Federal Court  Cour fédérale

20101022

Docket: T-1544-08

Citation: 2010 FC 1042

Ottawa, Ontario, October 22, 2010

PRESENT: The Honourable Mr. Justice O'Reilly

BETWEEN:

MERCK & CO. INC. AND
MERCK FROSST CANADA LTD.

Applicants

and

THE MINISTER OF HEALTH
AND APOTEX INC.

Respondents

REASONS FOR JUDGMENT AND JUDGMENT

I. Overview

[1] The applicant, Merck, asks me to order the Minister of Health not to issue a Notice of Compliance (NOC) to Apotex Inc. Merck relies on s. 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133. The NOC would permit Apotex to market a drug which combines two active ingredients, dorzolamide and timolol, used in the treatment of glaucoma. Merck currently markets a product containing those agents under the name “Cosopt”. Merck maintains that the Minister should not issue an NOC to Apotex until the expiry of two patents,

Canadian Patent No. 1,329,211 – the ‘211 patent, and Canadian Patent No. 2,065,965 – the ‘965 patent.

[2] In a companion case (T-1545-08), I found that Merck had not established that Apotex’s allegation of invalidity with respect to the ‘211 patent was unjustified and, therefore, denied Merck’s request for an order prohibiting the Minister from issuing Apotex an NOC based on the ‘211 patent. The parties agree that that outcome applies here as well. Therefore, the sole remaining question is whether Merck is entitled to an order prohibiting the Minister from issuing an NOC to Apotex based on Merck’s ‘965 patent.

[3] Apotex suggests that the putative invention in the ‘965 patent was anticipated in three earlier publications. In the alternative, Apotex argues that what Merck maintains is the real invention of the ‘965 patent, the co-formulation of dorzolamide and timolol, was obvious. Finally, Apotex submits that Merck acquired the ‘965 patent by virtue of a material misrepresentation to the patent office and, therefore, that the patent is invalid.

[4] The burden is on Merck to show that Apotex’s allegations are unjustified. I conclude that Merck has not met its burden in respect of Apotex’s first two allegations. Therefore, I must deny Merck’s request for an order of prohibition. In particular, I have found that part of the ‘965 was anticipated; the remainder was obvious. Apotex’s allegation of misrepresentation is unjustified.

[5] Therefore, the issues are:

1. Was the subject matter of the ‘965 patent anticipated by an earlier publication?
2. Is the alleged invention in the ‘965 patent obvious?
3. Did Merck acquire the ‘965 patent by a material misrepresentation?

II. Factual Background

(a) The invention

[6] Glaucoma is a visual impairment resulting from progressive damage to the optic nerve caused primarily by elevated intra-ocular pressure (IOP). IOP results from an excess of liquid, called aqueous humour, in the eye.

[7] Before it acquired the ‘965 patent, Merck scientists had been working on treatments for glaucoma for some time. Timolol, a ß-adrenergic antagonist (beta blocker), which could be applied topically, was effective for many, but not all, glaucoma patients. To help those patients who did not respond to timolol, Merck experimented with combining timolol with another drug, for example, pilocarpine. Those two particular compounds could not be combined in a single solution because their pH values were different. So, they had to be taken one after the other. Merck also experimented with timolol in combination with orally-administered carbonic anhydrase inhibitors (CAIs) but those compounds produced unwanted side effects.

[8] In the early 1990s, Merck found that the carbonic anhydrase inhibitor dorzolamide could, like timolol, be administered by drops. In due course, they tried combining the two ingredients in a single formulation. The result was the 2% dorzolamide, 0.5% timolol solution that is the essence of Merck's Cosopt product.

[9] The '965 patent, which issued in 1998, is entitled "Ophthalmic Compositions Comprising Combinations of a Carbonic Anhydrase Inhibitor and a ß-Adrenergic Antagonist". The summary refers to "novel ophthalmic compositions comprising a topical carbonic anhydrase inhibitor . . . and a ß-adrenergic antagonist" to be used in the treatment of ocular hypertension and glaucoma.

[10] The background section of the '965 patent explains that ß-adrenergic antagonists (beta blockers), especially timolol, are generally effective in treating glaucoma by way of topically-administered drops. However, beta blockers are not effective in some patients. Another form of therapy involves use of a carbonic anhydrase inhibitor (CAI). These had been used as an oral medicament and carried an array of side effects. However, a topical CAI had been disclosed in a US patent, and in a publication, as will be discussed below.

