Federal Court  Cour fédérale

Date: 20130319

Dockets: T-1420-11
T-288-12

Citation: 2013 FC 283

Toronto, Ontario, March 19, 2013

PRESENT: The Honourable Mr. Justice Hughes

Docket: T-1420-11

BETWEEN:

NOVARTIS PHARMACEUTICALS CANADA INC.

Applicant

and

TEVA CANADA LIMITED and THE MINISTER OF HEALTH

Respondents

and

NOVARTIS AG and BOEHRINGER MANNHEIM GmbH

Respondent Patentees

Docket: T-288-12

AND BETWEEN:

NOVARTIS PHARMACEUTICALS CANADA INC.

Applicant

and

TEVA CANADA LIMITED and
THE MINISTER OF HEALTH

Respondents

and

NOVARTIS AG and
ROCHE DIAGNOSTICS GmbH

Respondent
Patentees

REASONS FOR JUDGMENT AND JUDGMENT

HUGHES J.

[1] These reasons are common to two applications each brought by Novartis Pharmaceuticals Canada Inc. under the provisions of the *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 as amended (*NOC Regulations*). In each application, Novartis seeks to restrain the Minister of Health from issuing a Notice of Compliance to Teva Canada Limited; in one application it is in respect of 4 mg/5 ml strength of zoledronic acid IV infusion (T-1420-11) and in the other it is in respect of 5 mg/100 ml strength of zoledronic acid IV infusion (T-288-12) until the expiry of each of Canadian Letters Patent No. 1,338,895 and 1,338,937. The issues in each application are those of validity of those two patents. Infringement is not an issue in either application. Thus, the two applications proceeded on common evidence and argument and were heard together.

[2] For the reasons that follow, I find that Teva's allegations with respect to invalidity, on the basis of inutility and lack of sufficiency of the '895 patent, claim 14 to be justified thus the

application is dismissed with respect to that patent. I find that Teva's allegations with respect to invalidity of the '937 patent are not justified thus the application will be allowed in respect of that patent. The Applicant is entitled to half of its costs at the middle of Column IV.

[3] The following is an Index to these Reasons by paragraph number:

THE PARTIES

[4] The Applicant Novartis Pharmaceuticals Canada Inc. (Novartis) is the same in each application. It has listed each of the two patents at issue in accordance with the *NOC Regulations* and has itself obtained Notices of Compliance from the Minister of Health to sell a bone mechanism

regulator product in Canada containing zoledronate as an active ingredient. Novartis is a "first person" as described in the *NOC Regulations*.

[5] The Respondent Teva Canada Limited (Teva) is a "second person" as so described in the *NOC Regulations*. It seeks to sell generic versions of Novartis' drug. Application T-1420-11 deals with Teva's intent to seek a Notice of Compliance to sell such a drug for administration by IV infusion in a 4 mg/5 ml dose and has served upon Novartis a Notice of Allegation dated July 20, 2011 in accordance with the *NOC Regulations*. Application T-288-12 deals with Teva's intent to seek a Notice of Compliance to sell such a drug for administration by IV infusion in a 5 mg/100 ml dose and has served upon Novartis a Notice of Allegation dated December 23, 2011 in accordance with the *NOC Regulations*.

[6] The Respondent Minister of Health is charged with various duties under the *NOC Regulations*, including the issuance of a Notice of Compliance to a "second person", such as Teva, in appropriate circumstances. The Minister took no active role in these proceedings.

[7] Novartis asserts, and Teva does not challenge, that Canadian Patent 1,338,895 is owned by the Respondent Boehringer Mannheim GmbH and that Canadian Patent 1,338,937 is owned by the Respondent Novartis AG. Neither of these entities took any active role in these proceedings.

THE '895 PATENT GENERALLY

[8] Canadian Letters Patent No. 1,338,895 (the '895 patent) resulted from an application filed with the Canadian Patent Office on July 29, 1987. Therefore, that patent is governed by the

provisions of the "old" Patent Act, RSC 1985, c. P-4, applicable to patents, the application for which was filed in the Canadian Patent Office prior to October 1, 1989.

[9] The '895 patent claims priority from an application filed in the Federal Republic of Germany on August 1, 1986. This is the presumed "date of invention" upon which the issue of obviousness is to be determined provided that the priority document is in the evidence and supports the claimed invention. A different date of invention can also be proved by evidence as to what the inventors did.

[10] The '895 patent was issued and granted to Boehringer Mannheim GmbH on February 4, 1987. The patent is to be construed as of that date. The term of the patent is to be calculated as being seventeen (17) years from the date of grant; thus this patent's term will expire February 4, 2014.

[11] The '895 patent names Elmar Bosies and Rudi Gall, both of the Federal Republic of Germany, as inventors. The record shows that Bosies is deceased and Gall is "fearful of death"; therefore, we have no evidence from the inventors in these proceedings.

[12] Only claim 14 of the '895 patent is at issue in these proceedings.

THE '937 PATENT GENERALLY

[13] Canadian Letters Patent No. 1,338,937 (the '937 patent) resulted from an application filed with the Canadian Patent Office on October 19, 1987. Therefore, that patent, like the '895 patent, is governed by the provisions of the "old" *Patent Act*, applicable to patents applied for in Canada before October 1, 1989.

[14] The '937 patent claims priority from an application filed with the Swiss Patent Office on November 21, 1986. This is the presumed "date of invention" upon which the issue of obviousness is to be determined based on the evidence as discussed with respect to the '895 patent.

[15] The '937 patent was issued and granted to Ciba-Geigy AG of Switzerland on February 25, 1997. The patent is to be construed as of that date. The term of the patent is to be calculated as being seventeen (17) years from that date; thus, this patent's term will expire February 25, 2014.

[16] The '937 patent names Knut A. Jaeggi and Leo Widler, both of Switzerland, as inventors. One of them, Leo Widler, provided evidence in these proceedings.

[17] The '937 patent contains two (2) claims, claims 1 and 2, both of which are at issue in these proceedings.

THE EVIDENCE

[18] As is usual in these proceedings, the evidence took the form of affidavits, exhibits to affidavits, transcripts of cross-examination, and exhibits to cross-examination. The Court had no opportunity to see or hear the witnesses, or to observe their demeanour.

[19] The Applicants have filed the affidavits, with exhibits, of the following persons:

- Dr. Leo Widler: He is one of the named inventors of the '937 patent. He is a Senior Investigator, Global Discovery chemistry at the Novartis Research

Institutes for Biomedical Research in Basel, Switzerland. He provided some history as to bisphosphonates generally, and particular history leading up to the '937 patent. He was cross-examined.

- Dr. Martin Knauer: of Bensheim Germany He is a Patent Attorney employed by Roche Diagnostics GmbH as Director and Senior Patent Counsel for patent conflicts. He filed two affidavits attaching as exhibits documents of Boehringer Mannheim (acquired by Roche) relating to developments leading to the '895 patent. He was cross-examined.

- Dr. Frank H. (Hal) Ebetino (expert): of Blackrock, Ireland. He is a consultant in drug discovery and development with specific expertise in the bisphosphonate (BP) field. He is a Visiting Scholar at the University of Southern California, and a Visiting Research Professor at Queen's University, Belfast. He worked with Proctor & Gamble in the early development of BPs. He provided a history of the development of generations of BPs. He dealt with arguments and evidence of Teva as to obviousness and sufficiency of the "937 patent. He was cross-examined.

- Dr. Mark Lundy (expert): of West Chester, Ohio. He is President of Osteoresearch LLC, a consulting firm for the pharmaceutical industry. He received a PhD I Biomedical Sciences from Albany Medical College and started his courses in the bone field as a post-doctoral fellow in the Department of

Medicine and Anatomy at Loma Linda University in California. He joined Proctor & Gamble and did much of the early research into BPs there. He provided a history of the development of BPs and specific opinions respecting the '895 and '937 patents. He reviewed the documents provided by Dr. Knauer as to developments leading to the '895 patent. He addresses in particular statements as to utility made in Dr. Grynpas' affidavit. He was cross-examined.

- Dr. James J. Benedict (expert): of Aveda, Colorado, Vice-President of Research and Development at Cerapedics, Inc. He received a doctorate from the University of Wisconsin in Transition Metal Organometallic Chemistry. He began his career at Proctor & Gamble dealing with phosphonates and moved on to other organizations engaged in bone metabolism and bisphosphonate research. He gave a history of bisphosphonates and opinions as to inventiveness of the '895 patent and its sufficiency. He rebutted the evidence of some of Teva's witnesses. He was cross-examined.

- Ejvind Johannes-Christiansen (expert): of Hellerup, Denmark, a European patent attorney. He gave evidence as to when a Danish patent application, 1985 0 5996 was published and actually obtainable by the public. He was not cross-examined. At the hearing, Counsel for Teva advised the Court that Teva was not relying on the Danish application for any purpose in these proceedings.

- Eric McIntomny: a law clerk employed in the offices of the Applicants' Counsel. He provided, as exhibits, certain correspondence between the firms of Counsel representing Teva. He was not cross-examined.

[20] The Respondent Teva filed the affidavits, with exhibits, of the following persons:

- Dr. Stanley Michael Roberts (expert): of Devon, United Kingdom. He received a doctorate from the University of Salford, and did post-doctorates at the University of Zurich and Harvard University. He was a professor at various English Universities and Head of Chemical Research at Glaxo Group in Greenford, UK. He has received various honours and consults in a variety of areas, including medicinal chemistry, agrochemistry, biotechnology and combinatorial chemistry. He provides opinions as to obviousness respecting the '895 and '937 patents. He was cross-examined.

- Dr. Jouko Vepsalainen (expert): of Kuopio, Finland. He received a doctorate from the University of Joensuu, Finland; his thesis focused on halomethylene bisphosphonation. He worked exclusively in the area of bisphosphonates. He teaches and has written many scientific papers in that area. He submitted an affidavit and rebuttal affidavit directed to the obviousness of the '895 and '937 patents. He was cross-examined.

- Dr. Marc Grynpas (expert): of Toronto, Ontario. He is a Senior Scientist at the Samuel Lunenfeld Research Institute at Mount Sinai Hospital, Toronto; and a Professor in the Department of Laboratory Medicine & Pathobiology at the University of Toronto. He deals principally with utility in respect of the '895 and '937 patents. He was cross-examined.

- Christine Slattery: of Oakville, Ontario. She is fluent in English, French and German and is a freelance translator. She compared a European Patent Application in German, No. 0 170 228, with a United States patent in English 4,687,767. She found them to be almost identical. She was not cross-examined. Her evidence is not contested.

- John Coakley: of Hamilton, Ontario. He is a freelance translator fluent, among other things, in Danish and English. He compared Danish Patent Application No. 168754 with European Patent Application No. 0186405, in English, and found them to be mostly identical. He was not cross-examined. As previously stated, the Danish application is no longer at issue.

- Melissa Marie Dimilta: of Toronto, Ontario. An articling student in Teva's Counsel's office. She located and provided a copy of what is called the Schenck article.

- Louise McLean: of Toronto, Ontario. A law clerk in Teva's Counsel's office. She provided an affidavit and a reply affidavit. She was cross-examined. Her evidence served to make of record certain documents referred to in the Notices of Allegation and correspondence between the Counsel for the Applicants and Teva.

[21] In addition, certified copies of certain patents, including the '895 and '937 patents, as well as others, were filed.

[22] Each of the parties, at the hearing and in their memorandum, tried to marginalize the evidence of the experts of the other. Dr. Roberts, one of Teva's experts, was said to be too much of a generalist and had not been involved in research respecting bone treatment. He made a search of the prior art, but did not keep his notes, which he described as "hieroglyphics". Novartis' experts were said to be "too expert" in that they worked too close to the field at the time and were unable to see the matters clearly as would a "disinterested" scientist.

[23] I am unable to come to any conclusion that would cause me to reject, or give minimal weight, to the evidence of any expert for either party. Dr. Roberts spoke as a generalist; he conducted, in my opinion, a proper prior art search. Novartis' experts were close to the subject but gave what I find to be fair and disinterested opinions. All of the witnesses for both parties gave useful evidence. I find no reason to reject or be sceptical about any of it.

ISSUES

[24] The main issue is whether or not these applications for prohibition should be granted. That issue depends on whether the Court has been satisfied, or not, that Teva's allegations as to invalidity of the '895 and '937 patents are justified.

[25] In respect of the '895 patent, Teva's allegations as to invalidity are based on:

- obviousness
- lack of utility
- insufficiency

[26] With respect to the '937 patent, the allegations as to invalidity are based on:

- obviousness
- lack of utility
- insufficiency
- overbreadth

[27] In its Notice of Allegation, Teva also raised an issue as to double patenting. At a pre-trial conference, Teva's Counsel advised the Court that this issue would not be pursued.

BURDEN OF PROOF

[28] The issues relate only to Teva's allegations as to invalidity of the two patents at issue. I recently wrote on that subject in *Pfizer Canada Inc v Pharmascience Inc*, 2013 FC 120, and I repeat and adopt what I wrote at paragraphs 25 and 26:

> *[25] There have been many decisions addressing the question of burden when the issue in NOC proceedings is that of patent validity. I refer for instance to Pfizer Canada Inc v Apotex Inc, 2007 FC 26 at paras 9 and 12, and 2007 FCA 195, leave to appeal to Supreme Court refused; Pfizer Canada Inc v Canada (Minister of Health), 2012 FC 767 at para 42, affirmed in the result 2012 FCA 308.*
>
> *[26] To put the matter briefly, the Patent Act, subsection 43(2) affords a patent a presumption of validity. In NOC proceedings the "second person" must lead some evidence to rebut that presumption. Once such evidence has been led the Court must determine the issue of validity on the usual civil burden of proof having regard to all the relevant evidence.*

PERSON SKILLED IN THE ART

[29] The person skilled in the art (PSIA) or person of ordinary skill in the art (POSITA) is the person to whom a patent is directed and through whose eyes many issues respecting a patent are to be considered.

