File Number: 36654

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

BETWEEN:

ASTRAZENECA CANADA INC. ASTRAZENECA AKTIEBOLAG and ASTRAZENECA UK LIMITED

APPELLANTS (APPELLANTS)

- and -

APOTEX INC. and APOTEX PHARMACHEM INC.

RESPONDENTS (RESPONDENTS)

- and -

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

INTERVENERS

FACTUM OF THE INTERVENER, INTELLECTUAL PROPERTY OWNERS ASSOCIATION (Rule 42 of the Rules of the Supreme Court of Canada)

TORYS LLP

79 Wellington Street West, Suite 3000 Box 270, TD Centre Toronto, Ontario M5K 1N2 Fax: 416.865,7380

Andrew E. Bernstein Tel: 416.865.7678 abernstein@torys.com

Yael S. Bienenstock Tel: 416.865.7954 ybienenstock@torys.com

Counsel for the Intervener Intellectual Property Owners Association

GOWLING WLG (CANADA) LLP

160 Elgin Street, Suite 2600 Ottawa, Ontario K1P 1C3 Fax: 613.788.3587

Jeffrey W. Beedell Tel: 613.786.0171

jeff.beedell@gowlingwlg.com

Ottawa Agent for Counsel for the Intervener Intellectual Property Owners Association

SMART & BIGGAR

1100 – 150 York Street Toronto, Ontario M5H 3S5

Gunars A. Gaikis Yoon Kang Y. Lynn Ing

Tel: 416.593.5514 Fax: 416.591.1690

ggaikis@smart-biggar.ca ykang@smart-biggar.ca yling@smart-biggar.ca

Counsel for the Appellants

GOODMANS LLP

Barristers & Solicitors 3400 – 333 Bay Street Toronto, Ontario M5H 2S7

Harry B. Radomski Richard Naiberg Sandon Shogilev

Tel: 416.979.2211 Fax: 416.979.1234

hradomski@goodmans.ca rnaiberg@goodmans.ca sshogilev@goodmans.ca

Counsel for the Respondents

NORTON ROSE FULBRIGHT CANADA LLP

Royal Bank Plaza, South Tower Suite 3800, 200 Bay St., PO Box 84 Toronto, Ontario M5J 2Z4

Patrick E. Kierans Kristen Wall

Tel: 416.216.3904 Fax: 416.216.3930

patrick.kierans@nortonrose.com

Counsel for the Intervener Innovative Medicines Canada and

BIOTECanada

SMART & BIGGAR

900 – 55 Metcalfe Street, 10th Floor Ottawa, Ontario K1P 6L5

Colin B. Ingram

Tel: 613,232.2486 Fax: 613,232.8440

cbingram@smart-biggar.ca

Ottawa Agent for Counsel for the Appellants

NELLIGAN O'BRIEN PAYNE LLP

1500 – 50 O'Connor Street Ottawa, Ontario K1P 6L2

Christopher Rootham

Tel: 613.231.8311 Fax: 613.788.3667

christopher.rootham@nelligan.ca

Ottawa Agent for Counsel for the

Respondents

NORTON ROSE FULBRIGHT CANADA LLP

45 O'Connor Street Suite 1500

Ottawa, Ontario K1P 1A4

Jamie Macdonald

Tel: 613.780.8628 Fax: 613.230.5459

jamie.macdonald@nortonrosefulbright.com

Ottawa Agent for Counsel for the Intervener

Innovative Medicines Canada and

BIOTECanada.

