Date: 20080320

Docket: A-79-07

Citation: 2008 FCA 108

CORAM: **LINDEN J.A.**
NADON J.A.
RYER J.A.

BETWEEN:

PFIZER CANADA INC.
and WARNER-LAMBERT COMPANY, LLC

Appellants

and

THE MINISTER OF HEALTH
and RANBAXY LABORATORIES LIMITED

Respondents

Heard at Ottawa, Ontario, on May 22, 2007.

Judgment delivered at Ottawa, Ontario, on March 20, 2008.

REASONS FOR JUDGMENT BY: NADON J.A.

CONCURRED IN BY: LINDEN J.A.
RYER J.A.

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REASONS FOR JUDGMENT

NADON J.

INTRODUCTION:

[1] This is an appeal from an Order of von Finckenstein J. of the Federal Court, 2007 FC 91, dated January 25, 2007, dismissing the application of Pfizer Canada Inc. and Warner-Lambert Company, LLC (collectively "Pfizer") made pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133, for an Order prohibiting the Minister of Health from issuing a Notice of Compliance ("NOC") to Ranbaxy Laboratories Limited ("Ranbaxy") with

respect to atorvastatin calcium until after the expiration of Canada Letters Patent No 2,021,546 (the "546 patent").

[2] Pfizer asks this Court to set aside the Order of von Finkenstein J. and to issue a prohibition order, with costs on the appeal and the application.

THE FACTS

[3] U.S. Patent 4,681,893 (the "893 patent") and its equivalent Canadian Letters Patent No. 1,268,768 (the "768 patent") cover a large class of cholesterol-lowering compounds called statins, which decrease the production of cholesterol in the human body by inhibiting HMG-CoA reductase, an enzyme involved in the biosynthesis of cholesterol.

[4] On April 29, 1997, the 546 patent was issued to Warner-Lambert Company, a predecessor of the appellant Warner-Lambert Company, LLC. The patent has a filing date of July 19, 1990 and a publication date of January 22, 1991. It expires on July 19, 2010.

[5] The 546 patent claims a selection of the compounds covered by the 893 and 768 patents. It contains 12 claims directed at the lactone, dihydroxy-acid and five pharmaceutically acceptable salts of atorvastatin.

[6] Atorvastatin is an enantiomer. Enantiomers are molecules having the same chemical structure but differing in terms of the three-dimensional arrangements of their atoms. Each

enantiomer is the non-superimposable mirror image of the other enantiomer. A racemic mixture or racemate is a 50/50 mixture of the two enantiomers of a molecule. Although enantiomers have the same physical, chemical and spectral properties, their biological properties are often different. In general, one enantiomer is biologically active while the other is inactive. As a result, the active enantiomer is generally two times more active than the racemate.

[7] The 546 and 768 patents are listed with respect to atorvastatin calcium 10 mg, 20mg, 40mg and 80 mg tablets (the calcium salt of atorvastatin) and marketed by Pfizer under the trade name LIPITOR.

[8] Ranbaxy filed an Abbreviated New Drug Submission ("ANDS") with the Minister, seeking a NOC for its drug product RAN-ATORVASTATIN, comparing it to LIPITOR for the purposes of demonstrating bioequivalence. In its ANDS, Ranbaxy referenced the 546 and the 768 patents, as required to by the Regulations.

[9] On January 31, 2005, Ranbaxy sent a Notice of Allegation ("NOA") to Pfizer, alleging that in making, using and selling its product, it would not infringe the 768 patent and that the 546 patent was invalid for obviousness, double patenting, insufficiency and anticipation.

[10] Pfizer responded to Ranbaxy's NOA by filing a Notice of Application on March 17, 2005, disputing the allegations found in the NOA and arguing that they were not justified.

THE DECISION BELOW

[11] On January 25, 2007, von Finkenstein J. dismissed Pfizer's prohibition application. First, he found that the allegation of non-infringement with respect to the 768 patent was not justified. That finding was not appealed by Ranbaxy. Second, with respect to the 546 patent, the Judge concluded that the patent was invalid because it did not meet the requirements of subsection 27(3) of the *Patent Act*, R.S.C. 1985, c. P-4 (the "Act").

[12] The Applications Judge began his examination of the allegations made against the 546 patent by construing claim 6 of the patent which claims the calcium salt of atorvastatin. Although claim 6 is the only claim at issue in these proceedings, claims 1, 2 and 6 are relevant and they read as follows:

> Claim 1:
>
> [R-(R*,R*)]-2-(4-fluorophenyl)-[β],[δ]-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)-cabonyl]-1H</u>pyrrole-1-heptanoic acid or (2R-trans)-5-(4-fluorophenyl)-2-(1-methylethyl-N,4-diphen yl-1-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1H-pyrrole-3-carboxamide; and pharmaceutically acceptable salts thereof.
>
> Claim 2:
>
> A compound of Claim 1 which is [R-(R*,R*)]-2-(4-fluorophenyl)-[β],[δ]-dihydroxy-5-((1-methylethyl)-3-phenyl-4-[(phenylamino)-cabonyl]-1H</u>pyrrole-1-heptanoic acid.
>
> Claim 6:
>
> The hemicalcium salt of the compound of Claim 2.

[13] In *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FC 1471 ("*Novopharm*") von Finkenstein J. was similarly called upon to construe claim 6 of the 546 patent. In that case, he simplified the relevant claims in the following manner (at paragraph 35):

> Fortunately, these complex formulae have been given simpler names such that Claims 1, 2 and 6 can be read more easily as follows:
>
> Claim 1: Atorvastatin acid or atorvastatin lactone; and pharmaceutically acceptable salts thereof;
>
> Claim 2: Atorvastatin acid.
>
> Claim 6: The hemicalcium salt of the compound of Claim 2.