[11] The '965 patent goes on to note that the combination of a CAI with a beta blocker reduces IOP more than either drug alone. CAIs, such as dorzolamide, reduce IOP by inhibiting the production of aqueous humour in the eye. Beta blockers, such as timolol, decrease the flow of aqueous humour into the eye.

[12] The patent notes that one problem with the topical CAIs is that they usually have to be given three times a day to be effective. On the other hand, timolol can be given twice a day. Taking the two in combination could, therefore, be complicated for patients. However, given that the two ingredients have an additive effect, patients taking both products need only administer drops twice a day. As the '965 patent states, "[t]he combination of this invention maintains the desired lowering of intra-ocular pressure for a full twelve hours" resulting in greater patient compliance.

[13] The patent notes that the two ingredients could be taken separately, one after the other, or together in one solution. It makes clear, though, that the "use of a single solution containing both active medicaments is preferred."

[14] The patent includes 33 examples of the invention. The first is a solution comprising dorzolamide and timolol. The last is a report of a study in which dorzolamide and timolol were administered to patients with elevated IOP. Patients took a drop of 0.5% timolol at 8:00 am and at 8:00 pm. Ten minutes after each application, they took a drop of 2% dorzolamide. The results showed a reduction of IOP of between 13% and 21%. This study was previously authored by George Nardin, *et al*. and is discussed below in relation to the issues of anticipation and obviousness.

[15] All of the other examples in the patent describe co-formulations of CAIs and beta blockers. In each of the co-formulation examples, the pH of the end product is between 5.0 and 6.0.

[16] In the claims section of the ‘965 patent, the inventors claim a topical ophthalmic co-formulation of a CAI (including dorzolamide) and a beta blocker (including timolol) in a range of respective concentrations (Claims 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12). The specific concentration of 2% CAI and 0.5% beta blocker is set out in Claim 13. The patent also claims use of the co-formulation to reduce IOP for 12 hours and, accordingly, in twice-daily administration (Claim 3). The patent claims topical compounds in the form of a solution, gel, ointment, suspension or solid insert (Claim 15). Taken together, the claims cover the dorzolamide/timolol co-formulation in concentrations of 2% and 0.5% respectively, in a topical solution for twice-daily administration – in other words, the Cosopt product – but none is so narrow as to identify the specific ingredients in Cosopt, their respective concentrations, the other non-active compounds, or the resulting pH.

[17] Claims 16 to 20 of the patent cover use of a CAI “in conjunction with” a beta blocker for the treatment of IOP in patients who do not respond to the beta blocker alone. Claim 20 relates to separate formulations of a CAI and a beta blocker; Claim 21 claims the use of Claim 20. Claims 22 and 23 involve use of timolol.

III. Construing the ‘965 Patent

[18] In my view, a person skilled in the art of the subject matter of the ‘965 patent would include an ophthalmologist who is familiar with medicinal chemistry and pharmaceutical formulations and who has experience in the treatment of glaucoma. I must construe the patent through the eyes of that fictional person. In doing so, I must consider the whole of the patent to determine what, according to

the skilled person, is claimed by the inventors. The object is to identify the essential elements of the invention (*Whirlpool Corp.* v. *Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 at 1091). The patent is to be construed as of its date of publication, in this case, October 18, 1992.

[19] Merck maintains that the co-formulation of a CAI and a beta blocker as set out in Claims 1 to 15 of the patent is an essential element of the invention.

[20] As mentioned, the '965 patent deals with the combination of a topical carbonic anhydrase inhibitor (*e.g.*, dorzolamide) with a topical beta-adrenergic antagonist (*e.g.*, timolol). A "combination" of active ingredients can mean either that the two products are taken separately or that they are taken together. The patent notes that when a CAI is taken with a beta blocker, "there is experienced an affect that reduces the IOP below that obtained by either medicament individually".

[21] The '965 patent notes expressly that the two products could be taken seriatum or in a single solution. The latter is described as the preferred approach. A specific embodiment of the invention described in the patent is a 2% - .5% co-formulation of the two active ingredients. Indeed, the '965 patent specifically claims a co-formulation of a CAI and a beta blocker.

[22] In my view, the putative invention described in the '965 patent is a combination of a CAI with a beta blocker to treat glaucoma, particularly in patients who do not respond to timolol alone. A combination is not necessarily a co-formulation. Nevertheless, as described above, many of the patent's claims are specifically addressed to a co-formulation of a CAI with a beta blocker. In my

view, co-formulation is an essential element of those claims. Others, namely the use claims (16-20), address both co-administration of the two agents and co-formulations. Co-formulation, therefore, is not an essential element of those claims. I note that the patent does not claim the co-administration of a CAI and a beta blocker *per se* – only the use of those agents in co-administration for the treatment of glaucoma.