[30] The Applicants, in their Memorandum of Argument, propose the following definition of such a person:

> *77. Novartis' position is that a PSIA would be part of a discovery team at a pharmaceutical company looking for a new BP. The PSIA would have a Ph.D. degree with some experience in the BP field or, alternatively, a Master's or Bachelor's degree but with more experience investigating BPs. The discovery team would be*

> *composed of medicinal chemists, biologists, and sometimes other subspecialists such as physical chemists. However, the medicinal chemist would be the scientist determining which compounds to make and test. Further, the chemist would also have to have specific experience in BP chemistry.*

[31] Teva in its Memorandum of Argument proposes the following definition for such a person:

> *33. The skilled person is a skilled technician who has a mind willing to understand a specification addressed to him, who is "not a dullard, but lacking in imagination" and who is permitted to experiment when assessing obviousness, provided that the testing is routine and does not involve intense investigation. The skilled person "keeps up with the literature and is skilled in reading a patent, not only within the context of its subject matter, but also as a legal document. He reads patents in this and other jurisdictions as if he read them the day they were first made public, casting aside all he has learned since then".*
>
> *34. The parties agree that the skilled person for the 895 Patent and the 937 Patent would have had a few years of experience working in the area of drug design or a few years of education at the Ph.D. level in the pharmaceutical area. The skilled person was part of a project team, such as the team tasked with developing a new BP. It included a medicinal chemist who would determine which compounds to make and test. Biologists conducted tests in models to assess activity and completed the team.*

[32] The differences between the two are narrow. The Applicants state these differences as follows in their Memorandum:

> *78. Novartis' position is, for the most part, consistent with Teva's position with the exception of two important clarifications. First, the PSIA must have actual experience developing new BPs. Second, to the extent the PSIA includes a researcher from academia, such persons would only fall within the definition of a PSIA if the focus of their research was on drug discovery and if they had experience working with a drug discovery team at a pharmaceutical company in the BP field.*

[33] Teva argues at paragraphs 35 through 37 of its Memorandum that the Applicants' definition is too narrow and would have the effect of eliminating persons other than those who were employed by one of the five brand companies working on bisphosphonates at the time; it would include the elimination of Dr. Widler, one of the inventors named in the '937 patent and a witness for the Applicants.

[34] I accept Teva's definition as the most appropriate and find that the differences with their definition and that of the Applicants' are few, and that the Applicants' differences create a PSITA that is too narrowly defined.

THE '895 PATENT IN DETAIL

[35] The '895 patent is titled:

> *Diphosphonic Acid Derivatives, Processes for the Preparation Thereof and Pharmaceutical Composition Containing Them*

[36] It begins at page 1 by stating that the invention concerns "new diphosphonic acid derivatives; how to prepare them, and pharmaceutical compositions containing those derivatives:

> *The present invention is concerned with new diphosphonic acid derivatives, processes for the preparation thereof and pharmaceutical compositions containing them.*

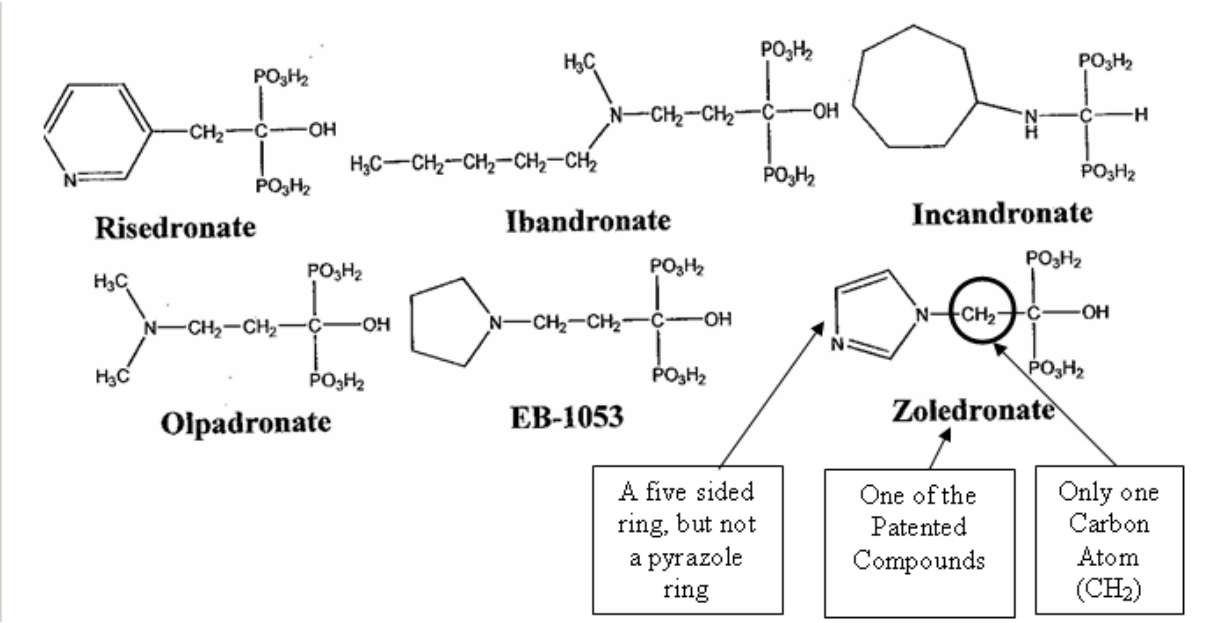
[37] At page 1 from lines 5 to 19, a number of patent applications, all German except for one European, are identified as disclosing certain diphosphonic acid derivatives. At page 23, some of these applications are more particularly identified as issued patents, although there is no particular

correlation with those listed at page 1 and at page 23. Counsel for the Applicants could not explain why.

[38] Returning to page 1, commencing at line 20, the '895 patent identifies a particular feature of its diphosphonic acid derivatives that differs from the previously described derivatives; namely, that:

> *…there is only one carbon atom between this diphosphonate residue and the heterocyclic radical and the heterocyclic radical is not a pyrazole ring…*

[39] I digress from the '895 patent for a moment to point out that this feature can be illustrated using the examples found at paragraph 25 of Novartis' Memorandum of Argument. That example is specific to one of the many compounds embraced by the '895 patent, Zoledronate, but it serves to illustrate what the patent says is the inventive concept:



[40] Returning to the '895 patent, the description at page 1, starting at line 20 and over to page 2, describes the features of this particular composition; namely, that these derivatives are suitable for the wider treatment of calcium metabolism disturbances:

> *We have now found that analogous derivatives of these compounds in which there is only one carbon atom between the diphosphonate residue and the heterocyclic radical and heterocycle is not a pyrazole ring also display these actions and , in addition, as good calcium complex formers, are suitable for the wider treatment of calcium metabolism disturbances. In particular, they can be very well used in cases in which the bone formation and breakdown is disturbed, i.e. they are suitable for the treatment of diseases of the skeletal system, for example osteoporosis, Bechterew's disease and the like.*
>
> *Moreover on the basis of these properties, they can also be used in therapy of bone matastases or urolithiasis and for the prevention of heterotopic ossifications. Furthermore, due to their influencing of the calcium metabolism, they form a basis for the treatment of rheumatoic arthritis, osteoarthritis and degenerative arthrosis.*

[41] From the middle of page 2 to page 3, line 18, there is a description of several of the components of the compound.

[42] Commencing at line 24 of page 3 to the end of page 9, several processes for the preparation of the compounds are described.

[43] From the top of page 10 to line 8 of page 11, there is a discussion as to pharmaceutically acceptable salts.

[44] At page 11, lines 9 to 18, there is a discussion as to various forms in which the pharmaceutical may be administered, liquid or solid.

[45] From line 19, page 11, to line 7, page 12, there is a description as to additives, sometimes called excipients.

[46] From lines 8 to 13 of page 12, a general description as to dosages which "can depend on various factors" is given.

[47] At page 13, a test of one of the compounds (not zoledronate) is described with results tabulated on Table 1 appearing on page 14.

[48] At pages 15 through to the middle of page 18, a large number of compounds are particularly identified as being "Preferred in the sense of the present invention". None of them is zoledronate.

[49] From the middle of page 18 to the end of page 22, a number of examples are provided, which are said to "show some of the process variants which can be used in synthesising the compounds according to the present invention". Zoledronate is not specifically identified as a compound which can be produced. However, Example 1 is said to produce a compound that would fall within the scope of claim 14 however, that compound is not zoledronate.

[50] Page 23 has already been discussed.

[51] The '895 patent ends with 25 claims. Claim 1 is a very broad claim encompassing a vast number of compounds. Claim 2 claims a narrower range of compounds, as does Claim 3. Claims 4 and 5, 15, 16, 17, and 18 are directed to specific compounds; none of them being zoledronate. Claims 6 and 7 are pharmaceutical composition claims dependent on one or more of claims 1 through 5. Claims 8 to 12 are claims directed to the use of the compounds claimed in one or more of claims 1 through 5. Claims 13 and 20 are directed to a process for making the compounds.

[52] Claim 14 is the claim at issue, which I will subsequently discuss in more detail.

[53] Claim 19 claims the composition of claim 14, as well as claims 15, 16, 17 or 18, with a compatible salt.

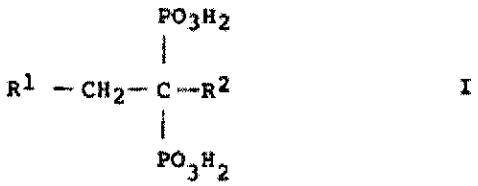
[54] Claim 21 claims the composition of claim 14, as well as claims 15, 16, 17 or 18, with a salt and carrier.

[55] Claims 22, 23, 24 and 25 are directed to the use of the composition of claim 14, as well as claims 15, 16, 17 or 18, for various medical purposes such as calcium metabolism disturbances, arthritis, diseases of the skeletal system, rheumatic arthritis, osteoarthritis, degenerative arthrosis therapy of bone metastases, and urolithiasis, and prevention of heterotropic ossification.

THE '895 PATENT – CLAIM 14

[56] Claim 14 of the '895 patent is the only claim that is at issue in these proceedings. That claim is an independent claim; that is, it does not incorporate by reference any other claim; it stands on its own. Claim 14 reads:

> *14. A heteroarylalkane diphosphonic acid of formula I*



I

> *Wherein R^1 is a 5-membered heteroaryl radical selected from imidazolyl, thiazolyl, oxazolyl, isoxazolyl, triazolyl, thiadiazolyl and oxadiazolyl, which is unsubstituted or substituted one or more times by lower alkyl, lower alkoxy, phenyl or halogen; R^2 is a hydrogen atom, hydroxyl group or an amino group or a salt thereof.*

[57] Claim 14 is directed to a class of compounds called heteroarylalkane diphosphonic acids, having the general formula depicted as Formula I, with a number of choices of atoms or combinations of atoms that can be placed at the R_1 and R_2 positions. The evidence is that a conservative estimate of the number of individual compounds that would be embraced by this claim is 1.2 million.

[58] Any one of a number of chemical structures may be placed at the R_1 position, each of which may be generally described as a five-membered heteroaryl radical, with the group within that general description restricted to the following:

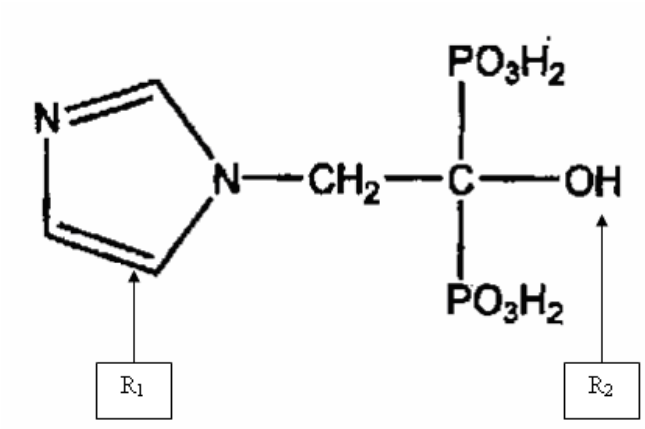
> *...selected from imidazolyl, thiazolyl, oxazolyl, isoxazolyl, triazolyl, thiadiazolyl and oxadiazolyl, which is unsubstituted or substituted one or more times by lower alkyl, lower alkoxy, phenyl or halogen;...*

[59] At the R_2 position, there may be a hydrogen atom, or a group of molecules selected from the hydroxyl group of molecules, or a group of molecules selected from the amino group of molecules.

[60] In the descriptive portion of the '895 patent, R_1 is part of a broader class referred to as Het and R_2 as X.

[61] Thus, in claim 14, there are a finite number of choices for R_1 and a finite number of choices for R_2. The total number of choices is calculated as being about 1.2 million.

[62] Among the resulting choices is that where R_1 is an imidazole ring joined to the Formula I structure at one of the nitrogen positions in the ring and where R_2 is a hydroxyl (OH). The resulting compound may be chemically depicted as follows:



[63] This compound is referred to in the evidence as zoledronate or zoledronic acid. It is the active ingredient in Novartis' commercial products. Teva wants to receive a Notice of Compliance to sell a generic version of those products, also containing zoledronic acid as the active ingredient.

[64] Thus to construe claim 14 it claims a class of some 1.2 million compounds all sharing a selection of molecules at the R_1 and R_2 positions placed on a biphosphonic backbone; zoledronate is but one of such compounds.

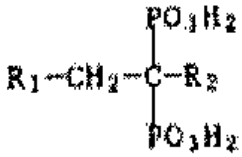
THE '937 PATENT IN DETAIL

[65] The '937 patent is titled:

> *Process for the Manufacture of Novel Substituted Alkanediphosphonic Acids*

[66] The patent begins at page 1 by stating that it relates to certain novel acids depicted as Formula I:

> *Novel substituted alkanediphosphonic acids*
>
> *The present invention relates to novel substituted alkanediphosphonic acids, in particular to heteroarylalkanediphosphonic acids of formula*



> *Wherein R_1 is a 5-membered heteroaryl radical which contains, as hetero atoms, 2 to 4 N-atoms or 1 or 2 N-atoms as well as 1 0- or s-*

> *atom, and which is unsubstituted or C-substituted by lower alkyl, phenyl or phenyl which is substituted by lower alkyl, lower alkoxy and/or halogen, or by lower alkoxy, hydroxy, di-lower alkylamino, lower alkylthio and/or halogen, and/or is N-substituted at a N-atom which is capable of substitution by lower alkyl, lower alkoxy and/or halogen, and R_2 is hydrogen, hydroxy, amino, lower alkylthio or halogen, and to the salts thereof, to the preparation of said compounds, to pharmaceutical compositions containing them, and to the use thereof as medicaments.*

[67] There follows at page 1 over to the upper third of page 3 a description of some of the constituents that may be used in creating the compound. This is followed at page 2 over to the first three lines of page 4 by a discussion of the salts that can be formed from the compound.

