Federal Court of Appeal | Cour d'appel fédérale

Date: 20100721

Docket: A-454-09

Citation: 2010 FCA 197

CORAM: **NADON J.A.**
SHARLOW J.A.
LAYDEN-STEVENSON J.A.

BETWEEN:

ELI LILLY CANADA INC.,
ELI LILLY AND COMPANY,
ELI LILLY AND COMPANY LIMITED and
ELI LILLY SA

Appellants

and

NOVOPHARM LIMITED

Respondent

Heard at Ottawa, Ontario, on June 21 and 22, 2010.

Judgment delivered at Ottawa, Ontario, on July 21, 2010.

REASONS FOR JUDGMENT BY: **LAYDEN-STEVENSON J.A.**

CONCURRED IN BY: NADON J.A.
SHARLOW J.A.

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REASONS FOR JUDGMENT

LAYDEN-STEVENSON J.A.

[1] The plaintiffs (Lilly) commenced an action for patent infringement against the defendant (Novopharm) with respect to Canadian Letters Patent No. 2,041,113 (the '113 Patent), a selection patent for the compound olanzapine (sold under the brand name Zyprexa), owned by Lilly. Olanzapine is used to treat schizophrenia.

[2] Years before, Lilly had obtained Canadian Letters Patent No. 1,075,687 (the '687 patent), a genus patent for approximately 15 trillion compounds predicted to be useful in the treatment of mild anxiety and certain kinds of psychotic conditions, such as schizophrenia and acute mania. The '687 Patent expired 15 years ago.

[3] Novopharm filed a statement of defence and counterclaim with respect to Lilly's infringement action. Novopharm asserted that Lilly's action could not succeed because the '113 Patent is invalid. Following a 44-day trial involving approximately 30 witnesses, a Federal Court judge (the trial judge) agreed with Novopharm and dismissed Lilly's action. The claims of the '113 Patent were held to be invalid. The Federal Court decision (2009 FC 1018) is reported at 353 F.T.R. 35.

[4] Lilly appeals from the Federal Court judgment. Although various submissions and arguments were advanced on appeal, the core issue raises a single question: do the conditions for a valid selection patent constitute an independent basis upon which to attack the validity of a patent? I conclude that the answer to the question is no. The trial judge reached the opposite conclusion. In my view, he erred in doing so and, because he approached the matter on that basis, he failed to address adequately the issues of obviousness, double patenting, utility and sufficiency.

Background

[5] Chlorpromazine, the first commercially available antipsychotic medicine, became available in 1953. Although useful in treating schizophrenia, it induced extrapyramidal side effects (EPS) such as serious involuntary twitching of the face and tongue and painful body distortions. Haloperidol, introduced in the 1960s, also produced EPS. These drugs have been referred to as “typical” or first generation antipsychotics. Clozapine, an “atypical” or second generation antipsychotic, was introduced in 1968. Clozapine did not induce EPS, but was found to cause serious haematological side effects (dramatic reduction of white blood cells), known as agranulocytosis, in some patients. It was withdrawn from the market and although it later returned, recipients must undergo strict monitoring of their white blood cell counts.

[6] During the 1970s, scientists, including Lilly scientists, searched for a safe, clozapine-like compound that would not yield the side effects of EPS and agranulocytosis. Drs. Jiban Chakrabarti and David Tupper, Lilly chemists, conducted research into drugs having useful activity on the central nervous system. As a result of their research, the '687 Patent, listing Chakrabarti and Tupper as its inventors, was filed in 1975, issued on April 15, 1980 and expired in April, 1995.

[7] The '687 Patent covered a broad genus (or class) of approximately 15 trillion thienobenzodiazapine compounds. It listed specific examples and described the criteria for “preferred” and “most preferred” compounds. It encompassed, but did not disclose, olanzapine. The trial judge concluded that olanzapine fell within the “most preferred” compounds (reasons for judgment, para. 23). The '687 Patent specifically disclosed flumezapine, ethyl flumezapine and

ethyl olanzapine (referred to as the '222 compound). It claimed flumezapine and ethyl flumezapine (claims 19 and 21).

[8] The '687 Patent stated that the thienobenzodiazapine compounds had displayed useful central nervous system activity in animal tests and had potent neuroleptic, sedative, relaxant and anti-emetic properties. They showed good CAR-CAT separation. CAR (conditioned avoidance response in rodents) test results suggest potential antipsychotic usefulness and CAT (liability to induce catalepsy in rodents) test results provide an indication regarding the occurrence of EPS. According to the patent, these properties rendered the compounds useful in the treatment of mild anxiety states and certain kinds of psychotic conditions, such as schizophrenia. The compounds boasted a high therapeutic index (wide margin between the effective dose and a gross toxic effect). The effective dosage range was very wide, from 0.1 to 20 mg per kg per day. The focus of the '687 Patent, as found by the trial judge, was on the compounds (their constituents, structure and the processes by which they could be made).

[9] Further research was conducted on some of the '687 Patent’s compounds. Dr. Chakrabarti published a paper in 1980 providing data on 76 of the compounds. Flumezapine and ethyl flumezapine initially appeared promising. However, ethyl flumezapine was abandoned in 1978 after dog studies revealed that the compound caused a reduction in white blood cells. Attention turned to flumezapine. This compound proceeded to clinical trials until reports of elevated liver enzymes and the muscle enzyme creatine phosphokinase (CPK) were reported in some patients in April, 1982. In consultation with the Food and Drug Agency (FDA), Lilly halted its trials.

Although it could have continued its studies of flumezapine, Lilly management concluded otherwise and further work on flumezapine was discontinued.

[10] An additional seven compounds, one of which was olanzapine, were subsequently synthesized. The Lilly research team favoured olanzapine (a methyl rather than an ethyl compound) because of its overall performance on a series of animal and *in vitro* tests. By 1983, Lilly was satisfied that olanzapine showed potential as an antipsychotic. Studies continued and in 1986 olanzapine was given to healthy volunteers. In 1989, clinical trials began with patients. Lilly decided to file the '113 Patent, which characterizes olanzapine as a selection from the class of the '687 Patent. The patent for olanzapine was filed in Canada on April 24, 1991 and the '113 Patent issued July 14, 1998.

[11] The '113 Patent disclosed that Lilly “discovered a compound which possesses surprising and unexpected properties by comparison with flumezapine and other related compounds.” It also referred to other perceived advantages of olanzapine over prior-known antipsychotic agents not included in the genus patent. It declared that olanzapine is an effective antipsychotic for treatment of schizophrenia, exhibiting high activity “at surprising low dosage levels.” The preferred treatment for adults was said to be from 0.1 to 20 mg per day. The '113 Patent also claimed the drug’s pharmaceutical compositions.

The Trial Judgment

[12] As noted earlier, the trial of Lilly's infringement action lasted 44 days and included the testimony of some 30 witnesses. Novopharm defended the infringement allegations against it and counterclaimed on the basis that the '113 Patent was invalid, specifically on grounds of anticipation, double patenting, wrong inventorship, obviousness, section 53 of the *Patent Act*, R.S.C. 1985, c. P-4 (the Act) and section 73 of the Act.

[13] In the reasons for judgment, the trial judge identified the '113 Patent's stated advantages over both the '687 Patent and other antipsychotic drugs. He determined that the declared advantages over the '687 Patent compounds included: lower incidence of liver enzyme elevations compared to flumezapine; lower CPK levels than flumezapine; lower ESP liability than flumezapine; and no increase in cholesterol compared to ethyl olanzapine. Regarding the other antipsychotic drugs, the stated advantages were found to be: higher efficacy at low doses; lower elevation of prolactin; lower ESP liability; and no alteration of white blood cell count.

[14] The trial judge reasoned that if these advantages amounted to a substantial advantage secured by the drug (or a substantial disadvantage avoided in comparison with the genus patent), if they were known or predicted at the time of filing, and if they were adequately disclosed, the '113 Patent would be a valid selection patent.

