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IMPROPER SELECTION: A SEPARATE GROUND OF PATENT INVALIDITY IN
CANADA?

Anna Wilkinson*

This paper will consider the principle grounds on which the validity of selection patents are attacked, namely anticipation, obviousness, double patenting, lack of utility and insufficiency, with a view to exploring the doctrinal underpinnings for challenging a selection patent as an “improper selection”. As will be discussed further below, “improper selection” comfortably fits within existing grounds of invalidity and, in particular, obviousness, lack of utility and, surprisingly, ambiguity.

I

SELECTION PATENTS

A definition of a selection patent was provided by Rothstein J., speaking for the Court, in the recent Supreme Court decision of *Sanofi-Synthelabo Canada Inc. v. Apotex Inc.*¹:

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¹ (2008), 69 CPR (4th) 251 (SCC) [*Sanofi-Synthelabo*].

In the context of chemical compounds, in general terms, a selection patent is one whose subject matter (compounds) is a fraction of a larger known class of compounds which was the subject matter of a prior patent.²

Rothstein J. referred to the following three criteria from *In Re: I.G. Farbenindustrie A.G.'s Patents*³ as the *locus classicus* of selection patents:

1. There must be a substantial advantage to be secured or disadvantage to be avoided by the use of the selected members.
2. The whole of the selected members (subject to "a few exceptions here and there") possess the advantage in question.
3. The selection must be in respect of a quality of a special character peculiar to the selected group. If further research revealed a small number of unselected compounds possessing the same advantage, that would not invalidate the selection patent. However, if research showed that a larger number of unselected compounds possessed the same advantage, the quality of the compound claimed in the selection patent would not be of a special character.⁴

While these principles appear to have informed the Court's analysis, Rothstein J. examined the validity of the patent-in-suit with regard to the principles of anticipation, obviousness, and double-patenting. The "special advantages" of the claimed compound were examined in connection with these inquiries and not as a stand-alone ground of patentability.

A valid selection may be "from a class of thousands or for a selection of one out of two".⁵

² *Ibid* at 254-255.

³ (1930), 47 R.P.C. 289 (Ch.D.) [*I.G. Farbenindustrie*].

⁴ *Sanofi-Synthelabo*, *supra* note 1 at 257.

⁵ See e.g. *Pfizer Canada Inc. v. Canada (Minister of Health)* (2006), 52 CPR (4th) 241, (FCA) at 244 (leave to appeal refused [2006] S.C.C.A. No. 355) citing *I.G.*

Selection patents “exist to encourage researchers to further use their inventive skills so as to discover new advantages for compounds within the known class.”⁶

Selection patents are subject generally to the same rules that apply to any other type of patent.⁷

II

PHARMACEUTICAL PATENTS

Not surprisingly, many selection patents are directed to pharmaceuticals. In Canada, there is a regulatory regime specific to pharmaceuticals that links the patent system with the regulatory approval system. Some key features of this system are explained here in order to provide context for the case law discussion that follows.

Before a drug product can be marketed in Canada, authorization must be obtained from the Minister of Health. Upon achieving regulatory approval, the Minister issues a Drug Identification Number or DIN and a Notice of Compliance (“NOC”). The *Patented Medicines (Notice of Compliance) Regulations*⁸ require the Minister of Health to maintain a register of patents pertaining to medicines for which Notices of Compliance have been issued (the “Patent Register”).⁹ The owner or licensee of a patent for a medicine who files a drug submission can seek to add the relevant patent(s) to the Patent Register by filing a patent list.¹⁰ If a second or subsequent entry drug manufacturer seeks a NOC in respect of a drug and in doing so directly or indirectly compares the drug with a drug on the Patent Register, with respect to each patent referenced on the Patent Register, the second or subsequent entry drug manufacturer must file a statement of acceptance that the NOC will not issue until the patent expires or an allegation that: the person appearing on the patent list is

Farbenindustrie and *E.I. Du Pont de Nemours & Co. v. Akzo NV* [1982] F.S.R. 303 (HL).

⁶ See e.g. *Pfizer Canada Inc. v. Canada (Minister of Health)*, *supra* note 5 at 244.

⁷ See e.g. *GlaxoSmithKline Inc. et al. and Pharmascience Inc. et al.* (2008), 72 CPR (4th) 295 (FCTD) at 318 [*GlaxoSmithKline*], and *Sanofi-Synthelabo*, *supra* note 1 at 282.

⁸ SOR/93-133 *as amended*.

⁹ *Ibid.* s.3(2).

¹⁰ *Ibid.* at s.4(1) and s.4(4)(d).

not the patentee or a person claiming under the patentee; the patent has expired; the patent is not valid; or the patent is not infringed.¹¹ Within 45 days of service of this “Notice of Allegation”, the patentee or licensee can bring an application in the Federal Court for an order prohibiting the Minister from issuing a NOC until after the patent expires.¹² This application is associated with a 24-month stay during which the Minister is prohibited from issuing a NOC to the second or subsequent entry drug manufacturer.¹³ While named in the style of cause, the Minister does not participate in the hearings of these applications. In disposing of the application, the Court may make an order prohibiting the Minister from issuing a NOC until after the expiration of the patent(s) that are the subject of the application, if it finds that none of the allegations at issue in the proceeding are justified or dismiss the application for a prohibition order if it finds that an allegation is justified.¹⁴ Notwithstanding the outcome of these proceedings, the patentee or licensee can sue the second or subsequent entry drug manufacturer for patent infringement. It should be noted that due to their summary nature, decisions arising out of prohibition proceedings have limited precedential value in terms of their pronouncements on patent law:

NOC proceedings were never intended to be substitutes for an infringement action...Similarly, it is inappropriate to rely on NOC proceedings to set binding precedent on controversial and uncertain questions in patent law [citations omitted].¹⁵

III

ANTICIPATION

A patent is to be granted for an “invention” defined by the *Patent Act*¹⁶ as “any new and useful art, process, machine,

¹¹ *Ibid.* s.5.

¹² *Ibid.* s.6(1).

¹³ *Ibid.* s.7(1)(e).

¹⁴ *Ibid.* s.6(2).

¹⁵ *Eli Lilly Canada Inc. v. Novopharm Ltd.* (2007), 62 CPR (4th) 161 at 176, *leave to appeal refused* [2008] S.C.C.A. No. 9.

¹⁶ *Patent Act*, R.S.C. 1985, c. P-4, *as amended* [*Act*].

manufacture or composition of matter” or improvement thereof.¹⁷ Section 28.2 of the current *Act* provides a specific framework for assessing the novelty of a Canadian patent.

The test for anticipation has been given various formulations. One frequently cited formulation of the test is that provided by Hugessen J.A. speaking for the Federal Court of Appeal in the decision of *Beloit Canada Ltd. et al. v. Valmet Oy*¹⁸:

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.¹⁹

IV

ANTICIPATION AND SELECTION PATENTS

In *Sanofi-Synthelabo*, Sanofi sought an order prohibiting the Minister of Health from issuing a NOC to Apotex in respect of clopidogrel bisulfate, marketed by Sanofi as PLAVIX. Sanofi held two Canadian patents: the genus patent 1,194,875 (the “875 Patent”) which disclosed more than 250,000 possible compounds and patent 1,336,777 (the “777 Patent”), which disclosed and claimed clopidogrel bisulfate, the dextro-rotary isomer of a racemate made and tested in the 875 Patent. Apotex alleged invalidity on the grounds of anticipation, obviousness and double patenting. The Applications Judge did not find the allegations to be justified and granted the order of prohibition.²⁰ The Federal Court of Appeal dismissed Apotex’s appeal.²¹ The Supreme Court dismissed the appeal.

