Date: 20080702

Docket: T-1548-06

Citation: 2008 FC 825

Ottawa, Ontario, July 2, 2008

PRESENT: The Honourable Madam Justice Snider

BETWEEN:

LES LABORATOIRES SERVIER,
ADIR, ORIL INDUSTRIES,
SERVIER CANADA INC.,
SERVIER LABORATORIES
(AUSTRALIA) PTY LTD and
SERVIER LABORATORIES LIMITED

Plaintiffs
(Defendants by Counterclaim)

and

APOTEX INC.

and

APOTEX PHARMACHEM INC.

Defendants
(Plaintiffs by Counterclaim)

REASONS FOR JUDGMENT AND JUDGMENT

I. Introduction

A. Overview

[1] The Plaintiffs (described below and collectively referred to as Servier) manufacture, distribute and sell a drug with the trademark of COVERSYL, used primarily in the treatment of

hypertension and cardiac insufficiency. The active ingredient in COVERSYL is perindopril, a compound covered by Canadian Patent No. 1,341,196 (the '196 Patent), which patent is owned by one of the Plaintiffs, ADIR. The other Plaintiffs – all corporate affiliates of ADIR – are engaged in some aspect of the distribution, manufacture or sale of COVERSYL in a number of countries throughout the world, including Canada.

[2] Since at least 2006, one of the Defendants, Apotex Pharmachem Inc. (Pharmachem), has manufactured a generic version of perindopril erbumine tablets at its facility in Brantford, Ontario, in 2 mg, 4 mg and 8 mg strengths, and tablets containing a combination of perindopril erbumine and indapamide (a diuretic). The products are sold to the other Defendant, Apotex Inc., which company, in turn, sells the 8 mg tablets in Canada and exports all dosages and the combination product to affiliated companies and others abroad.

B. Basis of the Claim and Counterclaim

[3] Servier asserts, in this action, that Pharmachem and Apotex Inc. (jointly referred to as Apotex) infringe its '196 Patent by the manufacture of all perindopril products in Canada and by the sale of the 8 mg tablets in Canada. Further, Servier claims that Apotex Inc. has induced others to infringe the '196 Patent.

[4] In its defence and counterclaim, Apotex asserts that all of the Plaintiffs with the exception of Servier Canada Inc. (Servier Canada) and ADIR have no standing to bring this action.

[5] While Apotex does not explicitly deny that its perindopril products fall within the claims of the '196 Patent, it contends that the patent is invalid because:

- the invention disclosed by the '196 Patent is not inventive in light of prior disclosures and the common general knowledge;
- ADIR was not the first inventor of the subject matter of the patent;
- the promised utility of the invention fails; and
- most of the claimed compounds had not been made and tested as of the application date in Canada and there was no sound basis to predict that they could be made and would have the promised utility.

[6] Apotex further argues that the manner in which ADIR obtained the '196 Patent should disentitle it to enforce that monopoly, even if otherwise valid. The '196 Patent was ultimately obtained by ADIR only after conflict proceedings which were ultimately resolved by a court-endorsed agreement among ADIR and two other parties. As a result of the manner in which the patent was obtained, Apotex claims damages pursuant to s. 36 of the *Competition Act*, R.S.C. 1985, c. C-34 (the *Competition Act*), in respect of an alleged breach of s. 45 of the *Competition Act*.

[7] Finally, Apotex argues, even if claim 5 – as it stands today – of the '196 Patent is otherwise valid, the proper scope of the monopoly granted thereby is not that defined in the twice-corrected claim 5. Apotex argues that the twice-corrected claim 5 is invalid because it is the result of the two certificates of correction which were not obtained in accordance with s. 8 of the *Patent Act*, R.S.C. 1985, c. P-4.

C. *Overview of Conclusion*

[8] For the reasons expressed in these Reasons for Judgment, and in very general terms, my overall conclusions are that:

- only ADIR, as patentee, and Servier Canada, who claims under the patentee, have standing to bring this action;

- the '196 Patent is valid and infringed by Apotex through the manufacture, in Canada, of the 2 mg, 4 mg and 8 mg strengths and the combination tablets and through the manufacture and sale in Canada of the 8 mg tablets;

- Apotex has not induced others to breach the '196 Patent; and

- Apotex fails in its claim for damages under the *Competition Act*.

D. *Applicable Law*

[9] The application leading to the patent in this proceeding was filed in Canada on October 1, 1981. According to s. 78.1-78.2 of the present *Patent Act*, patent applications filed before October 1, 1989, are to be dealt with under the provisions of the *Patent Act* as they read immediately before that date. Accordingly, references in these reasons to the *Patent Act* (referred to as the *Patent Act* or the *Act*) will, unless specifically noted otherwise, be to the *Act* as it stood immediately prior to October 1, 1989.

E. *Table of Contents*

[10] For assistance to the reader, I have set out a table of contents of these reasons for judgment.

II. Witnesses

[11] During 30 days of testimony in this trial, a number of witnesses – both factual and expert – were heard by the Court. In the following paragraphs, I will provide a brief overview of the witnesses and the areas to which they testified. Further particulars of the evidence will be provided as necessary throughout these reasons.

A. *Factual Witnesses*

[12] Servier presented a number of employees of the Servier group of companies (referred to as Groupe Servier) as fact witnesses:

- Mr. Michael Sumpter is the chief executive officer of Servier Canada. He spoke to the operations of Servier Canada and its relationship with the Groupe Servier entities. Mr. Sumpter also appeared later in the proceedings to discuss marketing strategies of Servier Canada.

- Dr. Sylvie Jaguelin, who now holds the title of « directeur des brevets » in Les Laboratoires Servier (LLS), joined Groupe Servier in 1985. She spoke to her role during the conflict proceedings, the settlement discussions and the subsequent corrections to claim 5 of the '196 Patent.

- Dr. Yves Langourieux is currently the managing director of Servier International and is in charge of Groupe Servier's operations for a geographic sector covering North America, Northern Europe, Central Europe and Eastern Europe. He has been with Groupe Servier since 1977. In addition to being a trial witness, he was discovered by Apotex during the pre-trial process. He spoke to the corporate structure of Groupe Servier.

- Dr. Guillaume de Nanteuil is the director of the division of medicinal chemistry for Groupe Servier. He presented, as business records, and explained a number of the laboratory and working notes related to the development of perindopril. Dr. de Nanteuil was also a discovery witness.

[13] Servier also produced Dr. Michel Vincent, who is one of the named inventors of the '196 Patent. Dr. Vincent is now retired from Groupe Servier. He testified on his role in the invention, including the laboratory work leading to the application of the patent and his continuing laboratory work post-application.

[14] Apotex presented a number of witnesses who spoke to the development by Apotex of its perindopril generic compounds, the formulation steps in making perindopril and the experimental testing and use of perindopril. They were: Mr. Stephen Horne, vice-president of research and development at Pharmachem; Mr. Donald John Barber, formulation manager of Apotex Inc.; Mr. John Leslie Hems, director of regulatory affairs for Apotex Inc.; and, Mr. Lance Lovelock, vice-president of quality for Apotex Inc.

[15] A number of Apotex officers or employees testified on the subject of Apotex's corporate structure and operations:

- Dr. Bernard Sherman is the founder of Apotex. He spoke to a number of topics including: Apotex's product development process; the role of affiliated international

companies; Apotex's production facilities in India; and, markets for perindopril and ACE inhibitors.

- Mr. Colin Darroch is the managing director of Apotex U.K. Ltd. (Apotex UK). He described the contractual arrangements in place with Apotex Inc. for the selling of perindopril in the United Kingdom.

- Mr. Roger Millichamp is the managing director of Apotex Pty Ltd (previously GenRx Pty Ltd. and referred to as GenRx). He described the arrangements in place with Apotex Inc. for the selling of perindopril in Australia, the regulatory process in Australia (including the approvals necessary for the production of perindopril in Apotex's India facilities) and Australian litigation involving GenRx and Servier.

- Mr. Gordon Fahner is the vice-president finance for Apotex Inc. He was a very helpful and informative witness on the global operations of Apotex Inc. and its affiliates, from a financial perspective. He also provided evidence on the shipping transactions involved in international sales to affiliates.

[16] Under subpoena, Mr. J. Nelson Landry appeared as an Apotex fact witness. Mr. Landry, now of counsel to Ogilvy Renault, was the lawyer of record and patent agent for Servier during the conflict proceedings. He spoke to two related issues: (a) the translation of claim 5 from English to French for purposes of the '196 Patent; and (b) the two corrections made to claim 5 in the '196

Patent. The subpoena for Mr. Landry was the subject of a motion to this Court; that motion was dealt with in *Laboratoires Servier v. Apotex Inc.*, 2008 FC 321.

[17] Dr. Elizabeth Smith was a fact witness who appeared in Newark, New Jersey, under Commission of this Court, made upon application by Apotex. Dr. Smith, who was and is an employee of Schering Corporation (Schering), is one of the named inventors of Canadian Patent No. 1,341,206 (the '206 Patent). The '206 Patent was issued to Schering as a result of the conflict proceedings and a consent order of Justice Nadon (discussed later in these reasons). Her testimony dealt with her involvement with the development of the Schering claims that became part of the conflict proceedings and her role in those proceedings.

[18] Under subpoena, Mr. Joel Patrick Roche appeared as an Apotex fact witness. He was counsel to the plaintiff, Sheila Wilson, in a class action commenced before the Ontario Superior Court of Justice in Court File No. 98-CV-158832. The named defendants in that action included a number of entities who are part of Groupe Servier.

[19] For completeness, I refer to two Apotex fact witnesses whose testimony was not referred to during final argument. Dr. Edward Lee-Ruff, a professor at York University, and Dr. Gabriella Mladenova, a post-doctoral student at York University, conducted certain experiments, at the request of counsel for Apotex. The experiments were intended to recreate the results of the '196 Patent.

[20] Another Apotex witness whose testimony was not explicitly referenced in final argument was Ms. Nadia Corelli-Rennie, the supervisor of special projects at Pharmachem. She produced the samples of compounds that were sent to Dr. Gavras, an Apotex expert, for testing.

B. *Expert Witnesses*

[21] This being a patent infringement action with counterclaims of invalidity and *Competition Act* offences, experts produced by both Apotex and Servier were very helpful to the Court. For purposes of this introductory section of the reasons, I will provide a very brief description of the witnesses' education and experience and the areas for which this Court found them to be qualified.

(1) Servier Expert Witnesses

[22] Dr. Paul Bartlett is a professor emeritus of chemistry at the University of California, Berkeley. Dr. Bartlett was qualified by the Court as an expert in synthetic chemistry and as a medicinal chemist. Of particular relevance to the issues remaining at the end of the trial, he provided evidence on the issues of claims construction, infringement, utility, sound prediction, obviousness and inventorship.

[23] Dr. Barry Trost is a professor of chemistry at Stanford University. He was accepted by the Court as an expert in synthetic organic chemistry, including processes for making compounds having medicinal use. Of particular relevance, Dr. Trost provided evidence on the issues of obviousness and sound prediction.

[24] Dr. Christopher Cimarusti, retired from Bristol-Myers Squibb (Squibb) in 2006 after having worked 37 years in the pharmaceutical industry, has been a consultant to the pharmaceutical and biotech industry since 2006. He was accepted as an expert in synthetic organic chemistry with particular knowledge and experience in medicinal chemistry. Of note, Dr. Cimarusti worked with Drs. Ondetti and Cushman at Squibb at the time when the Squibb scientists invented captopril, the first ACE inhibitor. His opinions and testimony were particularly helpful on the issues of claims construction, utility, obviousness, sound prediction and inventorship.

[25] Dr. Morris Karmazyn was qualified as an expert in the area of cardiovascular pharmacology, including the role of the renin-angiotensin system in cardiac function and the *in vivo* and *in vitro* experimental techniques used to assess biological activity of compounds. The main thrust of his expert evidence was directed to the experiments performed by Dr. Gavras (see below). Thus, his testimony is most relevant to the question of utility.

[26] Dr. Zola Horovitz was qualified as an expert in pharmacology with particular experience in the areas of hypertension and ACE inhibition. Since 1994, when he retired after 35 years at Squibb, Dr. Horovitz has been consulting, mostly to the pharmaceutical industry. In 1967, he started up Squibb's research program that led to the development of captopril. He worked with Drs. Ondetti and Cushman. In addition to commenting on the experiments performed by Dr. Gavras, and thus the question of utility, Dr. Horovitz addressed the issues of obviousness and sound prediction.

[27] Dr. Aslam Anis is a professor of health and economics at the University of British Columbia, within the faculty of medicine. He was qualified as an expert in the field of health economics, with particular expertise in regard to pharmaceutical markets and competition in such markets. He assisted the Court on the issue of the alleged breach of the *Competition Act*.

[28] Dr. Iain Cockburn was a second economist retained by Servier to address the issue of the alleged breach of the *Competition Act*. He was qualified as an expert in the field of health economics, with particular expertise in regard to econometrics, pricing, and demand modeling in pharmaceutical markets.

(2) Apotex Expert Witnesses

[29] Dr. Garland Marshall is a professor of biochemistry and molecular biophysics at Washington University. He was accepted as qualified to give expert evidence as a medicinal chemist with expertise in the areas of renin-angiotensin systems, cardiovascular pharmacology and hypertension and, within those areas, particularly with respect to ACE, angiotensin I, angiotensin II, ACE inhibitors and molecular recognition. His main areas of testimony related to the issues in this trial of utility, sound prediction, obviousness and inventorship.

[30] Dr. Eugene Thorsett is an organic synthetic chemist. In 1975, he joined Merck & Co., Inc. (Merck) in their research laboratories in Rahway, New Jersey. Dr. Thorsett was at Merck in 1980 when Merck first disclosed enalapril. He was accepted by the Court as qualified to give expert testimony in respect of organic chemistry, especially organic chemical synthesis and physical

organic chemistry as it relates to drug discovery, enzyme inhibitor design, especially proteolytic enzymes of the zinc-metalloprotease class such as ACE. He was also accepted as an expert in pre-clinical drug development. His main areas of testimony were on the issues of utility, sound prediction and obviousness.

[31] Dr. Robert McClelland holds a Ph.D. in chemistry from the University of Toronto, where he was a tenured professor in the chemistry department from 1980 to 2005. He was found to be qualified to provide evidence as an expert in the area of physical organic chemistry, especially reactive intermediates generated in nucleophilic substitution and addition reactions, and in the area of biological and medicinal chemistry, especially the properties of heterocyclic drugs and the syntheses of new analogs. While I accept Dr. McClelland's qualifications, I note that he has far less experience working within the ACE inhibition field than the other chemistry experts. He spoke to the issues of obviousness, utility, sound prediction and inventorship.

[32] Dr. Haralambos Gavras, a practising physician, is a professor of medicine at the Boston University School of Medicine. He has been intimately involved in the treatment of cardiovascular disease since at least 1972. Dr. Gavras was accepted by the Court as an expert in the treatment of cardiovascular conditions including hypertension and chronic heart failure and the use in pharmacology of ACE inhibitors. He provided the Court with very useful background information on the development of ACE inhibitors and the various treatments of hypertension. However, the main purpose of his testimony was to address the question of utility and to report on his experiments with some of the compounds included in claim 3 of the '196 Patent.

[33] Dr. Hans Brunner, a medical doctor with extensive experience in cardiovascular conditions, was called by Apotex, in reply, to respond to the criticism of Dr. Gavras's testing methodology. He was accepted as an expert in the treatment of cardiovascular conditions, including hypertension and chronic heart failure, and the use and pharmacology of ACE inhibitors.

[34] Dr. Aidan Hollis is an associate professor of economics at the University of Calgary. Although his Ph.D. thesis work was unrelated to health economics, Dr. Hollis has consulted in and provided advice to the pharmaceutical industry. He was accepted as qualified as an expert in economics with particular expertise in industrial organization and regulatory economics, particularly with reference to pharmaceutical markets and competition therein. As did Drs. Anis and Cockburn, Dr. Hollis provided his expert opinions and testimony on the question of the alleged violation of the *Competition Act*. He returned after the appearances of Drs. Anis and Dr. Cockburn as part of the reply case of Apotex.

(3) General Comments on the Expert Witnesses

[35] During the course of the trial, comments were made by both sides about the strength of the qualifications or testimony of witnesses for the other side. On the topic of obviousness, for example, each of Apotex and Servier asserted that the other parties' experts were viewing the question from "hindsight". The neutrality of more than one witness was impugned. To the extent that I must deal with individual criticisms as I address specific areas of the testimony, I will do so. However, I wish to make a few overall comments.

[36] Expert witnesses are selected by the parties to litigation. It is obvious that a party will not put forward an expert who disagrees with that party's position in litigation. It frequently happens that an expert who has appeared for a generic company in a litigation matter will not appear as an expert for a pharmaceutical company in the next litigation. The reverse is also true. From this practice, however, it does not follow, in my view, that experts who appear before the Court do so with any inherent bias. The experts that I had the pleasure of seeing in this trial were all eminently qualified in their fields and presented their opinions in a professional manner. That did not prevent any of them from vigorously supporting their own opinions and providing direct criticisms of the experts who came to contrary views.

[37] I wish to comment directly on the general criticisms directed to Dr. Bartlett, Dr. Cimarusti and Dr. Trost. In final argument, counsel for Apotex asserted as follows:

> But I am going to submit to My Lady, that if [you] consider my friends' three principal experts, Cimarusti, Bartlett and Trost, you will find, in my submission, that they lacked objectiveness, that they were advocates and that they constantly, constantly volunteered information in defence of their advocated position.

Counsel then passed up a listing of transcript page references for each of these three witnesses that, in his view, showed "Volunteering advocacy, lack of objectiveness, as well as errors, as well as contradictions . . .".

[38] I disagree with counsel's characterization of the evidence of these three experts. I will acknowledge that Dr. Bartlett, in his written report, allowed himself to use unprofessional terms in describing the evidence of experts who disagreed with him. He did not need to do that. Further, Dr. Trost appeared, at times, to be evading certain questions during cross-examination; I eventually had

to step in to speak to him. For neither witness do I find the problems so significant that I should discount their opinions. I also suspect that, if counsel for Servier had conducted the same exercise of finding instances of advocacy, lack of objectiveness, errors and contradictions for the Apotex experts, their lists would have been just as long.

III. Background

A. *Background to ACE Inhibitors including Perindopril*

(1) ACE Inhibitors Generally

[39] The experts did not disagree on the organic chemistry and biochemistry applicable to these proceedings. What follows is a very brief outline of that evidence.

[40] Amino acids are the basic building blocks from which living matter is constructed. By combining various numbers and groups of these acids in various configurations, larger structures known as peptides are formed. The bonds between these acids are known as peptide bonds. Still larger groups known as proteins may be formed from such acids.

[41] Enzymes are organisms present in the body that facilitate the conversion of materials such as proteins and peptides into other material. The enzyme that is of interest in this case is the angiotensisn-converting enzyme (ACE). ACE can bind with a compound known as angiotensin I to produce angiotensin II. This conversion increases blood pressure by constricting blood vessels.

[42] The drugs discussed in this case, including perindopril, enalapril, captopril, lisinopril and quinapril are all "ACE inhibitors". ACE inhibitors, such as perindopril, bind with ACE to prevent the conversion of angiotensin I to angiotensin II; the result is lower blood pressure.

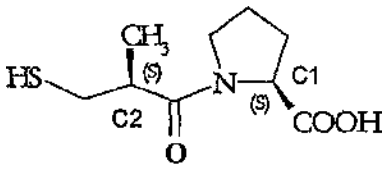
(2) History of ACE Inhibitors

[43] A number of the experts in this trial were present at various critical times during the history of ACE inhibitors and provided very useful evidence. A number of the articles produced in evidence were helpful. I summarize this evidence in the following paragraphs.

[44] Dr. Horovitz, who worked at Squibb from 1967, provided an excellent summary in his report of the early history of ACE inhibitors. The story begins in the late 1960s, when scientists began studying the venom of the *Bothrops jararaca*, an indigenous Brazilian snake, because it was known to reduce blood pressure. Scientists at Squibb isolated the active compound and synthesized a compound known as teprotide, a peptide. Teprotide was first tested on humans in 1973 and proved to be an effective anti-hypertensive agent in humans. However, teprotide was only effective through intravenous administration.

[45] The transformation of teprotide into an orally-effective ACE inhibitor occurred as a result of work done by a team of scientists working for Squibb, including Drs. Miguel Ondetti and David Cushman. Although the precise structure of ACE was not known at the time, the Squibb scientists were able to make some educated assumptions about a working model in the human body for ACE, relying upon what was known about another enzyme known as carboxypeptidase A. According to

Dr. Horovitz, one of the first steps taken by the Squibb scientists was to include a carboxyl group (HO_2C) at the terminal of the teprotide molecule based on prior art in relation to carboxypeptidase A. They then added a CH_2 to the backbone. Next, the scientists introduced a sulfhydryl (SH) group in the terminal position instead of the carboxyl group. This was captopril, the first small molecule, orally-effective, ACE inhibitor. As stated by Dr. Horovitz, "After almost ten years of work at Squibb, and the testing of thousands of compounds, Squibb finally had a drug that could be used for the treatment of hypertension and was orally active". The structure of captopril is set out below:

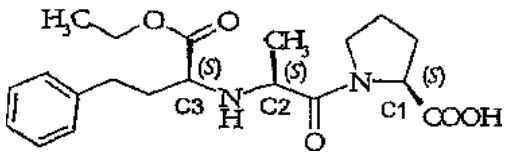


Captopril

[46] While captopril was a tremendous innovation, the presence of the sulphur atom was responsible for serious side effects in some people. One of the experts, Dr. Thorsett, was at Merck from 1975 through the next exciting years and provided his story of what happened next.

[47] In response to the problem of the side effects, Merck scientists (including Dr. Patchett) focussed on removing the sulfhydryl (SH) group (also referred to as a thiol group or thiol moiety). The result was enalapril. According to Dr. Marshall, who provided expert testimony on this point, enalapril "retained the Ala-Pro C-terminal unit while replacing the sufhydryl methylene group ($HSCH_2$-) in captopril with an N-carboxyalkyl moiety". While enalapril lacked the sulphur moiety present in captopril, what remained consistent from captopril to enalapril was the presence of the proline unit or five-membered ring structure on the right side of the compound. This new ACE

inhibitor had three stereocentres, all of which were in the (S) configuration. As of 1980, when the results of the scientists' work was confirmed, the mood at Merck was described by Dr. Thorsett as "electric". The structure of enalapril is set out below:



Enalapril

[48] On June 18, 1980, at a medicinal chemistry conference in Troy, New York (the Troy conference), Dr. Patchett presented Merck's new ACE inhibitor. The disclosure made by Merck at the Troy conference was widely anticipated by the ACE inhibitor community. Scientists at a number of pharmaceutical companies had been carrying out extensive research to develop new ACE inhibitor drugs. Dr. Vincent of Servier and Dr. Smith of Schering were two such scientists. Both of them had carried out some preliminary work that, they hoped, could build on or incorporate the Merck disclosure.

[49] As we will see in greater detail later in these reasons, both Dr. Vincent and Dr. Smith carried out work that led to the molecules that resulted in ramipril (Dr. Smith) and perindopril (Dr. Vincent).

(3) Schering's Work on ACE Inhibitors

[50] Although more will be said further on in this decision about the development work done by Schering during the late 1970s and early 1980s, it is helpful at this point to have an overview of the nature of the research work that was being done by Schering leading up to the application for what would become the '206 Patent and the compound ramipril. The evidence of Dr. Elizabeth Smith, both in oral testimony and an affidavit, was helpful.

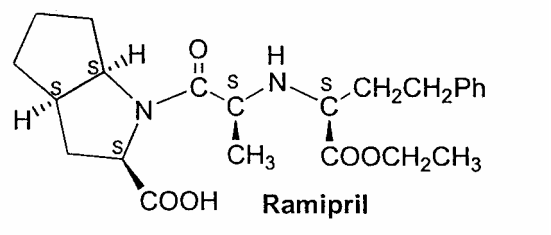
[51] Prior to the Merck announcement at the Troy conference in June of 1980, scientists at Schering, including Dr. Smith, were trying to develop an anti-hypertensive compound that would be more effective than captopril. While Merck's work involved the removal of the thiol group, Schering's work focussed on a different aspect of the captopril molecule - that is, the proline unit. By late 1979 or early 1980, Dr. Smith and her colleagues had found that the replacement of the proline in captopril with certain fused ring or spirocyclic moieties resulted in active compounds.

[52] As a result of the Merck disclosure at the Troy conference, the Schering scientists decided to try to create compounds based, in part, upon the Merck work on the thiol end of the molecule, but also using the fused ring moieties that Schering had already been working on in relation to the proline end of the molecule. That is, Schering's scientists decided to try using various bicyclic ring structures in place of the proline on an enalapril-type molecule. This proposed work was documented in an invention disclosure report dated June 20, 1980. According to Dr. Smith, this report shows the conception of the generalized structure of the compounds in what ultimately became the '206 Patent.

[53] Over the next few months, Dr. Smith and the other scientists at Schering made several of these compounds using different bicyclic ring structures. Initial testing of these compounds indicated that they demonstrated ACE inhibition activity.

[54] Throughout this time, Dr. Smith and her colleagues continued to create and test additional compounds using the bicyclic ring structure coupled with Merck's enalapril-type "backbone". One of the compounds created during this period, SCH 31335, contained molecules having a perhydroindole ring structure at the proline end. Preliminary pharmacological testing revealed that SCH 31335 was active *in vitro* and *in vivo*.

[55] On October 20, 1981, Schering applied for patent protection in Canada for its work in this area. The Canadian application ultimately resulted in the issuance of the '206 patent in March of 2001. The '206 Patent covers the molecule known as ramipril, a very successful commercialized compound. The structure of ramipril is set out below:



Ramipril

(4) ADIR's Development of Perindopril

[56] Dr. Vincent provided the Court with the history of how perindopril was developed within Groupe Servier. He described how Servier's work in ACE inhibitors began in 1977 after captopril

was invented. Dr. Vincent's work with ACE inhibitors began in 1978. He focused on the proline portion of captopril, hypothesizing that proline could be replaced by a larger substituent.

[57] Servier kept a record of the synthesis and analysis of compounds it created during this time in documents known as "S-sheets"; S-sheets are themselves classified by series. These were placed into evidence through another witness, Dr. de Nanteuil.

[58] Dr. Vincent's first attempt at a better captopril-like molecule began with the V-812 series. His work with the V-812 series continued through the winter of 1979/1980. By February 27, 1980, the scientists had synthesized S-8935, the first compound that contained the perhydroindole carboxylic acid in place of proline. The perhydroindole ring structure has, as its foundation, a 6,5 bicyclic ring with three chiral centres – two on the bridgehead (positions 3a and 7a) and one at the C2 position, where a carboxylic acid moiety is attached (-COOH). Testing results showed the compound to be very active. S-8935-1 was a turning point in Dr. Vincent's research. It drove home to Dr. Vincent the «grande importance» of chirality to the compound he was synthesizing and focused his future efforts on perhydroindole.

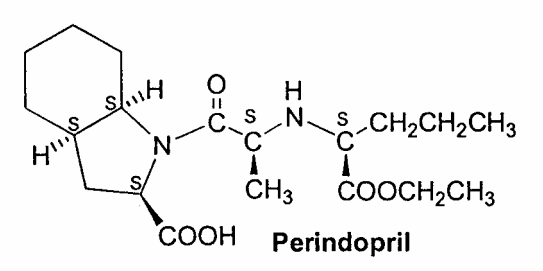
[59] Meanwhile, scientific progress outside of Servier marched steadily forward. Merck's disclosure of enalapril, at the Troy conference, had an immediate impact upon Dr. Vincent who returned to his laboratory and began a program to take into account the results disclosed at the conference; the V-827 series was born.

[60] Beginning in August 1980 Dr. Vincent synthesized and had tested a number of compounds as part of this series. Two of those compounds, S-9178-1 and S-9179-1, synthesized on August 26, 1980, combined a bicyclic proline substitution with the Merck backbone and a side chain ending with a methyl.

[61] After a number of other compounds were synthesized, with varying results, compound S-9332-1 was synthesized and sent for testing on December 4, 1980. Containing a variation of the Merck backbone with a « dicyclopropylméthyle » side chain, testing results of this compound were average. Shortly thereafter, S-9352-1 was synthesized and sent for testing on December 22, 1980. For Dr. Vincent, S-9352-1, « un Ether éthylique », opened the door for him to use a side chain between methyl and phenethyl.

[62] The first significant compound produced in 1981, S-9490-1, dated, April 6, 1981, combined perhydroindole with the Merck backbone but used a propyl on the side chain. When tested *in vivo* the results were excellent - better than captopril and enalapril. Reacting to this breakthrough, Dr. Vincent told Dr. Laubie, another of the named inventors of the '196 Patent, « Voilà un produit que ça vaudrait le coup de le commercialiser ». Work on the compound, which was not believed to be a pure stereoisomer, did not end there. In the weeks that followed S-9490-1 was sent for analysis to be studied more closely. On May 22, 1981, chromotogram analysis showed the compound was in fact an all-S isomer. On September 1, 1981, a maleate form of the compound (S-9490-2) was sent for testing, without great success; the compound was simply not stable enough to be

commercialisable. However, that same day S-9490-3, an all-S salt version, was tested. Perindopril had been successfully synthesized and tested.



(5) Conflict Proceedings

[63] The process to patent Servier's work began, in Canada, on October 1, 1981, when ADIR filed Application 387,093 (the '093 Application). In separate applications, other claimants also applied for the issuance of patents covering certain compounds. Of specific interest, Schering filed Patent Application 388,336 (the '336 Application) and Hoechst Aktiengesellschaft (predecessor to Sanofi-Aventis Deutschland GmbH and referred to as Hoechst) filed Patent Application 384,787 (the '787 Application). As provided for in the *Patent Act*, certain of the claims in the '093 Application were placed into conflict with claims in the other applications. In table form, the specifics of the applications and the claims in conflict are as follows:

Applicant	**Application No.**	**Date of Application**	**Claims in Conflict**
ADIR	the '093 Application	October 1, 1981	C19, C25 to C28, C33 and C34, C39 and C40
Schering	the '336 Application	October 20, 1981	C19, C39 and C40
Hoechst	the '787 Application	August 28, 1981	C19, C25 to C28
Hoechst	418,453 (the '453 Application)	December 23, 1982	C33 and C34

[64] In four decisions dated August 8, 1996, the Commissioner of Patents (the Commissioner) made determinations related to inventorship, pursuant to s. 43(7) of the *Patent Act*. In table form, the conclusions of the Commissioner were as follows:

Claim No.	First Invention Date	Claim Awarded To	Claims Refused To
C19	August 8, 1980	Schering ('336 App'n)	ADIR ('093 App'n), Hoechst ('787 App'n)
C25, C27	May 8, 1981	Hoechst ('787 App'n)	ADIR ('093 App'n)
C26, C28	October 2, 1980	ADIR ('093 App'n)	Hoechst ('787 App'n)
C33	October 8, 1981	Hoechst ('453 App'n)	ADIR ('093 App'n)
C34	December 29, 1981	Hoechst ('453 App'n)	ADIR ('093 App'n)
C39, C40	August 8, 1980	Schering ('336 App'n)	ADIR ('093 App'n)

[65] In accordance with s. 43(8) of the *Patent Act*, six proceedings were then commenced by way of actions in the Federal Court for the determination of the parties' respective rights in relation to the subject matter of the conflict claims. All of the proceedings were consolidated into Court File No. T-228-97 pursuant to the Order of Justice Joyal dated May 27, 1997 (the Joyal Order). This Order provided that each of the parties were entitled to contest any aspect of any decision of the Commissioner regarding the award of any claim declared to be in conflict between and amongst the parties irrespective of whether the party was directly involved in conflict proceedings in the Patent Office with respect to that particular claim.

[66] Subsequent to completion of discoveries, ADIR, Hoechst and Schering signed Minutes of Settlement wherein they agreed to settle the consolidated action. Shortly thereafter, on December 12, 2000, an Order on consent was issued by Justice Nadon (the Nadon Order) which provided for an allocation of the claims among the three parties. More specifically, it provided that, based on the '093 Application, ADIR was entitled to the issuance of a patent restricted to the claims

in Appendix A of the Minutes of Settlement. Ultimately, the result of the claims awarded to ADIR was the '196 Patent.

