SCC Court File No.: 35562

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

B E T W E E N:

APOTEX INC. and APOTEX PHARMACHEM INC.

Appellants
(Respondents)

– and –

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

Respondents
(Appellants)

– and –

FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE, CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES, CENTRE FOR INTELLECTUAL PROPERTY POLICY (CIPP), INTERNATIONAL ASSOCIATION FOR THE PROTECTION OF INTELLECTUAL PROPERTY (AIPPI), BIOTECANADA and CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

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TABLE OF CONTENTS

PART I. OVERVIEW

1. The Centre for Intellectual Property Policy (CIPP) invites the Court to consider precisely how the "patent bargain" underlying the *Patent Act*, RSC 1985, c P-4, "encourages innovation and advances science and technology."[1] CIPP submits that the "patent bargain" is a multidimensional concept that concerns not only inventors and the state, but also follow-on innovators, technology users and payers. A multidimensional understanding of the patent bargain would align this Court's patent jurisprudence with other intellectual property law[2] and help to balance various individual rights and social values.[3]

2. Multidimensional public interest principles inform and support CIPP's submissions that:

   A. Canadian patent law should be assessed functionally and holistically.
   B. Canada's utility rules are functionally consistent with international approaches.
   C. A holistic analysis of obviousness should consider all relevant factors, not one alone.

PART II. POSITION ON APPELLANTS' QUESTIONS

3. Without taking a position on whether the court below made any reversible errors, the intervener submits that an invention's utility is to be assessed on the basis of the applicant's voluntary statement of the invention's use and that the obviousness of the invention is to be determined holistically.

PART III. ARGUMENT

A. Canadian patent law should be assessed functionally and holistically.

4. The multidimensional patent bargain balances the rights and responsibilities of innovation system stakeholders: users must pay a fair share of the costs of innovation, patent applicants must not game the system and the public must receive the benefits promised in exchange for exclusive rights. Two principles help advance the patent bargain. First, to ensure fairness, one compares Canadian patent law to foreign systems and international norms through a *functional,* not formalistic, assessment. Second, maintaining domestic doctrinal coherence calls for a *holistic*, rather than piecemeal, analysis.

5. A *functional* assessment is especially important for comparative legal analyses. Leading texts explain

[1] *Teva Canada Ltd v Pfizer Canada Inc*, [2012] 3 SCR 625 at para 32.
[2] *Théberge v Galerie D'Art du Petit Champlain inc*, [2002] 2 SCR 336 at para 30.
[3] Jeremy Waldron, "From Authors to Copiers: Individual Rights and Social Values in Intellectual Property" (1992) 68:2 Chicago-Kent L Rev 841 at 862.

"functionality" as the "basic methodological principle for all of comparative law."[4] Courts comparing Canadian and foreign laws should look at what those laws do, not how they are labelled.

6. This Court has accepted the value of functional comparisons. In tort, both Justices La Forest and McLachlin (as she then was) drew on the comparative law insight that different legal systems may use different rules to solve the same problem with the same overall result.[5] Similarly, this Court recently adopted a functional comparison of foreign criminal laws.[6] A functional comparative analysis has also helped resolve an intellectual property case in the pharmaceutical industry. This Court noted that common law and civil law systems use the different doctrines of passing off and unfair competition to provide similarly effective protection for intellectual property.[7]

7. Judges deciding patent cases in general, and this case in particular, could benefit from a functional rather than formalistic comparative analysis. Canada's patent law is the result of its distinct history and courts' efforts to ensure, as stated by Justice Binnie in *Harvard College v Canada*, [2002] 4 SCR 45 at para 13, "that comparable jurisdictions with comparable intellectual property legislation arrive (to the extent permitted by the specifics of their own laws) at similar legal results."

8. As the specifics of countries' patent laws (e.g., patent claim construction, patentable subject-matter, presumptions of validity) vary considerably, international comparisons should be undertaken on a *holistic* basis. Adopting a holistic approach assists Canadian courts in preserving a coherent balance within patent law while ensuring functional consistency with overarching international principles.

9. The World Intellectual Property Organization (WIPO) Standing Committee on the Law of Patents cautioned against fragmented approaches: "the industrial applicability/utility requirement cannot be considered separately from other requirements."[8] The Supreme Court of the United States has also demonstrated a "holistic trend" in intellectual property law analyses.[9] CIPP submits that a holistic assessment of Canadian patent law is helpful and appropriate.

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[4] Konrad Zweigert & Hein Kötz, *An Introduction to Comparative Law*, 3rd ed (Oxford: Oxford University Press, 1998) at 34, 39 [translated by Tony Weir]; John Reitz, "How to do Comparative Law" (1988) 46:4 Am J Comp L 617 at 620-622.
[5] *Canadian National Railway Co v Norsk Pacific Steamship Co*, [1992] 1 SCR 1021 at 1079, 1143-1144. See also *Laferrière v Lawson*, [1991] 1 SCR 541 at 601-612.
[6] *R v Mabior*, [2012] 2 SCR 584 at para 50.
[7] *Ciba Geigy Canada Ltd v Apotex Inc*, [1992] 3 SCR 120 at 133.
[8] WIPO Standing Committee on the Law of Patents, "The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws" 2001 SCP5/Inf at para 24.
[9] Peter Lee, "Patent Law and the Two Cultures" (2010) 120 Yale LJ 2 at 46.