JEREMY DE BEER PROFESSIONAL CORPORATION

676 Roosevelt Avenue Ottawa, Ontario K2A 2A7

Jeremy de Beer E. Richard Gol

Tel: 613.263.9155 Fax: 613,562,5417

Jeremy@JeremydeBeer.ca

Counsel for the Intervener

Centre for Intellectual Property Policy

AITKEN KLEE LLP

100 Queen Street, Suite 300 Ottawa, Ontario K1P 1J9

Jonathan Stainsby Marcus Klee Devin Doyle Scott A. Beeser

Tel: 613.903.5099 Fax: 613.695.5854

istainsby@aitkenklee.com

Counsel for the Intervener

Canadian Generic Pharmaceutical Association

SAMUELSON-GLUSHKO CANADIAN INTERNET POLICY & PUBLIC

INTEREST CLINIC

University of Ottawa, Faculty of Law,

Common Law Section 57 Louis Pasteur Street Ottawa, Ontario K1N 6N5

Tamir Israel

Tel: 613.562.5800 Ext: 2914

Fax: 613.562.5417 tisrael@cippic.ca

Ottawa Agent for Counsel for the Intervener

Centre for Intellectual Property Policy

AITKEN KLEE LLP

Suite 300, 100 Queen Street Ottawa, Ontario K1P 1J9

Marcus Klee

Tel: 613.695.5858 Fax: 613.695.5854 mklee@aitkenklee.com

Agent for the Intervener

Canadian Generic Pharmaceutical Association

FASKEN MARTINEAU DUMOULIN LLP

The Stock Exchange Tower, Suite 3400, Victoria Square

C.P. 242, Succ. Tour de la Bourse

Montréal, Quebec H4Z 1E9

Julie Desrosiers

Kang Lee

Alain M. Leclerc

Tel: 514.397.7400 Fax: 514.397.7600

jdesrosiers@mtl.fasken.com

Counsel for the Intervener Fédération internationale des conseils en

propriété intellectuelle

FASKEN MARTINEAU DUMOULIN LLP

55 Metcalfe Street, Suite 1300 Ottawa, Ontario K1P 6L5

Yael Wexler

Tel: 613.696.6860 Fax: 613.230.6423 ywexler@fasken.com

Ottawa Agent for Counsel for the Intervener Fédération internationale des conseils en propriété intellectuelle

BELMORE NEIDRAUER LLP

TD South Tower, TD Centre 79 Wellington Street West, Suite 2401 Toronto, Ontario M5K 1A1

Jason Markwell Marian Wolanski Stefanie Di Giandomenico

Tel: 416.863.1771 Fax: 416.863.9171

jmarkwell@belmorelaw.com

Counsel for the Intervener Intellectual Property Institute of Canada

BORDEN LADNER GERVAIS LLP

World Exchange Plaza 100 Queen Street, suite 1300 Ottawa, Ontario K1P 1J9

Nadia Effendi

Tel: 613.237.5160 Fax: 613.230.8842 neffendi@blg.com

Ottawa Agent for Counsel for the Intervener Intellectual Property Institute of Canada

TABLE OF CONTENTS

PART I – OVERVIEW OF POSITION AND FACTS	1
Overview of position	1
IPO: The Intellectual Property Owners Association	
How is the "promise doctrine" currently used in practice?	
PART II – POSITION ON QUESTIONS RAISED	4
PART III – ARGUMENT	5
IPO proposes a two-step invention-based framework for utility	
1. What is the claimed invention at issue?	5
2. What must the claimed invention actually do to render it a useful invention?	7
IPO's purposive approach resolves the problem of the promise	8
Utility need not be disclosed in patents based on sound prediction	9
PART IV - COSTS	10
PART VI – TABLE OF AUTHORITIES	12
PART VII - STATUTORY PROVISIONS	13

PART I – OVERVIEW OF POSITION AND FACTS

Overview of position

- 1. At the heart of this appeal lies the question of how courts should assess whether a patent satisfies the statutory requirement of utility. But this appeal actually turns on a slightly different question: what is the purpose of patent disclosure? Is it intended to encourage inventors to tell the public everything they can about their invention, so that others can build on their scientific endeavors, or is it intended to be a trap for inventors, who risk losing the benefit of their inventions when they say too much?
- 2. This Court has answered this question many times, confirming that the purpose of disclosure is so that society can benefit from the inventor's knowledge. Disclosure lies at the heart of the patent system, which exists to coax inventive solutions into the public by encouraging inventors to disclose their inventions including their beliefs about what their invention does or might accomplish. In return, as part of the "patent bargain," the inventor acquires the exclusive right to exploit their invention for a limited time period.
- 3. The terms of that bargain are framed by the *Patent Act*. The *Act* sets out detailed requirements for what inventors must do in order to be granted a monopoly, including what they must disclose to the public about their invention. However, the Federal Courts' recent approach to utility where every word of the disclosure is at jeopardy of being a "self-inflicted wound" that can lead to invalidity is based on a misunderstanding of the "patent bargain." The "bargain" is a metaphor for the requirements of the *Patent Act*, which requires the creation and disclosure of useful inventions in exchange for a temporary monopoly. However, the bargain metaphor does not mean that each individual patent should be read as its own separate contract between the inventor and the public, with every word serving as a potentially invalidating contractual term.
- 4. The *Act* requires that an "invention" be "useful." For decades, this was understood as a minimum threshold, designed to prevent patents for useless inventions from cluttering the public registry. However, in its present form, the promise doctrine invites courts to parse the language of patent specifications, so that patent validity can turn on a judicial determination of whether a particular feature of the invention is a "promise" or merely an "advantage." By transforming

excess verbiage into a material promise, the doctrine has been recently used to invalidate many patents that easily meet the historical test for utility.