Accepting that selection patents were permitted in principle, Rothstein J. speaking for the Supreme Court considered the question

¹⁷ *Ibid.* s.2 (emphasis added).

¹⁸ (1986) 8 CPR (3d) 289 (FCA) [*Beloit*].

¹⁹ *Ibid.* at 297.

²⁰ (2005), 39 CPR (4th) 202 (FCTD).

²¹ (2006), 59 CPR (4th) 46 (FCA).

of anticipation in the context of selection patents.²² He found that the Applications Judge “overstated the stringency of the test for anticipation that the “exact invention” has already been made and publicly disclosed”²³ and went on to formulate a two-part test for anticipation:

When considering the role of the person skilled in the art in respect of disclosure, the skilled person is "taken to be trying to understand what the author of the description [in the prior patent] meant"...At this stage, there is no room for trial and error or experimentation by the skilled person. He is simply reading the prior patent for the purposes of understanding it.

If the disclosure requirement is satisfied, the second requirement to prove anticipation is "enablement" which means that the person skilled in the art would have been able to perform the invention [...]²⁴

Trial and error experimentation is permitted at the second stage, but not at the initial disclosure stage:

Once the subject matter of the invention is disclosed by the prior patent, the person skilled in the art is assumed to be willing to make trial and error experiments to get it to work. While trial and error experimentation is permitted at the enablement stage, it is not at the disclosure stage. For purposes of enablement, the question is no longer what the skilled person would think the disclosure of the prior patent meant, but whether he or she would be able to work the invention.²⁵

While permitted at the second stage, experimentation must be such that can be performed without undue burden.²⁶

²² *Sanofi-Synthelabo*, *supra* note 1 at 259-260.

²³ *Ibid.* at 261.

²⁴ *Ibid.* at 261.

²⁵ *Ibid.* at 262.

²⁶ *Ibid.* at 263.

Rothstein J. identified this two-part approach as a refinement of the *Beloit* test for anticipation:

The *Beloit* decision by which the applications judge rightly felt bound dealt with only one aspect of anticipation, that is, whether or not the invention in a patent had been disclosed in a single prior publication or patent. In that decision, Hugessen J.A. held that it had not. He had no need to consider the further point whether or not, had there been such a clear disclosure, the working of the invention was also enabled by that disclosure. That point was not in issue in *Beloit*. Explicitly separating disclosure and enablement is a refinement of the approach set out in *Beloit*.²⁷

Rothstein J. went on to consider what must be disclosed by the prior art genus patent to constitute anticipation:

In the context of genus and selection patents, in *E.I. Du Pont de Nemours & Co. (Witsiepe's) Application*, [1982] F.S.R. 303 (H.L.), Lord Wilberforce stated, at p. 311:

It is the absence of the discovery of the special advantages, as well as the fact of non-making, that makes it possible for such persons to make an invention related to a member of the class.

The compound made for the selection patent was only soundly predicted at the time of the genus patent. It was not made and its special advantages were not known. It is for those reasons that a patent should not be denied to the inventor who made and discovered the special advantages of the selection compound for the first time.

In the context of disclosure as explained in *Synthon*, "the absence of the discovery of the special advantages" to which Lord Wilberforce was referring in *Witsiepe's* means that the genus patent does not disclose the special advantages of the invention covered by the selection patent. Where there is no such disclosure, there is no discovery of the special advantages of the selection patent as compared to the genus patent, and the disclosure

²⁷ *Ibid.* at 262.

requirement to prove anticipation fails. At this stage, the person skilled in the art is reading the prior patent to understand whether it discloses the special advantages of the second invention. No trial and error is permitted. If in reading the genus patent the special advantages of the invention of the selection patent are not disclosed, the genus patent does not anticipate the selection patent. [Emphasis added]²⁸

Rothstein J. found no anticipation on the basis that the prior art genus patent did not amount to disclosure so as to satisfy the first stage of the anticipation test.

Accordingly, in the case of a true selection, i.e. one where the selected compound has not been made nor its advantage(s) disclosed in the prior art, there will be no anticipation because the first part of the two-part test for anticipation (disclosure) will not be satisfied.

In the recent decision of *Lundbeck Canada Inc. v. Canada (Minister of Health)*²⁹, Harrington J. granted an order of prohibition preventing the Minister of Health from issuing a NOC to Genpharm, Apotex and Cobalt in respect of a generic version of Lundbeck's escitalopram drug until the expiry of Canadian Patent No. 1,339,452 ("452 Patent"). While three separate proceedings were brought against the generic companies, the proceedings were heard consecutively and the Court issued one decision. All three generic companies alleged the 452 Patent was an invalid selection patent from one or more issued U.S. Patents. The U.S. Patents claimed citalopram, a racemate, while the 452 Patent claimed escitalopram, the S-enantiomer of citalopram. The Court found that the 452 Patent was not a selection patent on the basis that the prior genus patents did not disclose escitalopram, so the 452 Patent did not need to meet the requirements of a selection patent. The Court noted that if it had determined that the 452 Patent was a selection patent, it would have been invalid for not satisfying the requirements of a selection patent. Accordingly, an available defence to an allegation of improper selection may be that the prior patent does not cover the claimed selection even in a generic way.

²⁸ *Ibid.* at 263.

²⁹ (2009), 73 CPR (4th) 69 (FCTD).

V

OBVIOUSNESS

Historically the requirement for inventiveness (or “lack of obviousness”) was a judge-made requirement derived from the requirement that patents be granted for “inventions”.³⁰ The requirement that an invention must not be obvious is now a statutory requirement under section 28.3 of the *Act*.

A commonly cited test for obviousness is that provided by Hugessen J.A. in *Beloit*:

The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be asked is whether this mythical creature (the man in the Clapham omnibus of patent law) would, in the light of the state of the art and the common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy.³¹

VI

OBVIOUSNESS AND SELECTION PATENTS

The *Beloit* test for obviousness was revisited by the Supreme Court in *Sanofi-Synthelabo*. The Court considered whether the “obvious to try” standard was part of Canadian law. Looking to the law in foreign jurisdictions, the Court decided the obviousness standard should be reconsidered in Canada and, in particular, the restrictiveness with which the *Beloit* test had been interpreted.³²

³⁰See e.g. *Hughes and Woodley on Patents* (Loose-Leaf), 2008 LexisNexis Canada Inc. [*Hughes & Woodley*] at §12.

³¹ *Beloit*, *supra* note 18 at 294.

³² *Sanofi-Synthelabo*, *supra* at 270.

The Court held that the “obvious to try” test could be considered, but it “must be approached cautiously” and is “only one factor to assist in the obviousness inquiry”.³³ Rothstein J. formulated the test thus:

I am of the opinion that the "obvious to try" test will work only where it is very plain or, to use the words of Jacob L.J., more or less self-evident that what is being tested ought to work.

For a finding that an invention was "obvious to try", there must be evidence to convince a judge on a balance of probabilities that it was more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough.³⁴

Rothstein J. went on to adopt the four-step obviousness inquiry outlined by Oliver L.J. in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*³⁵, as updated by Jacob L.J. in *Pozzoli SPA v. BDMO SA*³⁶:

In the result I would restate the Windsurfing questions thus:

- (1) (a) Identify the notional "person skilled in the art";
- (1) (b) Identify the relevant common general knowledge of that person;
- (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 of the claim or the claim as construed;
- (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or

³³ *Ibid.* at 271.

