Federal Court of Appeal | Cour d'appel fédérale

CANADA

Date: 20090630

Docket: A-393-08

Citation: 2009 FCA 222

CORAM: **LINDEN J.A.**
EVANS J.A.
LAYDEN-STEVENSON J.A.

BETWEEN:

APOTEX INC.
and
APOTEX PHARMACHEM INC.

Appellants

and

ADIR and
SERVIER CANADA INC.

Respondents

Heard at Toronto, Ontario, on June 1-2, 2009.

Judgment delivered at Ottawa, Ontario, on June 30, 2009.

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

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

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REASONS FOR JUDGMENT

LAYDEN-STEVENSON J.A.

[1] This is an appeal by Apotex Inc. and Apotex Pharmachem Inc. (collectively Apotex) from the judgment of Justice Snider dated July 2, 2008, in an action for infringement of Canadian Patent No. 1,341,196 (the '196 Patent).

[2] The respondents, ADIR and Servier Canada Inc. (referred to throughout these reasons interchangeably as ADIR or Servier), commenced an action against Apotex alleging that it infringed

ADIR's '196 Patent. Apotex defended the action on several fronts. Among other things, it asserted: the '196 Patent is invalid because it is not inventive in light of prior disclosures and the common general knowledge; ADIR was not the first inventor; the patent lacks utility; and, there was no basis for sound prediction on the Canadian filing date. By counterclaim, Apotex claimed damages under section 36 of the *Competition Act*, R.S.C., 1985, c. C-34 (the *Competition Act*) on the basis that ADIR obtained the '196 Patent in breach of section 45 of the *Competition Act*.

[3] Justice Snider concluded, among other things, that claims 1, 2, 3 and 5 of the '196 Patent are valid and have been infringed by Apotex. She dismissed Apotex's counterclaim. Although Apotex advances several grounds of appeal and alleges many errors on the part of the trial judge, no issue is taken with respect to her determination on infringement (if her conclusion on validity is sustained) or remedies (if Apotex is unsuccessful on this appeal).

[4] For the reasons that follow, I conclude that Apotex's allegations of error largely relate to factual determinations made by the trial judge for which Apotex has not demonstrated palpable and overriding error. I also conclude that, to the extent that Apotex's arguments relate to questions of law, the trial judge did not err as alleged. Consequently, I would dismiss the appeal.

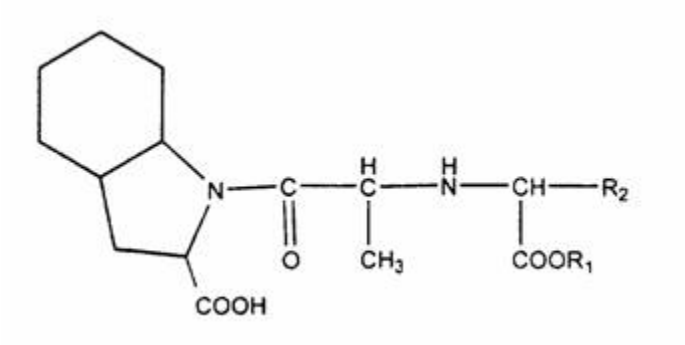
BACKGROUND

[5] ADIR is an innovator pharmaceutical company. It owns the '196 Patent. Servier exploits the patent rights in Canada. The application for the '196 Patent was filed on October 1, 1981. Consequently, the pre-October 1, 1989 version of the *Patent Act*, R.S.C. 1985, c. P-4 (the *Patent*

Act) applies. References to the *Patent Act* in these reasons, unless otherwise specified, are references to the pre-October 1989 *Patent Act*.

[6] The patent claims priority from two patent applications filed in France on October 2, 1980 and April 7, 1981. This proceeding concerns claims 1, 2, 3 and 5, which read:

1. Composés répondant à la formule générale



dans laquelle :

R1 représente un atome d'hydrogène ou un groupe alkyle de 1à 4 atomes de carbone

R2 représente un groupe alkyle linéaire de 1 à 6 atomes de carbone et leurs sels d'addition pharmaceutiquement acceptables.

2. Un composé selon la revendication 1 où R2 est un alkyle de 3 ou 4 atomes de carbone et leurs sels pharmaceutiquement acceptables.

3. Un composé selon la revendication 1 où R2 est un n-propyle et ses sels pharmaceutiquement acceptables.

> *5. Le composé selon la revendication 1 qui est le {N - [(1,S) éthoxycarbonyl - 1 butyle] (S) - alanyle} - 1 carboxy – 2(S) (3aS,7aS) perhydroindole et ses sels pharmaceutiquement acceptables.*

[7] The '196 Patent was issued following lengthy conflict proceedings involving applications filed by Schering Corporation (Schering) and Hoechst Aktiengesellschaft (Hoechst). The proceedings were ultimately resolved by order of the Federal Court, on consent, dated December 12, 2000. Claims 1-3 of the '196 Patent were issued on March 6, 2001 and expire on March 6, 2018. Claim 5 of the '196 Patent was twice corrected and was issued, in its present form, on May 14, 2001. It expires on May 14, 2018.

[8] At issue in this case is the development of angiotensin-converting enzyme (ACE) inhibiting compounds. ACE is an enzyme that can bind with the angiotensin I protein to produce angiotensin II, which increases blood pressure by constricting blood vessels. ACE inhibitors bind with ACE to prevent the conversion of angiotensin I to angiotensin II, thereby lowering blood pressure. The first orally effective ACE inhibitor, captopril, was invented by Bristol-Myers Squibb (Squibb) around 1977.

[9] Following the invention of captopril, other pharmaceutical companies began working to develop ACE inhibitor research programs. In response to the serious side effects experienced by some users of captopril, Merck & Co. (Merck) developed a new ACE inhibitor, enalapril, which it presented at a conference in Troy, New York (“the Troy conference”) on June 18, 1980. Enalapril has an N-carboxyalkyl moiety in place of captopril’s problematic sulfhydryl methylene group. Both captopril and enalapril contain the same proline unit.

[10] Both Schering and ADIR had been working with ACE inhibitors before the Troy conference. Following this disclosure, Schering and ADIR, among others, turned their attention to building upon the enalapril molecule.

[11] Schering's research focused on the use of various bicyclic rings in place of proline on an enalapril-like molecule. One of the Schering compounds created through this work contained molecules with a perhydroindole ring structure in place of the proline unit. Schering applied for a patent on October 20, 1981, and was eventually granted Canadian Patent No. 1,341,206 (the '206 Patent). The '206 Patent covers the ramipril molecule, an ACE-inhibiting compound. Schering and its licensees have marketed ramipril to great commercial success.

[12] ADIR's work also focused on the use of bicyclic rings in place of proline on the Merck backbone. In 1981, Dr. Vincent, an ADIR scientist, created a molecule with a perhydroindole ring on the proline end of an enalapril-like molecule (also referred to as the C-terminus), but also used a propyl on the side chain at the other end (also referred to as the N-terminus). On September 1, 1981, ADIR tested an enatiomerically-pure (S) salt of this compound, know as perindopril. It filed Canadian Patent Application No. 387,093 (the '093 Application) in respect of this work.

[13] Schering and Hoechst had also filed patent applications in respect of various ACE-inhibiting compounds. The Commissioner of Patents (the Commissioner) placed the '093 Application, Patent

Application 388,336 (Schering), Patent Application 384,787 (Hoechst), and Patent Application 418,453 (Hoechst) into conflict as provided for in the *Patent Act*.

[14] The Commissioner made determinations pursuant to subsection 43(7) of the *Patent Act* on August 8, 1996. None of the applicants were satisfied with the results and six proceedings were commenced in the Federal Court pursuant to subsection 43(8). These proceedings were later consolidated into Court File Number T-228-97 pursuant to an order of Mr. Justice Joyal (the Joyal order).

[15] ADIR, Hoechst, and Schering ultimately settled this proceeding. On December 12, 2000, Justice Nadon, then of the Federal Court, granted an order, on consent, allocating the claims among the parties (the Nadon order). The '196 Patent covers the claims awarded to ADIR.

[16] Servier is a licensee of ADIR and manufactures perindopril for sale in Canada. Perindopril is one of a family of compounds. It is an ACE inhibitor and is useful in the treatment of hypertension and cardiac insufficiency. Perindopril is the active ingredient in the medicine Servier sells in Canada under the trade-mark COVERSYL. Since at least 2006, Apotex, a generic company, has manufactured perindopril products in Canada and exported them internationally to affiliates and others.

THE TRIAL DECISION

[17] After 30 days of trial, Justice Snider determined that the '196 Patent is valid and Apotex had infringed it. As noted previously, she dismissed the Apotex counterclaim under the *Competition Act*. A summary of Justice Snider's conclusions follows.

Standing

[18] The trial judge held that only ADIR and Servier Canada had standing as plaintiffs. The evidence was not persuasive enough to support a finding that the non-ADIR foreign plaintiffs held a license to use the '196 Patent in Canada or could otherwise claim under the patentee, ADIR.