- 5. There is no principled reason for this Court to endorse this ongoing semantic battle. The *Act* contains a provision s. 53 that invalidates patents for intentional and material misrepresentations. Punishing mere over-disclosure with invalidity, where statements in a patent do not otherwise rise to this level, turns the incentives of the patent system on their head. It encourages inventors to say as little as possible, which is the antithesis of the intent of our patent system. For this reason, IPO strongly prefers and supports the abolishment of the promise doctrine.
- 6. If the Court is inclined to keep the promise doctrine, IPO submits that instead of focusing on what "promises" can be found in the patent specification, the doctrine should ask what utility is required to make the claimed invention actually inventive? This approach is based on the *Act*, where utility is a prerequisite for there to be a patentable invention, and has nothing to do with the words chosen to describe it. It is faithful to the patent bargain, as it requires sufficient utility for there to be a patentable invention, but will not invalidate a claim for failing to exceed that standard. In encouraging inventors to tell the public about their inventions, rather than penalizing them for saying too much, this approach furthers the policy rationales that animate the patent system. Finally, a focus on the claimed invention is consistent with the approach to validity in the *Act* and expressed by the courts, where it is the claim(s) that must be assessed, not the patent as a whole.
- 7. Regardless of what the Court does with the promise doctrine, IPO urges the Court to reiterate that there is no additional disclosure requirement associated with a patent based on a sound prediction. The Federal Courts have regularly misinterpreted certain *dicta* from this Court's decision in *Apotex v. Wellcome* as imposing such a requirement. This Court attempted to correct the problem in *Teva v. Pfizer*, but the Federal Courts have resisted this correction, causing ongoing mischief in the patent regime. There has never been any statutory basis for this requirement, and this Court should put it to rest.

IPO: The Intellectual Property Owners Association

8. The Intellectual Property Owners Association (IPO) is an international trade association representing individuals and companies who own intellectual property or are interested in

promoting fair and effective intellectual property rights worldwide. Members hold patents in a range of fields, including computer technology, biotechnology, household products, and natural resources. They believe that intellectual property rights promote the innovation, creativity, and investment needed to address major global challenges and to improve people's lives.

How is the "promise doctrine" currently used in practice?

- 9. As everyone agrees, part of the statutory bargain contained in the *Act* is the requirement that an invention be "useful." This means two things, as this Court held in *Wellcome*. First, the invention must actually be useful. Second, the inventors must have demonstrated or soundly predicted that the invention would be useful at the time of filing.
- 10. Although courts have long-held that a "mere scintilla" of utility can suffice, where the specification sets out an explicit "promise," courts have held that utility must be measured against that promise. Thus the question of "promise" effectively sets the bar for utility. The more significant the promise, the more onerous the utility requirement becomes.
- 11. The difficulty arises in parsing which words in the patent are "promises" and which ones are not. In the pharmaceutical context, the question is often whether the patented drug needs to be shown to have had some clinical effect (sometimes on humans) before the patent was filed, or whether it is sufficient to have shown a pharmacological effect (on test animals or *in vitro*).
- 12. Currently, the analysis is amorphous and inconsistent. Courts have construed promises modestly in some cases, but expansively in others, sometimes even in the same patent. In most cases, this analysis is based on a careful (but arbitrary) parsing of the words of the patent, with validity often turning on whether the patent says "will," "may," "could," or "is expected to."
- 13. The current approach to promise as a measure of utility is fundamentally flawed. Although it is purportedly based in the bargain theory, it ignores the central principles of that bargain, and upends it in the process. The "bargain" theory of patents is a metaphor for the statutory criteria set out in the *Act*. It does not mean that each patent should be read as its own

¹ In *Pharmascience Inc. v. Pfizer Canada Inc.*, 2011 FCA 102, at para. 12, Intervener's Book of Authorities (IBA), Tab 4, the promise was held to be "the treatment of glaucoma or ocular hypertension without substantial ocular irritation" and the patent was held to be valid. In *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, at paras. 24, 28 the promised utility was held also to include chronic treatment and the patent was held to be invalid, IBA, Tab 1

separate contract. Rather, the inventor upholds his or her end of the bargain by conceiving of and disclosing a new, useful and non-obvious invention.

14. Erroneously viewing the disclosure as defining the terms of the bargain, the promise doctrine leads to a complex quest for promises that invites courts to hold every statement in a patent to a standard of perfection, to elevate every assertion to the status of an "explicit promise," and to invalidate patents that disclose very useful inventions. It ignores the practical reality that the details of a patent specification exist for a variety of purposes, and should not be subjected to extreme parsing in the search for ever-increasing promises.² Reading patents in this way discourages inventors from revealing what they believe about their inventions lest those statements be transformed into promises. It fosters secretive research and delayed publication, notions that are antithetical to the patent regime.