³⁴ *Ibid.* at 271-272.

³⁵ [1985] R.P.R. 59 (C.A.).

³⁶ [2007] F.S.R. 37, [2007] EWCA Civ 588.

do they require any degree of invention? [Emphasis added]³⁷

Rothstein J. identified the fourth step as being where the issue of “obvious to try” will arise and identified a list of non-exhaustive factors that should be considered in this step of the inquiry.^{38,39}

In applying the four-step obviousness analysis, Rothstein J. looked to the specification of the 777 Patent to find the “inventive concept”:

The inventive concept of the claims is not readily discernable from the claims themselves. A bare chemical formula in a patent claim may not be sufficient to determine its inventiveness. In such cases, I think it must be acceptable to read the specification in the patent to determine the inventive concept of the claims. Of course, it is not permissible to read the specification in order to construe the claims more narrowly or widely than the text will allow.

In the present case, it is apparent that the inventive concept of the claims in the ‘777 patent is a compound useful in inhibiting platelet aggregation which has greater therapeutic effect and less toxicity than the other compounds of the ‘875 patent and the methods for obtaining that compound.[Emphasis added]⁴⁰

³⁷ *Sanofi-Synthelabo*, *supra* note 1 at 272.

³⁸ *Ibid.* at 273.

³⁹ The “obvious to try” standard as formulated by Rothstein J. was recently explained in the Federal Court of Appeal decision of *Apotex Inc. v. Pfizer Canada Inc. and Pfizer Ireland Pharmaceuticals and The Minister of Health* (2009), 72 CPR (4th) 141. In this case, the appellant argued that the Court in *Sanofi-Synthelabo* had incorporated a “worth a try” test into Canadian law. Noel J. speaking for the Court characterized the test adopted by the Supreme Court as “a precise application of the test loosely referred to as ‘worth a try’”:

The test recognized is “obvious to try” where the word “obvious” means “very plain”. According to this test, an invention is not made obvious because the prior art would have alerted the person skilled in the art to the possibility that something might be worth trying. The invention must be more or less self-evident. (at paras. 28-29).

⁴⁰ *Sanofi-Synthelabo*, *supra* note 1 at 274-275.

Accordingly, in selection patents the inventive concept of the claim (that which renders it inventive) is the advantage of the selection over the genus, which may be found with reference to the description. A proper selection, i.e. one with an actual and discernible advantage, will be inventive over the genus patent.

VII

DOUBLE PATENTING

The rationale for the prohibition against double patenting was outlined by Binnie J. speaking for the Supreme Court in the decision of *Whirlpool Corp. v. Camco Inc.*⁴¹:

It is common ground that the bargain between the patentee and the public is in the interest of both sides only if the patent owner acquires real protection in exchange for disclosure, and the public does not for its part surrender a more extended monopoly than the statutory 17 years from the date of the patent grant (now 20 years from the date of the filing of the patent application). A patentee who can "evergreen" a single invention through successive patents by the expedient of obvious or uninventive additions prolongs its monopoly beyond what the public has agreed to pay.⁴²

In considering a double patenting objection, it is the claims of the two patents that are compared.

The prohibition against double patenting relates back to the "evergreen" problem mentioned at the outset. The inventor is only entitled to "a" patent for each invention: *Patent Act*, s. 36(1).⁴³ If a subsequent patent issues with identical claims, there is an improper extension of the monopoly. It is clear that the prohibition against double patenting involves a

⁴¹ (2000), 9 CPR (4th) 129 (SCC) [*Whirlpool*].

⁴² *Ibid.* at 144.

⁴³ Subsection 36(1) of the *Act* provides: "A patent shall be granted for one invention only but in an action or other proceeding a patent shall not be deemed to be invalid by reason only that it has been granted for more than one invention."

comparison of the claims rather than the disclosure, because it is the claims that define the monopoly. The question is how "identical" must be the claims in the subsequent patent to justify invalidation.⁴⁴

In *Whirlpool*, Binnie J. identified two branches of double patenting: coterminous and obviousness-type. Binnie J. pointed to the decision of *Beecham Canada Ltd. v. Procter & Gamble Co.*⁴⁵ where the Federal Court of Appeal adopted the "identical or coterminous" standard and then distinguished this branch from the broader obviousness-type double patenting:

There is, however, a second branch of the prohibition which is sometimes called "obviousness" double patenting. This is a more flexible and less literal test that prohibits the issuance of a second patent with claims that are not "patentably distinct" from those of the earlier patent. ...

In *Consolboard*... Dickson J. referred to *Farbwerke Hoechst* as "the main authority on double patenting" ... which stood for the proposition that a second patent could not be justified unless the claims exhibited "novelty or ingenuity" over the first patent...⁴⁶

VIII

DOUBLE PATENTING AND SELECTION PATENTS

Given the nature of selection patents, it is not surprising that double patenting is frequently raised as a ground of invalidity. In *Sanofi-Synthelabo*, Rothstein J. rejected the proposition that a general concern about evergreening justified an attack on the doctrine of selection patents, giving two reasons:

First, a selection patent may be sought by a party other than the inventor or owner of the original genus patent. In such

⁴⁴ *Whirlpool*, *supra* note 41 at 157.

⁴⁵ (1982), 61 C.P.R. (2d) 1 (FCA).

⁴⁶ *Whirlpool*, *supra* note 41 at 158.

a case, anticipation or obviousness may be an issue, but evergreening does not arise.⁴⁷

...

Second and more importantly, selection patents encourage improvements by selection. The inventor selects only a bit of the subject matter of the original genus patent because that bit does something better than and different from what was claimed in the genus patent.⁴⁸

Rothstein J. went on to consider the *Whirlpool* decision:

Apotex argues that the focus in a double patenting challenge is on the claims of the two patents rather than on the disclosure. I agree. In *Whirlpool*, Binnie J. stated, at para. 63:

It is clear that the prohibition against double patenting involves a comparison of the claims rather than the disclosure, because it is the claims that define the monopoly.

Whirlpool was not a selection patent case. However, because selection patents are to be subject to the same considerations as other patents, the clear statement of Binnie J. in *Whirlpool* must apply to selection patents.

I agree with Apotex that a challenge to patent validity based on double patenting does not require the existence of identical language in the two patent claims. Even so, the wording of the claims, however different, must claim the same invention.

The invention defined by claim 14 of the '875 patent is not the same as the invention claimed by claim 1 of the '777 patent because the former is broader than the latter. [Emphasis added]⁴⁹

In finding no double patenting, Rothstein J. explained the decision as follows:

⁴⁷ *Sanofi-Synthelabo*, *supra* note 1 at 279.

⁴⁸ *Ibid.* at 280.

⁴⁹ *Ibid.* at 282.

A selection patent that claims a compound that is patentably distinct from the genus patent will not be invalid for obviousness double patenting. Here, out of the many compounds predicted to be effective as exhibiting platelet aggregation inhibiting activity in the '875 patent, it was found that the dextro-rotatory isomer of the racemate relevant in this case had beneficial properties over both the racemate and the levo-rotatory isomer. As I have explained above, the claims in the '777 patent reflect a patentably distinct compound from the compounds in the '875 patent. As a result, there is no basis for a challenge based on "obviousness" double patenting.

While double patenting requires a comparison of the claims of a genus and selection patent, it is necessary that the specification of the selection patent define in clear terms the nature of the characteristic which the patentee alleges to be possessed by the selection for which he claims a monopoly. [Emphasis added]⁵⁰

Accordingly, where a claimed selection is novel and inventive over the genus, the selection patent will not be invalid for double patenting.