IV. Standing

A. *Overview*

[67] Apotex challenges the standing of all but two of the Plaintiffs, ADIR and Servier Canada, to bring this action. ADIR is the named owner of the '196 Patent and Servier Canada exploits the patent rights in Canada. All of the other Plaintiffs, namely LLS, Oril Industries (Oril), Servier Laboratories (Australia) Pty. Ltd. (Servier Australia) and Servier Laboratories Limited (Servier UK) (collectively, the non-ADIR Foreign Plaintiffs) do not, in Apotex's submission, "work" the '196 Patent in Canada. Apotex submits that the non-ADIR Foreign Plaintiffs have been joined in this action in an attempt to recover for marketing activities in foreign jurisdictions where corresponding patents to the '196 Patent have expired.

[68] In turn, Servier asserts that each of the non-ADIR Foreign Plaintiffs holds an implied licence permitting each of them to "work" the '196 Patent and, therefore, meets the requirements for standing to bring this action, as described in s. 55(1) of the *Patent Act*.

B. *Statutory Provision*

[69] The source of the ability of the non-ADIR Foreign Plaintiffs to claim damages is found in s. 55(1) of the *Patent Act*. That provision of the *Patent Act* provides as follows:

55.(1) Any person who infringes a patent is liable to the patentee and to all persons claiming under him for all damages sustained by the patentee or by any person, by reason of the infringement. [Emphasis added.]	55.(1) Quiconque viole un brevet responsable, envers le breveté et envers toute personne se réclamant du breveté, des tous dommages-intérêts que cette violation a fait subir au breveté ou à cette autre personne. [Non souligné dans l'original.]

C. *Jurisprudence and Principles*

[70] The test for who qualifies as a person claiming under a patentee is not simply whether the patentee has consented to the person being joined as a plaintiff in an action; nor is it enough to demonstrate that two parties are related. In each case, the facts must demonstrate a credible and legally sufficient basis for claiming under a patentee (*Jay-Lor International Inc. v. Penta Farm Systems Ltd.* (2007), 59 C.P.R. (4th) 228 at paras. 31, 36 (F.C.) [*Jay-Lor*]).

[71] In *Signalisation de Montréal Inc. v. Services de Béton Universels Ltée* (1992), 46 C.P.R. (3d) 199 at 210-211 (F.C.A.), the Federal Court of Appeal held that:

> … a person "claiming under" the patentee is a person who derives his rights to use the patented intention, at whatever degree, from the patentee. The right to use an invention is one the monopoly to which is conferred by a patent. When a breach of that right is asserted by a person who can trace his title in a direct line back to the patentee that person is "claiming under" the patentee. It matters not by what technical means the acquisition of the right to use may have taken

> place. It may be a straightforward assignment or a licence. It may, as I have indicated, be a sale of an article embodying the intention. It may also be a lease thereof. What matters is that the claimant asserts a right in the monopoly and that the source of that right may be traced back to the patentee.

[72] More recently, in *Apotex Inc. v. Wellcome Foundation Ltd*. (1998), 79 C.P.R. (3d) 193 (F.C.T.D.), rev'd on other grounds (2000), 10 C.P.R. (4th) 65 (F.C.A.), rev'd on other grounds, [2002] 4 S.C.R. 153 [*Wellcome (T.D.)*], the court considered the relationship between two related companies who alleged infringement of a patent and provided some helpful analysis on the issue of the right to assert rights under s. 55(1) of the *Patent Act*. In that case, the patentee was Wellcome Foundation Ltd. (Wellcome). Glaxo Wellcome Inc. (GWI) manufactured, distributed and sold the patented product in Canada and claimed that it was entitled to bring an action for infringement because it held an implied exclusive licence from Wellcome to import, manufacture, use and sell the invention described in the patent. Although no written licence was produced to establish GWI as a licensee, GWI maintained that the licence was implied.

[73] The plaintiffs in *Wellcome (T.D.)* asserted that GWI failed to meet its onus to establish that it had an entitlement to sue under s. 55(1) of the *Patent Act*. Justice Wetston examined the evidence on the operational practices of GWI and Wellcome, both of whom were under the ownership, common care and control of Glaxo Wellcome plc.:

> Mr. Jenkins testified that, as part of the general corporate policy regarding licensing, the AZT patent was licensed by the Wellcome Foundation Ltd. to what was then Burroughs Wellcome Inc. He stated that within the corporation licenses were rarely written and were generally implied, except where the subsidiary was not wholly owned. He stated that generally the policy was that a subsidiary was given an exclusive license by implication. He further testified that this is the situation as it remains today.

> Mr. Jenkins also testified that there are no corporate documents which confirm this corporate policy of granting licenses. Furthermore, he stated that no discussions preceeded the grant of an implied license nor were any steps taken before the license was to become effective. Indeed it was argued that before the merger, both corporate groups had the same practice with respect to using implied licenses, and if there had been any concerns about GWI not being a subsidiary, the license would have been reduced to writing (*Wellcome (T.D.)*, above at paras. 365-366).

[74] Based upon his review of the facts of the case, Justice Wetston concluded, at paragraph 367, that "GWI is indeed able to trace an interest under the patent to the patentee in virtue of the corporate practices with respect to implied licensing within the group of companies under the care and control of Glaxo Wellcome plc".

[75] On appeal, this particular conclusion of Justice Wetston was upheld. In his judgment, Justice Rothstein commented as follows:

> It is perhaps not uncalled for to observe that this is not a case in which the alleged licensee is alone in advancing its claim for patent infringement. Here, the patentee is also before the Court as a co-plaintiff supporting the claim of GWI. It is difficult to conceive of what more is necessary to prove the existence of a licence than to have the licensor and licensee both attesting to the validity of the licence. Where both the patentee and the person claiming under the patentee are before the Court, are affiliated as being owned by the same parent and have an identity of interest in the litigation -- with the patentee supporting the person claiming under the patentee -- it is, to say the least, surprising that technical questions of status to sue would be advanced as a defence to infringement (*Apotex Inc. v. Wellcome Foundation Ltd.* (2000), 10 C.P.R. (4th) 65 (F.C.A.) aff'd [2002] 4 S.C.R. 153 at para. 99 [*Wellcome (C.A.)*]).

[76] In *Jay-Lor*, above, this Court found that there was an implied licence between Jay-Lor International Inc., the owner of the patent in issue and Jay-Lor Fabricating Inc., the company who manufactured and sold the patented machinery in Canada and the United States. The key facts

supporting that conclusion were that: (a) both companies were under the same control of one individual; (b) no other licence had been granted either explicitly or by implication to any third party; and (c) the two companies had structured their affairs in a manner consistent with a licensee-licensor relationship (*Jay-Lor*, above at para. 37).

[77] In sum, the Canadian jurisprudence has provided a broad interpretation of "persons claiming under" the patentee. The ability of a party to claim under a patentee does not necessarily require the existence of an express licence. Where no express licence exists, each case will be determined on its facts to determine whether an implied licence or other right exists that gives rise to a claim "under the patentee".

D. *The Evidence before the Court*

[78] In light of these principles, I turn to the evidence before the Court.

[79] I begin by reviewing the evidence about the relationship between the patentee and each of the non-ADIR Foreign Plaintiffs. Mr. Yves Langourieux, who is the managing director of Servier International, testified on the relevant corporate relationships. Mr. Langourieux's various positions with the Servier group of companies are indicative of the close corporate relationships; in addition to being the managing director of Servier International, he is the president of Servier Canada, on the board of directors of Servier U.K. and Servier Australia. Servier International is owned 100% by LLS. Mr. Langourieux reports to Dr. John Phillip Seta, the vice-president of operations for the Servier group of companies. Dr. Seta reports directly to Dr. Jacques-Paul Servier, the founder,

president and sole owner of what is referred to as Groupe Servier. Mr. Langourieux produced into evidence an organizational chart of Groupe Servier. The chart supports Mr. Langourieux's oral testimony of the inter-corporate relationships and demonstrates that each of the Plaintiffs (including ADIR, Servier Canada and the non-ADIR Foreign Plaintiffs) can trace 100% of their ownership back to Dr. Servier himself. I am satisfied that each of the Plaintiffs – including the non-ADIR Foreign Plaintiffs – is part of a closely-held family-owned group of companies. Further, based on the testimony of Mr. Langourieux, I accept that the general policies and directions for the Groupe Servier are set by Dr. Servier.

[80] In spite of the closely-held structure, I would not go so far as to refer to Groupe Servier as a single entity, as it was described by Mr. Langourieux. The very existence of distinct corporations within the family is direct evidence of more than one entity. Dr. Servier has, for reasons of his own, decided that numerous separate corporations should be created that fulfil various separate functions. Servier Canada, for example, operates in Canada. In Mr. Langourieux's words:

> The role of Servier Canada is to market, to promote, market sales and distribute the Servier products on the Canadian market. . . . For Servier Canada only.

[81] Mr. Langourieux confirmed that none of the non-ADIR Foreign Plaintiffs manufacture, offer for sale or import any of the compounds claimed in the '196 Patent into Canada. He also agreed that each local affiliate in a particular country has the focus of promoting, marketing, and registering the product in its specific jurisdiction. For example, Servier UK promotes, markets, sells and distributes the medicines of Groupe Servier in the U.K. market only. I have seen no evidence that Servier Canada sells perindopril in the United Kingdom. For that purpose, Servier UK exists. Servier Australia promotes, markets, sells and distributes the Servier products in the Australian and

New Zealand markets. Manufacturing of the active ingredient (the API) in COVERSYL is done by Oril Industries in France. Thus the evidence shows that the affiliated companies within Groupe Servier do not operate as a single entity; each has its own sphere of operation and its own responsibilities within Groupe Servier. Nevertheless, the non-ADIR Foreign Plaintiffs may still be able to satisfy s. 55(1) of the *Patent Act*, through a licence or other such arrangement.

[82] As noted above, the mere existence of a corporate affiliation is not conclusive evidence of a right under s. 55(1) of the *Patent Act*. There must be something more. That something more has consistently been described in the jurisprudence as a "licence" or some other arrangement (for example, a lease, an assignment, or a sale) that would give the affiliate the right to use the patent.

[83] In this case, there is no express licence by which any one of Servier Canada or the non-ADIR Foreign Plaintiffs is given the explicit right to use the '196 Patent. Servier contends, however, that all Groupe Servier companies hold an implied licence to use the '196 Patent. On this basis, Servier argues that Servier Canada and the non-ADIR Foreign Plaintiffs fall within the types of relationships that have been held to satisfy s. 55(1) of the *Patent Act* (such as in *Wellcome (T.D.)* and *Jay-Lor*, above). I turn to an examination of the evidence to see if that assertion is supported by the evidence.

[84] In my view, the facts presented to me are persuasive evidence with respect to the existence of an implied licence to Servier Canada. As in *Jay-Lor*, both ADIR and Servier Canada are under the same control. The relationship is similar to that in *Wellcome (T.D.)* where the party claiming

under the patentee operates the patent in Canada. Apotex does not dispute the standing of Servier Canada in this action.

[85] The situation with the non-ADIR Foreign Plaintiffs is more difficult.

[86] In his testimony, Mr. Langourieux described a "group policy", whereby implicit, unwritten licences are given "to all our operations for the purpose of running their activities":

> Q. Okay. I would like to, for you to explain to the Court how it is that Servier Canada has the right to use the 196, to exploit the 196 patent.
>
> A. In fact it's linked to the general policy of the Servier Group, and that policy is dictated by Dr. Servier. Servier views itself as a single world-wide enterprise that -- in which each subsidiary, and again this is the will of Dr. Servier -- each subsidiary has the right to use any patent of the Servier Group for commercial purposes for its own use.
>
> Q. And so that, for lack of a better word, is we can call it a patent policy, if you want?
>
> A. It is the position of Dr. Servier regarding patent. It is a patent policy, yes.
>
> Q. Okay. And is this patent policy written down?
>
> A. No, this is not written down. Again, it's the concept of a one single group world-wide with subsidiaries having the rights to use, to benefit from the patent of the Servier companies world-wide. We are a private organization, a private group that belongs to one man, Dr. Servier. All decisions and policies come up to the top. He makes the decision and the policies, and the subsidiaries then implement these policies.
>
> Q. And so therefore, what this means is that Servier U.K. Servier U.K., for example, has access to the patents of all the other Servier entities. Would that be correct?
>
> A. It does. It is correct.

> Q. Same thing with Servier Australia?
>
> A. The same thing with Servier Australia.
>
> Q. LLS?
>
> A. LLS.
>
> Q. Oril Industrie?
>
> A. Oril Industrie, and all Servier companies.
>
> Q. This unwritten policy, as you have explained it or identified it, is it something that -- is it communicated to the heads of the local subsidiaries, like Servier Canada, Servier U.K., Servier Australia?
>
> A. Not necessarily. This policy is known by the senior management of the company, but in the running of their business the CEO's, the managing directors of the operations do not need to have the details of their policy. Their tasks, their responsibility is to grow the business of the operations, that is to say to ensure that our medicines are recognized and known for their benefits by the doctors, the doctors know how use them, how to prescribe them, and the patients, the local patients in Canada and in Australia benefit from the benefits of our drugs.

[87] Notwithstanding the description of the group policy by Mr. Langourieux, I do not accept that the facts establish the existence of an implied licence that extends to the breadth asserted by Servier.

[88] As shown by the evidence, none of the non-ADIR Foreign Plaintiffs operates in Canada. In final argument, counsel for Servier tried to counter Apotex's arguments on the use of the patent by the non-ADIR Foreign Plaintiffs through the following hypothetical:

> It is wholly conceivable that if Servier Australia ran out of perindopril and Servier Canada had too much of it, that Servier Australia would purchase perindopril from Canada, or even in Canada.

> My friends' position would either prevent that situation from happening, because Servier Australia would not have a licence in Canada, or would make everybody stop, negotiate a sublicence under the '196 Patent, or bring in Adir to award Servier Australia a licence under the Canadian patent.
>
> That is nonsensical . . . when we view the manner in which the Servier group of companies views itself and operates.

[89] There are two problems with this line of reasoning. First, this argument is not based on any evidence that this has ever happened in the history of Groupe Servier; it is totally speculative. Secondly, it is not at all "nonsensical" to require affiliates to enter into some type of document to reflect legal rights.

[90] Further, none of these Plaintiffs has ever needed a licence in respect of the '196 Patent because none of their foreign activities relating to the manufacture, use or sale of perindopril can constitute an infringement of the '196 Patent.

[91] Quite clearly, the non-ADIR Foreign Plaintiffs do not use the '196 Patent in Canada or elsewhere. They do not need a licence from ADIR in respect of that patent. It is a stretch to say that the non-ADIR Foreign Plaintiffs are parties to an implied licence for the '196 Patent when no such licence is required.

[92] Additional support for a conclusion that no implied licence exists comes from an earlier Ontario Superior Court action to which some of the Groupe Servier companies were named. Specifically, in the 1970s and 1980s, Servier, as it had done worldwide, marketed in Canada diet drugs known as Ponderal (Fenfluramine) and Redux (Dexfenfluramine). On the basis of alleged

serious side effects, Servier was exposed to product liability claims abroad and in Canada. Class action proceedings were commenced in the Ontario Superior Court of Justice in the name of Sheila Wilson (Court File No. 98-CV-158832; referred to as the Wilson action). The defendants to the action were named as Servier Canada, LLS, Servier Amerique, Institut de recherches internationals Servier, Science Union et cie, Oril S.A. and Biofarma S.A. When asked, during discovery, to "Produce all of the licensing agreements governing relationships between Servier Canada, and any one or all of LLS, Science Union et Cie, Oril or Biofarma from 1978 to September 1997 relating to Ponderal or Redux", the response was "No such agreements exist".

[93] In a subsequently filed motion, the plaintiff sought to add other related companies (for example, Servier Monde). Various foreign Servier entities, including LLS, Oril and ADIR, resisted jurisdiction being taken over them by a Canadian court, on the basis, among others, that they "do not carry on business in Canada, and as such are not subject to the jurisdiction of this Court."

[94] These responses are in direct conflict with the evidence before me in this action as provided by Mr. Langourieux. I first note that most if not all of the named defendents in the Wilson action have been included in the organizational chart for the Servier Groupe. According to the evidence of Mr. Langourieux all of these companies would have "the rights to use, to benefit from the patent" at issue in the Wilson action; they would have an implied licence. Yet, when sued, those foreign affiliates made clear and unequivocal representations to the Court that they were not licensees. It seems to me that, if the licence exists and applies to all patents of the Groupe Servier, it would apply to the patents for Ponderal or Redux. Additionally, the denial by certain affiliates of Servier that

they carry on business in Canada is at odds with the view of Mr. Langourieux that all of the affiliates operate as a single entity.

E. *Conclusion*

[95] In sum, the Plaintiffs' assertion of what is, in essence, an inter-corporate world-wide open licence is not supported by the evidence before me. I am not persuaded, on a balance of probabilities, that the non-ADIR Foreign Plaintiffs hold a licence to use the '196 Patent or can otherwise claim under the patentee, ADIR. I conclude that these companies have no standing to bring this action.

V. Claims Construction

A. *The Law of Claims Construction*

[96] The first step in a patent suit is to construe the claims. The principles to be applied when construing the claims were stated by the Supreme Court in *Whirlpool Corp. v. Camco Inc*., [2000] 2 S.C.R. 1067 [*Whirlpool*], and require the Court to interpret the claims in dispute in a purposive way in order "to achieve fairness and predictability and to define the limits of the monopoly" (*Dimplex North America Ltd. v. CFM Corp.*, 2006 FC 586 at para. 49, aff'd 2007 FCA 278 [*Dimplex*]). Furthermore, where necessary, the whole of the patent, and not only the claims, should be interpreted (*Eli Lilly Canada Inc. v. Apotex Inc*, 2008 FC 142 at para. 25; *Eli Lilly Canada Inc. v. Novopharm Ltd*., 2007 FC 596 at para. 103).

[97] Construction of the claims is a matter for the Court to determine. The Court should construe the claims in light of the description in the specification, assisted, where necessary, by experts as to the meaning of technical terms if they cannot be understood by the Court from reading the specification (*Shire Biochem Inc. v. Canada (Minister of Health)*, 2008 FC 538 at para. 23 [*Shire*]; *Whirlpool,* above at para. 45).

[98] It is also important to recognize that purposive construction should be directed at the points at issue between the parties. To quote Justice Hughes in *Shire,* above at para. 22:

> The Court, however is not to construe a claim without knowing where the disputes between the parties lie. To quote Justice Floyd of the England and Wales High Court (Patent Court) in *Qualcomm Incorporated v Nokia Corporation* [2008] EWHC 329 (Pat) at paragraphs 7 to 11, who in turn quoted the late Justice Pumfrey (as he then was) in *Nokia v Interdigital Technology Corporation* [2007] EWHC 3077 (Pat), "it is essential to see where the shoe pinches so that one can concentrate on the important points."

[99] At all times, purposive construction requires the Court to construe the claims through the eyes of an ordinary person skilled in the art (*Whirlpool,* above at paras. 45, 53). Moreover, where a patent is of a highly technical nature, the person skilled in the art will be someone possessing a high degree of expert scientific knowledge and skill in the particular branch of the science to which the patent relates (*Aventis Pharma Inc. v. Apotex Inc*., 2005 FC 1283 at para. 64, aff'd 2006 FCA 64, leave to appeal to S.C.C. refused, [2006] S.C.C.A. No. 136 [*Aventis Pharma*]; *Apotex Inc. v. Syntex Pharmaceuticals International Ltd*., [1999] F.C.J. No. 548 at para. 38 (C.A.) (QL)).

[100] Lastly, as the '196 Patent was issued under the old *Patent Act*, all claims at issue are to be construed as of the date of issue and grant of the patent (*Pfizer Canada Inc. v. Canada (Minister of Health)*, 2005 FC 1725 at para. 36).

B. *Application of Principles to the Case at Bar*

(1) Person Skilled in the Art

[101] Apotex submits that the person skilled in the art of the '196 Patent is a medicinal chemist, a pharmaceutical formulator, a biochemist, a pharmacologist or a medical doctor with experience treating hypertension and/or cardiac insufficiency in humans. Further, the person skilled in the art has at least a Masters Degree with several years of experience.

[102] For its part, Servier submits that there is no real dispute as to the person skilled in the art, which it defines as a person having a Ph.D. in chemistry (synthetic organic chemistry or medicinal chemistry) or pharmacology or a person holding a medical degree. As with Apotex, Servier qualifies this definition by saying the person has “some relevant experience”.

[103] Having reviewed the parties’ submissions and the language of the specification of the '196 Patent, I am satisfied that the person skilled in the art includes individuals fitting both of these definitions. I would therefore characterize the person to whom the '196 Patent is addressed as being an individual having at least a few years experience in academia or industry in their respective field and holding a Masters or Ph.D. in synthetic organic chemistry; medicinal chemistry; pharmacology;

or biochemistry; or, a medical doctor having several years experience treating hypertension or cardiac insufficiency in humans.

[104] Although some of the expert witnesses testified that more specific experience is required in order to understand the '196 Patent I am satisfied the definition provided above corresponds with a "fair and generous view as to what sort of person comprises a person skilled in the art" (*Janssen-Ortho Inc. v. Novopharm Ltd.*, 2006 FC 1234 at para. 90, aff'd 2007 FCA 217, leave to appeal to S.C.C. refused, [2007] S.C.C.A. No. 442 [*Janssen-Ortho*]).

(2) Construction of the Claims at Issue

[105] I begin by making some brief preliminary observations.

[106] First, at issue in the present suit are claims 1, 2, 3 and 5 of the '196 Patent. The date of issuance, and therefore construction, for these claims is March 6, 2001, for claims 1-3, and May 14, 2001, for claim 5. This later date for claim 5 is due to the two corrections that occurred after the initial grant.

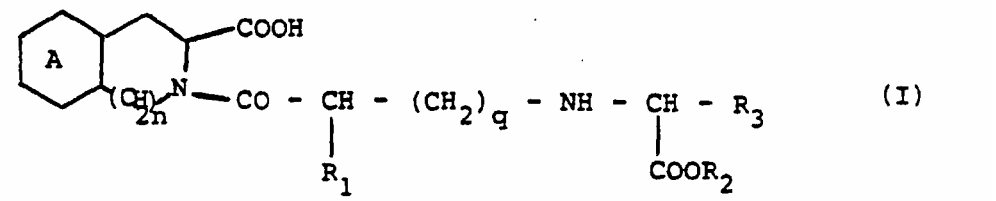
[107] Second, the '196 Patent is written in French. The significance of this point will become apparent later in these reasons.

(a) *Description*

[108] I now turn to the description of the '196 Patent.

[109] The description of the patent begins at page 1 which states:

> *La présente invention a pour objet de nouveaux imino diacides substitués, plus précisément des acides azabicycloalcane dicarboxyliques substitués et leur procédé de préparation.*
>
> *Spécifiquement l'invention concerne les composés répondant à la formule générale:*



(I)

> *dans laquelle :*
> *le cycle A est saturé et n = 0 ou 1, ou bien le cycle A est benzénique et n = 1,*
> *R_1 représente un groupe alkyle inférieur de 1 à 4 atomes de carbone pouvant porter un groupe amino,*
> *R_2 représente un atome d'hydrogène ou un groupe alkyle de 1 à 4 atomes de carbone,*
> *R_3 représente un groupe alkyle linéaire ou ramifié, mono-ou di-cycloalkyl-alkyle ou phényl-alkyle ayant au plus au total 9 atomes de carbone, ou bien un groupe alkyle sustitué de formule :*
>
> $$- (CH_2)_p - Y - \underset{\displaystyle R_4}{\overset{\displaystyle |}{CH - R_5}}$$
>
> *avec R_4 = H, alkyle inférieur (C_1 à C_4) ou cycloalkyle (de C_3 à C_6)*
> *R_5 = H, alkyle inférieur (C_1 à C_4), cycloalkyle (C_3 à C_6) ou alcoxycarbonyle,*
> *Y = S ou = N – Q où = H, acétyle ou benzyloxycarbonyle, et*
> *p = 1 ou 2, et*
> *q = 0 ou 1.*

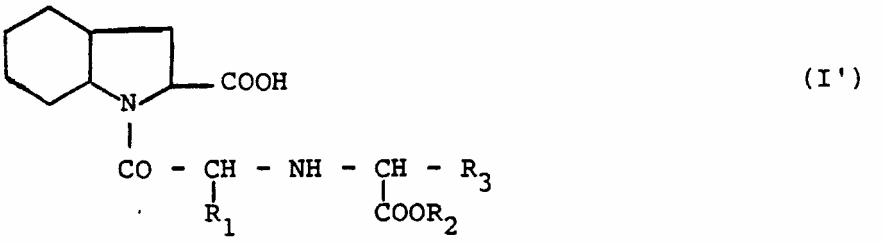
[110] In other words, page 1 of the '196 Patent alerts the skilled reader to the fact that the « objet » of the '196 Patent is substituted imino diacids, more precisely substituted azabicycloalcane dicarboxylic acids. Even more precisely, the « concerne » of the '196 Patent is compounds with structures falling into General Formula I. The included compounds vary depending on: the A-ring (which can be saturated or unsaturated); the size of the other ring (which depends on whether n = 0 or 1); the nature of the R_1, R_2, and R_3 groups; and the length of the side chain (which depends on whether q = 0 or 1).

[111] The number of compounds falling into General Formula I is further increased by the statement, on page 2 of the '196 Patent, that therapeutically compatible salts are also included. More importantly, the description states that the relevant compounds will have a varying number of chiral centres and that the alleged invention also includes racemic compounds as well as diastereomeric and enantiomeric isomers:

> *Les composés de formule (I) comportent au moins 3 atomes de carbone asymétrique. Selon la position des substituants et le degré d'hydrogénation, il existe 3 à 6 centres d'asymétrie. Les composés racémiques peuvent être dédoublés en leurs mélanges diastéréoisomères ou d'épimères, ou dédoublés en leurs énantiomères de manière connue. Ces divers isomères font partie de 1'invention de même que les composés racémiques.*

[112] Page 2 of the '196 Patent continues by directing the skilled reader to perhydroindole derivatives corresponding to compounds falling into a different formula:

> *L'invention comprend plus particulièrement les dérivés du perhydroindole (formule I ; A est saturé et n = 0) répondant a la formule générale :*



> *dans laquelle les symboles R_1, R_2 et R_3 ont la même signification que dans la formule (I), sous leur forme racémique ou d'isomères optiques, ainsi que leurs sels obtenus avec des acides ou des bases thérapeutiquement compatibles*

[113] This formula (General Formula I') is in fact a subset of General Formula I where the ring system on the C-terminus of General Formula I is specifically limited to a perhydroindole.

[114] A set of preferred compounds is then provided where R_1 in General Formula I' is defined to be « peut être utilement » as a methyl and R_3 in General Formula I' includes linear alkyls as previously defined in General Formula I but which does not include phenethyl. However, as acknowledged by both Apotex's and Servier's experts, this set of preferred compounds does not correspond to any of the claims in the '196 Patent.

[115] The next significant portion of the description begins on page 3 which sets out the utility of the alleged invention. The paragraphs contained therein describe some of the interesting pharmacological properties of compounds falling into the alleged invention, in particular the

inhibition of certain enzymes such as « *les carboxypolypeptidases, les enkephalinases ou la kininase II* » which in turn inhibits the transformation of angiotensin I into angiotensin II. The section continues by noting that the therapeutic use of these compounds:

> *L'emploi en thérapeutique de ces composés permet donc de réduire ou même supprimer 1'activité de ces enzymes responsables de la maladie hypertensive ou de 1'insuffisance cardiaque. L'action sur la kininase II a pour résultat 1'augmentation de la bradykinine circulante et également la baisse de la tension artérielle par cette voie.*
>
> *L'invention s'étend aussi aux compositions pharmaceuti-ques renfermant comme principe actif au moins un composé de formule générale I ou un de ses sels d'addi-tion, avec une base ou un acide minéral ou organique, en association avec un excipient inerte, non toxique, pharmaceutiquement acceptable*. [Emphasis added.]

[116] In short, a plain reading of the '196 Patent indicates that, through use of the compounds, it is possible to reduce the activity of enzymes responsible for hypertension or cardiac insufficiency. I will return to this point later in these reasons.

[117] The remainder of page 3 and the majority of page 4 describe how the patent includes compounds useful for pharmaceutical use and provides general guidance as to dosage forms and strength. Next, starting with the last paragraph on page 4, the patent sets out the process for preparing compounds falling into General Formula I. Six examples are then given, starting on page 6, to illustrate the preparation of compounds falling within the alleged invention. Analytical results on 28 compounds prepared in the examples, or through the use of similar techniques, are presented in two tables at pages 24-27. The compounds included in the tables are primarily, but not limited to, perhydroindole and include one compound (compound 4) with a phenyl ring.

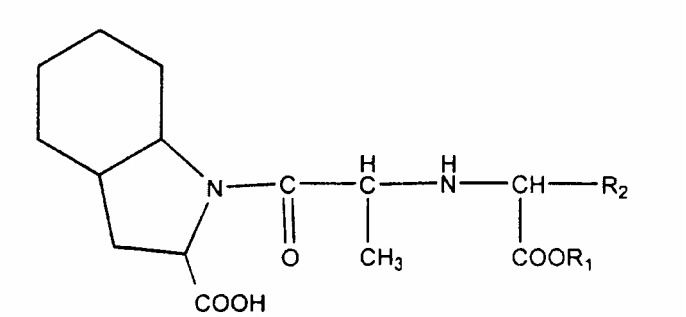
[118] Finally, on pages 28-29 of the '196 Patent, we come to a section entitled « *Etude pharmacologique des composés de l'invention* » wherein the '196 Patent provides a description of the pharmacological studies to which the compounds which were made were subjected.

[119] With this background in mind I turn to the claims at issue.

(b) *The Claims at Issue*

[120] Claim 1 reads:

1. Composés répondant à la formule générale



dans laquelle :

R_1 représente un atome d'hydrogène ou un groupe alkyle de 1à 4 atomes de carbone

R_2 représente un groupe alkyle linéaire de 1 à 6 atomes de carbone

et leurs sels d'addition pharmaceutiquement acceptables.

[121] Claim 2 reads:

Un composé selon la revendication 1 où R_2 est un alkyle de 3 ou 4 atomes de carbone

et leurs sels pharmaceutiquement acceptables.

[122] Claim 3 reads:

> *Un composé selon la revendication 1 où R_2 est un n-propyle*
>
> *et ses sels pharmaceutiquement acceptables.*

[123] Finally, claim 5 (as twice corrected) reads:

> *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.*

[124] With the description in mind, I find a person skilled in the art would have no trouble in construing the claims as follows:

- Claim 1 corresponds to a subset of compounds falling under General Formula I where R_1 is defined as a hydrogen atom or an alkyl group with one to four atoms, and R_2 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 contain 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 (*Dimplex*, above at para. 65).

- Claim 2 corresponds to a subset of compounds falling under claim 1 wherein R_2 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 R_2 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.

(3) Apotex's Argument that there is but one "Invention"

[125] Interpretation of the '196 Patent claims does not appear to be seriously in dispute. Rather, the point "where the shoe pinches" between the parties is 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 (as Apotex submits), or whether the claims should stand on their own (as Servier contends). To put it more generally, the question to be asked is: how should the claims be construed when a patentee claims only a portion of the compounds identified in the description?

[126] In my opinion, the answer to this question can be found in the cases of *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*].