[14] He then construed claim 6 as follows (at paragraph 44):

> Upon reading the patent, and taking into account the expert advice so as to read through the eyes of a person skilled in the art, the Court reads the disclosure as explaining the following:
>
> -- atorvastatin in its lactone form, its corresponding ring-opened acid form, and the pharmaceutically acceptable salts thereof is useful for lowering cholesterol levels in mammals, including humans.
>
> -- atorvastatin in its lactone form, its corresponding ring-opened acid form, and its pharmaceutically acceptable salts thereof provides an unexpected and surprising inhibition of cholesterol biosynthesis; unexpected in that it is a ten-fold increase over the inhibition provided by the racemic mixture. The data for this ten-fold increase comes from a CSI screen disclosed in the 893 Patent. All compounds for the CSI screen were prepared as described in the 893 Patent.
>
> -- the most preferred embodiment of the invention described in the 546 Patent is the hemicalcium salt of the atorvastatin acid.
>
> -- the compounds of the lactone form, the corresponding ring-opened acid form, and the pharmaceutically acceptable salts thereof all have generally equivalent utility.
>
> [Emphasis added]

[15] As von Finkenstein J. did not see any material difference between the evidence of the experts before him in *Novopharm*, above, and of those before him in the present matter, he accordingly adopted the same construction as in *Novopharm* (paragraph 62). Pursuant to that construction, the 546 patent promises a ten-fold increase in activity for atorvastatin in comparison to the racemic mixture. The calcium salt of atorvastatin is the preferred embodiment of the invention.

[16] After construing claim 6 of the 546 patent, the Judge turned to the allegation made by Ranbaxy in its NOA that the 546 patent did not fully and correctly describe the invention, contrary to subsection 27(3) of the Act. He therefore examined the data that Pfizer had obtained through two types of assays.

[17] The first type of assay is the Cholesterol Synthesis Inhibition (CSI) screen. It is an *in vitro* assay which measures the effect of a test compound on the entire cholesterol biosynthesis pathway. The ability of the compound to inhibit the reaction is expressed as the IC_{50} value, which represents the amount of test compound required to inhibit cholesterol biosynthesis by 50%. The lower the IC_{50}, the more potent the compound.

[18] The second type of assay is the Acute Inhibition of Cholesterol Synthesis (AICS) assay. It is an *in vivo* assay which measures the extent to which a test compound or its metabolites are absorbed, transported and ultimately active in the liver to inhibit cholesterol biosynthesis.

1. CSI Data

[19] The 546 patent refers to a single set of CSI data to support the claim of increased activity for atorvastatin in comparison to the racemate. The Applications Judge was of the view that the data could not be relied upon to support a claim of ten-fold increase in inhibition for two reasons. First, the data refers to the sodium salt of atorvastatin and not the calcium salt. It is therefore not possible to draw conclusions from one salt to another. Second, the alleged ten-fold increase is based on an averaging of data for the racemic salt collected across five different experiments. The averaging of CSI results for the atorvastatin racemate does not provide a scientifically meaningful result.

[20] Before the Applications Judge, Pfizer presented the results from the CSI 118 assay, which compares the calcium salt of atorvastatin to the racemic salt of atorvastatin. The Applications Judge found that the data could not be relied upon because the test compound was not completely dissolved in the stock solution. Without knowing the concentration of the test compound in the solution, it was not possible to quantify the results of the assay.

2. AICS Data

[21] Although the AICS data was not referred to in the 546 patent to support an increase in activity for atorvastatin, the applications judge nevertheless considered the data. It was a head-to-head comparison of the racemic calcium salt of atorvastatin against the calcium salt of atorvastatin. According to the Applications Judge, the AICS data was a reliable indicator of the inherent ability of atorvastatin calcium or its racemate to inhibit cholesterol synthesis. The data revealed an increase in activity for the calcium salt of atorvastatin that was only slightly more that two-fold that of the racemic salt of atorvastatin.

[22] According to the Applications Judge, the data did not substantiate the promise of a ten-fold increase in activity and, as a result, he concluded that the disclosure of the 546 patent was insufficient as it failed to comply with the requirements of subsection 27(3) of the Act:

> [122] While these cases undoubtedly set the bar for section 27(3) very low, Pfizer in this case has not vaulted over that low bar. In essence, the 546 Patent makes two assertions, one as to activity the other as to the preferred salt. The first assertion is that there is an unexpected and surprising inhibition of cholesterol biosynthesis because of the ten-fold increase in activity between atorvastatin calcium and the racemic calcium salt. However, from the evidence presented, this statement is incorrect. The only reliable data available, the AICS data, suggests an increase in activity barely over the expected two-fold when the racemate is resolved into its individual enantiomers. This is not anywhere close to ten-fold.
>
> [123] I fail to see how this amounts to 'correctly and fully describing the invention'. A patentee has an obligation to make truthful statements regarding the nature of the invention in the disclosure of the patent. This principle was discussed by Harold G. Fox in "The Canadian Law and Practice Relating to Letters Patent for Inventions", 4th ed. (Toronto: Carswell 1969) at 188:
>
> > If a word is used inaccurately, but the nature of its use appears sufficiently from the context, the patent will be good. Nor will a specification be construed as invalid if it possesses only small errors and inaccuracies that are in the nature of clerical errors, or amount only to such as the ordinary workman will recognize and correct. This rule does not apply, however, unless the errors and inaccuracies appear on the face of the specification. If they only appear after further experimentation, or if they amount to a false suggestion, even though immediately perceivable by the ordinary skilled workman, the specification will be insufficient. The patentee cannot rely on the skill and knowledge of the addressee to correct errors or false promises that he has inserted in the specification.
>
> [124] Here we clearly have an assertion of a ten-fold increased activity on the face of the specification. This false suggestion of a ten-fold increase in activity cannot be backed up by the data provided. Accordingly, I find the 546 Patent to be invalid for failing to meet the requirements of s. 27(3) of the Patent Act
>
> [Emphasis added]

[23] Before the applications judge, Ranbaxy also claimed that the 546 patent did not identify the physical properties of atorvastatin calcium that support the claim that it is the preferred embodiment of the invention, nor was there any data to support such a claim. Having found that the assertion of a ten-fold increase in activity was not correct, the applications judge did not find it necessary to test the assertion that the calcium salt of atorvastatin was the preferred embodiment of the invention.

[24] As the Applications Judge found that Pfizer did not prove that the allegation of insufficiency was unjustified, he did not consider the other allegations of invalidity raised by Ranbaxy in its NOA.

THE RELEVANT LEGISLATION

[25] Subsection 27(3) of the Act reads as follows:

(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.	(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.

THE ISSUES

[26] This appeal raises the following issues:

1. What is the applicable standard of review?
2. Did the Applications Judge err in dismissing the application for insufficiency?
3. Are the allegations of invalidity for obviousness, anticipation or double patenting justified?