IX

UTILITY

Utility is required by the *Act*. A patent is to be granted for an "invention": "any new and useful art, process, machine, manufacture or composition of matter" or improvement thereof.⁵¹

In the *Alsop's Patent* case⁵², Parker J. recognized that there are two "types" of utility:

[T]he well-known rule is that utility of an invention depends upon whether, by following the directions of the patentee, the result which the patentee professed to

⁵⁰ *Ibid.* at 283-284.

⁵¹ *Act*, *supra* note 16 at section 2 (emphasis added).

⁵² (1907) 24 R.P.C. 733.

produce can in fact be produced...Want of utility in this sense must however, in my opinion, be distinguished from want of utility in the sense of the invention being useless for any purpose whatever. In the case of an invention not serving any useful purpose at all, the Patent would no doubt be void, but not entirely for the same reason.⁵³

Utility does not have to be disclosed in the patent application, although how to use the invention must be disclosed. Subsections 27(3)(a) and (b) of the *Act* provide:

Specification. - 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;

In *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.*⁵⁴, Dickson J. speaking for the Supreme Court considered s. 36(1), a precursor to s. 27(3) of the current *Act*:

...the Federal Court of Appeal erred also in holding that s. 36(1) requires distinct indication of the real utility of the invention in question. There is a helpful discussion in 29 Hals., 3rd ed., p. 59, on the meaning of “not useful” in patent law. It means “that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do”. There is no suggestion here that the invention will not give the result promised. The discussion in Halsbury, *ibid.*, continues:

⁵³ *Ibid.* at 753.

⁵⁴ (1981), 56 CPR (2d) 145 (SCC) [*Consolboard*].

...the practical usefulness of the invention does not matter, nor does its commercial utility, unless the specification promises commercial utility, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested.

And concludes [at p. 60]:

...it is sufficient utility to support a patent that the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice...

Canadian law is to the same effect.⁵⁵

In the case of chemical patents, it is possible to satisfy the utility requirement for compounds that have not been made or tested through a doctrine of “sound prediction”. The doctrine of sound prediction has three components: there must be a factual basis for the prediction; the inventor must have at the date of the patent application an articulable and “sound” line of reasoning from which the desired result can be inferred from the factual basis; and there must be proper disclosure.⁵⁶

X

UTILITY AND SELECTION PATENTS

The issue of utility in the context of a selection patent was considered by the Federal Court of Appeal in the decision of *Pfizer Canada Inc. v. Canada (Minister of Health)*⁵⁷ (referred to here as *Pfizer v. Ratiopharm* to distinguish it from other cases with Pfizer in the style of cause). This case involved a selection of besylate salt of amlodipine (claimed in patent 1,321,393 (the “393 Patent”)) marketed by Pfizer as NORVASC. The selection was from a class of eighty pharmaceutically acceptable salts of amlodipine disclosed in a prior genus patent. The genus patent indicated that the preferred salts were the maleates. The applicants found these unsuitable for formulation into a dosage form and sought a replacement salt having an optimal

⁵⁵ *Ibid.* at 160-161.

⁵⁶ *Apotex Inc. v. Wellcome Foundation Ltd.* (2002), 21 CPR (4th) 499 (SCC) at 526.

⁵⁷ (2006), 52 CPR (4th) 241 (FCA), leave to appeal refused [2006] S.C.C.A. No. 335 (also cited *supra*, note 5) [*Pfizer v. Ratiopharm*].

combination of four formulation properties: solubility, stability, non-hygroscopicity and non-stickiness.

Ratiopharm alleged invalidity of the 393 Patent on the basis of anticipation, obviousness and being an improper selection patent. The Applications Judge found the patent to be an improper selection, concluding there was no disclosure of the advantage and that it was merely a non-patentable exercise in verifying the existing properties and testing the degree of known characteristics, based on the absence of explanation or justification for why certain salts from a known class were tested. The Applications Judge concluded that because the selection was not valid, the selection patent was invalid for obviousness-type double patenting and did not grant the order of prohibition.⁵⁸

Ratiopharm's Notice of Allegation, included an allegation that besylate offered no substantial or practically significant improvement in stability over any of the other salts tests in the 393 Patent. With respect to this allegation, the Applications Judge found the Notice of Allegation inadequate because it did not include the results of testing performed by a third party retained by Ratiopharm for that purpose.

The Court of Appeal distinguished verification from empirical research for the purpose of making a selection from a class:

The empirical investigation leading to an invention protected by a selection patent must involve "at the least the discovery that the selected members possess qualities hitherto undiscovered, particular to themselves and not attributable to them by virtue of the fact of their belonging to a class specified by an earlier invention"
...

On the other hand, verification means confirming predicted or predictable qualities of known compounds; i.e. components that have already been discovered and made. No one can claim a selection patent merely for ascertaining the properties of a known substance...[Citations omitted]⁵⁹

⁵⁸ (2006), 46 CPR (4th) 281 (FCTD).

⁵⁹ *Pfizer v. Ratiopharm*, *supra* note 57 at 247-248.

In concluding the Applications Judge applied the wrong test, Malone J.A. for the Court of Appeal noted that the Applications Judge found that “the Formulation Properties of any salt of amlodipine could never have been expected but must be determined empirically”.⁶⁰ Malone J.A. went on to find that had the Applications Judge applied the proper principles, he could only have concluded that the 393 Patent was a valid selection because “of Pfizer’s discovery of Besylate’s special Formulation Properties creating a special advantage in dosage stability and processability”.⁶¹

Under the heading “Special Advantage”, the Court characterized Ratiopharm’s argument as follows:

Ratiopharm urges that if Pfizer need only assert that the "unique combination" of Besylate's Formulation Properties cannot be predicted and therefore possess an unexpected advantage, then any amlodipine salt selected could be tested against any number of properties which could theoretically support a claim to "unique properties" that could not be predicted. They argue that this is absurd and that more disclosure details of selection of comparator salts, Formulation Properties and fully explained thresholds for acceptable results are essential to support Besylate's special advantage over the class.⁶²

In rejecting this argument, the Court turned to the statutory utility requirements:

To meet the statutory requirement in subsection 34(1) of the *Patent Act*,⁶³ ...that a patent be "useful", the selected species must have an advantage over the class as a whole ...

However, there are no special legal requirements regarding what particular type of advantage is required. The

⁶⁰ *Ibid.* at 249.

⁶¹ *Ibid.*

⁶² *Ibid.* at 250.

⁶³ R.S.C. 1985, c. P-4 subsection 34(1) of the “Old *Act*” recites “An applicant shall in the specification of his invention (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;”.

test for advantage is understood to include a disadvantage to be avoided, as is the case here ...[Citations omitted]⁶⁴

The decision, however, left open the possibility of challenging the utility on the basis that thresholds could be manipulated, the Court of Appeal pointing out that there was little evidence on the issue of thresholds because Ratiopharm had not objected to them within the Notice of Allegation.