[68] From the first full paragraph on page 4 to the first three lines of page 5, there is a description of the "valuable properties" of the compounds embraced by Formula I:

> *The compounds of formula I and salts thereof have valuable pharmacological properties. In particular, they have a pronounced regulatory action on the calcium metabolism of warm-blooded animals. Most particularly, they effect a marked inhibition of bone resorption in rats, as can be demonstrated in the experimental procedure described in Acta Endrocinol. 78, 613-24 (1975), by means of the PTH-induced increase in the serum calcium level after subcutaneous administration of doses in the range from about 0.01 to 1.0 mg/kg, as well as in the TPTX (thyroparathyroidectomised) rat model by means of hypercalcaemia induced by vitamin D_3 after subcutaneous administration of a dose of about 0.0003 to 1.0 mg. Tumor calcaemia induced by Walker 256 tumors is likewise inhibited after peroral administration of about 1.0 to 100 mg/kg. In addition, when administered subcutaneously in a dosage of about 0.001 to 1.0 mg/kg in the experimental procedure according to Newbould, Brit. J. Pharmacology 21, 127 (1963), and according to Kaibara et al., J. Exp. Med. 159 1388-96 (1984), the compounds of formula I and salts thereof effect a marked inhibition of the progression of arthritic conditions in rats with adjuvant arthritis. They are therefore eminently suitable for use as medicaments for the treatment of diseases which are associated with impairment of calcium*

> *metabolism, for example inflammatory conditions in joints, degenerative processes in articular cartilage, of osteoporosis, periodontitis, hyperparathyroidism, and of calcium deposits in blood vessels or prothetic implants. Favourable results are also achieved in the treatment of diseases in which an abnormal deposit of poorly soluble calcium salts is observed, as in arthritic diseases, e.g. ancylosing spondilitis, neuritis, bursitis, periodontitis and tendinitis, fibrodysplasia, osteoarthrosis or arteriosclerosis, as well as those in which an abnormal decomposition of hard body tissue is the principal symptom, e.g. hereditary hypophosphatasia, degenerative states of articular cartilage, osteoporosis of different provenance, Paget's disease and osteodystrophia fibrosa, and also osteolytic conditions induced by tumors.*

[69] From the first full paragraph at page 5 through to the middle of page 7, a large number of compounds are identified specifically as being to which the invention "relates" or "relates more particularly" or "preferably relates" or "relates firsts and foremost". Zoledronate is not specifically named, but does fall within the broad range of the compounds so identified.

[70] At the middle of page 7, this paragraph appears:

> *The invention relates specifically to the compounds of formula I and the salts thereof, especially the inner salts and pharmaceutically acceptable salts thereof with bases mentioned in the Examples.*

[71] There are about thirty two compounds specifically named in Examples 1 to 20 which are the Examples for the preparation of compounds, omitting repetitions. Zoledronate, written as:

> *2-(imidazol-1-yl)-1-hydroxyethane-1,1 diphosphonic acid*

is one of them. It appears in two of the examples; Example 11 and Example 13:

> *Example 11: The procedure of Example 1 is repeated, starting from 1-imidazoleacetic acid hydrochloride, 1-(1H-1,2,4-triazole) acetic acid hydrochloride, 1-pyrazoleacetic acid hydrochloride, and 3-pyrazoleacetic acid hydrochloride, to give the following compounds:*
>
> ***2-(imidazol-1-yl)-1-hydroxyethane-1, 1-diphosphonic acid**, m.p. 239°C (dec.),*
> *2-(1H-1,2,4-triazol-1-yl)-1-hydroxeyethane-1, 1-disphosphonic acid, m.p. 255°C (dec.),*
> *2-(pyrazol-1-yl)-1-hydroxyethane-1,1-diphosphonic acid, m.p. 234°C (dec.), and*
> *2-(pyrazol-3-yl)-1-hydroxyethane-1,1-disposphonic acid, m.p.*
>
> *(Emphasis added)*
>
> . . .
>
> *Example 13: With stirring and under reflux, 8.6 g (0.053 mole) of imidazol-1-ylacetic acid hydrochloride, 7.1 ml of 85% phosphoric acid and 25 ml of chlorobenzene are heated to 100°C. Then 13.9 ml of phosphorus trichloride are added dropwise at 100°C, whereupon evolution of gas occurs. Over the course of 30 minutes a dense mass precipitates from the reaction mixture. The batch is heated for 3 hours to 100°C and the supernatant chlorobenzene is removed by decantation. The residual viscous mass is heated for 3 hours to the boil, with stirring and under reflux, with 40 ml of 9N hydrochloric acid. The batch is then filtered hot with the addition of carbon and the filtrate is diluted with acetone, whereupon the crude **2-(imidazol-1-yl)-1-hydroxyethane-1, 1-diphosphonic acid precipitates**. This product is recrystallised from water. Melting point: 239°C (dec.). Yield: 41% of theory.*
> *(Emphasis added)*

[72] Returning to page 7 and through to the top of page 14, there is a discussion of the various processes by which the compounds may be produced.

[73] From the second paragraph at page 14 to the first paragraph of page 16, there is a description of the various forms and formulations that a pharmaceutical, including the compound, may take.

[74] The second paragraph at page 16 speaks to the use of the compound:

> *The present invention also relates to the use of the compounds of formula I and salts thereof preferably for the treatment of inflammatory conditions, primarily to diseases associated with impairment of calcium metabolism, e.g. rheumatic diseases and, in particular, osteoporoses.*

[75] From the middle of page 16 over to the top of page 17, dosage regimens are described.

[76] From the top third of page 17 to the top of page 24, there are twenty Examples directed to the preparation of the various compounds, including, as previously discussed, Examples 11 and 13, which describe the preparation of several specific compounds, one of which is zoledronate.

[77] From pages 24 to 27, Examples 21 to 25 are provided, in which various tablets, lozenges, capsules and injection liquids are discussed. None of them mention zoledronate specifically.

[78] Two claims follow: claims 1 and 2.

THE '937 PATENT – CLAIMS 1 & 2

[79] The '937 patent contains only two claims – claims 1 and 2 – both of which are at issue in these proceedings. Those claims read:

> *a. 2-(imidazol-1-yl)-1-hydroxyethane-1,1-diphosphonic acid, or a pharmaceutically acceptable salt thereof.*
>
> *b. A pharmaceutical composition containing a compound as claimed in claim 1 together with conventional pharmaceutical excipients.*

[80] Claim 1 relates to a single specific compound:

2-(imidazol-1-yl)-1-hydroxyethane-1,1-diphosphonic acid

or a pharmaceutically acceptable salt of that compound.

[81] This formula is yet another way that claimants could write the formula for zoledronate or zoledronic acid, which was one of the 1.2 million or so compounds falling within the number of compounds encompassed by claim 14 of the '895 patent as previously discussed.

[82] Claim 2 simply claims that this chemical compound is made into a pharmaceutical composition by mixing it with "conventional pharmaceutical excipients".

[83] No complex construction of claims 1 and 2 is needed. Claim 1 claims a single compound-zoledronate. Claim 2 is a mixture of zoledronate and pharmaceutical excipients.

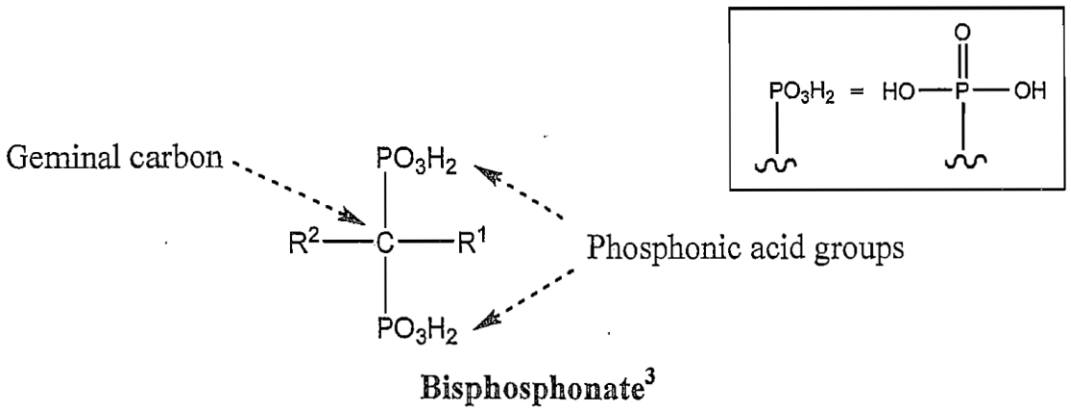
BISPHOSPHONATES – TECHINICAL BACKGROUND

[84] Both Novartis and Teva have provided, through their expert witnesses, as well as the assistance of Counsel at the hearing, considerable information as to the technical background respecting bisphosphonates and their use in treating certain bone diseases.

[85] Bones in the human body, as well as in other mammals, are comprised of various materials; including collagen, calcium, andphosphates. Some of this material is, in a continuing process, released into the body – a process called bone resorption – and new material is retrieved from the

body. This process continues during a person's lifetime and provides for bone growth as well as repair to cracked and damaged bone material. Due to aging and some diseases, this process may become unbalanced. In particular, more bone resorption than is desirable may occur, resulting in conditions such as osteoporosis.

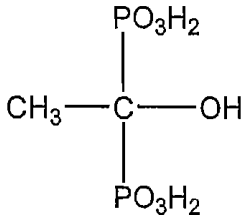
[86] In the late 1960's, researchers, particularly Dr. Fleisch, determined that a class of compounds known generally as bisphosphonates were useful in controlling the level of bone resorption. The general structure of a bisphosphonate can be depicted as follows:



Bisphosphonate[3]

[87] The PO_3H_2 molecules are the phosphonates; the C in the middle is sometimes referred to as the geminal carbon a name derived from the term Gemini (the astrological twins) since there are twin phosphonates attached. At the positions noted as R_1 and R_2 a number of different atoms or molecules may be attached by a "linker" molecule or molecules.

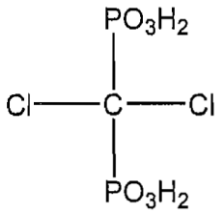
[88] One of the earliest bisphosphonates (or BPs, as they are called in these proceedings), is one known as etidronate, which had some commercial success. It can be depicted chemically as:



Etidronate

[89] Etidronate had been in existence since the late 1800's and was used, for instance, to prevent mineral build-up inside pipes. Its use as a bone resorption inhibitor was a new use that came about in the late 1960's and early 1970's when it was determined that it would bind to bone mineral surfaces and inhibit bone resorption.

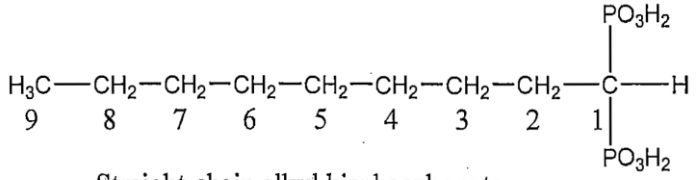
[90] Another early bisphosphonate used to control bone resorption was clodronate. It can be depicted as :



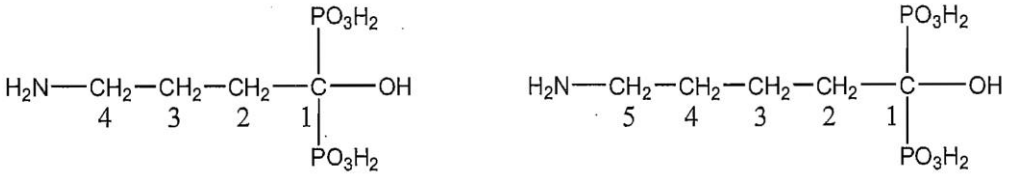
Cl_2MBP (clodronate)

where each of R_1 and R_2 is chlorine (Cl).

[91] Development of what is known as second generation bisphosphonates followed. Work was done with respect to the "linkers" between the geminal carbon and the R_1 molecule. Up to nine (9) linkers being carbon containing molecules (CH_2) were investigated. In paragraph 67 of his affidavit, Dr. Benedict provides illustration of such linkers.



Straight-chain alkyl bisphosphonate
with greatest antiresorptive activity

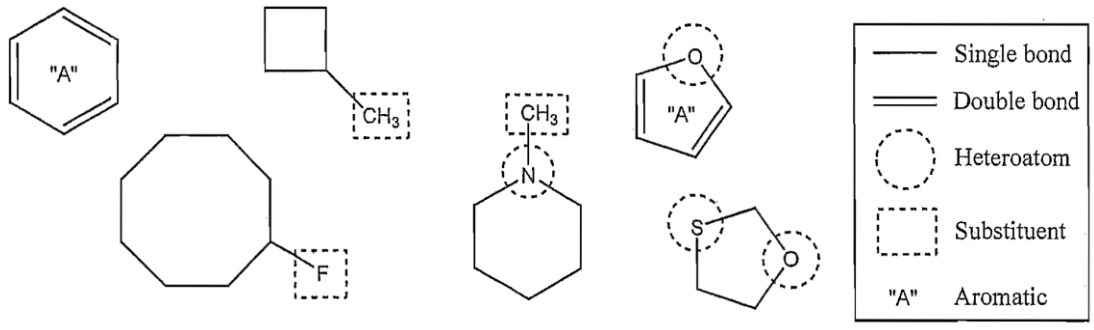


Straight-chain aminoalkyl bisphosphonates
with greatest antiresorptive activity

Effect of R^2 groups on antiresorptive activity

[92] Work also continued in the selection of suitable candidates for the atoms or molecules to be placed in the R_1 and R_2 position. Among the leading candidates for the R_1 position were molecules containing nitrogen (N), including ring-structured molecules having five or six sides.

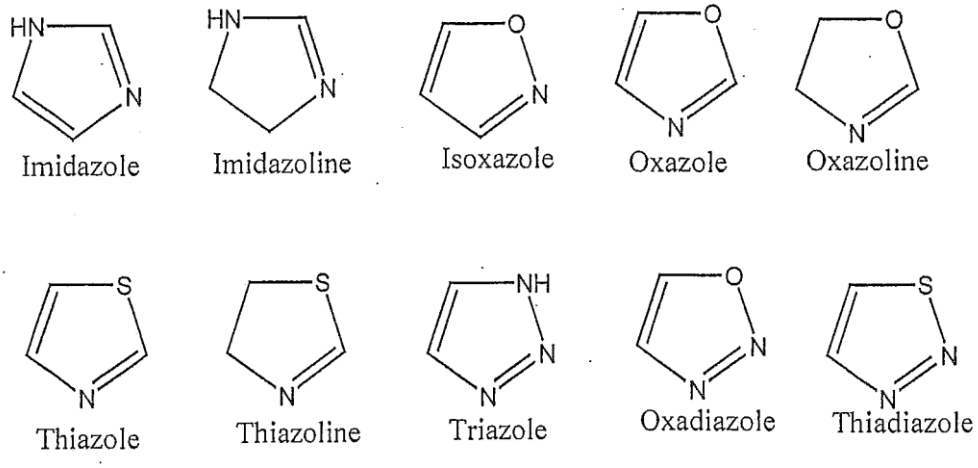
[93] Examples of rings having five sides (heterocycles), and those that are not, are illustrated at paragraph 98 of Dr. Benedict's affidavit.