PFIZER'S SUBMISSIONS

[27] Pfizer submits that the Applications Judge made the following errors:

1. He erroneously construed section 27(3) of the Act and ignored Supreme Court of Canada jurisprudence according to which a patent need not "describe in what respect the invention is new or in what way it is useful".
2. He misconstrued the teaching and promise of the patent. The patent promises that the enantiomer atorvastatin possesses a surprising and unexpected superior activity over the racemic mixture in inhibiting the synthesis of cholesterol. It does not promise a specific amount of increased activity. Although the patent includes data from the CSI assay which shows a ten-fold increase in activity, the CSI assay is an *in vitro* assay. There is no promise that *in vivo* atorvastatin calcium will have this level of increase in activity.

3. He erred in rejecting the CSI data, particularly the data from the CSI 118 assay, as being unreliable. The CSI 118 assay was the best data as it was the only head-to-head experiment comparing atorvastatin calcium to its corresponding racemic mixture and opposite enantiomer. This assay illustrates an approximate ten-fold increase in activity over its racemate *in vitro*. The applications judge should not have dismissed the data on the basis that a uniform suspension of the compound in the stock solution was not obtained. Pfizer's method did not require complete dissolution of the test compound. Ranbaxy did not provide the Court with any data to disprove the results of the CSI 118 or to contradict surprising and unexpected activity of atorvastatin, despite the fact that Ranbaxy had conducted its own tests.

4. He erred in relying on the AICS data. AICS is not a reliable indicator of the inherent or intrinsic potency of atorvastatin. It is an *in vivo* experiment which measures the bioavailability of a compound. Even if the AICS data could be relied upon, it shows the surprising activity of the calcium salt of atorvastatin versus its racemate. Whereas only a two-fold increase in activity could be expected, the AICS results revealed almost a three-fold increase in activity.

5. He failed to properly assess the expert evidence. His role was to weigh the evidence and make findings of fact. He failed to explain why he favoured the evidence of Ranbaxy's expert witnesses.

6. His findings are inconsistent with those made in the *Novopharm, supra*, proceedings where he held that the 546 patent was a valid selection patent with surprising and unexpected

advantages over the class from which it was selected. There is no material difference between the evidence in that case and in this case.

[28] Pfizer also submits that the other grounds of invalidity raised by Ranbaxy in its NOA are unjustified.

RANBAXY'S SUBMISSIONS

[29] Ranbaxy disagree with Pfizer's position and argues that the Applications Judge did not err in finding that the allegation of invalidity for insufficiency was justified.

1. He applied the correct legal test when considering the law of insufficiency.
2. He made no error in finding that the 546 patent promises that atorvastatin is ten-fold more active than its racemate.
3. He made no error in finding that the data before him did not support the promise of a ten-fold increase in activity.
4. He made no error in concluding that the 546 patent was insufficient on the basis that the promised ten-fold advantage did not exist.
5. His decision is not inconsistent with his earlier ruling in the *Novopharm, supra*, proceedings. There were marked differences between the records in the two cases.

[30] Ranbaxy further submits that the other allegations of invalidity set out in the NOA are justified.

ANALYSIS

1. What is the applicable standard of review?

[31] The characterization of the applicable legal test is a question of law, reviewable on the correctness standard: *Housen v. Nikolaisen*, [2002] 2 S.C.R. 235. The construction of a patent is also a question of law reviewable on the same standard: *Whirlpool v. Camco*, [2000] 2 S.C.R. 1067 at paragraph 76.

2. Did the Applications Judge err in dismissing the application for insufficiency?

[32] For the reasons that follow, I conclude that the Applications Judge was incorrect in dismissing Pfizer's application on the basis of insufficiency. He mischaracterized the scope of the disclosure requirement under subsection 27(3) of the Act and, in so doing, allowed Ranbaxy to attack, through an alternative means, the patent's utility, novelty and/or obviousness. His reasoning is inconsistent with the purpose of subsection 27(3).

(A) Disclosure requirement under the Act

[33] Subsection 27(3) of the Act provides that the specification of an invention (which includes both the disclosure and the claims in the patent) 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.

(i) Purpose of subsection 27(3):

[34] The disclosure requirement under the Act lies at the heart of the whole patent system: see *Consolboard Inv. v. MacMillan Bloedel (Saskatchewan) Ltd.*, [1981] 1 S.C.R. 504 at 517; *Pioneer Hi Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623 at paragraph 23. The granting of a patent is akin to a contract between the Crown and the inventor in which the latter receives an exclusive right to exploit his invention for a certain period in exchange for complete disclosure to the public of the invention and the way in which it operates: see *Pioneer Hi Bred, supra*, at paragraph 23. The description of the invention is therefore the *quid pro quo* for which the inventor is given a monopoly for a limited term of years on the invention: see *Consolboard, supra*, at 517. The Supreme Court has referred with approval (for example, in *Consolboard, supra*, at 517; in *Pioneer Hi Bred, supra*, at paragraph 23) to the following passage by Harold G. Fox in *Canadian Patent Law and Practice*, 4th ed. (1969) at p. 163:

> The consideration for the grant is double: first, there must be a new and useful invention, and secondly, the inventor must, in return for the grant of a patent, give to the public an adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired. The function of the description contained in the specification is both to enable the construction and use of the devices contained therein after the expiry of the patent, and also to enable others to ascertain with some measure of exactness the boundaries of the exclusive privilege upon which they may not trespass during the exercise of the grant.
>
> [Emphasis added]

(ii) Scope of subsection 27(3):

[35] In *Pioneer Hi Bred, supra*, at paragraph 27, the Supreme Court of Canada explained the scope of subsection 27(3) as follows:

> The applicant must disclose everything that is essential for the invention to function properly. To be complete, it must meet two conditions: it must describe the invention and define the way it is produced or built (Thorson P. in Minerals Separation North American Corp. v. Noranda Mines Ltd., [1947] Ex. C.R. 306, at p. 316). The applicant must define the nature of the invention and describe how it is put into operation. A failure to meet the first condition would invalidate the application for ambiguity, while a failure to meet the second invalidates it for insufficiency. The description must be such as to enable a person skilled in the art or the field of the invention to produce it using only the instructions contained in the disclosure (Pigeon J. in Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd., [1976] 1 S.C.R. 555, at p. 563; Monsanto Co. v. Commissioner of Patents, [1979] 2 S.C.R. 1108, at p. 1113) and once the monopoly period is over, to use the invention as successfully as the inventor could at the time of his application (Minerals Separation, supra, at p. 316).