In *GlaxoSmithKline*⁶⁵, GlaxoSmithKline and the Wellcome Foundation (referred to here collectively as “GSK”) sought an order prohibiting the Minister from issuing a NOC to Pharmascience until the expiry of Canadian Patent 1,340,083 (the “083 Patent”). GSK asserted the 083 Patent as a valid selection patent from GSK’s European Patent No. 0,099,493 (the “493 Patent”) that would be infringed if Pharmascience was permitted to produce the antiviral compound valacyclovir (marketed as VALTREX). Pharmascience alleged invalidity for anticipation, obviousness, non-utility, double patenting, lack of invention, insufficiency, disclosure, lack of sound prediction and improper selection. Barnes J. found that these grounds “overlapped” and it was not necessary to deal with them in a discrete way.⁶⁶ Acyclovir was a known antiviral drug, which although given orally presented problems of bioavailability. Valacyclovir is a prodrug formed by the molecular combination of acyclovir with the amino acid, L-valine. Barnes J. identified the subject matter claimed by the 493 Patent as a genus of aliphatic amino acid esters of acyclovir and the patent included a statement that the new ester compounds “surprisingly have an improved water solubility compared with acyclovir which enables the derivatives to be used to a greater extent than acyclovir in the formulation of aqueous preparations”.⁶⁷ The 083 Patent claimed the selection of the compound valacyclovir (the L-valine ester of acyclovir) asserting that it “surprisingly had improved bioavailability after oral administration compared with alanine and glycine esters mentioned [in the 493 Patent]”⁶⁸. Barnes J. found that

⁶⁴ *Pfizer v. Ratiopharm*, *supra* note 57 at 251.

⁶⁵ *GlaxoSmithKline*, *supra* note 7.

⁶⁶ *Ibid.* at 298-299.

⁶⁷ *Ibid.* at 302.

⁶⁸ *Ibid.* at 302-303.

the bioavailability advantage asserted as the inventive selection of the 083 Patent was neither anticipated nor obvious.

Turning to the issue of utility, Barnes J. noted that “[t]o establish that a compound has a peculiar advantage over the genus of compounds from which it was chosen requires that the advantage not be found or be predicted to be found in a large number of members of the genus.”⁶⁹ Barnes J. looked to the Federal Court of Appeal decision in *Pfizer v. Ranbaxy* (discussed further below) and found that Nadon J. indicated that evidence of an unexpected selection advantage over the compounds covered by the genus patent is a requirement, at least with respect to establishing utility.⁷⁰ With respect to the utility of valacyclovir, Barnes J. found as follows:

The utility of valacyclovir and the other esters of acyclovir as antiviral prodrugs has already been asserted in the 493 Patent. The specific utility of valacyclovir had to be found, therefore, not in its antiviral properties or in improved solubility but in its supposedly better oral bioavailability profile over the other members of the class from which it was selected. That utility had to be established either by testing or by sound prediction or both. If the utility of valacyclovir for enhanced oral bioavailability over the genus compounds was not scientifically demonstrated or soundly predicted as of the Canadian filing date, the 083 Patent must fail for lack of utility...The fact that later evidence may establish utility does not transform the earlier speculation into something inventive. [Emphasis added]⁷¹

Barnes J. found that there must be sufficient testing of genus compounds to support at least a sound prediction of a substantially unique or peculiar advantage for the selection.⁷² Barnes J. found GSK’s evidence with respect to surprising or unexpected bioavailability to be insufficient:

⁶⁹ *Ibid.* at 318.

⁷⁰ *Ibid.* at 319.

⁷¹ *Ibid.* at 319-320.

⁷² *Ibid.* at 320.

[T]here is no evidence produced by GSK to establish that that bioavailability advantage for valacyclovir asserted by the 083 Patent was then known or predicted to be substantially unique among the thousands of compounds claimed by the 493 Patent. For all I can tell from the evidence, valacyclovir was, at best, shown to have a qualitative bioavailability advantage over the other two esters tested but that finding says absolutely nothing about whether the same advantage would exist vis-à-vis a few, some, many, most or all of the other compounds claimed by the 493 Patent. This is hardly a sufficient basis to establish the legal requirement that a selection be of a special or peculiar character relative to the genus from which it was chosen...Another way of putting this is that the selection of one compound with an unquantified advantage over two others does not add anything of a substantial character to the existing knowledge relative to the substantial pool of other esters of acyclovir named by the 493 Patent...[Citation omitted]⁷³

In holding the allegations of invalidity justified on the basis of lack of utility, Barnes J. found as follows:

In a pharmaceutical selection patent, the invention is the discovery of a surprising or unexpected advantage of the selection over the genus of compounds from which it was chosen. The utility of such a selection is not found in the fact that it works to successfully treat some human condition or ailment but rather that it works surprisingly better than the compounds monopolized by the genus patent. That is the inventive promise and the inventive promise that must be established.⁷⁴

In light of the finding with respect to utility, Barnes J. found it unnecessary to consider the sufficiency of the disclosure under s. 27(3), however, looking to the Federal Court of Appeal decision in *Pfizer v. Ranbaxy*, Barnes J. noted:

⁷³ *Ibid.* at 326.

⁷⁴ *Ibid.* at 328-329.

The law in the area of disclosure has recently been clarified to a degree by the decision of the Federal Court of Appeal in *Pfizer v. Ranbaxy*, ... which held that, for a selection patent, the patentee need not disclose anything more than the surprising and unexpected advantage of the selection. No data or other evidence to the [sic] support that assertion is required to be published within the patent. Suffice it to say, though, that when a patentee is attempting to establish the utility of a selection by relying upon evidence of sound prediction, there may be an obligation to disclose in the patent the underlying facts and the line of reasoning which support the prediction...

It seems to me that if a patentee is relying on sound prediction to establish that its selection has some unexpected advantage over the genus, it does have a heightened obligation to disclose in the patent its line of reasoning because that is part of the *quid pro quo* for the claimed monopoly over the selection.[Emphasis added]⁷⁵

XI

SUFFICIENCY AND AMBIGUITY

Subsections 27(3)(a) and (b) of the *Act* set out the sufficiency requirement:

Specification. - 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;

Subsection 53(1) also deals with the requirements of the specification, but includes an element of intent to mislead on the part of the applicant:

⁷⁵ *Ibid.* at 330.

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.

The statutory basis for objecting to claims for ambiguity can be found in subsection 27(4) of the *Act*:

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

Sufficiency and ambiguity are two different objections and the standard to meet in each case is different:

Canadian courts have stated in a number of cases the test to be applied in determining whether disclosure is complete. 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...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.[Emphasis added]⁷⁶

The distinction has also been stated thus:

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;

⁷⁶ *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)* (1989), 25 CPR (3d) 257 (SCC) [*Pioneer Hi-Bred*] at 267-268.

ambiguity is directed to the issue as to whether the scope of the monopoly can be understood.⁷⁷

Ambiguity has been described as a “last resort” and rarely to be used. A Court should not find a claim ambiguous where it can be construed in a meaningful way.⁷⁸

The Supreme Court described the sufficiency requirement in *Consolboard*:

Section 36 of the Patent Act lies at the heart of the whole patent system. The description of the invention therein provided for is the quid pro quo for which the inventor is given a monopoly for a limited term of years on the invention....The consideration for the grant is twofold: "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".⁷⁹

Insufficiency is a technical attack that should not operate to defeat a patent for a meritorious invention, but the attack will succeed where a person skilled in the art cannot put the invention into practice.⁸⁰

XII

SUFFICIENCY AND AMBIGUITY AND SELECTION PATENTS

In *Eli Lilly Canada Inc. v. Novopharm Ltd.*⁸¹, Hughes J. found allegations that a selection patent was invalid justified on the basis of

⁷⁷ *Hughes & Woodley, supra* note 30 at §34.

⁷⁸ See *Hughes & Woodley, supra* note 30 at §33 and case law cited therein.

⁷⁹ *Consolboard, supra* note 54 at 154-155.