Rings that are not heterocycles **Heterocycles**

[94] Within the many types of five-sided rings containing nitrogen are those illustrated at paragraph 44 of Dr. Vepsalainen's affidavit.

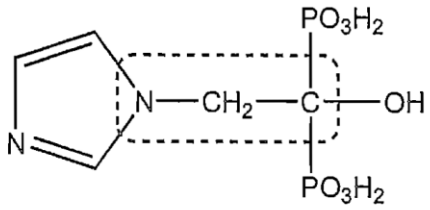
Nitrogen-containing Heterocycles included in the 895 Patent:



[95] There are also a number of corners on the five-sided ring where that ring may be chemically attached to a "linker" such as CH_2. These corners are given numbers according to chemical convention and where a structure is identical to another except for the corner at which the five-sided ring structure is attached to a linker, each structure is called an "isomer" of the other.

ZOLEDRONATE

[96] Zoledronate can be depicted chemically as follows:



(aminoethane group circled)

Zoledronate

[97] There is a "geminal" carbon (C) to which are attached two phosphonates (PO_3H_2). At the R_2 position there is a hydroxyl (OH) attached directly to the geminal carbon. The heterocylic ring at the R_1 position is attached through a nitrogen atom (N) through one carbon-containing "linker", CH_2. The heterocyclic ring is of the type known to chemists as an imidazole.

[98] Zoledronate has proven to be a very potent bone resorption inhibitor. A dose injected just once a year has, in many cases, proven to be effective.

[99] It is useful, to distinguish between a drug that is "effective" and one that is "potent". An "effective" drug is one that produces a desired result. A "potent" drug is one that is "effective" even at low doses. A determination of "Lowest Effective Dosage (LED)" of a drug is made by testing. The less of a drug that is required to achieve a desired effect, the more potent it is.

TESTING FOR POTENCY

[100] Scientists have determined that rats are a good model for determining the effectiveness and potency of a candidate drug in humans. A common test is that known as TPTX. In such a test, a group of laboratory rats are selected, their thyroid is removed, and they are fed various dosages of candidate drugs over a period of time. At the end, the rats are "sacrificed" and their bones examined. The results are tabulated. Those candidates requiring the lowest dosages in order to preserve the bones in a reasonable state are said to be the most potent.

WHAT DID THE '895 INVENTORS DO?

[101] Neither of the two persons named as inventors of the '895 patent gave evidence. One is dead and the other is, presumably, nearly dead. However, a patent agent knowledgeable about the files and records kept by the inventors, Dr. Knauer, did give evidence, including provision of the records made by or under the direction of, the inventors.

[102] It appears that, prior to the filing date of the application for the patent in Canada, July 29, 1987, the inventors made the compound that we now call zoledronate. The compound was made on April 3, 1987. The compound was tested in July 1987, prior to the Canadian filing date. Further testing was made after that date and, because of its potency, the drug was selected for further evaluation.

[103] The priority application was filed in Germany on August 1, 1986. A draft of that application, dated June 23, 1986, was provided in Dr. Knauer's second affidavit. At this time, only one

compound that would fall within the scope of claim 14 had been made and subjected to biological testing. It was not zoledronate.

WHAT DID THE '937 INVENTORS DO?

[104] Dr. Widler, one of the inventors named in the '937 patent, provided an affidavit and was cross-examined.

[105] He testified that, in 1986, he and the other named inventor, Dr. Jaeggi, were assigned to a project to come up with new bisphosphonates. In cross-examination, he admitted that he was familiar with patent applications of others shortly after they became public.

[106] Prior to the date upon which the application was filed in Canada, November 19, 1987, they had made zoledronate and tested it using the TPTX model.

[107] The priority patent application was filed in Switzerland on November 19, 1986. That application contained claims to the genus of the compounds as well as several specific compounds. Zoledronate was made and tested in July 1987, which is after the priority application was filed; but before the Canadian application was filed. There is a change from the data contained in the priority application to that found at page 4 of the Canadian patent. This change apparently reflects testing done respecting certain compounds (not specifically identified) between the two dates. We do not know if the testing done on zoledronate reflects or was modified by the results of the testing as reported in the patent, since the test results on zoledronate are not specifically identified or set out in the '937 patent.

THE CONFLICT - AND RESULTING CLAIMS

[108] Under the provisions of the "old" *Patent Act*, if two or more patent applications filed before October 1, 1989 in the Canadian Patent Office appeared to the examiners to claim, or could possibly claim, the same invention, the Commissioner of Patents could declare that a conflict existed between them. Section 43 of the "old" *Patent Act* required that the Commissioner of Patents request that the parties file affidavit evidence as to the date of invention. The Commissioner would review that evidence and award claims to one or other of the parties based on the Commissioner's determination as to which inventor was the "first to invent" the particular subject matter of a particular claim. Often, certain claims were awarded to one party and other claims to another. The process often took years to resolve. A re-examination by the Federal Court could follow.

[109] In the present case, the evidence of Dr. Widler indicates that Ciba-Geigy (now Novartis) became aware that its application had been placed in conflict with that of Boehringer. The parties resolved the matter between themselves so that Boehringer obtained the '895 patent with broad genus claims; the narrowest of which is the claim at issue, claim 14; while Ciby-Geigy obtained claims specific to only one compound, zoledronate, in the '937 patent.

[110] Thus, while in the beginning both applications contained claims to many compounds, by agreement, the '895 patent retained the broad genus claims, and the '937 patent retained the claims specific only to zoledronate. In the present case some nine years passed between the time the patent applications were filed in Canada and the two patents were granted. By that time it would have become apparent that zoledronate was the compound of commercial interest.

[111] Thus the parties, together, had the benefit of the '895 patent with its broad "cascading" claims which, at a minimum, in claim 14, "cascaded" to 1.2 million compounds while having another patent – the '937 patent – with two claims directed only to zoledronate, the commercially favoured compound.

[112] Dr. Robert's affidavit, paragraph 43, illustrates the benefits of a patent which "stakes out the ground" to a broad genus of compounds. It may discourage others from investigation into the genus:

> *43. The medicinal chemist would have been particularly interested in reviewing patents for molecules in the relevant area for several reasons. First, the patents would claim compounds thought to be valuable enough to protect.* ***Second, the patents would identify compounds the medicinal chemist should avoid where the goal was to find a drug for development****. Third, the patents would allow identification of unpatented molecules that would be expected to have the requisite activity. The medicinal chemist would have looked for trends or recurring features to signpost the pathway forward wherever possible.(emphasis added)*

[113] In the present situation, we have the discouraging patent '895, and the patent directed to the specific compound, the '937 patent; all as a result of protracted conflict proceedings.

OBVIOUSNESS

[114] I have recently reviewed the law in Canada as to obviousness and set out my views in *Pfizer Canada Inc v Pharmascience Inc*, 2013 FC 120. I repeat what I wrote at paragraphs 186 to 190:

> *186 The jurisprudence respecting obviousness has recently been established by the Supreme Court of Canada in Apotex Inc v Sanofi-*

Synthelabo Canada Inc, [2008] 3 SCR 265, 2008 SCC 61. Rothstein J wrote the unanimous reasons of the Court and, in particular, wrote at paragraphs 67 to 71:

> *67 It will be useful in an obviousness inquiry to follow the four-step approach first outlined by Oliver L.J. in Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd., [1985] R.P.C. 59 (C.A.). This approach should bring better structure to the obviousness inquiry and more objectivity and clarity to the analysis. The Windsurfing approach was recently updated by Jacob L.J. in Pozzoli SPA v. BDMO SA, [2007] F.S.R. 37 (p. 872), [2007] EWCA Civ 588, at para. 23:*
>
> > *In the result I would restate the Windsurfing questions thus:*
> >
> > *(1) (a) Identify the notional "person skilled in the art";*
> >
> > *(b) Identify the relevant common general knowledge of that person;*
> >
> > *(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;*
> >
> > *(3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;*
> >
> > *(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention' [Emphasis added.]*
>
> *It will be at the fourth step of the Windsurfing/Pozzoli approach to obviousness that the issue of "obvious to try" will arise.*
>
> > *i. When Is the "Obvious to Try" Test Appropriate'*
>
> *68 In areas of endeavour where advances are often won by experimentation, an "obvious to try" test might be appropriate. In such areas, there may be numerous interrelated variables with which to experiment. For*

example, some inventions in the pharmaceutical industry might warrant an "obvious [page294] to try" test since there may be many chemically similar structures that can elicit different biological responses and offer the potential for significant therapeutic advances.

ii. "Obvious to Try" Considerations

69 If an "obvious to try" test is warranted, the following factors should be taken into consideration at the fourth step of the obviousness inquiry. As with anticipation, this list is not exhaustive. The factors will apply in accordance with the evidence in each case.

> *1. Is it more or less self-evident that what is being tried ought to work' Are there a finite number of identified predictable solutions known to persons skilled in the art'*
>
> *2. What is the extent, nature and amount of effort required to achieve the invention' Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine'*
>
> *3. Is there a motive provided in the prior art to find the solution the patent addresses'*

70 Another important factor may arise from considering the actual course of conduct which culminated in the making of the invention. It is true that obviousness is largely concerned with how a skilled worker would have acted in the light of the prior art. But this is no reason to exclude evidence of the history of the invention, particularly where the knowledge of those involved in finding the invention is no lower than what would be expected of the skilled person.

71 For example, if the inventor and his or her team reached the invention quickly, easily, directly and relatively inexpensively, in light of the prior art and common general knowledge, that may be evidence supporting a finding of obviousness, unless [page295] the level at which they worked and their knowledge base was above what should be attributed to the skilled person. Their course of conduct would suggest that a skilled person, using his/her common general knowledge and the prior art, would have acted

> *similarly and come up with the same result. On the other hand, if time, money and effort was expended in research looking for the result the invention ultimately provided before the inventor turned or was instructed to turn to search for the invention, including what turned out to be fruitless "wild goose chases", that evidence may support a finding of non-obviousness. It would suggest that the skilled person, using his/her common general knowledge and the prior art, would have done no better. Indeed, where those involved including the inventor and his or her team were highly skilled in the particular technology involved, the evidence may suggest that the skilled person would have done a lot worse and would not likely have managed to find the invention. It would not have been obvious to him/her to try the course that led to the invention.*

187 This test was amplified by the Federal Court of Appeal in Apotex Inc v Pfizer Canada Inc, 2009 FCA 8, where Noel JA, for the Court, distinguished between mere possibilities and speculation, which is not the test; and more or less self-evident, which is the test. He wrote at paragraphs 28 to 30:

> *28 I take it from this that the test adopted by the Supreme Court is not the test loosely referred to as [page235] "worth a try". After having noted Apotex' argument that the "worth a try" test should be accepted (at paragraph 55), Rothstein J. never again uses the expression "worth a try" and the error which he identifies in the matter before him is the failure to apply the "obvious to try" test (at paragraph 82).*
>
> *29 The test recognized is "obvious to try" where the word "obvious" means "very plain". According to this test, an invention is not made obvious because the prior art would have alerted the person skilled in the art to the possibility that something might be worth trying. The invention must be more or less self-evident. The issue which must be decided in this appeal is whether the Federal Court Judge failed to apply this test.*
>
> *30 In my respectful view, he did not. While the Federal Court Judge does not use the phrase "obvious to try", his reasons show that he conducted his analysis along the dividing line drawn in Sanofi-Synthelabo. Specifically, he rejected the contention that the invention was obvious based on mere possibilities or speculation and looked for evidence that the invention was more or less self-evident.*

188 The test adopted by the Supreme Court of Canada is based on two United Kingdom decisions and is often referred to as the Windsurfing/Pozzoli test. This test was recently considered by the United Kingdom Court of Appeal (Civil Division) in MedImmune Limited v Novartis Pharmaceuticals UK Limited, [2012] EWCA Civ 1234. Lord Justice Kitchin wrote at paragraphs 85 to 90:

> *[85] It is often convenient, but by no means essential, to consider an allegation of obviousness using the structured approach explained by this court in Pozzoli v BDMO SA [2007] EWCA Civ 588, [2007] Bus LR D117, [2007] FSR 37 at 23:*
>
> > *'(1) (a) Identify the notional 'person skilled in the art';*
> >
> > *(b) Identify the relevant common general knowledge of that person;*
> >
> > *(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;*
> >
> > *(3) Identify what, if any, differences exist between the matter cited as forming part of the 'state of the art' and the inventive concept of the claim or the claim as construed;*
> >
> > *(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention"*
>
> *[86] Step (2) may pose some problems. In some cases, as in this one, the parties agree what the inventive concept is. This has the advantage of limiting the obviousness analysis to the essence of the invention. But often the parties do not agree and in such cases it will usually be a futile exercise for the court to seek to resolve their disagreement, for ultimately all that matters is what the patentee has claimed. As Lord Hoffmann said in Conor v Angiotech [2008] UKHL 49, [2008] 4 All ER 621, [2008] RPC 716 at 19 '... the patentee is entitled to have the question of obviousness determined by reference to the claim and not to some vague paraphrase based upon the extent of his disclosure in the description'.*

[87] I would add, so too is the Defendant. The patentee may have drawn his claim so broadly that it includes products or processes that owe nothing to the inventive contribution he has made, rendering the claim particularly vulnerable to an allegation of obviousness.

[88] Step (3) presents little conceptual difficulty. It simply requires the court to identify the differences between the prior art and the claim.

[89] It is step (4) which is key and requires the court to consider whether the claimed invention was obvious to the skilled but unimaginative addressee at the priority date. He is equipped with the common general knowledge; he is deemed to have read or listened to the prior disclosure properly and in that sense with interest; he has the prejudices, preferences and attitudes of those in the field; and he has no knowledge of the invention.

[90] One of the matters which it may be appropriate to take into account is whether it was obvious to try a particular route to an improved product or process. There may be no certainty of success but the skilled person might nevertheless assess the prospects of success as being sufficient to warrant a trial. In some circumstances this may be sufficient to render an invention obvious. On the other hand, there are areas of technology such as pharmaceuticals and biotechnology which are heavily dependent on research, and where workers are faced with many possible avenues to explore but have little idea if any one of them will prove fruitful. Nevertheless they do pursue them in the hope that they will find new and useful products. They plainly would not carry out this work if the prospects of success were so low as not to make them worthwhile. But denial of patent protection in all such cases would act as a significant deterrent to research.