[36] In *Hughes and Woodley on Patents*, 2nd ed., Volume 1, at 333, the authors describe the requirement that a disclosure be sufficient as follows:

> Insufficiency is directed to whether the specification is sufficient to enable a person skilled in the art to understand how the subject matter of the patent is to be made […] An allegation of insufficiency is a technical attack that should not operate to defeat a patent for a meritorious invention; such attack will succeed where a person skilled in the art could not put the invention into practice.
>
> [Emphasis added]

[37] Subsection 27(3) of the Act does not require that a patentee explain how well his invention works in comparison to other inventions. He is not required to describe in what respect his invention is new or useful, nor is he obliged to "extol the effect or advantage of his discovery, if he describes his invention so as to produce it": see *Consolboard, supra*, at 526.

(iii) Selection patents:

[38] The law with respect to selection patents was explained by this Court in *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FCA 214, where, at paragraphs 3 to 5, Malone J.A. stated:

> [3] There are two general classes of chemical patents. The first is the 'originating patent' where there is an originating invention involving the discovery of a new reaction or a new compound. The second is the 'selection patent', which is based on a selection from related compounds derived from the original compound and which have been described in general terms and claimed in the originating patent (see In the Matter *of I.G. Farbenindustrie A.G.'s Patents*, (1930) 47 R.P.C. 283 at page 321 per Maugham J.).
>
> [4] While there is little Canadian jurisprudence on the subject of selection patents, its elements are well defined in *I.G. Farbenindustrie*. Lord Diplock cited this decision with approval in the House of Lords where he stated that the 'inventive step in a selection patent lies in the discovery that one or more members of a previously known class of products possess some special advantage for a particular purpose which could not be predicted before the discovery was made' (see *Beecham Group Ltd. v. Bristol Laboratories International S.A.* [1978] R.P.C. 521 at page 579). All claimed members of the known class must have the advantage and the advantage must not be one that those skilled in the art would expect to find in a large number of the previously disclosed class (i.e. a quality of special character) (see *I.G. Farbenindustrie* at page 323).
>
> [5] Selection patents exist to encourage researchers to further use their inventive skills so as to discover new advantages for compounds within the known class. A selection patent can be claimed for a selection from a class of thousands or for a selection of one out of two (see for example *I.G. Farbenindustrie* at page 323 and *E.I. Dupont de Nemours & Co (Witsiepse's) Application*,[1982] F.S.R. 303 (H.L) at page 310).
>
> [Emphasis added]

[39] In *Beecham Group, supra*, at 579, Lord Diplock stated, in respect of selection patents, that "the *quid pro quo* for the monopoly granted to the inventor is the public disclosure by him in his specification of the special advantages that the selected members of the class possess" [Emphasis added]. This passage has been cited with approval by the Federal Court on a number of occasions:

see *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FC 1471, at paragraph 49; *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*, 2005 FC 390, at paragraph 56.

[40] Furthermore, in *Patent Law of Canada* (Gordon F. Henderson ed., Carswell Legal Publications, 1994), the learned authors write at page 211-212:

> When the invention consists of the selection of one or more members of a previously known group, based upon the discovery that the selected members have a previously unknown advantage over the others, the advantage must be disclosed in the specification in order to make full disclosure of the invention. As in other cases, however, what is claimed is not the advantage but the selected members. …
>
> [Emphasis added]

[41] Subsection 11.12 of the current edition of the *Manual of Patent Office Practice* has this to say on the topic of selection patents:

> A selection from members of a previously known class of substances may be patentable if the substance selected is unobvious and affords a new and useful result. There must be a special advantage arising from the selected substances and any advantage, novel property or use must be fully characterized in the description. The substance should be defined in an explicit manner within the claim.
>
> [Emphasis added]

[42] The above passages suggest that the disclosure requirement may be a bit more onerous for selection patents. This Court has considered selection patents in only two cases. It did not, however, in either case, suggest that a higher level of disclosure was required: see *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FCA 214; *Sanofi-Synthelabo Canada Inc. v. Apotex Inc*, 2006 FCA 421.

[43] In the present matter, von Finkenstein J. did not characterize the 546 patent as a selection patent. However, in the *Novopharm, supra*, proceedings, he did find that the 546 patent was a valid selection patent (at paragraph 96). Although the *Novopharm* decision was appealed and the case was heard by this Court, the parties settled the matter before a decision was rendered.

[44] In these proceedings, Pfizer asserts that the 546 patent is a selection patent. Ranbaxy, on the other hand, takes an entirely different view. At paragraph 13 of its Memorandum, it states:

> … Pfizer argues that claim 6 of the 546 Patent is a selection from the genus of compounds claimed in the 893 Patent. In making this argument, Pfizer disregards that the 893 Patent specifically claims, in claim 5, the lactone version of the racemate of atorvastatin.

[45] Ranbaxy's argument seems to be that the 546 patent is not a selection patent since it claims compounds covered by another patent. This position disregards the fact that selecting a narrow class of compounds covered by a genus patent is the very nature of the selection patent. Ranbaxy itself refers to the 546 patent as a selection later on its Memorandum, at paragraph 72:

> … Where an inventor has purported to make a selection based on a special advantage, the inventor must describe the special advantage that makes the invention novel over the prior art.

[46] In my opinion, there can be no doubt that the 546 patent is a selection patent. It covers the lactone, acid and pharmaceutically acceptable salts of atorvastatin, one of the many compounds covered by the 768 and 893 patents. The basis for the patent is that the compounds claimed therein display a special advantage, namely the surprising and unexpected inhibition of cholesterol

biosynthesis, i.e. greater than twofold. The calcium salt of atorvastatin, the compound specifically covered by claim 6, is the preferred embodiment of the invention: see 546 patent, Appeal Book, Volume 1, page 91.

(B) Disclosure in the 546 patent

[47] The paragraphs of the 546 patent which are relevant to the promise of an increase in inhibition of cholesterol biosynthesis for atorvastatin read as follows:

BACKGROUND OF THE INVENTION

[…]

Trans-([plus or minus])-5-(4-fluorophenyl)-2-(1-methylethyl)-N,4-diphenyl-1-[2-tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1H-pyrrole-3-carboxamide are among compounds of U,S. Patent No. 4,681,893 having usefulness as inhibitors of cholesterol biosynthesis. The compounds therein broadly include 4-hydroxypyran-2-ones and the corresponding ring-opened acids derived therefrom.

