Date: 20080102

Docket: T-209-06
T-210-06

Citation: 2008 FC 11

Ottawa, Ontario, January 2, 2008

PRESENT: The Honourable Mr. Justice Hughes

BETWEEN:

PFIZER CANADA INC. and
PARKE, DAVIS & COMPANY LLC

Plaintiffs

and

THE MINISTER OF HEALTH and
NOVOPHARM LIMITED

Defendants

REASONS FOR JUDGMENT AND JUDGMENT

[1] There are two Applications considered in these proceedings both brought under the *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 as amended (NOC Regulations). The medicine at issue is that commonly known as quinapril which is used in the treatment of hypertension. The Applicants, sometimes known as brand companies, sell drugs including quinapril in Canada under the name ACCUPRIL and, including quinapril in conjunction with hydrochlorothiazide as ACCURETIC. The Respondent Novopharm Limited wants to sell its generic version of those drugs and, in accordance with the NOC Regulations served two Notices of

Allegation on the Applicant Pfizer Canada Inc. asserting that the patent it listed in respect of the drugs, Canadian Patent 1,341,330 ('330 patent), was invalid for a variety of reasons. This prompted the Applicants to initiate these two proceedings to prohibit the Respondent Minister of Health from issuing a Notice of Compliance (NOC) to Novopharm to permit it to sell its generic versions of those drugs in Canada.

[2] For the reasons that follow, I find that the applications for prohibition are allowed with costs.

NOTICES OF ALLEGATION

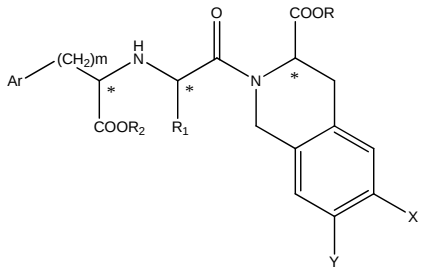
[3] Novopharm delivered two Notices of Allegation under the provisions of the NOC Regulations to Pfizer Canada Ltd. on December 23, 2005. They are essentially identical except that one is directed to a drug containing only quinapril as the active ingredient in a variety of dosages. It is sold by Pfizer under the name ACCUPRIL. The other is directed to a drug containing both quinapril and hydrochlorothiazide in a variety of dosages. It is sold by Pfizer under the name ACCURETIC. Both are directed to uses in the treatment of hypertension in humans and are known as angiotensin-converting enzyme inhibitors, commonly called ACE inhibitors.

[4] The only issue raised by Novopharm in its Notices of Allegation is the validity of the '330 patent for a variety of reasons. Infringement is not an issue. By an Order of this Court dated March 13, 2006 the two Applications brought by Pfizer, one in respect of each Notice of Allegation, were

consolidated. The Applications have, thereafter, proceeded together and were argued together. One set of Reasons and one Judgment is issued.

CHEMICAL BACKGROUND

[5] A brief discussion of the chemistry, specifically the stereochemistry, is required. The class of compounds described in the ’330 patent is said to be defined by a general formula - formula 1 - set out on the first page of the patent as follows:



[6] This formula depicts a class of compounds often described as being comprised of a head group which is the cyclic structure on the right side and a side chain which is the long structure to the left. The head group shown in formula I is derived from a molecule known as tetrahydroisoquinoline or THIQ.

[7] Although molecules can only be depicted in two dimensions on a piece of paper, in reality, the molecules are three-dimensional. The three-dimensional features of the molecule that are of interest in the present application are indicated in formula I by the three asterisks. These asterisks indicate what are called chiral centers, which identify carbon atoms that are bonded to four different groups of atoms. When viewed in three dimensions, there are two distinct ways that a single carbon atom can be bonded to four different groups. These are referred to as configurations. The number

of possible configurations for a particular molecule is defined by the formula 2^n where n is the number of chiral centers. Here we have three chiral centres so that the number of possible configurations is 2^3 or 8. Scientists sometimes use the term 'stereoisomer' to describe the relationship between compounds that are connected to the same atoms, but have different spatial configurations. Here there are eight possible stereoisomers.

[8] As molecules with different spatial configurations have different chemical properties, it is often important to determine which of the spatial configurations a chemist is referring to in a given diagram. As a result, chemists have adopted various conventions to distinguish the different spatial configurations. One common convention is to use the labels R or S to identify the manner in which a given carbon is bonded to the four groups. As the compounds described in formula I have three such carbons, each carbon will be assigned either an R or an S. The overall molecule will be identified by three letters, one referring to each of the asterisks or chiral centres, such as R,R,R, S,S,S, R,S,S, S,R,S, and so forth. There are eight possible three-letter combinations for the compounds identified in formula I. Each of these eight compounds can be described as a stereoisomer of the other seven compounds. Discussion in this case will involve whether or not the inventors invented, whether the patent discloses and whether the claims claim all 8 possible stereoisomers or just the S,S,S stereoisomer.

EARLIER LITIGATION OF THIS ’330 PATENT

[9] There has been previous litigation under the NOC Regulations dealing with the ’330 patent. That litigation involved a different generic, Apotex Inc. Novopharm was not a party to the litigation.

[10] That litigation was instituted by Pfizer Canada Inc., Warner-Lambert Company LLC and Parke, Davis & Company LLC as a result of a Notice of Allegation served by Apotex in which the validity of the ’330 patent was contested. Infringement of another patent, Canadian Patent 1,331,615 (’615 patent), which is a divisional of the ’330 patent, was also at issue there. It is not at issue here. In the present proceedings, Novopharm has directed its allegations only as against validity of the ’330 patent, thus the infringement aspect of the earlier proceedings is not important here.

[11] The Apotex proceeding (T-1633-03) was heard by Justice Heneghan of this Court who, in edited reasons delivered September 28, 2005 indexed as 2005 FC 1205, held that Pfizer et al. had not demonstrated that the allegations as to invalidity, on the basis of overly broad claims, and of non-infringement with respect to the ’615 patent, were not justified. Accordingly, the application for prohibition was dismissed.

[12] The decision was appealed and, in a decision given May 31, 2007, cited as 2007 FCA 209 the Federal Court of Appeal reversed the Trial Judge, allowed the appeal, and directed that an Order for prohibition be directed to preclude Apotex from receiving an NOC for its generic quinapril drug.

[13] As raised in and disposed of by the Federal Court and Federal Court of Appeal the invalidity allegations respecting the ’330 patent in the earlier Apotex proceedings were:

a) Lack of utility both as to actual utility and lack of sound production

The Trial Judge held that Apotex’s allegations were not justified in that while for some compounds actual utility had not been demonstrated, there was a sound basis for predicting the utility of what was claimed in claims 3 to 5 of the ’330 patent (paras. 68 to 82).

The Federal Court of Appeal agreed with this conclusion (paras. 150 to 154).

b) Anticipation

The Trial Judge found that Apotex had not put its allegation of anticipation “in play” and that the allegation was not supported by sufficient evidence (paras. 83 to 88).

The Federal Court of Appeal upheld the Trial Judge’s findings (paras. 135 to 140).

c) Obviousness

The Trial Judge held that the prior art cited by Apotex did not establish that the invention was obvious and that Pfizer had met its burden in demonstrating that this allegation was not justified (paras. 89 to 98).