189 Lord Justice Lewiston agreed and added at paragraph 184:

[184] In many 'obvious to try' cases, it is the idea of trying that constitutes the inventive step. It was no doubt this that led Sir Donald Nicholls V-C to say in Molnlycke AB v Procter & Gamble Ltd [1994] RPC 49 that '... obviousness connotes something which would at once occur to a person skilled in the art who was desirous of accomplishing the end'. (Emphasis added)

> *190 Lord Justice Moore-Bick agreed with both.*

[115] I have already identified the notional person skilled in the art, which is step 1(a) in the *Sanofi* test. Step 1(b) requires that the relevant common general knowledge be identified; however, that must be identified as of the date of the invention. Given that both patents at issue are "old" *Patent Act* patents, the common general knowledge must be ascertained as of the "date of the invention". In turn, such an inquiry must begin with "what is the invention". Step 2 of the *Sanofi* test requires identification of the "inventive concept" of the claim in question. Thus, I will begin with the "inventive concept" of claim 14 of the '895 patent.

[116] Justice Near (as he then was) summarized the law in this respect quite well in his decision *AstraZeneca Canada Inc v Teva Canada Limited*, 2013 FC 245, at paragraph 13:

> *[13] Despite AstraZeneca's protestations, this is not always the end of the analysis (see Apotex Inc v Sanofi-Synthelabo Canada Inc, 2008 SCC 61, [2008] SCJ No 63 [Sanofi] at para 77). Where, as in this case, the inventive concept of the claims is not discernible from the claims themselves because they present a bare chemical formula, the Court is directed to read the specification in the patent to determine the inventive concept of the claims (Sanofi, above, at para 77; Servier, above, at para 58; Teva Canada Ltd v Pfizer Canada Inc, 2012 SCC 60, [2012] SCJ No 60 [Teva v Pfizer] at para 50). The Supreme Court and the Federal Court of Appeal both recently reiterated the principle that "the entire specification, including the claims, must be considered in determining the nature of the invention" (Teva v Pfizer, above, at para 50; Allergan Inc v Canada (Minister of Health), 2012 FCA 308, [2012] FCJ No 1467 at para 73). However, this does not give the Court free rein to construe the claims as broadly or as narrowly as it wishes. The patentee is "entitled to have the question of obviousness determined by reference to his claim and not to some vague paraphrase based upon the extent of his disclosure in the description" (Servier, above, at para 69; Angiotech Pharmaceuticals Inc v Conor Medsystems Inc, [2008] UKHL 49 at para 19).*

THE '895 PATENT - THE INVENTIVE CONCEPT

[117] Claim 14 of the '895 patent claims some 1.2 million compounds, all having a bisphosphonate backbone; with several choices for one group of compounds directly linked to the geminal carbon, and with several choices for another group of compounds, all linked with a single carbon-containing linker such as CH_2 to the geminal carbon.

[118] The invention is described at pages 1 and 2 of the '895 patent, which I repeat in part:

> *The present invention is concerned with new diphosphonic acid derivatives, processes for the preparation thereof and pharmaceutical compositions containing them.*
>
> . . .
>
> *We have found that analogue derivatives of these compounds in which there is only one carbon atom between the diphosphonate residue and the heterocyclic radical and the heterocycle is not a pyrazole ring also display these actions and, in addition, as good calcium complex formers, are suitable for the wider treatment of calcium metabolism disturbances. In particular, they can be very well used in cases in which the bone formation and breakdown is disturbed.*

[119] I accept, with one caveat, the description of the inventive concept articulated by the Applicant at paragraph 143 of its Memorandum; that caveat is that the "family" of compounds is about 1.2 million members:

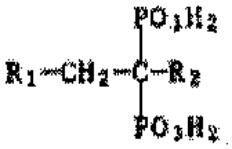
> *182. The inventive concept of claim 14 is a family of (about 1.2 million members) novel compounds containing a 5-membered ring, which is connected to the geminal BP carbon by a one-carbon linker (—CH_2—). These BP's have biological activity as calcium complex formers and inhibit bone resorption.*

THE '937 PATENT – THE INVENTIVE CONCEPT

[120] Claims 1 and 2 of the '937 patent are directed to one compound only, zoledronate, or zoledronate mixed with pharmaceutical excipients.

[121] The invention is diffusely described in the patent. I repeat part of page 1:

> *The present invention relates to novel substituted alkanediphosphonic acids, in particular to heteroarylalkanediphosphonic acids of formula*



(I),

> *Wherein R_1 (a number of compounds) and R_2 is (a number of atoms or compounds)*

[122] At page 4, the description states, in part:

> *The compounds of formula I and salts thereof have valuable pharmacological properties. In particular, they have a pronounced regulatory action on the calcium metabolism of warm-blooded animals. Most particularly, they effect a marked inhibition of bone resorption in rats, as can be demonstrated…*

[123] The description continues by describing a number of compounds as being preferred, most preferred, and first and foremost and concluding with a statement at page 7 that the invention relates

specifically to some 32 compounds found in the Examples. Zoledronate is one of them, but is not specifically mentioned in this description:

> *The invention relates specifically to the compounds of formula I and the salts thereof, especially the inner salts and pharmaceutically acceptable salts thereof with bases mentioned in the Examples.*

[124] The patent ends with two claims. Claim 1 is specific to zoledronate; claim 2 is directed to zoledronate, plus pharmaceutical excipients.

[125] I disagree with the description of the inventive concept as set out at paragraph 87 of the Applicant's Memorandum:

> *87. The inventive concept of the claims of the '937 Patent is that zoledronate is a novel compound that is an exceptionally potent inhibitor of bone resorption in rats.*

[126] My disagreement is that there is nothing in the claims, or in the description, to indicate that zoledronate is an "exceptionally potent inhibitor". It can be deduced from what is set out at page 4 of the patent that zoledronate is among the many compounds described that has certain potency. We do not know if it is the greatest or least or somewhere in between those encompassed by the description.

[127] At this point, the decision of the Supreme Court of Canada in *Teva Canada Limited v Pfizer Canada Inc*, 2012 SCC 60, must be considered. That decision was concerned with whether the

patent met the disclosure requirements of the *Patent Act*. The Supreme Court began by reaffirming the "bargain" theory of the patent system. LeBel J, for the Court, wrote at paragraph 32:

> *32 The patent system is based on a "bargain", or quid pro quo: the inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge. This is the basic policy rationale underlying the Act. The patent bargain encourages innovation and advances science and technology. Binnie J. explained the quid pro quo as follows in AZT, at para. 37:*
>
> > *A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the Patent Act.*

[128] Respecting adequate disclosure, he wrote at paragraph 34:

> *34 Therefore, adequate disclosure in the specification is a precondition for the granting of a patent. As Hughes J. stated in Eli Lilly Canada Inc. v. Apotex Inc., 2008 FC 142, 63 C.P.R. (4th) 406, at para. 74:*
>
> > *Thus, one must both advance the state of the art and disclose that advance in order to gain the patent monopoly. Failing to do so, thus invalidating the monopoly, can be in the form of one or more of several matters such as, the "invention" was not new, or the so-called invention was "obvious" or the disclosure was "insufficient" or "what you disclosed doesn't support the monopoly that you claim".*

[129] Concerning disclosure, the Court reviewed prior jurisprudence and concluded by affirming its previous decisions in *Consolboard* ([1981] 1 SCR 504) and *Pioneer Hi-Bred* ([1989] 1 SCR 1623) at paragraphs 51 and 52:

> *51 In Pioneer Hi-Bred, the Court referred to Consolboard in discussing the Act's disclosure requirements once again. Lamer J. (as he then was), writing for the Court, described those requirements as follows:*
>
> > *In summary, the Patent Act requires that the applicant file a specification including disclosure and claims (Consolboard Inc., supra, at p. 520). Canadian courts have stated in a number of cases the test to be applied in determining whether disclosure is complete. The applicant must disclose everything that is essential for the invention to function properly. To be complete, it must meet two conditions: it must describe the invention and define the way it is produced or built ... . The applicant must define the nature of the invention and describe how it is put into operation. A failure to meet the first condition would invalidate the application for ambiguity, while a failure to meet the second invalidates it for insufficiency. The description must be such as to enable a person skilled in the art or the field of the invention to produce it using only the instructions contained in the disclosure ... and once the monopoly period is over, to use the invention as successfully as the inventor could at the time of his application (Minerals Separation, supra, at p. 316). [Emphasis added; citations omitted; pp. 1637-38.]*
>
> *52 In Consolboard and in Pioneer Hi-Bred, the Court correctly analysed the disclosure requirements set out in s. 27(3) of the Act. The reasoning in those cases should be reaffirmed and applied in the case at bar.*

[130] The Court then addressed the particular patent at issue by defining the nature of the invention. This is the same exercise that I am doing now. LeBel J wrote at paragraph 53:

> *53 In determining whether the disclosure requirements have been met in this case, the first step is to define the nature of the invention in Patent '446. This must be done in order to comply with s. 27(3) of the Act, which requires, among other things, that the specification "correctly and fully describe the invention". Therefore, we must ask: What is the invention in Patent '446?*

[131] The patent under consideration by the Supreme Court contained a number of claims in what that Court described at paragraph 80 as "cascading" claims. It began with Claim 1, which at paragraph 73 the Court said involved over 260 quintillion claims, with claims 2 to 5 directed to progressively smaller groups. Claims 6 and 7 each related to only one compound. The Court held, at paragraph 75, that a "minor research project" would have to be conducted to determine whether claim 6 or claim 7 contained the correct (i.e. commercial) compound. In fact, claim 7 was directed to the compound known as sildenafil, the active ingredient in the drug sold under the name Viagra.

[132] As discussed by LeBel J at paragraph 56, it was argued by the patentee Pfizer that, so long as there was one claim specific to the compound at interest, there was adequate disclosure of the invention; regardless as to whether there were other specific or other general claims. At paragraphs 57 to 63 of LeBel J's Reasons, he reviewed previous jurisprudence and rejected any broad conclusion that could have been drawn from the previous jurisprudence as might have supported Pfizer's submissions.

[133] At paragraph 64, LeBel J adopted a "case-by-case basis" for considering the disclosure of a patent, and the invention was so disclosed:

> *64 It is possible, as in Boehringer, for each claim in a patent to disclose a separate invention. Where this issue is raised, however, individual patents must be considered on a case-by-case basis. In my view, the approach Teva advocates for at para. 119 of its factum is useful in this case: "... the specification as a whole must be examined to determine whether sildenafil and the other compounds claimed in the patent are linked so as to form a single general inventive concept". This is consistent with this Court's comment in Consolboard, at p. 520: "We must look to the whole of the disclosure*

and the claims to ascertain the nature of the invention and methods of its performance ... ."

[134] At paragraphs 66 and 67, the patent under consideration by the Supreme Court is seen to be very similar to the '937 patent:

66 In this case, if we consider the specification as a whole, there is nothing to support the view that the use of sildenafil for the treatment of ED is a separate invention from the use of any of the other claimed compounds for that same purpose. No specific attributes or characteristics are ascribed to sildenafil that would set it apart from the other compounds. Even if we take into consideration the fact that sildenafil is an "especially preferred compound", there is still nothing that distinguishes it from the other eight "especially preferred compounds". The use of sildenafil and the other compounds for the treatment of ED comprises one inventive concept.

67 In fact, the patent itself suggests that the entire class of claimed compounds will be effective in treating ED. The first sentence of the specification states: "This invention relates to the use of a series of [compounds] for the treatment of impotence" (A.R. vol. X, at p. 164 (emphasis added)). The following appears on the second page of the specification: "Unexpectedly, it has now been found that these disclosed compounds are useful in the treatment of erectile dysfunction." And page 11 of the specification contains this statement:

> *Thus the invention includes a pharmaceutical composition for the curative or prophylactic treatment of erectile dysfunction in a male animal, including man, comprising a compound of formula (I), or a pharmaceutically acceptable salt thereof, together with a pharmaceutically acceptable diluents, or carrier. [Emphasis added; A.R., vol. X, at p. 174.]*

The plural word "inventions" does not appear in Patent '446.

[135] Then the Supreme Court considers a situation, apparently put to it by Counsel, that a "divisional" patent could have been filed wherein the description would have been the same, but the claims restricted to one compound only; presumably sildenafil. At paragraph 68, LeBel J wrote:

> *68 There is no evidence on the record to suggest that Pfizer filed a divisional application under s. 36(2.1). It would be disingenuous for Pfizer to imply that there is one invention in the patent application for the purpose of complying with s. 36(1) and then to submit that each claim concerns a distinct invention for the purposes of this appeal. If Patent '446 is viewed as a whole, there is only one invention: the use of the compound or compounds that are effective in treating ED.*

[136] The problem with the patent before the Court, as stated in paragraph 80 of LeBel J's Reasons, was not that there were cascading claims - presumably overly broad - but that the patent claimed in two separate claims two compounds without making it clear which compound was the truly useful one.

> *80 I would not make too much of the fact that Claim 1 included over 260 quintillion compounds. The practice of cascading claims -- although it may, as in this case, result in claims that are overly broad -- is a common one that does not necessarily interfere in every case with the public's right to disclosure. The skilled reader knows that, when a patent contains cascading claims, the useful claim will usually be the one at the end concerning an individual compound. The compounds that do not work are simply deemed invalid. In accordance with s. 58, any valid claim -- in this case, Claim 7 -- survives despite the existence of invalid claims. However, the public's right to proper disclosure was denied in this case, since the claims ended with two individually claimed compounds, thereby obscuring the true invention. The disclosure failed to state in clear terms what the invention was. Pfizer gained a benefit from the Act -- exclusive monopoly rights -- while withholding disclosure in spite of its disclosure obligations under the Act. As a matter of policy and sound statutory interpretation, patentees cannot be allowed to "game" the*

> *system in this way. This, in my view, is the key issue in this appeal. It must be resolved against Pfizer.*

[137] In the present case, the '937 patent contains only two claims directed to one compound only, zoledronate. In effect, it is a "divisional" in that claims to any other compound have been removed.

[138] I find that, unlike the '895 patent, the '937 patent, because it claims only one compound, zoledronate, is, on a case-by-case basis, distinguishable from that considered by the Supreme Court in *Teva*. I find that the inventive concept of the '937 patent is that zoledronate is a useful inhibitor of bone resorption in rats and that, as such, is suitable for use as a medicament in the treatment of diseases in humans associated with impairment of calcium metabolism.

DATE OF THE INVENTION - '895 PATENT

[139] As I have found, the inventive concept of the '895 patent, as expressed in claim 14, is that there is a family of about 1.2 million members of compounds that have biological activity as calcium complex formers, and without bone resorption.

[140] As discussed under the caption "What did the '895 inventors do?" those inventors made and tested two compounds, only one of which falls within the parameters of claim 14 (and is not zoledronate) before the filing of the priority German application on August 1, 1986. A draft application dated June 23, 1986 is the first document to postulate that a "class", however broad, of compounds may be useful in testing bone disease. There is no support for leaping from one or two compounds to a class of 1.2 million compounds.