Claims Construction

[19] The construction of claims 1, 2, 3 and 5 of the '196 Patent was not contentious. Justice Snider performed a purposive construction of the claims. She identified the person skilled in the art (the skilled person) as an individual having at least a few years' experience in academia or industry in the respective field and holding a Master or Doctoral degree in synthetic organic chemistry, medicinal chemistry, pharmacology or biochemistry, or, a medical doctor having several years experience treating hypertension or cardiac insufficiency in humans.

[20] Justice Snider found that a skilled person would construe the claims at issue as follows:

> Claim 1 corresponds to a subset of compounds falling under General Formula I where R1 is defined as a hydrogen atom or an alkyl group with one to four atoms, and R2 is a linear alkyl group with one to six carbon atoms, and their pharmaceutically acceptable salts. Claim 1 has five chiral centres but does not specify any particular stereochemical designation for any of the stereocentres. It is an essential element that each compound of the claim contains both a bicyclic 6,5

perhydroindole moiety on the C-terminus and a linear alkyl group with one to six atoms on the N-terminus.

Claims 2, 3 and 5 are dependent on claim 1. As dependent claims they are necessarily more limiting than claim 1 and must be construed consistently with the larger claim.

Claim 2 corresponds to a subset of compounds falling under claim 1 wherein R2 is restricted to n-propyl or n-butyl, and their pharmaceutically acceptable salts. Claim 2 has five chiral centres but does not specify any particular stereochemical designation for any of the stereocentres.

Claim 3 corresponds to a still narrower set of compounds falling under claim 1 where R2 is limited to n-propyl, and their pharmaceutically acceptable salts. As with claims 1 and 2, claim 3 has five chiral centres but does not specify any particular stereochemical designation for any of the stereocentres. Because there are five chiral centres or stereocentres, claim 3 encompasses 32 (2^5) different compounds.

Finally, claim 5 (as it stands today) corresponds to a single stereoisomer where each of the 5 chiral centres is designated as (S). It is undisputed that claim 5 encompasses perindopril as well as its pharmaceutically acceptable salts. Although worded as a dependent claim (« Le composé selon la revendication 1 »), the claim is to a single compound. The words that indicate dependency are unnecessary to the construction of claim 5.

Nature of the Invention

[21] The debate between the parties was whether, in light of the description, the claims should be construed as being examples of one alleged invention or class of compounds encompassing all of General Formula I, or whether the claims should stand on their own. Justice Snider concluded that claims 1, 2, 3 and 5 form one or more inventions that are distinct from the larger class of compounds of General Formula I in the description. The invention claimed by the patent, on a purposive construction of the claims at issue, is that disclosed by claims 1, 2, 3 and 5.

Direct Infringement

[22] Justice Snider found there was ample evidence of direct infringement by Apotex. By its manufacture and sale of perindopril products under the trade name Apo-Perindopril, Apotex made, constructed, used, offered for sale and sold perindopril products that are included in claims 1, 2, 3 and 5 of the '196 Patent.

Inducement

[23] Justice Snider applied the test for inducement set out in *Warner Lambert v. Wilkinson Sword Canada Inc.* (1988), 19 F.T.R. 198, 19 C.P.R. (3d) 402 (F.C.T.D.) (*Warner Lambert*). She concluded that the first branch of the *Warner Lambert* test was not met and found there was no inducement.

Exemptions from Liability

[24] Justice Snider found that Apotex is not liable for the identified quantities of perindopril which fit within the regulatory and experimental use exemption of section 55.2 of the *Patent Act* (post October 1, 1989). Apotex is liable for its export sales. The infringement by Apotex involves, in part, the manufacture of perindopril for export. To that extent, Apotex infringed the '196 Patent and is liable to Servier Canada and ADIR.

Corrections to Claim 5

[25] Justice Snider rejected Apotex's claim of non-infringement of claim 5 on the basis that the Commissioner of Patents twice improperly corrected the claim.

Judicial Review

[26] In reaching this conclusion, the trial judge was not persuaded by Servier's argument that Apotex was required to proceed by way of judicial review. She found that sections 59 and subsections 60(1) and 60(2) of the *Patent Act* permit Apotex to make claims of invalidity based on unlawful actions of the Commissioner as a defense to infringement.

Standard of Review

[27] Justice Snider applied *Dunsmuir v. New Brunswick*, [2008] 1 S.C.R. 190 (*Dunsmuir*). She concluded the applicable standard of review was reasonableness and applied that standard.

Reasonableness of Decision

[28] The trial judge held that the decisions reached by the Commissioner to correct claim 5 under section 8 of the *Patent Ac*t were reasonable. She also concluded that the corrections were clerical errors.

Obviousness

C-terminus

[29] Justice Snider relied on the test for obviousness and the framework for applying the test set out in *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2007 FCA 217, 59 C.P.R. (4th) 116 (F.C.A.), leave to appeal dismissed, [2007] S.C.C.A. No. 442 (*Janssen-Ortho*). She was not persuaded that the addition of the 6,5 perhydroindole bicyclic ring was obvious.

Invention

[30] The trial judge found the invention to be a bicyclic 6,5 moiety on the C-terminus of the compound and a linear alkyl group with 1 to 6 carbon atoms on the N-terminus.

Person of Ordinary Skill

[31] As noted earlier, Justice Snider determined that the hypothetical skilled person includes a number of skilled individuals with experience in work or academia, holding a Master, Doctoral, or medical degree.

Body of Knowledge

[32] Justice Snider outlined the evidence forming the state of the art. She did not include the art outside the field of ACE inhibition cited by Apotex because Apotex had not established that a skilled person would look beyond the field at issue.

Climate in the Field

[33] Justice Snider found that the general trend in the prior art was that the S2 prime subsite of ACE was capable of accepting a wide variety of moieties, some of which were larger than perhydroindole. Further, the trial judge acknowledged there were two moieties taught in the prior art, tryptophan and THIQ, which contained bicyclics. She accepted that a medicinal chemist would have the skill to use SAR methodology to manipulate chemical compounds. However, she found that Apotex had not established how the skilled person, without inventiveness or ingenuity, could

collate the prior art on ACE inhibitors (and even some sources outside the ACE inhibition field), make some fundamental assumptions and combine this knowledge to come up with a perindopril molecule. The trial judge accepted expert evidence that small changes in structure can have unpredictable pharmacological effects.

Motivation

[34] Justice Snider found there was recognition after the Troy conference of a specific problem to solve, namely, to come up with a better ACE inhibitor than that developed by Merck. The evidence suggested the existence of a general motivation in the industry to build upon, and not merely work around, the Merck disclosure at the Troy conference. The evidence also suggested that inventive ingenuity was employed.

Time and Effort

[35] While it was uncontested that ADIR, Hoechst, Warner-Lambert and Schering developed compounds incorporating bicyclic ring modifications after Merck's disclosure at the Troy conference, the trial judge was not satisfied on the record that any of the other chemists discovered perindopril with its 6,5 bicyclic ring and a linear alkyl group. Further, there was no evidence that any of the other compounds were developed by persons of ordinary skill. Rather, Doctors Smith and Vincent were inventive and ingenious, not persons of ordinary skill.

Commercial Success

[36] It was not contested that Servier achieved commercial success with sales of perindopril.

N-terminus

[37] In addition to her conclusions regarding the C-terminus, Justice Snider observed that it was immaterial that there was no language in the description of the '196 Patent to limit the invention to a linear alkyl sidechain since the invention was not General Formula I. Further, although there was disclosure of substituents with linear alkyl sidechains, there was no evidence that a person of ordinary skill in the art would be expected to select this class of substituents from the numerous others recorded, without difficulty.

Utility

[38] Justice Snider found that Apotex had not satisfied its burden to show that the compounds of claims 1, 2 and 3 of the '196 Patent lack utility.

Promise of the '196 Patent

[39] Based on the patent's disclosure, Justice Snider held that the promise of the '196 Patent is that all of the compounds claimed will have some level of ACE inhibition when measured *in vitro* and that some of the compounds will have sufficient activity to treat hypertension and cardiac insufficiency.

The 1992 Vincent Article

[40] Justice Snider held that the 1992 *Vincent* Article does not, on a balance of probabilities, either expressly or by inference, demonstrate that any of the compounds of claim 3 of the '196

Patent lack utility. She accepted Dr. Vincent's explanation that the purpose of the article was not to describe absolute activity or inactivity. She noted that the underlying test data showed that none of the compounds had a zero activity level. She concluded that the "admission" of Dr. Laubie on this point was ambiguous in regard to whether there was zero activity *in vitro* or *in vivo*.

The Gavras Report

[41] Justice Snider determined that the Gavras Report did not establish a lack of utility for the compounds of claim 3. Since she already had found that a "therapeutic anti-hypertensive effect" is not the promise of the patent, she considered that the testing results were irrelevant. In any event, Justice Snider found that the testing methodology of Dr. Gavras was so seriously flawed she could give little weight to his results.