It is now unexpectedly found that the enantiomer having the R form of the ring-opened acid of trans-5-(4-fluorophenyl)-2-(1-methylethyl)-N,4-diphenyl-1-[2-tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1H-pyrrole-3-carboxamide; that is [R-(R*,R*)]-2-(4-fluorophenyl)-β, δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[phenyl amino)carbonyl]-1H-pyrrole-1-heptanoic acid, provides surprising inhibition of the biosynthesis of cholesterol (Appeal Book, Volume 1, p. 91).

[…]

However, an ordinarily skilled artisan may not predict the unexpected and surprising inhibition of cholesterol biosynthesis of the present invention in view of the disclosures in the prior art [Appeal Book, Volume 1, p. 92).

[…]

DETAILED DESCRIPTION OF THE INVENTION

[…]

The compounds according to the present invention and especially according to the compound of the formula I **inhibit the biosynthesis of cholesterol as found in the CSI screen that is disclosed in U.S. Patent No. 4,681,893**. The CSI data of the compound I, its enantiomer the compound II and the racemate of these two compounds are as follows:

COMPOUND	IC50(micromoles/liter)
[R-(R*R*)] isomer	0.0044
[S-(R*R*)]isomer	0.44
Racemate	0.045

Accordingly, the present invention is the pharmaceutical composition prepared from the compound of the formula I or II or pharmaceutically acceptable salts thereof.

These compounds are prepared as described in U.S. Patent No. 4,681,893 (Appeal Book, Volume 1, p. 99).

[Emphasis added]

[48] As to salt selection, the disclosure of the 546 patent provides:

Appropriate pharmaceutically acceptable salts within the scope of the invention are those derived from bases such as sodium hydroxide, potassium hydroxide, lithium hydroxide, calcium hydroxide, 1-deoxy-2(Methylamino)-D-glucitol, magnesium hydroxide, zinc hydroxide, aluminium hydroxide, ferrous or ferric hydroxide, ammonium hydroxide or organic amines such as N-methylglucamine, choline, arginine and the like. Preferably, the lithium, calcium, magnesium, aluminium and ferrous or ferric salts are prepared from the sodium or potassium salt by adding the appropriate reagent to a solution of the sodium or potassium salt, i.e., addition of calcium chloride to a solution of the sodium or potassium salt of the compound of the formula I will give the calcium salt thereof.

[…]

The most preferred embodiment of the present invention is [R-(R*R*)]-2-(4-fluorophenyl)-ß, δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenyl amino)carbonyl]-1H-pyrrole-1-heptanoic acid, hemicalcium salt (Appeal Book, Volume 1, page 95)

[Emphasis added]

(C) Allegations of insufficiency in the NOA

[49] In its NOA, Ranbaxy alleges that "the 546 patent is invalid on the basis of insufficient support" (Appeal Book, Volume 1, page 234). The relevant passages appear at pages 20 and 21 of the NOA (Appeal Book, Volume 1, pages 243 and 244):

> The disclosure of the 546 patent is not sufficient to correctly or fully describe the invention being claimed contrary to ss. 27(3) and 34(1) of the *Patent Act*, R.S.C. 1985, c. P-4 as amended. The disclosure does not support there being any novel or inventive aspect as claimed.
>
> The background in the 546 patent asserts at page 1, lines 14 to 22 that "it is now unexpectedly found that the enantiomer having the R form of the ring-opened acid of the [lactone]; that is [atorvastatin acid], provides surprising inhibition of the biosynthesis of cholesterol.
>
> The only support for the allegation that the described invention has surprising and unexpected properties is a single set of CSI data allegedly relating to the effectiveness of each of the two trans-enantiomers and the trans-racemate shown at page 8, lines 12 to 16, as follows:
>
> | COMPOUND | IC50(micromoles/liter) |
> |---|---|
> | [R-(R*R*)] isomer | 0.0044 |
> | [S-(R*R*)]isomer | 0.44 |
> | Racemate | 0.045 |
>
> Evidence presented in the U.S. trial, held at the end of 2004 in Delaware on the corresponding U.S. patent (5,273,995), by Dr. Scallen, showed that the above table is not representative of all the data collected by Pfizer, and also showed that the CSI experiments were not conducted properly. Ranbaxy relies on the non-confidential transcript of the evidence given by Dr. Scallen at the U.S. trial of *Pfizer, Inc., et al, v. Ranbaxy Laboratories et al.*, Court File number 03-209-JJF, on December 3, 2004.
>
> Dr. Scallen testified that the test results included in the 546 patent were limited to a non-representative, incomplete selection of *in vitro* CSI experiments. Specifically, Dr. Scallen testified that when all, or any, representative selection of the CSI experiments conducted by Pfizer are considered, the data as a whole showed tremendous variability, cannot draw scientifically valid conclusions from the data as a whole. In the words of Dr. Scallen, "one can't do science under those circumstances".

> Moreover, as explained Dr. Scallen, Pfizer has conducted more reliable *in vitro* AICS experiments which were not included in the 546 Patent. Dr. Scallen testified that these ACIS experiments showed an approximately two-fold difference between the racemate and the R-(R*R*) enantiomer. Dr. Scallen testified that his conclusions on the AICS data with conclusions drawn by Pfizer, in internal memoranda, after review of the same data. Dr. Scallen testified that his conclusions were consistent with the conclusions drawn by Pfizer that, as expected, the atorvastatin calcium is twofold more potent that the racemic calcium salt which contains 40% inactive isomer.
>
> Ranbaxy also notes that Pfizer did not call the Pfizer employee who conducted the AICS tests to testify at trial. That employee concluded, based on the two *in vivo* experiments, that the R-(R*R*) enantiomer was only twice as active as the racemate, and that the result was not surprising and unexpected.
>
> The inventor has access to all CSI, COR and AICS data and apparently chose only unrepresentative parts of that data to support the alleged "surprising" activity of the R enantiomer.
>
> [Emphasis added]

[50] Ranbaxy challenges the promise made by Pfizer in the 546 patent that atorvastatin displays unexpected and surprising increase in activity over the racemate. It does so by attacking the reliability of the data that underlies this promise. More specifically, Ranbaxy claims that the only support for the allegation that the described invention has surprising and unexpected properties is a single set of CSI data which is not representative of all the data collected by Pfizer through CSI experiments. The CSI data as a whole showed tremendous variability and was not reliable. The data obtained by Pfizer from AICS experiments, which was not included in the 546 patent, was more reliable and revealed only a two-fold difference between atorvastatin and its racemate.