The Federal Court of Appeal upheld the Trial Judge’s findings (paras. 129 to 134).

d) Claims Broader than the Invention or Disclosure

It was on this ground that the Trial Judge found that Pfizer had failed to show that the allegation was not justified hence the application was dismissed (paras. 99 to 108). She said at paragraph 107:

> *[107] In my opinion, these arguments are to be assessed relative to the construction of the patent. Since I have concluded that claims three (3) and five (5) should be construed so as to include compounds useful for reducing hypertension and having regard to the expert evidence that the S-configuration is the optimal configuration for high level ACE inhibition leading to anti-hypertensive results, I conclude that the claims encompassing all possible stereoisomers are overly broad.*

The Federal Court of Appeal reversed the Trial Judge in this respect (paras. 101 to 128). At paragraphs 126 and 127, they said:

> *[126] On the basis of the evidence before the Court, however, Pfizer's invention can be described as covering all stereoisomers of quinapril. The state of the art is to the effect that all stereoisomers were within the inventor's contemplation, as revealed by the use of a Markish* [*sic*] *formula and the fact that patents for other ACE inhibitors claimed and disclosed all stereoisomers. The wording of the claims and the expert evidence suggest that all stereoisomers of quinapril are claimed in the patent. In fact, the Trial Judge, in her introduction on the '330 patent, says that "... [t]he compounds have three chiral centres and all the stereoisomers sharing this common structure, that is both the S- and R-configurations stereoisomers, are within the scope of the claims" (Reasons of Heneghan J., para. 9).*
>
> *[127] In my view, a person skilled in the art would read the two paragraphs from the disclosure which I have reproduced at paragraph 120 of these Reasons as disclosing that the invention includes all stereoisomers. The skilled reader would be persuaded particularly by the clear statement in the second paragraph that "... all optical isomers and diastereo isomers and mixtures thereof are within the scope of this invention". Accordingly, in my view, a skilled reader would therefore understand that claims 3 and 5, although silent as to stereo*

> *configuration, include all stereoisomers. Thus, given that the invention clearly covers all stereoisomers and that the patent claims all stereoisomers, the patent cannot be described as claiming more than what was invented.*

e) Double Patenting

The Trial Judge found that Pfizer had shown that the claims at issue of the '330 patent were not invalid for double patenting having regard to a previously issued patent (the '615 patent), (paras. 109 to 115).

The Federal Court of Appeal upheld the Trial Judge's findings (paras. 141 to 149).

MULTIPLE NOC PROCEEDINGS

[14] The Federal Court of Appeal in another decision, *Sanofi-Aventis Canada Inc. v. Novopharm Limited*, 2007 FCA 163 at paragraph 50, has warned against multiple NOC proceedings once a final determination has been made with respect to a particular patent. The Court acknowledged however that a different generic could challenge the validity of the same patent if it had "better evidence or a more appropriate legal argument". The Court is required to balance the effect on the administration of justice against the unfairness to a party from precluding it from bringing forward its case. At paragraph 50, Sexton J.A. said:

> *[50] Finally, Sanofi-Aventis and Schering argue that a finding of abuse of process in this case will lead to unfairness. They say that while first persons will not be permitted to defend against allegations by subsequent generics after the same allegation made by an earlier generic has been found to be justified, subsequent generics will be permitted to repeat allegations already made earlier by other generics even if the earlier allegations were found to be unjustified. However, there is no unfairness in this scenario. All parties are held to the same standard: they must each put forward their entire case, complete*

> *with all relevant evidence, at first instance. The innovator is prevented from relitigating an issue already decided in a proceeding to which it was a party with the aid of additional evidence it chose not to adduce in the earlier proceedings. Generics likewise must put forward their full case at the first opportunity. Multiple NOAs issued by the same generic relating to a particular drug and alleging invalidity of a particular patent will generally not be permitted, even if different grounds for establishing invalidity are put forward in each. However, where one generic has made an allegation but has failed to put forward the requisite evidence and argument to illustrate the allegation is justified, it would be unjust to preclude a subsequent generic, who is apprised of better evidence or a more appropriate legal argument, from introducing it. Although this situation may give rise to the possibility of an inconsistent result, this concern is overridden by the potential for unfairness to the generic that is barred from bringing forward its case simply because another generic's approach was inadequate. In each situation, it is necessary to balance the effect of a proceeding on the administration of justice against the unfairness to a party from precluding it from bringing forward its case.*

[15] I faced the question of a previous determination by the Court in respect of a patent in NOC proceedings in *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596. One of the difficulties canvassed there, and it is a difficulty here as well, is that the record of the earlier proceedings is not of record in these proceedings. Thus, the Court is left to determine if there is "better evidence or a more appropriate legal argument" in the present proceeding as against the earlier proceedings only from what is revealed in the Reasons of the Courts in the earlier proceedings. I said in that case at paragraphs 62 and 99:

> *[62] The jurisprudence therefore provides that this Court, in its own discretion, can review the Reasons given in Apotex by Justice Gauthier and determine whether there is "better evidence" or "more appropriate legal argument" made by the generic in the present proceeding as to validity of the '113 patent than was presented in Apotex. If so, the better evidence and more appropriate arguments must be considered. If no better evidence*

> *or more appropriate argument is found, it would be an abuse to permit the matter to be considered again. The word "abuse" is not used in any sense so as to imply that the second generic has acted improperly, it has not; it could not have been known until a few days before the hearing of this case that the decision in Apotex would be released. The word "abuse" is used in the sense that it would be a waste of the Court's resources and possibly lead to unwanted inconsistent results, were the matter to be considered as a matter of first instance on this the subsequent occasion. The consideration in the second instance should only be one as to "better evidence" or "more appropriate" argument which, if determined to exist, must be considered as a matter of first instance. Of course if a different attack on validity is raised, one that was not raised in Apotex, it will be considered as a matter of first instance.*
>
> . . .
>
> *[99] In the present proceedings therefore, I am required to determine as to each of the arguments as to invalidity raised by Novopharm:*
>
> > *1. Is the argument new and different, in which case it will be determined as a matter of first instance.*
> >
> > *2. If the matter has been dealt with by Justice Gauthier is there, having regard to her Reasons, "better evidence" or "more appropriate legal argument" in this proceeding such that Justice Gauthier's finding should not be followed.*

[16] Before leaving the earlier proceedings, the question as to construction of the ’330 patent and the claims at issue, claims 3, 4 and 5, must be considered. Those same claims are at issue in the present proceeding. Once a patent has been construed in a proceeding, particularly where the Court of Appeal has construed the patent, it would require strong argument for a subsequent Court to come to a different result (see e.g. *Procter & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)* (2004), 32 C.P.R. (4th) 224 at para 19 (F.C.), aff’d 37 C.P.R. (4th) 289 (F.C.A.)).

[17] In the previous proceeding, 2007 FCA 209, the Federal Court of Appeal disagreed with the construction put on the patent and, in particular, claims 3 to 5, by the Trial Judge. The Court of Appeal construed the invention as claimed, to include all stereoisomers. It said at paragraphs 120 and 126-127:

> *[120] Therefore, it is necessary to review the disclosure in the '330 patent and to assess how the claims should be read in the light of that disclosure. Several portions of the '330 patent shed light on the invention being claimed. First, the abstract specifies that the invention relates to anti-hypertensive agents:*
>
> > *The compounds of the invention, their salts and pharmaceutical compositions thereof are useful as antihypertensive agents.*
>
> *Elsewhere, the disclosure refers to the use of the invention for the treatment of hypertension:*
>
> > *The compounds of this invention intervene in the renin → angiotensin I → angiotensin II sequence by inhibiting angiotensin I converting enzyme and reducing or eliminating the formation of the pressor substance angiotensin II, and therefore are useful in reducing or relieving hypertension. Thus by the administration of a composition containing one or a combination of compounds of formula I or pharmaceutically acceptable salts thereof, hypertension in the species of mammal suffering therefrom is alleviated...*
> >
> > *...The compounds of the invention can be utilized to achieve the reduction of blood pressure by formulating in compositions such as tablets, capsules or elixirs for oral administration or in sterile solutions or suspensions for parenteral administration. ('330 patent at 6, 9).*
>
> . . .
>
> *[126] On the basis of the evidence before the Court, however, Pfizer's invention can be described as covering all stereoisomers*