Sound Prediction

[42] Justice Snider applied the three-part test for sound prediction set out in *Apotex Inc. v. Wellcome Foundation Ltd.* (2002), 21 C.P.R. (4th) 499 (S.C.C.) (*Wellcome*) and concluded that Apotex had not met the burden of demonstrating the skilled person, as of the filing date, could not soundly predict that the trans compounds of claims 1, 2 and 3 would have utility.

The (R,R,R) Compounds

[43] The trial judge was not persuaded that Servier did not have a sound basis for predicting that compounds with the (R,R,R) configuration on the backbone of the molecule would possess the promised ACE-inhibitory utility of the '196 Patent. She held that the prior art, most notably Merck's European Patent Application 0 012 401 A1 (the '401 Application) and Patchett, A. A. et al., "A new

class of Angiotensin-converting enzyme inhibitors" 288 Nature 280 (the *Nature* paper), form a factual basis and sound line of reasoning for predicting that there would be some level of ACE inhibition, even if low.

The Trans Compounds

[44] Justice Snider rejected Apotex's allegations that Servier could not have soundly predicted the utility of the compounds in claims 1, 2 and 3 containing trans configuration of the two asymmetrical carbon atoms on the fused 6,5 bicyclic ring at the time of the Canadian filing date since a skilled person would not, as of the relevant date, have known how to synthesize such compounds.

Inventorship

[45] Apotex failed with respect to its argument that the ADIR scientists were not the first inventors of the compounds patented under the '196 Patent. Justice Snider interpreted subsection 61(1) of the *Patent Act* as applying only where there had been a "missed conflict." In considering the object of the *Patent Act* with respect to first inventorship and predictability, she found that Parliament provided that a patent issued pursuant to the conflict process is protected from further attacks on the question of inventorship, except in the circumstances contemplated by the *Patent Act*, specifically, paragraph 61(1)(*b*). As such, these proceedings were intended to be final on the issue of inventorship. Apotex's interpretation that inventorship could be raised whether or not conflict proceedings had occurred would have the effect of rendering meaningless the words "on which conflict proceedings should have been directed" in paragraph 61(1)(*b*).

[46] Justice Snider held that Apotex was precluded from challenging the validity of the '196 Patent on the grounds of inventorship because the claims involved in the conflict proceedings were ones on which conflict proceedings had been directed.

[47] The trial judge also concluded that Apotex had failed to satisfy its evidentiary burden to demonstrate that Schering scientist, Dr. Smith, was the first to know or use the invention of the '196 Patent. Although she accepted that Schering had made at least one compound with ACE inhibition activity that falls within General Formula I before the ADIR scientists made and tested their two compounds, as previously stated, she found that the invention of the '196 Patent was contained in the claims and not General Formula I.

Competition Act

[48] Justice Snider dismissed Apotex's counterclaim seeking damages pursuant to section 36 of the *Competition Act*. She concluded the law is settled that without "something more", the mere assertion of patent rights cannot be a violation under section 45 of *Competition Act*. Each step in the conflict proceedings and issuance of the '196 Patent was in accordance with the *Patent Act* or *Federal Courts Rules*. On the facts before her, she held that the requisite "something more" was not present. Thus, the '196 Patent could not give rise to a violation of section 45 of the *Competition Act*. Prior to the issuance of the '196 Patent, there could be no impairment of competition. Following the issuance of the patent, Servier had only as much market power as was inherent in the '196 Patent. ADIR was merely exercising its rights under the *Patent Act*.

[49] In the alternative, Justice Snider held that the two-year limitation period set out in subsection 36(4) of the *Competition Act* had expired. She found that since there was no ongoing collusion, the limitation period ran from the date of the settlement agreement or, at latest, the issuance of the patent. She further held that the discoverability principle did not apply since subsection 36(4) of the *Competition Act* expressly defines a specific date on which the limitation period begins, independent of knowledge of a cause of action. Even if the discoverability period did apply, Justice Snider held Apotex became aware of and received a copy of the Settlement Agreement in April 2003. As such, the latest date from which the two-year limitation period could run (based on discoverability) would be April 2003. She therefore found that Apotex was well beyond the two-year limitation contained in subsection 36(4) of the *Competition Act*.

[50] On the issue of whether ADIR's allegedly anti-competitive actions serve to disentitle Servier to equitable relief, Justice Snider held that in entering into the Settlement Agreement, Servier (or ADIR) was exercising its rights under the *Patent Act*. As such, the trial judge found that Apotex failed to show that there was conduct that would disentitle Servier to any of the equitable remedies that it may seek.

Remedies

[51] Justice Snider found that Servier Canada and ADIR are entitled to:

- A declaration of the validity of the '196 Patent;
- A permanent injunction, subject to the right of Apotex to sell its perindopril products for a further 30 days from the date of the judgment;

- Damages to be quantified subsequent to judgment (as a result of an Order dated March 14, 2007, in which Prothonotary Aronovitch provided for a bifurcation of the trial of this action so as to leave the calculation as to quantum of damage or profits to a later time); and

- Pre and post-judgment interest.

Issues

[52] Apotex alleges various errors on the part of the trial judge. Many of its arguments are largely a reiteration of those made to the trial judge. The alleged errors are subsumed under the titles identified below. Where distinct subsidiary issues arise with respect to a specific topic, they are so indicated.

(a) Nature of the Invention

(b) Obviousness

(1) the trial judge applied the wrong test;

(2) the trial judge tested as of the wrong date;

(3) the trial judge erred in unduly narrowing the field of relevant art;

(4) the trial judge erred in applying the standard.

(c) First Inventorship

(d) Utility

(e) Sound Prediction

(f) Claim 5 Corrections

(g) *Competition Act*

The Relevant Statutory Provisions

[53] The text of the statutory provisions referred to in these reasons is attached as Appendix “A”.

Nature of the Invention

[54] Apotex asserts that the trial judge erred in ascertaining the invention of the '196 Patent. Distilled, its arguments are that the trial judge asked herself the wrong question, erred in failing to follow *May & Baker Limited et al. v. Boots Pure Drug Company Limited* (1950), 67 R.P.C. 23 (H.L.) (*May & Baker*) and in concluding that the specific compounds claimed in the '196 Patent constitute separate inventions rather than various aspects of the same invention. At the end of the day, these allegations amount to a single complaint: Justice Snider did not agree with Apotex that the invention of the patent is the larger class of compounds of General Formula I and nothing more.

[55] The question identified by Apotex as central to its argument is: “what did [the alleged inventor] invent?” It argues that the trial judge erroneously concluded, contrary to *May & Baker* and subsection 36(1) of the *Patent Act* (which states that a patent shall only be granted for one invention), that claims, 1, 2, 3 and 5 of the '196 Patent disclose one or more inventions distinct from the larger class of compounds encompassed by General Formula I described in the specification. Such a conclusion, according to Apotex, “cannot be right as a matter of law” because it conflates the concepts of invention and monopoly.

[56] Apotex maintains *May & Baker* stands for the proposition that an invention cannot be found to exist in two specifically exemplified compounds distinct from the disclosed invention of a general class. Noting that there was no issue regarding the construction of the claims *per se*, Apotex

contends that the general formula found in the disclosure constitutes the invention. In relying on *C.H. Boehringer Sohn v. Bell-Craig Ltd.*, [1962] Ex. C.R. 201, aff'd., [1963] S.C.R. 410 (*Boehringer*) and *Hoechst Pharmaceuticals of Canada Ltd. v. Gilbert & Co.*, [1965] 1 Ex. C.R. 710, aff'd., [1966] S.C.R. 189 (*Hoechst*) to conclude otherwise, Apotex asserts that the trial judge erred because questions of construction and ascertainment of the invention disclosed by a patent are not matters of binding jurisprudential precedence.

[57] For a variety of reasons, I am not persuaded that Justice Snider erred as alleged. Paragraph 34(*a*) of the *Patent Act* requires an applicant to correctly and fully describe the invention and its operation or use as contemplated by the inventor. Paragraph (*e*) of the same section requires the applicant to particularly indicate and distinctly claim the part, improvement, or combination that he claims as his invention.

[58] *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 (*Whirlpool*) decides that claims construction is antecedent to issues of both infringement and validity. It also stands for the proposition that purposive construction requires a court to have regard to the whole of the patent (including the claims and the disclosure) when ascertaining the nature of the invention. Indeed, several of the authorities cited in Apotex's memorandum of fact and law illustrate the application of these principles. More recent authority indicates that the inventive concept need not be readily discernable from the claims, even in circumstances where construction of the claims is not in issue. A bare chemical formula may require recourse to the specification to determine the inventive

concept of the claims: *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 (*Sanofi*).

[59] The trial judge proceeded precisely in accordance with the holdings of the above-noted jurisprudence. She examined the patent as a whole to ascertain its invention in circumstances where there was really no debate as to the construction of the claims. When confronted with competing positions as to the nature of the invention, she turned to relevant jurisprudence where a broad class of compounds was described in the disclosure and narrower claims to compounds were stated in the claims. To assist in her analysis, she referred to *Boehringer, Hoechst* and the decision of this Court in *Merck & Co. Inc. v. Apotex Inc.*, 2006 FCA 323, [2007] 3 F.C.R. 588, leave to appeal refused, [2006] S.C.C.A. No. 507 (*Merck lisinopril*).