⁸⁰ See *Hughes & Woodley, supra* note 30 at §34 and case law cited therein.

⁸¹ (2007), 58 CPR (4th) 214 (FCTD) [*Eli Lilly*].

insufficiency.⁸² Eli Lilly brought an application to prohibit the Minister of Health from issuing a NOC to Novopharm in respect of tablets for oral administration of drugs containing certain dosages of olanzapine, marketed by Eli Lilly as ZYPREXA. In its Notice of Allegation, Novopharm alleged invalidity of Canadian patent 2,041,113 (the “113 Patent”). This patent for olanzapine was a selection with respect to Canadian patent 1,075,687, which disclosed a vast number of compounds (15 trillion).

The validity of the 113 Patent had previously been considered in another application under the *PM(NOC) Regulations* brought in response to a Notice of Allegation issued by Apotex. In this previous application, Gauthier J. granted an order of prohibition, finding that the allegations made by Apotex in respect to the issue of validity of the 113 Patent were not justified.⁸³ In the earlier decision, the grounds of invalidity raised were anticipation, obviousness, double patenting and an allegation of misleading description under section 53 of the *Act*. Hughes J. considered that there were two invalidity issues raised beyond those considered by Gauthier J.: sufficiency and utility.⁸⁴

The claims at issue recited the chemical formula for olanzapine, along with a use and composition thereof. Hughes J. summarized the construction of the claims provided by Gauthier J. as follows:

Thus, the construction put on the claims by Justice Gauthier was that they were directed to olanzapine as an antipsychotic agent, that, in a clinical situation, had a better overall profile than previously known antipsychotic agents (including those of the ‘687 Patent) because of a number of factors, at least five, and possibly six if cholesterol levels were included as a factor. She found no need to determine if cholesterol levels were essential for the purposes of constructions when addressing the reason of obviousness.⁸⁵

⁸² An appeal of this decision to the Federal Court of Appeal was dismissed as moot on the basis that a NOC had already issued to Novopharm after the decision of Hughes J.: see *supra*, note 15.

⁸³ 58 CPR (4th) 353 (FCTD), *aff’d* 68 CPR (4th) 167 (FCA).

⁸⁴ *Eli Lilly*, *supra* note 81 at 230.

⁸⁵ *Ibid.* at 242.

Hughes J. agreed with Gauthier J.'s findings with respect to anticipation, obviousness and double patenting. Turning to the issue of sufficiency, Hughes J. considered that the general jurisprudence as to sufficiency of disclosure had to be considered in light of the particular requirements of selection patents:

The question of sufficiency of disclosure when it comes to the selection patents...has particular importance. The general jurisprudence as to sufficiency of disclosure must be considered in light of the particular requirements respecting selection patents that the inventive feature of selection of a compound or group of compounds from a larger group must reside in the unexpected or surprising attributes of the selected compound or groups and that this inventive feature must be clearly set out in the specification. [Emphasis added]⁸⁶

Hughes J. identified the discussion of Dickson J. in the Supreme Court decision of *Consolboard*, with respect to disclosure of the utility in the specification as giving rise to difficulties when considering a selection patent. In particular, the statement that it is a requirement that an invention possess utility, but that the patentee is not required in the disclosure to describe in what way the invention is new or to extol the effect or advantage thereof.⁸⁷

Interestingly, Hughes J. went on to cite the following passage in *Pioneer Hi-Bred* where the Supreme Court distinguished the difference between ambiguity and utility:

...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 ... 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

⁸⁶ *Ibid.* at 255-256.

⁸⁷ *Ibid.* at 257.

failure to meet the second invalidates it for insufficiency...[Citations omitted]⁸⁸

Hughes J. held that mere statement of advantage was insufficient:

A patentee cannot merely state that the selected compound or group has advantages. The patentee must state clearly what the invention is, namely the specific advantages...⁸⁹

However, it is difficult to ascertain from the decision what amounts to a “clear statement” such as to render the patent disclosure sufficient.

Hughes J. however appears to commingle the issue of sufficiency with ambiguity:

The discussion as to sufficiency elsewhere in those Reasons is directed to whether the patentee put enough into the specification so as to enable a person skilled in the art to clearly identify and understand the invention. Intention so as to deliberately mislead is not an element in considering sufficiency. [Emphasis added]⁹⁰

As discussed above, the requirement to identify the invention is not an issue of sufficiency, but of ambiguity.

In fact, failure to clearly define the advantage (or, alternatively stated, to define the inventive concept) as giving rise to an ambiguity problem was recognized as long ago as in *Re IG Farbenindustrie AG*:

I must add a word on the subject of the drafting of the specification of such a patent. It should be obvious, after what I have said as to the essence of the inventive step, that it is necessary for the patentee to define in clear terms the

⁸⁸ *Ibid.* at 258-259, citing *Pioneer Hi-Bred*, *supra* note 76.

⁸⁹ *Eli Lilly*, *supra* note 81 at 261.

⁹⁰ *Ibid.* at 270.

nature of the characteristic which he alleges to be possessed by the selection for which he claims a monopoly. He has in truth disclosed no invention whatever if he merely says that the selected group possesses advantages. Apart altogether from the question of what is called sufficiency, he must disclose an invention; he fails to do this in the case of a selection for special characteristics, if he does not adequately define them. The cautions repeatedly expressed in the House of Lords as regards ambiguity, have, I think, special weight in relation to selections patents... [Emphasis added]⁹¹

Support for the proposition that insufficiency may not be the most appropriate ground on which to challenge a patent for “improper selection” can be found in the decision of *Pfizer Canada Inc. v. Canada (Minister of Health)*⁹² (referred to here as *Pfizer v. Ranbaxy* to distinguish it from other cases with Pfizer in the style of cause). The Federal Court of Appeal considered the decision of the Applications Judge finding allegations of invalidity of a selection patent justified based on lack of sufficiency. The case involved a selection patent for the selection from a genus patent to cholesterol lowering statin compounds. The selection patent claimed pharmaceutically acceptable salts of atorvastatin, including the calcium salt marketed under the brand name LIPITOR.⁹³ The Notice of Allegation alleged invalidity for obviousness, double patenting, insufficiency and anticipation.

⁹¹ *Farbenindustrie, supra* note 3 at 323.

⁹² (2008) 67 CPR (4th) 23 (FCA) [*Pfizer v. Ranbaxy*].

⁹³ The validity of the ‘546 Patent (LIPITOR) was also considered in the decision of Barnes J. in *Pfizer Canada Inc. v. Canada (Minister of Health)* (2008), 64 CPR (4th) 1 (FCTD). (This decision was released prior to the decision of the Federal Court of Appeal in *Pfizer v. Ranbaxy*). Barnes J. refused to issue an order prohibiting the Minister from issuing an NOC to the respondent Apotex on the basis that allegations of invalidity were justified. Barnes J. characterized the issues raised in the Notice of Allegation (“NOA”) as “substantive validity issues of selection, double patenting, obviousness and anticipation”, but only dealt with the issues of the sufficiency of the NOA and the validity of the selection. In regards to the validity of the selection, Barnes J. characterized the issue as follows:

[T]he principal question for determination is whether Pfizer has established that atorvastatin calcium has surprising or unexpected advantages sufficient to meet the legal requirements for a valid selection.