[141] In this regard, I note the evidence of the Applicant's expert, Dr. Ebetino who, in the summary of his opinions, states at paragraphs 23 and 24:

> *23. By 1987, there was an appreciation that BPs had a physical chemical and a biochemical or cellular effect that contributed to their ability to inhibit bone resorption. However, the biochemical/cellular mechanism of action was unknown. Therefore, there was no ability to predict the potency of a BP based on structure activity relationships.*
>
> *24. As taught to skilled persons by the pioneering researcher in the BP field (Dr. Fleisch) in 1985, it was dangerous to make assumptions about the activity of any new BPs based upon what was known about previous BPs. Each BP needed to be assessed on its own and had to be synthesized and tested in a biological model in order to assess its potency.*

[142] Therefore, the "date of invention" can be no earlier than the date of the draft of the priority application, June 23, 1986, wherein a "class" was articulated. I do not, at this point, go into whether such articulation was sound or sufficient.

DATE OF INVENTION – THE '937 PATENT

[143] As I have found, the inventive concept of the '937 patent is that zoledronate is a useful inhibitor of bone resorption in rats and that, as such, is suitable for use as a medicament in the treatment of diseases in humans associated with impairment of calcium metabolism.

[144] As discussed under the caption "What did the '937 inventors do?" the inventors made and tested zoledronate in rats in July 1987, which is after the filing of the priority application, but before the filing of the Canadian application. I find that the date of invention of the inventive concept of the '937 patent is July 1987.

[145] I have not chosen the priority filing date of the '937 patent, which is the filing date of the Swiss application, November 21, 1986, since there is no evidence that the inventors had made or tested zoledronate as of that date; nor is there any evidence that they could have, as of the priority date, soundly predicted that zoledronate would be the compound of choice.

WHAT WAS THE "COMMON GENERAL KNOWLEDGE" AND "STATE OF THE ART"

[146] The Supreme Court of Canada in *Sanofi,* at paragraph 67, adopted the approach of the United Kingdom Courts in *Windsurfing*, as restated in *Pozzoli*. I have set out this paragraph earlier in these Reasons. In step 1(b), the Court is asked to identify the relevant "common general knowledge" and in step 3, the Court is asked to identify the differences between the inventive concept and the "state of the art". Presumably, the state of the art may include knowledge that is not common or generally known.

[147] In the present case, we are to consider the common general knowledge or state of the art as of two different dates; for the '895 patent, it is June 23, 1986; whereas, for the '937 patent, it is July 1987. Fortunately, the evidence in the record provides only one significant event between those dates – the publication of what is referred to as the '057 patent application published on November 12, 1986.

[148] Dr. Roberts, an expert witness for Teva, summarized his conclusions as to trends in the art as of July 1986 at paragraphs 151 to 156 of his affidavit:

CONCLUSIONS/TRENDS AS OF JULY 1986

> *151. Based on the prior art, the skilled person would have known that bisphosphonate compounds inhibited bone resorption and were known to be effective in treating bone disorders.*
>
> *152. The known bisphosphonate compounds all shared the same bisphosphonate structure with substituents attached to the geminal carbon at the R and R_1 positions.*
>
> *153. The substituent at the R-position that maintained or often improved activity was the hydroxyl group.*
>
> *154. Compounds whole R_1 substituent contained at least one nitrogen atom tended to have greater activity that compounds that did not.*
>
> *155. The state of the art revealed that hydroxybisphosphonates containing 5-and 6-membered heterocyclic substituents at the R_1 position, connected by an alkyl chain (1 to 8 carbons in the case of 6-membered heterocyclic rings, 2 to 8 in the case of 5-membered nitrogen heterocyclic rings excluding substituted pyrazoles; and 1 to 8 in the case of substituted pyrazoles and 5-membered heterocyclic rings more generally) resulted in molecules active in inhibiting bone resorption.*
>
> *156. One 5-membered, nitrogen-containing heterocycle in particular, imidazole, was known to have an effect on bone resorption when substituted at the 1-position. A suggested mechanism of action ws through thromboxane synthetase inhibition. Imidazole had been used as a substituent at the R_1 position in a bisphosphonate compound for use in treating a variety of disorders relating to calcium metabolism or abnormal bone resorption including diseases of the skeletal system such as osteoporosis, Paget's disease, Bechterew's disease and also treatment of bone metastases, urolithiasis, prevention of heterotopic ossification, rheumatoid arthritis and osteoarthritis.*

[149] Dr. Roberts offered his opinion as to the '057 patent application published in November 1986. I set out paragraphs 172 to 175 of his affidavit, which gives the flavour as to how he tests that application. He acknowledges that the '057 application offers many choices, but he is of the opinion

that, given those choices, a person skilled in the art, at every juncture where a choice is to be made, makes a choice that he considers to be obvious. I am sceptical about such logic; it depends rather much on hindsight, knowing the result to be achieved. He says:

> *172. The skilled person would have applied the well known bisphosphonate chemistry to furnish the product with imidazole attached to the bisphosphonate moiety through a single carbon atom. The methyl bisphosphonate could, theoretically be attached at 1 of 3 possible positions on the imidazole ring. The chemistry to make all three compounds was well-established and extremely simple. Accordingly, the skilled medicinal chemist would likely have made all three of these obvious variations.*
>
> *173. If the skilled person were to select one, however, in my view, it would have been the one with the imidazole attached at the 1 position (through the nitrogen). This is because the literature indicated that an imidazole substituted at the 1-position (at the nitrogen) inhibited bone resorption.*
>
> *174. Following the 057 Application literally, the skilled person is taught to react imidazole with EHDP as opposed to applying the well-known bisphosphonate synthesis. The skilled person was well aware that these two compounds do not naturally react with each other to form a covalent bond, as was the concept of the 057 Application, but can easily be made to do so. In this case, the skilled person would have made the compound linking imidazole to EHDP at the 1 position first, if not exclusively.*
>
> *175. The easiest reaction is (and would have been) to activate the methyl group of etidronate and react it with the imidazole using the nitrogen atom of the imidazole. This would have resulted in an attachment at the 1-position (in other words, at the nitrogen atom). The attachment at position 1 is the molecule now known as zoledronic acid.*

[150] Dr. Roberts concludes, at paragraphs 249 to 252 of his affidavit, that the inventive concepts of each of the '895 patent and '937 patent would have been immediately apparent:

> ***J. WERE THE INVENTIVE CONCEPTS OF THE PATENTS IMMEDIATELY APPARENT?***
>
> ***(a) 895 Patent***
>
> *249. To the skilled person, it would have been obvious that a hydroxybisphosphonate attached to a 5-membered heterocycle, particularly one containing nitrogen, by a one-carbon link would have bone resorption inhibition activity. The alleged invention of the one carbon bridge between the geminal carbon and the heterocyclic substituent is uninventive and obvious.*
>
> *250. Accordingly, in my opinion, the asserted claims of the 895 Patent were immediately apparent and obvious by the invention date (even assuming it found by the Court to be as early as April 1986) based on the prior art as described above.*
>
> ***(b) 937 Patent***
>
> *251. In y opinion, claims 1 and 2 of the 937 Patent were obvious as at November 1986, based on the prior art as described above.*
>
> *252. All of the teachings leading to the 895 Patent had advanced even further by November of 1986. In particular, the 057 Application specifically and expressly taught that combining known bisphosphonates, such as what is now known as EHDP with an imidazole (the simplest one of which is imidazole itself) would result in a compound useful for treating diseases of bone metabolism. Since imidazole was the simplest compound, this would be the imidazole compound to have been used first. Linking EHDP with imidazole in the manner set out in the 057 Application, using the simplest and most obvious chemistry, would have yielded zoledronic acid, and nothing else.*

[151] Dr. Vepsalainen, another of Teva's experts, reaches similar conclusions at paragraphs 15 to 17 of his affidavit:

> ***IV. SUMMARY OF MY OPINION***
>
> ***895 Patent***
>
> *15. For the reasons set out below, in my opinion, claims 1-3, 6-8, 10, 12, 14, 19 and 21-25 of the 895 Patent claim subject matter that would have been obvious to the skilled person. The hydroxybisphonate compounds with nitrogen-containing heteroaromatic ring attachments claimed in the 895 Patent were, in material respects, almost identical to many of the prior art compounds. By July 29, 1986, and even earlier, the prior art had claimed that virtually all hydroxybisphosphonate, with aromatic and heteroaromatic rings substituents in the R_1 position, were active in treating calcium metabolism disturbances and other bone disease, whether the rings were attached to the central carbon by a 1-carbon or an 8-carbon bridge. The prior art made clear that a nitrogen in the R_1 position conferred additional activity.*
>
> *16. Even the narrowest claim of the 895 Patent claimed hydroxybisphosphonates with heteroaromatic nitrogen-containing rings attached to the central carbon by a 1-carbon bridge. There was nothing new or surprising about the fact that these compounds were said to have activity in treating calcium metabolism disturbances and other bone disease.*
>
> ***937 Patent***
>
> *17. Likewise, for the reasons I set out below, in my opinion, claims 1 and 2 of the 937 patent, claiming zoledronic acid, a hydroxybisphosphonate with an imidazole substituent attached to a 1-carbon bridge at the 1-position, would have been obvious to the skilled person. By November 21, 1986, and even earlier, there was substantial prior art teaching that hydroxybisphonates with nitrogen-containing heteroaromatic rings, including imidazole, had activity in treating calcium metabolism disturbances and other bone disease.*

[152] Not surprisingly, the Applicant's experts are of a different opinion. Dr. Ebetino summarizes his opinions at paragraphs 22 to 26 of his affidavit:

D. SUMMARY OF OPINIONS

22. The prior art and common general knowledge available to the uninventive but nonetheless skilled person in the BP field as of mid 1987 provided no clear trends or any logical guidance in the design of potent BPs. The prior art was contradictory and pointed in different research starting points and directions.

23. By 1987, there was an appreciation that BPs had a physical chemical and a biochemical or cellular effect that contributed to their ability to inhibit bone resorption. However, the biochemical/cellular mechanism of action was unknown. Therefore, there was no ability to predict the potency of a BP based on structure activity relationships.

24. As taught to skilled persons by the pioneering researcher in the BP field (Dr. Fleisch) in 1985, it was dangerous to make assumptions about the activity of any new BPs based upon what was known about previous BPs. Each BP needed to be assessed on its own and had to be synthesized and tested in a biological model in order to assess its potency.

25. The amount of time and effort required to synthesize and test new BPs was extensive. It is not the case that BP chemistry was routine or easy. The researchers developing new BPs were often faced with challenges not faced by researchers in other fields of medicinal chemistry.

26. It would not have been self-evident or plain to the skilled person to attempt to make a compound possessing the structure of zoledronate based on the prior art and common general knowledge. Even if an attempt to make zoledronate was worth a try, there was nothing in the art or common general knowledge which made it self-evident or very plain to the skilled person that it would be more potent than earlier disclosed BPs. Potency could only be learned upon making and testing the compound.

[153] Dr. Benedict was asked for his opinions only as to the '895 patent. He states at paragraphs 126 to 131 of his affidavit:

The Inventive Concept of Claim 14 Was Not More or Less Self-Evident

126. The differences that exist between the state of the art compounds and the class of inventive compounds disclosed in claim 14 are significant since one could not predict the activity of this class of compounds based on the activity of the prior art compounds until a member of the class of claim 14 had been synthesized and tested. As I described above, there could be profound differences in the potency of bisphosphonates that resulted from seemingly small changes to their structures. Estimating the activity of bisphosphonates based upon their structure was simply not possible before the synthesis and biological testing of the compound.

127. Further, there was very little data available in the published literature and patents regarding the antiresorptive activity of different bisphosphonates. This was especially the case for bisphosphonates containing rings linked to the geminal carbon. As I will discuss below in my comments regarding the affidavit of Dr. Vepsalainen, the only document (U.S. Patent 4,416,877) that he cites that discloses any antiresorptive activity data for bisphosphonates bearing rings shows that these compounds were marginally active at best. Further, Dr. Roberts apparently did not locate this document in his search and did not consider it to be a part of the relevant prior art.

128. The lack of data regarding the antiresorptive activity of bisphosphonates was further complicated by the fact that there are two different mechanisms at play that influence bisphosphonates' effects on bone metabolism: the physical-chemical effect and the cellular or biological effect. As I discussed above (beginning at paragraph 58), researchers were considering two main routes to increase the therapeutic index of bisphosphonates: (1) reducing their binding affinity to hydroxyapatite by modifying R^1 and (2) increasing the antiresorptive potency by modifying R^2.

129. However, the skilled person did not know the reason why the bisphosphonates inhibited bone resorption. While a biological (as opposed to a physical-chemical) mechanism had been postulated, the specific target (e.g. an enzyme) was not identified until the 1990's. Thus, one could not propose changes to the structure of the bisphosphonates based on characteristics of the target. In addition, unlike today, where the medicinal chemist has access to sophisticated computational molecular modelling programs, we did not have that type of technology to assist us in our development of novel bisphosphonates.