> *of quinapril. The state of the art is to the effect that all stereoisomers were within the inventor's contemplation, as revealed by the use of a Markish* [*sic*] *formula and the fact that patents for other ACE inhibitors claimed and disclosed all stereoisomers. The wording of the claims and the expert evidence suggest that all stereoisomers of quinapril are claimed in the patent. In fact, the Trial Judge, in her introduction on the '330 patent, says that "... [t]he compounds have three chiral centres and all the stereoisomers sharing this common structure, that is both the S- and R-configurations stereoisomers, are within the scope of the claims" (Reasons of Heneghan J., para. 9).*
>
> *[127] In my view, a person skilled in the art would read the two paragraphs from the disclosure which I have reproduced at paragraph 120 of these Reasons as disclosing that the invention includes all stereoisomers. The skilled reader would be persuaded particularly by the clear statement in the second paragraph that "... all optical isomers and diastereo isomers and mixtures thereof are within the scope of this invention". Accordingly, in my view, a skilled reader would therefore understand that claims 3 and 5, although silent as to stereo configuration, include all stereoisomers. Thus, given that the invention clearly covers all stereoisomers and that the patent claims all stereoisomers, the patent cannot be described as claiming more than what was invented.*

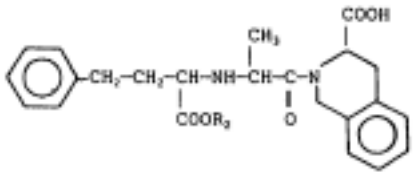
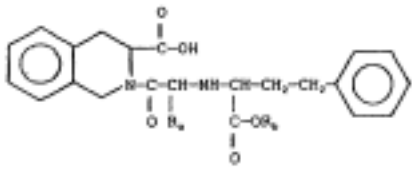
[18] With this interpretation in mind, I will turn first to the question of construction of claims 3, 4 and 5 of the ’330 patent.

CONSTRUCTION

[19] Before making a determination as to infringement or validity, the Court must construe the patent and, in particular, the claims at issue (*Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067 at para 43).

[20] The parties have agreed that only claims 3, 4 (as it depends from 3) and 5 are at issue. The parties have further agreed that, consistent with the construction of claims 3, 4 and 5 by the Federal Court of Appeal in the earlier proceedings as previously discussed, the claims cover all the stereoisomers of the compound described in the claims.

[21] These claims 3, 4 (as it depends from 3) and 5 read as follows:

> *3. A substituted acyl derivative of 1, 2, 3, 4 – tretrahydroisoquinoline-3-carboxylic acid of general formula IIa:*
>
> 
>
>
> IIa
>
> *Wherein R_2 represents a group selected from H, -CH_3 and -C_2H_5, and a pharmaceutically acceptable acid addition salt or solvated form thereof.*
>
> *4. A pharmaceutical composition comprising a substituted acyl derivative of 1, 2, 3, 4 – tetrahydroisoquinoline-3-carboxylic acid of the general formula IIa as defined in claim 3 or a pharmaceutically acceptable salt or solvated form thereof, and a pharmaceutically acceptable carrier.*
>
> *5. A compound having the general formula A:*
>
> 
>
>
> A
>
> *Wherein:*
>
> - *R_a is selected from:*

- *hydrogen; and*
- *C_{1-4} alkyl;*

- *R_b is selected from:*
  - *hydrogen; and*
  - *C_{1-4} alkyl;*

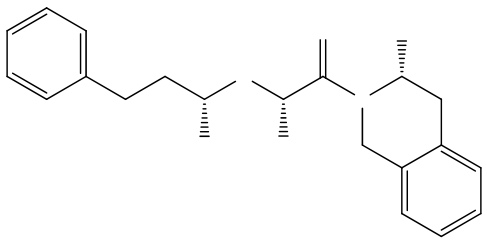
And its pharmaceutically acceptable salts.

[22] Thus to construe claim 3: it claims a compound as described, which is a class of compounds, in every one of its stereoisomeric forms, plus, added to the compound, is a pharmaceutically acceptable acid addition salt or a solvated form of that salt.

[23] Claim 4 claims all that which is claimed in claim 3 with the addition of a pharmaceutically acceptable carrier.

[24] Claim 5 claims a compound as described, which is a class of compounds, in every one of its stereoisomeric forms, together with pharmaceutically acceptable salts of that compound. The structure of the compound described in claims 3 and 4 is structurally similar to that described in claim 5, even though the drawings are oriented differently.

[25] The particular compound at issue, quinapril can be depicted as



and is described stereoisomerically as the S,S,S stereoisomer.

[26] Quinapril is among those compounds as described in claims 3, 4 and 5. The medicine used in ACCUPRIL is a pharmaceutically acceptable salt of quinapril as claimed in claim 5 namely quinapril hydrochloride.

ISSUES RAISED IN THESE PROCEEDINGS

[27] Counsel for the parties did a commendable job, after a pre-trial conference, in assembling materials for the hearing and in defining issues for the Court to determine. Further, Counsel for Novopharm advised the Court by letter dated November 27, 2007 that Novopharm will not be pursuing the issues of obviousness and double-patenting in these applications. Counsel for Pfizer advised the Court by letter dated December 12, 2007 that Pfizer will no longer be pursuing the issue as to whether Novopharm is a "second person" within the meaning of the NOC Regulations. As a result, the issues remaining for determination are:

1. Burden of Proof
    (a) What is the correct test?
    (b) To which issues is the application of the burden of proof relevant?

2. Claims broader than invention made and disclosed
    (a) Is there any "additional evidence" or "more appropriate legal argument" that would permit this Court to depart from the decision in the Apotex case?
    (b) Is "claims broader" a question of law, fact or mixed fact and law?

(c) In the context of this case, is "claims broader" a technical argument? If so, how does this impact the Court's analysis?

(d) What is the proper construction of the claims? [All parties agree that the claims cover all of the stereoisomers]

(e) What is the proper construction of the invention as it was disclosed in the '330 patent?

(i) To what extent may extrinsic evidence be used to construe the specification of a patent?

(ii) To what extent should the court consider the evidence of the drafter of the patent and for the inventors as to the nature of the invention?

(iii) What (if any) use can or should the Court make of other patents relating to ACE inhibitors in arriving at the proper construction of the invention?

(f) Are the claims broader than the invention made and disclosed?

3. Sound prediction

(a) Is there any "additional evidence" or "more appropriate legal argument" that would permit this Court to depart from the decision in the Apotex case?

(i) Is the evidence of Hoefle, Blankley or Klutchko any different in this case?

(ii) If so, is it different in a way that permits the Court to depart from the previous decisions?

(b) Is the test for lack of sound prediction met?

(i) What is the correct date for assessing sound prediction?

(ii) Is sound prediction a question of fact, law or mixed fact and law?

(iii) Does the test for sound prediction require the Court to consider what the inventors were *actually* thinking or does it look to the experts to say what the inventors *could* have predicted based on what was known to the inventors at the relevant time?

(iv) Are the elements of the test for sound prediction subjective or objective?

(v) Was there a factual basis to predict that the claimed compounds would have activity as ACE inhibitors and antihypertensives? This will include consideration of the following:

(A) Novopharm asserts that part of the factual basis that Pfizer relies on (reported data from a publication) is caused by contamination. Pfizer asserts that this is outside Novopharm's Notice of Allegation.

(B) Novopharm asserts that part of the factual basis that Pfizer relies on (that all of the compounds have activity in the dosage range given in the patent provided that in some cases there are administered at very high doses intravenously) is not supported because the intravenous doses relied upon are

not realistic. Pfizer asserts that this is outside Novopharm's Notice of Allegation.

(vi) Was there an articulable line of reasoning to predict that the claimed compounds would have activity as ACE inhibitors and antihypertensives?

(vii) Is the disclosure of the '330 patent proper?

(A) What is the impact of the last paragraph on page 3 of the '330 patent?

BURDEN OF PROOF

[28] The issue as to who bears the burden of proof, in particular where validity issues are raised in respect of a patent, continues to be raised by the parties in NOC proceedings.