[127] In *Boehringer,* above, the patent at issue described in general terms the process for the production of a large class of compounds. The patentee sued for alleged infringement of one of the patent claims (claim 8) which was limited to a single compound in the general class. Nowhere in the description was the single compound mentioned except "as an example cited to describe advantages which all members of this very large class of substances or possible substances are claimed to have and except in two of the examples of how the processes for making the class of substances may be carried out" (*Boehringer,* above at 210). In construing the patent in light of this apparent inconsistency, Justice Thurlow made the following useful remarks:

> In my opinion, the passages I have quoted support the view that a claim for a single substance appended to a disclosure purporting to relate only to the invention of a genus or class of substances should not have been allowed in view of s. 38(1) of the Patent Act because two different inventions or alleged inventions would be involved. But whether or not claim 8 should have been allowed in the patent here in question, as issued, the same subsection provides that no objection merely on the ground that the patent has been granted for more than one invention can succeed. Accordingly, as I view the matter, it becomes necessary because of the presence of claim 8 to

> read the specification not only to see what it says that refers to and describes an alleged invention of processes for the preparation of the class of substances but also to see what, if anything, it says that refers to and describes an invention of 2-phenyl-3-methyl morpholine and processes for its production. For, if the requirements of s. 36 of the Patent Act in respect of the description, etc., of the invention of 2-phenyl-3-methylmorpholine are complied with, the mere fact that the required information is mixed with and included as part of the description of another alleged invention will not by itself render claim 8 invalid. The problem of so reading the specification is embarrassing for by its context the disclosure throughout suggests one and only one invention. But, as a matter of construction of the specification, this suggestion of the specification must, I think, give way in order to give meaning to the specification as a whole which includes claim 8 and thus indicates that besides the invention of the class an invention of the single substance, 2-phenyl-3-methylmorpholine is involved in the disclosure (*Boehringer,* above at 209-210). [Emphasis added.]

[128] Justice Thurlow came to a similar conclusion in *Hoechst,* above at 718-719:

> I turn now to the specifications. The disclosure portion of these is the same in the case of all ten patents the only differences between them being in the claims and in certain supplementary examples which are admittedly not relevant to the present case. The disclosure does not purport to be one of an invention of tolbutamide alone or of it and a process or processes for its preparation but on the contrary purports to relate to a class of sulphonyl ureas of which tolbutamide is one member, and it proceeds to outline in general terms methods by which ureas of the class may be produced and to assert utility for the substances of the class. Tolbutamide is mentioned from time to time as an example of the class but not until one reaches claim 10 (13 in the case of the last patent) is there any indication that the invention is concerned with anything but a whole class of substances and general methods of producing them. In this respect the specifications resemble that considered in C.H. Boehringer Sohn v. Bell Craig Ltd. ([1962] Ex. C.R. 201.) and for the reasons there given at pages 209 to 215 I am of the opinion that these specifications should be regarded as purporting to disclose several different inventions, one or more pertaining to a class or classes of substances, another to the single substance known as tolbutamide and several others to the particular substances claimed in claims 11 to 19 inclusive (14 to 21 in the last). [Emphasis added.]

[129] *Hoechst* and *Boehringer* were both recently referred to by the Federal Court of Appeal in *Merck & Co. v. Apotex Inc*., 2006 FCA 323, leave to appeal to S.C.C. refused, [2006] S.C.C.A. No. 507 [*Merck (C.A.)*]. In *Merck (C.A.)*, Apotex argued that the trial judge had wrongly interpreted *Hoechst* and *Boehringer* as standing for "the broad proposition that each claim in a patent represents a separate invention". The Court of Appeal dismissed the argument after concluding that the trial judge had relied on the earlier decisions only for the narrow principle that where a patent application separately claims a class of chemical compounds and a single compound within that class, each separate claim discloses a separate invention (*Merck (C.A.),* above at para. 31). Thus, *Hoechst* and *Boehringer* remain authoritative on the question of defining the "invention".

[130] With this jurisprudence in mind I turn to the case before me.

[131] As previously noted, the description of the '196 Patent outlines the general chemical structure of a class of compounds (General Formula I) and the properties, preparation, and utility of compounds falling into the general class. Nowhere are claims 1, 2, 3 or 5 mentioned until one comes to the claims of the '196 Patent. Reading the patent as a whole, I conclude 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. As described in claim 1, the claimed class of compounds must have a bicyclic 6,5 perhydroindole moiety on the C-terminus and a linear alkyl group with 1 to 6 carbon atoms on the N-terminus. Both of these limitations are therefore essential elements of the '196 Patent. While the class of compounds of General Formula I may disclose an "invention", it is not the invention claimed. For that, we must turn to the claims of the '196 Patent.

[132] In oral argument before me, Apotex cited the case of *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd*., [1981] 1 S.C.R. 504 [*Consolboard*] in support of its argument that to determine "the" invention of the '196 Patent one has to look at the entire specification to ascertain the nature of the invention, the disclosure and the claims. In my opinion there is nothing inconsistent with this proposition and my conclusion that, in certain circumstance, reading the claims in light of the specification will reveal that there is more than one invention.

[133] In conclusion, the specifications, when read as a whole, assist the person skilled in the art in understanding the background to and substance of the claims. The description does not define an invention; rather, the claims read in the context of the description define the invention (or inventions) of the patent. In the case of the '196 Patent, I find that 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 and nothing more.

VI. Infringement

A. *Overview*

[134] Section 44 of the *Patent Act* confers on a patentee and his legal representatives "the exclusive right, privilege and liberty of making, constructing, using and vending to others to be used the invention" of a patent. Servier claims that Apotex infringes its rights under the '196 Patent, both directly and through inducement of others to infringe. Apotex concedes, to some extent, the direct infringement, subject to its counterclaims of invalidity (all of which are considered later in these

reasons). However, Apotex disputes the allegation of inducement and claims that certain of its perindopril-containing products are subject to exemption. In this section of the reasons, I examine these issues.

B. *Direct Infringement*

[135] The record of this trial contains ample evidence of direct infringement by Apotex. Briefly, the following facts related to Apotex's manufacture and sale of perindopril products, under the trade name Apo-Perindopril, are established:

- Apotex Inc. has purchased perindopril erbumine raw material since at least as early as April 30, 2004. From this material, Apotex used, manufactured (in Canada), sold, and continues to use, manufacture and sell, perindopril erbumine tablets in 2, 4 and 8 mg strengths, as well as tablets containing a combination of perindopril erbumine and indapamide.

- On February 1, 2007, Apotex Inc. obtained a Notice of Compliance (NOC) in Canada for Apo-Perindopril 8 mg tablets, which it has offered for sale and sold since at least as early as March 6, 2007, for consumption in Canada.

- Pharmachem, located in Canada, previously known as Brantford Chemicals Inc., has been, to date, the sole manufacturer and supplier of the perindopril raw material

acquired by Apotex Inc. and subsequently sold in Canada (8 mg tablet) and exported for sale elsewhere.

[136] By way of stipulation, Apotex has admitted that, subject to the validity of claims 3 and 5, and subject to the Court's construction of claim 5, the perindopril erbumine in Apo-Perindopril tablets falls within claims 3 and 5 of the '196 Patent.

[137] Dr. Bartlett testified that the drug substance contained in Apotex's perindopril products is included in each of claims 1, 2, 3 and 5 of the '196 Patent. This evidence was unchallenged.

[138] Thus, I find that Apotex makes, constructs, uses, offers for sale and sells perindopril products that are included in claims 1, 2, 3 and 5 of the '196 Patent. Subject to the discussions that follow in these reasons, Apotex directly infringes the '196 Patent.

C. *Inducement*

[139] Having concluded that Apotex has infringed the '196 Patent, the next question is whether any of Apotex's sales are acts of inducement. As stated in its Statement of Claim, Servier seeks a declaration that Apotex has induced a number of affiliated companies to infringe claims 1, 2, 3, and 5 of the '196 Patent. In particular, Servier alleges that Apotex has induced Apotex UK, GenRx, Katwijk Farma B.V. (Katwijk), Orifarm Supply A/S (Orifarm) (collectively referred to as the Foreign Purchasers) to infringe the '196 Patent.

[140] The evidence establishes that Apotex has sold its 2, 4 and 8 mg perindopril erbumine tablets for consumption outside of Canada to Apotex UK since July 24, 2006, to GenRx since October 20, 2006, to Katwijk since July 27, 2006, and to Orifarm since December 7, 2007. Apotex has sold its combination product to GenRx since at least as early as July 20, 2007. However, mere sale of an infringing product to the Foreign Purchasers is not sufficient to establish inducement.

(1) The Test for Inducement

[141] As stated by Chief Justice Jerome, as he then was, in *Warner Lambert v. Wilkinson Sword Canada Inc.* (1988), 19 C.P.R. (3d) 402 at 407 (F.C.T.D.) [*Warner Lambert*], "a defendant infringes the statutory rights of the plaintiff patentee where it knowingly induces or procures another to infringe the plaintiff's patent". To succeed in such a claim, a patentee wishing to rely on the doctrine of induced infringement must prove each of the following elements (*Warner Lambert* at 407; *AB Hassle v. Canada (Minister of National Health and Welfare)*, [2002] 3 F.C. 221 at para. 68 (T.D.), aff'd 2002 FCA 421, leave to appeal to S.C.C. refused, [2003] S.C.C.A. No. 531):

(a) the act of infringement was completed by the direct infringer;

(b) the completed act of infringement was influenced by the seller, to the point where without said influence, infringement by the buyer would not otherwise take place; and,

(c) the influence must knowingly be exercised by the seller, such that the seller knows that his influence will result in the completion of the act of infringement.

(2) Was the Act of Infringement completed by the Direct Infringer?

[142] The first branch of the test for inducement requires that Servier establish that the Foreign Purchasers infringed the '196 Patent. It is undisputed that the Foreign Purchasers distribute and sell perindopril tablets outside Canada. Those activities do not infringe the '196 Patent. Only if some part of the activity of the Foreign Purchasers takes place in Canada can I conclude that an act of infringement was completed by the direct infringer.

[143] Servier submits (correctly, in my view) that the purchase or possession of infringing articles in Canada, with a view to sale or trade, or for the purpose of export, constitutes infringement (H.G. Fox, *Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed. (Toronto: Carswell, 1969) at 393; ***Wellcome Foundation Ltd. v. Interpharm Inc.*** (1992), 41 C.P.R. (3d) 215 at 226-7 (F.C.T.D.) [*Fox*]; ***Monsanto Canada Inc. v. Schmeiser***, [2004] 1 S.C.R. 902 at paras. 55-58). In this case, Servier asserts that the Foreign Purchasers take title to the perindopril tablets in Canada and then export those tablets to the foreign jurisdiction. It follows, in their view, that the Foreign Purchasers complete acts of direct infringement of the '196 Patent.

[144] Assessing the merits of this assertion requires an examination of the contractual and delivery arrangements between Apotex and each of the Foreign Purchasers. As sales to Apotex UK are representative, I will focus on that relationship.

[145] Servier posits that the arrangement between Apotex Inc. and Apotex UK is defined by the Agreement dated May 1, 2006, between Apotex Inc. and Apotex UK (the Indemnity and Transfer Pricing Agreement). This position highlights the overarching problem with the Servier submission; the Indemnity and Transfer Pricing Agreement represents but one aspect of the overall commercial arrangement between the affiliates.

[146] The purpose of the Indemnity and Transfer Pricing Agreement appears to be two-fold. First, in clauses 1 to 4, it provides Apotex UK with an indemnity in the event that any action or proceeding "is commenced or threatened against [either party] and which alleges that the manufacture of the Product [defined as a generic version of COVERSYL] by Apotex and/or the distribution and sale of the Product by Apotex UK in the Territory [defined as the United Kingdom] infringes any third party patent or other intellectual property rights . . .". In such an event, Apotex "shall assume control and direct the defense of any such proceeding within the Territory and Apotex shall bear all costs and expenses of defending the proceeding". Secondly, the agreement establishes the "Transfer Pricing" of the products sold, in clause 5.

[147] For purposes of this analysis, the only other clause of note in the Indemnity and Transfer Pricing Agreement is clause 10 that provides that the Agreement "shall be governed by and construed in accordance with the laws of Ontario and the laws of Canada in force therein".

[148] The Indemnity and Transfer Pricing Agreement is silent on when title passes from Apotex Inc. to Apotex UK. This is not surprising given the limited purpose of the agreement. As confirmed by Mr. Darroch, no other agreement was produced that defines the point of title transfer or any other

terms governing the business relationship between the parties. Since the Indemnity and Pricing Agreement is obviously not the only agreement that sets out the relationship between the parties, we must look beyond that agreement to determine the question of title transfer. In the absence of any other written agreement, it is reasonable to conclude that the relationship between these two affiliates is, to a large degree, based upon verbal agreements and understandings. This would include any agreement as to the point at which title to the product is passed to Apotex UK, the purchasing affiliate.

[149] Here, we have consistent and clear testimony from both vendor (Apotex Inc.) and at least two of the Foreign Purchasers (GenRx and Apotex UK) that the parties intend title to the goods to pass upon delivery of the products to the foreign territory.

[150] On March 10, 2008, when questioned by counsel for Servier on the terms under which the perindopril tablets were shipped, Dr. Sherman commented as follows:

> The customer is buying it on the basis of delivery in Australia. It is our job to get it there.
>
> . . .
>
> It is CIF London, which means that we are responsible for shipment and for getting this to London, including the freight and insurance.
>
> . . .
>
> [T]he customer simply wants the goods delivered in Australia or in the United Kingdom. That's the basis on which they're paying for. It's our job to get it there. And whether or not we take insurance and would cover it or if we don't take insurance, if the goods are lost, it is our responsibility. So we are responsible for the goods until they actually arrive in Australia or in the United Kingdom and we are responsible for getting them there.

[151] Mr. Millichamp, the managing director of GenRx, provided the following testimony during his examination-in-chief:

> Q. Okay. And in terms of risk of loss and transfer of title to the goods, do you know when that occurs?
>
> A. Under these terms, the risk will pass - the risk will pass -- once it's cleared Customs in Australia and GenRx takes control of the product, the risk is passed to us.
>
> Q. And what about title?
>
> A. That's passing as well.

[152] Mr. Darroch, the managing director of Apotex UK, described the transfer of responsibility for the product purchased from Apotex Inc. by Apotex UK during examination-in-chief in the following terms:

> Q. And perhaps only your finance director knows, but do you know when Apotex U.K. takes responsibility for the product?
>
> A. Oh, yeah, I do. The . . . product becomes . . . the responsibility of Apotex U.K. at the point of clearing Customs, not before.
>
> . . .
>
> Q. Where does it clear Customs?
>
> A. Well, it depends. If it's coming directly from Canada, it will clear via Heathrow Airport. If it's coming, let's say, on any one of our other products, it would come in, say, from the Netherlands, it will clear at a port of receipt in the U.K.
>
> Q. But specifically with respect to perindopril?
>
> A. Oh, perindopril. It will clear through Heathrow.

[153] The evidence could not be much clearer. Even though the written agreements may be silent on this point, the intention of the Apotex Inc. and each of the Foreign Purchasers is that title does not pass until the product is delivered by Apotex Inc. to the destination country. Stated in the negative, the parties do not intend title to pass in Canada.

[154] Servier relies on the Ontario *Sale of Goods Act*, R.S.O. 1990, c. S.1 (*Sale of Goods Act*) and provisions of the Incoterms (discussed below) to support its position that title passes to the purchasing company upon delivery of the product in Toronto for carriage by way of air waybill to its destination. In doing so, Servier emphasizes the evidence before the Court on the method of shipment. A review of the various invoices and waybills introduced into evidence demonstrates that Apotex Inc. packages and delivers the product to a carrier for air freight to the country of destination. The documents provide evidence that Apotex Inc. uses Incoterms nomenclature – such as CIF, CPT or CIP – for its shipments and sales. I will consider each of these arguments.

[155] By virtue of s. 18(1) of the *Sale of Goods Act*, property in the goods "is transferred to the buyer at such time as the parties to the contract intend it to be transferred." The intention is not a question of the parties' subjective beliefs, but rather, the objective contractual intention (*Naber Seed & Grain Co. v. Prairie Pulse Inc.*, 2007 SKCA 58 at paras. 49-50, 59-60 [*Naber*]). Absent convincing evidence to the contrary, rule 5 of section 19 of the *Sale of Goods Act* presumes that the parties intend property in the goods to pass to the buyer when they are "unconditionally appropriated to the contract", which occurs when "the seller delivers the goods [to a carrier] for the purpose of transmission to the buyer". Thus, Servier submits, title to the perindopril products is

presumed to have passed when Apotex delivered the goods to the Canadian carrier for transmission to the Foreign Purchasers.

[156] There is one obvious problem with this argument. In this case and as discussed above, there is convincing evidence from the parties to the business transactions that the parties intend property in the perindopril tablets to pass to the buyer only once the tablets have cleared customs in the country of the purchaser. Further, *Naber* is of no assistance to Servier. The parties involved in that case were the seller and the buyer. Thus, the Saskatchewan Court of Appeal was required to choose between conflicting testimony. In contrast, the evidence before me is that both parties are in complete agreement on when title passes; there is no need to apply the presumption of the *Sale of Goods Act*.

[157] During final argument, Servier, for the first time, made reference to "Incoterms". Incoterms refers to the International Chamber of Commerce official rules of interpretation for trade terms, such as "C-Terms" "CIF", "CPT", "CIP", etc., in respect of the parties' contract of sale (see International Chamber of Commerce, *Incoterms 2000* (Paris: ICC Publishing S.A., 1999) at 5 [*Incoterms 2000*]). Where parties make their contracts subject to Incoterms, courts will apply those definitions, even where the Incoterm usage may be different from the common law. (see A.G. Guest, ed., *Benjamin's Sale of Goods*, 7th ed. (London: Thomson Sweet & Maxwell, 2005) at para. 18-002).

[158] The substance of Servier's argument on this point is this: since Apotex Inc. delivered shipments of perindopril products to carriers in Toronto, by virtue of the C-terms used in the commercial invoices, delivery was completed and the risk of loss or damage to the goods was transferred in Canada to the Foreign Purchasers (*Incoterms 2000* at 13-14, 65-66, 68, 73-75, 81-82, 84-85).

[159] Apotex objected to the introduction of *Incoterms 2000* at this stage of the trial, on the basis that this document could not be characterized as an authority (*AstraZeneca Canada Inc. v. Apotex Inc.*, 2003 FCA 487 at paras. 6-10, 15). I heard the arguments of the parties on this point and reserved my decision. Upon consideration of the arguments, I agree with Apotex on this point and would exclude the use of the Incoterms at this stage of the proceeding. Having said that, however, I am also not convinced that the Incoterms help Servier in its argument. I do not read the Incoterms as displacing the clear intention of the parties as to title or responsibility during transit.

[160] In conclusion, I am not persuaded that title to the perindopril or combination tablets passes to the Foreign Purchasers in Canada. It follows that there was no act of infringement by any of the Foreign Purchasers. Since Servier has failed to satisfy the first branch of the test for inducement, its claim on this point fails.

D. *Exemptions from Liability*

(1) Statutory Provisions

[161] Apotex relies on s. 55.2(1) of the *Patent Act* (post October 1, 1989) to submit that it should not be held liable for any infringement relating to its experimental and regulatory uses of perindopril. Apotex is also asserting that it is not liable for infringement in respect of: (a) its export sales; (b) the transfer of technology for the production of perindopril to affiliates in India; and (c) any manufacture, use or sale in or from India.

(2) Experimental and Regulatory Use

[162] I begin with the proposed exemption from liability based on s. 55.2(1) of the *Patent Act* (as it now applies). That provision states that:

55.2(1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.	55.2(1) Il n'y a pas contrefaçon de brevet lorsque l'utilisation, la fabrication, la construction ou la vente d'une invention brevetée se justifie dans la seule mesure nécessaire à la préparation et à la production du dossier d'information qu'oblige à fournir une loi fédérale, provinciale ou étrangère réglementant la fabrication, la construction, l'utilisation ou la vente d'un produit.

[163] The question of possible exemptions to liability was carefully analyzed by Justice Hughes in *Merck & Co. v. Apotex Inc*., 2006 FC 524 [*Merck (F.C.)*], rev'd on other grounds 2006 FCA 323 [*Merck (C.A.)*], leave to appeal to S.C.C. refused, [2006] S.C.C.A. No. 507. In *Merck (C.A.)* above, at para. 113, the Court of Appeal agreed with his application of s. 55.2(1). Thus, it appears to be settled that Apotex may claim an exemption from liability for certain amounts of the infringing product. Servier did not disagree but stated simply that the burden was on Apotex to demonstrate that the product was used for permitted purposes (such as obtaining regulatory approval or to comply with regulations).

[164] Meticulous evidence was led at trial about quantities of products that fell within the scope of one or more claims of the '196 Patent that Apotex Inc. or Pharmachem acquired or made for research and development, experimental or regulatory uses. A number of witnesses spoke to these quantities and to how they were manufactured, tested and stored. The uses for the allegedly exempt product include initial synthesis, scale-up, manufacture of submission/qualification batches, stability testing, bioequivalence studies and in-process sampling. The sample formulations and accompanying data were prepared and generated using Apotex's own inventory of bulk material, and that information was submitted and prepared for the purpose of submission to the regulatory authorities in Canada, the United States, and other jurisdictions that required it.

[165] Apotex has continued to generate, and to have available for submission, extensive written records containing the analytical and testing information for each lot of raw material and each batch of various finished goods required by the regulatory regimes in the jurisdictions in which it sells perindopril products. Apotex has retained samples of the bulk material it used and the finished

dosage forms it prepared in order to comply with the regulatory requirements governing the manufacturing of the various pharmaceutical products in the jurisdictions in which Apotex sells its perindopril formulations. Those regulations require Apotex to keep a record of its testing procedures, and compile information about its retained samples for the purpose of submission to the applicable regulatory authorities as a condition of maintaining its establishment licence, and in order to comply with specific regulatory requirements.

[166] Of critical importance, in my view, none of the raw material or the actual formulations that were made in the course of that development process were ever sold or used for a commercial purpose. The amounts of material that were used in the formulation development process were recorded on the raw material inventory cards for the corresponding lots of bulk material, or were entered into Apotex's SAP inventory system.

[167] Mr. Fahner reviewed these and related documents reflecting Apotex's use of perindopril. He prepared charts which identified the amount of raw material that Apotex used from each lot it received for the various research and development activities involved in the formulation development process, and a chart which identified the amounts of perindopril from each lot Apotex received that were sampled and retained for ongoing regulatory purposes.

[168] I am satisfied that the identified quantities of perindopril fit within the regulatory and experimental use exemption of s. 55.2 of the *Patent Act* (post October 1, 1989). The specific amounts that qualify under this exemption, as of January 15, 2008, were provided by Mr. Fahner in chart form (see exhibit D-193).

(3) Other Exemptions

[169] Apotex seeks two other exemptions. In my view, I am not able to rule definitively on these requested exemptions.

[170] Specifically, I have no argument or evidence on which I could base a decision that the transfer of technology for the production of perindopril to affiliates in India or any manufacture, use or sale in or from India does not infringe the '196 Patent. Nor am I entirely clear on what Apotex means by "transfer of technology". If Apotex is referring to a physical transfer of the quantities of perindopril that are caught by the exemption under s. 55.2(1), I could likely agree with Apotex's assertion. However, it should be obvious that Apotex could not use this "transfer of technology" exemption to send its entire existing inventory of perindopril from Canada to India.

[171] As to the request that I conclude that Apotex is not liable for its export sales, I have some difficulty. The infringement by Apotex involves, in part, the manufacture of perindopril for export. To that extent, I have found that Apotex has infringed the '196 Patent and is liable to Servier Canada and ADIR.

(4) Conclusion on Exemptions

[172] I find that the volumes of perindopril set out in Ex. D-193 fall within the s. 55.2 exemption as of January 15, 2008; Apotex is not liable for infringement for these quantities.

[173] I note that the evidence on this requested exemption was very detailed up to January 15, 2008. As stated by counsel for Apotex, there may be further quantities that are produced beyond that date that meet the requirements of s. 55.2(1). I expect that, post-trial, Apotex will continue to keep the same meticulous records of these amounts. Should there be any changes to the quantities produced or stored, Apotex should be prepared to provide the same level of evidence for purposes of the damages phase of these proceedings.

VII. Claim 5 Corrections

A. *Overview*

[174] It is not disputed that claim 5, as its stands today, is a claim to perindopril. Apotex concedes that the active ingredient of its Apo-Perindopril 2, 4 and 8 mg tablets and the perindopril in its combination tablet come within the scope of claims 1, 2, 3 and 5 (as it stands today) of the '196 Patent. However, Apotex contends that, even if the Court concludes that claims 1, 2 and 3 are valid, it does not infringe claim 5.

[175] The basis of this claim of non-infringement is that the Commissioner of Patents improperly corrected – twice – claim 5 of the Patent. In Apotex's view, since the certificates of correction were issued without legal basis, the determinative version of claim 5 is the one issued on March 6, 2001. Since the March 6 version did not claim perindopril, Apotex concludes that claim 5 is not infringed by the manufacture or sale of Apo-Perindopril 2, 4 and 8 mg tablets or the perindopril in its combination tablets.

[176] The arguments of the parties on this issue involve addressing the following questions:

1. Is Apotex precluded from bringing this attack on the certificates of correction in this action on the basis that the decision of the Commissioner to issue such certificates may only be impugned by application for judicial review made under s. 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7 (the *Federal Courts Act*)?

2. Is Servier precluded from raising the judicial review argument on the basis that it was not pleaded?

3. What is the standard of review of a decision of the Commissioner to issue a certificate of correction?

4. Did the Commissioner act unreasonably or incorrectly (depending on the standard of review) in concluding that the errors (or either of them) were "clerical errors" that could be corrected pursuant to the Commissioner's authority under s. 8 of the *Patent Act* as it stood in 2001?

B. *Background to the Issue*

[177] As discussed earlier in these reasons, the '196 Patent was issued subsequent to the Nadon Order. Attached to that Order were the Minutes of Settlement (the Settlement Agreement) entered into by ADIR, Hoechst and Schering and appended to the Settlement Agreement were the claims

that were to be issued to each party. The Nadon Order, the Settlement Agreement and the attached appendix of claims were all issued in English. Clause 1(a) of the Settlement Agreement provided that:

> Adir is entitled to the issuance of a patent based on pending application serial no. 387,093 restricted to the claims set out in Appendix A attached hereto[.]

[178] Pursuant to Clause 2(a) of the Settlement Agreement, the parties, *inter alia*, agreed that:

> Adir will amend Adir's Application to delete all claims currently within this application and replace those claims with the claims set out in Appendix A attached hereto[.]

[179] Appendix A set out the ADIR claims, including, of particular relevance to this issue, the following:

> 5. The compound (2S)-2-[(1S)-1-carbethoxybutylamino]-1-oxopropyl-(2S,3aS,7aS)-perhydroindole-2-carboxylic acid and its pharmaceutically acceptable salts thereof.

[180] As noted above, the '093 Application was filed with the Patent Office in French. The text of the '196 Patent, drawn from the '093 Application, had been prepared in French. As set out in the Patent Rules, S.O.R./96-423, s.172(3) (the *Patent Rules*), "The text matter of the abstract, the description, the drawings and the claims . . . shall be wholly in English or wholly in French". Accordingly, the claims were translated into French from the English language of the Settlement Agreement. This task was apparently carried out by Mr. Nelson Landry, as counsel and patent agent for ADIR. Once the translation was completed and the document submitted to the Patent Office, the '196 Patent was issued on March 6, 2001. As issued, claim 5 read as follows:

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

[181] As written, submitted and issued in the '196 Patent, this did not accord with the claim 5 of the Settlement Agreement, as approved by the Court in the Nadon Order and did not constitute a claim to perindopril. Specifically, this version had an (R,S) for the ethoxycarbonyl group in the nomenclature and a displaced (S) in relation to the carboxy group. As testified to by both Dr. Jaguelin and Mr. Landry, the problem was brought to the attention of Mr. Landry in a telephone call from Dr. Jaguelin, who had noticed the error, shortly after March 6, 2001**.**

[182] Mr. Landry, attempting to correct the error, filed a request for correction. The Commissioner issued a certificate of correction dated April 3, 2001, stating as follows:

> La formule de la rendivication 5 a été corrigé pur se lire comme suit
> "{N - [(2,S) éthoxycarbonyl - 1 butyle] (S) - alanyle} - 1 carboxy –
> 2 (S) (3aS,7aS) perhydroindole.["]

[183] Unfortunately, this version contained another error. Instead of replacing the (R,S) for the ethoxycarbonyl group with (1,S), the nomenclature was changed – as requested in the letter from Mr. Landry – to (2,S). Mr. Landry was advised of the mistake in a letter dated April 18, 2001, from Mr. Caignard, a colleague of Dr. Jaguelin and the individual in charge of patent procedures at the time.

[184] Mr. Landry made another letter request for a correction on April 25, 2001. The second – and final – certificate of correction was issued by the Commissioner on May 14, 2001. That certificate provided that:

> La formule de la rendivication 5 a été corrigé pur se lire comme suit
> "{N - [(1,S) éthoxycarbonyl - 1 butyle] (S) - alanyle} - 1 carboxy –
> 2 (S) (3aS,7aS) perhydroindole.["]

[185] At last, claim 5 of the '196 Patent was the claim to perindopril.

C. *Statutory Authority of the Commissioner*

[186] The Commissioner holds the authority to correct "clerical errors" pursuant to s. 8 of the *Patent Act*. The section, as it stood in 2001, provides:

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.

D. *Must Apotex Proceed by way of Judicial Review?*

[187] Servier contends that Apotex cannot attack the decision of the Commissioner to issue the certificates of correction in this action but must proceed by way of judicial review pursuant to s. 18.1 of the *Federal Courts Act*. In their view, the scheme of the *Federal Courts Act* (see, in particular, *Federal Courts Act*, ss. 2, 18(1), 18(3)) mandates a litigant to proceed by way of judicial review to have the decision of a federal board, commission or other tribunal invalidated. Servier relies on a number of decisions of the Federal Court of Appeal and this Court: see, for example, *Grenier v. Canada*, 2005 FCA 348, at paras. 20, 29, 31 [*Grenier*]; *Mohiuddin v. Canada*, 2006 FC 664; *Malkine v. Canada (Minister of Citizenship and Immigration)*, 2007 FC 573 at paras. 5, 15.

[188] On the facts of the situation before me, I am not persuaded that Apotex must proceed by way of judicial review. I do acknowledge, however, that the issue is not free from doubt.

[189] The case of *Grenier*, above, contains a careful discussion of the principles affecting the mandate of the Federal Court to hear and decide judicial reviews of the decisions of federal boards, commissions and tribunals. The Court expressed concern about the possibility of collateral attacks on tribunal decisions that might not incorporate an analysis of the correct standard of review of the tribunal's decision. The Court was also concerned with the finality of decisions of tribunals. At paragraph 31, Justice Létourneau, writing for the Court, stated that:

> The principle of the finality of decisions likewise requires that in the public interest, the possibilities for indirect challenges of an administrative decision be limited and circumscribed, especially when Parliament has opted for a procedure for direct challenge of the decision within defined parameters.

[190] On its face, the same principles apply to a decision of the Commissioner, acting under his authority of the *Patent Act*. Nevertheless, there are very significant distinctions to be made in this case.

[191] The jurisprudence referred to by Servier all involved litigants who were parties to the original decision of the federal tribunal and who clearly would have had standing to bring the judicial review.

[192] Mr. Grenier in *Grenier*, above, by way of example, was a prison inmate who had been sentenced to a one-hour administrative segregation by the institutional head of the prison. He did not apply for a judicial review of the decision, but, some three years later, brought an action for damages arising from the segregation. In those circumstances, the Court of Appeal concluded that Mr. Grenier, in accordance with s. 18 of the *Federal Courts Act*, had to apply directly to have this decision nullified or invalidated by way of judicial review.

[193] In the case before me, Apotex was not a party to the proceedings that resulted in the issuance of the two certificates of correction; it is arguable that Apotex had no standing to challenge the issuance of the certificates by way of judicial review. Apotex, absent a continuous watch of all Commissioner decisions and the '196 Patent file wrapper, would have had no knowledge of the certificates or the context in which they were issued. How then, could Apotex have brought an application for judicial review within the 30-day time limit set out in s. 18.1(2) of the *Federal Courts Act*?

[194] A further distinguishing feature of the case before me is that the decisions of the Commissioner to issue the certificates of correction arise from the *Patent Act*. In my view, this is a critical distinction. As is evident, the basis of the counterclaim being brought by Apotex is, *inter alia*, that claim 5 is invalid. Three different provisions of the *Patent Act* are relevant to this issue:

- Section 59 of the *Patent Act* provides that a defendant, "in any action for infringement, may plead as a matter of defence any fact or default which by this Act or by law renders the patent void . . ." ;

- Section 60(1) sets out that "any claim may be declared invalid or void by the Federal Court . . . at the instance of any interested person"; and

- Pursuant to s. 60(2), any person whose actions may be alleged to be infringing "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 patent]".