B. Canada's utility rules are functionally consistent with international approaches.

10. There are open questions about Canadian law on the invalidation of a patent for an invention that fails to do what the applicant promised.[10] This Court might helpfully answer those open questions. However, CIPP submits, this Court should not feel compelled to reach specific conclusions on the basis of a putative foreign or international legal standard. Endorsing longstanding jurisprudence that holds patent applicants to voluntary statements about an invention's use would keep Canadian law in line with its trading partners' laws and international laws. Canadian utility rules are consistent with both formal and informal international norms surrounding the substantive content of patentability requirements and are functionally equivalent to the patent laws of comparative jurisdictions viewed holistically.

1. No formal or informal international standards of utility or non-obviousness exist.

11. No international standards define the criteria for patentability.[11] Substantive requirements for novelty, utility/industrial applicability and non-obviousness/inventive step are not specified in international trade agreements such as the World Trade Organization *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS),[12] the *North American Free Trade Agreement* (NAFTA),[13] treaties such as the *Paris Convention for the Protection of Industrial Property*,[14] or procedural agreements such as the *Patent Cooperation Treaty* (PCT).[15]

12. The one attempt to harmonize substantive patent requirements, including utility, through the negotiation at WIPO of a Substantive Patent Law Treaty,[16] failed due to disagreements as to those requirements. Thus, the WIPO, the World Trade Organization (WTO), and World Health Organization (WHO) are clear: "There is no agreed international understanding about the definition and interpretation of these criteria. This creates important space for autonomous policymaking under applicable national and international law."[17]

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[10] E. Richard Gold & Michael Shortt, "The Promise of the Patent in Canada and Around the World" (2014) 30:1 CIPR 35 at 77-80 (corrected version).
[11] Jerome H Reichman, "Compliance of Canada's Utility Doctrine with International Minimum Standards of Patent Protection" (Remarks delivered at the 102nd Annual Meeting of American Society of International Law, 11 April 2014).
[12] Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, 1869 UNTS 299.
[13] 17 December, 1992, Can TS 1994 No 2.
[14] 20 March 1883, 828 UNTS 305.
[15] 19 June 1970, Can TS 1990 No 22.
[16] See WIPO, "Draft Substantive Patent Law Treaty", online: WIPO <www.wipo.int/patent-law/en/harmonization.htm>.
[17] WHO, WIPO & WTO, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health,*

13. There are at least two approaches to implementing international patent law. Under the Anglo-American approach, inventions must be new, non-obvious, useful, described and enabled. Under the *European Patent Convention* ("EPC"),[18] inventions must provide a technical solution to a technical problem, be new, make an inventive contribution, be capable of industrial application and be described and enabled. It is due to the diversity of approaches that there is no internationally standardized meaning of 'utility.'

2. A functional comparison of foreign laws reveals similarities in principles and results.

14. Consistent with international trade and other agreements, Canada's approach to utility is grounded in its *Patent Act.* As with its equivalents in 35 USC § 101 and Article 52(1) of the EPC, the Canadian *Patent Act* uses broad language. Parliament defined "invention" in section 2 as a "useful" art, process, machine, manufacture, composition of matter, or improvement. Paragraph 27(3)(*b*) of the *Act* requires an applicant to "set out clearly the … 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 … to make, construct, compound or use it." As in other jurisdictions, courts must interpret and apply the statutory language.

15. Recent discussion of the Canadian law of utility has caused much confusion. The creation of a straw-man 'promise' doctrine, and a supposedly heightened utility standard, muddles, rather than clarifies patent law. There are four fundamental problems with the straw-man critique of a promise doctrine:

    a) It presumes that the "invention" is the thing and/or process *per se* and not, as longstanding principle tells us, what the inventor states that thing and/or process does. As Lord Simmons in *May & Baker Ltd v Boots Pure Drug Co* (1950), 67 RPC 23 observed at 30, the point of describing the invention's utility "is to give subject matter to the invention."

    b) It imagines that an invention's utility might be judged against two different standards: what it really does, and what the applicant said it does. It further fails to explain how a court is to identify what the invention does other than through the inventor's own specification of utility.

Intellectual Property and Trade (Geneva: World Trade Organization, 2012) at 57.

[18] *Convention on the Grant of European Patents* ("European Patent Convention"), 5 October, 1973.

c) It effectively reads out the word 'useful' in the definition of invention by providing exclusive rights based on any use, however trivial (e.g., taking up space) or uninteresting (e.g., a meaningless process), whether known or unknown by the applicant.

d) It rewards guesswork rather than contributions of knowledge. "When one of the guesses later proved true, the 'inventor' would be rewarded the spoils instead of the party who demonstrated that the method actually worked," the United States Court of Appeals for the Federal Circuit (CAFC) explained in *Rasmusson v Smithkline Beecham*, 413 F (3d) 1318 at 1325 (Fed Cir 2005).

16. Awareness of these problems reveals why the CAFC has rejected arguments about allegedly heightened utility standards. *In re Fisher*, 421 F (3d) 1365 at 1369-1371 (Fed Cir 2005), the Court dismissed the applicant's argument that his invention was subjected to a 'heightened" utility requirement, holding that only one, rigorous standard applies.

17. The real issue in this Appeal is whether and how Canada's patent system should hold a patent applicant to the applicant's own voluntary statements about what an invention does, i.e. its usefulness. Canadian courts sometimes call these statements "promises" but the principle is more important than the label. A functional and holistic analysis of how different countries decide what an invention does—variously called its intended purpose, technical effect, or promised utility—and the extent to which the specification must support that use, shows internationally consistent outcomes respecting the multidimensional patent bargain.

18. Both the Trial Court (at para 174) and Court of Appeal (at para 71) found that the Respondents had, in fact, made voluntary statements about clopidgrel's use, although disagreeing on the statements' meaning and implications. This is not one of the rare cases where an applicant was silent on the invention's use.