PART II - POSITION ON QUESTIONS RAISED

- 15. IPO's position is that the specification-parsing approach to the promise doctrine has no basis in the statutory regime and undermines the bargain between an inventor and the public. It punishes inventors for making full disclosure and encourages challenges from those who seek to profit from over enthusiastic drafting, instead of encouraging competitors to make their own innovations. It should either be abolished or refined to focus on the question of "what is the utility required to support the claimed invention?"
- 16. IPO also submits that the additional disclosure requirements imposed by the Federal Courts when utility is based on a sound prediction are not required by the *Act*, and have always been based on a misinterpretation of this Court's decision in *Apotex v. Wellcome*. This Court clarified the test for sound prediction in *Teva v. Pfizer*, but the lower courts have thus far viewed this Court's clarification as *obiter dicta*, and have failed to apply it.

² In Apotex Inc. v. Sanofi-Aventis Canada Inc., 2013 FCA 186, at para. 125, Respondent's Book of Authorities (RBA), Tab 20, Gauthier, J.A. noted there can be reasons for including statements in the specification, such as compliance with other international patent regimes, that "have little to do with an intent to promise a result."

³ Apotex Inc., v. Wellcome Foundation Ltd., 2002 SCC 77 [Wellcome], Appellant's Book of Authorities (ABA), Tab

⁴ Teva Canada Ltd. v. Pfizer Canada Ltd., 2012 SCC 60 [Teva], ABA, Tab 51

PART III - ARGUMENT

- 17. For the reasons set out by the Appellants, IPO agrees that the promise doctrine should be abolished. As this Court has explained, intellectual property is "wholly statutory." The *Act* makes no mention of "promises." Moreover, it already contains adequate provisions to deal with disclosures that are insufficient or are incorrect, obscure, or misleading.⁶
- 18. In the alternative, IPO submits that this Court should revisit the way it analyzes utility. Consistent with this Court's overall approach to patent construction, IPO proposes a purposive approach. As this Court has long recognized, an inventor should be given "protection for that which he has actually in good faith invented." In *Free World Trust*, Justice Binnie explained, "The words chosen by the inventor will be read in the sense the inventor is presumed to have intended, and in a way that is sympathetic to accomplishment of the inventor's purpose expressed or implicit in the text of the claims." These fundamental principles of patent construction should not be disregarded when it comes to determining promised utility.

IPO proposes a two-step invention-based framework for utility

19. IPO's purposive approach involves a two-step inquiry. The first step seeks to focus the analysis on the particular art, process, machine, manufacture, or composition of matter that is actually at issue. The second step asks what that subject matter *does* in order to render it a useful invention, and makes that (and only that) the "promise." IPO submits that this purposive approach to utility will address many of the issues that have plagued the determination of promise in the courts below.

1. What is the claimed invention at issue?

20. Under IPO's proposed framework for assessing whether the utility is met, the first question is "what is the claimed invention?" As this Court has explained, the monopoly in a patent is defined by the claims. Often analogized to "fences," the claims warn the public against

⁵ Apotex Inc. v. Sanofi-Synthelabo Canada Inc., 2008 SCC 61, at para, 12 [Sanofi] RBA, Tab 21

⁶ Patent Act, R.S.C. 1985, c. P-4, ss. 27(3) and 53

⁷ Western Electric Co. v. Baldwin Internal Radio, [1934] S.C.R. 570, at 574, ABA, Tab 55; Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd., [1981] 1 SCR 504, at 521 [Consolboard], ABA, Tab 17

⁸ Free World Trust v. Électro Santé Inc., 2000 SCC 66, at para. 51 [Free World], ABA, Tab 22

trespassing on the inventor's property. The claims tell the public where they may, and may not, safely tread.

- 21. In practice, as this Court has recognized, those fences "often consist of complex layers of definitions of different elements ... of differing complexity, substitutability and ingenuity." For instance, a new machine can support "apparatus" claims that apply to the machine, and "method" claims that apply to the use of the machine to achieve a particular result. Similarly, a patent can have different "compound" claims of varying levels of specificity, and various "use" claims that claim different uses for the compound (e.g., basic pharmacological activity and the treatment of different diseases). The Federal Courts have recognized that different claims can have different utilities, or different promises. ¹⁰
- 22. This claim-by-claim approach to utility is consistent with the *Act*, which contemplates that certain claims (i.e., certain monopolies) can be invalid while others remain valid. ¹¹ Because the *Act* requires novelty and non-obviousness to be evaluated by reference to the "subject-matter defined by a claim," it also means the "invention" that must be useful is the same "invention" that must be both novel and non-obvious. ¹² Moreover, a claim-by-claim approach is consistent with the *Act*, which expressly instructs courts to consider validity on that basis. ¹³ This approach is a fundamental tenet of patent law. For decades, the courts have assessed validity by focusing on the claims at issue. ¹⁴
- 23. This focus on the claim is particularly relevant in this case. Apotex argues that this Court should endorse an approach to utility that measures every claim against all "promises" made in the disclosure—regardless of what the claims say, or which claims are actually at issue. This approach seeks to turn patent law on its head. The claims define the monopoly. Whether the inventor has lived up to their end of the statutory bargain must therefore be assessed by reference to the claim(s) at issue, to determine whether they are valid or invalid.