[51] These allegations, although placed under a heading entitled "sufficiency" in the NOA, have, in my respectful view, nothing to do with the disclosure requirement under subsection 27(3) of the

Act. Rather, they are relevant to an analysis of the utility, novelty and/or obviousness of a patent. This is clear from the first paragraph of the NOA cited above, according to which "[t]he disclosure does not support there being any novel or inventive aspect as claimed". What Ranbaxy is really challenging in its NOA under the heading of "sufficiency" is the fact that Pfizer obtained a selection patent without having provided reliable data showing that the narrow class of compounds selected was better than the compounds covered by the genus patent.

(D) Errors of the Applications Judge

[52] In my view, the Applications Judge erred in two respects. First, he erred in construing the 546 patent as promising a ten-fold increase in activity for atorvastatin as compared to its racemate. Second, he erred in focusing his subsection 27(3) analysis on whether the data substantiates the promise made by the patent.

(i) Construction of the patent:

[53] The decision in *American Cyanamid v. Ethicon Limited*, [1979] R.P.C. 215 at 261 (Ch.D.) stands for the proposition that although a patentee is not obligated to promise a result in the patent, if he does make such a promise, he will be held to it.

[54] The Applications Judge was incorrect in construing the 546 patent as promising a ten-fold increase in activity for atorvastatin as opposed to the racemate. Rather, the promise is that the compounds covered have an "unexpected and surprising inhibition of biosynthesis of cholesterol", i.e. greater than twofold (Appeal Book, Volume 1, page 92). Although the 546 patent goes on to

refer to CSI data set out in a table in support of this promise, in my opinion, the data is merely illustrative of the magnitude of this promise *in vitro*.

[55] Because a patent is notionally addressed to a person skilled in the art, its claims must be construed purposively, through the eyes of a person skilled in the art: see *Whirlpool, supra*, at paragraph 49; and *Consolboard, supra*, at 521. A person skilled in the art will be interested in whether the compounds claimed by the 546 patent have increased activity *in vivo*. They will know that CSI data, which represents the activity of a compound *in vitro*, does not reflect the activity of the compound *in vivo*. They will not read the patent as promising the exact increase in activity that is set out in the CSI data table. I cannot accept Ranbaxy's argument that "the patentee intended the data set out in the patent to promise a ten-fold increase in inhibiting the biosynthesis of cholesterol in humans, not just in a test tube" (Ranbaxy's Memorandum, paragraph 23).

(ii) Subsection 27(3) analysis:

[56] The Applications Judge was wrong in interpreting the disclosure requirement of subsection 27(3) of the Act as requiring that a patentee back up his invention by data. By so doing, he confused the requirements that an invention be new, useful and non-obvious with the requirement under subsection 27(3) that the specification disclose the "use" to which the inventor conceived the invention could be put: see *Consolboard, supra*, at 527. Whether or not a patentee has obtained enough data to substantiate its invention is, in my view, an irrelevant consideration with respect to the application of subsection 27(3). An analysis thereunder is concerned with the sufficiency of the disclosure, not the sufficiency of the data underlying the invention. Allowing Ranbaxy to attack the

utility, novelty and/or obviousness of the 546 patent through the disclosure requirement unduly broadens the scope of an inventor's obligation under subsection 27(3) and disregards the purpose of this provision.

[57] While it is true that subsection 27(3) requires that an inventor "correctly and fully describe" his invention, this provision is concerned with ensuring that the patentee provide the information needed by the person skilled in the art to use the invention as successfully as the patentee. The Supreme Court of Canada, in *Consolboard, supra*, at 526, cited with approval the following passage from *R. v. American Optical Company et al* (1950), 11 Fox Pat. C. 62 at p. 85:

> … It is sufficient if the specification correctly and fully describes the invention and its operation or use as contemplated by the inventor, so that the public, meaning thereby persons skilled in the art, may be able, with only the specification, to use the invention as successfully as the inventor could himself.
>
> [Emphasis added]

[58] The requirement that the specification of a patent be truthful and not be misleading is not covered by subsection 27(3), but rather by subsection 53(1) of the Act, which reads as follows:

Void in certain cases, or valid only for parts	**Nul en certains cas, ou valide en partie seulement**
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.	**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.

[59] Only two questions are relevant for the purpose of subsection 27(3) of the Act. What is the invention? How does it work?: see *Consolboard, supra*, at 520. In the case of selection patents, answering the question "What is the invention?" involves disclosing the advantages conferred by the selection. If the patent specification (disclosure and claims) answers these questions, the inventor has held his part of the bargain. In the case at bar, the 546 patent answers each of these questions.

[60] *What is the invention?* The invention consists of having identified an enantiomer, and in particular the calcium salt of that enantiomer, that is better at inhibiting the biosynthesis of cholesterol than would be expected, given the common knowledge and prior art at the time of application for the patent.

[61] *How does it work?* The 546 patent sets out the methods for producing the compounds covered by the patent.

[62] I also conclude that the fact that the 546 patent does not provide a justification as to why the calcium salt of atorvastatin is the preferred embodiment of the invention does not render the disclosure insufficient. As I have already indicated, there is no requirement that a patentee explain in the disclosure why and how his invention is useful. When read as a whole, a skilled reader would understand the patent as claiming that the calcium salt of atorvastatin is the compound covered by the 546 patent that demonstrates the most surprising and unexpected inhibition of cholesterol

biosynthesis because it has the most preferred physical properties. Pfizer was not required to include in the 546 patent data which supports its statement that the calcium salt of atorvastatin is the preferred embodiment of the invention, nor was it required to explain why the calcium salt was the preferred embodiment.

(E) ***Conclusion on disclosure under subsection 27(3)***

[63] The applications judge erred in construing the promise of the patent and mischaracterized the disclosure requirement under subsection 27(3) of the Act by asking whether there was sufficient data to substantiate the promise of the patent. Such an examination exceeds the scope of the provision. An attack on a selection patent on the basis that there is no data to support the claimed advantage is certainly relevant for the purposes of validity (most likely to the question of utility), but it is not relevant with respect to disclosure under subsection 27(3) of the Act.

[64] The patent must disclose the invention and how it is made. The 546 patent does this. It also discloses the advantages that underlie the selection. This, in my view, is the extent of the requirement under subsection 27(3) of the Act, the purpose of which is to allow a person skilled in the art to make full use of the invention without having to display inventive ingenuity.