19. Voluntary statements about usefulness are often made in patent specifications (including claims). Applicants may voluntarily state an invention's intended purpose to proactively overcome possible objections as to patentability, such as concerns about anticipation or obviousness. Ensuring that those voluntary assertions of an invention's purpose are known or predicted to be true prevents gaming of the patent system and ensures that the public obtains the benefit promised in exchange for exclusive rights.

i. United States patent law enforces promises through utility and enablement rules.

20. Courts in the United States evaluate an invention's use according to the applicant's own specification describing an intended purpose. "It is elementary," explained the United States Court of Customs and Patent Appeals in *Conner v Joris*, 241 F (2d) 944 at 947 (CCPA 1957), that an invention's utility is determined "pursuant to its intended purpose." While the invention's intended purpose may be inferred from the knowledge of a skilled reader, more often it is derived from the applicant's statements.

21. Whether the utility stated by the applicant meets the statutory standard depends, in the United States, on whether it is specific, substantial, and credible.[19] Once a court has identified the invention's purpose intended by the applicant, and determined that this purpose meets the minimum standard of utility, attention turns to the enablement requirement under 35 USC § 112. The specification must provide an evidentiary basis to support the invention's intended purpose. It must do "more than state a hypothesis and propose testing to determine the accuracy of that hypothesis," held the CAFC in *In re '318 Patent*, 2008-1594, 2009-1070 at 16 (Fed Cir 2009).

22. Because it is impossible to effectively enable use of an invention without describing what that use is, the utility and enablement analyses are complementary. *Petito v Puritan's Pride*, No 13 Civ 8074 PAE (SD NY 2014) is a recent example. Petito claimed a composition of compounds with enhanced chondroprotective activity and "also promised other benefits."[20] As no party contended that the promised benefits failed to meet the minimum standard of utility, analysis moved to enablement. In granting summary judgment that the patent was invalid, the court held: "Plaintiffs do not explain why a person of ordinary skill would have regarded the composition as described as useful. Instead, plaintiffs essentially state that such a person should defer to the application's conclusory claim that this is so."[21]

23. Cases such as *Petito*, *In re '318 Patent*, and others[22] show how tribunals in the United States find the 'promise' in the applicant's statement of intended purpose, and require that the specification, together with the skilled reader's general knowledge, provide an evidentiary basis for the person of ordinary skill to believe that the invention fulfills this promise.

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[19] See *In re Fisher*, 421 F (3d) 1365 at 1370-1372 (Fed Cir 2005); see also United States Patent and Trademark Office, *Manual of Patent Examining Procedure*, s 2107(II).
[20] *Petito v Puritan's Pride*, No 13 Civ 8074 PAE at 3 (SD NY 2014) .
[21] *Petito v Puritan's Pride*, No 13 Civ 8074 PAE at 23 (SD NY 2014) .
[22] See, e.g., *CreAgri Inc v Pinnaclife Inc*, No 11 CV 6635 LHK (ND Cal 2013); *Ex Parte Lars Breimer and Reinhard Von Roemeling*, 2011 WL 1211210 (Bd Pat App & Interf).

ii. European patent law holds applicants to their stated solutions to technical problems.

24. A functionally similar analysis under the EPC begins by determining the technical problem that the invention solves. As explained by the European Patent Office's (EPO) appellate board in case T 39/93, OJ 1997 134 at para 5.3.1, the skilled reader starts with the applicant's specification of the problem. In interpreting the specification, "alleged but unsupported advantages cannot be taken into consideration in respect of the determination of the problem to be solved," the board warned in T 1724/07 at para 2.2. It elaborated, in T 1329/04 at para 10, that "enumerating any and all putative functions of a given compound is not the same as providing technical evidence as regard a specific one."

25. If the specification does not provide supporting evidence for the advantages claimed, the board has clarified that the skilled reader will attempt to "reformulate the problem in a less ambitious manner" (T2184/10 at para 20) "as long as the problem can be clearly deduced by the skilled person from the application as originally filed" (T 386/89 at para 4.3). Where this cannot be done, the purported invention is "not a technical invention at all" explained the board in T 0939/92, OJ 1996 309 at para 2.5.1. For example, in T 0415/11 at paras 46.1, 53, the board struck down Novartis' claims over a preparation for a meningococcus vaccine, since the board could not "acknowledge that the problem is solved by the claimed subject-matter."

26. When the technical problem is reformulated less ambitiously than an applicant promised, the invention is often found to be obvious. Thus, the board found that pharmaceutical patent claims over a solution used in dialysis (T 1724/07 at para 2.7), a statin-aspirin combination (T 0107/08 at paras 2.2, 2.3.1), an aerosol formulation for delivering medications (T 0287/99 at paras 6.3, 8.2.6) and a new form of the drug Coversyl (T 1753/06 at paras 10.4, 10.9) did not satisfy the inventive step requirement on this basis. There are at least 10 additional examples in 2014 alone.[23]

27. In sum, under the EPC, a patent applicant must provide an evidentiary basis for the solution to the stated technical problem. In the absence of this evidence, either the 'invention' is not an invention at all, or the technical problem risks being reformulated so that the invention is obvious. Holistically, this system ensures that applicants do not overpromise on the usefulness of their inventions.

[23] T 2184/10 at paras 20.1, 23; T 0141/12 at paras 2.6, 2.8; T 2112/11 at paras 12, 15.1; T 1501/09 at paras 3.8, 3.10; T 1189/12 at paras 10, 13.2; T 2082/11 at paras 3.6.1, 3.8.3; T 0832/10 at paras 6, 9.4; T 0303/10 at paras 49, 54; T 0875/10 at paras 6, 8; and T 0447/10 at paras 4, 4.2.

iii. Commonwealth countries hold patent applicants to their promises of utility.