[60] The trial judge determined that the circumstances before her were consistent with those in *Boehringer, Hoechst* and *Merck lisinopril*. That being the case, she found that General Formula I did not constitute the invention of the patent as urged by Apotex. Rather, she concluded that claims 1, 2, 3 and 5 of the '196 Patent are for one or more inventions that are distinct from the larger class of compounds in General Formula I in the description.

[61] *May & Baker* was distinguished from circumstances where, as in *Boehringer*, *Hoechst* and *Merck lisinopril*, the class of compounds described by a general formula is disclosed in the specification, but the claims are limited to a compound and a small genus around the compound. In *May & Baker*, the issue was whether an amendment to disclaim a genus and add a claim to two

compounds produces a substantially different invention. The Court held that to permit the amendment of the specification would claim an invention substantially different from that claimed in its original form. This Court, in *Merck lisinopril*, at paragraph 38, noted that in *May & Baker*, the two substances were not specifically named in any claims but were only named as examples as part of a broader class. Hence, they were there considered as examples of a broad inventive class. That was not the situation in *Merck lisinopril* and it is not the situation here.

[62] To bolster its position, Apotex refers to cases dealing with double patenting. Those authorities are of no assistance. Double patenting prohibits more than one patent being issued with respect to the same invention. The authorities do not stand for the principle for which they are cited.

[63] Contrary to Apotex's submission, Justice Snider did not suggest that the *Boehringer*, *Hoechst* and *Merck lisinopril* authorities stand for the proposition that each claim discloses a separate invention. Rather, she concluded that this case is one where reading the claims in light of the specification results in more than one invention. Notably, subsection 36(1) of the *Patent Act* contemplates the possibility of a patent containing more than one invention.

[64] More significantly, the issue in the present proceeding is the same as that considered and decided against Apotex in *Merck lisinopril*. In its written submissions, Apotex did not address *Merck lisinopril* except by way of footnote where it alleged that Justice Snider wrongly interpreted the case (an observation that I have rejected). No argument was tendered with respect to *Miller v. Canada (Attorney General),* 2002 FCA 370, 220 D.L.R. (4th) 149. There, Justice Rothstein, then of

this Court, discussed the test to be met in order for the Court to overrule its own decisions. Simply put, the test is one of manifest error. Apotex made no such allegation in regard to *Merck lisinopril*.

[65] At the hearing of this appeal, and despite its candid acknowledgement that it had made the same arguments in *Merck lisinopril*, Apotex continued to rely on *May & Baker* and insisted that it applied, rather than *Merck lisinopril*. This submission was primarily based on the allegation that perindopril had not been disclosed in the '093 Application. The short answer to that allegation is that claim 8 of the '093 Application claimed perindopril and its stereoisomers.

[66] Moreover, after hearing extensive evidence and argument and reviewing the patent in its totality, the trial judge concluded otherwise. As previously stated, she determined the circumstances before her were consistent with those in *Boehringer*, *Hoechst* and *Merck lisinopril*. That conclusion was open to her on the record and I can detect no reviewable error in this respect. Consequently, this ground of appeal fails.

Obviousness

[67] The question of obviousness is largely a factual inquiry. The trial judge applied the framework articulated in *Janssen-Ortho*. Subsequently, the Supreme Court of Canada issued its decision in *Sanofi*. The *Janssen-Ortho* framework is not inconsistent with that described in *Sanofi*. Therefore, the trial judge's factual determinations are equally relevant to the *Sanofi* analysis. To the extent that a specific *Sanofi* factor may not have been analysed, it will be necessary to determine

whether the trial judge's factual conclusions are sufficient to respond to the Supreme Court's *Sanofi* analysis. I will return to that issue later in these reasons.

(1) *The trial judge applied the wrong test*

[68] Apotex submits Justice Snider erred by directing the obviousness inquiry to the claims of the '196 Patent. In so doing, it argues that the trial judge specifically and erroneously rejected as relevant what the disclosure taught about inventiveness. Had she construed the entire specification, she would have concluded that the invention was the class of compounds described in General Formula I.

[69] This submission, in my view, constitutes a second kick at the can regarding Apotex's first argument with respect to the nature of the invention. I endorse and adopt the reference from *Angiotech Pharmaceuticals Inc. v. Conor Medsystems Inc.*, [2008] UKHL 49 (*Angiotech*) at paragraph 19 relied upon by Servier in this regard. In *Angiotech,* Lord Hoffman stated that "the invention is the product specified in a claim and the patentee is entitled to have the question of obviousness determined by reference to his claim and not to some vague paraphrase based upon the extent of his disclosure in the description." This is consistent with the observation of this Court in *Janssen-Ortho* that "what is in issue is the patent claim as construed by the Court" (paragraph 25). It is also consistent with *Sanofi* where, in describing the appropriate framework for an obviousness inquiry, Justice Rothstein stated, at paragraph 67, that the second step is the need to "identify the inventive concept of the claim in question or if that cannot readily be done, construe it." No error has been established in this respect.

(2) *The trial judge tested as of the wrong date*

[70] Apotex claims that Justice Snider erred by choosing the filing date of the '093 application (October 1, 1981) rather than the filing date of the priority application (October 2, 1980). Perindopril had not been synthesized or tested until September 1, 1981. No reason is advanced as to why the choice of the earlier date would assist its obviousness argument. Indeed, choosing the latter date had the effect of encompassing more prior art that could be relied upon by Apotex (for example, the *Nature* paper published on November 20, 1980).

[71] At the hearing of this appeal, Apotex's counsel was questioned regarding paragraph 55 of *Merck lisinopril* where this Court stated that where a Canadian application contains material relating to subject-matter invented after the priority date, that subject-matter cannot benefit from that date. Such a defect in the priority claim will not invalidate the entire patent, but will simply result in the application bearing the Canadian filing date. Counsel's response was that its point is not a major one.

[72] Apotex has not demonstrated that the trial judge erred in choosing October 1, 1981 as the date of invention. I agree with Servier that since Justice Snider found that claims 1, 2, 3 and 5 of the '196 Patent were not obvious as of October 1, 1981, she undoubtedly would have made the same finding based on the earlier date when less prior art would have been available to the skilled person.

(3) *The trial judge erred in unduly narrowing the field of relevant art*

[73] Obviousness is considered with reference to the prior art that a skilled person would look to in order to solve the problem addressed by the patent. This is ordinarily referred to as the general common knowledge. Justice Snider concluded that it cannot be presumed that a skilled person would look to prior art outside the field of ACE inhibition, absent evidence to that effect. On the basis of the evidence before her, she was not persuaded that the skilled person would look outside this field. This is a factual finding.

[74] Apotex contends, because the trial judge defined the skilled person as a composite, including a medical doctor with experience treating hypertension or cardiac insufficiency, it was unreasonable to suppose that a doctor treating such conditions would not have regard to other possible treatments for those conditions. However, Doctors Gavras and Brunner, Apotex's expert medical doctors, provided no evidence that non-ACE inhibition prior art was relevant. I fail to see how the trial judge can be faulted.

[75] Apotex has not demonstrated reviewable error in Justice Snider's assessment of the evidence regarding whether the skilled person would look outside the field of ACE inhibition. On the record, it was open to the trial judge to make the finding that she made.

(4) *The trial judge erred in applying the standard*

[76] Apotex identifies this allegation as its "most important argument" in relation to obviousness. Notably, the arguments made before this Court are largely a reiteration of those made in the first

instance before Justice Snider. Additionally, Apotex's argument, in part, constitutes a rehashing of its thesis regarding the nature of the invention. Its position in this respect was rejected by the trial judge, with whom I agree. It bears repeating that the onus is on Apotex to establish, on a balance of probabilities, that a claim is obvious: *Whirlpool; Sanofi*.

[77] Justice Snider concluded that the essential elements of the claims in issue are the use of both a 6,5 perhydroindole moiety and a linear alkyl group with one to six atoms on either end of the molecule. She determined that the prior art taught the use of bulky moieties, including tryptophan and THIQ (both of which contain bicyclics). However, she found that there were differences between tryptophan and THIQ and the 6,5 bicyclic ring used in perindopril, such that it would not have been obvious to a skilled person to use the latter.

[78] The crux of Apotex's argument is that it had been shown in the art that "considerable variation could be made to the general framework of a non-peptic ACE inhibitor particularly at the C-terminus." Additionally, given Merck's disclosure at the Troy conference and its resulting '401 application, coupled with the *Nature* disclosures, any one of a number of substitutions could be made at the other end, that is the N-terminus (the side chain), with good activity.

[79] The difficulty with these arguments is that Justice Snider found otherwise. In relation to the C-terminus and specifically the 6,5 perhydroindole moiety, after careful consideration of the evidence, the trial judge determined that it would not have been obvious to a skilled person to design an ACE inhibitor with a perhydroindole carboxylic acid moiety at the C-terminus despite the

disclosure of tryptophan and THIQ in the prior art. Justice Snider specifically identified and listed a number of differences, in comparing tryptophan and THIQ with the perhydroindole carboxylic acid moiety, to support her finding that the skilled person would not have been motivated to use a perhydroindole carboxylic acid moiety (paragraphs 253-256 of her reasons).