⁹ Free World, at paras. 14-15, ABA, Tab 22

¹⁰ Apotex Inc. v. Pfizer Canada Inc., 2014 FCA 250, at paras. 85-89, ABA, Tab 6; Reasons for Judgment of the Federal Court of Appeal in Court File No. A-420-14, 2015 FCA 158, at para. 5, Record of the Appellants, Tab 3; Teva Canada Limited v. Novartis Pharmaceuticals Canada Inc., 2016 FCA 230, at para. 23, IBA, Tab 5

¹¹ Patent Act, s. 58

¹² Patent Act, ss. 28.2(1) and 28.3

¹³ Patent Act, s. 58

¹⁴ Wellcome, at paras. 4, 57, ABA, Tab 9; Monsanto v. The Commissioner of Patents, [1979] 2 SCR 1108, at 1110, RBA, Tab 48; Mailman et al., v. Gillette Safety Razor Co. (1932), [1933] 1 DLR 8, at 9 (SCC), RBA Tab 44

24. A straightforward example shows both the absurdity and impracticality of Apotex's proposed approach. A patent may contain separate claims for a new compound to treat both inflammation and colon cancer. If the compound turns out to treat inflammation, but not colon cancer, the claim for colon cancer will properly be invalid. Apotex is arguing that the claim to treat inflammation should also be invalid, notwithstanding that it lives up to the promise disclosed in that claim. The Federal Courts have soundly rejected this approach, for good reason: 15 it runs contrary to the structure of the *Act* and would encourage an inventor to file multiple applications to prevent invalid claims from "infecting" valid claims. This Court should reject it, in favour of a claim-by-claim approach to construing promised utility.

2. What must the claimed invention actually do to render it a useful invention?

- 25. Utility is a key aspect of what transforms a method or contraption into a patentable invention. Thus, once the claimed invention has been identified, IPO's purposive approach to utility asks, "What utility is required to support the invention as claimed?" This step requires the court to identify the claimed invention and how it works so as to actually be a useful invention. The key question is thus: "What must the claimed art, process, machine, manufacture, or composition of matter (or improvement thereof) actually do so that it provides benefit?"
- 26. This approach starts with the premise that an invention satisfies the utility requirement if it provides the public with a "new article, or a better article, or a cheaper article, or affords the public a useful choice." Thus, the utility requirement does not mandate that the claimed invention supersede or be better than the prior art, but merely that it be capable of providing some identifiable benefit. This threshold of utility is not high. This framework seeks to separate what the invention *must* do (failure of which will invalidate the claim for lack of utility) from lofty rhetoric or sloppy drafting about the advantages of the invention (which can only lead to invalidity if they offend section 27(3) or section 53 of the *Act*). This approach also leads to certain practical consequences, set out below.
- 27. Where the claim includes utility, the invention must have that utility. Sometimes the claim itself will set out a specific utility (such as for a new use for an old compound). If it does, then of course that utility must be required to support the invention, and that utility should be the

¹⁵ Apotex Inc. v. Pfizer Canada Inc. 2014 FCA 250, at paras. 85-89, ABA, Tab 6

¹⁶ Consolboard at 525, ABA, Tab 17

"promised utility" for that claim. This was precisely the Court's concern in *Wellcome* when it explained that "when a new use is the gravamen of the invention, the utility required for patentability must ... either be demonstrated or be a sound prediction." Thus, as a general matter, where utility is set out in the claim itself, the court should avoid looking to the disclosure to import additional promises into the claim. This approach is consistent with this Court's instructions in conducting the obviousness analysis, in which the disclosure should only be consulted when the inventive concept "is not readily discernable from the claims themselves." ¹⁸

- 28. Where the claim does not set out utility, the proposed utility will determine it. The utility analysis is more challenging where the claim is silent on utility. However, in those circumstances, IPO submits that asking "what utility is required to make the invention useful?" provides a principled answer to the sometimes difficult question of "useful for what?" IPO's approach ensures that statements in the disclosure are treated as promises only when they are integral to what makes the invention inventive in light of the prior art. The disclosure should not be read to impose promises beyond that which is required.
- 29. Thus, in practice, a court would determine whether a purported promise is a necessary part of the inventive concept or if it is simply secondary information about the invention. Only the former is part of the utility required to support the invention (or "promise").
- 30. Although IPO takes no position on the outcome of this case, the facts are illustrative: a patent for an unquestionably useful invention like esomeprazole should not be invalidated merely because a non-material use, identified at an early stage, was not robustly borne out in development. The purpose of sound prediction is to encourage researchers to publish their work while it is still in development. The promise doctrine should not detract from that purpose and discourage full disclosure.