[15] He concluded that there was insufficient evidence of the advantages identified by the '113 Patent. Specifically, the trial judge determined: the stated advantages were not substantial and peculiar; a person skilled in the art (POSITA) would not be able to appreciate any inventive

difference between the '687 Patent and the '113 Patent; the test for sound prediction was not met; Lilly had very little idea about what olanzapine's effect was likely to be; and the '113 Patent did not meet the requirements for adequate disclosure. His penultimate conclusion was that the '113 Patent did not meet the requirements for a valid selection patent. In brief reasons, the trial judge concluded that the '113 Patent was invalid for double patenting, anticipation and insufficiency of disclosure. He also summarily addressed the issue of obviousness.

Standard of Review

[16] The standard of review is articulated in *Housen v. Nikolaison*, [2002] 2 S.C.R. 235. There, the Supreme Court reiterated that an appeal is not a re-trial of a case. Questions of law are to be determined on a standard of review of correctness. This means that an appellate court is at liberty to replace the opinion of the trial judge with its own. The standard of review for findings of fact is palpable and overriding error, that is, the factual findings cannot be reversed in the absence of an error that is plainly seen.

Statutory Provisions

[17] The text of all statutory provisions referred to in these reasons is attached as Schedule "A".

Issues

[18] As stated at the outset, the first and primary issue is whether the conditions for a valid selection patent constitute an independent basis upon which to attack the validity of a patent. This issue raises a question of law and is therefore reviewable on a standard of correctness. Issues regarding anticipation, obviousness, sufficiency and double patenting also arise. The applicable standards of review for these issues will be identified as each allegation of invalidity is addressed.

Selection Patents

[19] To properly situate the first issue, an appreciation of the nature of selection patents is required. The dearth of Canadian jurisprudence on the subject of selection patents was noted in *Pfizer Canada Inc. v. Canada*, [2007] 2 F.C.R. 137, 2006 FCA 214, leave to appeal dismissed, [2006] S.C.C.A. 335 (*Pfizer*). The topic has surfaced more frequently since that observation was made, most notably in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*., [2008] 3 S.C.R. 265, 2008 SCC 61 (*Sanofi*).

[20] Although not restricted to chemical patents, selection patents more commonly arise in that context. Simply stated, the originating (or genus) patent typically refers, in general terms, to a group of products or processes from all of which a particular result (or results) may be obtained or predicted. If a property, quality or use in relation to one or more members of the genus is subsequently discovered, that discovery may be an invention giving rise to a valid selection patent. As explained in *Pfizer* and *Sanofi*, selection patents exist to encourage researchers to further use their inventive skills so as to discover new advantages for compounds within the known class.

[21] A selection patent can be claimed for a selection from a class of thousands or for a selection of one out of two. In this case, as noted earlier, the '687 Patent covered a genus of approximately 15 trillion thienobenzodiazapine compounds. The '113 Patent is directed to a specific chemical compound, olanzapine, or an acid addition salt thereof.

[22] In *Sanofi*, a question was raised as to whether the fact that a patent had been issued for a genus of compounds necessarily means that a patent could not be issued for any compound falling within the genus. In other words, would it be impossible, as a matter of law, for any selection patent to be valid. Rothstein J., writing for the Court, referred to a line of authority stemming from *I.G. Farbenindustrie A.G.'s Patents* (1930), 47 R.P.C. 289 (Ch.D.) (*I.G. Farbenindustrie*) in support of the conclusion that a system of genus and selection patents is acceptable in principle. At paragraph 10 of his reasons, Rothstein J., relying on Maughan J. in *I.G. Farbenindustrie,* described the characteristics of a valid selection patent as follows:

> 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.

[23] While the *I.G. Farbenindustrie* conditions are clear enough, the question that arises in this case did not arise in that case, or in *Sanofi*. That question is: at what stage, or where, are the noted

conditions for a valid selection patent to be addressed? That is the primary issue and it is an important one. As noted earlier, it is a question of law for which the standard of review is correctness.

Do the conditions for a valid selection patent constitute an independent basis upon which to attack the validity of a patent?

[24] Lilly asserted, in its written submissions, that the trial judge erred by creating an "illegitimate amalgam by merging the doctrine of sound prediction of utility with obviousness and sufficiency and in the process required Lilly to provide proof of the inventive step (i.e. the advantages) in the disclosure." In Lilly's view, the "selection" issue goes to the question of obviousness and is properly addressed as part of that inquiry.

[25] Novopharm criticized Lilly's approach as being nothing other than a disguised and impermissible attack on the factual determinations of the trial judge. It maintained that Lilly prosecuted and pleaded the '113 Patent as a selection patent. Accordingly, Novopharm attacked it as such, arguing, among other things, that "Lilly had failed to demonstrate or soundly predict that olanzapine had the substantial or peculiar advantages promised for it in the '113 Patent." It emphasized the trial judge's findings that the alleged advantages "are not substantial and peculiar advantages for olanzapine over and above the '687 class (nor over prior known antipsychotics)." Novopharm summarized its position stating "there is no utility in the patent."

[26] At the hearing of the appeal, the submissions in this respect were somewhat nuanced. Lilly clarified and focussed its position, arguing that there is no foundation in law for an independent validity attack based solely on the *I.G. Farbenindustrie* criteria. At the same time, it steadfastly maintained its assertion that the validity of a selection patent goes to obviousness. Novopharm, for its part, argued that the trial judge applied the proper approach "set out 80 years ago in *I.G. Farbenindustrie*… the foundation of selection patent law in Canada." It referred to the definition of "invention" in section 2 of the Act and insisted that, in a selection patent, the advantages are part of the invention. If the advantages are not established, there is no invention. According to Novopharm, the trial judge construed the '687 and '113 Patents and then conducted a utility analysis.

[27] In my view, a challenge directed to a determination that the conditions for a selection patent have not been met does not constitute an independent basis upon which to attack the validity of a patent. Rather, the conditions for a valid selection patent serve to characterize the patent and accordingly inform the analysis for the grounds of validity set out in the Act – novelty, obviousness, sufficiency and utility. In short, a selection patent is vulnerable to attack on any of the grounds set out in the Act. I arrive at this conclusion for a variety of reasons.

[28] As noted in *Sanofi*, the conditions set out in *I.G. Farbenindustrie* describe selection patents (para. 9). In other words, the conditions are akin to a definition. Rothstein J. found *I.G. Farbenindustrie* to be a useful starting point for the analysis to be conducted (para. 11). It only

stands to reason that in undertaking an analysis of novelty, obviousness, sufficiency and utility, one should know the nature of the beast with which one is dealing.

[29] The comments of Lord Walker in *Synthon B.V. v. SmithKline Beecham plc*, [2006] 1 All E.R. 685, [2005] U.K.H.L. 59 *(Synthon)* at paragraphs 57-58, reproduced below, were specifically cited with approval in *Sanofi*.

> The law of patents is wholly statutory and has a surprisingly long history… In the interpretation and application of patent statutes, judge-made doctrine has over the years done much to clarify the abstract generalities of the statutes and to secure uniformity in their application.
>
> Nevertheless, it is salutary to be reminded, from time to time, that the general concepts which are the common currency of patent lawyers are founded on a statutory text, and cannot have any other firm foundation.

Notably, the Act contains no reference to invalid selection.

[30] In *I.G. Farbenindustrie*, at page 322, Maugham J specifically stated as follows:

> On consideration, I think it would be unwise to endeavour to state in definite language all the conditions on which a selection patent must depend; for after all a selection patent does not in its nature differ from any other patent and is open to attack on the usual grounds of want of subject-matter, want of utility, want of novelty and so forth.

Similarly, in *Sanofi*, at paragraph 9, Rothstein J. confirmed that a selection patent does not in its nature differ from any other patent. The same view is expressed in Harold G. Fox, *Canadian Patent Law and Practice*, 4th ed. (Toronto: Carswell, 1969) (Fox) at p. 91.