[80] Apotex suggests these differences are "technical, chemical differences between tryptophan and THIQ" and are "false distinctions" made with the benefit of hindsight. I disagree. Apotex provides no basis to support its suggestion that the trial judge ought to have ignored such distinctions. More importantly, in my view, the trial judge's observations in this respect were correct.

[81] Apotex also argues the trial judge erred by giving insufficient weight to the fact that other chemists had created compounds using bicyclic ring substitutions following the Troy conference. Justice Snider determined it was not clear whether any of these scientists had actually discovered perindopril and, even if they had, they were inventors rather than skilled persons. *Sanofi* makes a similar distinction between the highly skilled person and the ordinary skilled person (paragraph 71). In any event, even if the trial judge was in error on this point, it is but one factor to consider. It is by no means determinative and cannot be said to constitute palpable and overriding error.

[82] Next, Apotex maintains that Servier's expert evidence on sound prediction belies its claim of non-obviousness. It refers, in particular, to the evidence of Doctor Bartlett that four early compounds tested by ADIR provided a sound basis to conclude that perhydroindole "would be

tolerated at the ACE binding sight." From this, Apotex extrapolates the proposition that the THIQ and the 6,5 indoline are "far closer" to perhydroindole than these other compounds and therefore, perhydroindole was an obvious choice.

[83] Apotex cites no evidence to justify its assertion that THIQ and the 6,5 indoline are "far closer" to perhydroindole than the earlier-tested compounds. I am not prepared to find palpable and overriding error on the basis of bare assertions, unsupported by evidence.

[84] With respect to the N-terminus, Apotex claims that any one of a number of substitutions could be made at the other end of the enalapril/captopril molecules with good activity because of Merck's disclosure at Troy and its resulting '401 Application and *Nature* disclosures. Among these were linear alkyls, including methyl, ethyl and n-propyl, branched alkyls, cycloalkyl and phenethyl. In essence, Apotex's contention is that because the Merck backbone was known, the only invention is substitution, which is obvious.

[85] Again, the trial judge concluded otherwise. Justice Snider specifically addressed this issue and concluded that while the *Nature* paper and the Troy symposium slides did disclose a number of linear alkyl groups, these documents would not have motivated a skilled person to choose a linear alkyl group (paragraph 265 of her reasons). There was nothing in the prior art to lead a skilled person to substitute the phenethyl in enalapril with the propyl in perindopril. Having considered and appreciated the evidence regarding the N-terminus side chain, it was open to the trial judge to arrive at the conclusion that the addition of a linear alkyl side chain to the N-terminus was not obvious.

[86] Apotex's "final observation" regarding the bicyclic ring is that, in commenting that "there were suggestions in the prior art that such a ring might work", the trial judge appears to "have resorted in effect to a worth-a-try analysis." This argument was not pursued at the hearing. Justice Snider also concluded that the endeavour of combining all the elements from the prior art to produce such a design required ingenuity and inventiveness. In my view, the trial judge's comments merely foresee the self-evident requirement subsequently articulated in *Sanofi*. Justice Snider was not satisfied that the invention was self-evident.

[87] To return to where I began, Justice Snider concluded that the invention of the claims in suit is the use of both a 6,5 perhydroindole moiety on the C-terminus and a linear alkyl group on the N-terminus. Nowhere in its submissions does Apotex address the combination that Justice Snider determined to be the invention.

[88] Finally, it remains to determine whether Justice Snider's analysis regarding obviousness is consistent with that articulated in *Sanofi* (released after this matter was determined). For completeness, I will briefly review the *Sanofi* framework to ensure that no relevant and significant factor was overlooked.

[89] Justice Snider identified the notional skilled person and there is no allegation of error with respect to her determination (paragraphs 101-104, 251 of her reasons). The identification of the relevant art is contained at paragraphs 229-240 and 252 of her reasons. The inventive concept of the

claim in question is found at paragraphs 125-133 and 206 of her reasons. The differences between tryptophan and THIQ and perindopril are delineated at paragraph 253. As noted earlier, the issue of whether it is more or less self-evident that what is being tried ought to work is addressed at paragraph 256 of Justice Snider's reasons. Justice Rothstein stated in *Sanofi*, at paragraph 66, that mere possibility that something might turn up is not enough. Further, she noted that small changes in structure can have unpredictable pharmacological effects (paragraph 255). The extent, nature and amount of effort required to achieve the invention is described at paragraphs 254-256 of her reasons, while motive from the prior art to find the solution is delineated at paragraphs 257-259. Although she does not deal with it in her analysis on obviousness, Justice Snider was alert to the course of conduct followed which culminated in the making of the invention (paragraphs 58-62 of the reasons) and she commented, at paragraph 260, that the inventiveness and ingenuity of the work performed by Dr. Vincent was unquestioned.

[90] In my view, Justice Snider's determinations are consistent with the *Sanofi* framework. Apotex has not demonstrated that Justice Snider erred in concluding that its obviousness challenge failed.

First Inventorship

[91] In addition to its submissions on obviousness, Apotex contends that the ADIR scientists were not the first inventors of the '196 Patent. Accordingly, it says that the patent is invalid.

[92] Justice Snider dismissed Apotex's argument that Schering first invented the subject matter of the '196 Patent. Following a detailed and comprehensive analysis of subsection 61(1) of the *Patent Act* (paragraphs 393 to 427 of her reasons), she concluded that Apotex was barred from attacking the validity of the '196 Patent unless it could establish the existence of a "missed conflict". Based on her interpretation of paragraph 61(1)(*b*), Justice Snider concluded that there was no missed conflict because the words "should have been" must be interpreted as meaning should have been, but were not, directed.

[93] However, Justice Snider also made a specific factual determination, irrespective of her interpretation of paragraph 61(1)(*b*). Apotex first had to demonstrate that the invention had already been known or used by some other person. The trial judge concluded that Apotex failed to establish that Schering invented the '196 Patent before ADIR. After hearing all witnesses, including Dr. Smith of Schering, Justice Snider concluded that Apotex had not discharged its burden in this respect.

[94] The trial judge painstakingly reviewed the evidence and arguments in this respect at paragraphs 442-443 of her reasons. As indicated at paragraph 454 of her reasons, Apotex relied on its assertion that the invention of the '196 Patent is General Formula I in the specification. As stated earlier, that thesis has been rejected by both the trial judge and this Court. Justice Snider concluded that Apotex adduced no evidence that Schering had invented any compounds falling within claims 1, 2, 3 and 5 of the patent. Apotex, having taken its position at trial, now asserts that Schering invented a structure including both perhydroindole and a linear alkyl chain, but cites no evidence in

support of its assertion. To the contrary, it states that “it could hardly be said that the failure of the Schering scientists to synthesize a linear alkyl side-chain could prevent it from including same within the scope of its invention.”

[95] The trial judge determined that the claims of the '196 Patent define the invention. Claim 5 relates to perindopril while claims 1, 2 and 3 are directed to a small class of compounds around perindopril containing both a bicyclic 6,5 perhydroindole moiety on the C-terminus and a linear alkyl group with one to six atoms on the N-terminus (paragraphs 124, 131, 133 and 250 of her reasons).

[96] I agree with Servier, citing a plethora of authority at paragraph 40 of its memorandum of fact and law, that:

> For Apotex to succeed, it must establish that Dr. Smith “planted [her] flag at the precise destination before the patentee” meaning “for [the] purpose of practical utility, equal to that given” by the '196 Patent.

[97] I also agree with Servier that Apotex must establish that Dr. Smith either demonstrated the utility of the invention by testing all compounds falling within the claimed class, or soundly predicted the utility, failing which she has made no invention.

[98] It is common ground that Dr. Smith and the Schering team did not make or test any compounds falling within the claims during the relevant time period. Consequently, the utility of the claimed compounds, including perindopril, could not be soundly predicted. As determined by the

trial judge, Apotex's allegations were simply not borne out by the evidence. Moreover, as previously noted, Justice Snider specifically rejected Apotex's submissions after hearing Dr. Smith, all pertinent evidence and reviewing that evidence (including Dr. Smith's "invention disclosure notebook" as well as her conflict affidavit). The trial judge also concluded elsewhere in her reasons that only the ADIR scientists had the requisite sound prediction to be true inventors (paragraph 380 of her reasons). Notably, Apotex has appealed that determination only with respect to the making of the trans compounds.

[99] Apotex has not established palpable and overriding error on the part of the trial judge regarding her unequivocal finding that it had failed to satisfy its evidentiary burden to demonstrate that Dr. Smith was the first to know or use the invention of the '196 Patent. This is sufficient to dispose of the issue of first inventorship. It is not necessary to address paragraph 61(1)(*b*) of the *Patent Act*.

