Federal Court  Cour fédérale

Date: 20141219

Docket: T-22-13

Citation: 2014 FC 1070

Ottawa, Ontario, December 19, 2014

PRESENT: The Honourable Madam Justice Gleason

BETWEEN:

TEVA CANADA INNOVATION AND TEVA PHARMACEUTICAL INDUSTRIES LTD.

Applicants

and

APOTEX INC. AND THE MINISTER OF HEALTH

Respondents

PUBLIC JUDGMENT AND REASONS

(Confidential version of Judgment and Reasons issued November 12, 2014)

[1] The applicants, Teva Canada Innovation and Teva Pharmaceutical Industries Ltd. [collectively, Teva], seek an order pursuant to section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [the PMNOC Regulations] to prohibit the Minister of Health [the Minister] from issuing a Notice of Compliance [NOC] to the respondent, Apotex Inc.

[Apotex], for approval to sell a generic version of rasagiline, a drug used in the treatment of Parkinson's disease.

[2] Teva markets rasagiline under the brand name AZILECT in two forms, 0.5 mg and 1.0 mg rasagiline mesylate tablets. It owns two Canadian patents in relation to rasagiline that are listed on the Patent Register established under subsection 3(2) of the PMNOC Regulations: Canadian Patent 2,232,310 [the 310 Patent] and Canadian Patent 2,174,449. Only the 310 Patent is at issue in this proceeding. It was published on April 10, 1997 (but claims a priority date to September 20, 1995, due to an earlier filing in Israel). The 310 Patent was granted on January 8, 2008 and will expire on September 18, 2016.

[3] Apotex filed an Abbreviated New Drug Submission with the Minister seeking NOCs for 0.5 and 1.0 mg rasagiline mesylate tablets branded as APO-Rasagiline [the Apotex Products]. On November 20, 2012, Apotex served Teva with a Notice of Allegation [NOA] with respect to the 310 Patent and 0.5 and 1.0 mg rasagiline tablets in which it asserted that the Apotex Products would not infringe the 310 Patent and that the 310 Patent was invalid.

[4] Teva initiated this prohibition proceeding on January 4, 2013. It asserts only Claims 2 and 31 of the 310 Patent against Apotex and says that the Apotex Products infringe these Claims and that the 310 Patent is valid. Teva thus requests that the Minister be prohibited from issuing NOCs for the Apotex Products until the 310 Patent expires.

[5] As the Minister has not yet issued an NOC to Apotex, it seeks to have details of its formulation redacted in the public version of these Reasons to protect its commercial interests. I believe it appropriate to redact those details of the Aptoex formulation that are not essential to understanding these Reasons. However, these details will be revealed in Apotex' Product monographs if it is granted an NOC and markets the Apotex Products. Accordingly, if and when the Minister issues an NOC to Apotex for the Apotex Products, Apotex shall advise the Court within 48 hours of receipt of the NOC and the redactions shall be removed from the public version of these Reasons.

I. Overview

[6] The 310 Patent is entitled "Stable Compositions Containing [Rasagiline]" and discloses that the stability of rasagiline formulations can be significantly improved by the addition of large amounts of "pentahydric or hexahydric alcohols". The specification refers to three of these alcohols as being "typically" used in making the invention to which the 310 Patent pertains, namely, mannitol, sorbitol and xylitol. The examples contained in the 310 Patent disclose test results for stability studies conducted with mannitol, sorbitol and xylitol. No test results are reported in the 310 Patent for any other alcohol nor is any other alcohol coming within the class of pentahydric or hexahydric alcohols mentioned in the 310 Patent.

[7] Claims 2 and 31 of the 310 Patent are composition claims and extend to compositions that include at least 60% by weight of a pentahydric or hexahydric alcohol. Claims 2 and 31 of the 310 Patent are dependent on Claim 1. The three Claims provide as follows:

> 1. A pharmaceutical composition in tablet form comprising an amount of R(+)-N-propargyl-1-aminoindan or a pharmaceutically acceptable salt thereof, and at least one alcohol selected from the group consisting of pentahydric and hexahydric alcohols.
>
> 2. The pharmaceutical composition of claim 1, wherein said at least one alcohol comprises at least 60% by weight of the total composition.
>
> 31. The pharmaceutical composition of claim 2, wherein the composition comprises 1.56 mg of the pharmaceutically acceptable salt of R(+)-N-propargyl-1-aminoindan.