[31] Further, in *Sanofi*, Rothstein J. incorporated his inquiry regarding the alleged advantages of clorpidogrel bisulfate (Plavix) into his analyses of anticipation, obviousness and double patenting. He did not conduct an independent analysis with respect to the conditions of selection patents. It is no answer to say, as Novopharm did, that in *Sanofi*, advantages were not in issue. It is readily apparent from Novopharm's memorandum of fact and law and its oral argument that, in the context of a selection patent, the alleged advantages are always in issue due to the patent's very nature.

[32] Finally, the selection patent is discussed in relation to the requirement of sufficiency in *Terrell on the Law of Patents*, 16th ed. (London: Street& Maxwell, 2006) (Terrell) at pp. 279, 294. The selection patent is addressed specifically in relation to anticipation in *Re E.I. du Pont de Nemours & Co. (Witsiepe's) Application*, [1981] F.S.R. 377 (C.A.), aff'd. [1982] F.S.R. 303 (H.L.) *(E.I. Du Pont)*. Of course, as stated by Lilly, obviousness is relevant to the validity of a selection patent and, as Novopharm asserted, so is utility. The notion of selection permeates the entire analysis in relation to each of the grounds of alleged invalidity.

[33] Novopharm referred to no authority, and I have not found any, where the analysis of the conditions for a valid selection patent, without more, has rendered a patent invalid. It is safe to say that the paucity of authority, considered in combination with my comments above, indicates that no such freestanding ground of attack exists. To reiterate, a determination that the conditions for a selection patent have not been met does not constitute an independent basis upon which to attack the validity of a patent. To the extent that paragraph 27 of *Pfizer* or the dissenting reasons in *Apotex Inc. v. Janssen-Ortho Inc.*, 2009 FCA 212, 392 N.R. 71, 75 C.P.R. (4th) 411 may be taken to imply

otherwise, they should be disregarded. A selection patent is the same as any other patent. Its validity is vulnerable to attack on any of the grounds set out in the Act.

Application to this Case

[34] In this case, the trial judge, in identifying the issues, recognized that the main issue was the validity of the '113 Patent. He noted that Novopharm attacked the validity of the '113 Patent on numerous grounds. Then, at paragraph 10, he stated:

> […] but I am persuaded that the main one – that the '113 is not a valid selection patent – is supported by the preponderance of evidence and, therefore, I deal with the others briefly at the end of my reasons.

Novopharm's other grounds were: anticipation, double patenting, wrong inventorship, obviousness, section 53 of the Act (misrepresentation) and section 73 of the Act (deemed abandonment). The grounds relating to wrong inventorship and those relating to sections 53 and 73 of the Act were not pursued on appeal and I will say nothing further about them.

[35] The trial judge examined the '113 Patent specifically in relation to the proclaimed advantageous qualities of olanzapine. He divided the advantages into two categories: the advantages of olanzapine over the other compounds of the '687 Patent and its superiority over other known antipsychotic drugs. He identified the claims in issue, then asked, "is the '113 Patent a valid selection patent?" He summarized the patent's contents and then determined that the first step was 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." The second step, from the trial judge's perspective, was to "decide whether at least one of them could be considered a substantial

advantage over the '687 compounds and somewhat peculiar to olanzapine." If so, the third step involved a determination of "whether the disclosure of that substantial and special advantage in the '113 Patent was adequate." The trial judge concluded that if the answer to any one of the questions was negative, he was obliged to find the '113 Patent to be invalid.

[36] In his analysis, the trial judge answered the first identified question (whether the asserted advantages were known or soundly predicted at the time of filing) by referring briefly to selected expert evidence regarding the data and testing with respect to each of the alleged advantages in the '113 Patent. He concluded that the evidence showed no advantage for olanzapine over flumezapine or ethyl olanzapine ('687 Patent compounds) and no factual basis or line of reasoning for a prediction that olanzapine would have the asserted advantages over those compounds or a line of reasoning that would support a sound prediction. He also concluded that there was insufficient disclosure in the patent of any factual basis or line of reasoning. He reached the same conclusion with respect to any alleged advantage in comparison with other antipsychotic drugs.

[37] The trial judge answered the second question (whether the alleged advantages were substantial and peculiar) in the negative. He found, again on the expert evidence regarding the data and testing, that to the extent they existed at all, their magnitude was insignificant. He was particularly critical of the results of the study in dogs. Regarding the third question (adequate disclosure), he concluded that if the patent had set out the factual basis and line of reasoning on which the assertions of substantial and special advantages were based, then the disclosure requirements for a valid selection patent would have been satisfied. However, since he had already

concluded, in answering the first question, that there were no advantages established and no factual basis or line of reasoning for a sound prediction, he found that the '113 Patent's disclosure was insufficient.

[38] The trial judge ultimately concluded, on the basis just described, that the '113 Patent was not a valid selection patent. Except for obviousness, which I will come to later, he reasoned, largely on the same basis, that most of "the other grounds of attack on the '113 Patent [became] superfluous."

[39] It is readily apparent that the trial judge regarded the *I.G. Farbenindustrie* conditions of a selection patent as an independent basis upon which to attack the validity of the '113 Patent. I have concluded earlier that a determination that the conditions for a selection patent have not been met does not constitute an independent basis upon which to attack a patent's validity. A selection patent is the same as any other patent. Its validity is vulnerable to attack on any of the grounds set out in the Act. It necessarily follows that the trial judge erred in determining the validity of the '113 Patent on the basis that he did. That is not to say, however, that his analysis is not relevant to the issue of utility, or other grounds of validity.

Construction

[40] The relevant claims of the '113 Patent are claims 3, 6, 13, 14, 15 and 16. Those claims state:

Claim 3: 2-Methyl-10-(4-methyl-1-piperazinyl)-4H-thieno-[2,3-b][1,5] benzodiazepine.

Claim 6: The use of a compound according to claim 2 or 3 for the manufacture of a medicament for the treatment of schizophrenia.

Claim 13: A pharmaceutical composition comprising of the compound of claim 3 together with a pharmaceutically acceptable diluent or carrier therefore.

Claim 14: A pharmaceutical composition in a capsule or tablet form comprising 0.1 to 20 mg of the compound of claim 3.

Claim 15: A pharmaceutical composition in capsule or tablet form compromising 0.5 to 10 mg of the compound of claim 3.

Claim 16: A pharmaceutical composition in capsule or tablet form compromising from 2.5 to 5 mg of the compound of claim 3 together with a pharmaceutically acceptable diluent or carrier therefore.

[41] The trial judge, at paragraph 46 of his reasons, construed the claims as follows:

- Claim 3: Olanzapine;
- Claim 6: The use of olanzapine for the manufacture of a drug for the treatment of schizophrenia;
- Claim 13: A pharmaceutical composition comprising olanzapine and a pharmaceutically acceptable diluent or carrier;
- Claim 14: A pharmaceutical composition in capsule or tablet form containing 0.1 to 20 mg of olanzapine;
- Claim 15: A pharmaceutical composition in capsule or tablet form containing 0.5 to 10 mg of olanzapine;
- Claim 16: A pharmaceutical composition in capsule or tablet form containing 2.5 to 5 mg of olanzapine and a pharmaceutically acceptable diluent or carrier.

[42] No issue was taken by either Lilly or Novopharm with respect to the trial judge's construction of the claims.

Anticipation

[43] Section 2 of the Act stipulates that an invention must be novel. When approaching an inquiry as to novelty, the invention must not have been anticipated. The reformulated approach to anticipation is articulated in *Sanofi*. To succeed in invalidating a patent on grounds of anticipation, an alleged infringer (here Novopharm), must satisfy the requirements of prior disclosure and enablement, considered separately.

[44] With respect to disclosure, section 28.2 of the Act is the governing section. Among other things, it requires that the invention was not disclosed "in such a manner that it became available to the public in Canada or elsewhere" more than one year before the patent was filed. Although *Sanofi* addressed disclosure in the context of the predecessor Act, the principles enunciated in *Sanofi* remain applicable. The POSITA reads the particular piece of prior art to understand whether it discloses the second invention. The evidence to be considered is comprised solely of the prior art, as the POSITA would understand it. No trial and error or experimentation is permitted.