130. As I describe in Part V of my affidavit ("Scientific Background"), there were many possible directions that a person

> *skilled in the art could take in trying to develop novel bisphosphonates. Further, even once a particular direction was chosen, due to the very limited knowledge of structure-activity relationships, there was very little guidance at that point. An expression that we used at Procter & Gamble was that we had to "kiss a lot of frogs" before potent new bisphosphonate was found.*
>
> *131. Thus, in my opinion, it was not more or less self-evident that the inventive concept of claim 14 ought to work. As I mentioned above, one could not predict the activity of a particular class of bisphosphonates before synthesizing and testing a member of the class.*

[154] Having read the evidence of all the expert witnesses, both in their affidavits and in cross-examination, I am left with the view that, even given a broad number of choices for atoms or molecules or compounds that could be attached, even using one carbon linker, to the geminal carbon backbone of a bisphosphonate, there is still too much uncertainty as to whether any particular combination will be useful. As an example, I quote paragraph 109 of Dr. Grynpas' (Teva's expert) affidavit:

> *109. The Boehringer Patent claims a wide range of compounds for a broad range of uses. The Boehringer Patent's specification only provides data for two of the claimed compounds. These data show that these two similar compounds have at least a 10-fold difference in potency. Again, with only two compounds tested, the skilled person would not have known if the range covered by these two tested compounds represented the whole range, or the top or bottom of the range. It is therefore not possible for the skilled person to evaluate the potency of any of the other claimed compounds. Furthermore, based on the information in the specification, that person would not be able to draw any conclusions with respect to the potential utility of each of these claimed compounds for the treatment of the claimed uses.*

[155] Dr. Benedict (one of the Applicant's experts) gave this answer to question 760 during his cross-examination

> *760. I am asking whether a compound that has a two-carbon chain linker would make it self-evident that a compound with a one-carbon chain linker ought to have the same activity.*
>
> *THE WITNESS: I am willing to answer the question.*
>
> *MR. RENAUD: You can answer the question.*
>
> *THE WITNESS: Based on my experience in the bisphosphonate world, if I was told that the molecule had a two-carbon atom linker and it had activity, and we will define that activity as being able to inhibit bone resorption, then to me it would be interesting to make the one-carbon atom molecule and test it. It would be interesting to me to do that.*
>
> *I would, just based on my experience, be hesitant to predict if it would be better than or less good than the molecule with the two-carbon atom chain based on what I knew about bisphosphonates in 1986 and earlier.*

[156] Dr. Benedict, in his affidavit, addressed the dangers involved in leaping to conclusions as to a general class from a single compound. At paragraph 162 of his affidavit, he wrote:

> *162. Second, I note that one would have no idea what the effect of shortening the chain length would be until a member of the class had been synthesized and tested. While the '524 and '228 Applications disclose a broad class of compounds, including the compounds referred to as (a) and (b) in Dr. Roberts' depiction, these Applications do not disclose any data such that a person skilled in the art could identify a structure-activity relationship between the length of the chain and the anti-resorptive activity of the bisphosphonate.*

[157] Dr. Roberts (one of Teva's experts) said much the same in answer to question 532 and 533 of his cross-examination:

> *532. Q. In paragraph 253 of your affidavit, you state:*
>
> *"...In my view, the claims of the '895 patent, even the narrowest asserted claim, were obvious. If, however, the court finds otherwise, in my view, the skilled person would have found it obvious to make an test the claimed compounds or any one of the hydroxylated claimed compounds, expecting that the tested compounds would be useful for inhibiting bone resorption to treat bone metabolic disorders, as the predecessor compounds had been..."*
>
> *That is your opinion, correct?*
>
> *A. Yes.*
>
> *533. Q. In your opinion, once any one of the hydroxylated claimed compounds claimed in the '895 patent were made and shown to have activity in inhibiting bone resorption, the skilled person would equally expect that the compounds would be useful for inhibiting bone resorption and to treat bone metabolic disorders, as the predecessor compounds had been; correct?*
>
> *A. I think testing one compound would not be enough to support the whole patent.*

[158] At paragraph 104 of his affidavit, Dr. Ebetino (one of the Applicant's experts) referred to a scientific paper written by Dr. Russell, whom he described as a current leader in the field in 2011, and quoted the following passage from that paper, Exhibit M:

> *It should be remembered that despite the intensive efforts of medicinal chemists throughout the 1980s the identification of promising BPs was largely an empirical exercise. Any new BP had*

> *to be treated to determine its biological activity, which could not be predicted from its structure alone. Even quite close structural analogues could show striking differences in biological activity. It is only in the past decade or so, after the molecular mechanisms of action have become much clearer, has it been possible to relate structure to activity on a more scientific basis.*

[159] I conclude that it would not be "more or less self evident" that the class of compounds claimed in claim 14 of the '895 patent or zoledronate as claimed in the '937 patent ought to work as of their respective dates of invention.

[160] I agree that researchers working in the area may have perceived a "hole", as Teva's Counsel put it, in the state of the art in that the "one carbon linker" had not been explored. However, given the numerous choices for what are described as the R_1 and R_2 positions, even if some are more apparent than others, and given that there was no real predictability as to what might work. This would be the same whether one considers common general knowledge or state of the art. I cannot conclude that it was "self evident" that what is claimed in either patent ought to work.

[161] I conclude, as did Kitchin LJ of the United Kingdom Court of Appeal in *MedImmune Limited v Novartis Pharmaceuticals UK*, [2012] EWCA Civ 1234, that one cannot raise the bar too high in respect of obviousness. Research ought to be rewarded, not discouraged:

> *[90] One of the matters which it may be appropriate to take into account is whether it was obvious to try a particular route to an improved product or process. There may be no certainty of success but the skilled person might nevertheless assess the prospects of success as being sufficient to warrant a trial. In some circumstances this may be sufficient to render an invention obvious. On the other hand, there are areas of technology such as pharmaceuticals and biotechnology which are heavily dependent on research, and where*

> *workers are faced with many possible avenues to explore but have little idea if any one of them will prove fruitful. Nevertheless they do pursue them in the hope that they will find new and useful products. They plainly would not carry out this work if the prospects of success were so low as not to make them worthwhile. But denial of patent protection in all such cases would act as a significant deterrent to research.*

[162] I find, therefore, that neither claim 14 of the '895 patent, nor claims 1 and 2 of the '937 patent, are invalid for obviousness. Teva's allegations in this respect are not justified.

LACK OF UTILITY - PLEADING

[163] Teva has alleged that each of claims 14 of the '895 patent, and claims 1 and 2 of the '937 patent, are invalid for lack of utility. Applicant's Counsel argues that Teva did not set out in its Notice of Allegations, sufficient in respect of the arguments that it now makes. I disagree. Sections 1.4.2 and 2.2.2 of that Notice, which spans some three pages each, provide sufficient basis for the arguments made before me.

UTILITY – CLAIM 14 OF THE '895 PATENT

[164] The evidence shows that the inventors named in the '895 patent tested two compounds, neither of which was zoledronate, and only one of which falls within the scope of claim 14 of the '895 patent, before filing the priority application in Germany. In the following year, before the Canadian application was filed, they had also made and tested zoledronate. However, the question is not with respect to these specific compounds, but to the class of 1.2 million compounds embraced by claim 14. I repeat what Dr. Grynpas (one of Teva's experts) wrote at paragraph 109 of his affidavit:

> *109. The Boehringer Patent claims a wide range of compounds for a broad range of uses. The Boehringer Patent's specification only provides data for two of the claimed compounds. These data show that these two similar compounds have at least a 10-fold difference in potency. Again, with only two compounds tested, the skilled person would not have known if the range covered by these two tested compounds represented the whole range, or the top or bottom of the range. It is therefore not possible for the skilled person to evaluate the potency of any of the other claimed compounds. Furthermore, based on the information in the specification, that person would not be able to draw any conclusions with respect to the potential utility of each of these claimed compounds for the treatment of the claimed uses.*

[165] Dr. Lundy, whom the Applicant put forward to rebut Dr. Grynpas, took a rather measured and cautious approach in considering the matter. At paragraphs 98 to 100, he very carefully attempts to define and distinguish the wording that he uses and that of the patent:

> *98. At page 2, lines 5 to 11, the inventors state:*
>
> > *Moreover <u>on the basis of these properties</u>, they can also be used in the therapy of bone metastases or of urolithiasis and for the prevention of heterotopic ossifications. Furthermore, <u>due to their influencing of the calcium metabolism, they form a basis for the treatment of</u> rheumatoic arthritis, osteoarthritis and degenerative arthrosis.*
>
> *99. In the underlined passages above, the inventors are telling the skilled reader that, based upon the ability of the compounds to be good calcium complex formers ("these properties"), they can be used to influence calcium metabolism, which is at the core of the identified calcium metabolic disorders. The compounds therefore "form a basis" for the treatment of certain identified medical conditions.*
>
> *100. Again, the statements underlined above would not, in my opinion, teach the skilled reader that the inventors were stating that the new compounds would be immediately useful in the treatment of any medial condition. I reach this opinion on the basis of the qualifying language used in the patent and the fact that a skilled person would, upon reading the patent as a whole, readily*

> *understand that these new compounds would have to undergo rigorous safety and efficacy studies before these compounds could be considered to be a therapeutic solution in the treatment of identified diseases of the skeletal system.*

[166] Dr. Lundy reviews the inventors' notebooks and comes to the conclusion at paragraph 121 of his affidavit, without stating why, that "the compounds of claim 14 were useful". At paragraph 122, he declined to comment on sound prediction:

> *121. Thus, based upon the information in the '895 Patent as confirmed by the testing in the Knauer affidavit, I am of the opinion that the inventors had, before July 29, 1987, demonstrated that the compounds in claim 14 were useful as calcium complex formers and inhibitors of bone resorption in rats, and therefore had the potential to be used in the treatment of calcium metabolism disturbances.*
>
> *122. Given this demonstration of the utility, I understand that it is unnecessary for me to consider the issue of sound prediction. However, I have considered the issue of sound prediction below in relation to my comments upon the affidavit of Dr. Grynpas.*

[167] Given Dr. Lundy's answers on cross-examination as exemplified by the answer to question 760 set out earlier in these Reasons that he would have to test before knowing utility, I find that the inventors named in the '859 patent did not, as of the Canadian filing date, establish that the class of 1.2 million compounds embraced by claim 14 had utility.

[168] Further, there is nothing in the description of the '859 patent that any witness said would establish a basis for sound prediction that all members of that class would have utility. In brief, the state of the art was at the empirical stage where compounds would have to be assessed individually. There was no consensus in the state of the art at the time that there was a basis for drawing conclusions as to a class.

[169] Lord MacDermott put the situation well in *May & Baker Limited v Boots Pure Drug Company* (1950), 67 RPC 23 (HL) at page 50:

> *Before proceeding to consider the original specification and the nature of the invention it claims it will be appropriate to mention two matters which, while this particular art remains in an empirical state, appear to me to be necessary consequences of that characteristic. In the first place an invention in this chemo-therapeutic field must be in respect of a substance which has actually been produced. There cannot be an empirical discovery in respect of a bare formula. And secondly, the discovery of each new compound having a therapeutic value is a separate invention. If the inventor is bound to say – "I have made" a new substance which I find has therapeutic value, but I cannot be certain that any "other substance, no matter how similar its molecular structure, will have such a value "until I made and test it" then, as it seems to me, the inventive step he has taken must attach to the single substance he has made and to it alone. And if he has made and proved several such substances the position must, I think, remain the same for, while the art retains its empirical nature, the worth of each new substance is a new discovery. But when the inventor can say that his inventive step is such that each of the various new products which manifest it must have therapeutic value, and that although some of them have never been made, then, as I see the matter, the state of the art will have changed. It will have lost its empirical nature, at least to some extent, and the chemist will have found some law or principle by which he may predicate therapeutic effect in advance.*

[170] I find that Teva's allegations as to lack of utility of claim 14 of the '895 patent are justified.

LACK OF UTILITY – CLAIMS 1 & 2 OF THE '937 PATENT

[171] Unlike the '895 patent, the claims of the '937 patent are directed to one compound only, zoledronate. The inventors made and tested that compound before the Canadian application was filed and found it to be useful for the stated purpose namely, a pronounced regulatory action on the calcium metabolism of warm-blooded animals.

[172] I find that Teva's allegations as to lack of utility in respect of claims 1 and 2 of the '937 patent not to be justified.

SUFFICIENCY - PLEADING

[173] Teva has alleged that each of the '859 and '937 patents lack sufficiency and do not show how to make and use the compounds claimed in the claims at issue. Applicant's Counsel argues that Teva did not set out in its Notice of Allegations sufficient allegations in respect of the arguments that it now makes. I disagree. Sections 1.4.3 and 2.2.3 of that Notice provide a sufficient basis for the arguments made before me.

SUFFICIENCY – LEGAL PRINCIPLES

[174] As discussed earlier in *Teva*, supra, the Supreme Court of Canada reaffirmed its earlier decisions in *Consolboard* and *Pioneer Hi-Bred* in establishing that, for a disclosure be sufficient, it must enable a person skilled in the art, having only the disclosure, to put the invention into practice. LeBel J wrote at paragraphs 51 and 52:

> *51 In Pioneer Hi-Bred, the Court referred to Consolboard in discussing the Act's disclosure requirements once again. Lamer J. (as he then was), writing for the Court, described those requirements as follows:*
>
> > *In summary, the Patent Act requires that the applicant file a specification including disclosure and claims (Consolboard Inc., supra, at p. 520). Canadian courts have stated in a number of cases the test to be applied in determining whether disclosure is complete. The applicant must disclose everything that is essential for the invention to function properly. To be complete, it must meet two conditions: it must describe the invention and define the way it is produced or built ... . The applicant must define the nature of the*

> *invention and describe how it is put into operation. A failure to meet the first condition would invalidate the application for ambiguity, while a failure to meet the second invalidates it for insufficiency. The description must be such as to enable a person skilled in the art or the field of the invention to produce it using only the instructions contained in the disclosure ... and once the monopoly period is over, to use the invention as successfully as the inventor could at the time of his application (Minerals Separation, supra, at p. 316). [Emphasis added; citations omitted; pp. 1637-38.]*
>
> *52 In Consolboard and in Pioneer Hi-Bred, the Court correctly analysed the disclosure requirements set out in s. 27(3) of the Act. The reasoning in those cases should be reaffirmed and applied in the case at bar.*

[175] As the Supreme Court in *Consolboard* affirmed, the specification does not have to set out all the advantages, nor all the reasons why the invention works. Dickson J, for the Court, wrote at page 526:

> *As Thorson P. stated in R. v. American Optical Company et al. at p. 85:*
>
> *Nor is it any objection to the sufficiency of the disclosures that the advantages of the invention as enumerated by Professor Price were not set out in the specification…If an inventor has adequately defined his invention he is entitled to its benefit even if he does not fully appreciate or realize the advantages that flow from it or cannot give the scientific reasons for them. It is sufficient if the specification correctly and fully describes the invention and its operation or use as contemplated by the Inventor, so that the public, meaning thereby persons skilled in the art, may be able, with only the specification, to use the invention as successfully as the Inventor could himself.*

SUFFICIENCY – DATE FOR DETERMINATION

[176] The date upon which sufficiency is to be determined becomes important in this case. Teva asserts that the date for determination is the date of filing the application in Canada. The Applicant

asserts that it is the date of publication which, in this case, is the dates upon which the patents were issued and granted.

[177] For the same reasons as discussed with respect to utility, I find that the '895 patent, claim 14, is insufficient, even at the date that the patent was issued and granted. No further discussion is required in respect of that patent.

[178] The matter is different with respect to the '937 patent, claims 1 and 2. The patent was issued and granted with only two claims – both specific to zoledronate. For the same reasons as previously set out, I have distinguished this patent from that considered by the Supreme Court in *Teva* on the basis that the claims were specific to zoledronate, only. However, when the application was filed in Canada, the application contained claims to many compounds, including genus claims and claims to specific compounds; including, but not restricted to, zoledronate. If I were to consider sufficiency as of the date of filing the application, I would find that the application was no different than that considered by the Supreme Court in *Teva*, and thus was invalid for lack of sufficient disclosure.