28. Canadian patent law is illustrative of the way that Commonwealth countries (with the exception of the United Kingdom (UK) which, since 1977, has adhered to the EPC) address voluntary statements about an invention's usefulness. While some early UK cases relied on legislative provisions holding a patent invalid if "obtained on a false suggestion or representation,"[24] Canadian law solely derives from a second and independent vein: whether the inventor provided a sufficient evidentiary basis to support or predict the invention's intended use.[25] Australian patent law has preserved both bases for invalidity—false suggestion and failure to meet the patent's promise—and continues to treat these as distinct and separable grounds.[26] New Zealand, like Canada, treats the failure to provide sufficient evidence of intended purposes as a ground for invalidity for want of utility.[27]

29. While, there is no obligation to expressly explain how an invention is useful,[28] an applicant who voluntary states the invention's intended use provides the basis for the utility analysis. "Two things must be described in the disclosures of a specification," explained President Thorson in *Minerals Separation North American Corporation v Noranda Mines, Ltd*, [1947] Ex CR 306 at 316, "one being the invention, and the other the operation or use of the invention contemplated by the inventor."

30. Although an invention, by definition, must be "useful," Canadian courts have not considered *how* useful it must be to warrant a patent. The Court of Appeal in Chancery provided some insight in *Badische Anilin und Soda Fabrik v Levinstein* (1885), 29 ChD 366 (CA) at 408, when it held that an invention that only provides a prospect for further research does not meet the standard. CIPP submits that an invention must be at least as useful as the patent applicant states it to be. Whether Canada should adopt the utility requirement of credibility, specificity and significance—as both Australia and New Zealand[29] have done to align with the United States—is a question not before the Court. Nor is the question before

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[24] See, e.g., *Patents Act, 1949* (UK), 12, 13 & 14 Geo VI, c 87, s 32(1)(j), recodifyng earlier law.
[25] For an extensive review of the history of asserted utility in Canada, see E. Richard Gold & Michael Shortt, "The Promise of the Patent in Canada and Around the World" (2014) 30:1 CIPR 35 at 49-57 (corrected version).
[26] *Pracdes Pty Ltd v Stanilite Electroncis Pty Ltd* (1995), 35 IPR 259 (Sup Ct NSW), recognized that a failed promise could either lead to invalidity for lack of utility (under then *Patents Act* s 100(1)(h), now s 138(3)(b)) or, alternatively, as being a false suggestion (under then *Patents Act* s 100(1)(k), now s 138(3)(d)). These are separate grounds, the latter involving a "material misrepresentation" (at 275).
[27] *Hammar Maskin AB v Steelbro New Zealand Limited*, [2010] NZCA 83 at para 76.
[28] *Consolboard Inc v MacMillan Bloedel*, [1981] 1 SCR 504 at 520; *Teva Canada v Pfizer Canada*, [2012] 3 SCR 625 at para 50.
[29] For New Zealand, *Patents Act 2013* (NZ), 2013/68, s 10. For Australia, see *Patents Act 1990* (AUS), 83 s 7A, as amended by *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*, 2012/35. The *Raising the Bar Act* implements, among other things, the *US-Australia Free Trade Agreement*, 43 ILM 1248, art 17.9(13) (18 May 2004).

the Court whether, in assessing the disclosure of utility, courts may consider post-filing evidence, which in both the United States and Europe is permitted only to buttress a *prima facie* conclusion of validity.[30]

31. In Canada, the specification together with a skilled reader's general knowledge must provide a basis to conclude that the invention's intended purpose is fulfilled. In cases involving predictions, the applicant must provide a line of reasoning and factual basis, properly disclosed. However, as explained by the Federal Court of Appeal in *Bell Helicopter v Eurocopter*, 2013 FCA 219 at para 155, where the "prediction is based on knowledge forming part of the common general knowledge and on a line of reasoning which would be apparent to the skilled person …, the requirements of disclosure may readily be met by simply describing the invention in sufficient detail such that it can be practiced."

32. Australian and New Zealand laws have the same overall effect: the invention must deliver the result promised in the specification.[31] That the invention serves another purpose is not relevant.[32] The use that the specification must facilitate is the use the applicant described, i.e. what the applicant promised.

iv. There is no evidence that outcomes in Canada are different than elsewhere.

33. While the outcomes of particular cases concerning the same invention may vary from country to country, there is no evidence on the record (nor any empirical research that suggests) that the pattern of outcomes is different in Canada than elsewhere. Indeed, there are many examples of patents that have been invalidated elsewhere, but remain valid in Canada.[33]

C. A holistic analysis of obviousness should consider all relevant factors, not one alone.

34. A holistic patentability analysis advances the public interest goal of a fair and balanced patent system by ensuring that both patent holders and those making use of technology can reasonably predict the outcome of cases. As the present Appeal illustrates—through the very different appreciations of the facts by the trial judge (at para 783) and the Court of Appeal (at para 80)—a focus on a single factor

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[30] In the United States, this was most recently discussed in *CreAgri v Pinnaclife*, No 11 CV 6635 LHK (ND Cal 2013), p. 32 (post-filing evidence is only admissible "to substantiate any doubts as to the asserted utility" where those test results "pertain to the accuracy of a statement already in the specification") citing *In re Brana*, 51 F (3d) 1560 at 1567 n 19 (Fed Cir 1995). In Europe, this is explained in T 1329/04 at para 12.

[31] *Pracdes Pty Ltd v Stanilite Electroncis Pty Ltd* (1995), 35 IPR 259 at 272-275 (Sup Ct NSW); *Hammar Maskin AB v Steelbro New Zealand Ltd*, [2010] NZCA 83 at para 76.