[45] Where disclosure is found to exist, the second requirement (enablement) requires the POSITA to be able to perform the invention. Enablement is assessed having regard to the particular piece of prior art as a whole. The prior art must provide the POSITA, using his or her common general knowledge, with enough information to allow the subsequently claimed invention to be

performed without undue burden. Where the invention arises in a field of technology where trials and experiments are generally carried out, routine trials are acceptable.

[46] In *Sanofi*, Rothstein J. is clear that in the case of a valid selection patent, the claimed compound is soundly predicted at the time of the genus patent, but it is not made and its special advantages are not known. After citing Lord Wilberforce's observation in *E.I. Du Pont* that, "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", Rothstein J. concludes 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" (para. 31).

[47] The trial judge did not consider the elements of the *Sanofi* approach. He concluded that "by definition, the '113 Patent was anticipated by the '687 Patent." Lilly argued that the trial judge erred in concluding as he did and ought to have applied what it characterized as the *Sanofi* anticipation test. Novopharm insisted that Lilly's position ignored the factual findings that no substantial and peculiar advantages were possessed by olanzapine. Further, according to Novopharm, the *Sanofi* analysis breaks down when applied to a selection with no advantages. It was open to the trial judge to find that the '113 Patent was lacking in novelty.

[48] With respect, *Sanofi* is binding authority. A determination with respect to anticipation falls to be conducted in accordance with the elements of the approach set out in that authority and the trial judge's failure to conduct an analysis in this respect is an error of law. Novopharm's position and the trial judge's statement, in my view, serve to illustrate the precariousness of addressing a

selection patent differently than any other patent. *Sanofi* specifically cautions against such an approach. The trial judge's view of anticipation was tainted by his determination that olanzapine was not the subject of a valid selection patent, which in turn was founded on his misguided view that the conditions for a valid selection patent constitute an independent basis upon which to assess a patent's validity. That said, I think it is open to this Court, on the basis of the trial judge's findings and the record, to determine whether the '113 Patent was anticipated.

[49] At paragraph 51 of his reasons, the trial judge defined the POSITA as one who would "possess a conglomeration of knowledge and experience in medicinal chemistry, toxicology, psychiatry, and pharmacology, as well as a capacity to interpret data from animal studies and appreciate their relevance to the treatment of human disease." No issue has been taken regarding the identification or the qualifications of the POSITA.

[50] Lilly maintained that the expert evidence with respect to the two pieces of prior art (exclusive of the '687 Patent) relied upon by Novopharm was to the effect that there was no specific disclosure of olanzapine or its advantages in the prior art. Novopharm did not suggest otherwise. It merely relied upon the '687 Patent and the trial judge's finding.

[51] In general terms, the '687 Patent discloses a process for synthesizing an immense number of compounds having a three ring structure in common. The trial judge concluded that the patent's focus was on the compounds – their constituents, their structure and the processes by which they

could be made. He said that the utility lay “in their potential use in the treatment of central nervous system disorders, including schizophrenia.”

[52] Turning to the disclosure requirement of anticipation, it bears repeating that, at this stage of the inquiry, it is the content of the prior art (the '687 Patent) that is relevant, not whether the content is true. Olanzapine was not one of the examples described in the '687 Patent. It was one of a large class of most preferred compounds described by reference to several criteria. It was not specifically disclosed in the '687 Patent. Nor had it been made before. Since its advantages (as alleged in the '113 Patent) could not have been ascertained until it was made, it was not disclosed, as defined in *Sanofi*, by the '687 Patent.

[53] Non-disclosure is sufficient to defeat Novopharm’s allegation of invalidity on the basis of anticipation. Since Novopharm must satisfy both requirements (disclosure and enablement) there is no need to address enablement because Novopharm fails on the disclosure prong of the test. The '113 Patent was not disclosed and therefore was not anticipated by the '687 Patent.

Obviousness

[54] Section 28.3 of the Act requires that an invention not be obvious. *Sanofi* endorsed the inquiry for obviousness set out in *Windsurfing International Inc. v. Tabur Marine* (*Great Britain*) *Ltd*., [1985] R.P.C. 59 (C.A.) (*Windsurfing*), restated in *Pozzoli SPA v. BDMO SA*, [2007] EWCA Civ 588 (*Pozzoli*), which requires the court to:

1. (a) Identify the notional “person skilled in the art”;

(b) Identify the relevant common 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 do they require any degree of invention.

[55] At the fourth stage of the *Windsurfing* approach, the issue of "obvious to try" arises. To find that an invention was "obvious to try", and therefore invalid for obviousness, *Sanofi* teaches "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" (para. 66). The "obvious to try" inquiry will be appropriate in areas of endeavour where advances are often won by experimentation, such as in the pharmaceutical industry. A non-exhaustive list of factors to be taken into consideration is proposed at paragraph 69 of *Sanofi*.

1. Is it more or less self-evident that what is being tried ought to work?
Are there a finite number of identified predictable solutions known to persons skilled in the art?

2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that trials would not be considered routine?

3. Is there a motive provided in the prior art to find the solution the patent addresses?

[56] The actual course of conduct that culminated in the making of the invention may be an important factor. In this inquiry, it is not enough that there is a possibility of finding the invention.

The invention must be self-evident from the prior art and common general knowledge in order to satisfy the “obvious to try” test.

[57] In the context of a selection patent, the obviousness analysis considers the special properties of the compound, along with its alleged advantages, as described in the selection patent disclosure, for it is there that the inventiveness of the selection lies.

[58] The trial judge cited the *Sanofi* test for obviousness. Then, at paragraphs 145-149 of his reasons, he stated:

> [145] It is clear that this test assumes an inventive step in arriving at the subject-matter of the patent in issue. As will be clear from the discussion above, I cannot find an inventive step in Lilly’s decision to develop olanzapine. In effect, Lilly was working on its own patent, the '687, trying to find a compound that could be safely administered to humans and achieve the purpose underlying the '687 Patent itself – good antipsychotic activity and low EPS.
>
> [146] By the time the patent was filed in April 1991, Lilly had not found any unexpected, substantial or special qualities for olanzapine that would justify a fresh monopoly. 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.
>
> [147] I would not conclude that the selection of olanzapine as a development compound was an obvious choice. It made sense to try a non-ethyl, non-flourol compound given the problems with earlier compounds. But olanzapine was not the only candidate under consideration, and did not even appear to be particularly active. It was not “more or less self-evident” that olanzapine would work.
>
> [148] I think the best way to characterize olanzapine in 1991 is that it was an “almost invention” to use Justice Binnie’s term (*Apotex Inc. v. Welcome Foundation Ltd.*, above at para. 84). It was neither obvious nor a genuine invention. It was a compound that showed promise and, later, some of the early positive indications were borne out. Lilly received some early signals of safety and efficacy, but nothing that would support an assertion of surprising and

> unexpected properties, and nothing that would set olanzapine apart from the other '687 compounds.
>
> [149] I find that the development of olanzapine was neither obvious nor an invention. However, I must emphasize that I am using the term "invention" strictly in the legal sense, as the law applies to selection patents. Scientists, whether at Lilly or elsewhere, may well regard olanzapine as an invention, perhaps even a remarkable one. But that is not the question before me.

[59] Lilly accepted as correct the trial judge's finding that the selection of olanzapine as a development compound was not an obvious choice and that it was not more or less self-evident that olanzapine would work. However, it asserted that the concurrent finding that olanzapine was not an invention was nonsensical. Lilly submitted that the finding of non-invention (related to whether there was enough data to support the advantages) should not have been relevant to the obviousness analysis. The patentee is not required to prove the advantages in order to have a selection patent.

[60] Novopharm argued that the trial judge's finding that olanzapine was not obvious was made "in the context of the 'obvious-to try' analysis from *Sanofi* and the selection of olanzapine as a development compound." According to Novopharm, the trial judge was simply saying that it was not obvious to select this specific member of the class. The approach mandated by *Sanofi* presumes an "inventive step" which the trial judge had already found to be missing. In light of the evidence before him, it was open to the trial judge to conclude that olanzapine could not be said to be obvious under the "obvious to try" test from *Sanofi* (which assumed advantages). There was no "invention" because no advantages were demonstrated or soundly predicted in 1991.