[8] The Apotex Products contain more than 60% weight of an alcohol that is commonly called [ ].

[9] The sole issue that arises with respect to infringement of the 310 Patent by Apotex in this application is whether [ ] is a "pentahydric" or "hexahydric alcohol". Teva's expert witnesses opine that it is; Apotex' experts opine the opposite.

[10] For the reasons detailed below, I prefer the evidence tendered by Apotex and accordingly have concluded that [ ] is not a pentahydric or hexahydric alcohol. I have thus determined that Apotex' non-infringement allegation is justified and that this application for prohibition will be dismissed, with costs.

II. The Experts

[11] Teva filed evidence from three experts, Dr. Jerry Atwood, Dr. Steven Byrn and Dr. Norman Weiner.

[12] Dr. Atwood is Professor and Chairman of the Department of Chemistry at the University of Missouri-Columbia. He holds a B.S. degree in Chemistry and Mathematics and a Ph.D. in Chemistry. He has published hundreds of articles and has consulted widely for industry in the fields of pharmaceutical chemistry and polymer chemistry, including in relation to the formulation of pharmaceuticals. He has given expert evidence previously in several proceedings, almost always on behalf of patentees. His mandate was to provide an opinion related to patent construction and infringement.

[13] Dr. Byrn is a Professor of Medicinal Chemistry at Purdue University, where he was the Head of the Department of Industrial and Physical Pharmacy. He has published over 160 articles and is the past Chair of the FDA Pharmaceutical Sciences Advisory Committee and the U.S. Pharmacopeia Chemistry 5 Expert Committee. He has consulted widely for pharmaceutical companies and has given evidence on many occasions previously, likewise virtually always for patentees. His mandate was to provide an opinion related to construction and infringement.

[14] Dr. Weiner is an Emeritus Professor of Pharmacy at the University of Michigan. He has over 45 years experience in the pharmaceutical field, particularly in pharmaceutical chemistry and drug delivery systems. He has authored or co-authored more than 170 publications and has consulted for many companies regarding physical and chemical stability of raw materials and solid dosage forms. His mandate was to provide an opinion relating to construction, infringement, and invalidity (insufficiency, ambiguity, obviousness and utility).

[15] Apotex filed evidence from two experts, Dr. Harold Hopfenberg and Dr. Anthony Palmieri.

[16] Dr. Hopfenberg is a Professor Emeritus of Chemical Engineering and Biomedical Engineering and Director Emeritus of the Kenan Institute for Engineering, Technology & Science at North Carolina State University. He has an S.B., an S.M. and a Ph.D. in Chemical Engineering. He has consulted in industry and has served on the editorial boards of various journals. His mandate was to provide an opinion related to patent construction, utility, obviousness, ambiguity, insufficiency, and infringement.

[17] Dr. Palmieri is a registered pharmacist and a faculty member at the Department of Pharmaceutics at the University of Florida, College of Pharmacy. He has a Ph.D. in Pharmaceutics and has worked at the university's Office of Technology Licensing. He has authored over 80 publications and has served on the steering committee for the Handbook of Pharmaceutical Excipients. He has consulted for pharmaceutical companies and has previously provided evidence on behalf of both innovator and generic companies. His mandate was to provide an opinion related to construction, utility, obviousness, and infringement.

III. The Matters the Parties and their Experts Agree On

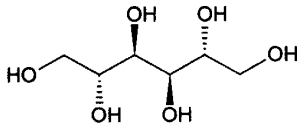
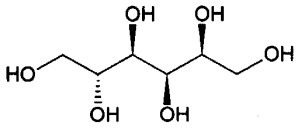
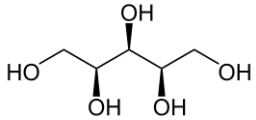
[18] In reviewing the facts relevant to the issue of whether the Apotex Products infringe the 310 Patent, I commence by reviewing the relevant factual matters that are not in dispute.