[32] *Pracdes Pty Ltd v Stanilite Electroncis Pty Ltd* (1995), 35 IPR 259 at 273 (Sup Ct NSW).

[33] See, e.g., Canadian Patents No 2415438, 2393298, 2420893 and 2446615, which remain valid in Canada despite the invalidity of their European or US counterparts as determined in T 1753/06, T 0415/11 and in *CreAgri* and in *Petito*.

makes the patent's validity uncertain and unpredictable. A holistic analysis ensures that every factor is relevant, and thus predictably relevant, even if given different weights.

35. This Court, in *Apotex Inc v Sanofi-Synthelabo Canada Inc*, [2008] 3 SCR 265, adopted a holistic approach to the law of obviousness. After aligning Canadian patent law with that of the US and UK through the inclusion of an 'obvious to try' test,[34] the Court expressly noted that this test was "only one factor to assist in the obviousness inquiry."[35] The Court cautioned courts to consider other "secondary considerations that [will] prove instructive,"[36] such as success in the market, motivation and awards.[37]

36. A recent decision of the CAFC illustrates how a holistic analysis of obviousness could operate.[38] The court rejected the argument that "a new chemical entity, as a matter of law, cannot be obvious when the claimed invention possesses unexpected properties."[39] Instead, it held, "unexpected results do not *per se* defeat, or prevent, the finding that a modification to a lead compound will yield expected, beneficial properties. Rather, as secondary considerations of non-obviousness, they come into play in determining 'the ultimate question of patentability'."[40] Taking into account a variety of factors—whether the compound selected was a lead compound, whether there was motivation for the research programme and whether the compound had unexpected properties and other indicia such as commercial success, long-felt need, and evidence of unexpected properties—the CAFC found the invention to be obvious.

PART IV. SUBMISSIONS ON COSTS

37. The CIPP does not seek costs, and submits that it should not be liable for any costs.

PART V. ORDER SOUGHT

38. The CIPP seeks no specific order or disposition of this Appeal. The CIPP requests permission to present oral submissions in support of its position.

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[34] *Apotex Inc v Sanofi-Synthelabo Inc*, [2008] 3 SCR 265 at paras 57-60, 68-69.
[35] *Apotex Inc v Sanofi-Synthelabo Inc*, [2008] 3 SCR 265 at para 64.
[36] *Apotex Inc v Sanofi-Synthelabo Inc*, [2008] 3 SCR 265 at para 63 quoting *KSR International Co v Teleflex Inc*, 127 US 1727 at 1739 (2007).
[37] *Apotex Inc v Sanofi-Synthelabo Inc*, [2008] 3 SCR 265 at para 67. This is in line with the patent law of the United States that requires that "all evidence relevant to obviousness or nonobviousness be considered, and be considered collectively." See *In re Cyclobenzaprine Hydrochloride Extended–Release Capsule Patent Litigation*, 676 F (3d) 1063 at 1078 (Fed Cir 2012).
[38] *Bristol-Myers Squibb Company v Teva Pharmaceuticals USA, Inc*, No 2013-1306 at 14 (Fed Cir 2014).
[39] *Bristol-Myers Squibb Company v Teva Pharmaceuticals USA, Inc*, No 2013-1306 at 14 (Fed Cir 2014).
[40] *Bristol-Myers Squibb Company v Teva Pharmaceuticals USA, Inc*, No 2013-1306 at 15 (Fed Cir 2014).

ALL OF WHICH IS RESPECTFULLY SUBMITTED THIS 15th day of September 2014.

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PART VI. TABLE OF AUTHORITIES

Authority **Reference in Argument**

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6	*Bristol-Myers Squibb Co v Teva Pharmaceuticals USA, Inc*, No 2013-1306 (Fed Cir 2014)	36
7	*Canadian National Railway Co v Norsk Pacific Steamship Co*, [1992] 1 SCR 1021	6
8	*Ciba Geigy Canada Ltd v Apotex Inc*, [1992] 3 SCR 120 at 133	6
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10	*Consolboard Inc v MacMillan Bloedel*, [1981] 1 SCR 504	29
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12	*Ex Parte Lars Breimer and Reinhard Von Roemeling*, 2011 WL 1211210 (Bd Pat App & Interf)	23
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14	*Harvard College v Canada*, [2002] 4 SCR 45	7
15	*In re '318 Patent*, 2008-1594, 2009-1070 (Fed Cir 2009)	21-23
16	*In re Cyclobenzaprine Hydrochloride Extended–Release Capsule Patent Litigation,* 676 F (3d) 1063 (Fed Cir 2012)	35
17	*In re Fisher*, 421 F (3d) 1365 (Fed Cir 2005)	16, 21
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19	*May & Baker Ltd v Boots Pure Drug Co* (1950), 67 RPC 23 (HL)	15
20	*Minerals Separation North American Corp v Noranda Mines Ltd*, [1947] Ex CR 306	29
21	*Petito v Puritan's Pride*, No 13 Civ 8074 PAE (SD NY 2014)	22-23, 33

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25	T 0107/08	26
26	T 0141/12	26
27	T 0287/99	26
28	T 0303/10	26
29	T 0415/11	25, 33
30	T 0447/10	26
31	T 0832/10	26
32	T 0875/10	26
33	T 0939/92, OJ 1996 309	25
34	T 39/93, OJ 1997 134	24
35	T 1189/12	26
36	T 1329/04	24, 30
37	T 1501/09	26
38	T 1724/07	24, 26
39	T 1753/06	26, 33
40	T 2082/11	26
41	T 2112/11	23, 26
42	T 2184/10	25-26
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46	E. Richard Gold & Michael Shortt, "The Promise of the Patent in Canada and Around the World" (2014) 30:1 CIPR 35 (corrected version)	10, 28
47	Peter Lee, "Patent Law and the Two Cultures" (2010) 120 Yale LJ 2	9

PART VII. STATUTORY PROVISIONS

United States Code Title 35 – Patents

35 USC § 101, Inventions Patentable
35 USC § 112, Specification

(Subsection (e) added Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-567 (S. 1948 sec. 4603); subsection (e) amended and subsections (f) - (j) added Sept. 16, 2011, Public Law 112-29, sec. 3(a) (effective March 16, 2013), 125 Stat. 284.)