[61] It is common ground that, but for the trial judge's finding of no inventive step, the *Sanofi* approach analysis would have led him to the conclusion that olanzapine was not obvious. In my view, the determinations of non-inventive and non-obvious are inconsistent and cannot stand

together. Such a finding constitutes palpable and overriding error. Further, in concluding that there was no inventive step, the trial judge was misled because of his independent determination that the conditions of a valid selection patent had not been met. That inquiry included consideration of evidence that is not to be considered as part of the obviousness inquiry. Rather, it goes to utility. Instead of construing the patent to ascertain the inventive step, the trial judge was influenced by his earlier determination. This tainted his analysis.

[62] The inventive concept in the '113 Patent's claims is the olanzapine compound. The specification indicates that it is useful in treating schizophrenia with superiority over other compounds of the '687 Patent. The particulars of olanzapine's alleged superiority are specified at paragraph 38 of the trial judge's reasons and are summarized at paragraph 13 of these reasons. Of particular note are what the trial judge characterized as olanzapine's declared advantages over flumezapine, one of the claimed compounds of the '687 Patent.

[63] The '687 Patent disclosed generally 15 trillion compounds predicted to have useful central nervous system activity. The compounds' properties were predicted to have high therapeutic index and to be useful in the treatment of mild anxiety states and certain kinds of psychotic conditions, such as schizophrenia and acute mania. It listed specific examples and encompassed, but did not disclose, olanzapine. It specifically disclosed and claimed flumezapine and ethyl flumezapine. There was no disclosure in the '687 Patent of the specific beneficial properties of olanzapine, a methyl compound, over the claimed, or any other of the '687 Patent's compounds. In the context of

a selection patent, the inventive step is olanzapine, coupled with its advantages, over the compounds of the '687 Patent.

[64] Having determined that the inventive concept of the '113 Patent is olanzapine, coupled with its advantages, the remainder of the trial judge's analysis yields a conclusion of non-obviousness, in accordance with the *Sanofi* directive.

Double Patenting

[65] There are two categories of double patenting: same invention patenting (two patents are the same or have an identical or coterminous claim) and obviousness patenting (the claims of the patents are not identical or coterminous but the later patent has claims that are not patentably distinct from the other patent): *Pharmascience Inc. v. Sanofi-Aventis Canada Inc*., [2007] 2 F.C.R. 103, 2006 FCA 229 (*Sanofi/Plavix*).

[66] *Sanofi* addresses the issue of double patenting. Rothstein J. explains that although evergreening is a legitimate concern, it is not a justification for an attack on the doctrine of selection patents. A selection patent may be sought by a party other than the inventor or owner of the original genus patent. Moreover, 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 from what was claimed in the genus patent.

[67] Although Rothstein J. was discussing Plavix, many of his comments are equally applicable to this case. For example, he states that sound prediction is usually the basis for granting the original

genus patent when the patent covers an enormous number of possible compounds. Not every compound will have been tested. It may be later determined that some of the subject matter of the original genus patent did not work or did not work as well as the subject matter of the selection patent. That information is valuable. That may leave parts of the original genus patent open to challenge (in this case it is too late since the '687 Patent expired in 1995). However, it does not affect the validity of the selection patent. Notably, in this case, the trial judge characterized flumezapine and ethyl flumezapine (the claimed compounds of the '687 Patent) respectively as a "tainted product" and an "abject failure."

[68] The trial judge opined, because there was no invention, there was no need to analyze whether the invention was double patented. He nonetheless concluded that olanzapine was double patented by the '687 and '113 Patents.

[69] Lilly contended, in the absence of a determination that the patent claims were identical or coterminous, it was not open to the trial judge to conclude as he did. Further, Lilly alleged that the claims of the '113 Patent were patentably distinct from those of the earlier patent. Lily pointed to *Sanofi's* teaching that a selection patent is not invalid for double patenting merely because the selection is within the ambit of the prior genus patent.

[70] Novopharm asserted that the key lies in the criterion that the selection patent claims a compound patentably distinct from the genus patent. Since the trial judge found there were no advantages, it necessarily followed that olanzapine was not patentably distinct from the class (there

was no invention). The '113 Patent claimed a monopoly over a compound that was protected by the claims of the '687 Patent. The lack of a patentable distinction between the genus and selection patents (with respect to olanzapine) rendered olanzapine double patented.

[71] Again, without conducting an analysis of the issue, the trial judge concluded that there was no need to do so. His conclusion resulted from the mistaken view that an examination regarding the conditions for a valid selection patent constitutes an independent basis upon which to attack a patent's validity. His finding regarding the issue with which he was confronted was tainted by his earlier error. The failure to conduct the appropriate analysis is an error of law.

[72] A challenge to patent validity based on double patenting does not require the existence of identical language in the two patent claims. Nonetheless, for the challenge to succeed, the wording of the claims, however different, must claim the same invention. The invention claimed in the '687 Patent is not the same as the invention claimed by the '113 Patent because, as was the case in *Sanofi*, the former is broader than the latter. Additionally, the claims of the '687 and '113 Patents are neither identical nor coterminous. There was no suggestion, nor could there be, that the claims were identical. The primary claim (claim 1) in the '687 Patent is a process claim for the preparation of a class of compounds based on a specific formula. The additional claims are for variants of the formula and process. Where specific compounds are claimed, they are claimed in relation to the process of making the various compounds of the formula. The primary claim (claim 3) in the '113 Patent is a product claim to a specific compound, olanzapine, for the treatment of schizophrenia (claim 6). The additional claims relate to the composition of olanzapine in various forms. The

patents do not cover the same area, therefore, their claims are not coterminous. Consequently, the requirements to establish same invention double patenting have not been met.

[73] Obviousness double patenting 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. However, 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 innumerable compounds predicted to be effective as exhibiting usefulness in the treatment of schizophrenia, it was found (according to the patent) that olanzapine had beneficial properties over flumezapine and other compounds coming within the '687 Patent. The claims in the '113 Patent are patentably distinct from the claims in the '687 Patent. The challenge based on obviousness double patenting fails.

Utility

[74] Section 2 of the Act requires that the subject matter of a patent be new and useful. The general principle is that, as of the relevant date (the date of filing), there must have been either demonstration of utility of the invention or a sound prediction of the utility. Evidence beyond that set out in the specification can, and normally will, be necessary.

[75] To establish lack of utility, the alleged infringer must demonstrate “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" : *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504 (*Consolboard*).

[76] Where the specification does not promise a specific result, no particular level of utility is required; a "mere scintilla" of utility will suffice. However, where the specification sets out an explicit "promise", utility will be measured against that promise: *Consolboard*; *Pfizer Canada Inc. v. Canada* (*Minister of Health*), [2009] 1 F.C.R. 253, 2008 FCA 108 (*Ranbaxy*). The question is whether the invention does what the patent promises it will do.

[77] Fox, at pages 149-150 states as follows:

> On the issue of utility it is sufficient that the specification gives the public a choice means provided that choice is a useful one, or gives a new, better or cheaper article, or is of advantage under special circumstances…Utility in law means such utility as will be beneficial to the public […]
>
> The true test of utility of an invention is whether it will, when put into practice by a competent person, do what it assumes to do, and be practically useful at the time when the patent is granted, for the purpose indicated by the patentee. (my emphasis)

[78] With respect to selection patents, the inventiveness lies in the making of the selected compound, coupled with its advantage or advantages, over the genus patent. The selection patent must do more, in the sense of providing an advantage or avoiding a disadvantage, than the genus patent. The advantage or the nature of the characteristic possessed by the selection must be stated in the specification in clear terms (*Sanofi*, para. 114). In other words, the selection patent must promise an advantage in the sense that, if the advantage is not promised, the patentee will not be able to rely on the advantage to support the patent's validity.