[195] There is no exception carved out for claims of invalidity based on unlawful actions of the Commissioner. It follows that Apotex may raise its allegations of unlawful decisions of the Commissioner in the context of an action. Requiring Apotex to bring an application for judicial review of the Commissioner's issuance of the two certificates of correction would render ss. 59 and 60(1)-(2) meaningless.

[196] For these reasons, I conclude that the better legal view is that Apotex is not limited to raising the actions of the Commissioner in issuing the certificates of correction in an application for judicial review.

[197] Apotex raises one additional defence to Servier's assertions that Apotex lacked the capacity to raise the issue of the corrections other than by way of judicial review. In final argument, Apotex argued that Servier's pleadings made no reference to this objection. I agree that the pleadings are silent. However, since I am finding that Servier's objection on capacity grounds cannot be sustained on its merits, there is no need to consider the failure of Servier to include the objection in their pleadings.

[198] Having concluded that the issue of the lawfulness of the Commissioner's decisions need not be determined through an application for judicial review, I now consider the arguments raised.

E. *Standard of Review of a Commissioner's Decision*

[199] Any analysis of the lawfulness of the Commissioner's decisions to issue the two certificates of correction must begin with an assessment of the appropriate standard of review of the decisions in issue. Apotex argues that the question of whether a requested amendment constitutes a "clerical error" is a question of pure law to which the standard of review of correctness should apply. Servier argues that the decision attracts the standard of reasonableness. For the reasons set out in the following, I prefer Servier's proposed standard of review.

[200] The methodology to determine the appropriate standard of review of a decision of an administrative tribunal was recently reformulated in *Dunsmuir v. New Brunswick*, 2008 SCC 9 [*Dunsmuir*]. Justices Bastarache and Lebel, writing for the majority, summarize the new "standard of review analysis" at paragraph 62 of the decision:

> In summary, the process of judicial review involves two steps. First, courts ascertain whether the jurisprudence has already determined in a satisfactory manner the degree of defence to be accorded with regard to a particular category of question. Second, where the first inquiry proves unfruitful, courts must proceed to an analysis of the factors making it possible to identify the proper standard of review.

[201] Applying *Dunsmuir,* I turn first to the existing jurisprudence on the standard of review with respect to s. 8 of the *Patent Act*.

[202] The case law with respect to s. 8 of the *Patent Act* is limited but consistent.

[203] In *Pason Systems Corp. v. Canada (Commissioner of Patents)*, 2006 FC 753 [*Pason*], Justice Hughes determined that a Commissioner's decision under s. 8 involves two steps, each with its own standard of review:

> This involves two steps, first there must be a determination in that there has been such an error, then the Commissioner "*may*" correct that error, that is, a discretion remains. The determination as to whether a "*clerical error*" exists is essentially factual, it requires no special expertise that the Commissioner may possess in patent or scientific matters. A reasonable but not high degree of deference can be afforded to the Commissioner in this regard. The second step, that of determination as to whether to correct an error if it is seen to exist is discretionary (see *Bayer v. Commissioner of Patents* (1980), 53 C.P.R. (2d) 70, per Justice Mahoney at 74 (FCTD) and requires a substantial degree of deference (*Pason,* above at para. 21).

[204] Justice Barnes came to a similar conclusion in *Dow Chemical Co. v. Canada (Attorney General)*, 2007 FC 1236 at paras. 14-15, 26 where, quoting in part *Bristol-Myers Squibb Co. v. Commissioner of Patents* (1997), 138 F.T.R. 144, aff'd (1998) 82 C.P.R. (3d) 192 (F.C.A.), he noted that the second step "should not be overturned unless unreasonable" while the first step was deserving of "considerable deference".

[205] In other words, both Justices Barnes and Hughes have concluded that the appropriate standard of review with respect to both steps of a s. 8 decision is reasonableness. Accordingly, it appears that the courts have "determined in a satisfactory manner the degree of defence to be accorded" to the decision at issue in the case at bar and I need not continue any further. However, as outlined below, I reach the same conclusion after carrying out my own review of the relevant factors.

[206] To begin, I find I am again in agreement with Justice Hughes in *Pason,* above at para. 21, where he finds that *CertainTeed Corp. v. Canada (Attorney General)*, 2006 FC 436 neatly summarizes three of the four relevant factors applicable to the standard of review analysis:

- The *Act* does not contain a privative clause and s. 41 of the *Act* allows an appeal from a decision of the Commissioner. Accordingly, this first factor is neutral.

- The Commissioner is experienced in dealing with patent applications and appeals under the *Act*. He has expertise in that area and accordingly, his decisions will attract a high degree of deference.

- The purpose of the *Act* is to encourage invention and to regulate the issuance of patents in Canada; see *Pope Appliance Corp. v. Spanish River Pulp and Paper Mills Ltd.*, [1929] A.C. 269 (Canada P.C.).

[207] With respect to the nature of the question before the Court, Apotex, in essence, argues that the Commissioner erred in granting the certificates of correction as the corrections were not clerical in nature. In other words, Apotex takes issue with the first step of the Commissioner's decision under s. 8.

[208] The determination of what constitutes a clerical error is highly factual (*Pason,* above at para. 21) and, at best, a question of mixed fact and law. This factor therefore suggests some deference.

[209] When taken together with the other factors, (none of which suggests a correctness standard), I conclude the appropriate standard of review is reasonableness.

F. *Was either of the Decisions of the Commissioner Unreasonable?*

[210] The Commissioner issued the certificates pursuant to s. 8 of the *Patent Act*. In order to do so he had to be satisfied that the corrections were "clerical errors". As described in *Dunsmuir*, at paragraph. 47, on a standard of reasonableness, the Court must determine whether the Commissioner's decisions fall "within a range of possible, acceptable outcomes which are defensible in respect of the facts and law".

[211] I begin with what the jurisprudence has said about clerical errors. A clerical error pursuant to s. 8 of the *Act* has been described as one that "arises in the mechanical process of writing or transcribing" (*Bayer Aktiengesellschaft v. Commissioner of Patents* (1980), 53 C.P.R. (2d) 70 at 73 (F.C.T.D.)).

[212] Apotex asserts that the errors made by Mr. Landry cannot be characterized as clerical errors.

[213] Mr. Landry, who acted as counsel and patent agent to ADIR during the relevant periods, appeared as a witness at this trial under subpoena to speak only on the issue of the corrections. Mr. Landry's evidence establishes that the first error arose during translation. As Mr. Landry testified, he knew that the '196 Patent had to be issued in French, whereas the Settlement Agreement and Appendix A were in English. Mr. Landry's testimony was that he worked with both the '093

Application (which was in French) and the English version of claim 5 to draft the French version of claim 5 for the '196 Patent. The result of his deliberation contained two errors: (a) an (R,S) for the ethoxycarbonyl group in the nomenclature instead of (1,S); and, (b) a displaced (S) in relation to the carboxy group. In making his first correction of the error, Mr. Landry committed the second error. Instead of asking that the (R,S) for the ethoxycarbonyl group be replaced with (1,S), Mr. Landry mistakenly requested that it be replaced with (2,S).

[214] Apotex submits that an error that is committed in the process of translating a document or a sentence therein is fundamentally different from an error which arises in the copying, writing or transcribing of information from one document to another. The latter processes are mechanical in nature and require little, if anything, in the way of original and conscious thought. Accordingly, they are accepted as the defining characteristics of a "clerical" error. On the other hand, the act of translation, both general and especially in the specific circumstances of this case, involves a thought process that is, in Apotex's view, the very antithesis of a clerical error. Translation, particularly here, is not simply a matter of looking at equivalent words in an English-French dictionary and replacing an English term with its French literal counterpart. Apotex submits that an error arising from such a process cannot, in law, amount to a clerical error.

[215] The second correction can be easily dealt with. In my view, it is not unreasonable to consider the mistaken insertion of (2,S) in place of (1,S) to be a clerical error. Contrary to the assertion of Apotex, such a mistake is more likely than not to be mechanical in nature and made without thought. Indeed, had Mr. Landry applied any original and conscious thought to the process,

he would have realized his error. The inclusion of (1,S) for the ethoxycarbonyl group is clearly set out in claim 5 in English in Appendix A to the Settlement Agreement.

[216] The first correction, arising as it did during the translation, may be more problematic. In general, translation is a difficult task. In approaching the translation of claim 5 from the English Appendix A to the French version required for the '196 Patent, Mr. Landry was required to apply some thought and analysis. As noted, he worked with the French language '093 Application as well as the appendix to the Settlement Agreement.

[217] Guidance to Patent Office officers is set out in the Manual of Patent Office Practice (MPOP). In the current version of the MPOP (Patent Office, *Manual of Patent Office Procedure*, (Ottawa-Gatineau: Canadian Intellectual Property Office, 2006) paragraph 23.04 deals with s. 8 corrections. Paragraph 23.04.02 provides that correction of a translation mistake is not a transcription mistake. Apotex relies on the MPOP to demonstrate the unreasonableness of the Commissioner in concluding that the first correction was a "clerical error". There are at least three problems with Apotex's use of the current MPOP. The first is that the MPOP in use at the time of the corrections (Canadian Patent Office, *Manual of Office Practice*, (Ottawa-Hull: Canadian Intellectual Property Office, 1998) did not state that a translation error was not a transcription error. Secondly, the MPOP is a guideline; it cannot be binding on the Commissioner.

[218] Thirdly, a reasonable view of the errors is that they were not translation errors. The fact that the errors arose during the process of translation, does not automatically make them "translation errors". This view is supported by the dictionary meaning of "translate" or "translation". As

described in the Canadian Oxford Dictionary, the most relevant meaning of " translate" is to "express the sense of (a word, sentence, speech, book, etc.) in another language" (*Concise Canadian Oxford Dictionary, s.v.* "translate"). "Translation" is "the act or an instance of translating" or "a written or spoken rendering of the meaning of a word, speech, book, etc." (*Concise Canadian Oxford Dictionary*, *s.v.* "translation"). Stated in other words, translation involves the expression of words, sentences, speeches, books, etc. from one language to another. Thus, a person involved in the redaction of a patent, may err in translating particular sentences or technical terms into another language. In this case, however, the errors of Mr. Landry did not arise from the translation of the claims or their words; rather they arose during the process of translation. Each of the errors related to a letter/number configuration (such as R,S or 1,S) and not to "words, sentences, speeches, books, etc." Thus, the errors may reasonably be characterized as merely incorrect alpha-numeric designations and not translation errors. It follows that the decision of the Commissioner, even if the current MPOP had been in effect, cannot be said to be unreasonable.

[219] Finally, I observe that, throughout the exercise, claim 5 of the '196 Patent was defined – albeit in English – in Appendix A to the Settlement Agreement. All parties to the Settlement Agreement were aware that a claim to perindopril was to be awarded to ADIR. In addition, the Commissioner was aware of the specific claim 5 awarded to ADIR. Before the Commissioner was the entire file wrapper of the '196 Patent. Thus, all documents and correspondence leading to the grant of the '196 Patent formed part of the record. Of particular significance, the Commissioner had the Nadon Order where the final resolution of the conflict was documented. The Commissioner was required to give effect to that document; indeed, any decision of the Commissioner to vary the Nadon Order, without further Court order, could likely have been the subject of judicial review. An

explicit term of that Order was that ADIR was entitled to the claims set out in Appendix A of the Settlement Agreement, one of which was ADIR's claim to:

> 5. The compound (2S)-2-[(1S)-1-carbethoxybutylamino]-1-oxopropyl-(2S,3aS,7aS)-perhydroindole-2-carboxylic acid and its pharmaceutically acceptable salts thereof.

[220] Thus, the Commissioner, in this case, was faced with an unusual set of facts. He was not operating in a situation where a patentee was attempting to change the chemical formula of a claim based solely on the assertion of the patentee. Here, the Commissioner could read the claim from the Nadon Order and compare the requested corrections to that claim. He would be aware that the object of the corrections was to achieve the results contemplated by the Nadon Order. I acknowledge that this does not explain why the Commissioner accepted the first, incorrect request for a certificate of correction. Nevertheless, overall, I am satisfied that the existence of the Appendix A claim 5 acted as a backstop. Today, as a result of the two certificates of correction, ADIR's patent reflects accurately ADIR's claim to perindopril as described in claim 5 of the '196 Patent.

[221] In light of the unusual facts of this case and the record that was before the Commissioner, I find that the Commissioner's decisions to issue the two certificates of correction fall within a range of possible, acceptable outcomes. They are reasonable decisions and should not be overturned.

G. *Conclusion on this issue*

[222] Having considered the arguments on this issue, I conclude that the certificates of correction were not issued without legal basis (as asserted by Apotex). It follows that claim 5 of the '196 Patent is not invalid by reasons of unlawfully issued certificates of correction.

VIII. Obviousness

A. *The Law*

[223] Apotex argues the '196 Patent is invalid for obviousness.

[224] I begin with the relevant legal principles.

[225] The first point to stress is that the onus lies on the attacking party to establish that a claim is obvious on a balance of probabilities.

[226] Much has been written about the test for obviousness in the case law. However, I think that the Federal Court of Appeal in *Janssen-Ortho Inc. v. Novopharm Ltd.*, 2007 FCA 217, leave to appeal to S.C.C. refused, [2007] S.C.C.A. No. 442 [*Janssen-Ortho (C.A.)*], has now provided a very useful summary of the test for obviousness and the manner in which a trial judge should approach the question. Justice Sharlow, writing for the Court of Appeal in *Janssen-Ortho (C.A.)*, outlined the test for obviousness at paras. 23-24:

> The accepted legal test for obviousness is stated as follows in the leading case of *Beloit Canada Ltd. et al. v. Valmet OY* (1986), 8 C.P.R. (3d) 289 (F.C.A.) at page 294, per Hugessen J.A.:
>
> > The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be asked is whether this mythical creature (the man in the Clapham omnibus of patent law) would, in the light of the state of the art and of common general

> knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy.

The inquiry mandated by the *Beloit* test is factual and functional, and must be guided by expert evidence about the relevant skills of the hypothetical person of ordinary skill in the art, and the state of the art at the relevant time. The expert evidence must be carefully assessed as to its credibility and reliability. The classic warning from *Beloit* about hindsight must always be borne in mind (at page 295, per Hugessen J.A.):

> Every invention is obvious after it has been made, and to no one more so than an expert in the field. Where the expert has been hired for the purpose of testifying, his infallible hindsight is even more suspect. It is so easy, once the teaching of a patent is known, to say, "I could have done that"; before the assertion can be given any weight, one must have a satisfactory answer to the question, "Why didn't you?"

[227] Of particular assistance, at paragraph 25, Justice Sharlow described a number of factors that could "guide the required factual inquiry" and that could be used "as a framework for the factual analysis that must be undertaken". Justice Sharlow then listed and explained the following non-exhaustive list of factors that could guide the factual inquiry. Those factors are the following:

Principal factors

1. The invention

2. The hypothetical skilled person referred to in the *Beloit* quotation

3. The body of knowledge of the person of ordinary skill in the art

4. The climate in the relevant field at the time the alleged invention was made

5. The motivation in existence at the time [of] the alleged invention to solve a recognized problem

6. The time and effort involved in the invention

Secondary factors

7. Commercial success

8. Meritorious awards

[228] Obviousness must be assessed as of the date of the invention (*Pfizer Canada Inc. v. Canada (Minister of Health)*, 2005 FC 1205 at para. 89, rev'd on other grounds 2007 FCA 209, leave to appeal to S.C.C. refused, [2007] S.C.C.A. No. 377 [*Pfizer*]). In the case at bar, nothing turns on whether the date of invention is October 1, 1981, as claimed by Apotex in its pleading, or October 1, 1980, as claimed by Apotex in final argument. Accordingly, I will use the later date of October 1, 1981.

B *The State of the Art*

[229] With this law in mind, I turn to a review of the relevant prior art.

[230] Apotex, in its submissions, referred to a number of scientific papers as being representative of the state of the art. Apotex submits that the significance of these papers, all of which relate to the captopril series of compounds, is as follows:

- Cushman *et al*., "Inhibition of Angiotensin-Converting Enzyme by Analogs of Peptides from *Bothrops jaracara* Venom" (1973) Experientia 29/8 1032 (the

Experientia paper): demonstrated the reasonable activity of the tripeptide Phe-Ala-Pro as an ACE inhibitor, thus teaching that proline (Pro) at the C-terminus contributed to binding to ACE;

- Miguel A. Ondetti & Bernard Rubin & David W. Cushman "Design of Specific Inhibitors of Angiotensin-Converting Enzyme: New Class of Orally Active Antihypertensive Agents" 196 Science 441 (the *Science* paper): taught the preferred stereochemistry of the captopril series of compounds by providing test data for stereoisomers of captopril;

- Cushman *et al*., "Design of Potent Competitive Inhibitors of Angiotensin-Converting Enzyme Carboxyalkanoyl and Mercaptoalkanoyl Amino Acids" (1977) 16 No. 25 Biochemistry 5484 (the *Biochemistry* paper); Cushman *et al*., "Design of New Antihypertensive Drugs: Potent and Specific Inhibitors of Angiotensin-Converting Enzyme" (1978) XXI No. 3 Progress in Cardiovascular Diseases 176 (the *Progress in Cardiovascular Diseases* paper): together these papers indicated that the substrate specificity of the active site of ACE was "very broad" and that the moiety at the C-terminus could vary. Further, while they taught that proline was preferred at the C-terminus, they also indicated that more sterically demanding amino acids still retained activity; and

- Hong-Son Cheung *et al.*, "Binding of Peptide Substrates and Inhibitors of Angiotensin-converting Enzyme, Importance of the COOH - Terminal Dipeptide

Sequence" (1979) 255 No. 2 Issue January 25 401 (the *Biological Chemistry* paper): taught that tryptophan, a moiety of greater steric size than proline, had greater activity than proline when substituted for proline at the C-terminus.

[231] Apotex submits that the teachings of these papers were reinforced by a number of U.S. patents obtained by Squibb (U.S. Patent 4,046,889, U.S. Patent 4,154,942, U.S. Patent 4,105,776, U.S. Patent 4,113,715, and U.S. Patent 4,105,789) which taught that other amino acids could be used in place of proline at the C-terminus position.

[232] In addition to captopril-related prior art, Apotex relies on prior art associated with Merck's work with enalapril. This prior art includes disclosures made at the Troy conference, 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). The significance of this prior art, Apotex submits, is three-fold:

- They taught that compounds in the S-configuration were to be preferred.

- They gave examples and taught that the preferred class of the enalapril class of compounds included compounds where the side chain was a linear alkyl rather than a phenethyl.

- They taught that bulkier moieties, including tryptophan, thiaproline and pipecolic acid, could be substituted for proline at the C-terminus.

[233] Apotex also relies on European Patent Application 0 012 845 B1 (the Tanabe Application). The Tanabe Application, Apotex submits, discloses a class of compounds with a 6,6 bicyclic substitution (tetrahydroisoquinoline or THIQ) in the place of proline on the captopril backbone. From this disclosure, therefore, one skilled in the art would understand that moieties as bulky as THIQ at the C-terminus would bind to ACE.

[234] Finally, Apotex relies on a limited number of non-ACE inhibition art for the proposition that bicyclic ring systems, including 6,5 ring systems, were known in the literature as of 1976 and were incorporated into non-ACE inhibitor anti-hypertensives.

[235] Servier does not dispute that the content of the aforementioned art is anything other than as stated by Apotex. Rather, Servier argued that some of the art cited by Apotex should not be relied on for two reasons:

1. Reliance on prior art outside the field of ACE inhibition is "not only improper at law, it is scientifically unsound"; and

2. The Tanabe Application was not known by Dr. Marshall prior to this case.

[236] Turning to Servier's first argument, I disagree that reliance on prior art outside the field at issue will always be improper in law. However the jurisprudence does indicate that it cannot be assumed that the unimaginative, non-inventive technician skilled in the art would consider art in

other fields (*Almecon Industries Ltd. v. Nutron Manufacturing Ltd*., [1996] F.C.J. No. 240 at para. 67 (T.D.) (QL), aff'd (1997), 72 C.P.R. (3d) 397, leave to appeal to S.C.C. refused, [1997] S.C.C.A. No. 374). In other words, there must be some reason, supported by evidence, which would justify a person skilled in the art to look beyond the field at issue. It is here where I find Apotex has stumbled.

[237] A review of the Apotex experts on this point reveals several problems. Dr. Marshall's evidence is undermined by the fact that he was provided with the non-ACE inhibition references by counsel for Apotex. Dr. Thorsett's affidavit and testimony is vague and general; he failed to direct the Court to any specific piece of prior art which one skilled in the art would have been directed to. Finally, Dr. McClelland relied solely on prior art stemming from Squibb and Merck. Accordingly, his testimony is of no assistance to the Court on this point.

[238] In sum, Apotex has failed to convince me that the person skilled in the art would go beyond the field of ACE inhibition. However, I note that my conclusion on this point does not detract from the other papers, patents, and disclosures noted above, all of which involve ACE inhibition.

[239] With respect to Servier's second argument, I find it goes to the weight of Dr. Marshall's testimony, as discussed below, and does not warrant excluding the Tanabe Application from the relevant field of prior art. Indeed, neither Servier nor any of its experts suggested the Tanabe Application should not be considered as valid prior art.

[240] In sum, I am satisfied that the aforementioned prior art formed the state of the art as of October 1, 1981. The teachings of this art can be succinctly stated as follows:

- A working hypothesis of ACE, its nature, and how inhibitors interacted with ACE, had been developed and published by scientists at Squibb and Merck;

- It was known that the effects of binding from modifying different parts of an inhibitor molecule were largely independent. Thus, one skilled in the art would hope for, and not be surprised to see, that a modification to the proline ring in captopril that maintained or increased activity would have a similar or increased effect relative to enalapril;

- It was known that the S2 prime subsite of ACE was capable of accepting a large volume such as tryptophan and THIQ; and

- By October 1, 1981, it had been shown that considerable variation could be made to the framework of a non-peptidic ACE inhibitor, particularly at the C-terminus.

C. *Position of the Parties*

[241] Having set out the relevant prior art I will now summarize the position of the parties.

[242] Apotex divides its submissions on the obviousness of the '196 Patent into essentially two categories. First, it submits that the addition of the perhydroindole 6,5 ring to the Merck backbone was obvious. In support of this argument Apotex relies on: (i) the prior art evidencing the promiscuity of the S2 prime subsite of ACE to accept large moieties; (ii) Servier's "effective admission" in the '196 Patent and the '093 Application that there is no distinction between THIQ and perhydroindole; (iii) the general skill of a medicinal chemist to use structure activity relationship (SAR) methodology to modify these rings as necessary; (iv) the fact that there were chemists at Hoechst, Warner-Lambert and Schering that also incorporated bicyclic ring modifications following the Troy conference; and (vi) the alleged motivation of these different groups of chemists. Second, Apotex submits that the rest of the invention of the '196 Patent, namely the addition of linear alkyl side chain, was obvious in light of the fact such side chains were included in the '401 Application and the *Nature* paper and because there is nothing in the description of the '196 Patent that suggests the invention is limited to a linear alkyl side chain.

[243] In response, Servier submits that, with respect to the addition of the perhydroindole 6,5 ring, the prior art, including the Tanabe Application, is too different from the perhydroindole in perindopril to make the '196 Patent obvious. With respect to the addition of the side chain Servier submits that neither the *Nature* paper nor the '401 Application teaches the n-propyl side chain in claims 3 and 5 of the '196 Patent. At best, n-propyl is one of billions of compounds disclosed. Further, Servier submits that perindopril is the only post-captopril ACE inhibitor to have received regulatory approval in Canada whose side chain is a propyl. Finally, Servier stresses that the crystal structure of ACE was not known until 2003 and submits that the commercial success of perindopril should be taken into account in any discussion of the obviousness of the '196 Patent.

D. *Application of the Law to Facts*

(1) Obviousness of the 6,5 bicyclic ring

[244] I will address each of Apotex's arguments in light of the factors discussed in *Janssen-Ortho (C.A.),* beginning with the question of the obviousness of the addition of the 6,5 perhydroindole bicyclic ring.

[245] Before I begin, however, I wish to comment on some general criticisms levelled by Apotex to the Servier experts.

[246] Apotex submits that each of Drs. Trost, Cimarusti and Bartlett erred by applying the legal test, a matter that goes beyond their expertise. In each case, the expert was provided a definition or test for obviousness from Servier's counsel; their reports stated and addressed the elements of the test. Apotex asserted that I should ascribe no weight to opinions that were on the ultimate legal question. I agree. It is not up to the experts to provide the answer to the question of whether or not the compounds in the '196 Patent were obvious; that is the job of this Court. However, that does not mean that the opinions and evidence that these experts have given should, as a whole, be given no weight. It means that I must come to my own conclusion on the question of obviousness and I have done so.

[247] Apotex also submits that the experts erred when they "parsed the art" by taking each segment of the art and analyzing it as against the invention, rather than considering the building

blocks of prior art together as a whole. I cannot see fault in the approach taken by each of the Servier experts for this reason, even if I accept that this was their approach. As noted above, I am not relying on any legal conclusions of the experts. Ultimately, I am accountable for choosing the approach to the evidence and opinions that have been put before me, however they were presented.

(a) *The Invention*

[248] Apotex submits that there is no inventive distinction between the 6,5 perhydroindole bicyclic moiety and other moieties, such as THIQ, and that Servier has, in the disclosure of both the '196 Patent and '093 Application, effectively admitted that there is no distinction. This is essentially a repetition of its argument that there is but one invention in the '196 Patent.

[249] It is also true that Servier includes THIQ compounds in Table 1 of the '196 Patent disclosure. This cannot be taken as an admission by Servier that there is no inventive distinction between the two chemical structures. Indeed, by not claiming compounds with a THIQ moiety, Servier can be seen as recognizing the differences between the two moieties.

[250] To repeat my earlier finding, claim 1 of the '196 Patent forms an invention that is distinct from the larger class of compounds of General Formula I in the description. This invention has 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. The fact that the descriptions of the '196 Patent and of the '093 Application do not distinguish between a perhydroindole ring and other moieties is immaterial.

(b) *The Skilled Person*

[251] The hypothetical skilled person in the case at bar includes a number of skilled individuals with experience in work or academia and holding a Masters, Ph.D., or medical degree. While the person of ordinary skill in the art is a capable "technician", he or she has "no scintilla of inventiveness or imagination" (*Beloit Canada Ltd. et. al v. Valmet OY* (1986), 8 C.P.R. (3d) 289 (F.C.A.)). I would only add that I agree with Apotex that, in this case, such an individual would have knowledge of SAR methodology. I will return to this point when addressing the fourth factor below.

(c) *Body of Knowledge*

[252] I have already summarized the body of knowledge the person of ordinary skill in the art would be expected to have. With the exception of the non-ACE inhibition prior art, I largely agree with Apotex's summary of the state of the art as it existed prior to October 1, 1981.

(d) *Climate in the Field*

[253] The fourth factor enumerated in *Janssen-Ortho (C.A.)* is the climate of the field at issue at the relevant time. I accept 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. I accept that two of the moieties that were taught in the prior art, tryptophan and the THIQ in the Tanabe Application, contain bicyclics (in tryptophan as an indole side chain). Furthermore, I accept that a medicinal chemist would have the skill to use SAR methodology to

manipulate chemical compounds. Nevertheless, I still have doubts as to the obviousness of the 6,5 perhydroindole ring in the '196 Patent from the prior art. As pointed out by Dr. Cimarusti, the prior art does not show a single example of a perhydroindole carboxylic acid moiety in a compound said to have ACE inhibition. Accordingly, the person of skill would have to select and then combine a series of disclosures from the prior art. I summarize the complications which a person of ordinary skill in the art would have encountered with tryptophan and THIQ (the prior art which Apotex focused on) as follows:

- Tryptophan:
    - Contains a flexible side chain whereas perindopril does not. It was unknown how this side chain fit into the S2 prime subsite.
    - The amino group connects to the backbone of the molecule whereas in perindopril it is the ring nitrogen that makes the connection.
    - Tryptophan contains double bonds whereas perindopril does not. Although I accept that the skilled user could potentially have used SAR methodology to reduce the bonds, it is an additional complication;

- Tanabe Application:

    - The skilled user would have to take the THIQ of the Tanabe Application and combine it with the Merck side chain resulting in a compound called quinapril. Although by no means determinative, it is insightful that the Federal Court of Appeal affirmed a lower ruling that quinapril was not obvious based on either a June 19, 1980 or October 3, 1980 date (*Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 FCA 209 at paras. 133-134, leave to appeal to S.C.C. refused, [2007] S.C.C.A. No. 377 [*Pfizer (C.A.)*];

    - The THIQ in the Tanabe Application contains a 6,6 ring with double bonds whereas perindopril contains a 6,5 ring without double bonds. This results in different structural and electronic properties such that it would be expected to interact differently. As with tryptophan, the skilled technician would have to overlook these differences and reduce the bonds; and

    - Finally, the skilled user would have to know to select a linear alkyl chain from the possible side chains in the Merck disclosures. Regardless of whether I accept Apotex's claim that the linear alkyl side chain is not part of the 196 invention below, I note that this is an additional complication.

[254] As acknowledged by Servier, a mosaic of prior art may be assembled in order to render a claim obvious. Even uninventive skilled technicians would be presumed to read a number of professional journals, attend different conferences and apply the learnings from one source to another setting or even combine the sources. However, in doing so, the party claiming obviousness must be able to demonstrate not only that the prior art exists but how the person of ordinary skill in the art would have been led to combine the relevant components from the mosaic of prior art. This case is a good example. Apotex asks the Court to conclude that a person of ordinary skill in the art, without inventiveness or ingenuity, could collate a relatively large number of discrete pieces of knowledge from a lengthy list of 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.

[255] Another factor that makes the task more difficult is that, as conceded by Dr. Marshall, small changes in structure can have unpredictable pharmacological effects

[256] The experts produced by Apotex who spoke to this issue focussed on each of the individual components from the prior art. When speaking of the obviousness of the 6,5 bicyclic ring, none of those experts effectively explained how a person skilled in the art would have known to combine all of the disclosures of the prior art to come up with the perhydroindole ring structure. I accept that there were suggestions in the prior art that such a ring might work. However, combining all of the suggestions of the prior art is, in my view, likely a task that required ingenuity and inventiveness. Overall, I prefer the expert evidence of Drs. Trost, Bartlett and Cimarusti.

(e) *Motivation*

[257] Moving to the next factor, only one of Apotex's witnesses, Dr. Marshall, spoke of the motivation that existed within the ACE inhibition field around October 1, 1980. In chief, he stated:

> They were precluded by the IP position of Squibb from going in certain directions. And so one of the directions that many, I think at least four different pharmaceutical companies that I have knowledge of, went was to basically make bicyclic analogs of, like, THIQ, for example, the tetrahydroisoquinoline, or various other indole derivatives and so on to basically replace the proline because they had plenty of evidence that there was room to make modification.

[258] In short, Dr. Marshall opines that the motivation of Servier was merely to get around Merck's IP position. I find this opinion to be completely speculative. Dr. Marshall was not working at Merck, Squibb, or any other company involved with ACE inhibition at the relevant time. His opinion on this point is not supported by any corroborating evidence. In contrast, Dr. Horovitz, who was working at Squibb in 1980, had this to say:

> I think I just had mentioned that we had a big effort -- when we saw that Merck had accomplished a better captopril, if you would, we had a big effort trying to protect our franchise, which we discovered, and trying to get compounds that were ACE inhibitors that had advantages over captopril and hopefully enalapril, although we didn't understand enalapril fully at that time.
>
> And we were unsuccessful until early to mid '80s, when we discovered a compound called to fosinopril, but we were putting all of our basic knowledge in the field which we pretty much at Squibb had discovered, and we still weren't able to do that until much later.

[259] In other words, at least at Squibb, 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. This testimony is support that a general motivation existed in the industry to build upon,

rather than merely work around, Merck, and suggests that inventive ingenuity was employed in the case at bar.