35 U.S.C. 100 (pre-AIA) Definitions.

[Editor Note: Pre-AIA 35 U.S.C. 100(e) as set forth below is ***is not applicable*** *to any patent application subject to the first inventor to file provisions of the AIA (see* ***35 U.S.C. 100 (note)****). See* ***35 U.S.C. 100(e)-(j)*** *for the law otherwise applicable.]*

When used in this title unless the context otherwise indicates -

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(e) The term "third-party requester" means a person requesting ex parte reexamination under **section 302** or inter partes reexamination under **section 311** who is not the patent owner.

(Subsection (e) added Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-567 (S. 1948 sec. 4603).)

35 U.S.C. 101 Inventions patentable.

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

(Public Law 112-29, sec. 33, 125 Stat. 284 (Sept. 16, 2011) provided a limitation on the issuance of patents (see **AIA § 33**).)

35 U.S.C. 102 Conditions for patentability; novelty.

[Editor Note: Applicable to any patent application subject to the first inventor to file provisions of the AIA (see ***35 U.S.C. 100 (note)****). See* ***35 U.S.C. 102 (pre-AIA)*** *for the law otherwise applicable.]*

(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

(2) the claimed invention was described in a patent issued under section **151**, or in an application for patent published or deemed published under section **122(b)**, in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

(b) EXCEPTIONS.—

(1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—

(A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

(B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

(2) DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.—A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if—

(A) the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;

(B) the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

(C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

(c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.—Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—

(1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;

(2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(d) PATENTS AND PUBLISHED APPLICATIONS EFFECTIVE AS PRIOR ART.—For purposes of determining whether a patent or application for patent is prior art to a claimed invention under subsection (a)(2), such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application—

(1) if paragraph (2) does not apply, as of the actual filing date of the patent or the application for patent; or

(2) if the patent or application for patent is entitled to claim a right of priority under section **119**, **365(a)**, or **365(b)** or to claim the benefit of an earlier filing date under section **120**, **121**, or **365(c)**, based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.

(Amended July 28, 1972, Public Law 92-358, sec. 2, 86 Stat. 501; Nov. 14, 1975, Public Law 94-131, sec. 5, 89 Stat. 691; subsection (e) amended Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-565 (S. 1948 sec. 4505); subsection (g) amended Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-590 (S. 1948 sec. 4806); subsection (e) amended Nov. 2, 2002, Public Law 107-273, sec. 13205, 116 Stat. 1903; amended Sept. 16, 2011, Public Law 112-29, sec. 3(b), 125 Stat. 284, effective March 16, 2013.*)

(Public Law 112-29, sec. 14, 125 Stat. 284 (Sept. 16, 2011) provided that tax strategies are deemed to be within the prior art (see **AIA § 14**).)

NOTE:** The provisions of **35 U.S.C. 102(g)**, as in effect on ***March 15, 2013, shall also apply to each claim of an application for patent, and any patent issued thereon, for which the first inventor to file provisions of the AIA apply (see **35 U.S.C. 100 (note)**), if such application or patent contains or contained at any time a claim to a claimed invention to which is ***not*** subject to the first inventor to file provisions of the AIA.]

35 U.S.C. 102 (pre-AIA) Conditions for patentability; novelty and loss of right to patent.

[Editor Note: With the exception of subsection (g)),* ***not applicable*** *to any patent application subject to the first inventor to file provisions of the AIA (see* ***35 U.S.C. 100 (note)****). See* ***35 U.S.C. 102*** *for the law otherwise applicable.]*

provisional application may be treated as an application filed under subsection (a). Subject to **section 119(e)(3)** of this title, if no such request is made, the provisional application shall be regarded as abandoned 12 months after the filing date of such application and shall not be subject to revival after such 12-month period.

(6) OTHER BASIS FOR PROVISIONAL APPLICATION.—Subject to all the conditions in this subsection and **section 119(e)** of this title, and as prescribed by the Director, an application for patent filed under subsection (a) may be treated as a provisional application for patent.

(7) NO RIGHT OF PRIORITY OR BENEFIT OF EARLIEST FILING DATE.—A provisional application shall not be entitled to the right of priority of any other application under **section 119** or **365(a)** of this title or to the benefit of an earlier filing date in the United States under **section 120**, **121**, or **365(c)** of this title.

(8) APPLICABLE PROVISIONS.—The provisions of this title relating to applications for patent shall apply to provisional applications for patent, except as otherwise provided, and except that provisional applications for patent shall not be subject to **sections 115**, **131**, **135**, and **157** of this title.

(Amended Aug. 27, 1982, Public Law 97-247, sec. 5, 96 Stat. 319; Dec. 8, 1994, Public Law 103-465, sec. 532(b)(3), 108 Stat. 4986; Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-582, 588 (S. 1948 secs. 4732(a)(10)(A), 4801(a)).)