[29] I canvassed that issue in *GD Searle & Co. v. Novopharm Limited*, 2007 FC 81 and concluded at paragraph 39:

> *[39] The question of burden of proof in NOC proceedings, where issues of validity are raised, was canvassed in Pfizer Canada Inc. v.* Canada, (2006), 46 C.P.R. (4th) 281, at paragraphs 6 to 12, in *Abbott Laboratories v. Apotex Inc.*, 2006 FC 1558, at paragraphs 85 to 94, and in *Pfizer Canada Inc. v. Apotex Inc.,* 2007 FC 26, at paragraphs 5 to 12. The Respondent (generic) must put the invalidity allegations in play, the Applicant may respond by asserting *the presumption of validity. Should the Applicant lead no evidence as to validity but the Respondent does lead some evidence, the Applicant would place itself at a serious disadvantage. Once the evidence is in, the Applicant bears the ultimate burden to establish that the allegations of invalidity are not justified.*

[30] Sharlow J.A. of the Federal Court of Appeal in a unanimous decision of a panel comprising her, Malone and Ryer JJ.A. in *Abbott Laboratories v. Canada (Minister of Health)*, 2007 FCA 153 considered the matter and held that the Applicant bears the burden of establishing its entitlement to an order for prohibition. As to validity, the Applicant may rely on the presumption of validity but, if the record contains any evidence capable of rebutting that presumption, the Court must weigh that evidence. She said at paragraphs 9 and 10:

> *[9] It is now beyond debate that an applicant for a prohibition order under the NOC Regulations bears the burden of establishing its entitlement to the order. Abbott argues that the Judge in this case failed to recognize and apply that principle correctly, in light of the presumption of validity in subsection 43(2) of the Patent Act, R.S.C. 1985, c. P-4, which reads as follows:*
>
> > *43. (2) After the patent is issued, it shall, in the absence of any evidence to the contrary, be valid and avail the patentee and the legal representatives of the patentee for the term mentioned in section 44 or 45, whichever is applicable.*
> >
> > * * *
> >
> > *43. (2) Une fois délivré, le brevet est, sauf preuve contraire, valide et acquis au breveté ou à ses représentants légaux pour la période mentionnée aux articles 44 ou 45.*
>
> *[10] In my view, the Judge made no such error. The presumption in subsection 43(2) is weakly worded (Apotex Inc. v. Wellcome Foundation Limited, [2002] 4 S.C.R. 153, per Justice Binnie at paragraph 43). It cannot determine the outcome of prohibition proceedings under the NOC Regulations if, as in this case, the record contains <u>any</u> evidence that, if accepted, is capable of rebutting the presumption (see Rubbermaid (Canada) Ltd. v. Tucker Plastic Products Ltd. (1972), 8 C.P.R. (2d) 6 (F.C.T.D.) at page 14, and Bayer Inc. v. Canada (Minister of National Health and Welfare) (2000), 6 C.P.R. (4th) 285, at paragraph (9).*

[31] Subsequently, another panel of the Federal Court of Appeal comprising Linden, Nadon and Sexton JJ.A. addressed the issue of burden but without reference to the decision of the panel in *Abbott*, *supra*. This was the decision of the Federal Court of Appeal in the earlier litigation involving quinapril and Apotex which must be considered in light of the direction by Sexton J.A. in *Sanofi* as to multiple proceedings. Apparently, *Abbott* had not been drawn to their attention. Nadon J.A. for the Court reviewed some of the jurisprudence on the issue of burden at paragraphs 101 to 111 in *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 209, his conclusions are set out at paragraphs 109 and 110:

> *[109] Thus, a first person under the Regulations has the overall burden of establishing, on a balance of probabilities, that the allegations of invalidity contained in a second person's NOA are not justified. Although the first person has the initial burden, because of the presumption of the validity of a patent set out in section 45 of the pre-1989 Act, it can meet this burden merely by proving the existence of the patent. The second person then has the burden of adducing evidence of invalidity and of putting the allegations of invalidity contained in its NOA "in play". To do so, the second person must adduce evidence which is not clearly incapable of establishing its allegations of invalidity. Hence, not only must the second person's NOA contain a sufficient factual and legal basis for its allegations, but it must also adduce evidence of invalidity at trial.*
>
> *[110] Once the second person has adduced sufficient evidence, on a balance of probabilities, the first person must, also on a balance of probabilities, disprove the allegations of invalidity set out in the NOA. As explained by my colleague Sharlow J.A. at paragraph 9 of her Reasons in Bayer, supra:*
>
> > *[9] The operation of the statutory presumption in the face of evidence of invalidity depends upon the strength of the evidence. If the evidence proves, on a balance of probabilities, that the patent is invalid, the presumption is rebutted and is no longer relevant. ...*

[32] I do not view the reasoning of the two panels of the Federal Court of Appeal to be in substantial disagreement. Justice Mosley of this Court reconciled these decisions in his Reasons in *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 971 at paragraphs 44 to 51. What is required, when issues of validity of a patent are raised:

1. The second person, in its Notice of Allegation may raise one or more grounds for alleging invalidity;
2. The first person may in its Notice of Application filed with the Court join issue on any one or more of those grounds;
3. The second person may lead evidence in the Court proceeding to support the grounds upon which issue has been joined;
4. The first person may, at its peril, rely simply upon the presumption of validity afforded by the *Patent Act* or, more prudently, adduce its own evidence as to the grounds of invalidity put in issue.
5. The Court will weigh the evidence; if the first person relies only on the presumption, the Court will nonetheless weigh the strength of the evidence led by the second person. If that evidence is weak or irrelevant the presumption will prevail. If both parties lead evidence, the Court will weigh all the evidence and determine the matter on the usual civil balance.
6. If the evidence weighed in step 5 is evenly balanced (a rare event), the Applicant (first person) will have failed to prove that the allegation of invalidity is not justified and will not be entitled to the Order of prohibition that it seeks.

[33] If the matter were an ordinary action for, say, infringement of a patent where validity is put in issue, the party challenging validity bears the burden such that, it must put in evidence to support the allegation of invalidity. The patentee may rely on the presumption but only to the extent that the attacking party must lead some reliable evidence to support its allegation. At the end of the day, the Court must weigh the evidence on the usual civil burden of proof (*Tye-Sil Corp. Ltd. v. Diversified Products Corp.* (1991), 35 C.P.R. (3d) 350 at 357-359 (F.C.A.)). Only if the Court finds the evidence to be "evenly balanced" (a rare event) would the question of burden arises in an ordinary case the party attacking validity, bearing the burden, would fail.

VALIDITY OF THE '330 PATENT

(1) Effect of Earlier Proceedings

[34] In the context of the NOC Regulations, Novopharm has challenged the validity of the '330 patent in its Notices of Allegation sent to Pfizer causing Pfizer to institute the present proceedings. The objective of these proceedings is to prohibit the Minister of Health from issuing a Notice of Compliance to Novopharm which Notice, in the absence of any other restriction, would permit Novopharm to sell generic versions of Pfizer's quinapril drugs in Canada. I am advised that there are other restrictions in the form of other proceedings respecting another patent. That is not relevant here.

[35] The challenges made by Novopharm to the validity of the '330 patent have been reduced to two: (1) claims broader than the invention; and (2) lack of sound prediction. Challenges to the

validity of the same claims of the ’330 patent as are at issue here were made by another generic, Apotex, in the earlier proceedings as discussed previously. Pfizer was successful in the Federal Court of Appeal in persuading the Court that Apotex’s assertions as to invalidity on those grounds were not justified.

[36] Accordingly, under the provisions of subsection 6(2) of the NOC Regulations, the Court made an Order prohibiting the Minister from issuing a Notice of Compliance to Apotex. There were other issues in the earlier proceedings, all resolved against the interests of Apotex, which are not relevant here.

[37] The Federal Court of Appeal in *Sanofi*, *supra*, has cautioned against multiple proceedings by different generics in which the validity of the same patent continues to be challenged in circumstances where such a challenge by a generic in earlier proceedings has failed. That Court indicated that a balanced approach was necessary which, on the one hand would consider whether better evidence or more appropriate legal argument was made by a subsequent generic thus making it unfair that such matters should not be raised, while, on the other hand, being mindful that the resources of the Court and others, such as the Minister who administers the NOC Regulations should not be wasted by repeated proceedings, even if skilfully presented and argued.

[38] NOC proceedings are flooding the Court system at a rate which, roughly calculated, at the current pace, means that three proceedings are instituted for each one disposed of by the Court. The NOC Regulations require that the proceedings be disposed of by the Court within 24 months from

institution barring consent of the parties to an extension. Rarely is such consent, except for perhaps a few weeks, forthcoming. The Court accepts the challenge. However, where essentially the same matters as were previously disposed of are raised again, the Court must come to grips with the question as to whether there is an unnecessary waste of the Court's resources.