[179] Canadian law has not been clear as to what is the date for considering sufficiency. Under the "old" *Patent Act*, an application was filed and never available to the public until it was issued and granted. There was no time limit as to how long an application could remain in the Patent Office, provided that timely responses to examiner's office actions were made. Where a patent application was in conflict with another, years could elapse, as is the case here, before a patent was issued and granted. While an application was pending, claims could be added, removed or changed. The disclosure, subject to correction of clerical and editing errors, a specification could not be amended

to describe or add matter not "reasonably inferred" from the specification as originally filed (*Patent Rules* SOR/96-423, Rule 181).

[180] Under the "new" *Patent Act*, applicable to applications filed after October 1, 1989, a patent application is available to the public eighteen months after its Canadian or priority filing date, if applicable. Thus, eighteen months or less after an application was filed, it was published. Amendments to the claims and description could still be made before the patent was issued and granted, on the same basis as an "old" *Patent Act* application but at least the public could see what was going on.

[181] Thus, for "old" *Patent Act* patents, there is a choice of two dates to consider; the application date, and the date of publication, which was the date the patent was issued and granted. For a "new" *Patent Act* patent, there is a choice of three dates; the application date, the publication date (18 months after the Canadian, or if applicable, priority application), and the date that the patent was issued and granted.

[182] Binnie J for the Supreme Court in *Free World Trust v Électro Santé Inc*, [2000] 2 SCR 1024, established that the critical date for claim construction was the date of publication (i.e. for "new" *Act* patents, 18 months after first filing an application; for "old" *Act* patents, the date the patent was issued and granted). He expressly left open whether the same date would apply in respect of consideration of sufficient disclosure. It is to be noted that he relied on decisions of the United Kingdom Courts in that regard when he wrote at paragraph 53:

> *53 The date of publication continues to be the critical date in England: Terrell, supra, at p. 106, although Lord Hoffmann (as he now is) has observed that "there is an important difference between the 1949 [Patent Act] and the 1977 [Patent Act]" which requires the date of application (or priority date) to become the critical date for certain purposes: Biogen Inc. v. Medeva PLC, [1997] R.P.C. 1 (H.L.), at p. 54. In that case the court was dealing with the sufficiency of disclosure, but some English judges have taken the cue to construe claims as of the date of application as well, e.g., Dyson Appliances Ltd. v. Hoover Ltd., [2000] E.W.J. No. 4994 (QL)(Pat. Ct.), at para. 48(k). In Canada, Reed J. advocated a similar position in [page1055] AT & T Technologies, Inc. v. Mitel Corp. (1989), 26 C.P.R. (3d) 238 (F.C.T.D.), at p. 260, even in the absence of these statutory changes. While there may be some advantages to the establishment of a single critical date for multiple purposes including obviousness, sufficiency and claims construction, my view is that Canadian law does not support the date of application as the critical date for claims construction.*

[183] The only other decision of the Supreme Court of Canada that touches on the matter is that of *Pioneer Hi-Bred Limited v Commissioner of Patents*, [1989] 1 SCR 1623. It must be noted, however, that the Court was dealing there only with a patent application; no patent had been granted. The issue of sufficiency arose in the context as to whether a patent application directed to hybrid corn was sufficient in describing how the hybrid was developed. Lamer J, for the Court, wrote at pages 1637 and 1638:

> *It appears to me that the duty of disclosing the steps followed in arriving at an invention is a general principle of patent law recognized by the domestic legislation of many countries (in the United Kingdom, see Patents Act 1977 (U.K.), 1977, c. 37, s. 14(3); in the U.S., see 35 U.S.C. § 112 (1982); see also the West German legislation, in s. 35(2) and international treaties (Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7647, Art. 5; European Convention, October 5, 1973, Art. 83).*
>
> *In summary, the Patent Act required that the applicant file a specification including disclosure and claims (Consolboard Inc., supra, at p. 520). Canadian courts have stated in a number of cases*

> *the test to be applied in determining whether disclosure is complete. The applicant must disclose everything that is essential for the invention to function properly. To be complete, it must meet two conditions: it must describe the invention and define the way it is produced or built (Thorson P. in Minerals Separation North American Corp. v. Noranda Mines Ltd., [1947] Ex. C.R. 306, at p. 316). The applicant must define the nature of the invention and describe how it is put into operation. A failure to meet the first condition would invalidate the application for ambiguity, while a failure to meet the second invalidates it for insufficiency. The description must be such as to enable a person skilled in the art or the filed of the invention to produce it using only the instructions contained in the disclosure (Pigeon J. in Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd., [1976] 1 S.C.R. 555, at p. 563; Monsanto Co. v. Commissioner of Patents, [1979] 2 S.C.R. 1108, at p. 1113) and once the monopoly period is over, to use the invention as successfully as the inventor could at the time of his application (Minerals Separation, supra, at p. 316).*

[184] Turning to the United Kingdom jurisprudence, I start with the brief summary provided by the authors of *Terrell on the Law of Patents* (16th ed), Sweet & Maxwell, London, 2006 at paragraph 7 – 93:

> *On what date is the sufficiency of a specification to be judged?*
>
> *The House of Lords in Biogen Inc v Medeva Plc held that the correct date for assessing sufficiency for the purposes of the 1977 Act was the date of application, because matter may not be added and an insufficient application should not become sufficient because of general developments in the state of the art after the filing date. It had previously been considered that the relevant date was the date of publication, but that is no longer good law.*

[185] The House of Lords in *Biogen Inc v Medeva Plc*, [1997] RPC 1 was required to address the date upon which sufficiency was to be considered because of changes to the United Kingdom *Patent Act* in 1977. Prior to those changes, a Court could invalidate a patent if a claim lacked a "fair basis" in the description. After 1977, the Court or the Comptroller (like our Commissioner of

Patents) could revoke a patent if it did not disclose the invention clearly and completely enough (section 72(1)(c), *Patent Act* 1977, 1977, c. 37). Lord Hoffman, whose opinion the other members of the House adopted, considered the question at length. I will repeat all of what he said; however, in brief, he held that the relevant date for considering sufficiency was the date of application. This was done essentially on a policy consideration. An application, once it was filed, could not be amended. An applicant should not be able to take advantage of intervening advances in the state of the art so as to render sufficient an insufficient application as filed. He said, as reported at pages 53 and 54:

> *14. Sufficiency*
>
> *If your Lordships are agreed that, lacking the support of an earlier priority dated, the patent is valid for obviousness, it is unnecessary to consider whether it was also invalid for insufficiency and therefore liable to be revoked under section 72(1)(c). But the reasoning by which I have come to the conclusion that the patent was not entitled to the earlier priority also, in my view, leads to the conclusion that it was insufficient. I should however mention one point of some general importance concerning the construction of this provision which arose in the course of argument. This is the question of the date on which the specification must "disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art". The Court of Appeal thought it was the date of filing of the application, which in this case was 21 December 1979. Aldous J. said it was the date upon which the application was published, which was 28 May 1986. On the latter view, a specification may be insufficient when the application is filed but satisfy section 72(1)(c) because of advances in the art made between then and the date of publication. I do not think that the point arises in this case, because, whatever date one chooses, the patent did not disclose any method for making the antigens other than the disclosed in Biogen 1. It therefore remained insufficient for the purposes of sustaining a claim to every recombinant DNA method. Nevertheless, since the point was argued and there was a difference of view in the courts below, I shall shortly express my own opinion.*

Aldous J. followed a number of authorities which held that the date of publication was the date for deciding the question of sufficiency under the Patents Act 1949. The reasoning was that the purpose of requiring a specification was to allow the public to work the invention after the expiry of the monopoly. This in itself might suggest that it was enough if the disclosure was sufficient when the patent expired. But, as Buckley L.J. said in Standard Brands Inc.'s Patent (No. 2) '1981] R.P.C. 499, 529, the public was also entitled to know as soon as the patent is published whether it was valid or not. This pointed to the date of publication. He also drew attention to the fact that the specification might have been amended after filing. Such amendments would be treated as relating back to the date of filing and it would therefore be inappropriate to test sufficiency by reference to the specification originally filed.

In my view, however, there is an important difference between the 1949 and 1977 Acts which make decisions on the earlier Act an unsafe guide. Section l72(1)(c) of the 1977 is not only intended to ensure that the public can work the invention after expiration of the monopoly. It is also intended to give the court in revocation proceedings a jurisdiction which mirrors that of the Patent Office under section 14(3) or the E.P.O. under article 83 of the EPC, namely, to hold a patent invalid on the substantive ground that, as the E.P.O. said in Exxon/Fuel Oils (T 409/91) [1994] O,J. E.P.O. 653, paragraph 3.3, the extent of the monopoly claimed exceeds the technical contribution to the art made by the invention as described in the specification. In the 1949 Act, this function was performed by another ground for revocation, namely that the claim was not "fairly based on the matter disclosed in the specification" (section 32(1)(i)). The requirement of sufficiency was therefore regarded as serving a narrower purpose. But the disappearance of "lack of fair basis" as an express ground for revocation does not in my view mean that general principle which it expressed has been abandoned. The jurisprudence of the E.P.O. shows that it is still in full vigour and embodied in articles 83 and 84 of the EPC, of which the equivalents in the 1977 Act are section 14(3) and (5) and section 72(1)(c).

Section 72(1)(c) can only give effect to this principle if the relevant date for compliance is the date of application. It would be illogical if a patent which ought to have been rejected under section 14(3) is rendered immune from revocation under section 72(1)(c) by advances in the art between the date of application and the publication of the specification. The provisions for amendment, so far from detracting from this view, seem to me to support it. Section 76(2) says that the amended application shall not disclose matter

> *which extends beyond that previously disclosed. In other words, the application may not add new matter to make an insufficient application sufficient. It seems to me in accordance with this scheme that an insufficient application should also not become sufficient because of general developments in the state of the art after the filing date. I therefore agree on this point with the Court of Appeal.*

[186] That decision would make sense in Canada under the scheme of either the "old" or "new" *Patent Act*, were it not for the recent decision of the Supreme Court of Canada in *Teva*.

[187] The *Teva* decision has caused me to distinguish the '937 patent at issue here from that considered by the Supreme Court on the basis that in the '937 patent, the claims were limited to a single compound. Claims can be added, removed or amended at any time during the application process, whether one is dealing with the "old" or "new" *Patent Act*. Even after a patent has been issued and granted it may, within a limited period, be reissued with fewer or more or different claims; claims may be reduced by disclaimer and possibly even by dedication. The patentee is not seeking advantages because of advances in the scientific state of the art; but rather, is seeking to keep up with the state of the jurisprudence.

[188] I find that the most appropriate date for consideration of sufficiency of a Canadian patent is, as found by Buckley LJ in *Standard Brands*, as referred to by Lord Hoffman in *Biogen*, that of the date of publication. That is the date that the public is seized with the application. That is the date that the person applying for the patent has committed to claims for the invention in a manner available to the public. In the case of an "old" *Act* patent, this would be the day that the patent was issued and granted. In the case of a "new" *Act* patent, it would be the date of publication.

[189] Using this date, since as of the date the '937 patent - an "old" *Act* patent - was issued and granted, the patent claims were restricted to zoledronate, and thus the patent is distinguishable from that considered by the Supreme Court of Canada in *Teva*. Accordingly, I find, in this case, that Teva's allegations as to insufficiency of the '937 patent are not justified.

CONCLUSIONS AND COSTS

[190] In conclusion, I have found that Teva's allegations as to invalidity of the '895 patent, claim 14, on the grounds of invalidity and insufficiency, are justified. The application in respect of that patent must be dismissed.

[191] I have found Teva's allegations as to invalidity of the '937 patent, claims 1 and 2, not to be justified. The application in respect of that patent will be allowed.

[192] The Applicant has been successful in part. While I appreciate that, in the result, the Applicant will secure an Order for prohibition for the longer term of the two patents at issue; costs are intended to defray, in part, the expenses of the litigation. In this case, using a rough measure, I allocate half the expenses to each patent.

[193] Costs are awarded at the middle of Column IV, which is usual in these cases. Costs of a senior and junior Counsel at the hearing are awarded. Experts fees are awarded provided that they are reasonable and do not exceed the fees of senior Counsel for like time involvement. Disbursements related to travel for conducting or defending a cross-examination of a witness, but

not otherwise, are awarded. I consider business class travel to be reasonable when traveling to Europe. All costs, expert fees, disbursements and applicable taxes, are to be reduced by one-half.

JUDGMENT

FOR THE REASONS PROVIDED:

THIS COURT ORDERS AND ADJUDGES THAT:

1. This application in respect of Canadian Patent 1,338,895 is dismissed;

2. This application in respect of Canadian Patent 1,338,937 is allowed;

3. The Minister of Health is prohibited from issuing a Notice of Compliance to Teva Canada Limited in respect of 4mg/5ml strength and 5mg/100ml strength of zoledronic acid I.V. infusion until after the expiration of Canadian Letters Patent No. 1,338,937, which, unless otherwise determined by this Court, is until after February 25, 2014;

4. The Applicant is entitled to recover from Teva one-half of its costs, calculated at the middle of Column IV, and one-half of its disbursements and applicable taxes, on the basis as set out in the Reasons.

"Roger T. Hughes"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKETS:	T-1420-11 and T-288-12
STYLE OF CAUSE:	NOVARTIS PHARMACEUTICALS CANADA INC. v TEVA CANADA LIMITED, ET AL
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	March 4, 5, 6, 7, 2013
REASONS FOR JUDGMENT AND JUDGMENT:	HUGHES J.
DATED:	March 19, 2013

APPEARANCES:

Anthony Creber Livia Aumand	FOR THE APPLICANT Novartis Pharmaceuticals Canada Inc. (T-1420-11 and T-288-12)
Jeffrey Leon Dominique T. Hussey Chandimal Nicholas	FOR THE RESPONDENT Teva Canada Limited (T-1420-11 and T-288-12)
No appearance	FOR THE RESPONDENT PATENTEES Novartis AG and Boehringer Mannheim GmbH (T-1420-11)
No appearance	FOR THE RESPONDENT The Minister of Health (T-1420-11 and T-288-12)
No appearance	FOR THE RESSPONDENT PATENTEES Novartis AG and Roche Diagnostics GmbH (T-288-12)

SOLICITORS OF RECORD:

Gowling Lafleur Henderson LLP Ottawa, Ontario	FOR THE APPLICANT Novartis Pharmaceuticals Canada Inc. (T-1420-11 and T-288-12)
Bennett Jones LLP Ottawa, Ontario	FOR THE RESPONDENT Teva Canada Limited (T-1420-11 and T-288-12)
Not represented	FOR THE RESPONDENT PATENTEES Novartis AG and Boehringer Mannheim GmbH (T-1420-11)
William F. Pentney Deputy Attorney General of Canada	FOR THE RESPONDENT The Minister of Health (T-1420-11 and T-288-12)
Not represented	FOR THE RESPONDENT PATENTEES Novartis AG and Roche Diagnostics GmbH (T-288-12)