# IN THE SUPREME COURT OF CANADA

(ON APPEAL FROM THE FEDERAL COURT OF APPEAL)

BETWEEN:

ASTRAZENECA CANADA INC, ASTRAZENECA AKTIEBOLAG, and ASTRAZENECA

TO: THE REGISTRAR OF THE SUPREME COURT OF CANADA

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## TABLE OF CONTENTS

PART I. OVERVIEW1
PART II. POSITION ON APPELLANTS' QUESTIONS1
PART III.ARGUMENT1
A. The patent bargain involves diverse stakeholders, not just the inventor and state
B. Utility is related to, not isolated from, other criteria for patentability
C. An invention must be as useful as the applicant says it is, from a skilled reader's view
Applying the word "useful" in context requires a skilled reader's view of the invention
"Useful" in patent law has been consistently linked to applicants' promises for a long time
There are not two standards of utility; there is one standard involving distinct questions5
Proposed "scintilla" and "not devoid of" standards do not determine what an invention must do5

- 6. The standard for patent utility should be determined bearing all of these stakeholders' perspectives in mind. Each one has an interest in ensuring an invention does what the applicant promised. Of course, as this Court has stated, "those who directly benefit from an invention should be asked ... to pay for it, at least in part." But also, Canadians must gain "something more than speculation" in exchange for monopoly rights. Courts should reduce uncertainty, otherwise "competition is 'chilled'." In the words of the Supreme Court of the United States, "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Courts should ensure that "the granting of a patent is not abused to the financial detriment of Canadian patients and their insurers". Perhaps most importantly, "patentees cannot be allowed to 'game' the system".
- 7. Holding patent applicants to their promises about what an invention does supports Canadian innovation policy in several ways. It disciplines applicants to

applicability/utility requirement cannot be considered separately from other requirements."9

- 10. Since utility is integrally related to other criteria for patentability, CIPP supports the Appellants' submission that "there is only one patent construction for all purposes: an invention cannot be read up for one purpose and down for another". This principle applies equally to all parties in patent disputes, including patent applicants. In particular, the utility requirement prevents applicants from exaggerating statements, perhaps intending to persuade examiners of an invention's novelty or non-obviousness, without being bound to those statements when assessing an invention's utility.
- 11. A corollary of the skilled reader's single construction of the invention's us

patentable subject-matter must have *the* utility that a skilled reader determines the patent applicant claims.

15. The place to begin any validity analysis is with the skilled reader. She determines what are the essential and non-essential elements of the subject-matter. She then identifies that subject-matter's utility, which is what that subject-matter does. Based on a skilled reader's understanding, the court can determine whether the applicant's specified use is useful enough, and whether that usefulness is demonstrated or soundly predicted. This accords with the plain language of the Act, in both English and French, used to define "invention": One first determines what the claimed subject-matter is, and then one establishes whether it has the characteristic of being useful (présentant le caractère ... de l'utilité).

#### "Useful" in patent law has been consistently linked to applicants' promises for a long time.

16. While patent law is a creature of statute, courts have long interpreted statutory language in light of its history, purpose, and well-settled principles. Since 1787, courts in the United Kingdom have held that claimed subject-matter must possess the utility that a skilled reader determines the patent applicant asserted in the specification: "[I]f the process, as directed by the specification, does not produce that which the patent professes to

into practice by a competent person, do what it assumes to do ... for the purpose indicated by the patentee." <sup>16</sup>

20. Similar language regarding promises continues to be used today in Canada, and in other jurisdictions including Australia, Israel and New Zealand.<sup>17</sup>

There are not two standards of utility; there is one standard involving distinct questions.

- 21. The trial decision being considered in this appeal states (at paragraph 90) the utility doctrine as requiring a scintilla of utility, except in cases where an explicit promise was made, but concludes: "In essence, '[t]he question is whether the invention does what the patent promises it will do." This and other recent Federal Court decisions ostensibly create a two-tiered utility doctrine.
- 22. CIPP submits that applying one standard—that an invention must have *the* utility a skilled reader determines the applicant claims—avoids the oversimplified dichotomy between cases involving explicit promises and cases where nothing at all is said about an invention's usefulness. A more robust framework would separate the question of *what* the subject-matter does from questions of *how much* the subject-matter does and *whether* that was sufficiently disclosed.
- 23. The promised utility doctrine, if such a "doctrine" exists, ensures an invention does what the applicant says it does. The other aspects of utility—whether how much the invention does is enough to cross the threshold of patentability, and whether utility was demonstrated or soundly predicted—are not at issue on the facts of this appeal.

Proposed "scintilla" and "not devoid of" standards do not determine what an invention must do.

24. The strength of Canada's utility doctrine is its focus on a clear and objective standard for identifying what the claimed subject-matter does, based on the skilled reader's view. Ignoring the applicant's promises, and requiring only that an invention have an abstract scintilla of, or not be devoid of, utility

<sup>16</sup> Harold G Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed (Toronto: Carswell, 1969) at 150 (IBoA, V1, T15).