[39] The parties are not without their remedies. The NOC proceedings provide, to the patent owner or its nominee, a chance to gain what amounts to a permanent injunction for the lifetime of the patent(s) involved if successful and, at least, a 24 month temporary injunction simply by instituting the proceeding. The generic has gained the opportunity to reference data as to matters such as safety and efficacy, previously submitted by the patentee/nominee, to the Minister. However, regardless of the result of the NOC proceedings, free of any jurisprudential constraint such as *res judicata*, the patentee can always institute proceedings for infringement of the patent(s). The generic can always institute proceedings to challenge the validity of the patent(s). Whether or not a patentee or a generic is precluded from litigating or relitigating a question in the context of the NOC Regulations, the fundamental right to an action respecting infringement or validity is unaffected. A party may be required to change its tactics but its fundamental rights are unaffected.

[40] The NOC Regulations are extra administrative processes tied to the protection of public health. They provide remedies in unique circumstances that are directed to the Minister that would, in certain circumstances, prohibit the Minister from granting a Notice of Compliance to an applicant generic drug company. Two decisions of the Federal Court of Appeal are instructive in this regard.

One is *Pfizer Canada Inc. v. Canada (Attorney General)*, 2003 FCA 138 where Strayer J.A. said, for the Court at paragraph 26:

> *[26] Instead, the Regulations provide an extra administrative process tied to the protection of public health, designed, on the one hand, to assist the development and preparation for marketing of generic drugs at a time prior to issue of an NOC when their sale would still be an infringement of a current patent. At the same time it gives patentees extra protection: by merely applying for prohibition they can normally prevent the issue of an NOC to a generic for 24 months.*

[41] The other is *Novartis AG v. Apotex Inc*., 2002 FCA 440 where Strayer J.A., again, for the Court said at paragraph 9:

> *[9] I believe that the fundamental principles applicable are those stated in the reasons of Isaac J.A. in the Pfizer case, as approved and followed by another panel of this Court in the Rhoxalpharma case less than one year ago. The basic principle is that the extraordinary procedures provided by the Regulations are for the public law purpose of enabling the Trial Division to prevent a public officer from issuing a Notice of Compliance, designed for the protection of the public's health, if the patentee can show that the patents, as referred to by a generic company in its notice of allegation seeking a Notice of Compliance, are owned by the applicant "first person" and that the relevant claims are not invalid and would be infringed. This is a finding of the Court for the limited purpose of deciding whether or not the Minister can issue a Notice of Compliance: no one could suppose that this is a scheme designed for res judicata determinations of the scope or validity of patents. As Isaac J.A. said at 253-54 of the Pfizer case:*
>
> > *[25] It should be noticed that a decision by this Court that the appeals are moot does not mean that the appellants are without remedies. They may commence actions for infringement if so advised and the facts warrant. This Court has been very clear on the fact that s. 6 proceedings are not adjudicative of the rights of the patentee. In Merck Frosst Canada, [1994] F.C.J. No. 662, supra, at 319, Hugessen J.A.*

> *rejected the notion that prohibition proceedings could be assimilated to an action of any kind:*
>
> > *The proceedings are not an action and their object is solely to prohibit the issuance of a notice of compliance under the Food and Drug Regulations. Manifestly, they do not constitute "an action for infringement of a patent" ...*
>
> *In these circumstances, it is idle to suggest that any decision that this Court makes in these appeals could be used to attack collaterally a judgment in an infringement action.*

As Isaac J.A. also pointed out in Pfizer at 252, by subsection 7(4) of the Regulations the period of automatic stay of the issue of an NOC expires when, inter alia, the application for prohibition is "dismissed by the court". This has been interpreted by this Court to mean "dismissed by the Trial Division", given the special and self-contained scheme of the Regulations. (Hoffman-LaRoche Ltd. v. Canada (1996), 70 C.P.R. (3d) 206). It does not mean "dismissed by the Federal Court of Appeal".

[42] Thus, while it is recognized that a second generic is a different person than a first generic and that the proceedings are two different proceedings, the remaining matters are the same. The patentee, “first person”, is the same, the patent is the same, the Minister is the same and the relief sought is the same, prohibition against the Minister. Identity of parties or privies, even under the strict doctrine of issue estoppel is not an essential requirement. Again, I reference Strayer D.J. (as he is now) in *Estenson v. Canada (Attorney General),* 2007 FC 538 at paragraphs 19 to 24:

> *[19] It is well established that for issue estoppel to prevent further proceedings to try a question:*
>
> > *i) the same question must have been decided in an earlier proceeding;*

ii) the decision in the earlier proceeding must be final;

iii) the parties to the previous decision or their privies are the same persons as the parties to the proceedings in which the estoppel was raised or their privies.

(see e.g. Angle v. Minister of National Revenue, [1975] 2 S.C.R. 248 at paragraph 254; Danyluk v. Ainsworth Technologies Inc., [2001] 2 S.C.R. 460 at paragraphs 54-61.)

[20] Looking at the second condition first, I think it is not in dispute that the decision of the Chairman of the Review Tribunal under the Agriculture and Agri-Food Administrative Monetary Penalties Act is final. There is no provision for appeal under that Act and the time for judicial review has long since passed.

[21] A more difficult question is as to whether the same question was involved before that Review Tribunal as would be before an adjudicator in respect of the Applicant's accreditation under his AVA. Admittedly the legal issues are different. The former involved a possible violation of paragraph 69(1)(b) of the Health of Animals Regulations whereas the latter will involve what is essentially a breach of contract of the Applicant's accredited veterinarian agreement. It is sufficient, however, for issue estoppel that there be some question vital to the outcome of both cases which is the same in all material respects. See Rasanen v. Rosemount Instruments Ltd. (1994), 68 O.A.C. 284 at paragraphs 31, 32, 88, 89. While the different legal framework might well preclude cause of action estoppel, here we have a determination of fact which is equally applicable in both cases. The factual question fundamental to any finding of responsibility in respect to either the Applicant or Mr. Tebrinke is: was the OTM head discovered at the Tyson plant from an animal in the load certified by the Applicant and exported by Mr. Tebrinke to the United States? Unless that question can be answered in the affirmative, then neither one should be responsible: not Mr. Tebrinke under the Health of Animals Regulations, nor the Applicant under his contract which requires him to certify accurately.

[22] The most difficult question to answer is the third, namely are the same parties involved or their privies? I should first say that in my view that test should be applied more rigorously to the person who suffers the negative impact of estoppel. In this case that party is in reality the same in both cases, namely the CFIA.

Admittedly in this case the party seeking to take advantage of estoppel was not personally a party to the Tebrinke proceedings which found Tebrinke not guilty but I have concluded that for these purposes the Applicant and Mr. Tebrinke were privies. I think there must be some flexibility in identifying privies for this purpose. In Sopinka, Lederman, Bryant, The Law of Evidence in Canada (Butterworth's, second edition) at paragraph 19.86 it is said:

> *It is impossible to be categorical about the degree of interest which will create privity. It has been said that "there must be a sufficient degree of identification between the two to make it just to hold that the decision to which one was party should be binding in proceedings to which the other is party".*

[23] An authority cited there was the case of Gleeson v. J. Wippell & Co. Ltd., [1977] 3 All E.R. 54 at paragraph 60. This passage from the Law of Evidence in Canada was quoted with approval by Justice Binnie in the Supreme Court of Canada in the Danyluk case supra at paragraph 60. In the case of Rasanen, supra, an employee who was terminated initiated proceedings under the Employment Standards Act of Ontario for termination pay and also brought an action in the Superior Court for damages for constructive dismissal. Under the Employment Standards Act it was ultimately held that he was not entitled to termination pay. In his court action that decision was held to create issue estoppel so he could not prosecute a claim there for termination pay. On appeal, the Ontario Court of Appeal, in affirming the trial judge's decision noted that the parties in the two proceedings were actually different: in the Employment Standards Act proceeding the parties were the employer and an Employment Standards officer whereas in the court action the parties were the employee and the employer. Nevertheless, an identity of interest was found between the employee and the Employment Standards officer and they were held to be privies: see particularly paragraphs 34 and 88. Here, the Applicant and Mr. Tebrinke had an identical interest in challenging the allegation that the offending cow had been in the load which the Applicant certified and the grower exported. They had been engaged in a joint enterprise to effect the exportation of authorized cattle. The Applicant gave evidence for Mr. Tebrinke and the chairman of the Tribunal attached considerable weight to his evidence. The CFIA having had the opportunity to prove the identity of the OTM head and having