IPO's purposive approach resolves the problem of the promise

31. As set out below, IPO's purposive framework answers many of the theoretical and practical problems that can result from the Federal Courts' current approach to promise.

¹⁷ Wellcome at para. 56, ABA, Tab 9

¹⁸ Sanofi at para. 77, ABA, Tab 7

¹⁹ Wellcome at para. 66, ABA, Tab 9

- 32. Consistent with the patent bargain. Most importantly, IPO's approach is consistent with the metaphor of the patent bargain. It ensures that if the inventor lives up to his or her end by providing the public with a new and useful disclosure, then he or she will have the benefit of the monopoly. In other words, the approach protects against "promise inflation" in the utility analysis (where language in the disclosure is relied on to require a level of utility that might well exceed that required for the inventor to satisfy his or her end of the bargain).
- 33. Encourages full and frank disclosure. This approach also encourages full and frank disclosure. Because early publication drives further innovation, an inventor should not be penalized for revealing contemplated uses that later do not bear fruit. Of course, material misstatements intended to mislead will always be subject to s. 53. However, statements made in good faith (regardless of whether they are phrased with a "will," "may," "could," or "should") ought not be pulled from the specification and elevated to the level of a promise.
- 34. **Predictability and consistency across the validity analysis.** IPO's approach also has the advantage of consistency across the validity analysis. It ensures that the "invention" assessed for utility is the same "invention" assessed for novelty and non-obviousness. This approach also fosters predictability because inventors and the public can rely on utility that is readily discernable in a claim, or is otherwise part of the inventive concept.
- 35. Ensures that the patent registry is not littered with useless patents. At the same time, this approach will provide a check on the patent system and ensure that the patent registry is not littered with useless patents every valid claimed invention will be required to be sufficiently useful to justify its inventiveness. No more and no less.

Utility need not be disclosed in patents based on sound prediction

36. An invention-based approach to utility also resolves the question of whether there is a disclosure requirement associated with utility when the patent is based on a sound prediction. Patents based on demonstration are not required to prove their utility,²⁰ but since *Wellcome*, the courts have imposed "a heightened obligation to disclose the underlying facts and the line of

²⁰ Consolboard at 521, ABA, Tab 17; Pfizer Canada Inc. v. Pharmascience Inc., 2013 FC 120, at para. 153, IBA, Tab 3

reasoning" when utility is established by sound prediction."²¹ This additional requirement is inconsistent with both the *Act* and this Court's more recent jurisprudence.

- 37. No disclosure requirement for utility in the Act. This Court in Teva Canada Ltd v. Pfizer Canada Ltd., noted that the additional disclosure requirement is inconsistent with the statutory scheme. Subsection 27(3) sets out detailed disclosure requirements for all patents. It does not mention any additional requirements specific to utility. In fact, this Court has held that it is an error to confuse the requirement of establishing that an invention has utility with the requirement to establish that utility exists in the specification.²²
- 38. No disclosure requirement in this Court's jurisprudence. The Federal Courts have also misinterpreted this Court's jurisprudence. In Wellcome, Justice Binnie, simply said that "proper disclosure" must be made.²³ He did not set out the content of that disclosure, or require anything more than the disclosure ordinarily required by the Act. To the extent that Wellcome left any ambiguity about the disclosure requirement in sound prediction cases, that ambiguity was resolved by this Court in Teva, where it clarified that "proper disclosure" does not require any disclosure of utility.²⁴ Despite this Court's comments, the Federal Courts continue to require additional disclosure in sound prediction cases (while acknowledging it is not required for demonstrated utility).²⁵ There is no justification for this. Upholding the "bargain" principle means insisting on the requirements of the Act, while rejecting extra-statutory requirements.

PART IV - COSTS

39. IPO does not seek costs and asks that no costs be awarded against it.

²¹ Eli Lilly Canada Inc. v. Apotex Inc., 2009 FCA 97, at para. 14, RBA, Tab 34

²² Consolboard at 521, ABA, Tab 17

²³ Wellcome at para. 70, ABA, Tab 9

²⁴ Teva at para. 40, ABA, Tab 51: "Nothing in [Wellcome] suggests that utility is a disclosure requirement; all it says is that "the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction"...this does not mean that there is a separate requirement for the disclosure of utility. In fact, there is no requirement whatsoever in s. 27(3) to disclose the utility of the invention."