[23] It is worth emphasizing that the precise nature of the co-formulation – that is, the other non-active ingredients and the resulting pH – is not an essential part of the invention. None of the claims refers to those aspects of the co-formulation. There is no discussion of any co-formulation difficulties or solutions in the patent.

i. Issue One – *Was the subject-matter of the '965 patent anticipated by an earlier publication?*

[24] The relevant date is the priority date of the '965 patent, April 17, 1991. The question is whether the subject-matter of the '965 patent had been anticipated by a public document, whether a publication or another patent, prior to that date. Anticipation includes both disclosure and enablement. A patent will be considered invalid only if the prior art permitted a skilled worker to understand what was disclosed without trial and error or experimentation (*Apotex Inc.* v. *Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 at para. 25). Further, if there is disclosure, one must then consider whether the skilled person would have been able to perform the invention, with some trial and error or experimentation, if necessary, in order to get it to work

(*Sanofi*, above, at para. 27). Justice Roger Hughes summarized the relevant requirements of anticipation as follows:

- For there to be anticipation, there must be both disclosure and enablement of the claimed invention.
- The disclosure does not have to be an "exact description" of the claimed invention. The disclosure must be sufficient so that when read by a person skilled in the art willing to understand what is being said, it can be understood without trial and error.
- If there is sufficient disclosure, what is disclosed must enable a person skilled in the art to carry out what is disclosed. A certain amount of trial and error experimentation of a kind normally expected may be carried out.
- If a person carrying out the prior disclosure would infringe the claim then the claim is anticipated.

(*Abbott Laboratories* v. *Canada (Minister of Health)*, 2008 FC 1359, 71 C.P.R. (4th) 237 at para. 75)

[25] Apotex alleges that the '965 patent was anticipated by three publications. The first is a short abstract by F.P. Gunning, *et al*. published in a journal called "International Ophthalmology" in 1991. The journal published abstracts from the 185th meeting of the Netherlands Ophthalmic Group. It is unclear whether the presentation took place before April 17, 1991. The abstract notes that the search for a topical CAI began as early as 1955. Merck had some success in this search in the late

1980s. Gunning states that “preliminary results indicate a better additive effect of MK-507 with timolol”. MK-507 was Merck’s internal designation for dorzolamide.

[26] Merck submits that this publication does not anticipate the ‘965 patent because it says nothing about co-formulation and it does not explicitly identify dorzolamide. Expert evidence submitted by the parties confirms that the Gunning abstract does not disclose a co-formulation of dorzolamide and timolol. Further, no particulars are given as to the concentration of the two medicaments, the dosing schedule, or the degree to which IOP was reduced.

[27] In my view, the Gunning abstract does not meet the test for disclosure. It did not contain enough information to lead a skilled person to the subject matter of the ‘965 patent.

[28] The second piece of prior art in issue is a European patent (No. 0,296,879) filed in 1988. The patent is similar to the ‘211 patent that is the subject of T-1545-08. It covers a genus of CAIs. The patent states that the “medicament in the novel topical ocular formulations comprises one of the novel compounds of this invention either alone or in combination with a ß-adrenergic blocking agent such a timolol”. It goes on to say that “[i]n such combinations the two active agents are present in approximately equal amounts.”

[29] Merck argues that the ‘879 patent does not anticipate the ‘965 patent because, again, it contains no information about dosing, concentrations, or the effect of combining the two ingredients. Merck also submits that, like Gunning, the ‘879 patent does not teach a co-formulation.

However, in my view, the possibility of co-formulation is at least alluded to in the ‘879 patent in the phrase “the two active agents are present in approximately equal amounts”. In any case, there is too little information in the ‘879 patent to lead a skilled person to the subject matter of the ‘965 patent and, therefore, the disclosure requirement is not met.

[30] The most important publication on the question of anticipation is another abstract, this one authored by George Nardin, *et al*., included in a book entitled “Investigative Ophthalmology and Visual Science Annual Meeting”, published in May 1991, but the abstract would have been distributed earlier. Merck concedes that Nardin is prior art for the purposes of this proceeding. Three of Nardin’s co-authors were Merck employees.