Utility

[100] Apotex argues that Justice Snider erred in construing the promised utility of the invention. It claims that the specification contains several specific promises of pharmaceutical utility: in particular, a promise of antihypertensive therapeutic use. Additionally, Apotex contends that the trial judge erred: in limiting the promise of the patent to ACE inhibition activity *in vitro*; in refusing to have regard to the abstract of the '196 Patent to assist in determining its promise; and in determining whether the promise had been met.

[101] Determining the promise of a patent is an aspect of claims construction, a question of law: *Bristol-Myers Squibb Co. v. Apotex Inc.*, 2007 FCA 379 at paragraph 27. Generally, it is an exercise that requires the assistance of expert evidence and so it was in this case.

[102] Justice Snider concluded that the '196 Patent contains an unambiguous promise of ACE inhibition. Whether it also promised "all of the compounds will have utility as anti-hypertensive medicine in humans", as asserted by Apotex, was not clear to the trial judge from reading the patent. Accordingly, she turned to the expert evidence. Faced with conflicting views, she weighed the evidence and adopted what she considered to be the "better and more reasonable view." She expressed a preference for Servier's experts' evidence over that of Apotex's experts. She found Apotex's experts inappropriately required that each and every compound to be "successful to the point of being a drug that a doctor could prescribe." The trial judge concluded that therapeutic use was expressed to be possible, but not guaranteed.

[103] Apotex argues that the "context" does not support this construction. I reject that submission. A declaration that the compounds of General Formula I have interesting pharmaceutical properties does not guarantee all compounds will have therapeutic use. Similarly, the description's statement that the invention extends to pharmaceutical compositions containing as an active ingredient at least one compound from General Formula I does not guarantee that all compounds will have therapeutic use.

[104] As for the trial judge's refusal to consider the abstract of the '196 Patent to ascertain the promise of the patent, in my view, she was correct in concluding that section 175 of the *Patent Rules* precludes such consideration. The fact that the abstract in *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902 (*Monsanto*) at paragraph 18 was quoted, among other portions of the disclosure of that patent, does not indicate that the abstract may be used to determine the promise of the patent. Further, *Monsanto* does not use the abstract to assess utility.

[105] Rule 175(1) of the *Patent Rules* specifically provides that the abstract cannot be taken into account for the purpose of interpreting the scope of protection sought or obtained. See also: Roger T. Hughes and Dino P. Clarizio, *Hughes and Woodley on Patents*, 2nd ed., looseleaf (Markham: LexisNexis Canada Inc. 2005) at page 302. Rule 175(2) prescribes the contents of the abstract for the purpose of reference, not to aid construction. The promise of a patent, as noted earlier, is an aspect of claims construction. Apotex does not suggest that the abstract is relevant to claims construction. To the contrary, it accepts that it is not (memorandum of fact and law at paragraph 70). The trial judge did not err in refusing to consider the abstract as a factor in determining the promise of the patent.

[106] Apotex claims that Justice Snider incorrectly determined the promise of the '196 Patent to be "that all of the compounds claimed will have some level of ACE inhibition when measured *in vitro* and that some of the compounds will have sufficient activity to treat hypertension and cardiac insufficiency" (paragraph 293 of her reasons). It points to the patent specification and says there is "no indication whatsoever in the patent specification of such a qualified promise." Rather, the only

testing that is disclosed in the specification is at page 29 where the activity of the compounds when administered to conscious dogs, i.e. *in vivo*, is described.

[107] Apotex is correct that the *in vitro* limitation is not contained in the patent. The words "when measured *in vitro*" must be deleted from the trial judge's conclusion. The promise of the patent should be reformulated (based on the findings of the trial judge) as "all of the compounds claimed will have some level of ACE inhibition and some of the compounds will have sufficient activity to treat hypertension and cardiac insufficiency."

[108] The error, in all likelihood, occurred as the result of extrinsic evidence (the *Vincent* study). According to that evidence, only 4 of the 32 potential versions of perindopril were tested *in vivo* and they were tested because they had the most promise.

[109] However, extrinsic evidence is not necessary for a skilled person to understand that the test was conducted only on a subset of the compounds claimed. On Apotex's reading of the patent, each single compound listed in the claims had been synthesized. (The thrust of Apotex's attack on the utility of the patent is that the patent promised all of the compounds claimed would have some level of ACE inhibition and that they would all have the therapeutic effect of lowering blood pressure.) Apotex has elsewhere acknowledged not only that ADIR had not in fact synthesized all of the compounds (memorandum of fact and law at paragraph 65) but also that they could not possibly have done so (reasons of the trial judge at paragraph 453). Accordingly, with or without the *Vincent*

study, a skilled person could not have concluded that the patent promised that every version of the compound would lower blood pressure.

[110] It seems to me that the trial judge may have been endeavouring to remind Apotex that ADIR's *in vitro* testing of the 32 perindopril stereoisomers, among other compounds, was sufficient to establish a sound prediction that all of the compounds in the class had the minimal requisite ACE-inhibiting properties to meet the low standard set by the promise of the patent. Her only error was to insert the words "*in vitro*" into her articulation of the promise. The remainder of her logic stands. The error does not affect the outcome, nor does Apotex suggest otherwise.

[111] Apotex also alleges errors with respect to Justice Snider's assessment of the evidence on the alleged lack of utility of the claimed compounds. These arguments are centered on the trial judge's findings in relation to the 1992 *Vincent* Article (supported by the underlying internal pharmacological testing data that was not contradicted by Apotex) and the alleged admission of Dr. Laubie. Although Apotex alleges factual and legal errors, it does not identify any legal errors. The alleged errors relate to factual determinations, which are reviewable only if palpable and overriding error is demonstrated.

[112] Justice Snider extensively addressed these issues at paragraphs 296-319 of her reasons. Her finding that the 1992 *Vincent* Article does not, on a balance of probabilities, either expressly or by inference, demonstrate that any of the compounds of claim 3 of the '196 Patent lack utility was open to her on the basis of the factual and expert evidence before her. Similarly, the determination

regarding the evidence of Dr. Laubie was hers to make. The weighing of evidence is not the function of an appellate court.

[113] Apotex has not demonstrated error on the part of the trial judge in ascertaining the utility of claims 1, 2, and 3 of the '196 Patent. Consequently, its attack with respect to utility fails.

Sound Prediction

[114] Relying on *Wellcome,* Apotex asserts that the trans compounds claimed were not soundly predicted because the '196 Patent does not disclose a methodology for making them. It relies on paragraphs 69 and 70 of *Wellcome* to support its submission that sound prediction requires not only a sound prediction that the purported invention will work, but also a sound prediction that the invention can be made.

[115] Justice Snider determined that the relied-upon passage does not refer to the need to predict the making of a compound as an element of sound utility. Rather, in *Wellcome,* the court stated that a patent must disclose how the patent can be used or practised (the requirement of sufficiency) and also that the patentee must have a sound basis for predicting that the invention will work. *Wellcome* refers only to utility as being the relevant inquiry in regard to sound prediction. Apotex provides no authority wherein the making of an invention was implicated in the inquiry regarding the soundness of prediction.

[116] As Justice Snider noted, the utility of a class of chemical compounds can be soundly predicted by "reference to the architecture of the particular class" (paragraph 376 of her reasons). Apotex has not argued that the trans compounds could not be soundly predicted to have utility as ACE inhibitors, if they could be made. The sufficiency of disclosure is the appropriate line of inquiry to sustain an allegation that the subject matter of a patent could not be made. Consequently, the trial judge did not err in law in concluding that the sufficiency of the disclosure of the method of manufacture of the trans compounds is not a matter of sound prediction. Apotex did not advance any argument with respect to the sufficiency of the '196 Patent.

[117] In any event, Apotex has not demonstrated palpable and overriding error regarding Justice Snider's factual determinations that, as of the date of the Canadian filing, "the inventors' prediction that all of the compounds included in claim 3 of the '196 Patent would have activity as ACE inhibitors was sound", or that it had not discharged its burden to persuade her that a skilled person "could not soundly predict that the trans compounds of claims 1, 2 and 3 would have utility" (paragraph 380 of her reasons).

Claim 5 Corrections

[118] This issue was addressed extensively before Justice Snider. Paragraphs 174-222 of her reasons comprehensively set out the manner in which it was treated. Briefly, claim 5 of the '196 Patent, as it was originally issued on March 6, 2001, did not constitute a claim to perindopril. The Commissioner granted two certificates of correction on April 3 and May 14, 2001, respectively. Apotex argues that Justice Snider erred in finding these certificates to have been validly issued.

[119] At trial, Apotex relied on section 59 of the *Patent Act* to justify its position that it could put the Commissioner's decisions in issue. That section provides that a defendant in an action for infringement may plead in defence any fact or default, which by the *Patent Act* or by law, renders the patent void. Relying on *Grenier v. Canada*, 2005 FCA 348, [2006] 2 F.C.R. 287 (C.A.) and *Pason Systems Corp. v. Canada* (*Commissioner of Patents*), 2006 FC 753, 54 C.P.R. (4th) 40, Servier took the position that Apotex could not advance its argument because its proper recourse was an application for judicial review. Servier maintains its position on appeal and contends that Apotex's quarrel is not with the validity of the patent as required by section 59, but with the validity of the certificates.