(f) *Time and Effort*

[260] Turning to the next *Janssen-Ortho (C.A.)* factor, it is uncontested that four different groups of chemists – ADIR, Hoechst, Warner-Lambert and Schering – developed compounds incorporating bicyclic ring modifications after Merck's disclosure at the Troy conference. Apotex submits that the fact that so many competitors in the same field came to the same structure around the same time suggests a finding of obviousness. The first problem with this assertion is that it is not clear on the record that any of the other chemists discovered perindopril, with its 6,5 bicyclic ring and a linear alkyl group. But, more importantly, there was no evidence before me that any of the other compounds were developed by persons of ordinary skill. We cannot equate the work of Drs. Smith and Vincent, whose inventiveness and ingenuity is unquestioned, with that of the person of ordinary skill in the art. Thus, this argument by Apotex provides no support to their obviousness argument.

(g) *Commercial Success*

[261] With respect to commercial success, it is uncontested that perindopril represents 80% of Servier Canada's sales and a significant portion of ACE inhibitor sales in Canada. This secondary factor, although of limited weight, favours a finding of non-obviousness.

(h) *Meritorious Awards*

[262] Finally, as no evidence was produced as to whether perindopril received meritorious awards, I find this factor to be neutral.

[263] Upon consideration of all the *Janssen-Ortho (C.A.)* factors I am not persuaded that the addition of the 6,5 perhydroindole bicyclic ring was obvious. Accordingly, I need not address Apotex's argument with respect to the linear alkyl side chain. Nevertheless, I make the following additional observations.

(2) Obviousness of linear alkyl side chain

[264] First, as with Apotex's argument regarding the 6,5 perhydroindole bicyclic moiety, Apotex's argument that there is no language in the description of the '196 Patent limiting the invention to a linear alkyl side chain is immaterial. Again, the invention at issue in the case at bar is not General Formula I but the compound, as claimed, having a bicyclic 6,5 moiety on the C-terminus and a linear alkyl group with 1 to 6 carbon atoms on the N-terminus.

[265] Second, although I recognize that both the *Nature* paper and the '401 Application include substituents with linear alkyl side chains, it does not mean that a person of ordinary skill in the art would be expected to know to select, without difficulty, this class of substituents among the many others written down (*Janssen-Ortho (C.A.),* above at para. 25).

E. *Conclusion*

[266] In conclusion, Apotex has not met its burden to establish, on a balance of probabilities, that claims 1, 2, 3 and 5 of the '196 Patent were, as of October 1, 1981, obvious.

IX. Utility

A. *Overview*

[267] The *Patent Act* defines an invention as something that is "new and useful" (*Patent Act*, s. 2). From this comes the concept of "utility".

[268] A number of principles associated with the law of utility are well established through the jurisprudence. To begin, the overarching concept is that, as of the relevant date, there must have been a demonstration of utility of the invention or, lacking that, a sound prediction of utility based on the information and science available at the time of the prediction (see, for example, *Merck & Co. v. Apotex Inc.* (2005), 41 C.P. R. (4th) 35 at para. 121 (F.C.); *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 26 at paras. 36-40, aff'd 2007 FCA 195, leave to appeal to S.C.C. refused, [2007] S.C.C.A. No. 371). Sound prediction is addressed in the following section of these reasons.

[269] As with the other questions of validity, Apotex bears the burden. To prove lack of utility, Apotex must show "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do" (*Consolboard*, above at 525).

[270] Beyond this general statement of the law, there are a number of other guiding posts:

- Where the specification does not promise a specific result, no particular level of utility is required - a "mere scintilla" of utility will suffice (*Fox*, above at 153). However, as stated in *Consolboard*, above, where the specification sets out an explicit "promise", utility must be measured against that promise;

- Utility does not depend upon marketability (*Consolboard*, above at 525; *Aventis Pharma*, above at paras. 271-272). In other words, in assessing whether an invention has utility, the issue is not whether the invention is sufficiently useful as to be able to support commercialization, unless commercial utility is specifically promised;

- The relevant date has been held to be the filing of the Canadian patent application (*Aventis Pharma*, above at paras. 88-96); and

- Where a claim is to a class of compounds, lack of utility of one or more of the compounds will invalidate all of the compounds of that particular claim (*Aventis Pharma Inc. v. Apotex Inc.,* 2006 FCA 64 at para. 26, leave to appeal to S.C.C. refused, [2006] S.C.C.A. No. 136).

[271] Quite simply stated, the question is whether the invention does what the patent promises that it will do.

[272] Apotex submits that there are compounds within claims 1, 2 and 3 of the '196 Patent that lack utility. The two key pieces of evidence that, in Apotex's view, lead one to that conclusion are: (a) an article titled Vincent *et al.*, "Synthesis and ACE Inhibitory Activity of the Stereoisomers of Perindopril (S 9490) and Perindoprilate (S 9780)" (1992) 9 Drug Design and Discovery 11 (the 1992 Vincent Article); and, (b) the testing performed by Dr. Gavras. The question of the utility of claim 5 is not in issue; the evidence is clear that the inventors had made and tested the compound of claim 5 (as twice corrected) prior to the filing of the '093 Application.

B. *Promise of the Patent*

[273] Central to the question of utility (and sound prediction which is discussed in the next section) is the promise of the patent. As noted, utility is measured against what the patentee promises will be accomplished by his invention. The views of Apotex and Servier on this important concept diverge dramatically.

(1) Position of Apotex

[274] In simple terms, Apotex argues that the '196 Patent promises that all of the claimed compounds will have ACE inhibitory effect and therapeutic use as an anti-hypertensive. In reaching this conclusion, Apotex relies on the expert testimony of Dr. Gavras, Dr. Marshall, Dr. Thorsett, Dr. McLelland and Dr. Brunner.

[275] Dr. Gavras, in his expert report, opines that:

> [T]he '196 Patent promises that the compounds of the invention will inhibit the conversion of Angiotensin I to Angiotensin II to obtain a reduction in the hypertensive activity of Angiotensin II of about:
>
> 1) 50% to 100% after 30 to 90 minutes after administration, and
>
> 2) 40 to 80% more than 6 hours after administration.
>
> Some compounds (unidentified in the '196 Patent) remain active 24 hours after administration. Thus, according to the '196 Patent teachings, the compounds of the invention will be useful in reducing or suppressing the activity of the enzymes responsible for hypertension and/or cardiac insufficiency.

[276] Dr. Marshall also examined utility of the claims from a basic premise that all of the claims of the '196 Patent promised utility in the treatment of hypertension and/or cardiac insufficiency. Similarly, Dr. Thorsett provides his expectation that all of the compounds are able to inhibit "the conversion of angiotensin I to angiotensin II and thus provide anti-hypertensive action and cardiac insufficiency treatment which is the utility ascribed to the compounds taught in the '093 Application". Dr. McLelland also began his consideration of the question of utility with his opinion that utility/sound prediction could only be shown if "all of the compounds forming the subject

matter of claims 1, 2 and 3 of the '196 Patent would have pharmaceutical and therapeutic utility as ACE inhibitors, and thus would be useful in the treatment of hypertension and/or cardiac insufficiency". A similar opinion was expressed by Dr. Brunner.

[277] Apotex also refers to the Abstract of the '196 Patent, which includes a direct statement that « Ces composés sont utiles comme médicaments. »

(2) Position of Servier

[278] The experts put forward by Servier took a narrower view of the promise of the '196 Patent. Dr. Bartlett was asked to examine the utility promised for the compounds disclosed by the patent. Key facets of his opinion are the following:

- The '196 Patent teaches first and foremost that the compounds disclosed have utility as inhibitors of certain enzymes, among them ACE;

- An anti-hypertensive effect of the compounds is not expressly promised in the patent, although one skilled in the art would understand that the utility of an ACE inhibitor is as a potential anti-hypertensive agent; and

- The '196 Patent makes no quantitative promise for all of the compounds, as stated by Dr. Gavras. Nor would someone skilled in the art interpret the '196 Patent to mean that every compound was tested.

[279] In his expert report, Dr. Cimarusti concluded that the '196 Patent teaches that the compounds claimed all have ACE inhibition activity. He opined that a person skilled in the art would expect some of the compounds of the invention would have the activity necessary to treat hypertension or cardiac insufficiency. Further, he stated, "[N]o person skilled in the art would expect that each compound claimed in the '196 Patent would have pharmacological activity necessary to treat hypertension and cardiac insufficiency in humans."

[280] Similarly, Dr. Karmazyn summarized the promise of the '196 Patent as follows:

> In summary, a person skilled in the art would understand the utility of the patent to be enzyme inhibition, in particular inhibition of carboxypolypeptidases, enkephalinases or ACE. There is no teaching as to a particular threshold of inhibition nor any promise of clinical or commercial utility.

(3) Analysis

[281] In determining this question of the promise of the patent, I must remind myself that: "(...) where the language of the specification, upon a reasonable view of it, can be so read as to afford the inventor protection for that which he has actually in good faith invented, the court, as a rule, will endeavour to give effect to that construction (...)" (*Consolboard*, above at 157).

[282] Having considered all of the expert evidence of all of the experts and the specification of the '196 Patent, I find that the opinions of Drs. Bartlett, Cimarusti and Karmazyn are to be preferred to those of Drs. Gavras, Marshall, Thorsett, McLelland and Brunner.

[283] Some of the Apotex witnesses were reading the patent document as requiring commercial utility. Of particular note, I refer to Dr. Brunner's testimony. He was told by Apotex's counsel that commercial utility is not to be confused with utility in terms of patentability of the invention. In spite of this, when cross examined, Dr. Brunner agreed that his concept of utility for this patent was that a doctor would be able to prescribe the compound for treatment of hypertension or cardiac insufficiency. This interpretation of the patent was also the basis of Dr. Gavras's testimony. By requiring that each and every compound needs to be successful to the point of being a drug that a doctor could prescribe, the experts are infusing their reading of the patent with the need for a commercialized product.

[284] The first and most significant reference to the utility of the '196 Patent is contained in three paragraphs on page 3 of the specification:

> *Les composés selon l'invention ainsi que leurs sels pos-sèdent des propriétés pharmacologiques intéressantes. Ils exercent notamment une activité inhibitrice sur certaines enzymes, comme les carboxypolypeptidases, lest enkephalinases ou la kininase II. Ils inhibent notamment la transformation du décapeptide angiotensine I en l'octapeptide angiotensine II, responsable dans certains cas de l'hypertension artérielle, en agissant sur l'enzyme de conversion.*
>
> *L'emploi en thérapeutique de ces composés permet donc de réduire ou même supprimer 1'activité de ces enzymes responsables de la maladie hypertensive ou de 1'insuffisance cardiaque. L'action sur la kininase II a pour résultat 1'augmentation de la bradykinine circulante et également la baisse de la tension artérielle par cette voie.*

> *L'invention s'étend aussi aux compositions pharmaceuti-ques renfermant comme principe actif au moins un compose de formule générale I ou un de ses sels d'addi-tion, avec une base ou un acide minéral ou organique, en association avec un excipient inerte, non toxique, pharmaceutiquement acceptable.*

[285] I think that there can be no doubt that the promise of ACE inhibition is made, unambiguously and without reservation, in the first paragraph cited above. As translated, this passage states clearly that the compounds inhibit the transformation of the decapeptide angiotensin I to the octapeptide angiotensin II.

[286] The second paragraph refers to the therapeutic use but is to some degree ambiguous. Do the words « *permet donc de réduire ou même supprimer 1'activité de ces enzymes . . .* » mean that all of the compounds will have utility as anti-hypertensive medicines in humans? Or, is the specification of the patent stating that therapeutic use of the compounds may have therapeutic value? This ambiguity is reflected in the disparate views of the experts. If there was one common meaning, I would have expected all of the experts to have come to the same view. They did not.

[287] In my view, the passages cited do not teach that every one of the compounds has the same or any therapeutic use in humans. The better and more reasonable view of the second paragraph, read in its entirety with the balance of the '196 Patent, is that it contains an explanation of how a particular compound could be put to therapeutic use. In other words, the patent teaches that the ACE inhibition exhibited by all of the compounds makes it possible that they could be used to treat hypertension and cardiac insufficiency. I do not read a guarantee into those words as was done by Drs. Gavras, Marshall, Thorsett, McLelland and Brunner.

[288] Finally, I refer to the sentence in the Abstract or Précis that reads « Ces composés sont utiles comme médicaments. » Apotex submits that this is another embodiment of the promise of the patent. I do not agree. These exact words were also contained in the '093 Application. Subsection 175(1) of the *Patent Rules* is a response to Apotex's argument. That provision states that:

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.	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.

[289] The direction and intent of this provision is clear; the abstract cannot be taken into account in interpreting the scope of protection sought or obtained. Whatever the purpose of the abstract, it cannot be used – before or after the issuance of the patent – to construe the patent or its promise.

[290] My assessment of the promise of the '196 Patent is not inconsistent with the determination of Justice Heneghan in *Pfizer*, above. In that case, Justice Heneghan was asked to examine the utility of claims of Canadian Patent No. 1,341,330 ('330 Patent), which patent covers quinapril. Pfizer argued that a purposive construction of the relevant claims, including reference to the specifications, discloses that the invention of the '330 Patent relates to ACE inhibition. On the other hand, Apotex argued that all of the claims of the '330 Patent promise compounds useful in reducing or relieving hypertension, which is distinct from ACE inhibition. It submitted that not all ACE inhibitors have sufficient inhibition activity to be capable of acting as an anti-hypertensive useful in the treatment of hypertension. With reference to the specification of the '330 Patent, Justice Heneghan concluded that the claims of the '330 Patent would be read by a person skilled in the art

as referring to compounds useful for the relief of hypertension (*Pfizer*, above at para. 64). However, it appears clear that she reached this conclusion on the basis of specific words in the '330 Patent. The abstract of the patent stated that: "The compounds of the invention, their salts and pharmaceutical compositions thereof are useful as antihypertensive agents" [Emphasis added]. Another example of this direct promise could be seen in the sentence in the specification that read:

> 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 (*Pfizer*, above at para. 65).

[291] Although reversed in the Federal Court of Appeal, the Court of Appeal concluded that Justice Heneghan's characterization of the promise "is reasonable in light of the passage cited above and the overall [tenor] of the disclosure" (*Pfizer (C.A.)*, above at para. 121).

[292] There are important distinctions to be made between the "overall [tenor] of the disclosure" disclosed in the specification for the '330 Patent and that of the '196 Patent. In particular, there is no statement in the '196 Patent, as there was for the '330 Patent, that the compounds of the invention, their salts and pharmaceutical compositions thereof are useful as antihypertensive agents.

[293] In sum, I conclude 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.

[294] With this promise in mind, I turn to the two arguments made by Apotex.

C. *The 1992 Vincent Article*

[295] Apotex's first argument relates to the 1992 Vincent Article. The paper, while published in 1992, was the result of work carried out by a number of employees within Groupe Servier beginning in 1985. Two of the authors – Dr. Vincent and Dr. Jaguelin – appeared as witnesses at the trial and spoke to the 1992 Vincent Article. Dr. Laubie did not appear as a witness at the trial. However, he was a witness on discovery for Servier and was examined on, *inter alia*, the 1992 Vincent Article.

(1) Context of the 1992 Vincent Article

[296] I think that it is useful to situate the 1992 Vincent Article. What was disclosed? What did the authors conclude?

[297] It is clear that the authors assumed the huge task of producing and testing the 32 stereoisomers of perindopril (referred to as **1** (S SS SS) in the paper, that being a reference to the chirality of the 5 stereocentres of perindopril). But why did they do that? I begin by looking at the text of the 1992 Vincent Article. The article's abstract is of some limited help in this regard:

> Perindopril, a powerful ACE inhibitor contains 5 chiral carbons, thus there is the possibility of $2^5 = 32$ stereoisomers for the general structure 1. These 32 stereoisomers were synthesized by cross-coupling the 8 stereoisomer of perhydroindole 2-carboxylic acid benzylester with the 4 stereoisomers of 2-(1-carbethoxybutylamino) propionic acid 4, then hydrogenating the resulting benzylesters. Each stereosoismer of perindopril furnished by saponification the corresponding diacids stereoisomer 2 of perindoprilate which is the active form of perindopril. For each of the 32 stereoisomer 2 the *in vitro* ACE inhibitory potency (IC_{50}) was determined. Four of them,

> including perindoprilate, had activities in the nanomolar range, and four more were ca. 10 x less active. The four acid esters 1 corresponding respectively: to the four most active diacids 2 *in vitro* were studied (1 mg/kg *via* the oral route) for their *in vivo* activity in dogs. It could be concluded that p.o. absorption of the active acid esters 1 and their activation to the active diacid 2 depended only on the chiralities of the two ring junction carbons of the perhydroindole ring.

[298] Turning to the actual text of the article, we see a brief history of the development of perindopril at page 12, where the authors state:

> Many difficulties were encountered during the course of the synthesis of **1** (S SS SS), mainly because it contains five asymmetric carbon atoms. Thus there is the possibility of 25 = 32 stereoisomers for the general structure **1**.
>
> These problems have been solved and now large quantities of **1** (S SS SS) are produced industrially. Nevertheless, one or several stereoisomers of **1** and/or **2** could be present as impurities in some batches. Moreover, these "impurities" could be eventually active as inhibitors of ACE. For these reasons, we decided to realize the synthesis of the thirty-two stereoisomers of **1** and of the thirty-two stereoisomers of **2** [perindoprilate].
>
> Here we describe the synthesis of these sixty-four compounds and we also report the values obtained by measuring the inhibitory activity (IC_{50}) of the stereoisomers of **2** on ACE *in vitro*. The knowledge of IC_{50} for all stereoisomers of **2** is the source of very interesting chirality-activity relationships.

[299] After spending considerable time describing the method of synthesis, the authors reported on the *in vitro* testing of the 32 isomers of diacid 2, beginning at page 18. On the basis of the testing results, the compounds were divided into three groups. The first group of four compounds (with configurations (S SR SS), (S RS SS), (S SS SS) and (S RR SS) demonstrated the highest activity. The second group of four (S SS SR), (S SR SR), (S RR SR) and (S RS SR) "retained 1/10 of the

activity given by the first group derivatives". The authors reported on the remaining 24 compounds as follows:

> A *third group* contained all of the other compounds, with low to zero activities. Their C_2 and/or C_9 being of R configuration, no rational conclusions can be drawn from their structure-activity relationships. These compounds seemed not to be able to bind to the active site of ACE. [Emphasis added.]

[300] The authors went on to test the group 1 compounds *in vivo*.

(2) Table I in the 1992 Vincent Article

[301] One prong of Apotex's attack on the utility of the '196 Patent is that a number of the 32 compounds claimed by claim 3 of the '196 Patent are not active as ACE inhibitors. That is, even on the narrower construction of the promise of the '196 Patent, many of the stereoisomers of perindopril show no ACE inhibition. Apotex points to the statement in the 1992 Vincent Article (set out above) that describes 24 of the stereoisomers that would be covered by claim 3 of the '196 Patent as having "low to zero activities" and as seeming to be unable "to bind to the active site of ACE".

[302] Both parties and a number of expert witnesses referred extensively to Table I, at page 19 of the article. I have reproduced the information contained in Table I in the following chart:

TABLE I

Configuration of 2					
2	3a	7a	9	11	IC_{50} (nM)
S	S	R	S	S	1.1
S	R	S	S	S	1.2
S	S	S	S	S	1.5
S	R	R	S	S	3.3
S	S	S	S	R	12.2
S	S	R	S	R	29.4
S	R	R	S	R	39.8
S	R	S	S	R	54.0
R	R	S	S	S	108.0
S	S	S	R	S	1.1×10^3
R	S	S	S	S	1.9×10^3
S	S	R	R	R	2.6×10^3
R	R	S	S	R	5.5×10^3
S	S	R	R	S	7.1×10^3
R	R	S	R	S	7.8×10^3
R	S	R	R	R	23×10^3
S	R	R	R	R	33×10^3
R	S	S	S	R	36×10^3
R	S	R	S	R	47×10^3
R	S	R	S	S	60×10^3
R	R	R	R	R	$\sim 10^5$
S	R	R	R	S	$\sim 10^5$
R	R	R	S	S	$\sim 10^5$
S	R	S	R	R	$\sim 10^5$
R	R	R	R	S	$\sim 10^5$
R	R	S	R	R	$\sim 10^5$
S	S	S	R	R	10^5
R	S	S	R	S	10^5
R	R	R	S	R	10^5
R	S	S	R	R	10^5
R	S	R	R	S	10^5
S	R	S	R	S	10^5

[303] The measure of activity was the IC_{50} value. Dr. Horovitz, in his expert report, described the IC_{50} measurement as follows:

> IC_{50} refers to the concentration of the drug that inhibits fifty percent (50%) of the activity of the enzyme *in vitro*. The lower of the IC_{50} value, the less amount of compound is necessary to inhibit the response. In other words, the lower the number for IC_{50}, the more potent the compound. IC_{50} is usually expressed in terms of moles per litre (M). The calculation of IC_{50} is made from the assessment of the activity of a compound at different concentrations. An IC_{50} is the standard measure of an activity of a compound at different concentrations. An IC_{50} is the standard measure of activity of a compound *in vitro*, both in 1981 and today.

(3) Dr. Laubie's Admission

[304] An important aspect of the evidence that, in Apotex's view, supports their position comes from an "admission" by Dr. Laubie. Dr. Laubie is one of the named inventors of the '196 Patent and a co-author with Dr. Vincent and others of the 1992 Vincent Article. Dr. Laubie was examined in discovery. The parties agreed that his discovery testimony would be accepted as read in and that Dr. Laubie would not be called as a witness in the trial.

[305] Apotex submits that Dr. Laubie agreed with the conclusion at page 20 of the 1992 Vincent Article that a number of the compounds in Table I had "low to zero activities" *in vitro*. In response, Servier contends that, during the discovery questioning, Dr. Laubie was referring to *in vivo* activity and not to *in vitro* activity. The difference is important; a compound may be active *in vitro* and inactive *in vivo*. If Dr. Laubie was speaking of *in vivo* – and not *in vitro* compounds, this aspect of Apotex's argument is substantially weakened.

[306] I begin by setting out the entire passage from the discovery of Dr. Laubie by counsel for Apotex:

> BY MR. RADOMSKI:
>
> Q. Okay, can we look at page 20, the paragraph before the one that reads in vivo studies. I'm wondering whether what is expressed in this paragraph was your view when this paper was written about the third group of compounds that are discussed in this paragraph?
>
> MR. RADOMSKI: I'm happy for you to translate the paragraph for the, Doctor ([r]eferring to the interpreter.)
>
> THE WITNESS: All of these products that you see here and the results, all of these are inactive products, 10 minus 3, all of these are inactive.
>
> BY MR. RADOMSKI:
>
> Q. He's pointing to the table on page 19; is that right?
>
> A. Yes.
>
> Q. And you say all of these products in table 1 are inactive?
>
> A. Not all of them.
>
> Q. Which?
>
> A. I would say, if you look at this series, there are at the most three or four active products in vivo.
>
> Q. They're the first three or four?
>
> A. Yes.
>
> Q. And the balance, in your view, are inactive?
>
> A. That is correct.
>
> Q. And so going back to the paragraph on page 20, before the heading "in vivo studies", I take it you agree with the conclusion in that paragraph?
>
> A. Yes.

[307] The question is whether, from this transcript reference, I can conclude that Dr. Laubie admitted that the third group of compounds had "little to zero" activity *in vitro*. There are a number of difficulties with this passage. First, while the words *in vivo* appear twice in the extract, there are no explicit references to *in vitro*. While Mr. Radomski may have been clear, in his own mind, that he was asking about *in vitro* activity, he did not put those words to the witness. In contrast, when Dr. Laubie stated, "I would say, if you look at this series, there are at the most three or four active products in vivo", it is clear that the witness was focussed on *in vivo* activity – at least at that moment. At best, there is ambiguity.

[308] I also take into account that the examination involved an interpreter. In that situation, it is always possible that either the witness or the counsel misunderstood the questions or answers.

[309] In light of the explicit reference to "in vivo" by Dr. Laubie and the difficulties inherent in translation, I find that it is more likely than not that Dr. Laubie was speaking about *in vivo* activity.

[310] However, even if Dr. Laubie's words can be interpreted as an admission, any such admission must be weighed with the other evidence relating to the meaning of the 1992 Vincent Article.

(4) The Purpose of the 1992 Vincent Article

[311] The purpose for which the article was written must be considered.

[312] As written, it appears to me that the first purpose of the paper was to report on the successful synthesis of the 32 stereoisomers of each of perindopril and perindoprilate. Secondly, the paper was intended to stress the importance of chirality on structure-activity relationships. This second objective was attained by comparing the relative activities of the various compounds, with the focus on those with the highest activities (group 1). To put this into the negative, I would not read the 1992 Vincent Article as a description of the absolute activity of all 32 stereoisomers of perindopril.

[313] As stated by Dr. Bartlett, the purpose of the 1992 Vincent Article was "to compare the levels of ACE inhibitory activity among the various stereoisomers, not to establish the presence or absence of activity for any particular stereoisomer." In Dr. Bartlett's view, the article "only establishes that the IC_{50} values of certain compounds are no better than 10^{-4} nM, not that they fail to meet the utility promised by the '196 Patent." I agree with this assessment by Dr. Bartlett.

(5) The Underlying Data

[314] It is helpful that we have the underlying internal pharmacological testing data for all of the results shown in Table I in the 1992 Vincent Article. Each and every one of the compounds showed some activity. This is evidenced by the pharmacological testing sheets, where it appears that a cut-off point of 10^{-5} nM was used for reporting purposes. However the pharmacological data show that, as the concentrations increased, the compounds showed good inhibition. For example, Dr. Horovitz discussed the all-R stereoisomer of perindopril which, at the highest concentration tested, inhibited ACE by 46%. His unchallenged and uncontradicted evidence is that, had a higher concentration

been tested, an inhibition over the 50% mark would have occurred and a precise IC_{50} value could have been calculated.

[315] The Apotex experts provided little insight or opinion on the internal pharmacological testing data. Dr. Marshall suggested that any activity seen with R stereoisomers was due to some contamination with S stereoisomers. Dr. Marshall admitted not only that this was speculation but that the R stereoisomers have some IC_{50} potency themselves which is not due to contamination.

[316] Why would the authors not refer to the actual test results for the least active compounds but refer only to approximate values? The answer to this comes from the purpose of the paper. The authors were examining relative activity and not absolute activity. In that context, they were only pointing out the relative lack of activity and their own disinterest in the compounds that would not be capable of commercialization. However, the fact remains; the internal pharmacological testing data demonstrate that all of the compounds had ACE inhibition activity. This, in my view, satisfies the requirement that a "mere scintilla" of utility be shown.

(6) Dr. Vincent's Testimony

[317] Finally, I turn to the testimony of Dr. Vincent, one of the authors. When asked about the "low to zero" comments in the paper and Table I, Dr. Vincent stated the following:

> Là, j'ai exagéré. Ce ne sont pas des composés qui n'ont pas d'activité. S'ils avaient une activité zéro, dans la colonne de droite on aurait mis zéro, on n'aurait pas mis des chiffres.

> Ces chiffres sont élevés, mais il y a une très petite activité. Cette très petite activité veut dire que ces produits ne seraient pas, de toute façon, commercialisables.
>
> Ça veut dire que ces produits sont d'une activité faible, non nulle, mais qui ne sont pas commercialisables. Je crois qu'il faut insister là-dessus.
>
> Le zéro est de trop. Si c'était zéro, j'aurais mis zéro. Il y a pas zéro. [Emphasis added.]

[318] When asked during cross-examination about the sentence in the paper that reads, "These compounds seemed not to be able to bind to the active site of ACE", Dr. Vincent's response was:

> [S]'ils avaient été totalement incapables de se lier, je n'aurais pas écris "Ces composés ne semblent pas être capables." J'aurais écrit "Ces composés ne se lient pas." Et ça aurait été en relation avec ce zéro, qui lui, est une erreur.

(7) Conclusion in Respect of the 1992 Vincent Paper

[319] Weighing all of the evidence before me with respect to the meaning of the 1992 Vincent Article, I find that the 1992 Vincent Paper 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. I make this finding, in spite of the reference in the journal article to "low to zero activity", based on the following evidence:

- The evidence of Dr. Laubie on this point is, at best, ambiguous;

- The purpose of the article was not to describe absolute activity or inactivity;

- Table I does not state that the least active, third group, of compounds had "zero" activity;

- As evidenced by the underlying pharmacological testing data, an IC_{50} value was obtained for every one of the compounds; and

- Dr. Vincent, one of the authors, was clear in his explanation of the "low to zero" activity.

D. *Dr. Gavras's Testing Report*

[320] Apotex's second argument on utility relates to testing performed by Dr. Gavras. In Apotex's view, the test results demonstrate that at least one of the compounds of claim 3 of the '196 Patent lacks utility.

(1) Description of the Testing

[321] At the request of counsel to Apotex, Dr. Gavras carried out supervised *in vivo* and *in vitro* testing of three compounds to evaluate their ACE inhibiting capacity and anti-hypertensive activity in comparison to perindopril. Dr. Gavras's results and testing methodology were set out in his report (the Gavras Report).

[322] The three compounds tested against perindopril consisted of an (R RR RR) stereoisomer of perindopril and two analogs. As such, they would all have been included in claim 3 of the '196 Patent. As described in the Gavras Report, the compounds were:

A – (R,R,R,R,R)-Perindopril methyl ester analog

B – (R,R,R,R,R)-Perindopril butyl analog

C – (R,R,R,R,R)-Perindopril

[323] Compound D was perindopril as set out in claim 5 (as twice corrected) of the '196 Patent.

[324] Dr. Gavras described his task as follows:

> The compounds were to be tested *in vitro* for their capacity to inhibit the effect of pure ACE to hydrolyze peptide substrates by removing two amino acids from the C-terminal of a polypeptide . . . ; and in vivo for their capacity to inhibit conversion of angiotensin I (Ang I) to angiotensin II (Ang II) in normotensive rats and for their capacity to lower the blood pressure in renin-dependent hypertension of renovascular hypertensive rats in the early phase of hypertension, which is purely angiotensin-dependent.

[325] Dr. Gavras noted that all four compounds were provided and utilized for the *in vitro* testing in ester form. Dr. Gavras acknowledged, in his report, that all four compounds should have been completely deesterfied prior to testing since "the active compounds *in vivo* are the diacids". Nevertheless, he noted that Compound D, even though in ester form, gave almost complete ACE inhibition.

[326] Dr. Gavras reported that, relative to compound D (perindopril), compound A had a 50% inhibitory capacity *in vitro*; and that *in vitro* effects of compounds B and C were described as "totally devoid of ACE inhibiting activity".

[327] The *in vivo* studies on normotensive rats showed that none of the three compounds (A, B or C) could inhibit the conversion of exogenously injected Ang I to Ang II; and complete inhibition by Compound D.

[328] The *in vivo* testing on rats with renovascular hypertension of the two-kidney-one-clip type showed no drop in blood pressure for compounds A, B or C; and a 47 mmHg fall in mean blood pressure lasting for several hours for Compound D.

(2) Apotex's Argument

[329] As stated in their written final argument, Apotex's position on this issue is the following:

> When the question of whether all of the compounds claimed by claims 1, 2 and 3 of the '196 Patent are able to generate a therapeutic anti-hypertensive effect is asked, Apotex respectfully submits that the *in vivo* testing performed by Dr. Gavras clearly demonstrates that some of the compounds do not provide such an effect.

(3) Apotex's Underlying Premise

[330] The first point to highlight is that Apotex's argument assumes that the promise of claims 1, 2 and 3 is that the compounds of those claims have a "therapeutic anti-hypertensive effect". As discussed above, I do not accept this broad interpretation of the promise of the '196 Patent. Accordingly, Dr. Gavras's testing conclusions, as relied on by Apotex, are not relevant.

(4) Problems with the Testing Methodology

[331] However, even if I were to carry on to assess the results obtained by Dr. Gavras, I would come to the conclusion that the results should be given little to no weight.

[332] Drs. Horovitz, Cimarusti and Karmazyn, in particular, were very critical of Dr. Gavras's testing methodology, to the point where they concluded that the experimental design renders it impossible to determine whether compounds A, B or C had ACE inhibition activity.