²⁵ Eli Lilly Canada Inc. v. Hospira Healthcare Corp., 2016 FC 47, at para. 48, IBA, Tab 2

October 18, 2016

ALL OF WHICH IS RESPECTFULLY SUBMITTED

as agent For

Andrew E. Bernstein

as agent for

Yael S. Bienenstock

Counsel for the Intervener, Intellectual Property Owners Association

PART VI – TABLE OF AUTHORITIES

Authority	Paragraphs in Parts I & III
Apotex Inc. v. Pfizer Canada Inc., 2011 FCA 236	12
Apotex Inc. v. Pfizer Canada Inc., 2014 FCA 250	21, 24
Apotex Inc. v. Sanofi-Aventis Canada Inc., 2013 FCA 186	14
Apotex Inc. v. Sanofi-Synthelabo Canada Inc., 2008 SCC 61	17, 27
Apotex Inc. v. Wellcome Foundation Ltd., 2002 SCC 77	16, 22, 27, 30, 38
Astrazeneca Canada Inc. v. Apotex Inc., 2015 FCA 158	21
Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd., [1981] 1 S.C.R. 504	18, 26, 36, 37
Eli Lilly Canada Inc. v. Apotex Inc., 2009 FCA 97	36
Eli Lilly Canada Inc. v. Hospira Healthcare Corp., 2016 FC 47	38
Free World Trust v. Électro Santé Inc., 2000 SCC 66	18, 21
Mailman et al., v. Gillette Safety Razor Co. (1932), [1933] 1 DLR 8	22
Monsanto v. The Commissioner of Patents, [1979] 2 SCR 1108	22
Pfizer Canada Inc. v. Pharmascience Inc., 2013 FC 120	36
Pharmascience Inc. v. Pfizer Canada Inc., 2011 FCA 102	12
Teva Canada Limited v. Novartis Pharmaceuticals Canada Inc., 2016 FCA 230	21
Teva Canada Ltd. v. Pfizer Canada Ltd., 2012 SCC 60	16, 38
Western Electric Co. v. Baldwin International Ltd., [1934] S.C.R. 94	18

PART VII – STATUTORY PROVISIONS

Patent Act, R.S.C. 1985, c. P-4, ss. 27(3), 28.2(1), 28.3, 53 & 58

Specification

- 27(3) The specification of an invention must
 - (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
 - (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;
 - (c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and
 - (d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.

Mémoire descriptive

- 27(3) Le mémoire descriptif doit :
 - (a) décrire d'une façon exacte et complète l'invention et son application ou exploitation, telles que les a conçues son inventeur;
 - (b) exposer clairement les diverses phases d'un procé-dé, ou le mode de construction, de confection, de composition ou d'utilisation d'une machine, d'un objet manufacturé ou d'un composé de matières, dans des termes complets, clairs, concis et exacts qui permettent à toute personne versée dans l'art ou la science dont relève l'invention, ou dans l'art ou la science qui s'en rapproche le plus, de confectionner, construire, composer ou utiliser l'invention;
 - (c) s'il s'agit d'une machine, en expliquer clairement le principe et la meilleure manière dont son inventeur en a conçu l'application;
 - (d) s'il s'agit d'un procédé, expliquer la suite néces-saire, le cas échéant, des diverses phases du procédé, de façon à distinguer l'invention en cause d'autres inventions.

Subject-matter of claim must not be previously disclosed

- 28.2 (1) The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed
 - (a) more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subjectmatter became available to the public in Canada or elsewhere:
 - (b) before the claim date by a person not mentioned in paragraph (a) in such a manner that the subject-matter became available to the public in Canada or elsewhere;
 - (c) in an application for a patent that is filed in Canada by a person other than the applicant, and has a filing date that is before the claim date; or
 - (d) in an application (the "co-pending application") for a patent that is filed in Canada by a person other than the applicant and has a filing date that is on or after the claim date if
 - (i) the co-pending application is filed by
 - (A) a person who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for Canada an application for a patent disclosing the subject-matter defined by the claim, or
 - (B) a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to citizens of Canada an application for a patent disclosing the subject-matter defined by the claim,

Objet non divulgué

- 28.2 (1) L'objet que définit la revendication d'une de-mande de brevet ne doit pas :
 - (a) plus d'un an avant la date de dépôt de celle-ci, avoir fait, de la part du demandeur ou d'un tiers ayant obte-nu de lui l'information à cet égard de façon directe ou autrement, l'objet d'une communication qui l'a rendu accessible au public au Canada ou ailleurs;
 - (b) avant la date de la revendication, avoir fait, de la part d'une autre personne, l'objet d'une communication qui l'a rendu accessible au public au Canada ou ailleurs;
 - (c) avoir été divulgué dans une demande de brevet qui a été déposée au Canada par une personne autre que le demandeur et dont la date de dépôt est antérieure à la date de la revendication de la demande visée à l'ali-néa (1)a);
 - (d) avoir été divulgué dans une demande de brevet qui a été déposée au Canada par une personne autre que le demandeur et dont la date de dépôt correspond ou est postérieure à la date de la revendication de la de-mande visée à l'alinéa (1)a) si :
 - (i) cette personne, son agent, son représentant lé-gal ou son prédécesseur en droit, selon le cas :
 - (A) a antérieurement déposé de façon régulière, au Canada ou pour le Canada, une demande de brevet divulguant l'objet que définit la revendi-cation de la demande visée à l'alinéa (1)a),
 - (B) a antérieurement déposé de façon régulière, dans un autre pays ou pour un autre pays, une demande de brevet divulguant l'objet que définit la revendication de la demande visée à l'alinéa (1)a), dans le cas où ce pays protège les droits de cette personne par traité ou convention, relatif aux brevets, auquel le Canada est partie, et ac-corde par traité, convention ou loi une protection similaire aux citoyens du Canada,