[79] However, no specific number of advantages is required. One advantage may be enough or any number of seemingly less significant advantages (when considered separately) may suffice when considered cumulatively, provided that, in either case, the advantage is substantial. It is also important to appreciate that there is a distinction between the promised advantage and the data upon which it is based. For example, in *Ranbaxy*, the disclosure provided data indicating a ten-fold increase in activity for the selected compound in a particular test. While the trial judge in that case held that the data constituted a promise of ten-fold increase, this Court disagreed and held that the POSITA would not view the data as a promise, but rather as support for a promise of increased activity generally (paras. 52-55).

[80] The promise of the patent must be ascertained. Like claims construction, the promise of the patent is a question of law. Generally, it is an exercise that requires the assistance of expert evidence: *Bristol-Meyers Squibb Co. v. Apotex Inc*., 2007 FCA 378, F.C.J. No. 1579 at para. 27. This is because the promise should be properly defined, within the context of the patent as a whole, through the eyes of the POSITA, in relation to the science and information available at the time of filing.

[81] Ultimately, for the purpose of utility regarding a selection patent, the question to be determined is whether, as of the date of filing, the patentee had sufficient information upon which to base the promise. In an infringement action, the patentee benefits from the presumption of validity

(s. 43(2) of the Act) and the alleged infringer bears the onus of demonstrating that the patentee did not have sufficient information upon which to base the promise.

[82] If the alleged infringer is able to establish that there was insufficient information upon which to base the promise, the patentee may nevertheless have had sufficient information upon which to make a sound prediction of the promise. The date for the soundness of the prediction is the date of the filing of the patent. However, by its nature, the doctrine of sound prediction presupposes that further work remains to be done: *Apotex v. Wellcome Foundation*, [2002] 4 S.C.R. 153 (*AZT*) at p. 190. Consequently, the promise need not have been met at the date of filing although it must ultimately be borne out.

[83] The tripartite test for sound prediction is articulated at page 186 of *AZT*: there must be a factual basis for the prediction; the inventor must have an articulable line of reasoning from which the desired result can be inferred from the factual basis; and there must be proper disclosure of the factual basis and line of reasoning, although it is not necessary to provide a theory as to why the invention works.

[84] *AZT* does not define the threshold required for sound prediction. However, Binnie J. states that more than mere speculation is required (para. 69). He also provides the following indicia:

- the requirement is that the claims be fairly based on the patent disclosure (para. 59);
- it must be *prima facie* reasonable that the patentee should have a claim (para. 60);
- it cannot mean a certainty (para. 62);

- the desired result must be able to be inferred from the factual basis (para. 70).

[85] In my view, these indicia signify that a sound prediction requires a *prima facie* reasonable inference of utility. Notably, in *AZT*, the factual basis for the sound prediction of a new use compound rested upon the results of an *in vitro* test of AZT against the HIV in a human cell line along with Glaxo's data on AZT, including animal tests (para. 72). The line of reasoning was found to be Glaxo's knowledge of the mechanism for reproduction of a retrovirus.

[86] The underlying rationale for sound prediction is explained in *AZT* at page 184 as follows:

> The doctrine of "sound prediction" balances the public interest in early disclosure of new and useful inventions, even before their utility has been verified by tests (which in the case of pharmaceutical products may take years) and the public interest in avoiding cluttering the public domain with useless patents, and granting monopoly rights in exchange for misinformation.

[87] The above-noted inquiries (promise of the patent, information upon which to base the promise and information to soundly predict the promise) are discrete inquiries. Each requires a separate analysis.

[88] Lilly asserted that the trial judge's "illegitimate amalgam" required Lilly to prove the advantages of olanzapine as part of the utility analysis. It reiterated its position that the advantages are relevant to obviousness and have no bearing on whether olanzapine meets the utility criteria. Additionally, Lilly claimed that although it had demonstrated the advantages, the trial judge failed

to ask the correct question and erroneously "required a high standard of certainty" in his application of sound prediction.

[89] Novopharm responded that the trial judge had concluded with respect to each of the advantages that "the invention does not do what the specification promises it will do." Moreover, according to Novopharm, the legal and factual flaw in Lilly's utility argument was its failure to address the *Consolboard* test or the requirements of *I.G. Farbenindustrie*.

[90] I do not accept Lilly's position that the advantages are relevant only to obviousness. Notably, Lilly refers to the advantages in its submissions regarding novelty (memorandum of fact and law at para. 60) and with respect to double patenting (memorandum of fact and law at paras. 143-145). Nor do I accept that the *I.G. Farbenindustrie* conditions constitute an independent basis upon which to attack a patent's validity.

[91] The difficulty with the trial judge's analysis is that he got off on the wrong foot when he identified the issue at the outset (whether the '113 Patent was a valid selection patent). It is not clear what the trial judge might have concluded had he not analyzed each of the grounds of validity from this perspective. In some instances, the factual findings of the trial judge have been sufficient to enable this Court to conduct the appropriate analysis. In other instances, that may not be possible.

[92] The evidence with respect to utility will generally go well beyond the patent's content. An analysis in this respect will typically include a summary of the content of the pertinent evidence.

The recitation need not be lengthy; the objective is to provide the substance of the evidence required to conduct the analysis. Where the expert evidence is contradictory, an indication of what evidence is accepted or preferred, and why, will be stated. Credibility findings, if any, will be specified. Factual determinations required for the analysis will be delineated and the legal analysis will follow. Such information enables an appellate court to engage in meaningful review.

[93] I have stated earlier that the promise of the patent is to be ascertained at the outset of an analysis with respect to utility. The promise is to be construed by the trial judge within the context of the patent as a whole, through the eyes of the POSITA in relation to the science and information available at the time of filing. The promise of the patent is fundamental to the utility analysis.

[94] The trial judge does not refer specifically to the promise of the patent. In a section of his reasons entitled “olanzapine advantages over the other '687 compounds”, various terms are used. For example, he states that the '113 Patent proclaims a number of advantageous qualities for olanzapine; it identifies certain advantages of olanzapine over the other compounds from the '687 Patent; it boasts the superiority of olanzapine over other known antipsychotic drugs used in the treatment of schizophrenia and related conditions (para. 33); and it displays surprising and unexpected properties as compared to flumezapine and other related compounds (para. 34).

[95] Reference is made to a dog study in which olanzapine was compared with ethyl olanzapine (a '687 compound), which the trial judge interprets as an assertion of the superiority of olanzapine over ethyl olanzapine in terms of its liability for elevating cholesterol in humans (para. 37). I will

say more about the dog study later. There follows a listing of the specific areas of superiority the '113 Patent declares for olanzapine over the '687 compounds (para. 38).

[96] Next, the trial judge begins a discussion under the heading “olanzapine’s advantages over other antipsychotic drugs”. Similar terminology is used. The '113 Patent describes olanzapine’s function as an antagonist at various brain receptions. The characteristics suggest that olanzapine has potential as a drug with relaxant, anxiolytic or anti-emetic properties and might be useful in treating psychotic conditions, including schizophrenia (para. 39). In reviewing the experimental screens, clinical trials and open study, similar terminology is used: “states, shows, describes.”

[97] In describing the statement “overall, therefore, in clinical situations, the compound of the invention shows marked superiority and a better side effects profile than prior known antipsychotic agents”, the trial judge depicts it as the “broadest and stoutest assertion about olanzapine in the '113 Patent.” Because of this statement’s placement in the disclosure, the trial judge concludes (with respect to other antipsychotic drugs) that a “fair interpretation of the patent is that it asserts the superiority of olanzapine in respect of the side effects specifically identified in it, most importantly, the ones that presented the greatest concern to schizophrenia patients – EPS and agranulocytosis”.

[98] I have difficulty concluding that the summarized paragraphs constitute a construction of the patent or an analysis of its promise. If that is their intent, then I have difficulty determining exactly what the trial judge construed the promise of the patent to be. Regardless, assuming for the moment

that the noted paragraphs do constitute construction of the patent's promise, there are problems with it.

[99] Referring solely to the patent's specification, I would be inclined to construe its promise in much broader terms. Specifically, I would conclude that, on its face, the '113 Patent promises that olanzapine, in the treatment of schizophrenia, shows marked superiority to flumezapine and other '687 compounds, has a better side effects profile than prior known antipsychotic drugs and has a highly advantageous activity level. However, that option is not open to me for I do not know how the POSITA would read the patent, based on the science and information available at the relevant time.