[120] Justice Snider reasoned that Apotex's standing to initiate an application for judicial review was questionable. She concluded, on the basis of her interpretation of section 59 and subsections 60(1) and 60(2) of the *Patent Act*, that Apotex was not precluded from raising the Commissioner's actions in issuing the certificates. She determined that the Commissioner's decision should be reviewed on a standard of review of reasonableness and concluded that the Commissioner's decision was reasonable.

[121] Apotex claims the trial judge erred in her determination of the standard of review because the question "was one of first impression", that is, "whether the statutory conditions for correction had been met."

[122] Although the submissions of the parties on this issue are extensive and raise novel and interesting points, in my view, it is not necessary for this Court to rule on the propriety of Justice Snider's conclusions regarding the availability to Apotex of judicial review or on her selection of reasonableness as the applicable standard of review. At the end of the day, Apotex's argument must fail.

[123] While the trial judge concluded that the Commissioner's decision was reasonable, she additionally, in effect, granted Apotex's wish for a *de novo* examination of the matter. She heard the evidence of counsel/patent agent Mr. Landry and Doctor Jaguelin of Servier and examined the associated documents. She heard evidence that the naming conventions of chemical compounds are different in English and French.

[124] Having heard the evidence and examined the documents, Justice Snider made a factual determination. She concluded, unequivocally, that the errors were clerical mistakes in the form of incorrect alphanumeric designations. They were made in the course of translation, but were not translation errors. That finding falls squarely within the definition articulated in *Bayer AG v. Commissioner of Patents*, [1981] 1 F.C. 656; (1980), 53 C.P.R. (2d) 70 (F.C.T.D.) that a clerical error is an error that arises in the mechanical process of typewriting or transcribing and that its characteristic does not depend at all on its relative obviousness or the relative gravity or triviality of its consequences.

[125] At the risk of redundancy, this Court will not interfere with factual determinations of trial judges in the absence of palpable and overriding error. Apotex's argument that "the standard against which the factual inquiry must be made is a legal question" sets the bar too high. At best, the trial judge's determination gives rise to a question of mixed fact and law and is heavily oriented toward the factual side. Therefore, the standard of review of her determination remains the same.

[126] Apotex has not demonstrated palpable and overriding error in relation to Justice Snider's factual determination. A review of the evidence that she considered leads inescapably to the conclusion that the finding was open to her. Accordingly, Apotex cannot succeed even if the trial judge erred in her conclusions (and I make no determination in this regard) with respect to the availability of judicial review and the choice of the applicable standard of review in relation to the Commissioner's decision.

Competition Act

[127] In its counterclaim, Apotex alleged that ADIR contravened section 45 of the *Competition Act* by entering into a settlement agreement with Schering and Hoechst in Federal Court proceeding T-228-97.

[128] Briefly, to contextualize this allegation, I will review again the circumstances. When ADIR filed the '093 Application, certain of its claims were placed into conflict with claims in other applications filed by Schering and Hoechst. The Commissioner made determinations related to inventorship with respect to the claims in conflict. Six proceedings were commenced in the Federal

Court, pursuant to subsection 43(8) of the *Patent Act*, for determination of the parties' respective rights in relation to the subject matter of the conflict claims. Mr. Justice Joyal ordered that the proceedings be consolidated into Court File Number T-228-97. The Joyal order also provided that each of the parties was entitled to contest any aspect of any decision of the Commissioner regarding the award of any claim declared to be in conflict, irrespective of whether the party was directly involved in conflict proceedings with respect to that particular claim.

[129] After the completion of the examinations for discovery, ADIR, Schering and Hoechst entered into Minutes of Settlement resolving the actions. On December 12, 2000, Mr. Justice Nadon issued an order, on consent, which provided for the allocation of the claims among ADIR, Schering and Hoechst. The order stated that ADIR was entitled to the issuance of a patent restricted to the claims in Appendix A to the order. The result of the claims awarded to ADIR was the '196 Patent.

[130] Apotex asserts that the settlement agreement ensuring each of the parties would obtain patents covering commercialized ACE inhibitors was unlawful as being anti-competitive. Relying upon what it describes as ADIR's "perception", Apotex alleges that ADIR entered the agreement to avoid the result that either no claims covering perindopril would issue or there would be overlapping claims encompassing perindopril awarded to multiple parties. The acquisition of the '196 Patent is said to have unduly lessened competition in the ACE inhibitor market, thereby injuring Apotex and entitling it to damages pursuant to section 36 of the *Competition Act*.

[131] Justice Snider carefully reviewed the applicable principles delineated in *Molnlycke AB v. Kimberley-Clark of Canada Ltd. et al.* (1991), 36 C.P.R. (3d) 493 (F.C.A.) (*Molnlycke*); *Eli Lilly and Co. v. Apotex Inc.*, 2004 FCA 232, 32 C.P.R. (4th) 195 (F.C.A.) (*Eli Lilly 1*) and *Eli Lilly and Co. v. Apotex Inc.*, 2005 FCA 361, 44 C.P.R. (4th) 1 (F.C.A.) (*Eli Lilly 2*), as well as the pertinent provisions of the *Competition Act*. She considered the circumstances leading to and surrounding the settlement agreement and ultimately dismissed the counterclaim on the basis that, at every step of the process, ADIR had exercised its rights under the *Patent Act* and the *Federal Courts Rules*, and nothing more. Alternatively, she determined, in any event, Apotex's claim was statute-barred.

[132] Apotex contends that the trial judge misdirected herself in failing to consider the circumstances surrounding the settlement agreement in 2001. By looking at the patent through the lens of validity in 2008, Justice Snider allegedly ignored the possibility that, had the conflict proceedings been decided by the Federal Court rather than settled, ADIR may not have been granted exclusive patent rights. It ostensibly follows that the "probability" exists that the "exclusive acquisition of the patent rights provided ADIR with greater market power than it would otherwise have had."

[133] This Court has repeatedly held that undue impairment of competition cannot be inferred from evidence of the exercise of rights under the *Patent Act* alone. Apotex's arguments are based on speculation. It provides no evidence of the alleged "probability" of greater market power and no evidence of the alleged "probability" that the parties to the conflict proceedings would have been granted overlapping claim to perindopril.

[134] There is no suggestion that the Federal Court could not have awarded the claims in issue precisely as they were so allocated. Indeed, Apotex concedes at paragraph 91 of its memorandum of fact and law that the court could have awarded one party an exclusive claim over perindopril.

[135] More importantly, as evidenced at paragraph 472 of Justice Snider's reasons, the parties agreed that the proposition emanating from the jurisprudence is that there must be "something more" beyond the mere assertion of patent rights to sustain a finding of contravention of section 45 of the *Competition Act*. The trial judge's finding bears repeating. "Every step of the process – from the applications of each of the parties, through the settlement process and the Nadon Order to the ultimate issuance of the '196 Patent – was in accordance with the rights of ADIR under the *Patent Act* and the *Federal Courts Rules*. The settlement agreement was simply one step in ADIR's exercise of patent rights" (paragraph 475 of her reasons).

[136] I can find no fault with the conclusion of the trial judge in this respect. Again, it is a factual determination and Apotex has not demonstrated palpable and overriding error. This is not to say there might never be circumstances where a settlement agreement could constitute the "something more" contemplated in the *Eli Lilly* cases. It is not the situation here. I have some difficulty conceptualizing that an agreement effecting a remedy that was open to the court to grant and was placed before the court for its approval could constitute an offence under the *Competition Act*.

[137] Since this determination is fatal to Apotex's counterclaim, there is no need to address the matter of the limitation period.

Conclusion

[138] This disposes of the arguments advanced by Apotex. I would dismiss the appeal with costs.

"Carolyn Layden-Stevenson"
J.A.

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

"I agree
John M. Evans J.A."

SCHEDULE "A"
to the
Reasons for judgment dated June 30, 2009
in
APOTEX INC.
and
APOTEX PHARMACHEM INC.
and
ADIR and
SERVIER CANADA INC.
A-393-08

Patent Act, R.S.C. 1985, c. P-4	*Loi sur les brevets*, (L.R., 1985, ch. P-4)
8. Clerical errors in any instrument of record in the Patent Office do not invalidate the instrument, but they may be corrected under the authority of the Commissioner.	8. Un document en dépôt au Bureau des brevets n'est pas invalide en raison d'erreurs d'écriture; elles peuvent être corrigées sous l'autorité du commissaire.
34(1)An applicant shall in the specification of his invention	34(1) Dans le mémoire descriptif, le demandeur:
(a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;	(a) décrit d'une façon exacte et complète l'invention et son application ou exploitation, telles que les a conçues l'inventeur;
[…]	…
(e) particularly indicate and distinctly claim the part, improvement or combination that he claims as his invention.	(e) indique particulièrement et revendique distinctement la partie, le perfectionnement ou la combinaison qu'il réclame comme son invention.
36(1) A patent shall be granted for one invention only but in an action or other proceeding a patent shall not be deemed to be invalid by reason only that it has been granted for more than one invention.	36(1) Un brevet ne peut être accordé que pour une seule invention, mais dans une instance ou autre procédure, un brevet ne peut être tenu pour invalide du seul fait qu'il a été accordé pour plus d'une invention.