- (ii) the filing date of the previously regularly filed application is before the claim date of the pending application,
- (iii) the filing date of the co-pending application is within twelve months after the filing date of the previously regularly filed application, and
- (iv) the applicant has, in respect of the copending application, made a request for priority on the basis of the previously regularly filed application.

Invention must not be obvious

- 28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to
 - (a) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and
 - (b) information disclosed before the claim date by a person not mentioned in paragraph (a) in such a manner that the information became available to the public in Canada or elsewhere.

Void in certain cases, or valid only for parts

53 (1) A patent is void if any material allegation in the petition of the applicant in respect of the patent is un-true, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, and the omission or addition is wilfully made for the purpose of misleading.

Exception

(2) Where it appears to a court that the omission or addition referred to in subsection (1) was an involuntary error and it is proved that the patentee is entitled to the remainder of his patent, the court shall render a judgment in accordance with the facts, and shall determine the costs, and the patent shall be held valid for that part of the invention

- (ii) la date de dépôt de la demande déposée anté-rieurement est antérieure à la date de la revendica-tion de la demande visée à l'alinéa a),
- (iii) à la date de dépôt de la demande, il s'est écou-lé, depuis la date de dépôt de la demande déposée antérieurement, au plus douze mois,
- (iv) cette personne a présenté, à l'égard de sa de-mande, une demande de priorité fondée sur la de-mande déposée antérieurement.

Objet non evident

- 28.3 L'objet que définit la revendication d'une demande de brevet ne doit pas, à la date de la revendication, être évident pour une personne versée dans l'art ou la science dont relève l'objet, eu égard à toute communication :
- (a) qui a été faite, plus d'un an avant la date de dépôt de la demande, par le demandeur ou un tiers ayant ob-tenu de lui l'information à cet égard de façon directe ou autrement, de manière telle qu'elle est devenue accessible au public au Canada ou ailleurs;
- (b) qui a été faite par toute autre personne avant la date de la revendication de manière telle qu'elle est devenue accessible au public au Canada ou ailleurs.

Nul en certains cas, ou valide en partie seulement

53 (1) Le brevet est nul si la pétition du demandeur, re-lative à ce brevet, contient quelque allégation importante qui n'est pas conforme à la vérité, ou si le mémoire des-criptif et les dessins contiennent plus ou moins qu'il n'est nécessaire pour démontrer ce qu'ils sont censés démon-trer, et si l'omission ou l'addition est volontairement faite pour induire en erreur.

Exception

(2) S'il apparaît au tribunal que pareille omission ou addition est le résultat d'une erreur involontaire, et s'il est prouvé que le breveté a droit au reste de son brevet, le tribunal rend jugement selon les faits et statue sur les frais. Le described to which the patentee is so found to be entitled.

Copies of judgment

(3) Two office copies of the judgment rendered under subsection (1) shall be furnished to the Patent Office by the patentee, one of which shall be registered and remain of record in the Office and the other attached to the patent and made a part of it by a reference thereto.

Invalid claims not to affect valid claims

58 When, in any action or proceeding respecting a patent that contains two or more claims, one or more of those claims is or are held to be valid but another or others is or are held to be invalid or void, effect shall be given to the patent as if it contained only the valid claim or claims.

brevet est réputé valide quant à la partie de l'invention décrite à laquelle le breveté est reconnu avoir droit.

Copies du jugement

(3) Le breveté transmet au Bureau des brevets deux compies authentiques de ce jugement. Une copie en est enre-gistrée et conservée dans les archives du Bureau, et l'autre est jointe au brevet et y est incorporée au moyen d'un renvoi.

Revendications invalids

58 Lorsque, dans une action ou procédure relative à un brevet qui renferme deux ou plusieurs revendications, une ou plusieurs de ces revendications sont tenues pour valides, mais qu'une autre ou d'autres sont tenues pour invalides ou nulles, il est donné effet au brevet tout comme s'il ne renfermait que la ou les revendications va-lides.