35 U.S.C. 112 Specification.

*[Editor Note: Applicable to any patent application filed on or after September 16, 2012. See **35 U.S.C. 112 (pre-AIA)** for the law otherwise applicable.]*

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

(c) FORM.—A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

(d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

(e) REFERENCE IN MULTIPLE DEPENDENT FORM.—A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

(f) ELEMENT IN CLAIM FOR A COMBINATION.—An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

(Amended July 24, 1965, Public Law 89-83, sec. 9, 79 Stat. 261; Nov. 14, 1975, Public Law 94-131, sec. 7, 89 Stat. 691; amended Sept. 16, 2011, Public Law 112-29, sec. 4(c), 125 Stat. 284, effective Sept. 16, 2012.)

35 U.S.C. 112 (pre-AIA) Specification.

*[Editor Note: **Not applicable** to any patent application filed on or after September 16, 2012. See **35 U.S.C. 112** for the law otherwise applicable.]*

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

(Amended July 24, 1965, Public Law 89-83, sec. 9, 79 Stat. 261; Nov. 14, 1975, Public Law 94-131, sec. 7, 89 Stat. 691.)

35 U.S.C. 113 Drawings.

The applicant shall furnish a drawing where necessary for the understanding of the subject matter sought to be patented. When the nature of such subject matter admits of illustration by a drawing and the applicant has not furnished such a drawing, the Director may require its submission within a time period of not less than two months from the sending of a notice thereof. Drawings submitted after the filing date of the application may not be used (i) to overcome any insufficiency of the specification due to lack of an enabling disclosure or otherwise inadequate disclosure therein, or (ii) to supplement the original disclosure thereof for the purpose of interpretation of the scope of any claim.

(Amended Nov. 14, 1975, Public Law 94-131, sec. 8, 89 Stat. 691; Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-582 (S. 1948 sec. 4732(a)(10)(A)).)

35 U.S.C. 114 Models, specimens.

The Director may require the applicant to furnish a model of convenient size to exhibit advantageously the several parts of his invention.

Convention on the Grant of European Patents (*European Patent Convention*), 5 October, 1973

Article 52(1)

ZWEITER TEIL
MATERIELLES PATENTRECHT

Kapitel I
Patentierbarkeit

Artikel 52[38, 39]
Patentierbare Erfindungen

(1) Europäische Patente werden für Erfindungen auf allen Gebieten der Technik erteilt, sofern sie neu sind, auf einer erfinderischen Tätigkeit beruhen und gewerblich anwendbar sind.

(2) Als Erfindungen im Sinne des Absatzes 1 werden insbesondere nicht angesehen:

a) Entdeckungen, wissenschaftliche Theorien und mathematische Methoden;

b) ästhetische Formschöpfungen;

c) Pläne, Regeln und Verfahren für gedankliche Tätigkeiten, für Spiele oder für geschäftliche Tätigkeiten sowie Programme für Datenverarbeitungsanlagen;

d) die Wiedergabe von Informationen.

(3) Absatz 2 steht der Patentierbarkeit der dort genannten Gegenstände oder Tätigkeiten nur insoweit entgegen, als sich die europäische Patentanmeldung oder das europäische Patent auf diese Gegenstände oder Tätigkeiten als solche bezieht.

PART II
SUBSTANTIVE PATENT LAW

Chapter I
Patentability

Article 52[38, 39]
Patentable inventions

(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

(3) Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

[38] Geändert durch die Akte zur Revision des Europäischen Patentübereinkommens vom 29.11.2000.
[39] Siehe hierzu Entscheidungen der Großen Beschwerdekammer G 1/98, G 1/03, G 2/03, G 3/08 (Anhang I).

[38] Amended by the Act revising the European Patent Convention of 29.11.2000.
[39] See decisions of the Enlarged Board of Appeal G 1/98, G 1/03, G 2/03, G 3/08 (Annex I).

DEUXIEME PARTIE
DROIT DES BREVETS

Chapitre I
Brevetabilité

Article 52[38, 39]
Inventions brevetables

Art. 54, 56, 57, 100, 138
R. 26, 27, 29

(1) Les brevets européens sont délivrés pour toute invention dans tous les domaines technologiques, à condition qu'elle soit nouvelle, qu'elle implique une activité inventive et qu'elle soit susceptible d'application industrielle.

(2) Ne sont pas considérés comme des inventions au sens du paragraphe 1 notamment :

a) les découvertes, les théories scientifiques et les méthodes mathématiques ;

b) les créations esthétiques ;

c) les plans, principes et méthodes dans l'exercice d'activités intellectuelles, en matière de jeu ou dans le domaine des activités économiques, ainsi que les programmes d'ordinateur ;

d) les présentations d'informations.

(3) Le paragraphe 2 n'exclut la brevetabilité des éléments qu'il énumère que dans la mesure où la demande de brevet européen ou le brevet européen concerne l'un de ces éléments, considéré en tant que tel.

[38] Modifié par l'acte portant révision de la Convention sur le brevet européen en date du 29.11.2000.
[39] Cf. les décisions de la Grande Chambre de recours G 1/98, G 1/03, G 2/03, G 3/08 (Annexe I).

Patent Act, RSC 1985, c P-4

section 2
paragraph 27(3)(b)

Publication and printing of documents

(2) The Commissioner may publish any document open to the inspection of the public under section 10 and may print or cause to be printed, for distribution or sale, any such document.

R.S., 1985, c. 33 (3rd Supp.), s. 7.

Publication

(2) Le commissaire peut faire publier pour vente ou distribution tout document accessible pour consultation sous le régime de l'article 10.

L.R. (1985), ch. 33 (3e suppl.), art. 7.

APPLICATION FOR PATENTS

DEMANDES DE BREVETS

Commissioner may grant patents

27. (1) The Commissioner shall grant a patent for an invention to the inventor or the inventor's legal representative if an application for the patent in Canada is filed in accordance with this Act and all other requirements for the issuance of a patent under this Act are met.