(F) ***Are the allegations of obviousness, double patenting and anticipation justified?***

[65] I now turn to Ranbaxy's allegations of obviousness, double patenting and anticipation. Because of his conclusion in regard to the subsection 27(3) issue, the Judge made no findings as to whether Ranbaxy's allegations under these headings were justified.

[66] In its NOA, Ranbaxy alleges that the 546 patent is invalid for obviousness, double patenting and anticipation. Pfizer counters these allegations by saying that because the 546 patent is a selection patent, its validity depends solely on it having unexpected advantages over the class from which it is selected.

[67] In *Novopharm*, above, von Finckenstein J. examined the allegations of invalidity for obviousness, double patenting and anticipation with respect to the 546 patent and found that they were not justified. This conclusion was based on his finding that the 546 patent was, on its face, a valid selection patent claiming a tenfold advantage of atorvastatin over the racemate. In his view, the fact that the 546 patent was a valid selection provided a complete answer to the allegations of invalidity (see paragraphs 56 and 96 of his Reasons). In so concluding, the Judge emphasized the fact that Novopharm's allegations of invalidity based on anticipation, obviousness and double patenting did not challenge the 546 patent on the ground that it was not a valid selection, nor did they challenge its utility.

[68] In the present matter, Ranbaxy challenges the validity of the 546 patent on the basis of obviousness, double patenting and anticipation, but it does not, under those headings, attack the sufficiency of the data that underlies the invention claimed in the 546 patent. I therefore reach the same conclusion reached by von Finkenstein J. in *Novopharm*, above, i.e. that the NOA does not constitute a sufficient basis upon which to challenge the data underlying the 546 patent.

[69] On its face, the 546 patent is a selection patent, the validity of which depends on it having unexpected advantages over the class from which it is selected. By failing to attack the data underlying the selection under the headings of anticipation, obvious and double patenting, Ranbaxy has not challenged the validity of the selection. Consequently, as von Finkenstein J.A. held in *Novopharm*, above, there is no need to examine Ranbaxy's allegations under those headings. However, I will nonetheless say a few words regarding the issues of double patenting and anticipation.

(i) Double patenting:

[70] Ranbaxy alleges, in its NOA, that a number of the claims of the 546 patent are invalid for double patenting (Appeal Book, Volume 1, pages 239-240):

> Canadian Patent No. 1,330,441 ("the 441 Patent"), entitled "Process for Trans-6-[2-(Substituted-Pyrrol-1YL)Alkyl] Pyran-2-One Inhibitors of Cholesterol Synthesis", have a filing data of February 7, 1989 and priority dates of February 22, 1988 and February 1, 1989 based on U.S. Patent application Nos. 158,439 and 303,733 respectively, also issued to Warner-Lambert. The 441 Patent was filed over a year prior to the filing of the 546 Patent.
>
> The 441 Patent discloses processes for preparation of, *inter alia*, atorvastatin lactone, atorvastatin acid and pharmaceutically acceptable salts thereof. Further, the 441 Patent disclosure teaches atorvastatin acid at page 22, lines 1 to 3: " a dihydroxy acid and pharmaceutically accepted salts thereof, corresponding to the opened lactone ring of compounds of structural Formula 1".
>
> The 441 Patent teaches at page 2, lines 2 to 7, that the processes disclosed in the 893 U.S. Patent:
>
> > … do not produce enantiomerically pure products. The materials produced by the earlier methods can be separated in enantiomerically pure products but the process is very expensive, time-consuming, and results in the loss of more than 50% of the starting material.
> >
> > The object of the present invention is an improved process for preparing the compounds described above by using a novel synthesis.

> Example 3 of the 441 Patent teaches two step-by-step methods to produce atorvastatin lactone.
>
> Further, the 441 Patent discloses that the R(R*R*) single enantiomer is particularly valuable as a hypolipidemic and hypocholesterolemic agent (page 1, I.18-25) and that it is the preferred isomer (page 44, I.33-35).

[71] Specifically with respect to claim 6 of the 546 patent, the NOA provides (Appeal Book, Volume 1, page 241):

> As noted above, Claim 6 of the 546 Patent specifies the hemicalcium salt of atorvastatin acid recited in claim 2 of the 546 Patent. Claim 12 of the 441 Patent claims, inter alia, processes for making atorvastatin acid and pharmaceutically acceptable salts thereof. The 441 Patent (p. 20, I.16) teaches calcium salts to be pharmaceutically accepted salts. The calcium salt of atorvastatin acid would be obvious to a person skilled in the art based on the disclosure and the Monkhouse article, supra.
>
> Accordingly, claim 6 of the 546 Patent was not patentably distinct from claim 12 of the 441 Patent. Therefore, claim 6 of the 546 Patent was without any novelty or ingenuity over claim 12 of the 441 Patent, and is invalid for double patenting.

[72] On the topic of double patenting, the NOA concludes (Appeal Book, Volume 1, page 241):

> The compounds of the 546 Patent do not result in a further invention over and above the end products of the processes described in the 441 Patent. Thus, claims 1, 2, 3, 6, 11 and 12 of the 546 Patent do not exhibit any novelty or ingenuity over claims 12 and 14 of the 441 Patent and, therefore, claims 1, 2, 3, 6, 11 and 12 of the 546 Patent are invalid for double patenting.

[73] In its Notice of Application, Pfizer responds to this allegation as follows (Appeal Book, Volume 1, page 83):

> The 441 Patent includes claims for improved process of compounds […]. It does not claim [compounds][…] as molecules exhibiting surprisingly potent activity as inhibitors of

> cholesterol biosynthesis or having any other unexpected characteristics. Nor does the 441 Patent claim atorvastatin calcium as a compound exhibiting surprising potent activity as an inhibitor of cholesterol biosynthesis or having any other unexpected properties.
>
> In addition, the allegation of double patenting based on the 441 Patent cannot be justified because the 546 Patent expires before the 441 Patent and there is thus no extension of the monopoly of the 546 Patent.
>
> Claim 6 of the 546 Patent is patently distinct over the claims of the 441 Patent. There is no double patenting as alleged by Ranbaxy.

[74] Ranbaxy's submission, put at its simplest, is that the process claims of the 441 patent and the product claims of the 546 patent are, in reality, two aspects of the same invention. Hence, as a result, there is no ingenuity in taking the products disclosed in the 441 patent and separately patenting them in the 546 patent. Thus, the 546 patent is not patently distinct from the 441 patent.