> *failed to do so in the Tebrinke case, should not have the opportunity to relitigate the exact same question of fact even within a different legal setting.*
>
> *[24] I therefore find that the CFIA is estopped from further proceedings against the Applicant in respect of this particular animal. As it was at liberty to proceed until the decision in the Tebrinke case of November 2, 2006 estopped it, I will direct that the suspension issued on April 3, 2006, be terminated as of November 2, 2006 and that all further proceedings as notified to the Applicant by the CFIA's letter of April 3, 2006 in respect of the animal bearing the CCIA ear tag 271 629 357 be terminated.*

[43] Thus, in the context of NOC proceedings, in particular this one, it is entirely appropriate to consider whether the resources of the Court and the Minister are being unduly taxed by a generic that raises essentially the same questions as were raised by another generic in previous proceedings, and failed. The Court must be mindful that the generic always has the remedy of a proceeding to challenge the validity of a patent in the usual way. The Court is also mindful that, if a different question is raised as to validity in subsequent proceedings, that question should be considered as it was, for instance, in *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FC 596, previously discussed.

[44] Therefor, where the same issue, validity, is raised, and the same questions in that respect, are raised, here “claims broader” and “sound prediction”, this Court will approach those questions having in mind that there was previous litigation in the NOC context and there always remains, free from the constraints of *res judicata*, the alternative for an action where there can be full discovery and observation of witnesses, in person, by the Court.

(2) Claims Broader

[45] The law as to whether validity of a claim in a patent can be challenged for overbreadth has been succinctly and clearly stated by Thurlow J. (as he then was) in *Farbewerke Hoechst A/G v. Canada Commissioner of Patents)*, [1966] Ex. C.R. 91 (aff'd, [1966] S.C.R. 604) at paragraph 20 in which he said:

> *There are two fundamental limitations on the extent of the monopoly which an inventor may validly claim. One is that it must not exceed the invention which he has made, the other is that it must not exceed the invention which he has described in his specification.*

[46] The first limitation is a question of fact, what is the invention that the inventor(s) have made. The second is a question of construction of the disclosure of the patent to determine what it says. In both cases a comparison must then be made of the claims at issue to determine if the "breadth" of the claim exceeds either what the inventor(s) actually did or what the disclosure actually says. In the event that evidence from the inventor(s) is not available and secondary evidence such as notebooks, memoranda and evidence of colleagues is unavailable or unsatisfactory, it is reasonable to assume that the disclosure of the patent coincides with that which the inventor(s) invented.

[47] Construction of the disclosure of the patent, as well as construction of the claims, is the task of the Court, not experts or the inventor(s). The Court may be informed by experts as to the meaning of words, terms and the science and background that are pertinent, but the Court must be careful not to let the experts supplant the role of the Court. Construction does not become a battle of experts; it is a duty of the Court. As I said in *Eli Lilly Canada v. Novopharm Ltd.*, 2007 FC 596 (appeal dismissed as moot, 2007 FCA 359) at paragraphs 103 and 104:

> *[103] A patent decision should, begin with a construction of the patent (Whirlpool Inc. v. Camco Inc. [2000] 2 S.C.R. 1067 at para. 43). This applies not only to the claims but to the whole of the patent as well when required (Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Inc. [1976] 1 S.C.R. 555 at page 563; Western Electric Co. v. Baldwin International Radio of Canada, [1934] S.C.R. 570 at page 572).*
>
> *[104] Construction is a task for the Court alone (Whirlpool supra; Burton Parsons supra.) the role of an expert, if required, is limited to assisting the Court in putting the Court in the position of a person skilled in the art of the relevant time (Halford v. Seed Hawk Inc., [2006] F.C.J. No. 1205, 2006 FCA 275 at para 11). In Dableh v. Ontario Hydro [1996] 3 F.C. 751 at paragraph 33 the Federal Court of Appeal stated what the role of the expert is:*
>
> > *It is a matter of accepted law that the task of constructing a patent's claim lies within the exclusive domain of the trial judge. In strict legal theory it is the role of expert witnesses, that is those skilled in the art, to provide the judge with the technical knowledge necessary to construe a patent as though he or she were so skilled. Where the experts disagree, it is incumbent on the trial judge to make a binding determination.*

[48] In the earlier proceedings respecting the ’330 patent, 2007 FCA 209, the Federal Court of Appeal construed the same claims as are at issue here and as previously discussed, concluded that a proper construction of those claims meant that all stereoisomers of the compounds were included. The parties in the present proceedings concur with that construction. The Federal Court of Appeal also construed the disclosure (specification). That was their duty as a matter of law. Their conclusion, as expressed by Nadon J.A. for the court was summarized at paragraphs 126 and 127 of the Reasons:

> *[126] On the basis of the evidence before the Court, however, Pfizer's invention can be described as covering all stereoisomers of quinapril. The state of the art is to the effect that all*

> *stereoisomers were within the inventor's contemplation, as revealed by the use of a Markish* [*sic*] *formula and the fact that patents for other ACE inhibitors claimed and disclosed all stereoisomers. The wording of the claims and the expert evidence suggest that all stereoisomers of quinapril are claimed in the patent. In fact, the Trial Judge, in her introduction on the '330 patent, says that "... [t]he compounds have three chiral centres and all the stereoisomers sharing this common structure, that is both the S- and R-configurations stereoisomers, are within the scope of the claims" (Reasons of Heneghan J., para. 9).*
>
> *[127] In my view, a person skilled in the art would read the two paragraphs from the disclosure which I have reproduced at paragraph 120 of these Reasons as disclosing that the invention includes all stereoisomers. The skilled reader would be persuaded particularly by the clear statement in the second paragraph that "... all optical isomers and diastereo isomers and mixtures thereof are within the scope of this invention". Accordingly, in my view, a skilled reader would therefore understand that claims 3 and 5, although silent as to stereo configuration, include all stereoisomers. Thus, given that the invention clearly covers all stereoisomers and that the patent claims all stereoisomers, the patent cannot be described as claiming more than what was invented.*

[49] Novopharm's Counsel argues that two things are raised in the present proceedings that were not raised in the earlier. One is that, as a matter of law, the Federal Court of Appeal erred in referring to other patents for the purpose of construing the '330 patent. This says Novopharm's counsel is reflected in the statement in paragraph 126, *supra*:

> *...and the fact that patents for other ACE inhibitors claimed and disclosed all stereoisomers.*

[50] It is quite correct to say that a patent cannot be construed with respect to extrinsic evidence (see e.g. *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067 at paragraph 49(f)). It is also correct for the Court to put itself in a position to consider the context and use to which words in the patent

are put (e.g. *Whirlpool*, *supra* at paragraph 49(d)). While it is not entirely clear how the Federal Court of Appeal treated the "other ACE patents", whatever they may be, it is sufficient, in the context of NOC proceedings, to conclude that a higher Court than this one did consider the issue of construction of the patent and made a reasoned determination.

[51] The second matter raised by Novopharm in this context is that of evidence and, in particular, the evidence from the inventors themselves which goes to the second branch of the test as stated by Thurlow J. in *Hoechst supra*, namely, do the claims exceed what the inventors actually invented. The named inventors of the '330 patent are Milton L. Hoefle and Sylvester Klutchko. Both filed affidavits as fact witnesses in the present proceedings and both were cross-examined. In addition, Dr. Clifton Blankley, a chemist who handwrote the first draft of what ultimately became the '330 patent filed an affidavit in the present proceedings and was cross-examined. He was not a lawyer or patent agent. He testified as a fact witness.