Délivrance de brevet

27. (1) Le commissaire accorde un brevet d'invention à l'inventeur ou à son représentant légal si la demande de brevet est déposée conformément à la présente loi et si les autres conditions de celle-ci sont remplies.

Application requirements

(2) The prescribed application fee must be paid and the application must be filed in accordance with the regulations by the inventor or the inventor's legal representative and the application must contain a petition and a specification of the invention.

Dépôt de la demande

(2) L'inventeur ou son représentant légal doit déposer, en la forme réglementaire, une demande accompagnée d'une pétition et du mémoire descriptif de l'invention et payer les taxes réglementaires.

Specification

(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 descriptif

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

Claims

(4) The specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.

Revendications

(4) Le mémoire descriptif se termine par une ou plusieurs revendications définissant distinctement et en des termes explicites l'objet de l'invention dont le demandeur revendique la propriété ou le privilège exclusif.

Alternative definition of subject-matter

(5) For greater certainty, where a claim defines the subject-matter of an invention in the

Variantes

(5) Il est entendu que, pour l'application des articles 2, 28.1 à 28.3 et 78.3, si une revendica-

Patents Act, 1949 (UK), 12, 13 & 14 Geo VI, c 87

paragraph 32(1)(j)

Revocation and surrender of patents

Revocation of patent by court.

32.—(1) Subject to the provisions of this Act, a patent may, on the petition of any person interested, be revoked by the court on any of the following grounds, that is to say,—

(*a*) that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in the United Kingdom;

(*b*) that the patent was granted on the application of a person not entitled under the provisions of this Act to apply therefor;

(*c*) that the patent was obtained in contravention of the rights of the petitioner or any person under or through whom he claims;

(*d*) that the subject of any claim of the complete specification is not an invention within the meaning of this Act;

(*e*) that the invention, so far as claimed in any claim of the complete specification, is not new having regard to what was known or used, before the priority date of the claim, in the United Kingdom;

(*f*) that the invention, so far as claimed in any claim of the complete specification, is obvious and does not involve any inventive step having regard to what was known or used, before the priority date of the claim, in the United Kingdom;

(*g*) that the invention, so far as claimed in any claim of the complete specification, is not useful;

(*h*) that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, or does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection;

(*i*) that the scope of any claim of the complete specification is not sufficiently and clearly defined or that any claim of the complete specification is not fairly based on the matter disclosed in the specification;

(*j*) that the patent was obtained on a false suggestion or representation;

(*k*) that the primary or intended use or exercise of the invention is contrary to law;

(*l*) that the invention, so far as claimed in any claim of the complete specification, was secretly used in the United Kingdom, otherwise that as mentioned in subsection (2) of this section, before the priority date of that claim.

28

Patents Act 1990 (AUS), 83

section 7A

ways that make no substantial contribution to the working of the invention.

(5) For the purposes of subsection (4), the information is of the following kinds:

(a) prior art information made publicly available in a single document or through doing a single act;

(b) prior art information made publicly available in 2 or more related documents, or through doing 2 or more related acts, if the relationship between the documents or acts is such that a person skilled in the relevant art would treat them as a single source of that information.

(6) For the purposes of subsection (4), each kind of information set out in subsection (5) must be considered separately.

[*Notes: (1) For the meaning of* ***document*** *see section 2B of the Acts Interpretation Act 1901.*

(2) See also the definitions of ***prior art base*** *and* ***prior art information*** *in Schedule 1: see also paragraph 18(1)(b) and section 98.*]

7A Meaning of useful

(1) For the purposes of this Act, an invention is taken not to be useful unless a specific, substantial and credible use for the invention (so far as claimed) is disclosed in the complete specification.

(2) The disclosure in the complete specification must be sufficient for that specific, substantial and credible use to be appreciated by a person skilled in the relevant art.

(3) Subsection (1) does not otherwise affect the meaning of the word ***useful*** in this Act.

9 Secret use

For the purposes of this Act, the following acts are not to be taken to be secret use of an invention in the patent area:

(a) any use of the invention by or on behalf of, or with the authority of, the patentee or nominated person, or his or her

Patents Act 2013 (NZ), 2013/68

section 10

ferred to in subparagraphs (i) and (ii) and during the period of the exhibition, by any person without the consent of the inventor:

(e) that disclosure was due to, or made in consequence of, the invention being publicly worked, at any time during the 1-year period immediately preceding the filing date of the patent application, by any of the following persons if the working was effected for the purpose of reasonable trial only and if it was reasonably necessary, having regard to the nature of the invention, that the working for that purpose should be effected in public:

(i) the patentee or nominated person:

(ii) any person from whom the patentee or nominated person derives title:

(iii) any person with the consent of the patentee or nominated person:

(iv) any person with the consent of any person from whom the patentee or nominated person derives title.

(2) For the purposes of this section,—

inventor, in relation to an invention,—

(a) means the actual deviser of the invention; and

(b) includes any owner of the invention at the relevant time

specified exhibition means an exhibition (whether held in New Zealand or elsewhere) that is declared to be an international or industrial exhibition by the Commissioner in a notice that is publicly notified.

Compare: 1953 No 64 s 60; Patents Act 1977 s 2(4), (5) (UK)

10 Meaning of useful

An invention, so far as claimed in a claim, is **useful** if the invention has a specific, credible, and substantial utility.

11 Computer programs

(1) A computer program is not an invention and not a manner of manufacture for the purposes of this Act.

(2) Subsection (1) prevents anything from being an invention or a manner of manufacture for the purposes of this Act only to