AIPPI, "Questionnaire Apotex Inc v Sanofi-Aventis: Australia", online: AIPPI Amicus Brief Committee <a href="http://aippi.org/wp-content/uploads/2015/02/Answ\_Quest\_Q221\_Apotex\_Australia1.pdf">http://aippi.org/wp-content/uploads/2015/02/Answ\_Quest\_Q221\_Apotex\_Australia1.pdf</a> (IBoA, V1, T9); AIPPI, "Questionnaire Apotex Inc v Sanofi-Aventis: Israel", online: AIPPI Amicus Brief Committee <a href="http://aippi.org/wp-content/uploads/2015/02/Answ\_Quest\_Q221\_Apotex\_Israel.pdf">http://aippi.org/wp-content/uploads/2015/02/Answ\_Quest\_Q221\_Apotex\_Israel.pdf</a> (IBoA, V1, T11); \*Hammar Maskin AB v Steelbro New Zealand Ltd, [2010] NZCA 83 at para 76, aff'd [2010] NZSC 65, (IBoA, V1, T5).

<sup>&</sup>lt;sup>18</sup> AstraZeneca Canada Inc v Apotex Inc, 2014 FC 638 at para 90, (Appellants' Record V1, Part 1, T1) citing Eli Lilly Canada Inc v Novopharm Limited, 2010 FCA 197 at para 76 (ABoA, V1, T18).

would effectively read the word useful out of the *Patent Act*.

- 25. The word "scintilla" in patent law was traditionally used in the phrase "scintilla of invention" to refer to the minimum quantum of inventiveness (non-obviousness) required. Harold Fox seems to be the first to reference "scintilla of utility" as the quantum of utility subject-matter must have: "no particular quantum of utility is necessary; and a mere scintilla of utility is sufficient for validity". 20
- 26. Courts began citing Fox for the proposition that a scintilla is enough utility in 2005 in Aventis Pharma Inc v Apotex Inc. 21 It was more recently—in an academic blog, and in an international trade dispute that the so-called promised doctrine was criticized as new and different from the standard of a scintilla.<sup>22</sup> It is important, however, not to conflate how much usefulness is enough for a patentable invention and what the invention must be useful for. How useful an invention must be (the quantum) is a different question than what usefulness an invention must have (the promise).
- 27. The Appellants' submit that unless a specific use is set out in a claim itself, 23 subject-matter is useful if it is not useless or not devoid of utility.<sup>24</sup> The phrase "not devoid of utility" is not present in the *Patent Act*. It has been derived from this Court's decision in *Monsanto*. <sup>25</sup> CIPP submits that *Monsanto* does not support such a diluted and meaningless utility standard.
- 28. The issue in *Monsanto* concerned compounds that science might later establish to be "devoid of utility" in the sense that those compounds would not inhibit the premature vulcanization of rubber, which was the invention's promised usefulness. Justice Pigeon did not mean the compounds might be devoid of a utility, in the abstract. He meant the compounds might be devoid of the utility indicated. This Court then examined whether the patentees' "prediction of utility", was sound and reasonable, but did not discuss the process through which the court had identified the promised utility.

<sup>&</sup>lt;sup>19</sup> Crosley Radio Corp v General Electric Co, [1935] Ex CR 190 at 195 (IBoA, V1, T3).

<sup>&</sup>lt;sup>20</sup> Harold G Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed (Toronto: Carswell, 1969) at 153 [emphasis in original] (IBoA, V1, T15).

<sup>&</sup>lt;sup>21</sup> Aventis Pharma Inc v Apotex Inc, 2005 FC 1283 at para 271 (IBoA, V1, T1).

Norman Siebrasse, "What is the Promise of the Patent?" (14 March, 2011), Sufficient Description (blog), online: <a href="http://www.sufficientdescription.com/2011/03/what-is-promise-of-patent.html">http://www.sufficientdescription.com/2011/03/what-is-promise-of-patent.html</a> (IBoA, V1, T21); Eli Lilly and Company v Government of Canada, "Government of Canada: Observations on Issues Raised in Amicus Submissions" at paras 15-17 (22 April 2016) UNCT/14/2 (Ch 11 Panel), online:

<sup>&</sup>lt;a href="https://icsid.worldbank.org/apps/ICSIDWEB/cases/Pages/casedetail.aspx?CaseNo=UNCT/14/2&tab=DOC">https://icsid.worldbank.org/apps/ICSIDWEB/cases/Pages/casedetail.aspx?CaseNo=UNCT/14/2&tab=DOC</a> (IBoA, V1, T13).

<sup>&</sup>lt;sup>23</sup> Appellants' Factum 86, 89, and 163.

<sup>&</sup>lt;sup>24</sup> Appellants' Factum at paras 61, 155.