[52] Justice Heneghan, the Trial Judge in the earlier proceedings respecting the '330 patent, 2005 FC 1205, at paragraphs 18 to 43 carefully listed the witnesses in the proceeding before her including whether they were cross-examined. She indicated at paragraph 22 that both Hoefle and Klutchko filed affidavits but did not say that they were cross-examined. Given that she was careful to say when other witnesses were cross-examined it is reasonable to conclude that neither Hoefle nor Klutchko were cross-examined in the earlier proceeding. Heneghan J. states at paragraph 21, that Blankley filed an affidavit and was cross-examined.

[53] Novopharm's counsel in the present proceeding submits that there is "better evidence" here than in the earlier proceeding. That "better evidence" is in the cross-examination of Hoefle which, Novopharm's counsel asserts, indicates that the invention worked only with compounds in the S,S,S configuration and not with all 8 possible stereoisomers. Thus, it is argued, the claimed invention, namely all stereoisomers, is broader than the inventors actually made, namely only the S,S,S stereoisomer. Indicative of some of the cross-examination of Hoefle is that found at pages 38 to 40 of the transcript (pages 567-569 of the Application Record):

> *Q. And you say in the sentence that begins five lines in, this was part of the appreciation that there was a class of compounds with a common utility, the invention that eventually got incorporated into the '330 patent. Do you see that?*
>
> *A. Yes.*
>
> *Q. And again, these aren't your words, but what was the class of compounds with common utility you're referring to here?*
>
> *A. We're referring to the Merck derivatives of the tetrahydroisoquinoline. In other words, we were only interested in one compound, and that was the tetrahydroisoquinoline derivative. And there are others like the substituted dimatoxies* [*sic*] *that we looked at, but we didn't see any, you know, advantage in them.*
>
> *Q. Right.*
>
> *A. -- those were the compounds that were made at that point in time, that we knew.*
>
> *Q. And those –*
>
> *A. And that's what were included in the patent.*
>
> *Q. And that's what you were interested in?*
>
> *A. Yes.*

> *Q. And that included only compounds with the THIQ moiety in the S configuration, correct?*
> *A. Of the compounds we made, that is a correct statement. How the patent is written, I'm not sure. I mean the—you know.*
>
> *Q. Your invention wasn't a THIQ in the R configuration, was it?*
>
> *A. No. We were – our invention was the Merck analogue. As far as we knew, that was the S, S, S, all the way through.*
>
> *Q. Because that's what you thought was required for activity, correct?*
>
> *A. Correct.*

[54] Pfizer's counsel on the other hand argues that Hoefle's evidence must be read in its entirety whereby a different picture would emerge, namely that while work proceeded with the S,S,S compounds, more than just that was conceived by the inventors. Typical of the portions indicated by Pfizer's counsel is the answer given by Hoefle in cross-examination at pages 24 and 25 of the transcript (pages 553 and 554 of the Application Record):

> *Q. Okay. In paragraph 17, seven lines down, there's a sentence that begins, thus. Do you see that?*
>
> *A. Got it.*
>
> *Q. Thus, it was my understanding that the novel compound which Mr. Klutchko and I had conceived would also have an S configuration at each of its three chiral centers. Do you see that?*
>
> *A. Yes.*
>
> *Q. And that's correct?*
>
> *A. Yes.*
>
> *Q. That was the compound you had conceived, correct?*

> *A. Well, actually we had conceived more than that. The point is that it was our best educated guess based on prior history and the literature that the most active compound in this series would be the one that had the S, S, S, configuration.*

[55] The evidence of Hoefle is not conclusive as to what it was exactly that the inventors had invented, whether just the S,S,S stereoisomer or all eight stereoisomers. It would be far preferable to observe Hoefle as a witness at trial than to make a conclusion based on evidence that, arguably, could be interpreted one way or the other. It cannot be said that this evidence is truly "better" in the NOC proceeding context, than that which the Courts gave consideration in the earlier proceeding.

[56] The other named inventor Klutchko, was not examined in this area. If Novopharm believed that it was important to do so in order to achieve "better" evidence, it should have done so. It didn't. The evidence of Blankley in these proceedings does not assist in resolving this question.

[57] Thus there is no "better evidence" in this proceeding such that this Court should re-visit the finding of the Federal Court of Appeal in the earlier proceeding. As previously discussed, this Court will not disturb in the NOC context, the legal findings of the Federal Court of Appeal.

[58] Therefore, on the "claims broader" question, there is no basis for re-visiting the conclusion reached in the earlier proceeding by the Federal Court of Appeal, which was that the attack on the validity of the claims asserted of the '330 patent is not justified within the context of the NOC Regulations. There is no need to address the detailed list of matters raised as issues by the parties other than or has been done here.

(3) Sound Prediction

[59] The question of sound prediction was considered by the Federal Court of Appeal in the earlier proceeding under the caption "Lack of Utility" at paragraphs 150 to 154 of its Reasons, 2007 FCA 209. It said:

> *[150] Although Heneghan J. found that Pfizer had not demonstrated utility at the date of invention, she nevertheless found that the patent was valid because of the doctrine of sound prediction.*
>
> *[151] Apotex argues that Heneghan J. was wrong to conclude that the utility of the compounds claimed in the '330 patent was soundly predicted at the relevant time of October 3, 1980 (the priority date). In its view, because there was no evidence that any of the claimed compounds had been tested as of that date, the prediction of utility was unsound. I cannot agree.*
>
> *[152] In support of its argument that some testing is required before the utility of an invention will be found to be sound, Apotex points to the decision of the Federal Court in Apotex v. Wellcome Foundation Ltd. (1998), 145 F.T.R. 161. However, on appeal, the Supreme Court (at [2002] 4 S.C.R. 153) took a different view of the doctrine of sound prediction. In its view, in order for a prediction to be sound, "... there must be a factual basis for the prediction" (at paragraph 70). Although in two earlier Supreme Court decisions, "... the factual basis was supplied by the tested compounds," the Supreme Court in Apotex, supra was satisfied that "other factual underpinnings, depending on the nature of the invention, may suffice" (at paragraph 70). Accordingly, testing is not an absolute requirement for a patent based on sound prediction. Moreover, in a case such as the one before us where there is considerable data about the utility of related compounds such as captopril, enalapril and the Tanabe compound, there was evidence on which Heneghan J. could find that there was a factual basis to predict the utility of the invention disclosed in the '330 patent.*
>
> *[153] In any event, Pfizer points, correctly in my view, to this Court's recent decision in Aventis Pharma Inc.v Apotex Inc., 2006 FCA 64, which held that the relevant date for assessing the soundness of a prediction was the Canadian filing date, in this*

> *case, September 30, 1981. Contrary to Apotex's NOA and to Heneghan J.'s finding, the relevant date is not the priority date which, in this case, is October 3, 1980. Further, in ts NOA of July 24, 2003, Apotex refers to testing of quinapril that showed the compound reduced blood pressure in rats. The results of those tests were received on December 8, 1980, well before the Canadian filing date. Accordingly, even if some testing were required to establish a sound prediction, such testing was conducted in this case.*
>
> *[154] The issue of sound prediction is a mixed question of fact and law, in respect of which there was evidence in the record. In particular, Dr. Wasley and Dr. Anderson testified that a person of ordinary skill would have a sound basis to predict that all compounds claimed would have utility, on the basis of the captopril patents, enalapril disclosure and application, Tanabe patent and the inventor's knowledge regarding certain other compounds. It cannot be said that in concluding as she did, that the Judge made an overriding and palpable error.*

[60] Novopharm's counsel argues that the Federal Court of Appeal erred in law in asking the wrong question. Counsel argues that the Court of Appeal incorrectly considered whether a "skilled person" such as Wasley or Anderson would have had a sound basis to predict the utility of all stereoisomers. The proper question, counsel argues, is whether its inventors themselves, as a factual matter, had a sound basis to make such a prediction.