Citing *Consolboard*, Nadon J. for the Court of Appeal noted that subsection 27(3) of the *Act* does not require a patent to describe its advantages.⁹⁴ However, Nadon J. noted that the Federal Court had approved on a number of occasions of the statement of Lord Diplock in the selection case of *Beecham Group Ltd. v. Bristol Laboratories International S.A.*⁹⁵ 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”.⁹⁶ While noting commentary suggesting that the disclosure requirements may be a bit more onerous for selection patents, Nadon J. also noted that the Court had considered selection patents in only two cases and it did not in either case suggest a higher level of disclosure was required.⁹⁷

Nadon J. went on to characterize the challenges made by Ranbaxy to the validity of the patent:

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.⁹⁸

Ranbaxy alleged the data provided in the patent description was not representative of all the data collected by Pfizer and was unreliable and that more reliable data obtained by Pfizer, but not supportive of the inventive advantage, was not included within the description. Nadon J. then found that such allegations were not properly characterized as allegations of insufficiency:

Barnes J.’s decision does not explicitly address whether “invalid selection” is a stand alone ground of invalidity or whether it merely shorthand for an allegation made under one of the existing grounds of invalidity. The decision would appear to find basis in insufficiency and anticipation and/or obviousness: see paragraphs [115], [118] and [120].

⁹⁴ *Pfizer v. Ranbaxy*, *supra* note 92 at 36.

⁹⁵ [1978] R.P.C. 521.

⁹⁶ *Pfizer v. Ranbaxy*, *supra* note 92 at 37.

⁹⁷ *Ibid.* at 37-38.

⁹⁸ *Ibid.* at 41.

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.⁹⁹ [Emphasis added]

The Court held that the Applications Judge had wrongly interpreted the disclosure requirements of subsection 27(3) of the *Act*:

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.¹⁰⁰

⁹⁹ *Ibid.* at 42.

¹⁰⁰ *Ibid.* at 43.

The Court characterized the standard to be applied under subsection 27(3) as follows:

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.

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.

How does it work? The 546 patent sets out the methods for producing the compounds covered by the patent.¹⁰¹

Nadon J. went on to conclude that the fact that there was no disclosure of a justification for why the calcium salt of atorvastatin was the preferred embodiment did not render the disclosure insufficient:

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.¹⁰²

¹⁰¹ *Ibid.* at 44.

¹⁰² *Ibid.* at 44.

The Court noted that the requirement to be truthful and not misleading is not covered by subsection 27(3), but subsection 53(1) of the *Act*.¹⁰³

Nadon J. went on to note that Ranbaxy had not challenged the sufficiency of the data underlying the invention under the headings of obviousness, double patenting or anticipation and the Notice of Allegation was therefore insufficient to challenge the patent on this basis.

Nadon J. did not exclude the possibility that a lack of data to support a claimed advantage could form the basis of a validity challenge:

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*.¹⁰⁴

XIII

SELECTION PATENTS AND THE SOUND PREDICTION ANALYSIS

The Federal Court recently considered the ZYPREXA patent again in the context of an infringement action brought by Eli Lilly against Novopharm.¹⁰⁵ This decision is currently under appeal. Novopharm attacked the patent on a number of grounds including anticipation, double-patenting, and obviousness. O'Reilly J. purported to make his decision based on a ground of invalidity that he described as “invalid selection”.¹⁰⁶ A review of the reasons for decision, however, reveals a utility analysis made with respect to the advantage(s) of the selected compound.

O'Reilly J. identified a three step analysis:

¹⁰³ *Ibid.* at 43.

¹⁰⁴ *Ibid.* at 45.

¹⁰⁵ *Eli Lilly Canada Inc. v. Novopharm Ltd.* (2009), 78 CPR (4th) 1 (FCTD) [*Eli Lilly, infringement proceeding*].

¹⁰⁶ *Ibid.* at 7.

Therefore, the first step I must take is to decide whether one or more of the asserted advantages of olanzapine was known to exist, or was soundly predicted, at the time the '113 patent was filed in 1991. Second, I must decide whether at least one of them could be considered a substantial advantage over the '687 compounds and somewhat peculiar to olanzapine. And, if so, the third question is whether the disclosure of that substantial and special advantage in the '113 patent was adequate. If I decide any one of them in the negative, I must find the '113 patent to be invalid.¹⁰⁷

O'Reilly J. identified from the patent four advantages relative to the compounds of the genus 687 Patent and, in particular, flumezapine and ethyl olanzapine, for which comparative data was provided in the 113 Patent.¹⁰⁸ Interestingly, O'Reilly J. went on to identify additional advantages in respect of “prior known antipsychotic agents”, noting that flumezapine and ethyl olanzapine had not been “used for the treatment of schizophrenia or any other condition”:

In my view, reading the '113 patent as a whole, the skilled reader, aware of the '687 patent, would interpret the alleged superiority of olanzapine over other antipsychotic drugs on the market as being another major advantage of olanzapine over the other '687 compounds.¹⁰⁹

With respect to prior known antipsychotic agents, O'Reilly J. identified four specific comparisons.¹¹⁰

¹⁰⁷ *Ibid.* at 18.

¹⁰⁸ *Ibid.* at 17 [(i) has lower elevations of liver enzymes than flumezapine, (ii) lower elevations of CPK than flumezapine; (iii) less EPS liability than flumezapine; and (iv) does not elevate cholesterol; but ethyl olanzapine does.].

¹⁰⁹ *Ibid.* at 17-18.

¹¹⁰ *Ibid.* [(i) high level of efficacy at low doses; (ii) lower elevation of prolactin; (iii) lower EPS liability; and (iv) no alteration of white blood cell count.].

In the first step of the analysis - deciding whether one or more of the asserted advantages of olanzapine was known to exist, or was soundly predicted - a sound prediction analysis (a utility analysis) was made of each of the advantages identified. O'Reilly J. found there was a lack of factual basis for each advantage or a prediction thereof, or a sound line of reasoning from which the advantage could be soundly predicted from the facts provided.

In the second step of the analysis, O'Reilly J. considered the question of whether at least one advantage could be considered a substantial advantage over the genus compounds and somewhat peculiar to olanzapine. O'Reilly J. held the comparisons made "did not relate to the class as a whole" and that he had "no evidence that any advantage was peculiar to olanzapine."¹¹¹ Clearly with a genus patent of 15 trillion compounds, comparative data across the class would be impossible. O'Reilly J. seemed to place significance on the comparisons in the '113 patent being made to "failed compounds",¹¹² although this hardly seems significant given that the selection is from a genus of "unselected" compounds.

O'Reilly J. adopted something akin to a utility analysis under this step of the analysis:

The invention described in the '687 patent was a class of compounds that would be useful in the treatment of psychotic conditions and acute mania, and that would have low EPS liability. By contrast, the invention described in the '113 patent is a drug that is safer and more effective in the clinical treatment of patients than other antipsychotic drugs on the market. This is clearly a substantial advantage that would set olanzapine apart from the rest of the '687 class. However, as outlined above, the broad assertion in the '113 patent was unsupportable at the time Lilly applied for it.¹¹³

¹¹¹ *Ibid.* at 36.

¹¹² *Ibid.* at 37.

¹¹³ *Ibid.*

The advantage would only be incapable of support (i.e. would be unsupported) if it was not demonstrated or predictable at the time the application was applied for (i.e. if the test for utility could not be satisfied.)