29. The core problem with the "scintilla" standard is that it would entirely dilute the utility requirement. The core problem with the "not devoid of utility" standard is that it is tautological: It begs the question, *what* utility? In the abstract, every composition of matter and every process has *a* use, no matter how trivial. Reducing the standard of utility to "scintilla" or, alternatively, "not be devoid of utility" would mean the mere existence of the claimed subject-matter renders it useful. Parliament would not have put a word in section 2 of the *Patent Act* that has no practical meaning or effect.

#### Patent applicants often specify an invention's usefulness for strategic reasons.

- 30. This Court has acknowledged that there is no obligation upon applicants to describe an invention's utility.<sup>27</sup> Thus, the decision to disclose the demonstrated, predicted, or potential usefulness of subject-matter is sometimes more strategic than legal.
- 31. The simplest cases that might raise issues about utility are, as the Appellants allude, <sup>28</sup> new use claims. That is because a specific use is, by definition, stated e

necessarily in the claims. An applicant's statements about subject-matter's "use as contemplated" and the steps or methods enabling others to "use" the invention cannot be ignored by a skilled reader assessing how exactly the invention is "useful".

#### D. Canada's patent laws are consistent with foreign laws and international norms.

Canada's utility rules are consistent with its key trading partners' patent laws.

- 35. The Appellants describe the utility requirement in Canada as "out of step with the corresponding requirements in other major jurisdictions." CIPP submits that other jurisdictions apply legal doctrines with the effect of ensuring that a putative invention does what a patent applicant says it does.
- 36. Accepted comparative law methodology requires that when comparing law from different legal systems—such as from Canada, the United States, and under the European Patent Convention ("EPC")—one compares rules with similar *functions* rather than rules with similar *labels*. Rules have similar functions if they address the same underlying problem, even if they do so differently.
- 37. United States patent law ensures that an invention does what the applicant asserts it will do through the enablement requirement and non-obviousness analysis.<sup>32</sup> The EPC holds patent applicants to assertions of function through a combination of the technicality requirement and the inventive step analysis.<sup>33</sup> Despite different court procedures, rules of evidence, presumptions of validity, and methods of patent construction, all of Canada's trading partners' patent systems hold applicants to their statements about a putative invention's use.

Canada's utility rules are consistent with international norms and practices.

38. Beyond the lack of evidence on the record<sup>34</sup> to support a claim that Canada is out of step with other jurisdictions, there is no international consensus on how countries must address the issues raised in this

<sup>31</sup> Konrad Zweigert & Hein Kötz, *An Introduction to Comparative Law*, 3rd ed (Oxford: Oxford University Press, 1998) at 34, 39 [translated by Tony Weir] (IBoA, V1, T25); John Reitz, "How to do Comparative Law" (1998) 46:4 Am J Comp L 617 at 620–2 (IBoA, V1, T19).

<sup>34</sup> Respondents' Factum at para 131.

<sup>&</sup>lt;sup>30</sup> Appellants' Factum at para 134.

<sup>&</sup>lt;sup>32</sup> E Richard Gold & Michael Shortt, "The Promise of the Patent in Canada and Around the World" (2014) 30 CIPR 35 at 66–70 (ABoA, V3, T57); Jacob S Sherkow, "Patent Law's Reproducibility Paradox" (forthcoming 2017) 66 Duke LJ, online: <a href="http://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2735181">http://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2735181</a> (IBoA, V1, T20).

<sup>&</sup>lt;sup>33</sup> E Richard Gold & Michael Shortt, "The Promise of the Patent in Canada and Around the World" (2014) 30 CIPR 35 at 70–73 (ABoA, V3, T57); AIPPI, "Questionnaire Apotex Inc. v Sanofi-Aventis: Germany", online: AIPPI Amicus Brief Committee <a href="http://aippi.org/wp-content/uploads/2015/02/Answ\_Quest\_Q221\_Apotex\_Germany.pdf">http://aippi.org/wp-content/uploads/2015/02/Answ\_Quest\_Q221\_Apotex\_Germany.pdf</a> (IBoA, V1, T10).

appeal.<sup>35</sup> Rather, there is an international consensus that countries implement broad principles of patent law in a way that best advances their national interest. Variations in domestic patent law are normal.

39.

## PART VI.

V1 T17	Closest Trading Partner" (2016) 32 CIPR 1	
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IBoA V1 T19	John Reitz, "How to do ComparativLaw" (1998) 46:4 Am J Comp L 617	36
IBoA V1 T20	Jacob S Sherkow, "Patent Law's Reproducibility Paradox" (forthcoming 2017) 66 Duke LJ, online: <a href="http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2735181">http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2735181</a>	37
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IBoA V1 T23	WHO, WIPO, & WTO, Promoting Access to Medical Technologies and Innovation: Intersections betweenulptic health, interestual property and trade(Geneva: World Trade Organization, 2012)	38
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## PART VII. STATUTORY PROVISIONS

Patent Act, RSC 1985, c P-4

# Interpretation

### **Definitions**

2 In this Act, except as otherwise provided,

- 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.
- 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 nécessaire, le cas échéant, des diverses phases du procédé, de façon à distinguer l'invention en cause d'autres inventions.