[100] While I have difficulty concluding that the trial judge's comments constitute a construction of the promise of the patent, it is possible that he had reason to construe the patent's promise in such a manner for he had the benefit of hearing the expert evidence. This gives rise to another problem.

[101] There is no reference in the trial judge's reasons to the expert evidence regarding the promise of the patent. Throughout his reasons, the only indication as to the content of the testimony at trial is contained in those portions where the trial judge reviews each of the alleged advantages cited in the patent's disclosure. (This testimony largely relates to conflicting opinions regarding the propriety of tests, the manner in which they were conducted and the reliability of the data which resulted from them).This is particularly troublesome for it does not provide a basis upon which to

conduct meaningful appellate review on a question of law, for which the applicable standard of review is correctness.

[102] To illustrate, I refer to an example. In addressing the alleged advantages (to which I will return later), the trial judge noted that “Novopharm contested on numerous grounds the assertion in the '113 Patent about olanzapine’s advantage with respect to cholesterol” (para. 80). Among other things, Novopharm disputed the viability of using a dog model for predicting cholesterol effect in humans. The trial judge briefly reviewed the evidence of three experts in this respect. Only one, Dr. Bauer, felt the dog was a good model for predicting cholesterol effects in humans. However, his theory had been developed after the '113 Patent was filed. He agreed that the prevailing view in 1991 was that the dog was not a good model for cholesterol studies.

[103] Therefore, the unanimous opinion (on the basis of the evidence referred to) was that the dog was not a good model for cholesterol studies. Notwithstanding, the trial judge concludes that “the reference in the '113 Patent to the dog study and the cholesterol findings implies a concern about the potential effect in humans” (paras. 37, 38, 52, 93). Query, when the unanimous expert opinion was that the dog was not a good model for predicting cholesterol effects in humans, how could it be that a POSITA would read the reference to cholesterol levels in dogs as implying a concern about its potential effect in humans?

[104] In summary on this issue, the assessment and weighing of the evidence are the domain of the trial judge, subject to appellate review only for palpable and overriding error. In the absence of

any reference to the evidence relied upon by him to determine the promise of the patent, meaningful appellate review cannot be conducted.

[105] The trial judge separately analyzed each specific advantage referred to in the patent's disclosure. In so doing, it is clear from his reasons, that he required each advantage to reach the level of a promise of the patent. With respect, this is putting the cart before the horse. While there is nothing offensive about looking at each of the alleged advantages, the examination and analysis is to be conducted with a view to the overarching issue – the promise of the patent. Again, the trial judge's approach was driven by his perception that he was required to determine whether the conditions for a valid selection patent had been met, independent of the proper analysis required for assessing the ground of utility.

[106] Also of concern in relation to the analysis of each specific advantage is whether the trial judge had an appreciation of the distinction between the promised advantage (if the specific advantage was indeed promised) and the data upon which it is based. *Ranbaxy* addresses this distinction and has been referred to earlier. Finally, the approach taken, in the manner in which it was taken, precludes the possibility that any number of seemingly less significant advantages (when considered separately) may suffice when considered cumulatively, provided that the cumulative advantage is substantial.

[107] I should also mention that I share Lilly's concern as to the level of proof required by the trial judge. While I do not agree with Lilly that the trial judge elevated the requisite proof to a "regulatory standard", I am somewhat concerned by the trial judge's comments that Lilly had no

proof of anything (para. 110). The presumption of validity applies and the onus is on Novopharm to establish that the patent lacks utility.

[108] The trial judge asked whether the '113 Patent was a valid selection patent. In the context of that analysis (which does not constitute an independent basis upon which to attack the validity of a patent) he concluded that the patent's advantages were not known or soundly predicted. These issues relate to utility. For the foregoing reasons, I conclude that the utility analysis was fatally flawed largely as a result of the trial judge getting off on the wrong foot in the first instance.

[109] The failure to provide any foundation for the construction of the patent's promise leaves this Court without any basis upon which to conduct a meaningful review. In the absence of an accurate articulation or ascertainment of the promise, review of the analysis of the alleged advantages is not possible because they cannot be viewed in relation to the overarching promise of the patent. Given the deficiency in the record, the issue of utility must be returned to the Federal Court for determination.

[110] Before turning to the next issue, sufficiency of disclosure, one final observation should be made. In my view, the trial judge misdirected himself in relation to the threshold requirement for a sound prediction. Although the soundness of the prediction is a question of fact, the proper test must be utilized. In *AZT*, Binnie J. held that the "tests" that had been conducted in that case were the factual basis for the sound prediction. While tests may not in every case provide a sufficient factual basis, if they exist, they are a good starting point.

[111] The trial judge concluded (in requiring a sound prediction for each of the advantages assessed individually) that in some instances there was insufficient evidence (factual basis), and in other instances there was no factual basis, upon which a sound prediction could be made. Earlier, at paragraph 18 of his reasons, he summarized the various tests conducted in mice and rats to determine a compound's potential as an antipsychotic drug. At paragraph 57, he refers to the use of olanzapine in human trials, specifically, an open-label clinical trial involving ten patients and four studies involving a total of twenty healthy volunteers. In my view, it is a palpable and overriding error to conclude there was no factual basis for a sound prediction.

[112] The relevant question in this instance is whether there was an articulable line of reasoning from this factual basis to infer the sound prediction. Although the trial judge considered whether there was a line of reasoning for the advantages, he failed to turn his mind to the threshold required to support it. I concluded earlier in these reasons that a sound prediction requires a *prima facie* reasonable inference of utility.

Sufficiency of Disclosure

[113] In addition to meeting the tests for patentability, an invention must also be sufficiently disclosed. The specification represents the bargain between the Crown on behalf of the public and the inventor (*Consolboard)*. Accordingly, the patent must contain enough information to allow a POSITA to make the invention. The claims must be precisely laid out, without being overbroad. If the disclosure requirements are not met, the patent will be invalid even if it is new, useful and not

obvious. These requirements for a patent specification are set out in subsections 27(3) and 27(4) of the Act.

[114] The most recent guidance from this Court regarding the interpretation of these provisions is found at paragraph 59 of *Ranbaxy*:

> 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. (emphasis mine)

[115] The trial judge observed that there were "two intersecting disclosure obligations on Lilly." The first was Lilly's duty to "set out the basis on which olanzapine is believed to have a substantial and peculiar advantage over the '687 compounds." The second was Lilly's duty to "set out the sound prediction for that advantage." In the trial judge's view, the two disclosure requirements were "coextensive." At paragraph 138 of his reasons, he commented that "if the disclosure requirements for sound prediction had been met, so would the disclosure requirement for a selection patent." He concluded that the '113 Patent's disclosure was insufficient.

[116] Lilly argued that the trial judge failed to follow *Ranbaxy*, binding authority, which specifically held that whether the patentee had obtained enough data to support the invention was irrelevant to the subsection 27(3) disclosure issue. Lilly pointed to the facts in *Sanofi* to support its position that a simple statement of the advantages is sufficient (provided it is stated in clear terms). It submitted that the '113 Patent disclosed the advantages that underlie the invention and maintained

that there was no finding that a POSITA could not put the invention into practice. Therefore, the trial judge erred in concluding that the disclosure requirements were not met.

[117] Novopharm contended that the "substantial agreement among the experts was that the disclosure of the advantages in the '113 Patent was vague, confusing and puzzling." Such evidence buttressed the trial judge's finding that the patent failed to disclose a factual basis or line of reasoning to support the predicted advantage. According to Novopharm, binding precedent required that, for a selection patent to be valid, the advantages had to be set out clearly and adequately and where the patent was based on predicted advantage, it had to disclose the factual basis and sound line of reasoning for the prediction.

[118] This issue concerns the interpretation of the disclosure requirements of the Act. It is a question of law and is to be reviewed on a standard of review of correctness.