[31] Apotex argues that Nardin disclosed the invention of the ‘965 patent and that a skilled person would have been able, based on what was disclosed, to work the invention without difficulty. The Nardin abstract is entitled “Activity of the Topical CAI MK-507 bid When Added to Timolol bid”. The letters “bid” indicate twice-daily administration. As mentioned, a summary of the study is set out in Example 33 of the ‘965 patent. As described above, the abstract summarizes a study in which dorzolamide and timolol were administered to patients with elevated IOP. Patients took a drop of 0.5% timolol at 8:00 am and at 8:00 pm. Ten minutes after each application, they took a drop of 2% dorzolamide. The results showed a reduction of IOP between 13% and 21%.

[32] Merck maintains that Nardin does not identify dorzolamide, so it does not disclose the subject matter of the ‘965 patent. Further, Nardin’s study did not involve a co-formulation of

dorzolamide and timolol; clearly, the two ingredients were administered separately. No information is provided about how a co-formulation at the proper pH could be achieved and no data is provided about the effect of administering the two agents together. I agree.

[33] However, it is clear that Nardin discloses the concentrations of the two ingredients and data on the additive effect of the two agents in reducing IOP. To my mind, Nardin discloses and enables a skilled person to use the two medicaments in twice-daily administration for reduction of IOP, with dorzolamide in a 2% concentration and timolol in a 0.5% concentration. I accept that Nardin does not identify MK-507, but Merck has not provided any evidence that a skilled person would have been unable to determine that it was dorzolamide. The identity of MK-507, by chemical name and structure, was published well before the relevant date. Apotex points to a number of publications in support of its argument that dorzolamide was a known chemical (Supplementary Affidavit of Dr. Leibowitz, para. 33). Justice Floyd, in the U.K. suggested that there was a number of ways in which a skilled person could determine the identity of MK-507, including simply picking up the phone and calling a Merck scientist (*Teva UK Ltd.* v. *Merck & Co., Inc.*, [2009] EWHC 2952 (Pat), [2009] All E.R. (D) 136 (Dec) at para. 84). It was not a secret.

[34] To my mind, therefore, the use claims of the ‘965 were clearly anticipated by Nardin. The co-formulation claims, however, were not. The natural question that arises, however, is whether a co-formulation was obvious after Nardin.

V. Issue Two – *Is the alleged invention in the '965 patent obvious?*

[35] Again, the relevant date is the priority date, April 17, 1991.

[36] There is a four-part test for determining obviousness:

1. Identify the person skilled in the art and the relevant common general knowledge;
2. Identify the inventive concept of the claim in question or, if that cannot readily be done, construe it;
3. Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept;
4. Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps that would have been obvious to the skilled person or do they require a degree of invention?

(*Sanofi*, above, at para. 67)

(1) Step One – The Skilled Person

[37] As mentioned above, for purposes of the '965 patent, a person skilled in the art would be an ophthalmologist with experience in the treatment of glaucoma, and who is familiar with medicinal chemistry and pharmaceutical formulations. The common general knowledge of that person would include familiarity with the various treatments for glaucoma available at the relevant time, including beta blockers and orally administered CAIs, and the need in some cases to treat patients with more

than one agent. The person would also be conversant with the literature relating to topically administered CAIs, including dorzolamide. He or she would also have been aware of the contents of topical formulations and, especially, the need to arrive at a solution with a neutral, or near-neutral, pH value to ensure that it could be safely and comfortably used by patients. Further, the skilled person would have been aware of the importance of enhancing patient compliance, for example, by keeping the number of applications per day to a minimum (*e.g.*, twice daily).

(2) Step Two – The Inventive Concept

[38] As discussed above, the ‘965 claims a co-formulation of a CAI and a beta blocker, and the use of those agents, either by way of co-administration or co-formulation, in the treatment of glaucoma. Given my finding that co-administration of those agents was anticipated by Nardin, the relevant inventive step for this analysis is co-formulation.

(3) Step Three – The Differences

[39] No co-formulation of a CAI and a beta blocker was disclosed in prior art. However, as mentioned, the use of a CAI and a beta blocker in co-administration, indeed, the use of dorzolamide and timolol specifically, was disclosed by both Gunning and Nardin. The additive effect of co-administration was also disclosed in those publications. Merck’s expert, Dr. Serle, acknowledged that co-administration of two agents was a common practice in the treatment of glaucoma. So, for present purposes, I need only consider whether co-formulation amounted to an inventive step.

(4) Step Four – Was Co-formulation Obvious?