[61] All parties agree that what is called the "AZT" decision of the Supreme Court of Canada (*Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153) is the appropriate authority to consider in respect of "sound prediction". A later question has arisen as to what date is appropriate for considering whether a sound prediction could have been made, the priority date or the Canadian filing date. In the present proceeding it is unnecessary to resolve that debate since whether it is one date or the other the evidence is the same.

[62] The AZT case, particularly at paragraph 70, provided a three part test for considering sound prediction: (1) a factual basis for prediction (2) the inventors must have an articulable and sound line of reasoning and (3) there must be proper disclosure. More particularly Binnie J. for the Court said at paragraph 70:

> ***70*** *The doctrine of sound prediction has three components. Firstly, as here, there must be a factual basis for the prediction. In Monsanto and Burton Parsons, the factual basis was supplied by the tested compounds, but other factual underpinnings, depending on the nature of the invention, may suffice. Secondly, 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. In Monsanto and Burton Parsons, the line of reasoning was grounded in the known "architecture of chemical compounds" (Monsanto, at p. 1119), but other lines of reasoning, again depending on the subject matter, may be legitimate. Thirdly, there must be proper disclosure. Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practised: H. G. Fox, The Canadian Law and Practice Relating to Letters Patent for Inventions (4th ed. 1969), at p. 167. It is generally not necessary for an inventor to provide a theory of why the invention works. Practical readers merely want to know that it does work and how to work it. In this sort of case, however, the sound prediction is to some extent the quid pro quo the applicant offers in exchange for the patent monopoly. Precise disclosure requirements in this regard do not arise for decision in this case because both the underlying facts (the test data) and the line of reasoning (the chain terminator effect) were in fact disclosed, and disclosure in this respect did not become an issue between the parties. I therefore say no more about it.*

[63] It is important to remember the context in which the "AZT" case arose. The patent was directed to a new use of an old compound. The question as to sound prediction was whether, as of

the relevant date, the inventor had a proper basis for making a sound prediction as to that new use.

Binnie J. said at paragraph 52:

> ***52*** *It is important to reiterate that the only contribution made by Glaxo/Wellcome in the case of AZT was to identify a new use. The compound itself was not novel. Its chemical composition had been described 20 years earlier by Dr. Jerome Horwitz. Glaxo/Wellcome claimed a hitherto unrecognized utility but if it had not established such utility by tests or sound prediction at the time it applied for its patent, then it was offering nothing to the public but wishful thinking in exchange for locking up potentially valuable research turf for (then) 17 years. As Jackett C.J. observed in Procter & Gamble Co. v. Bristol-Myers Canada Ltd. (1979), 42 C.P.R. (2d) 33 (F.C.A.), at p. 39:*
>
> > *By definition an "invention" includes a "new and useful process". A "new" process is not an invention unless it is "useful" in some practical sense. Knowing a new process without knowing its utility is not in my view knowledge of an "invention".*

[64] The factual basis for the determination as to sound prediction was addressed by Binnie J. at paragraphs 65 and 69:

> ***65*** *However, where, as here, the trial judge accepts on the evidence that the inventors could in fact make a sound prediction that an old compound (AZT) offers a hitherto unexpected utility in the treatment and prophylaxis of HIV/AIDS, then (and only then) does their disclosure of "the invention" offer real consideration for the monopoly benefits they seek.*
>
> ...
>
> ***69*** *With respect, I think Parliament intended to get something more than speculation in exchange for the grant of a patent monopoly (a point which is further discussed below). On the other hand, I do not think, with respect, that the doctrine of sound prediction is limited to the narrow ambit ascribed to it by the trial judge. Once it is accepted that in appropriate circumstances utility can be predicted in advance of complete testing (whether of untested chemical compounds or otherwise), there seems no*

> *reason in principle why the doctrine should not be applied more generally, depending, of course, on the expert evidence. There is no doubt that care must be taken that the doctrine is not abused, and that sound [page186] prediction is not diluted to include a lucky guess or mere speculation. The public is entitled to obtain a solid teaching in exchange for the patent rights.*

[65] Each case will turn on its facts as Binnie J. stated at paragraph 71:

> ***71*** *It bears repetition that the soundness (or otherwise) of the prediction is a question of fact. Evidence must be led about what was known or not known at the priority date, as was done here. Each case will turn on the particularities of the discipline to which it relates. In this case, the findings of fact necessary for the application of "sound prediction" were made and the appellants have not, in my view, demonstrated any overriding or palpable error.*

[66] The Federal Court of Appeal in the earlier ’330 patent NOC proceedings did not address itself to the wrong question. To repeat paragraph 154 of their decision (2007 FCA 209):

> *[154] The issue of sound prediction is a mixed question of fact and law, in respect of which there was evidence in the record. In particular, Dr. Wasley and Dr. Anderson testified that a person of ordinary skill would have a sound basis to predict that all compounds claimed would have utility, on the basis of the captopril patents, enalapril disclosure and application, Tanabe patent and the inventor's knowledge regarding certain other compounds. It cannot be said that in concluding as she did, that the Judge made an overriding and palpable error.*

[67] The question is one of mixed fact and law. The Court of Appeal considered the “*inventors knowledge regarding certain other compounds*” as well as the knowledge that would have been possessed of persons of ordinary skill. There is no error of law such that this Court, in the context of an NOC proceeding, should not follow the conclusion reached by the Federal Court of Appeal

that the allegation of invalidity of the asserted claims of the ’330 patent is not justified. There is no reason to address in any more detail than has been done here the list of issues raised by the parties.

IN CONCLUSION

[68] In conclusion, in the context of an NOC proceeding, there has not been demonstrated that, on the same questions as to invalidity as raised by another generic in earlier NOC proceedings respecting the asserted claims of the ’330 patent, there is any better evidence or more appropriate argument in the present proceeding. The applications by Pfizer for prohibition will, therefore, be allowed with costs.

COSTS

[69] Pfizer is entitled to its costs and disbursements. Neither party has asserted that costs be assessed at other than at the default level being the middle of Column III. I find that that is the appropriate level for taxation. At the hearing, each of Pfizer and Novopharm had three counsel gowned. Pfizer may tax costs for one senior and one junior counsel. For attendance when Pfizer counsel were conducting cross-examination, costs for one senior and one junior counsel, if present, may be taxed. When attending cross-examination of a Pfizer witness by Novopharm, only one counsel’s costs, at the senior level, may be taxed.

[70] As to disbursements, there is a continued concern as to experts. Only five experts can put in evidence without leave of the Court. Here Pfizer had six and no leave. Only the costs of five

experts can be allowed; Maycock was frequently referred to by Pfizer in argument and his costs are allowed. Costs of four other experts only may be taxed. Pfizer may choose which four.

[71] The fees charged by the experts must be carefully scrutinized. They must be reasonable and should not exceed fees charged by Pfizer's senior counsel for the same amount of time. Nothing is to be allowed for any in-house Pfizer counsel or outside counsel or attorneys other than counsel of record. Disbursements as to photocopies are to be carefully scrutinized. Multiple copies of material beyond that provided to the Court and the other side are to be limited to three. If any non-arms length copying service was used, than the actual cost of copies is to be assessed. If an arms length service was used then the actual cost, if reasonable, is to be assessed. Travel costs if incurred for counsel who appeared at trial or cross-examination is to be reasonable.

[72] Since applications T-209-06 and T-210-06 were heard together, no duplication as to costs or disbursements is allowed unless shown to have been actually incurred.

JUDGMENT

For the Reasons given:

THIS COURT ORDERS AND ADJUDGES that:

1. Each of Applications T-209-06 and T-210-06 is allowed;
2. The Respondent, the Minister of Health, is prohibited from issuing a Notice of Compliance to the Respondent Novopharm Limited in respect of its Applications respecting quinapril hydrochloride and quinapril hydrochloride and quinapril hydrochloride and hydrochlorothiazine at issue in these proceedings, at least until the expiry of Canadian Patent No. 1,341,330;
3. The Applicants are entitled to their costs and disbursements to be taxed in accordance with the Reasons given.

"Roger T. Hughes"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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