[119] My first observation is that the trial judge does not refer to and does not appear to have relied upon the evidence Novopharm cited to "buttress" the sufficiency conclusion. Second, in this case, sufficiency fell to be determined by an analysis of the patent in accordance with the directions contained in the Act and in *Ranbaxy*. The trial judge did not follow this approach.

[120] The trial judge correctly noted that there were two disclosure requirements in play: the *AZT* "line of reasoning" disclosure (the third condition for sound prediction) and the "duty to set out the basis on which olanzapine is believed to have a substantial and peculiar advantage over the '687

compounds" (the requirement that the patent set out what the invention is and how it works). However, the two requirements are separate and distinct. It is incorrect to equate one to the other. The "sufficiency" attack on the patent's validity relates to subsection 27(3) of the Act.

[121] The trial judge used what he considered to be the *AZT* requirement to determine the sufficiency of the disclosure. He concluded that the disclosure was insufficient because it did not meet the *AZT* hurdle. This approach is not consistent with the statutory requirements for sufficiency as set out in the Act and it is not consistent with the interpretation of those requirements set out in *Ranbaxy*. To reiterate, the patent must contain a disclosure of the compound and its advantage or advantages and a teaching of how it works.

[122] As stated in *Consolboard*, it is a well established principle that a patent specification is addressed, not to the public generally, but to persons skilled in the particular art (p. 521). The trial judge does not refer to or mention the expert evidence with respect to putting the invention into practice.

[123] As was the situation with the issue of utility, there are insufficient factual determinations in the trial judge's reasons to enable this Court to conduct a meaningful review of this issue. Consequently, the issue of sufficiency must be returned to the Federal Court for determination.

Conclusion

[124] For these reasons, I would allow the appeal with costs and set aside the judgment of the Federal Court. I would remit the utility and sufficiency of disclosure grounds of alleged invalidity

with respect to the '113 Patent to the Federal Court for determination in accordance with these reasons.

"Carolyn Layden-Stevenson"
J.A.

"I agree
M. Nadon J.A."

"I agree
K. Sharlow J.A."

SCHEDULE "A"
To the Reasons of:
Eli Lilly Canada Inc. et al
v
Novopharm Limited

A-454-09

Patent Act (R.S., 1985, c. P-4)	**Loi sur les brevets (L.R., 1985, ch. P-4)**
2. In this Act, except as otherwise provided,	**2.** Sauf disposition contraire, les définitions qui suivent s'appliquent à la présente loi.
"invention" "invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter;	***"invention"*** « invention » Toute réalisation, tout procédé, toute machine, fabrication ou composition de matières, ainsi que tout perfectionnement de l'un d'eux, présentant le caractère de la nouveauté et de l'utilité.
[…]	[…]
Specification **27.** (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	**Mémoire descriptif** **27.** (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

invention from other inventions.

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

[…]

Subject-matter of claim must not be previously disclosed
28.2 (1) The subject-matter defined by a claim in an application for a patent in Canada (the "pending application") must not have been disclosed
(*a*) more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such a manner that the subject-matter became available to the public in Canada or elsewhere;
(*b*) before the claim date by a person not mentioned in paragraph (*a*) in such a manner that the subject-matter became available to the public in Canada or elsewhere;
(*c*) in an application for a patent that is filed in Canada by a person other than the applicant, and has a filing date that is before the claim date; or
(*d*) in an application (the "co-pending application") for a patent that is filed in Canada by a person other than the applicant and has a filing date that is on or after the claim date if
(i) the co-pending application is filed

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

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

[…]

Objet non divulgué
28.2 (1) L'objet que définit la revendication d'une demande de brevet ne doit pas :
a) plus d'un an avant la date de dépôt de celle-ci, avoir fait, de la part du demandeur ou d'un tiers ayant obtenu de lui l'information à cet égard de façon directe ou autrement, l'objet d'une communication qui l'a rendu accessible au public au Canada ou ailleurs;
b) avant la date de la revendication, avoir fait, de la part d'une autre personne, l'objet d'une communication qui l'a rendu accessible au public au Canada ou ailleurs;
c) avoir été divulgué dans une demande de brevet qui a été déposée au Canada par une personne autre que le demandeur et dont la date de dépôt est antérieure à la date de la revendication de la demande visée à l'alinéa (1)*a*);
d) avoir été divulgué dans une demande de brevet qui a été déposée au Canada par une personne autre que

by
(A) a person who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for Canada an application for a patent disclosing the subject-matter defined by the claim, or
(B) a person who is entitled to protection under the terms of any treaty or convention relating to patents to which Canada is a party and who has, or whose agent, legal representative or predecessor in title has, previously regularly filed in or for any other country that by treaty, convention or law affords similar protection to citizens of Canada an application for a patent disclosing the subject-matter defined by the claim,
(ii) the filing date of the previously regularly filed application is before the claim date of the pending application,
(iii) the filing date of the co-pending application is within twelve months after the filing date of the previously regularly filed application, and
(iv) the applicant has, in respect of the co-pending application, made a request for priority on the basis of the previously regularly filed application.

le demandeur et dont la date de dépôt correspond ou est postérieure à la date de la revendication de la demande visée à l'alinéa (1)*a*) si :
(i) cette personne, son agent, son représentant légal ou son prédécesseur en droit, selon le cas :
(A) a antérieurement déposé de façon régulière, au Canada ou pour le Canada, une demande de brevet divulguant l'objet que définit la revendication de la demande visée à l'alinéa (1)*a*),
(B) a antérieurement déposé de façon régulière, dans un autre pays ou pour un autre pays, une demande de brevet divulguant l'objet que définit la revendication de la demande visée à l'alinéa (1)*a*), dans le cas où ce pays protège les droits de cette personne par traité ou convention, relatif aux brevets, auquel le Canada est partie, et accorde par traité, convention ou loi une protection similaire aux citoyens du Canada,
(ii) la date de dépôt de la demande déposée antérieurement est antérieure à la date de la revendication de la demande visée à l'alinéa *a*),
(iii) à la date de dépôt de la demande, il s'est écoulé, depuis la date de dépôt de la demande déposée antérieurement, au plus douze mois,
(iv) cette personne a présenté, à l'égard de sa demande, une demande de priorité fondée sur la demande déposée antérieurement.

Withdrawal of application
(2) An application mentioned in paragraph (1)(*c*) or a co-pending application mentioned in paragraph

Retrait de la demande
(2) Si la demande de brevet visée à l'alinéa (1)*c*) ou celle visée à l'alinéa (1)*d*) a été retirée avant d'être devenue accessible au public, elle est réputée,

(1)(*d*) that is withdrawn before it is open to public inspection shall, for the purposes of this section, be considered never to have been filed.

Invention must not be obvious
28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to
(*a*) information disclosed more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere; and
(*b*) information disclosed before the claim date by a person not mentioned in paragraph (*a*) in such a manner that the information became available to the public in Canada or elsewhere.

pour l'application des paragraphes (1) ou (2), n'avoir jamais été déposée.

Objet non évident
28.3 L'objet que définit la revendication d'une demande de brevet ne doit pas, à la date de la revendication, être évident pour une personne versée dans l'art ou la science dont relève l'objet, eu égard à toute communication :
a) qui a été faite, plus d'un an avant la date de dépôt de la demande, par le demandeur ou un tiers ayant obtenu de lui l'information à cet égard de façon directe ou autrement, de manière telle qu'elle est devenue accessible au public au Canada ou ailleurs;
b) qui a été faite par toute autre personne avant la date de la revendication de manière telle qu'elle est devenue accessible au public au Canada ou ailleurs.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-454-09
(APPEAL FROM A JUDGMENT OF THE FEDERAL COURT DATED OCTOBER 5, 2009, NO. T-1048-07	
STYLE OF CAUSE:	Eli Lilly Canada Inc. et al v. Novopharm Limited
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	June 21 and 22, 2010
REASONS FOR JUDGMENT BY:	LAYDEN-STEVENSON J.A.
CONCURRED IN BY:	NADON J.A. SHARLOW J.A.
DATED:	July 21, 2010

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