59. The defendant, in any action for infringement of a patent may plead as a matter of defence any fact of default which by this Act or by law renders the patent void, and the court shall take cognizance of that pleading and of the relevant facts and decide accordingly.

59. Dans toute action en contrefaçon de brevet, le défendeur peut invoquer comme moyen de défense tout fait ou manquement qui, d'après la présente loi ou en droit, entraîne la nullité de brevet; le tribunal prend connaissance de cette défense et des faits pertinents et statue en conséquence.

60(1) A patent or any claim in a patent may be declared invalid or void by the Federal Court at the instance of the Attorney General of Canada or at the instance of any interested person.

(2) Where any person has reasonable cause to believe that any process used of proposed to be used or any article made, used or sold or proposed to be made, used or sold by him might be alleged by any patentee to constitute an infringement of an exclusive property or privilege granted thereby, he may bring an action in the Federal Court against the patentee for a declaration that the process or article does not or would not constitute an infringement of the exclusive property or privilege.

60(1) Un brevet ou une revendication se rapportant à un brevet peut être déclaré invalide or nul par la Cour fédérale, à la diligence du procureur général du Canada ou à la diligence d'un intéressé.

(2) Si une personne a un motif raisonnable de croire qu'un procédé employé ou dont l'emploi est projeté, ou qu'un article fabriqué, employé ou vendu ou dont l'emploi ou la vente par elle, pourrait, d'après l'allégation d'un breveté, constituer une violation d'un droit de propriété ou privilège exclusif accordé de ce chef, elle peut intenter une action devant la Cour fédérale contre le breveté afin d'obtenir une déclarations que ce procédé ou cet article ne constitue pas ou ne constituerait pas une violation de ce droit de propriété ou de ce privilège exclusif.

61(1) No patent or claim in a patent shall be declared invalid or void on the ground that, before the invention therein defined was made by the inventor by whom the patent was applied for, it had already been known or used by some other person, unless it is established that

61(1) Aucun brevet ou aucune revendication dans un brevet ne peut être déclaré invalide ou nul pour la raison que l'invention qui y est décrite était déjà connue ou exploitée par une autre personne avant d'être faite par l'inventeur qui en a demandé le brevet, à moins qu'il ne soit établi que, selon le cas :

(a) that other person had, before the date of the application for the patent, disclosed or used the invention in such manner that it had become available to the public;
(b) that other person had, before the issue of the patent, made an application for patent in Canada on which conflict proceedings should have been directed; or
(c) that other person had at any time made an application in Canada which, by virtue of section 28, had the same force and effect as if it had been filed in Canada before the issue of the patent and on which conflict proceedings should properly have been directed had it been so filed.

a) cette autre personne avait, avant la date de la demande du brevet, divulgué ou exploité l'invention de telle manière qu'elle était devenue accessible au public;
b) cette autre personne avait, avant la délivrance du brevet, fait une demande pour obtenir au Canada un brevet qui aurait dû donner lieu à des procédures en cas de conflit;
c) cette autre personne avait à quelque époque fait au Canada une demande ayant, en vertu de l'article 28, la même force et le même effet que si elle avait été enregistrée au Canada avant la délivrance du brevet et pour laquelle des procédures en cas de conflit auraient dû être régulièrement prises si elle avait été ainsi enregistrée.

Patent Rules, SOR/96-423

175(1) An application shall contain an abstract that provides technical information and that cannot be taken into account for the purpose of interpreting the scope of protection sought or obtained.

(2) The abstract shall consist of a brief technical statement of the description indicative of the utility of the invention and the manner in which the invention is distinguishable from other inventions.

Règles sur les brevets, DORS/96-423

175(1) La demande contient un abrégé qui présente de l’information technique et qui ne peut être pris en considération dans l’évaluation de l’étendue de la protection demandée ou obtenue.

(2) L’abrégé est un bref exposé technique de la description et indique l’utilité de l’invention ainsi que la façon dont elle se distingue d’autres inventions.

Competition Act,
R.S.C. 1985, c. C-34

36(1) Any person who has suffered loss or damage as a result of

(a) conduct that is contrary to any provision of Part VI, or
[…]

(3) For the purposes of any action under subsection (1), the Federal Court is a court of competent jurisdiction.

(4) No action may be brought under subsection (1),
(a) in the case of an action based on conduct that is contrary to any provision of Part VI, after two years from
(i) a day on which the conduct was engaged in, or
(ii) the day on which any criminal proceedings relating thereto were finally disposed of, whichever is the later; and
(b) in the case of an action based on the failure of any person to comply with an order of the Tribunal or another court, after two years from

(i) a day on which the order of the Tribunal or court was contravened, or
(ii) the day on which any criminal proceedings relating thereto were finally disposed of, whichever is the later.

45(1) Every one who conspires, combines, agrees or arranges with another person

Loi sur la concurrence
(L.R., 1985, ch. C-34)

36(1) Toute personne qui a subi une perte ou des dommages par suite :

a) soit d'un comportement allant à l'encontre d'une disposition de la partie VI;
….

(3) La Cour fédérale a compétence sur les actions prévues au paragraphe (1).

(4) Les actions visées au paragraphe (1) se prescrivent :
a) dans le cas de celles qui sont fondées sur un comportement qui va à l'encontre d'une disposition de la partie VI, dans les deux ans qui suivent la dernière des dates suivantes
(i) soit la date du comportement en question,
(ii) soit la date où il est statué de façon définitive sur la poursuite;

b) dans le cas de celles qui sont fondées sur le défaut d'une personne d'obtempérer à une ordonnance du Tribunal ou d'un autre tribunal, dans les deux ans qui suivent la dernière des dates suivantes :
(i) soit la date où a eu lieu la contravention à l'ordonnance du Tribunal ou de l'autre tribunal,
(ii) soit la date où il est statué de façon définitive sur la poursuite.

45(1) Commet un acte criminel et encourt un emprisonnement maximal de cinq ans et une amende maximale de

(a) to limit unduly the facilities for transporting, producing, manufacturing, supplying, storing or dealing in any product,

(b) to prevent, limit or lessen, unduly, the manufacture or production of a product or to enhance unreasonably the price thereof,

(c) to prevent or lessen, unduly, competition in the production, manufacture, purchase, barter, sale, storage, rental, transportation or supply of a product, or in the price of insurance on persons or property, or

(d) to otherwise restrain or injure competition unduly,
is guilty of an indictable offence and liable to imprisonment for a term not exceeding five years or to a fine not exceeding ten million dollars or to both.

(2) For greater certainty, in establishing that a conspiracy, combination, agreement or arrangement is in contravention of subsection (1), it shall not be necessary to prove that the conspiracy, combination, agreement or arrangement, if carried into effect, would or would be likely to eliminate, completely or virtually, competition in the market to which it relates or that it was the object of any or all of the parties thereto to eliminate, completely or virtually, competition in that market.

dix millions de dollars, ou l'une de ces peines, quiconque complote, se coalise ou conclut un accord ou arrangement avec une autre personne :
a) soit pour limiter, indûment, les facilités de transport, de production, de fabrication, de fourniture, d'emmagasinage ou de négoce d'un produit quelconque;
b) soit pour empêcher, limiter ou réduire, indûment, la fabrication ou production d'un produit ou pour en élever déraisonnablement le prix;
c) soit pour empêcher ou réduire, indûment, la concurrence dans la production, la fabrication, l'achat, le troc, la vente, l'entreposage, la location, le transport ou la fourniture d'un produit, ou dans le prix d'assurances sur les personnes ou les biens;

d) soit, de toute autre façon, pour restreindre, indûment, la concurrence ou lui causer un préjudice indu.

(2) Il demeure entendu qu'il n'est pas nécessaire, pour établir qu'un complot, une association d'intérêts, un accord ou un arrangement constitue l'une des infractions visées au paragraphe (1), de prouver que le complot, l'association d'intérêts, l'accord ou l'arrangement, s'il était exécuté, éliminerait ou éliminerait vraisemblablement la concurrence, entièrement ou à toutes fins utiles, sur le marché auquel il se rapporte, ni que les participants, ou l'un ou plusieurs d'entre eux, visaient à éliminer la concurrence, entièrement ou à toutes fins utiles, sur ce marché.

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-393-08
(APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE SNIDER OF THE FEDERAL COURT, DATED JULY 2, 2008, DOCKET T-1548-06)	
STYLE OF CAUSE:	APOTEX INC. and APOTEX PHARMACHEM INC. v. ADIR and SERVIER CANADA INC**.**
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	June 1-2, 2009
REASONS FOR JUDGMENT BY:	LAYDEN-STEVENSON J.A.
CONCURRED IN BY:	LINDEN J.A., EVANS J.A
DATED:	June 30, 2009

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