 54
71.	Reichman, H. & Cooper Dreyfuss, R., "Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty" (2007) 57 Duke LJ 85 at 89	34	RBA, Tab 9

Court File No. 36654

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

B E T W E E N:

ASTRAZENECA CANADA INC., ASTRAZENECA AKTIEBOLAG and ASTRAZENECA UK LIMITED

Appellants

– and –

APOTEX INC. and APOTEX PHARMACHEM INC.

Respondents

– and –

INNOVATIVE MEDICINES CANADA AND BIOTECANADA and CENTRE FOR INTELLECTUAL PROPERTY POLICY and CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION and FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE and INTELLECTUAL PROPERTY OWNERS ASSOCIATION and INTELLECTUAL PROPERTY INSTITUTE OF CANADA

Interveners

FACTUM OF THE INTERVENER, CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION ("CGPA")

AITKEN KLEE LLP
Suite 3350, 181 Bay Street
Toronto, ON M5J 2T3

Jonathan Stainsby
Scott A. Beeser

Tel: 647-317-6868/6869
Fax: 613-695-5854
E-mail:
jstainsby@aitkenklee.com
sbeeser@aitkenklee.com

Counsel for the Intervener, CGPA

AITKEN KLEE LLP
Suite 300, 100 Queen Street
Ottawa, ON K1P 1J9

Lesley Caswell

Tel: 613-903-5033
Fax: 613-695-5854
E-mail:
lcaswell@aitkenklee.com

Agents for the Intervener, CGPA