[333] Dr. Brunner replied, in his Reply Affidavit and in oral testimony, to the various criticisms of Dr. Gavras testing methodology. During his oral testimony, Dr. Brunner described what I believe was his approach to all of the criticisms as follows:

> I would -- my point is that this is -- as I said before, this is not a study submitted to a scientific journal to describe the three compounds with the positive control of the fourth of perindopril.
>
> This is just evaluation to these three compounds to fulfil the promise of the patent, or not, which is therapeutic utility.

[334] The problem that I see with this line of reasoning is that, while the study was not done for submission to a scientific journal, it was done for the purpose of invalidating a patent. This is a very serious consequence. While I would not demand perfect compliance with the norms required for peer-reviewed publications, I would expect an adequate level of scientific rigour.

[335] I turn to the specific criticisms.

[336] Lack of statistical analysis. No statistical analyses were conducted on any of the testing results. Apotex and Dr. Brunner (in addition to his general rejection of all of the criticisms) dismiss this criticism on the basis that statistical analysis is not needed when no activity is shown. If this were the only concern that I had with the testing, I would likely agree with Dr. Brunner.

[337] State of test compounds. Even Dr. Gavras acknowledged that all four compounds should have been completely deesterfied prior to testing since "the active compounds *in vivo* are the diacids". Theoretically, none of the compounds should have shown results *in vitro***.** Nevertheless, Dr. Gavras found that Compound A inhibited ACE, relative to perindopril, by 50%. To explain this apparent anomaly, Dr. Gavras was forced to assume that some of the compounds had partly deesterified. Yet, because no analytical testing was conducted, Dr. Gavras had no way of knowing whether or to what extent the other compounds had deesterified. The state of the compounds thus remains a mystery and the effect of partial deesterification on the testing is unknown. This is a serious shortcoming in the testing.

[338] Only one concentration/dose tested. Contrary to the protocol that he established, Dr. Gavras did not test multiple concentrations or doses of the compounds *in vitro*. The reason given was that to determine relative efficacy, one only needs to give one dose. Accordingly, the only conclusion that can be made from the Gavras Report is what effect one concentration dose had on inhibiting ACE. There is no evidence whatsoever that a higher concentration or dose would not have resulted in increased ACE inhibition activity. I agree with this criticism.

[339] Waiting period for *in vivo* activity assessment. Dr. Gavras's protocol mandated that the level of activity for each compound be tested for several hours after administration *in vivo*. However, Dr. Gavras admitted that in only one animal (Ql) did he wait more than 20 minutes. In the opinions of both Dr. Karmazyn and Dr. Horowitz, the consequence of not waiting the minimum 30 minutes to one hour is that one cannot be certain that the compound has converted to the active diacid form. In my view, this is another serious flaw.

[340] Lack of controls and lack of randomization. Dr. Gavras did not a use sham control and did not randomize his animals in the *in vivo* testing. Drs. Horowitz and Karmazyn opined that both are important controls to ensure that an effect or lack thereof is not attributable to the design protocol. Particularly on the question of randomization, I agree with the criticisms.

[341] Having reviewed the evidence and testimony surrounding the testing by Dr. Gavras, I conclude that the results are seriously compromised by the problems described above. The cumulative impact of the problems pointed out by the experts cannot be ignored. Accordingly, I would give no weight to the Report of Dr. Gavras on the testing of the compounds.

(5) Conclusion on the Gavras Report

[342] In summary on the Gavras Report and its relationship to utility, I find that Apotex's arguments do not establish a lack of utility for the compounds of claim 3. The reasons, as described in detail above, are as follows:

(a) Apotex relies on the Gavras Report to demonstrate that certain of the compounds of claim 3 do not have a "therapeutic anti-hypertensive effect". Since this is not the promise of the patent, the testing results are irrelevant.

(b) In any event, the testing methodology of Dr. Gavras is so seriously flawed that little weight can be given to his results.

E. *Conclusion on Utility*

[343] Based on the above analysis, I find that Apotex has not satisfied its burden to show that the compounds of claims 1, 2 and 3 of the '196 Patent lack utility.

X. Sound Prediction

A. *Overview*

[344] Given that Apotex has failed to persuade me of the lack of utility of the compounds of Claim 3 on the basis of the Gavras Report or the 1992 Vincent Article, I turn to the notion of sound prediction. As noted in the section that precedes, the law requires that, as of the relevant date, there must have been a demonstration of utility of the invention or, lacking that, a sound prediction of utility based on the information and science available at the time of the prediction.

[345] As noted, claims 1, 2 and 3 are claims to a class of compounds. The evidence before me shows that some but not all of the compounds were tested by the inventors prior to application of the patent. It is not, however, essential that complete testing have been carried out. The doctrine of sound prediction can be relied upon by an inventor to justify patent claims whose utility has not been actually demonstrated, but can be soundly predicted based upon the information and expertise available (*Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 [*Wellcome (S.C.C.)*]). Because there was not testing of all of the compounds included in claims 1, 2 and 3, the question is whether, based on the information and science available at the time of the prediction, the inventors could make a prediction of utility for all of the compounds claimed.

[346] The soundness or otherwise of the prediction is a question of fact.

[347] In *Wellcome (S.C.C.)* above, at para. 70, the Supreme Court of Canada articulated a three-part test that must be satisfied in order to establish that a sound prediction has been made by the purported inventor. The three elements of the test are:

1. There must be a factual basis for the prediction;

2. The inventor must have an articulable line of reasoning from which the desired result can be inferred from the factual basis; and

3. There must be proper disclosure, although it is not necessary to provide a theory as to why the invention works.

[348] To be sound, a prediction does not need to amount to a certainty, as it does not exclude the risk that some compounds within the area claimed may prove to be devoid of utility. The test contemplates that the Canadian filing date be used for the purposes of assessing the soundness of the prediction.

[349] Thus, the question is whether, as of the date of the Canadian filing, ADIR and its scientists had a factual basis for their prediction, and an articulable line of reasoning from which the desired result could have been inferred from the factual basis.

[350] Under the heading of sound prediction, Apotex makes two separate assertions:

1. The inventors could not have predicted that the compounds with an (R,R,R) configuration on the backbone would have any ability to fulfill the promise of the patent; and

2. The '196 Patent does not disclose any methodology as to how to make the trans perhydroindole molecules claimed by claims 1, 2 and 3.

[351] I will consider each of these in turn.

B. *Prediction of Utility of the (R,R,R) Compounds*

[352] I begin my analysis by noting that Dr. Brunner did not did not speak to the soundness of the all-R backbone. His testimony is therefore not relevant to this issue. Furthermore, a review of Dr. Gavras's testimony reveals he erroneously approached the question of sound prediction by examining *ex-post facto* material such as the 1992 Vincent Article as well as his own testing of the '196 Patent. Accordingly, I give no weight to his opinion with respect to this issue either.

[353] Apotex correctly points out that the '196 Patent, in claims 1, 2 and 3, claims a number of compounds with one or more stereocentres in the R-configuration. As of October 1, 1981, the inventors had not tested any compounds with an (R,R,R) configuration on the backbone of the claimed molecule. Apotex submits that the named inventors of the '196 Patent did not have, and could not have had, a prediction that compounds with the (R,R,R) configuration on the backbone of the molecule would possess the promised utility of the '196 Patent. Indeed, Apotex asserts that, in light of the state of the art as of the filing date of the '196 Patent, the undeniable prediction would be that such compounds would not possess utility as anti-hypertensive agents or even as ACE inhibitors.

[354] In support of its claim, Apotex relies on a number of captopril-related scientific papers which Apotex argues demonstrate that it was known, as of October 1, 1981, that compounds with

the S-configuration on the two stereocentres of captopril and its analogs had markedly superior activity in comparison to those with the R-configuration. These papers include:

- the *Experientia* paper*;*
- the *Science* paper;
- the *Biochemistry* paper*;*
- the *Progress in Cardiovascular Diseases* paper; and
- the *Biological Chemistry* paper.

[355] Apotex submits that the teachings of the captopril-related papers were reinforced by the Merck disclosures at the Troy conference in June 1980, in the '401 Application, and in the *Nature* paper, which, together, stated that compounds with the S-configuration were significantly more active than compounds with the R-configuration and that the S-configuration was to be preferred.

[356] Servier, for its part, relies on the same prior art cited by Apotex, above, but offers a different interpretation as to how the art would be understood by the person skilled in the art. In brief, Servier submits that a proper reading of the prior art suggests that compounds with the (R,R,R) configuration would have less but still some activity.

[357] I agree with Apotex that, as of October 1, 1981, the prior art had taught that the (S,S,S) configuration at the three stereocentres of the backbone was preferred to the (R,R,R) configuration. I also agree that the prior art had demonstrated that compounds with an all S-configuration showed significantly more activity than compounds with the R-configuration. Regardless, upon reviewing the prior art, I am still not persuaded that Servier did not have a sound basis for predicting that compounds with the all R-configuration would have ACE inhibitory activity. In making this conclusion I return to the promise of the patent at issue.

[358] To reiterate my earlier finding, the promise of the '196 Patent was that all of the compounds claimed would have some level of ACE inhibition when measured *in vitro* and that some of the compounds would have sufficient activity to treat hypertension and cardiac insufficiency. There was no prediction or promise that all of the compounds of claims 1, 2 and 3 would be capable of treating hypertension or cardiac insufficiency. It follows that there was no prediction that any of the compounds with an all R-configuration on the backbone would necessarily be capable of treating hypertension or cardiac insufficiency.

[359] While admittedly demonstrating that compounds with the R-configuration had a low level of activity as compared to those with the S-configuration, the conclusion I draw from the prior art relied on by Apotex is that compounds with the R-configuration at various positions of the backbone would be expected to have some level of ACE inhibition. Indeed, this was not disputed by Apotex's experts, Drs. Marshall, McClelland, and Thorsett, who agreed that some activity was

recorded in the prior art when stereoisomers with the R-configuration had been used. For example, in his affidavit, Dr. Thorsett writes:

> By the filing date of the '093 Application… it had been established as part of the common knowledge of the person skilled in the art that certain stereochemical configurations at centers 1-3… namely one or more of them being "R" was readily associated with an extremely poor and non-useful inhibitor activity against ACE in vitro. [Emphasis added.]

[360] Similarly, Dr. McClelland's affidavit states:

> Taking into account the multiple binding, the skilled person would understand that multiple changes from (S) to (R) would result in compounds that were very poor inhibitors of ACE, if they inhibited at all, and that such compounds would not be useful in the treatment of hypertensive disease or cardiac insufficiency. [Emphasis added.]

[361] During cross-examination of Dr. Marshall the following exchange took place with respect to the *Biochemistry* paper:

> Q. But the question is not whether there is significant activity. The question is whether there is a recorded activity.
>
> A. There is a recorded activity. And I think the reason it's recorded is because of the contamination problem. I can't be sure of that, because there was no effort made at that time, nor were there methods available to quantitate the amount of contamination. [Emphasis added.]

[362] While Dr. Marshall suggested that the recorded activity was due to possible contamination, it is clear that he was merely speculating on the issue, and did not disagree that the prior art did in fact record activity when the R-configuration was used.

[363] In my view, even a poor level of ACE inhibition supports a prediction of some level of ACE inhibition.

[364] In addition to the prior art, I find that the teachings that the soundness of Servier's prediction was reinforced by the making and testing by Servier of perindopril, which falls within claim 3 of the '196 Patent. Although, it is true that Servier had not tested any compounds with an (R,R,R) configuration on the backbone of the claimed molecule as of the filing date, the state of knowledge at the time suggested that compounds with the same backbone, but in the R-configuration, would have some level of ACE inhibition.

[365] The case at bar can be contrasted with *Aventis Pharma*, above, where Justice Mactavish found that claim 12 of the '206 Patent had not been soundly predicted. Claim 12 of the '206 Patent had described a group of eight stereoisomers with a 5,5 bicyclic ring structure in lieu of the proline ring in the class of compounds disclosed and claimed by Merck in the enalapril patent. The prediction at issue was characterized by Justice Mactavish at paragraph 110 of her decision as follows:

> What precisely was Schering's prediction? Schering states that it predicted that by putting bicyclic rings on the proline end of an enalapril molecule, one would have compounds that would be useful as ACE inhibitors and anti-hypertensive agents. [Emphasis added.]

[366] This is an entirely different prediction than that made by Servier in the case at bar, namely that all compounds in claim 3 would have some level of ACE inhibition and some would have sufficient activity to treat hypertension and cardiac insufficiency. *Aventis Pharma* can be further distinguished from the case at bar given that, in contrast to the case before me, it involved a proceeding under the *Patented Medicine (Notice of Compliance) Regulations*, S.O.R./93-133 (*NOC Regulations*) and, prior to the filing date, the chirality of the only compound that had been created by the inventors was unknown (*Aventis Pharma,* above at para. 130).

[367] In sum, the combined teachings of the prior art, most significantly the *Nature* paper and the '401 Application (which used the same Merck backbone as perindopril), convince me that it is more likely than not that the inventors had a factual basis and sound line of reasoning upon which they could predict that the compounds of claim 3 would have some level of ACE inhibition.

[368] Apotex did not argue, on this point, that the '196 Patent does not satisfy the disclosure element of the three part test for sound prediction. In any event, even if it had, I am satisfied that the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practised (*Wellcome (S.C.C.),* above at para. 70).

C. *The "Trans" Compounds*

[369] Each of the compounds claimed by claims 1, 2 and 3 contains a fused 6,5 bicyclic ring. There are two asymmetrical carbons on the ring fusion or bridgehead. This means that there can be four possible configurations at the sites of these two carbons. Where the two hydrogen atoms are on the same side as each other, the configuration is referred to as "cis"; when they are on opposite sides to each other, the configuration is referred to as "trans". As an example, one half of the 32 compounds claimed by claim 3 are in the trans configuration.

[370] Apotex argues that neither the '093 Application nor the '196 Patent discloses a process to make the trans configuration and that a person skilled in the art would not, as of the relevant date, have known how to synthesize such compounds. Thus, they argue, the inventors had no basis on which to predict that the trans configurations would have utility as ACE inhibitors. Apotex does not

argue that the trans compounds could not have been predicted to have utility; rather, they submit only that the inventors did not know how to make the trans compounds. In support of its proposition, Apotex cites: (a) *Wellcome (S.C.C.)*, above, at paras. 69, 70, 84; and, (b) *Aventis Pharma*, above at para. 86.

[371] In effect, Apotex is arguing that the test for sound prediction can only be met if the inventors can satisfy two requirements: (a) that the trans compounds would have utility to meet the promise of the patent; and (b) the inventors would have and disclose, in the patent, a sound prediction of how to make the trans compounds.

[372] With respect to the *Wellcome (S.C.C.)* decision, Apotex refers to the comments of Justice Binnie, on a hypothetical patent for the Wright brothers' airplane and argues that these comments are authority for its position. Specifically, at paragraph 82, Justice Binnie stated the following:

> The hypothetical Wright brothers patent relates to a new and useful product, rather than (as here) to a new *use* for an old product, but all the same it illustrates, I think, the flaw in the Glaxo/Wellcome argument. The mere idea of a "heavier-than-air flying machine" is no more patentable than would be "anything that grows hair on bald men" (emphasis in original): *Free World Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024, 2000 SCC 66, at para. 32. The patent (even in this improbable scenario) would have to teach precisely *how* the machine could be made to fly. Section 34(1)(b) of the Patent Act requires the applicant to set out in the specification "the method of constructing, making ... or using a machine ... in such full, clear, concise and exact terms as to enable any person skilled in the art ... to make, construct ... or use it". This means the Wright brothers' hypothetical patent would have to describe, amongst other things, how to design an air foil that creates "lift" by reducing the air pressure on the upper surface of the wing as the air rushes over it, as well as a suitable airborne method of forward locomotion. If the essentials of the heavier-than-air flying machine were set out with sufficient precision to allow the reader actually to make a flying machine that flies, it is hard to accept the "hypothetical" that experts

> would continue to insist, after it had flown, that the prediction was unsound. [Emphasis added.]

[373] In my view, Apotex has taken the paragraph from the *Wellcome (S.C.C.)* decision out of context.

[374] The patent at issue in that case related to a new use for a known compound – the use of the drug AZT for the treatment of HIV/AIDS. The issue of sound prediction or utility was of prime importance. As stated by Justice Binnie, at paragraph 55:

> if the utility of AZT for the treatment of HIV/AIDS was unpredictable at the time of the patent application, then the inventors had not made an invention and had offered nothing to the public in exchange for a 17-year monopoly except wishful thinking.

[375] Justice Binnie described the overall objective of the notion of sound prediction as follows, at para. 66:

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

[376] Nowhere in the analysis leading to this overarching statement does Justice Binnie refer to the need to know how to predict the making of a compound as a component of utility. Indeed, it appears to me that there may be cases – particularly in the context of pharmaceutical genus patents – where the utility of a particular class of compounds can be established by reference to the architecture of the particular class. That does not mean that the inventors may avoid telling the

world how to practise the patent; that is precisely why the specifications of a patent must be sufficient.

[377] I next observe that the quote from paragraph 82 of the *Wellcome (S.C.C.)* decision is contained in a section of the reasons entitled "*Glaxo/Wellcome's After-the-Fact Validation Theory*". In this section of the reasons, Justice Binnie was considering Glaxo/Wellcome's contention that, because AZT turned out to have both treatment and (limited) prophylactic properties, its prediction must necessarily have been sound, and the patent upheld on that basis. In rejecting this argument, Justice Binnie was responding to the example that had been relied on, before the Supreme Court, by Glaxo/Wellcome. I am not convinced that, by making these comments on a hypothetical airplane patent, Justice Binnie meant to revise the test for sound prediction as submitted by Apotex.

[378] If we look to paragraph 83 of the decision, we see the following statement:

> On the other hand, if the patent failed to disclose the essentials of a heavier-than-air flying machine, such that no one could "soundly predict" whether or not the ill-defined thing could get off the ground, then the patent would be rightly invalidated, even though the inventors had eventually flown some sort of machine in the meantime.

[379] In sum, what is necessary for satisfying the test is disclosure of "the essentials". In the case before me that requires that someone (our person skilled in the art) could soundly predict whether or not the trans compounds would have utility as ACE inhibitors and not whether or not they can be made.

D. *Conclusion*

[380] With respect to the issue of sound prediction, I am satisfied, on a balance of probabilities, 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. Further, I am also not persuaded that Apotex has met its burden of demonstrating that a person skilled in the art, as of the date of filing the '093 Application, could not soundly predict that the trans compounds of claims 1, 2 and 3 would have utility.

XI. Inventorship

A. *Overview*

[381] Apotex asserts that the named inventors of the '206 Patent, namely Elizabeth M. Smith, Bernard R. Neustadt and Elijah H. Gold (collectively, the Schering inventors), first invented the "invention" of the '196 Patent. It follows that the claimed invention of the '196 Patent was "known or used by another person" (as contemplated by s. 27(1)(a) of the *Act*) before it was invented by the ADIR scientists. Accordingly, Apotex claims, the ADIR inventors were not entitled to the issuance of the '196 Patent.

[382] Servier first submits that s. 61(1) of the *Act* prohibits Apotex from challenging the inventorship of the '196 Patent. Further, Servier argues, Apotex has failed to prove, on a balance of probabilities, that the Schering inventors knew or used the subject-matter of claims 1, 2, 3 or 5 in the '196 Patent.

[383] Apotex further asserts that, even on the interpretation of s. 61(1) proposed by Servier, certain third person claims that should have been placed in conflict by the Commissioner were not placed into conflict (referred to as missed conflicts). Thus, Apotex argues, there were missed conflicts and they fall within the exception of s. 61(1)(b). Servier disagrees.

[384] The sub-issues raised in respect of the inventorship question are the following:

1. Does s. 61(1) of the *Act* preclude Apotex from challenging the validity of the '196 Patent on the grounds of inventorship; or, can Apotex challenge the patent's validity on the grounds of inventorship on the basis that s. 61(1)(b) of the *Act* applies? This is a question of statutory interpretation revolving around the words "on which conflict proceedings should have been directed".

2. Did the Commissioner's failure to place certain claims in conflict with those of ADIR result in a missed conflict such that the prohibition of s. 61(1) does not apply? The response to this question requires that I address the question of whether only the Commissioner may "direct" that claims be placed into conflict or whether the Court, by order, may do so.

3. Has Apotex satisfied its evidentiary burden to demonstrate that Dr. Smith or Schering was the first to know or use the "invention" of the '196 Patent? This is a factual determination for the most part.

B. *Relevant Statutory Framework under the Patent Act*

[385] I begin by reviewing the relevant statutory provisions of the *Patent Act*, reminding the reader that the operative provisions are those contained in the *Act* as it existed in 1981.

[386] Of critical importance to the issues before me, the overall scheme under the *Act* was one of first to invent. By contrast, the scheme under the current *Patent Act* can be described as first to file. The notion of first inventorship is embodied in s. 27(1) of the *Act*:

Subject to this section, any inventor or legal representative of an inventor of an invention that was (a) not known or used by any other person before he invented it, (b) not described in any patent or in any publication printed in Canada or in any other country more than two years before presentation of the petition hereunder mentioned, and (c) not in public use or on sale in Canada for more than two years prior to his application in Canada,	Sous réserve des autres dispositions du présent article, l'auteur de toute invention ou le représentant légal de l'auteur d'une invention peut, sur présentation au commissaire d'une pétition exposant les faits, appelée dans la présente loi « le dépôt de la demande » , et en se conformant à toutes les autres prescriptions de la présente loi, obtenir un brevet qui lui accorde l'exclusive propriété d'une invention qui n'était pas : a) connue ou utilisée par une autre personne avant que lui-même l'ait faite; b) décrite dans un brevet ou dans une publication imprimée au Canada ou dans

may, on presentation to the Commissioner of a petition setting out the facts, in this Act termed the filing of the application, and on compliance with all other requirements of this Act, obtain a patent granting to him an exclusive property in the invention.	tout autre pays plus de deux ans avant la présentation de la pétition ci-après mentionnée; c) en usage public ou en vente au Canada plus de deux ans avant le dépôt de sa demande au Canada.

[387] Recognizing that more than one person might claim inventorship to similar or overlapping subject matters, Parliament provided means for identifying and resolving such a conflict. To begin, s. 43(1) of the *Act* defines when a conflict exists:

Conflict between two or more pending applications exists	Se produit un conflit entre deux ou plusieurs demandes pendantes dans les cas suivants:
(a) when each of them contains one or more claims defining substantially the same invention; or	a) chacune d'elles contient une ou plusieurs revendications qui définissent substantiellement la même invention;
(b) when one or more claims of one application describe the invention disclosed in one of the other applications.	b) une ou plusieurs revendications d'une même demande décrivent l'invention divulguée dans l'autre ou les autres demandes

[388] The balance of s. 43 sets out the procedures to be followed in declaring and dealing with conflicts. Of particular significance in this motion are two provisions. The first is s. 43(7) which provides for the issuance of a decision by the Commissioner in which he determines “which of the applicants is the prior inventor to whom he will allow the claims in conflict”. The second is s. 43(8) which permits a party to a conflict to commence proceedings in the Federal Court for a “determination of [the] respective rights” of the parties to the conflict.

[389] In practical terms, the proceedings under s. 43(8) are commenced by way of an action, with full discovery and other procedures allowed by the *Federal Courts Rules*. When s. 43(8) is engaged, the Commissioner's decision is suspended and no patents may issue until the Federal Court determines that:

(a) there is in fact no conflict between the claims in question;	a) de fait, il n'existe aucun conflit entre les revendications en question;
(b) none of the applicants is entitled to the issue of a patent containing the claims in conflict as applied for by him;	b) aucun des demandeurs n'a droit à la délivrance d'un brevet contenant les revendications concurrentes, selon la demande qu'il en a faite;
(c) a patent or patents, including substitute claims approved by the Court, may issue to one or more of the applicants; or	c) il peut être délivré, à l'un ou à plusieurs des demandeurs, un ou des brevets contenant des revendications substituées, approuvées par le tribunal;
(d) one of the applicants is entitled as against the others to the issue of a patent including the claims in conflict as applied for by him	d) l'un des demandeurs a droit à l'encontre des autres, à la délivrance d'un brevet comprenant les revendications concurrentes, selon la demande qu'il en a faite.

[390] While s. 27(1) accords the right to a patent to the first inventor, the *Act* also contemplates that legal proceedings may be brought with respect to the validity of patents (see *Act*, starting at s. 53). In particular, s. 59 of the *Act* permits a defendant (such as Apotex) in a patent infringement action to plead "any fact or default which by this *Act* or by law renders the patent void". Under s. 60(1) of the *Act*, a patent or any claim in a patent may be "declared invalid or void by the Federal Court . . . at the instance of any interested person."

[391] However, when the validity of a patent is being challenged on the question of inventorship, s. 61(1) is a limiting or qualifying provision:

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	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;	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) 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	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) 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.	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.

[392] No arguments were raised as to s. 61(a) or (c) of the *Act* and accordingly my analysis will be limited to s. 61(1)(b).

C. *Interpretation of s. 61(1)(b)*

(1) General Comments and Position of Parties

[393] Inventorship, as discussed above, is the key to the issuance of patents under the *Act*; the first inventor is entitled to the patent. Sections 61(1) and 27(1), read together, indicate the manner in which a patent can be held to be invalid on the grounds of prior inventorship. As stated in s. 61(1)(b), no patent will be declared invalid on the grounds of prior inventorship by some other person unless the challenging party can establish that the other person had, before the issue of the patentee's patent, made an application for patent in Canada on which conflict proceedings should have been directed. Stated in other words, a party may only successfully raise inventorship as an issue if: (a) the invention in the patent or claim had already "been known or used by some other person"; (b) the other person made a patent application for this prior invention in Canada; and (c) "conflict proceedings should have been directed".

[394] In this case, there is no question that there were a number of persons who applied for Canadian patents involving ACE inhibitors and that a number of claims described in the various applications were placed into conflict by the Commissioner. There is disagreement between Apotex and Servier as to whether any of those applications disclosed an invention that was known or used before the patent application of ADIR and whether there were conflicts that existed and were not

declared. If Servier's interpretation of s. 61(1)(b) is correct, Apotex will not be able to dispute the inventorship as to the third person claims that were put into conflict. However, even if Servier is correct on the proper interpretation of s. 61(1)(b), Apotex may still be able to raise the inventorship issue on the basis that there was a missed conflict. These two sub-issues are dealt with later in these reasons.

[395] With respect to this sub-issue, Apotex and Servier differ on the interpretation of the phrase "on which conflict proceedings should have been directed". Servier asserts that s. 61(1)(b) applies to the case at bar because, not only should conflict proceedings have been directed, they actually were so directed. In effect, they argue that, under s. 61(1)(b), an attack on the basis of prior inventorship is not permitted where, as here, another person's invention was known and put into conflict proceedings. That is, s. 61(1)(b) applies only when there has been a "missed conflict". This appears to be the literal interpretation of s. 61(1)(b).

[396] Apotex argues that Servier is reading language into s. 61(1)(b) that, in effect, limits the application of the provision. In their view, this violates a basic principle of statutory interpretation (Ruth Sullivan, *Sullivan and Driedger on the Construction of Statutes*, 4th ed. (Toronto: Butterworths, 2002), at 131). Thus, they assert, the provision means simply that the circumstances which ought to have given rise to conflict proceedings pursuant to s. 43(1) of the *Act* must have existed (in simple terms, similar or overlapping claims). In their view, whether the conflict proceedings actually occurred is immaterial. On Apotex's interpretation, any of the patents arising from the '093, '336, '787 and '453 Applications would potentially satisfy the requirement of

s. 61(1)(b), provided that the challenging party could demonstrate that there was an earlier disclosure of the invention to the public.

[397] There is no reported jurisprudence directly on point with respect to the proper interpretation of s. 61(1)(b) (see *Les Laboratoires Servier v. Apotex Inc.* (2007), 61 C.P.R. (4th) 408 at para. 46 (F.C.A.)). Given this fact, I turn to a fresh consideration of the meaning of s. 61(1)(b).

[398] It is a well-established principle of statutory interpretation that words of a statute are to be read in their entire context in their grammatical and ordinary sense harmoniously with the scheme of the *Act*, the object of the *Act*, and the intention of Parliament (Elmer Driedger, *Driedger on the Construction of Statutes* (2nd ed.) (Toronto: Butterworths, 1983), cited in *Rizzo & Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27, at para. 21[*Rizzo Shoes*]). Keeping this guidance in mind, the place to begin is with an examination of the context of conflict proceedings under the *Act*.

(2) The Context of Conflict Proceedings

[399] Under the scheme of the *Act*, conflict proceedings were an important feature of determining the question of first inventorship in co-pending applications and, hence, the right to a patent. Conflicts arose when an application disclosed one or more claims (a) defined "substantially the same invention" (s. 43(1)(a)); or (b) described "the invention disclosed in one of the other applications" (s. 43(1)(b)). Under s. 43(3) of the *Act*, the Commissioner was to notify the affected applicants if any of these claims were "so nearly identical that, in the opinion of the Commissioner, separate patents to different patentees should not be granted". After the applicants made

submissions and filed affidavits (see ss. 43(4) and 43(5)), the Commissioner determined "which of the applicants is the prior inventor to whom he will allow the claims in conflict" (s. 44(7)). It is interesting to note that there were no oral proceedings held and, in fact, the applicants in conflict were not even provided copies of the other applicants' affidavits until after the Commissioner reached his decision. If any of the applicants disagreed with the Commissioner's determinations, they had the right to commence "proceedings in the Federal Court for the determination of their respective rights" (s. 44(8)). In that situation, the Commissioner could not issue any patents until the Federal Court proceedings resulted in one of a number of ultimate resolutions. Those possible outcomes of s. 44(8)(a) to (d) are set out in the provision (see above). One of the possible outcomes (and, the one that occurred in the case before me) is that set out in s. 44(8)(c) whereby the Court approves substitute claims that may be issued to one or more of the applicants. In brief, the conflict proceedings set out in the *Act* provided a very detailed process for determining the issue of first inventorship.

[400] The *Act* does not provide for third party intervention. That is, the *Act* does not give a non-applicant the ability to challenge the Commissioner's decisions. Does that mean that, once a patent is issued, conflict proceedings foreclose a third party from ever challenging the patent? The answer is clearly no.

[401] A number of cases have considered the role of conflict proceedings. In *Texaco Development Corp. v. Schlumberger Ltd.* (1966), 49 C.P.R. 225 at 233 (Ex. Ct.), it was held that s. 45 of an earlier *Patent Act* (s. 43 under the *Act*) allowed an interruption in the processing of an application for a patent "for the sole purpose of deciding which of two applicants is the inventor." Justice Jackett was

careful, however, to state that all other objections to the granting of a patent "should be dealt with in the ordinary course of events". In other words, he acknowledged that, because of the operation of the statute, inventorship is carved out for special treatment.

[402] *Nekoosa Packaging Corp. v. Amca International Ltd*. (1989), 27 C.P.R. (3d) 153 at 157-8 (F.C.T.D.), aff'd (1994), 56 C.P.R. (3d) 470 (F.C.A.) [*Nekoosa Packaging Corp.*] is also relevant on this point and helpful as Justice Cullen spent considerable time in summarizing the state of the law at that time. The case involved a patent infringement action which had been preceded by a conflict action. The earlier conflict action had resulted in a final determination by the Federal Court of Appeal. The court in the subsequent patent infringement action held that a determination by the court made during conflict proceedings does not give rise to an argument of estoppel in later proceedings respecting the validity of a patent. This was because conflict actions are directed to the issue of priority and do not put an imprimatur on the validity of claims in conflict beyond directing the Commissioner to issue a patent containing such claims. In short, the plaintiffs were not prevented from bringing claims of invalidity on the grounds of obviousness. It should be noted that, in the case before Justice Cullen, prior inventorship was not an alleged ground of invalidity. Thus, this case is a good example of a consistent line of jurisprudence that states that other grounds of invalidity may be raised after the conclusion of conflict proceedings. The reasoning is apparent. Conflict proceedings deal only with inventorship; thus, no other possible grounds of invalidity have been considered during such conflict proceedings.