[40] In *Sanofi*, Justice Rothstein set out some additional factors to consider within this fourth step of the analysis (at para. 69, 70). This analysis is sometimes referred to as the "obvious to try" step:

- Is it more or less self-evident that what is being tried ought to work? Is there a finite number of identified predictable solutions known to skilled persons?
- What is the extent, nature and amount of effort required? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
- Is there a motive provided in the prior art to find the solution?
- The actual course of conduct that culminated in the invention.

[41] Merck argues that a co-formulation was not a predictable or obvious product of the prior art. Putting a CAI and a beta blocker in the same solution was, Merck says, a real invention. The prior art merely, at most, alerted the skilled worker to the possibility that a co-formulation might be possible which would not be enough to make it obvious (see *Apotex Inc.* v. *Pfizer*, 2009 FCA 8, 72 C.P.R. (4th) 141 at para. 29). At the time, there were no topical CAIs approved for clinical use, so a topical formulation for dorzolamide alone was not available on the market. A co-formulation of two agents for topical administration would have been several steps away.

[42] Merck's experts state that it might have been difficult to arrive at a co-formulation. Dr. Serle opined that issues such as solubility, penetration, and adverse interactions often arise in trying to achieve a co-formulation of two agents. In 1991, the focus was on achieving a good topical CAI. A co-formulation of a CAI and a beta blocker would have been "premature". She went on to state that it "took considerable ingenuity and effort to resolve these issues". Further, if a formulator tried to combine dorzolamide with timolol at neutral pH, he or she would fail. It was learned in 1995 that dorzolamide was unstable at neutral pH. A formulator would have had to alter the formulation, or the concentration of dorzolamide, to arrive at an effective and stable co-formulation.

[43] Dr. Sugrue stated that there were "unknowns" that had to be investigated, such as concentration, dosing schedule and the pharmaceutical formulation. Considerable experimentation would have been required, he believed. Further, he expressed surprise that a twice-daily administration of the co-formulation reduced IOP just as much as co-administration of dorzolamide at three times a day, along with timolol at twice a day.

[44] Merck also points out that the prior art references, specifically Gunning, the '879 patent and Nardin, were all disclosed to the patent examiner; still, the patent issued. Merck suggests that the examiner's conclusion that the patent was valid is entitled to some deference.

[45] With respect to the conclusion of Justice Floyd in the U.K. case that a co-formulation was obvious, Merck says that the test of obviousness he applied was different. Justice Floyd found that, after Nardin, a co-formulation would have been "a startlingly obvious thing to consider". That test,

Merck says, was rejected in *Sanofi*, above, in favour of an "obvious to try" test – "obvious to consider" would not be enough to render a patent invalid. Further, Justice Floyd considered whether a development team would have found the formulation exercise so difficult that it would have abandoned it. In Canada, by contrast, the question is simply whether prolonged and arduous experimentation was required or mere routine tests.

[46] In my view, Merck's submissions do not prove that Apotex's allegation of obviousness is unjustified.

[47] There is nothing in the patent itself that suggests that there was anything inventive about the co-formulation of a CAI and a beta blocker. No difficulties are mentioned. The patent sets out 32 different examples of co-formulation. Nothing suggests that co-formulation was as difficult as Merck's experts thought it might have been. I have no evidence before me as to the steps the inventors took to arrive at the co-formulation. In the circumstances, all indications seem to be that co-formulation was routine. I have no evidence from Merck about any difficulties or arduous experimentation being required to arrive at a co-formulation. Nor do I have any evidence of difficulty in arriving at an acceptable pH. Timolol had been formulated at a pH of 6.8, whereas dorzolamide was formulated at 6.0. In other words, the desired pH for a co-formulation could likely be found within that narrow range. Dr. Sugrue referred to the need for Merck to carry out "detailed studies" to achieve an appropriate co-formulation, but no evidence about those studies was provided.

[48] As for the alleged difficulty in co-formulating dorzolamide and timolol specifically, it must be noted that the patent does not claim that specific combination of agents, or specify any particular pH at which those two compounds should be combined. Further, the patent does not discuss any difficulties associated with co-formulating dorzolamide with timolol or teach how the co-formulation might be achieved. A fair reading of the patent, including the many examples of co-formulation, would lead a skilled reader to conclude that co-formulation was achieved by routine measures.

[49] While Merck's experts might have been surprised that dorzolamide could be effective when dosed twice daily with timolol instead of three times daily, this effect was clearly disclosed in both Gunning and Nardin. A skilled person would have expected the same effect in a co-formulation of the two agents.