Under the third step of the analysis, O'Reilly J. identified two disclosure obligations: the duty to set out the basis on which olanzapine is believed to have a substantial and peculiar advantage over the 687 compounds and the duty to set out the basis for the sound prediction for that advantage. O'Reilly J. found the two disclosure requirements to be "coextensive" and not satisfied.¹¹⁴

It is interesting to contrast the outcome in this case with that of a recent United Kingdom (UK) Court of Appeal decision where the corresponding patent for ZYPREXA was upheld.¹¹⁵ The patent was challenged for anticipation and obviousness over a prior Eli Lilly specification that disclosed the genus and also for obviousness in view of a piece of non-patent prior art. Eli Lilly also sought to defend the patent as a valid "selection patent". Considering the law of selection patents as laid down in *I.G. Farbenindustrie's Patents*,¹¹⁶ the Court relegated these rules to old law.¹¹⁷ The Master of the Rolls noted that the 1977 UK Patent Act "was expressly enacted to create a "new" regime for patents" and was "intended to be interpreted in accordance with the EPC".¹¹⁸ Noting that selection patent rules from *I.G. Farbenindustrie's Patents* did not form part of the European Patent Office (EPO) Guidelines for Examination and had not been applied in an EPO Board of Appeal decision cited to them, Lord Justice Jacob in a concurring decision held them no longer part of UK patent law.¹¹⁹

The Court adopted an obviousness approach based on the practice of the EPO Boards when analyzing claims for a product or class of products falling within a greater class.¹²⁰

Lord Justice Jacob characterized the standard applied by the EPO:

¹¹⁴ *Ibid.* at 39.

¹¹⁵ *Dr Reddy's Laboratories (UK) Limited v. Eli Lilly and Company Limited*, [2009] EWCA Civ 1362 (hereinafter "*Dr Reddy's*").

¹¹⁶ *I.G. Farbenindustrie*, *supra*.

¹¹⁷ *Dr Reddy's*, *supra* at para 37.

¹¹⁸ *Ibid.* at para 103.

¹¹⁹ *Ibid.* at para 37.

¹²⁰ *Ibid.* at para 40.

What then does the EPO do? The answer is essentially this: that it regards what can fairly be regarded as a mere arbitrary selection from a class as obvious. If there is no more than an arbitrary selection then there is simply no technical contribution provided by the patentee.¹²¹

While the Master of the Rolls noted that in some cases the Board had indicated that a selection patent must show that the selected compound has an advantage which other compounds do not have, the requirement can be satisfied by comparing the claimed compound with the closest prior art, i.e. structurally the most similar compound in the group from which the claimed compound has been selected.¹²²

The Court rejected the proposition that the selection of olanzapine was arbitrary and held the patent not obvious in view of the genus specification.¹²³

Lord Justice Jacob noted the trial Judge's conclusion that if it been necessary to shown compliance with the *I.G. Farbenindustrie's Patents* rules, the patent failed to do so, but observed that this showed that the rules were too strict:

It shows, to my mind, that the rules are too strict. They would mean that a technical advance of the sort made by Lilly would be unpatentable. That in turn would mean that it would not be worthwhile doing the sort of thing that Lilly did by developing the disclosure of their Patent further and bringing olanzapine to market. Unpatentability would have meant this medicine would not have been available.¹²⁴

In the Canadian case, O'Reilly J. also considered the question of inventiveness, but came to a different conclusion.¹²⁵ O'Reilly J. did not conclude "that the selection of olanzapine as a development compound was an obvious choice" noting that "olanzapine was not

¹²¹ *Ibid.* at para 44.

¹²² *Ibid.* at para 112.

¹²³ *Ibid.* at paras 53 to 58 and paras 110 and 111.

¹²⁴ *Ibid.* at paras 77 to 78.

¹²⁵ *Eli Lilly, infringement proceeding, supra* note 105 at 41.

the only candidate under consideration, and did not even appear to be particularly active” and it “was not “more or less self-evident” that olanzapine would work.”¹²⁶ However, he found the testing of olanzapine to be “routine”:

Lilly had merely carried out routine testing of olanzapine's properties. It had some early signals of safety and efficacy in a few small studies of healthy volunteers and patients. Lilly scientists showed persistence, diligence and sound science in getting olanzapine that far. New methods of synthesis had to be worked out (after an explosion in the lab during synthesis of flumezapine). But that is not enough for a patent. There must be an invention. And, in the context of a selection patent, the invention is the discovery of unexpected, substantial and special advantages.¹²⁷

In an introductory portion of his decision, O’Reilly J. described the development of olanzapine in the years following the 1975 filing of the genus 687 Patent. Testing on ethyl flumezapine was wound down in 1978 and clinical trials on flumezapine were halted in 1982 after receiving reports of elevated liver enzymes and the muscle enzyme CPK in some patients. Olanzapine was first synthesized shortly after the discontinuation of flumezapine. O’Reilly J. noted that at first olanzapine was not considered by all researchers to be a good choice for development and testing was ongoing until filing of the patent application in 1983.¹²⁸ He summarized the testing that had been performed at the time of filing:

By the time it filed the '113 patent, Lilly had received the results of its healthy volunteer studies, as well as some preliminary data from its clinical trials. It had also concluded a six-month study in dogs. The patent mentions these studies and provides some general information about what they disclosed.¹²⁹

¹²⁶ *Ibid.* at 41.

¹²⁷ *Ibid.* at 40-41.

¹²⁸ *Ibid.* at 10-12.

¹²⁹ *Ibid.* at 12.

If the choice of olanzapine was not obvious, characterizing the years of product development as entirely routine so as to make a finding of obviousness would seem to be a high standard to apply.

The stringency with which the sound prediction standard is applied (if at all) will influence the result in this type of decision. Particularly in a case such as ZYPREXA, where a selection is made from an enormous genus and the selection has merit, it would seem appropriate to have some deference to the expertise of the applicant in making the selection based on the testing performed. In this regard, the patenting of arbitrary choices for which there is no evidence to predict advantageous properties over the genus would clearly be precluded by practical considerations. Also, given that “the same rules” are to apply to selection patents, the broad definition of utility from *Consolboard*, which includes affording the public a useful choice could still be relevant.¹³⁰ In the ZYPREXA context, identifying a compound from a vast class and demonstrating its clinical potential in early clinical trials arguably affords the public a new and useful choice, while requiring proof of a superior side effects profile and clinical utility applies a higher standard to selection patents.

XIV

CONCLUDING NOTE

The Supreme Court decision of *Sanofi-Synthelabo* established the tests to be applied in assessing the novelty and inventiveness of a selection patent. The decision clarified that in the case of a true selection, there is no anticipation because the genus patent will not satisfy the disclosure requirement of the anticipation test. In the case of obviousness, the inventive concept of the claims may be ascertained with reference to the specification. The inventive concept can be found in the special advantage of the selected compound. With respect to double patenting, if the claims of a selection patent are novel and inventive over the genus patent, the patent will not be invalid for double patenting: the claims are not to the same invention, the claims of the genus patent are broader than those of the selection patent. If the inventive concept or advantage cannot be ascertained, there is no inventive concept and the patent may be invalid for obviousness. An

¹³⁰ *Supra* note 54.

inability to ascertain the inventive concept of a claim presumably also means such a claim would be invalid for ambiguity. If the invention does not fulfil the “promise” of the selection patent (i.e. the stated advantage), it may be invalid for lack of utility. Testing and evidence thereof may be required where the patentee is relying on sound prediction to establish that its selection has some unexpected advantage over the genus; however, this proposition is presently under appeal. An allegation of improper selection can be considered mere “shorthand” for alleging one of the existing applicable grounds of invalidity. Clearly identifying, expressing and assessing these grounds of invalidity could lead to more doctrinal clarity and jurisprudential development of these existing grounds, while ensuring that selection patents continue to be subject to the same rules that apply to other types of patents.