[403] The case law on the interpretation of s. 61(1) of the *Act* appears, at first blush, to be at odds with the jurisprudence on the scope of conflict proceedings. On the one hand, conflict proceedings have been generally held not to decide the issue of the validity of the patent. On the other hand, those validity claims relating to inventorship of the patent, are precluded from being raised by s. 61(1) if there is no "missed conflict". If both lines of authority are accepted, the result is to make conflict decisions by the Commissioner of Patents, or, if appealed, by the Federal Court, while not necessarily determinative of inventorship (as held in *Nekooska Packaging Corp.*), unimpeachable on that issue. In my view, such an interpretation of s. 61(1) is logical and should be adopted.

(3) Intent of Parliament

[404] *Rizzo Shoes* teaches that the intention of Parliament should be considered when interpreting the provisions of a statute. In this case, the precursor to s. 61(1) was first enacted by Parliament in 1932, *An Act to Amend the Patent Act*, S.C. 1932, c. 21, s. 4. Discerning the intention of Parliament some 76 years after the inclusion of a provision in a statute is difficult. We do know, from the timing of the enactment, that at least some of the impetus for the provision came from the decision of the Judicial Council of the Privy Council in *Rice v. Christiani*, [1931] 4 D.L.R. 273 (P.C.) [*Christiani (P.C.)*], a decision rendered on appeal from the Supreme Court of Canada (*Christiani v. Rice*, [1930] S.C.R. 443 (S.C.C.) [*Christiani (S.C.C.)*]). The question before the Courts can be described as follows: could a Danish company (Christiani) whose process for making a cellular concrete building material known as porous cement patent was invented first and patented in Denmark, challenge the validity of Mr. Rice's Canadian patent for the identical process?

[405] Although the validity of Mr. Rice's Canadian patent was upheld at trial in the Exchequer Court, the result was overturned on appeal to the Supreme Court of Canada. In turn, the decision of the Supreme Court was affirmed by the Privy Council.

[406] In interpreting the provisions of the *Patent Act* in force at that time, the Privy Council concluded that:

> [T]he knowledge and user of Bayer [the inventor who subsequently assigned his patent rights to Christiani] and his associates, before December 21, 1922, although in Denmark and although secret and confidential, and not made available to the public, was, upon the true construction of s. 7 of the Act of 1923, sufficient to invalidate the appellant's [Dr. Rice's] patent (*Christiani (P.C.)*, above at 283). [Emphasis added.]

[407] In doing so, their Lordships expressly overruled two Exchequer Court decisions in *The Queen v. La Force*, 4 Ex. C.R. 14 and *Gerrard Wire Tying Mach. Co. Ltd. v. Cary Mfg. Co.*, [1926] 3 D.L.R. 374, where contrary conclusions were reached.

[408] As described by Apotex counsel in final argument, *Christiani (P.C.)* allowed "the secret person hiding out in the hills" to challenge the validity of a patent. Apotex submits that the intent of Parliament in amending the *Patent Act*, in 1932, was only to undo this stark result – to prevent those secret persons holding patents elsewhere from asserting first inventorship after the fact by restoring the pre-*Christiani (P.C.)* law. In Apotex's view, Parliament never intended to do any more than that; Parliament did not intend to prevent a third party, such as Apotex, from subsequently challenging the validity of a patent on the grounds of inventorship. There are a number of problems with Apotex's version of the intent of Parliament.

[409] The first problem is that Apotex presented no evidence, such as Hansard or transcripts from the Parliamentary or Committee debates that took place at that time. Their view is, at best, speculation that Parliament's sole intention was to prevent the "secret person hiding out in the hills" from challenging inventorship.

[410] The next problem is that, if Parliament had intended to act only in the limited way proposed by Apotex, it could have done so with much clearer language. Parliament could have brought the pre-*Christiani (P.C.)* law back into effect simply by requiring that a challenge to inventorship could not be sustained unless the challenger had made a patent application that was co-pending. That is not what is stated in s. 61(1). It can be inferred that Parliament chose not to prevent only co-applicants from contesting inventorship but enacted the provision to apply generally to all persons who would challenge the validity of a patent on the grounds of inventorship.

(4) The Object of the *Patent Act*

[411] The final problem with Apotex's interpretation of s. 61(1) is that it ignores the scheme of the *Act* vis-à-vis the critical concept of "first inventorship". Apotex appears to be arguing that Parliament would never have intended to remove the right of a third party to challenge the question of first inventorship. I acknowledge that, with Servier's (and my) interpretation, third parties are precluded from being part of the process for the determination of conflict proceedings. In response, I observe, firstly, that a third party is not prohibited from raising the existence of prior art; this is a question of anticipation that is often raised in infringement proceedings. Thus, the potential problem is limited to only those situations where there are competing applications and declared conflicts.

[412] Next, I note the extensive process set out in the *Act*, involves the careful review by the Commissioner and subsequent involvement of the Federal Court. It appears to me that the goal of ensuring patent security for the person ultimately determined through this process is in keeping with the concept of first inventorship.

[413] In any interpretation of patent legislation, and therefore the patent system, it is helpful to recall Justice Binnie's comments in *Free World Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024 at paras. 41-43 [*Free World Trust*], that,

> The scope of patent protection must not only be fair, it must be reasonably predictable . . .The patent owner, competitors, potential infringers and the public generally are thus entitled to clear and definite rules as to the extent of the monopoly conferred.

[414] This is particularly true under the *Patent Act* where the defining concept is one of inventorship. The intent of the legislative scheme is to provide a means for identifying the true first inventors and dealing with conflicts that may arise prior to the issuance of the patent. Where a patent has issued pursuant to this process, Parliament has provided that it is protected from further attacks on the question of inventorship, except in the circumstances contemplated by the *Patent Act*, specifically, s. 61(1)(b).

[415] I further observe that none of the jurisprudence dealing with invalidity allegations after conflict proceedings considered the special circumstances of inventorship. Thus, the cases do not directly conflict in any way with the interpretation of s. 61(1)(b) put forward by Servier.

[416] I also highlight another concern with Apotex's interpretation of the provision. The difficulty with their interpretation of the words "should have been directed" is that it renders s. 61(1)(b) essentially meaningless. With the interpretation proposed by Apotex, the existence of conflicts is immaterial. An established principle of statutory interpretation is that Parliament has intended the words in a statute to have meaning. On Apotex's interpretation, the phrase would capture not only missed conflicts, but every application where conflict proceedings were directed. A declared conflict, regardless of how it was resolved, would become irrelevant thereby removing from the operation of the *Act* any concept of certainty for the issued patent. In effect, Apotex is also reading words into the provision; in their view, the provision should read: an application on which conflict proceedings should have been directed, whether or not they were so directed. In the alternative, they are reading the provision as an application on which conflict proceedings could have been directed. In either case, Apotex is providing an interpretation that, in my view, cannot be read harmoniously with the scheme of the *Act*.

(5) Relevant Jurisprudence

[417] As noted above, there is no jurisprudence directly on point. Nevertheless the provision has been referred to on at least three occasions. These cases in my view, provide an interpretation that is consistent with that asserted by Servier.

[418] An example of the use of s. 61(1)(b) of the *Act* is set out in *AT & T Technologies, Inc. v. Mitel Corp.* (1989), 26 C.P.R. (3d) 238 (F.C.T.D.) [*AT & T*], where the validity of a patent was in issue. According to the defendant, the AT & T patent was invalid because the named inventors

"were not the first to invent and there existed a patent application in the patent office at the time the AT & T patent was filed, with which it should have been put in conflict" (*AT&T*, above at 265). As discussed by Justice Reed in that case, s. 27(1) of the *Act* accords the first inventor the right to the grant of a patent.

[419] However, Justice Reed also acknowledged the qualification of the "first inventorship" requirement by s. 61(1)(b). After a careful review of the evidence before her, which included two patent applications, Justice Reed concluded, as follows, at page 272:

> There is no doubt that the two patent applications should have been put in conflict.
>
> ...
>
> All that must be proved is that there was a prior invention of the process, and device, before the plaintiff's invention date and that there were patent applications which should have been put in conflict. This has been proven. The plaintiff's patent is therefore clearly invalid.

[420] As I read this holding, the conclusion of invalidity was made for two reasons: (1) there was a prior invention; and (2) there were patent applications that should have been put in conflict. Both requirements had to be met. Had the defendant been unable to satisfy the Court that there were patent applications that should have been put in conflict, the defendant would not have been able to meet the test set out in s. 61(1)(b) and the patent would not have been declared invalid on the ground of prior inventorship. In sum, Justice Reed gave an interpretation to s. 61(1)(b) that is consistent with that proposed by Servier in this motion.

[421] This interpretation of s. 61(1)(b) was adopted by Justice Mactavish in *Aventis Pharma*, above at paras. 341-344, where the learned Justice was considering an argument of patent invalidity by the respondent based on s. 61(1)(b) of the *Act*. In Justice Mactavish's view, the respondent, to be successful, had to establish that "there was both prior knowledge or use by Hoeschst, *and* a missed conflict" [emphasis in original]. However, it should be noted that, as Justice Mactavish concluded that the respondent had failed to establish that there was prior knowledge or use by Hoechst, she did not need to deal with the issue of whether, in that case, there was a missed conflict (*Aventis Pharma,* above at para. 349). However, once again, we have a judicial interpretation of s. 61(1)(b) that accords with that proposed by the Plaintiffs.

[422] The next case in which s. 61(1)(b) has been considered is *Pfizer (C.A.)*. The issue before the Court of Appeal was whether the trial judge had erred in applying the wrong test for anticipation. In response, Justice Nadon, speaking for the Court of Appeal, endorsed the written submissions of Pfizer, the respondent to the appeal, at paragraph 138:

> It appears from paragraphs 85 and 86 of Heneghan J.'s Reasons that she did apply the anticipation by prior publication test. In this respect, I find particularly convincing paragraph 27 of Pfizer's Reply Memorandum of Fact and Law which states:
>
> > Apotex argues that Justice Heneghan erred by failing to consider s. 27(1)(a) of the Patent Ac[t], which requires a patent to be "known or used" by any other person before the inventor invented it. This was not an error. Section 61(1) prevents a patent from being invalidated on the basis that it was "known or used" unless it was "disclosed or used ... in such manner that it had become available to the public" or if it was the subject of an application for a patent in Canada on which "conflict proceedings should have been directed." Neither of these conditions are met in this case. There is no evidence that the Hoechst patent application was known to the public. Moreover, this

> is not a case in which "conflict proceedings *should have been directed*". Rather, conflict proceedings *were* directed, *did* occur, and the patent ultimately issued to Warner Lamber. [Emphasis in original.]

[423] Justice Nadon continued his analysis by pointing out that Apotex had not filed into evidence a copy of the Hoechst Patent. Thus, it was impossible to discern the filing or issuance date of that patent. Accordingly, Justice Nadon did not have to directly assess whether conflict proceedings that resulted in a settlement met the requirement of s. 61(1)(b). Nevertheless, I infer from his endorsement of the entire submission of *Pfizer (C.A.)* that he did not disagree with this proposition.

[424] The *Pfizer (C.A.)* case is particularly instructive because it involves a situation that is very similar to that before me. The applicants in that case relied on two patents. One of those patents (the '330 Patent) was placed in conflict with a patent owned by a German company. The Commissioner determined that the German company was the first to invent and awarded the patent to that company. In 1999 a consent judgment was entered whereby the '330 Patent was issued only to the applicants.

[425] Thus, in sum, a consideration of the case law supports the interpretation that I would provide to the provision.

(6) Conclusion on this Issue

[426] An interpretation of s. 61(1)(b) as set out above is consistent with the principles identified in *Free World Trust*, consistent with both the s. 61(1)(b) and conflict proceedings lines of authority,

and helps, not hinders, the patent system embodied in the *Act*. On this purposive interpretation of the statutory provisions of the *Patent Act*, it is entirely consistent to separate out the concept of inventorship for "special treatment". By preventing a finding of invalidity where conflict proceedings have been directed, the foundation concept of first inventorship is protected. On the other hand, no special provisions are contained within the *Patent Act* that would protect a patentee from other grounds of invalidity attacks. Accordingly, those other grounds may be raised in the usual course. In my view, this is the result that Parliament intended.

[427] Furthermore, it should be emphasized again that such an interpretation would be limited to precluding parties where there is no "missed conflict" from advancing an allegation of prior inventorship. Other grounds for questioning the validity of a patent are unaffected.

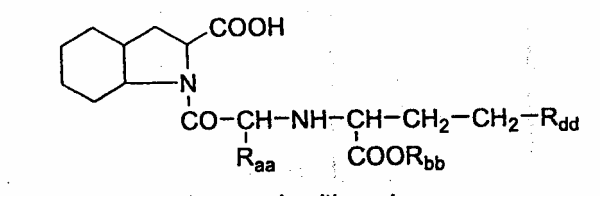
D. *Was there a Missed Conflict?*

[428] Apotex submits that, even if paragraph 61(1)(b) requires that a party prove a missed conflict before it can raise a first inventorship allegation, there was, in fact, a missed conflict in the present case. A description of the conflict proceedings is contained in section IIIA(5) of these Reasons.

[429] The missed conflict, in Apotex's view, relates to an alleged "almost complete overlap of subject matter" between claim C39, which was awarded to Schering, and claim C26, which was awarded to ADIR. Schering was not made a party to conflict claim C26 by the Commissioner. Apotex argues that the failure to place claim C39 in conflict with claim C26 constitutes a missed conflict within the meaning of paragraph 61(1)(b).

[430] The two claims are as follows:

C26 Compounds having the general formula H

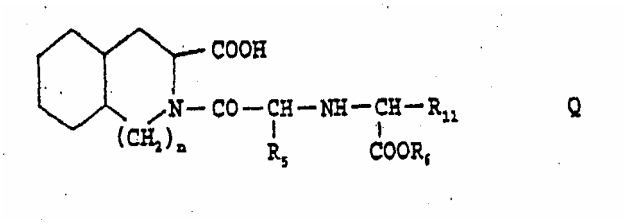


wherein:

- R_{aa} represents a C_{1-4} alkyl group which may contain an amino group;
- R_{bb} is selected from:
  - hydrogen; and
  - C_{1-4} alkyl; and
- R_{dd} is selected from:
  - C_{1-4} alkyl;
  - C_{3-7} cycloalkyl; and
  - phenyl

and their pharmaceutically acceptable salts.

C 39 A compound having the general formula Q:



wherein :

- n is selected from 0 or 1;
- R_5 is selected from;
  - C_{1-4} alkyl group which may be substituted with amino;
- R_6 is selected from;
  - hydrogen; and
  - C_{1-4} alkyl and
- R_{11} is selected from;
  - C_{1-9} alkyl;
  - phenyl-C_{1-3} alkyl; and
  - -$(CH_2)_{1-2}$-Y-C_{1-4} alkyl wherein:
    - Y is selected from:
      - S; and
      - NH

and its pharmaceutically acceptable salts

[431] To persuade me that there was a missed conflict in respect of Schering's claim C39, Apotex must demonstrate two things:

(a) that the C39 and C26 claims should have been placed in conflict because they were "so nearly identical that, in the opinion of the Commissioner, separate patents to different patentees should not be granted" (s. 43(3)); and

(b) the subsequent Order of Justice Joyal, dated May 27, 1997, consolidating a number of court files, did not have the effect of bringing all of the claims referred to in the relevant Court files – including the C39 and C26 claims – into conflict.

[432] Assuming for purposes of this question, without deciding, that there was an "almost complete overlap" between Schering's claim C39 and ADIR's claim C26, would there have been a missed conflict? Had the Commissioner's decision been accepted by the parties and the patents issued, I think that the answer would be yes. However, the Joyal Order cannot be ignored.

[433] As noted earlier, none of Hoechst, ADIR or Schering was pleased with the Commissioner's decisions. Each, as allowed for under the scheme of the *Act*, brought applications to the Federal Court. Six separate actions were commenced. The Joyal Order, made upon consent, consolidated all of the Court files and continued the action as Court file no. T-228-97. Of particular relevance, clause 2 of the Order provided as follows:

> In the T-228-97 action ("the action"), any of the parties shall be entitled to contest any aspect of any decision of the Commissioner of Patents pursuant to s. 43(8) of the *Patent Act* RSC 1985, c. P-4 regarding the award of any particular claim declared to be in conflict between and amongst any of the parties to this action by the Commissioner, namely, conflict claims C17 through C40 inclusive (the "conflict claims"), and claim any relief available pursuant to s. 43(8) of the *Patent Act* with respect to any conflict claim, including whether a claim is patentably distinct, irrespective of whether that party was directly involved in conflict proceedings in the Patent Office with respect to that particular claim, provided that all parties shall be permitted to plead issues concerning the degree of support for any such conflict claim within the disclosure of any patent application referred to in the conflict proceedings among the parties.

[434] The effect of this provision of the Order cannot be clearer; all of Claims C17 to C40 were placed into conflict for purposes of the Federal Court action. Each party was granted the right to claim entitlement to any of the conflict claims, C17 to C40, which includes C26 and C39, whether or not that party had been "directly involved" in the Commissioner's findings of conflict and whether or not the Commissioner had declared a conflict. Thus, even though Schering had not been invited by the Commissioner to argue that it was the inventor of the subject-matter of its claim C39 in priority to ADIR's claim C26, it was now granted the right to do so.

[435] Apotex, in effect, argues that only a conflict declared by the Commissioner can meet the requirements of s. 61(1)(b); such a declaration cannot be made by the Court. In support of their position, they point to the case of *Radio Corp. of America v. Hazeltine Corp.* (1977), 33 C.P.R. (2d) 211 (F.C.A.) [*Radio Corp*], where the Federal Court of Appeal ruled that the Commissioner was entitled to place additional claims in conflict after an initial declaration involving claims that had been put in conflict some three years earlier.

[436] In my view, the words of s. 61(1)(b) do not restrict the conflict to one declared by the Commissioner. In the words of the provision, s. 61(1)(b) operates where there has been an application "on which conflict proceedings should have been directed". There is no limitation on who may declare the conflict. Nor, is the term "conflict" defined in the *Act*. Certainly, the procedure outlined in s. 43 sets out that the process of declaring conflicts must be initiated and carried out by the Commissioner. However, this does not prevent the Court, in exercise of its authority, from declaring other claims to be in conflict for the subsequent Court proceedings.

[437] The case of *Radio Corp.* obviously is authority for a conclusion that the Commissioner may add claims to a conflict even where a previously declared conflict exists. It does not stand for the proposition that only the Commissioner may do so. Nor does it address the question of the application or interpretation of s. 61(1)(b).

[438] Further, Apotex submits that the specific claims 1, 2, 3 and 5 of the '196 Patent were never explicitly part of ADIR's '093 Application. Thus, Apotex argues, a conflict should have been directed for claims 1, 2, 3 and 5 and was not. Since no conflict was declared, the claims are ones for which "conflict proceedings should have been directed", within the sense of s. 61(1)(b). There was a missed conflict and Apotex should be entitled to question first inventorship. Once again, I do not agree.

[439] By the terms of s. 43(8)(c), the Court, in conflict proceedings, may direct that "substitute claims" be issued. That is exactly what was done here. Whether or not the precise wording of the ADIR claims or the claims issued to Schering and Hoechst was included in the patent applications, there is, in my mind, no question that the specific claims fall within the subject matter of the applications for patent that had been declared in conflict. Thus, I conclude that the specific ADIR claims were properly part of the conflict. Claims 1, 2, 3 and 5 of the '196 Patent fall within the meaning of s. 61(1)(b). There was no missed conflict.

E. *Who was the First Inventor of the '196 Patent?*

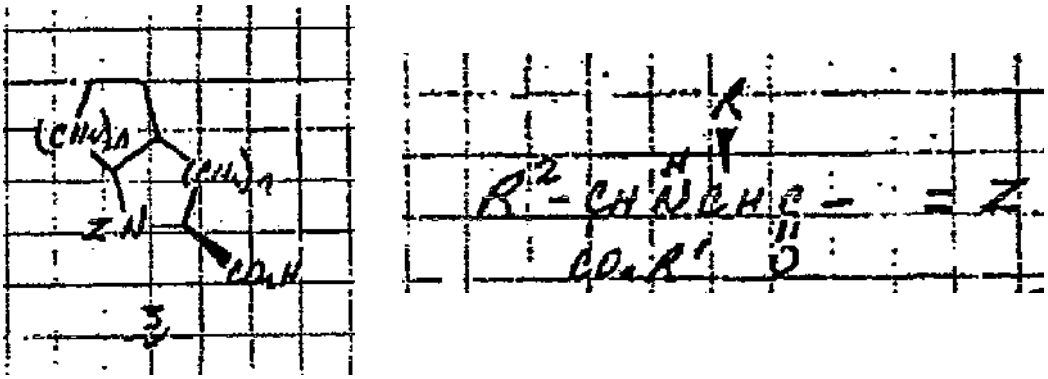
[440] The foregoing is sufficient to dismiss the inventorship claim of Apotex. However, in the event that I am wrong on the questions of the interpretation of s. 61(1)(b) and whether there were, in spite of that interpretation, "missed conflicts", I turn to the remaining question; that is, was Dr. Smith the first to invent the invention of the '196 Patent, as argued by Apotex? To succeed on this question, Apotex must discharge the "weighty burden" of proving that Dr. Smith knew or used the subject-matter of those claims by reason of having invented them prior to ADIR (*Diversified Products Corp v. Tye-Sil Corp.* (1991), 35 C.P.R. (3d) 350 at 363 (F.C.A.)).

[441] Subsection 27(a) of the *Act* limits the grant of a patent to an inventor of an invention where it was not known or used by any other person before he invented it. Thus, where the invention was first known or used by another, an inventor may not receive a patent for that invention (see, for example, *AT&T*, above at 265).

[442] The Court heard the testimony of Dr. Smith, in Newark, New Jersey, under subpoena and by way of commission (as provided for in r. 272 of the *Federal Courts Rules*). Dr. Smith, a long-time employee of Schering, is an eminent scientist. She is one of the named inventors of the '206 Patent, one of the other patents that issued pursuant to the Settlement Agreement and the Nadon Order. As part of the conflict proceedings in Court File No. T-228-97, Dr. Smith provided an affidavit that was in the public domain. That affidavit became an exhibit in this action and was spoken to by Dr. Smith.

[443] The Troy conference, held in June 1980, and its important role in the development of the compounds claimed by ADIR, Schering and Hoechst are discussed earlier in these reasons. Dr. Smith's evidence is that, prior to the Troy Conference, Schering had already undertaken efforts to develop an ACE inhibitor, employing modifications to captopril. Dr. Smith attended the Troy Conference in June of 1980 where the structure of compounds including enalapril, enalaprilat and lisinopril were disclosed.

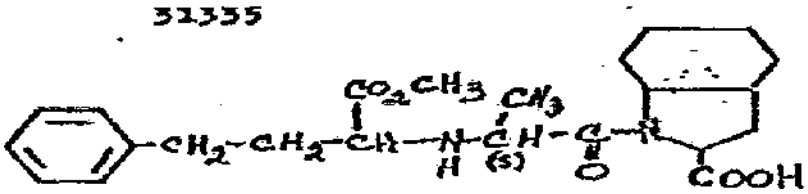
[444] Upon returning from Troy, Dr. Smith immediately knew that the combination of the bicyclics that Schering had been working with, the spiral moiety and the perhydroindole moiety, and Merck's new backbone should be as good or better than that which was disclosed at Troy. On June 20, 1980 (two days following the Troy conference), Dr. Smith recorded, in a notebook she referred to as her "invention disclosure book", her drawings of compounds comprising a bicyclic substitution variation for the proline moiety of the Merck backbone with attendant substituents, as follows:



[445] This disclosure encompassed a number of substitutions for R, R_1 and R_2, including the substitution of R_2 with lower alkyl, and included all possible stereoisomers. The disclosure encompassed a number of bicyclic rings and also provided a method of synthesis for the spiral

moiety substitution for proline and for the perhydroindole substitution for proline, both attached to the Merck backbone.

[446] One of compounds made by Dr. Smith following the Troy Conference and following the drafting of the disclosure set out above was SCH 31335. SCH 31335 combines a perhydroindole with the Merck backbone and was depicted by Dr. Smith as having the following structure:



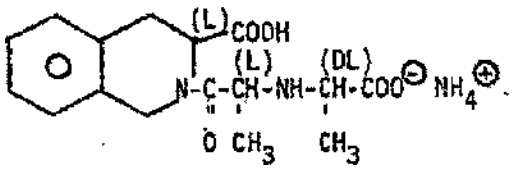
[447] SCH 31335 was made on August 7, 1980 and was sent for analytical testing on August 13, 1980. SCH 31335 was tested *in vitro* on August 15, 1980 and was tested *in vivo* no later than August 21, 1980, when the results were reported to Dr. Smith. Dr. Smith testified that the results from the testing indicated that SCH 31335 was active as an ACE inhibitor *in vitro* and *in vivo*.

[448] As a result, the Schering inventors had synthesized and tested an active compound for ACE inhibition that contained a bicyclic substitution for the proline moiety and the Merck backbone by August 21, 1980.

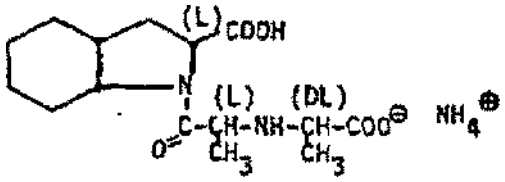
[449] Apotex contrasts these discoveries and disclosures with those of the ADIR scientists and submits that the ADIR scientists did not synthesize and test a compound that contained a bicyclic substitution for the proline moiety and the Merck backbone until after August 26, 1980.

[450] As testified to by Dr. Vincent and described in the "S-series" notebooks the ADIR scientists synthesized two compounds with a bicyclic proline substitution added to the Merck backbone as set out in S-9178-1 and S-9179-1. The structure of those two compounds is as follows:

S-9178-1



S-9179-1



[451] Both compounds were synthesized on August 26, 1980, and transmitted to pharmacological testing on that same day. S-9178-1 was tested *in vivo* starting August 28, 1980 and the results of the *in vivo* testing were reported on September 11, 1980. S-9179-1 was tested *in vivo* starting August 29 and the results of the *in vivo* testing were reported on August 29 and in September of 1980.

[452] On this evidence, Apotex points out that Dr. Vincent synthesized and Dr. Laubie tested two compounds that contained a bicyclic substitution for the proline moiety and the Merck backbone after the work and testing of Dr. Smith. This, they submit is sufficient to show that Dr. Smith and her fellow Schering inventors were the first to invent the "purported invention" of the '196 Patent.

[453] What does Apotex mean by the "purported invention"? The answer to that question is the key to this analysis. Apotex asserts that the invention is a "class of compounds". During final argument, Apotex's counsel summarized the argument in this way:

> The invention was a class. In order to determine who invented the class, we know that neither Schering nor Adir could possibly make anywhere close to the number of compounds in the class. Neither of them did that. And so we know that they and all of the others who purported to invent classes did so on the basis of a sound prediction to the class. That then drives you to ask the question, who first had the ability to make that sound prediction? I could argue, but I don't need to that when Dr. Smith wrote down what she wrote down she had already invented.
>
> And I will argue that to My Lady, that even without the making of a compound, by the writing down of the structure with all of the substituents and the synthesis and saying all of the stereochemical isomers because of her work with captopril and bicyclics, she had in the words of the Supreme Court of Canada, a sound basis for making the prediction that all of these compounds would work as ACE inhibitors and antihypertensives but she did more.
>
> Before the Adir inventors or scientists made a single compound that fell within the class of compounds that they say invented, Dr. Smith actually made one of the compounds and, thus, if necessary completed her conception by making a compound that worked within the class and she had a sound basis for predicting that she had a class invented.

[454] As confirmed during final oral argument by counsel for Apotex, the class of compounds to which Apotex refers is that set out as General Formula I in the '196 Patent specification. The three compounds described by Apotex (Schering's SCH 31335 and ADIR's S-9178-1 and S-9179-1) fall within the compounds that would be included in General Formula I set out in the specifications of the '196 Patent. Thus, there is no doubt that the Schering scientists 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. Apotex, on the other hand, presents no evidence to show that the two

Schering compounds (or any other earlier-made compounds) fall within claims 1, 2, 3 or 5 of the '196 Patent. Thus it follows that Apotex's argument can only succeed if the "invention" of the '196 Patent includes all of the compounds of General Formula I.

[455] The problem with Apotex's submission on the issue of inventorship is that the invention of the '196 Patent is not General Formula I. I have already discussed and determined the scope of the invention in the section of these reasons dealing with the '196 Patent construction. As held in paragraph 133, 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 and nothing more.

F. *Summary of Inventorship Issue*

[456] The counterclaim of Apotex on the grounds that the ADIR scientists were not the first inventors of the compounds patented under the '196 Patent must fail on the basis that:

- On a proper statutory interpretation, s. 61(1) of the *Act* precludes Apotex from challenging the validity of the '196 Patent on the grounds of inventorship. This is because the claims involved in the conflict proceedings were ones "on which conflict proceedings should have been directed".

- There were no "missed conflicts" Both Schering's claim C39 and the individual claims 1, 2, 3 and 5 of the '196 Patent were incorporated into the conflict proceedings.

- In any event, Apotex has failed to satisfy its evidentiary burden to demonstrate that Dr. Smith was the first to know or use the invention of the '196 Patent.

XII. ***Competition Act* Claim**

A. *Overview*

[457] As described earlier in these reasons, the conflict claims before the Commissioner were ultimately resolved through settlement among ADIR, Schering and Hoechst. The settlement was embodied in the Minutes of Settlement (also referred to as the Settlement Agreement) that were attached to the Nadon Order.

[458] In its counterclaim, Apotex seeks damages pursuant to s. 36 of the *Competition Act*. As pleaded and in summary form, the allegations of Apotex related to this requested remedy are as follows:

- the actions of ADIR and the other parties to the Settlement Agreement "ensured that the parties to the [Settlement] Agreement would gain effective control over the manufacture and supply of a number of ACE inhibitors, including those within the scope of the claims of the '196 Patent, and thereby prevent, limit or lessen unduly, competition in the market for ACE inhibitors";

- the parties entered into the Settlement Agreement "willfully, for the purpose and with the effect of preventing, limiting or lessening unduly the competition in the market for ACE inhibitors"; and

- the parties to the Settlement Agreement "have conspired . . . to prevent, limit or lessen unduly . . . competition . . . contrary to section 45 of the Competition Act" .

[459] In determining this aspect of Apotex's counterclaim, a number of sub-issues have been raised:

1. Does the existence of a valid patent preclude Apotex from raising a *Competition Act* claim relating to the manner in which the patent was issued?

2. Is Apotex precluded from bringing this *Competition Act* claim on the basis of the limitation set out in s. 36(4)(a)?

3. Has Apotex satisfied its burden to demonstrate that the Plaintiffs have committed the elements of the s. 45 offence?

4. Even if Apotex's claim is statute-barred by the operation of s. 36(4), do ADIR's anti-competitive actions serve to disentitle ADIR to the relief sought in its claim?

B. *Relevant Statutory Provisions*

[460] Sections 36 and 45 of the *Competition Act* together create a civil cause of action where a party has suffered a loss or damage as a result of an agreement that unduly lessens or prevents competition. The basis of the offence alleged is set out in s. 45(1), in Part VI, of the *Competition Act*:

45. (1) Every one who conspires, combines, agrees or arranges with another person (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,	45. (1) Commet un acte criminel et encourt un emprisonnement maximal de cinq ans et une amende maximale de 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;

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

[461] Entitlement to bring a civil action for damages is set out in s. 36(1)(a):

36. (1) Any person who has suffered loss or damage as a result of	36**.** (1) Toute personne qui a subi une perte ou des dommages par suite :
(a) conduct that is contrary to any provision of Part VI, or	a*)* soit d'un comportement allant à l'encontre d'une disposition de la partie VI;
. . .	. . .
may, in any court of competent jurisdiction, sue for and recover from the person who engaged in the conduct or failed to comply with the order an amount equal to the loss or damage proved to have been suffered by him, together with any additional amount that the court may allow not exceeding the full cost to him of any investigation in connection with the matter and of proceedings under this section.	peut, devant tout tribunal compétent, réclamer et recouvrer de la personne qui a eu un tel comportement ou n'a pas obtempéré à l'ordonnance une somme égale au montant de la perte ou des dommages qu'elle est reconnue avoir subis, ainsi que toute somme supplémentaire que le tribunal peut fixer et qui n'excède pas le coût total, pour elle, de toute enquête relativement à l'affaire et des procédures engagées en vertu du présent article.