[75] In *Pharmascience Inc. v. Sanofi-Aventis Canada Inc.*, 2006 FCA 229, at paragraphs 67-68, Sharlow J.A. summarized the law on double patenting as follows:

> [67] "Double patenting" refers to certain judge made rules that have been devised to prevent the "evergreening" of patents. Evergreening is the undue extension of the statutory monopoly in a particular patent by means of a series of patents with obvious or uninventive additions (*Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067, at paragraph 37).
>
> [68] The jurisprudence has so far identified two categories of double patenting. In the first category, "same invention patenting", two patents are the same or have an identical or conterminous claim. The second category, "obviousness double patenting", is somewhat broader. In obviousness double patenting, the claims of the patents are not identical or conterminous, but the later patent has claims that are not patentably distinct from the other patent, or involve no novelty or ingenuity.

[76] In my opinion, the double patenting allegations are not justified. The 441 patent covers processes, whereas the 546 patent covers compounds. As explained by Hughes & Woodley (at §15, page 172), "[a] previous patent for a product produced by a claimed process does not invalidate a later patent for the product alone for reasons of double patenting" (see: *Aventis Pharma Inc. v. Mayune Pharma (Canada) Inc.*, [2005] F.C.J. No. 1437 at paragraphs 72-76 (Q.L.)).

[77] Furthermore, according to Hughes and Woodley (§15, page 172), "[w]here a patent has been found to be a proper selection patent, therefore not obvious, there is no double patenting" (see: *Glaxo SmithKline Inc. v. Apotex Inc.*, [2003] F.C.J. No. 886 at paragraph 48 (Q.L.)).

[78] I therefore agree with the following conclusion reached by von Finkenstein J. in *Novopharm*, above, where he said:

> [100] In same invention double patenting, the claims must be identical or co-terminus. Since the 441 Patent is a process patent, it is obviously not the same as the 546 Patent, which claims a compound. Given that the 546 Patent is a selection from the group of compounds disclosed in the 768 Patent (the Canadian equivalent of the US 893 Patent), the 546 Patent is obviously not identical with the claims of the 768 Patent.
>
> [101] As far as obviousness double patenting is concerned, the claims or disclosure must exhibit novelty or ingenuity in order for the second patent to be valid. (See *Sanofi-Synthelabo Canada Inc.*, supra at para. 86).
>
> [102] As the Court found that the 546 Patent was a selection patent, by definition it is novel and unexpected. It thus cannot be invalid on the basis of obviousness double patenting.

(ii) Anticipation:

[79] Ranbaxy submits that the 546 patent is anticipated by the 768 patent which discloses atorvastatin calcium. The NOA attacks the novelty of the 546 patent as follows (Appeal Book, Volume 1, page 244):

> If on the construction of the 768 Patent, its claims are found to include th R(R*R*) enantiomer, then Claims 1, 2, 3, 6, 11 and 12 of the 546 Patent are invalid as lacking novelty in light of the 893 U.S. Patent (which corresponds to the 768 Patent). On that construction, the 893 Patent would disclose the R(R*R*) enantiomer and pharmaceutically acceptable salts thereof for use as a hypocholesterolemic or hypolidemic agent. All essential elements of Claims 1, 2, 3, 6, 11 and 12 of the 546 Patent would then be found in the 893 U.S. Patent. Those claims would not be novel, hence they would be invalid.

[80] Pfizer responds to this allegation in its Notice of Application, as follows (Appeal Book, Volume 1, page 83):

> Ranbaxy also asserts that claim 6 of the 546 Patent is invalid by reason of lack of novelty in view of the 893 Patent. This assertion is without merit. Claim 6 of the 546 Patent claims subject-matter which is novel over the disclosure of the 893 Patent. Claim 6 is not anticipated by the 893 Patent.

[81] The test for anticipation was enunciated by this Court in *Beloit Canada Ltd. v. Valmet OY* (1986), 8 C.P.R. (3d) 289, which the Supreme Court of Canada adopted in *Free World Trust v. Electro Santé Inc.* (2000), 9 C.P.R. (4th) 168:

> One must, in effect, be able to look at a prior, single publication and find in it all the information which, for practical purposes, is needed to produce the claimed invention without the exercise of any inventive skill. **The prior publication must contain so clear a direction that a skilled person reading and following it would in every case and without possibility of error be led to the claimed invention**.
>
> [Emphasis added]

[82] In *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FCA 214, this Court made it clear that the test for anticipation was a difficult one to meet. At paragraph 36, Malone J.A. put it as follows:

> [36] This is a difficult test to meet. The Applications Judge held that a person skilled in the art would not know why to select Besylate as one of the initial choices of salt, would not know whether it would form a salt of amlodipine in the solid state and would not know the particular properties of Besylate or their advantage for pharmaceutical formulation. As a result of these facts, he found that a person skilled in the art would not in every case and without possibility of error be led to the claimed invention. In so doing he did not make a palpable and overriding error because there was evidence on which to base his findings.

[83] The allegation of anticipation, in my view, is not justified. A claim to a specific chemical compound cannot be anticipated by a prior art reference which only teaches a broad class of genus of compounds into which the compound falls because the prior art reference does not give directions which inevitably result in the specific compound (see *Sanofi-Synthelab Canada Inc. et al v. Apotex Inc. et al* (2005), 39 C.P.R. (4th) 202 at paragraph 55, affirmed 2006 FCA 421 at paragraphs 25-27; *Pfizer Canada Inc. v. Apotex Inc.*, [1997) F.C.J. No. 1087 (Q.L.), 77 C.P.R. (3d) 547 (T.D.); *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FCA 214, [2006] F.C.J. No. 894 (Q.L.)). Ranbaxy did not allege that the prior art teaches that the calcium salt of atorvastatin would have greater inhibition activity than expected, i.e. more than two-fold.

CONCLUSION

[84] For these reasons, I would allow the appeal, set aside the judgment of the Federal Court and, rendering the judgment which ought to have been rendered, I would prohibit the Minister from issuing a Notice under section C.08.004 of the *Food and Drug Regulations* to Ranbaxy for

atorvastatin calcium, until after the expiry of the 546 patent. I would also allow Pfizer its costs both in the appeal and in the application.

"M. Nadon"
J.A.

"I agree.
A.M. Linden J.A."

"I agree.
C. Michael Ryer J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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