[50] The fact that there was no topical formulation of dorzolamide on the market does not establish that such a formulation was unknown at the relevant time – several publications made reference to it, as did the '879 patent. Nor does that fact support the argument that a co-formulation with timolol would not have been obvious to the skilled person.

[51] As for deference to the patent examiner, it is not clear to me that deference is warranted under the Regulations (see *Aventis Pharma Inc.* v. *Apotex Inc.*, 2006 FCA 64, 46 C.P.R. (4th) at para.. 10). In any case, however, I am not satisfied that the examiner was directed to Nardin, the most significant piece of prior art. Nardin is cited in an almost illegible footnote in a publication

provided to the examiner by Merck. Under the circumstances, I think it is unlikely the examiner had any awareness of Nardin.

[52] I find, to use Justice Hughes' words, that in respect of co-formulation something was lacking in terms of anticipation. However, the gaps were readily filled when considering obviousness (*Shire Biochem Inc.* v. *Canada (Minister of Health)*, 2008 FC 538, 67 C.P.R. (4th) 94, at para. 78). In particular, I find it was more or less self-evident that a co-formulation would work as well as co-administration. No evidence of difficult or prolonged experimentation to achieve a co-formulation was tendered. Indeed, no evidence about the course of conduct leading to a co-formulation was provided. The prior art and the general common knowledge in the field would have motivated a skilled person to attempt to co-formulate dorzolamide and timolol. It was obvious.

VI Issue Three – *Did Merck acquire the '965 patent by a material misrepresentation?*

[53] The *Patent Act* provides that a patent is invalid if the patentee makes a material allegation to the patent examiner that is untrue and was wilfully made for the purpose of misleading the examiner.

[54] Apotex argues that Merck wilfully mislead the patent examiner in respect of a material issue. Apotex suggests that Merck caused the patent examiner to believe that the principal named inventor of the '965 patent, John J. Baldwin, discovered the additive effect of dorzolamide and timolol which allowed for a twice daily administration of dorzolamide in conjunction with timolol.

[55] Apotex submits that Merck knew that it was Nardin who had made this discovery and, therefore, one can infer that Merck intended to cause the examiner to believe otherwise. Apotex suggests that Merck's conduct - failing to disclose Nardin to the examiner explicitly (it was buried in a footnote) and then incorporating Nardin's results into Example 33 of the '965 patent – supports an inference that Merck wilfully mislead the examiner and caused the examiner to conclude that Baldwin, not Nardin, was the inventor.

[56] Apotex's argument would have had considerable force had I not already concluded that co-formulation of a CAI with a beta blocker was an essential element of many of the patent's claims, and that co-formulation was not anticipated by Nardin. Given my construction of the patent, I cannot conclude that failure to disclose Nardin explicitly to the examiner, or that the inclusion of Nardin's results in the '965 patent, should result in finding that Apotex's allegation of invalidity on this ground is justified. To my mind, Merck's communication with the patent examiner was not untruthful in respect of a material issue. Further I have no basis on which to conclude that it was made wilfully for the purpose of misleading the examiner.

[57] Therefore, I find that Apotex's allegation of invalidity based on s. 53 is not justified.

VII. Conclusion and Disposition

[58] Merck has failed to discharge its burden of proving that Apotex's allegations of invalidity in respect of the '965 patent are unjustified. Therefore, I must dismiss Merck's application, with costs.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. The application is dismissed with costs.

"James W. O'Reilly"
Judge

Annex “A”

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

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 untrue, 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 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.

Loi sur les brevets, L.R.C. 1985, ch. P-4

Nul en certains cas, ou valide en partie seulement

53. (1) Le brevet est nul si la pétition du demandeur, relative à ce brevet, contient quelque allégation importante qui n’est pas conforme à la vérité, ou si le mémoire descriptif et les dessins contiennent plus ou moins qu’il n’est nécessaire pour démontrer ce qu’ils sont censés démontrer, 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 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 copies authentiques de ce jugement. Une copie en est enregistrée et conservée dans les archives du Bureau, et l’autre est jointe au brevet et y est incorporée au moyen d’un renvoi.

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

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APPEARANCES:

Brian Daley Judith Robinson Kativa Ramamoorthy	FOR THE APPLICANTS
Andrew Brodkin Richard Naiberg	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

OGILVY RENAULT LLP Montreal, QC.	FOR THE APPLICANTS
GOODMANS LLP Toronto, ON.	FOR THE RESPONDENTS