[462] Relevant to this action, claims under Part VI of the *Competition Act* must be brought within a limitation period set out in s. 36(4)(a):

(4) No action may be brought under subsection (1),	(4) Les actions visées au paragraphe (1) se prescrivent :
(a) in the case of an action based on conduct that is contrary to any provision of Part VI, after two years from	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) a day on which the conduct was engaged in, or	(i) soit la date du comportement en question,
(ii) the day on which any criminal proceedings relating thereto were finally disposed of,	(ii) soit la date où il est statué de façon définitive sur la poursuite;
whichever is the later . . .	

C. *The Existence of the Patent as a Bar*

[463] As I have determined, the '196 Patent is valid. Further, absent any court determination to the contrary, the other patents that resulted from the Settlement Agreement are also valid. There was no evidence presented to the Court that the parties to whom these valid patents were issued did anything contrary to the provisions of the *Patent Act* in order to obtain those patents. Each of ADIR, Schering and Hoechst acted within their rights under the *Patent Act*. Nevertheless, the question is whether the manner in which they did so can constitute an offence under s. 45 of the *Competition Act*.

[464] A patent excludes all but the patentee (and its assignees or licensees) from making, constructing, using and vending the invention of the patent (*Patent Act*, s. 44). In this case, so long as the '196 Patent is in effect, no other party may sell perindopril. Thus, the very existence of a patent lessens competition. On its face, this is in direct conflict with the provisions of the *Competition Act*, which legislation has as its stated purpose:

1.1 The purpose of this Act is to maintain and encourage competition in Canada in order to promote the efficiency and adaptability of the Canadian economy, in order to expand opportunities for Canadian participation in world markets while at the same time recognizing the role of foreign competition in Canada, in order to ensure that small and medium-sized enterprises have an equitable opportunity to participate in the Canadian economy and in order to provide consumers with competitive prices and product choices.	1.1 La présente loi a pour objet de préserver et de favoriser la concurrence au Canada dans le but de stimuler l'adaptabilité et l'efficience de l'économie canadienne, d'améliorer les chances de participation canadienne aux marchés mondiaux tout en tenant simultanément compte du rôle de la concurrence étrangère au Canada, d'assurer à la petite et à la moyenne entreprise une chance honnête de participer à l'économie canadienne, de même que dans le but d'assurer aux consommateurs des prix compétitifs et un choix dans les produits.

[465] In spite of this apparent conflict, Courts have consistently held that the existence of a patent is not an offence under the *Competition Act* (see, *Molnlycke AB v. Kimberly-Clark of Canada Ltd. et al*. (1991), 36 C.P.R. (3d) 493 at 499 (F.C.A.) [*Molnlycke*]; *Eli Lilly and Co. v. Apotex Inc.* (2005), 44 C.P.R. (4th) 1 at para. 30 (F.C.A.) [*Eli Lilly (F.C.A. 2)*]; *Eli Lilly and Co. v.*

Apotex Inc. (2004), 32 C.P.R. (4th) 195 paras. 14-16 [*Eli Lilly (F.C.A. 1)*]). As noted in *Molnlycke*, at page 498:

> Certainly the existence of a patent is apt to limit, lessen, restrain or injure competition - monopolies do - but its issuance and the inherent impairment of competition has been expressly provided for by an Act of Parliament, which has made provision for compulsory licensing in circumstances where it has considered the ordinary incidence of the statutory monopoly to be contrary to public policy. It is the existence of the patent, not the manner in which issue was obtained or how and by whom its monopoly is agreed to be enforced and defended, that impairs competition. [Emphasis added.]

[466] Apotex, I believe, acknowledges that the patent itself cannot be the focus of an offence under the *Competition Act*. In their view, it is not the patent that constitutes the offence but the actions of ADIR, Hoechst and Schering in obtaining the patent. As described in a response to an undertaking provided during the discovery of Mr. Peter Gingras, global program manager to Apotex Inc., the Settlement Agreement limited or lessened competition in the ACE inhibition market:

> By enabling the participants to control the commencement and duration of the monopoly periods for medicinal substances in the relevant market, and control, and thereby limit, the entry of competing substances in the same market.

[467] This is not the first time that similar arguments have been made to the Courts.

[468] A good example of that is contained in the decision of the Federal Court of Appeal in *Molnlycke*, above. In that case, Molnlycke A.B. and Kimberley-Clark of Canada Ltd. (K-C Canada) had brought an action against Proctor and Gamble Inc. (P&G) for infringement of Canadian patent entitled “Disposable Diapers with Refastenable Tabs”. A patent for the invention was originally issued to Molnlycke, under no. 1,213,702, November 12, 1986. K-C U.S. was a licensee of that patent and K-C Canada its sublicensee. That patent was surrendered and reissued on August 2,

1988, under no. 1,239,752. By assignment recorded in the Patent Office on October 14, 1988, Molnlycke A.B. assigned the reissued patent to K-C Canada and commenced the action on October 21, 1989 against P&G. In its defence and counterclaim, P&G alleged, *inter alia*, an agreement among Molnlycke A.B., K-C Canada and K-C U.S which contravened s. 45(1) of the *Competition Act*.

[469] In allowing the appeal and dismissing the counterclaim the Court of Appeal commented on the interaction between the *Competition Act* and the *Patent Act* at page 499:

> Parliament has, in the Patent Act, defined a "due" impairment of competition. In my opinion, as a matter of law, it is not arguable that the impairment of competition inherent in the exercise of rights expressly provided by that Act - the obtaining of a patent or reissue of a patent, its assignment and action by the assignee to enforce its monopoly - can be undue. It follows that undue impairment of competition cannot be inferred from evidence of the exercise of those rights alone.

[470] The Court of Appeal revisited *Molnlycke*, above, in the related cases of *Eli Lilly (F.C.A. 1)* and *Eli Lilly (F.C.A. 2)*, above. In those cases, Eli Lilly and Company and Eli Lilly Canada Inc. (Lilly) had commenced an action against Apotex for infringement of eight patents related to the antibiotic cefaclor. Four of the eight patents had been assigned, after their issuance to Shionogi & Co. Ltd. (Shionogi), by Shionogi to Lilly. In its counterclaim, Apotex claimed damages under the *Competition Act*. Apotex argued that the assignment by Shionogi of four existing patents to Lilly, who already held a number of patents, resulted in one company, Lilly, acquiring patent rights that allowed it to control all of the commercially viable processes for making cefaclor where, before the agreement, those processes were controlled by two companies, Shionogi and Lilly. The effect, Apotex asserted, was anti-competitive. Lilly submitted that, since patents were assignable under

s. 50 of the *Patent Act* and because of *Molnlycke*, above, Apotex was precluded from bringing its counterclaim. The Court of Appeal agreed with Apotex that the counterclaim was not precluded.

[471] In both *Eli Lilly (F.C.A. 1)* and *Eli Lilly (F.C.A. 2)*, the Courts held open the possibility that agreements related to patents could, in certain circumstances, be the subject of a claim under ss. 36 and 45 of the *Competition Act*. In *Eli Lilly (F.C.A. 2),* above at paragraph 21, Justice Evans concluded that s. 50 of the *Patent Act* (the right to assign a patent) "does not immunize an agreement to assign a patent from section 45 of the *Competition Act* when the assignment increases the assignee's market power in excess of that inherent in the patent rights assigned" [emphasis added]. In his conclusion, at paragraph 36, he stated as follows:

> To conclude, in my respectful opinion, the Judge erred in law by holding that the assignment of patents is exempt from section 45 when, by reason of the assignee's existing ownership of other patents, the assignment transfers more market power than that inherent in the patents assigned. He also erred in regarding Molnlycke as authority for the proposition that, in these circumstances, any lessening of competition could not be undue for the purpose of section 45. [Emphasis Added.]

[472] It appears to me that the Court of Appeal in both *Eli Lilly (F.C.A. 1)* and *Eli Lilly (F.C.A. 2)* must be read as qualifying or expanding on *Molnlycke*, above. Before me both counsel remarked that the case law stands for the proposition that there must be "something more" beyond the mere assertion of patent rights. On the basis of these two cases, I agree. The question becomes: what is "something more"?

[473] In *Eli Lilly (F.C.A. 1)* and *Eli Lilly (F.C.A. 2)*, Lilly added to its existing patents through assignments and had shut all other potential competitors out of the market. That was, in the view of Justice Evans, "something more". In *Molnlycke*, above, this "something more" did not exist since the only effect of the assignment was that a different company could sue the defendant for infringement.

[474] The significant difference between *Eli Lilly (F.C.A. 1)* and *Eli Lilly (F.C.A. 2)* and that before me relates to the lack of existing ownership by ADIR of patent rights that would result in more market power than that inherent when patents are obtained. The assignment agreement between Shionogi and Lilly was entered into after the grant of the eight patents; in other words, those parties already held a certain level of market power granted to them through the patents. The action of combining those two sets of patents through assignment, after the patents had issued, resulted in a total control of the cefaclor market. The Courts in *Lilly (F.C.A. 1)* and *Eli Lilly (F.C.A. 2)* concluded that this was "something more" than the exercise of patent rights.

[475] In contrast, the situation before me involves a settlement agreement that was entered into prior to the grant of the patents to ADIR, Schering and Hoechst. Until and unless the patents issued, there could be no market power held by ADIR and no impairment of competition. While it is true that ADIR had applied for and was awaiting final resolution of the conflict proceedings, the *Patent Act* provided for appeals of the Commissioner's decisions regarding the conflicts to the Federal Court. Moreover, the rules and practices of the Federal Court allow for the settling of actions. 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.

[476] Had ADIR already held patents related to perindopril or even to other ACE inhibitors, it is arguable that there would have been "something more", as it would have gained more market power than that inherent in its obtaining the '196 Patent.

[477] Here, however, regardless of whether perindopril is in the same market as other ACE inhibitors, ADIR could only gain as much market power as that inherent in the '196 Patent. Since there is no evidence it obtained this power by methods other than that authorized by the *Patent Act*, there is nothing more and *Molnlycke* applies.

[478] In sum, because ADIR was merely exercising its rights under the *Patent Act* to obtain patents and nothing more, I am satisfied that Apotex's claim for damages under the *Competition Act* must fail.

D. *Limitation Period*

[479] In the event that I am wrong in my conclusion that ADIR was exercising its rights under the *Patent Act* in a manner that precludes Apotex from claiming damages under the *Competition Act*, I will consider the next issue – the application of the limitation period in s. 36(4) of the *Competition Act*. As noted above, s. 36(4)(i) precludes a party from bringing an action under s. 36 "based on conduct that is contrary to any provision of Part VI, after two years from a day on which the conduct was engaged in".

[480] Servier submits that Apotex is statute-barred from bringing the counterclaim under the *Competition Act* by virtue of s. 36(4) of the *Competition Act* for two reasons: (a) the "conduct", being the entering into the Settlement Agreement, occurred some six years prior to the commencement of the counterclaim; and (b) Apotex has known of the Settlement Agreement since April 2003. Apotex, in turn, argues that the conduct of ADIR occurred, not only on the date that ADIR entered into the Settlement Agreement but has occurred on every day thereafter so long as the patents that issued from the Settlement Agreement are in effect. Further, it argues, an interpretation of s. 36(4) as proposed by Servier would preclude Apotex from ever bringing an action under the *Competition Act*. This is because Apotex could only bring an action under s. 36 of the *Competition Act* where it has "suffered loss or damage"; its loss or damage only flows from a successful claim by Servier of infringement of the '196 Patent by Apotex.

[481] In spite of the capable arguments of counsel for Apotex on this point, I am of the view that the conduct in this case is most likely the entering into of the Settlement Agreement. At the latest, the conduct is the issuance of the '196 Patent (and the patents to Schering and Hoechst that also resulted from the Nadon Order). The undue lessening of competition (if it exists) is the effect of the alleged conspiracy and not the "conduct".

[482] This view is supported by the words of the statutory offence. Specifically, s. 45 provides that "Every one who conspires, combines, agrees or arranges with another person [to unduly lessen competition] . . . is guilty of an offence . . ." The offence is the conspiracy or agreement. The effect of the conspiracy or agreement is undue lessening of competition. While the undue lessening of competition may continue, the act of the conspiracy will, in most cases, occur at an identifiable

time. Thus, when we come to the limitation set out in s. 36(4), the provision refers to the day on which the agreement or conspiracy was entered into. The conduct, for purposes of this action, was the date of the Settlement Agreement among ADIR, Schering and Aventis – in or around December 2000. Thus, the two-year limitation set out in s. 36(4) has been exceeded.

[483] My conclusion may have been different if I had evidence of continuing collusion or agreement among the parties to the Settlement Agreement. I do not. In fact, the evidence is that the parties to the agreement actively compete (for example, as explained by Mr. Sumpter, through the use of visual aides comparing the utility of the various 'prils used by Servier's sales force team). The situation in *351694 Ontario Ltd. v. Paccar of Canada Ltd.*, 2004 FC 1565 [*Paccar*], a case relied upon by Apotex, was quite different.

[484] In *Paccar*, the plaintiffs had been selling truck parts at a deep discount. In response the defendants instituted a rule (referred to as the Palings rule) under which parts were provided to dealers. The operation of the Palings rule "reduces the dealer's possibility for profit and likely will diminish sale. An inference can be drawn that under these circumstances it amounts to act of discrimination in the supply of goods [contrary to s. 61(1)(b) of the *Competition Act*]" (*Paccar*, above at para. 26). Justice Von Finkenstein concluded, at paragraph 27 that:

> This Palings rule was an ongoing rule which remained in place with respect to both dealerships right until the date of termination; i.e. well into the limitation period.

[485] At paragraph 30, the learned judge stated:

> Given my finding above regarding possible violations of s. 61(1)(b) based on the Palings rules, and given that this rule was applied to both dealerships any allegations in respect of parts based on proven violation of s. 61(1)(b) would not be barred by s. 36(4)(a)(1).

[486] The facts of *Paccar* are distinguishable from the case before me. In *Paccar*, there was continuing co-operation between the plaintiffs, presumably under some on-going agreement. The Palings rule continued to be applied by the plaintiffs. In effect, the agreement did not terminate. The act of conspiracy occurred every time a transaction occurred under the Palings rule. In the case before me, there is no such evidence. Upon the Nadon Order or, at the latest, the issuance of the patents, the Settlement Agreement had no continuing effect; it was fully executed. This is a significant distinction.

[487] I conclude that the limitation period runs from the date of the Settlement Agreement or, at the latest, the date of the issuance of the '196 Patent.

[488] The discoverability principle can, in some circumstances, operate to extend a limitation period. This principle operates where a party could not reasonably have known about the existence of an event. In this case, Servier asserts that, since the statutory limitation period in s. 36(4) expressly runs from a specific date independent of knowledge, the discoverability principle cannot apply. I think that this is likely a correct view of the law (see *Fehr v. Jacob* (1993), 85 Man. R. (2d) 64 (Man. C.A.)).

[489] However, the discoverability principle, if it applies, does not assist Apotex. It is arguable that Apotex had effective knowledge of the Settlement Agreement either: (a) as soon as it was placed on the public record in Court File T-228-97 as an appendix to the Nadon Order; or (b) when the '196 Patent issued in 2001. At either of those two points in time, Apotex could be presumed to have been aware that a patent had issued for perindopril and that the '196 Patent had issued pursuant to an agreement among three companies. Even if I cannot definitively conclude that Apotex knew about the alleged conspiracy in 2001, the evidence before me is unequivocal that Apotex knew about the Settlement Agreement no later than April 2003. Mr. Peter Gingras, global program manager with Apotex Inc., in responses to undertakings given during his examination in discovery, advised that Apotex became aware of and received a copy of the Settlement Agreement in April 2003. Thus, even if the discoverability principle applies, the latest date from which the two-year limitation period runs would be April 2003. Apotex is, therefore, well beyond the two-year limitation of s. 36(4).

[490] For these reasons, I find that Apotex is statute barred from bringing an action under s. 36 of the *Competition Act* on the basis that Apotex brings this action more than two years after the alleged conduct was engaged in.

E. *Conclusion*

[491] Apotex's counterclaim under the *Competition Act* fails on the grounds that: (a) ADIR was exercising its rights under the *Patent Act*; and (b) in any event, Apotex brought this action beyond

the two-year limitation set out in the *Competition Act*. Accordingly, I do not need to deal with the substance of the arguments and conflicting expert evidence put forward on Apotex's counterclaim.

[492] Apotex also asks that, even if the claim is statute barred, I consider whether ADIR's anti-competitive actions serve to disentitle Servier to the relief it seeks. In short, Apotex's argument is that anti-competitive conduct can disentitle a party to equitable relief.

[493] In response to this argument, I return to my first conclusion in this section. In entering into the Settlement Agreement, Servier (or ADIR) was exercising its rights under the *Patent Act*. Apotex has not shown that ADIR did anything more than that which was explicitly contemplated by the provisions of the *Patent Act* and the *Federal Courts Rules*. On these facts, Apotex has failed to show that there was conduct that would disentitle Servier to any of the equitable remedies that it may seek.

[494] Apotex's counterclaim for damages under s. 36 of the *Competition Act* will be dismissed.

XIII. Remedies

A. *Overview*

[495] Servier Canada and ADIR have been successful in this action, except with respect to their claim of inducement. The '196 Patent as well as claims 1, 2, 3 and 5 of the '196 Patent are found to

be valid and infringed by Apotex, subject to certain exemptions afforded by section 55.2(1) of the *Patent Act*. Servier seeks the following remedies:

- A declaration that the '196 Patent is valid and subsisting;
- A declaration that Apotex Inc. and Pharmachem have infringed claims 1, 2, 3 and 5 of the '196 Patent;
- A permanent injunction on various terms;
- Damages or, if they so elect, an accounting of profits;
- Punitive or exemplary damages;
- Pre-judgment and post-judgment interest and all applicable taxes;
- Costs of the proceedings on a solicitor-client basis or an elevated scale; and
- All experts' fees

[496] In general, the Court's authority to grant the requested relief arises from specific provisions in the *Patent Act* or the *Federal Courts Act*. Section 55 of the *Patent Act* provides that the patentee and all persons claiming under the patentee (in this case, Servier Canada and ADIR) are entitled to

damages. Section 57 of the *Patent Act* permits the Court to award an injunction and an accounting of profits in appropriate circumstances. Normally, an order for delivery up of infringing material would follow the award of an injunction. The Court has power to award pre-judgment interest; ss. 36 and 37 of the *Federal Courts Act* directs the Court to look at the laws of an appropriate province in that regard. The Court has inherent power to award exemplary or punitive damages where appropriate, and to award costs.

B. *The Bifurcation Order*

[497] By Order dated March 14, 2007, 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. In specific terms, the Order stated as follows:

> 2. Pursuant to Rule 107(1), this matter may proceed to trial without requiring the parties to adduce evidence at trial, or to conduct discoveries, or make production on any issue of fact where such evidence relates solely to:
>
> a. the calculation of the quantum of damages suffered by the plaintiffs as a result of the infringement by defendants of Canadian Patent 1,341,196 (hereinafter the "'196 Patent");
>
> b. the calculation of the quantum of profits made by the defendants as a result of the infringement by defendants of the '196 Patent; and
>
> c. the calculation of the quantum of the defendants' damages resulting from a breach by plaintiffs of section 45 of the *Competition Act*.

3. A hearing under Rules 107 and/or 153 of the *Federal Courts Rules* shall be conducted following the final determination of all remaining issues herein, if it then appears that such issues are required to be decided, including necessary documentary and oral discovery.

C. *Permanent Injunction*

[498] Servier submits that the issuance of a permanent injunction against Apotex, effective immediately upon Judgment, is an appropriate remedy in this case to prevent Apotex from further infringing the '196 Patent until patent expiry (*Merck (C.A.)*, above at para. 69).

[499] While not objecting in principle to the imposition of a permanent injunction, Apotex submits that a "grace" period of 30 days be allowed before the injunction comes into effect. This was done recently in *Janssen-Ortho*, above.

[500] The grant of a permanent injunction is a discretionary remedy *(Janssen-Ortho*, above at para. 133). I acknowledge, as pointed out by Servier, that the Plaintiffs in this action acted swiftly to bring this action. However, Apotex's sale of the 8 mg tablets of perindopril in Canada was done in compliance with the *NOC Regulations*. Servier's failure to seek the protection of the *NOC Regulations* for its 8 mg tablet enabled Apotex to obtain the necessary NOC for that dosage. This situation where Apotex was legally able to sell the 8 mg tablets in Canada (subject to any claim of infringement, of course) is, in my view, similar to the facts in *Janssen-Ortho*, above.

[501] Thus, as was done in *Janssen-Ortho*, above, I am prepared to allow a 30 day period after my judgment before the injunction will come into effect with respect to the sale of perindopril. During

that time, Apotex may continue to sell or otherwise dispose of its perindopril products already in its possession, custody or control, but only in the normal course of business and provided that all monies received in respect thereof are accounted for and held in a separate trust fund to be paid to Servier, or as they may direct, by October 31, 2008. These monies are to be taken into consideration, by way of set off or otherwise, when a final calculation as to damages is made.

D. *Damages or Profits*

[502] It is accepted by both parties that, once a patentee has successfully demonstrated infringement, the court has the discretion to grant the patentee's choice of remedies – either damages (as provided for in s. 55 of the *Patent Act*) or an accounting of profits (pursuant to s. 57). Servier wishes to be able to elect an accounting of profits and asks this Court to so direct. Apotex argues that I should not exercise my discretion in this case.

[503] While both damages and accounting of profits are intended to provide compensation to a wronged plaintiff, the fundamental principles underlying the two remedies and the practical considerations are substantially different.

[504] The object of an award of damages is to make good any loss suffered by the plaintiff as a result of the defendant's infringement of the patent. Quantification of the award is based on the losses suffered by the plaintiff; any gains realized by the defendant because of its wrongdoing are not relevant. On the other hand, an accounting of profits is based on the premise that the defendant, by reason of its wrongful conduct, has improperly received profits which belong to the plaintiff. The

objective of the award is to restore those actual profits to their rightful owner, the plaintiff, thereby eliminating whatever unjust enrichment has been procured by the defendant. Calculation is based on the profits wrongfully gained by the defendant; any other losses suffered by the plaintiff are irrelevant.

[505] An accounting of profits is not an easy calculation. As was stated by the late Justice Rouleau, of this Court, when speaking about such an accounting in *Beloit Canada Ltd. v. Valmet-Dominion Inc.* [1994] F.C.J. No. 682 at para. 3 (T.D.) (QL), rev'd in part [1995] F.C.J. No. 733 (C.A.) (Q.L.), leave to appeal to S.C.C. refused, [1995] S.C.C.A. No. 388:

> This was undoubtedly a most expensive, lengthy and difficult reference and one which clearly underlines the pitfalls of granting the remedy of an accounting of profits other than in exceptional and appropriate circumstances and after due deliberation by the court.

[506] In spite of practical difficulties, the Court of Appeal in *Beloit Canada Ltd. v. Valmet Oy* (1992), 45 C.P.R. (3d) 116 at 119 (F.C.A.), stated that it could:

> ...see no reason in principle why a patentee, whose property has been wrongly appropriated through infringement, should not recover all the profits, direct and indirect, derived by the infringer from his wrongful infringement.

[507] It is necessary for a party seeking an equitable remedy, such as profits, to show some basis for the exercise of equity (*Janssen-Ortho*, above at para. 132).

[508] In my view, there are a number of facts in this case that show a sound basis for an exercise of discretion:

- There has been no inequitable conduct by the Plaintiffs which would disentitle them to such relief.

- In contrast to the situation before the Court in *Merck (F.C.)*, above, where there was delay in bringing the matter to trial, Servier commenced this action and cooperated in bringing the matter to trial in a relatively short period of time.

- With Apotex infringement dating back only to 2006, quantification of profits should not be unduly complex.

- Servier Canada has continued to fully promote its perindopril products in Canada, and has taken steps to maintain competitiveness. Once again, this situation differs from that before Justice Hughes in *Merck (F.C.)*, above, where the plaintiffs "threw in the towel".

[509] In contrast, the behaviour of Apotex must also be taken into account. Apotex, fully aware of the '196 Patent, chose Canada as the manufacturing site for perindopril products. Apotex could have avoided all of the manufacturing infringement by making perindopril-containing products outside of Canada. This is not just speculation. As acknowledged by a number of witnesses for Apotex, Apotex also has manufacturing facilities in India and is in the process of obtaining authorization to

produce perindopril from that site. Indeed, as stated by Dr. Sherman, during his testimony, Apotex had "determined that it would make sense to have the facilities outside of Canada qualified in case it turned out we would lose at trial". I have no problem with Apotex and other related companies arranging their business affairs in any way they see fit. However, they must also bear the consequences of their choices where they are perfectly aware that a patent will be infringed. In this case, Apotex chose to make perindopril in Canada fully knowing that making perindopril would constitute infringement and that it might be required to disgorge its profits.

[510] Apotex notes that it was able to obtain an NOC for the 8 mg tablets due to an oversight on the part of Servier and asks that I take this into account in determining whether profits should be available to Servier. In my view, on the facts of this case, the failure of Servier to protect the 8 mg dosage is not material. Apotex did not commence sales of the 8 mg tablets until after the launch of this lawsuit, when Apotex was well aware that Servier was aggressively asserting its patent rights. Once again, I believe that Apotex should not now be permitted to isolate itself from an election of profits on the basis of its commercial decisions and the oddities of Canada's *NOC Regulations*.

[511] Balancing the facts in this case, I am persuaded that I ought to exercise my discretion and allow Servier to elect an accounting of profits.

E. *Interest*

[512] Servier requests an award of pre-judgment interest running from the date of the first shipment or sale by Apotex in 2006 of infringing perindopril products at the average bank prime

commercial lending rate plus one and a half percent (1.5%), or in any event no less than five percent (5%), compounded semi-annually. Servier requests the same compounded rate for post-judgment interest. The parties acknowledge that, if Servier elects an account of profits, determination of interest should be done as part of the reference or pre-judgment trial that determines profits.

[513] In the event that Servier elects an award of damages, I see no reason to depart from the conclusions of my colleague Justice Hughes in *Janssen-Ortho*, above at paras. 135-136 (see also *Merck (F.C.)*, above at para. 241):

> Pre-judgment interest is allowed in respect of any monetary award of damages. It should not be compounded. The rate of such interest should be calculated separately for each year since the infringing activity began at the average annual bank rate established by the Bank of Canada as the minimum rate at which it makes short term advances to the banks listed in Schedule I of the *Bank Act*, R.S.C. 1985, c. B-1.
>
> Post-judgment interest, not compounded, follows the establishment of the quantum of damages at the rate of five percent (5%) established by the *Interest Act*, R.S.C. 1985, c. I-15, s. 4.

F. *Punitive or Exemplary damages*

[514] Servier also seeks punitive or exemplary damages. The parties are agreed that it would be premature for me to make that determination prior to the reference on damages. As stated by Justice Sharlow, writing for the Court of Appeal in *Apotex Inc. v. Merck & Co.,* 2003 FCA 291 at para. 34:

> The purpose of punitive damages is to punish, to deter the wrongdoer and others, and to denounce wrongful behaviour. Punitive damages are awarded only where compensatory damages and other normal civil remedies are insufficient to accomplish those objectives, and in an amount that is no greater than necessary to accomplish that objective: Whiten, supra; Hill v. Church of Scientology of Toronto, [1995] 2 S.C.R. 1130. It is axiomatic that until all the ordinary civil

> remedies are finally determined (which in this case would include a determination as to whether the remedy is an award of damages or an accounting of profits, and the quantum), it is impossible to determine whether punitive damages are required to meet the objectives of punishment, deterrence and denunciation.

[515] Accordingly, consideration of the issue of exemplary or punitive damages will be deferred until after damages or profits are awarded.

G. *Conclusion*

[516] In sum, Servier Canada and ADIR will be entitled to the following, as more particularly described in the foregoing and in the judgment:

- 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 this judgment;

- Damages to be quantified subsequent to this judgment;

- Pre and post-judgment interest.

[517] I take no decision and express no views, as part of this judgment, on the question of punitive or exemplary damages.

XIV. Overall Conclusion

[518] For these reasons, Servier's claim will be allowed insofar as it relates to Servier Canada and ADIR; the claims of all other Plaintiffs will be struck. Apotex's counterclaim is dismissed.

[519] I reserve as to costs and ask that the parties provide written submissions as to costs, within thirty (30) days from the delivery of these Reasons. These submissions should address those matters set out in Rule 400(3) of the *Federal Courts Rules* as well as experts, number of counsel, disbursements, any offer to settle and any other matter relevant to the award of costs. These submissions should not exceed ten (10) pages.

JUDGMENT

For the Reasons set out herein, following the trial of this action, **this Court adjudges and declares as follows:**

1. Les Laboratoires Servier, Oril Industries, Servier Laboratories (Australia) Pty Ltd and Servier Laboratories Limited are hereby struck from the style of cause of this action and shall have no rights as Plaintiffs in respect of this action;

2. Claims 1, 2, 3 and 5 of Canadian Letters Patent No 1,341,196 are valid and have been infringed by the Defendants, Apotex Inc. and Apotex Pharmachem Inc., or either of them, by their manufacture, sale, offering for sale and other dealing in perindopril containing products in Canada;

3. An injunction shall issue to take effect after the expiry of thirty (30) days from the date of issue of these Reasons prohibiting the Defendants and all those over whom they may exercise control, from manufacturing, selling, offering for sale or otherwise dealing in perindopril containing products in Canada; provided, however, that from the date of issue of these Reasons until the expiry of said thirty (30) days, the Defendant may continue to sell or dispose of such product as it already has in its possession, custody or control as of the date of issue of this Judgment, in the normal course of business and provided that all monies received in respect thereof are accounted for and held in a separate trust fund to be paid to the Plaintiffs, or as they may direct, by October 31, 2008;

4. The Defendants may, at their election, do one of the following in respect of perindopril containing products in their possession, custody or control as of the date of issue of this Judgment:

a) Sell them in the normal course of business in accordance with paragraph 3 above, provided that all unsold product at the end of the thirty (30) day period shall be treated in the manner provided in one of b) or c) below;

b) Destroy them and provide an appropriate affidavit of a responsible officer of the Defendants to that effect; or

c) Deliver them up to the Plaintiffs at a place and manner as the Plaintiffs may direct provided that if such delivery is to take place outside of the Greater Toronto area it shall be at Plaintiffs' expense;

5. The Plaintiffs are entitled to elect either an accounting of profits of the Defendants or all damages sustained by them by reason of the activities of the Defendant which infringe claims 1, 2, 3 or 5 of the '196 Patent. A separate trial, preceded by discovery if requested, shall be held to determine either an accounting of the Defendants' profits or the quantum of damages. Any monies paid as set out in paragraph 3 above shall be taken into consideration by way of set off or otherwise, in the final calculation of damages or profits.

6. The Plaintiffs are entitled to pre-judgment interest on the award of damages (if elected), not compounded, at a rate to be calculated separately for each year since infringing activity began at the average annual bank rate established by the Bank of Canada as the minimum rate at which it makes short term advances to the banks listed in Schedule 1 of the *Bank Act*, R.S.C. 1985, c. B-1. In the event that the Plaintiffs elect an accounting of profits, interest will be determined as part of the separate trial referred to in paragraph 5;

7. The Plaintiffs are entitled to post judgment interest, not compounded, at the rate of five percent (5%) per annum. This interest shall commence upon the final assessment of the damage or profits amount;

8. The question of exemplary or punitive damages is deferred until after the award of damages or profits has been determined; and

9. The parties shall make submissions as to costs within thirty (30) days hereof in the manner set out in the Reasons.

10. The Defendants' Counterclaim is hereby dismissed.

"Judith A. Snider"
Judge

FEDERAL COURT
SOLICITORS OF RECORD

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REASONS FOR JUDGMENT AND JUDGMENT:	SNIDER J.
DATED:	July 2, 2008

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