[19] In this regard, the parties and their experts concur that alcohols are organic compounds that have at least one hydroxyl group (i.e. a group comprised of an oxygen and hydrogen atom, represented by the formula -OH) and no other carbon-oxygen functional group with a higher order of precedence in the chemical nomenclature system (see in this regard the Affidavit of Anthony Palmieri III, sworn November 19, 2013 [Palmieri affidavit] at para 67 Applicant's Record [AR], p 1810; Affidavit of Dr. Harold Hopfenberg sworn November 19, 2013 [Hopfenberg affidavit] at para 30 AR, p 1499; Affidavit of Dr. Jerry Atwood sworn August 16, 2013 [Atwood affidavit] at paras 26 and 27 AR, p 57; Affidavit of Dr. Stephen Byrn sworn August 19, 2013 [Byrn affidavit] at paras 21-22 AR, p 210; Affidavit of Dr. Norman Weiner sworn August 19, 2013 [Weiner affidavit] at paras 22-23 AR, p 274).

[20] There also is no dispute that the term "pentahydric" refers to five hydroxyl, or "-OH" groups, and that the term "hexahydric" refers to six hydroxyl groups (Palmieri affidavit at para 68 AR, pp 1810-1811; Hopfenberg affidavit at paras 30 and 49, AR, pp 1499 and 1505; Atwood affidavit at para 22 AR, p 56; Byrn affidavit at para 20 AR, p 210; Weiner affidavit at para 22 AR, p 274).

[21] It is likewise undisputed that mannitol, sorbitol and xylitol are simple, straight chain sugar alcohols that contain five (in the case of xylitol) or six hydroxyl groups (in the case of mannitol and sorbitol) (Palmieri affidavit at para 69 AR, p 1811; Hopfenberg affidavit at paras 31- 32, AR, pp 1499-1500; Atwood affidavit at para 23 AR, p 56; Byrn affidavit at para 22 AR, pp 210-211).

[22] The parties likewise agree that the chemical formulae and molecular structures of mannitol, sorbitol and xylitol are as follows (Palmieri affidavit at para 189 AR, p 1851; Hopfenberg affidavit at para 31 AR, p 1500; Byrn affidavit at para 25 AR, p 213; Weiner affidavit at para 25 AR, p 275):

Mannitol	Sorbitol	Xylitol
$C_6H_{14}O_6$	$C_6H_{14}O_6$	$C_5H_{12}O_5$
		

[23] The parties further agree that [ ] is an alcohol that[[

] It is similarly undisputed that the chemical formula for [ ] is [

]

(See in this regard Palmieri affidavit at para 168 and 189 AR, pp 1843 and 1850-1851; Hopfenberg affidavit at para 60, AR, p 1509; Byrn affidavit at paras 24-26 AR, pp 212-213; Weiner affidavit at paras 24-25 AR, p 275, as corrected by cross-examination at Questions 192 and 193 AR, p 2567).

[24] As is apparent from the foregoing, the [

].

[25] There is also no dispute that [ ] is now a relatively commonly-used pharmaceutical excipient. However, it was not as commonly-used by pharmaceutical formulators in April 1997, the date the 310 Patent was published.

[26] Finally, the parties and their experts are in substantial agreement regarding the attributes of the notional skilled person, from whose vantage point the 310 Patent is to be construed. They concur in this regard that the skilled person is a pharmaceutical formulator with practical experience. This person would have a master's, doctoral or, perhaps, a bachelor's degree in chemical engineering, organic chemistry, pharmacy, pharmaceutics, pharmaceutical chemistry, medicinal chemistry, or a related field and experience working as a formulator. Moreover it is not disputed that the skilled person would not necessarily be an expert in chemical nomenclature, but the parties agree that he or she would have learned about naming conventions applied by chemists in undergraduate chemistry courses (see in this regard: Palmieri affidavit at paras 25 and 57 AR, pp 1800-1801 and 1808; Hopfenberg affidavit at paras 17 and 27, AR, pp 1495 and 1498-1499; Atwood affidavit at para 11 AR, p 53; Byrn affidavit at para 15 AR, p 209; Weiner affidavit at para 21 AR, p 274; Teva memorandum at para 37 AR, p 2813; Apotex memorandum at para 37; Respondent's Memorandum [RM], para 26).

IV. The Points in Dispute

[27] I turn now to the points in dispute. The parties diverge on several points, but only one of them is material to the infringement issue, namely, what is meant by the terms "pentahydric and hexahydric alcohols".

[28] Teva asserts that a skilled person would understand these terms to include any alcohol molecule that contains five or six hydroxyl groups or any alcohol molecule that contains an alcohol moiety (i.e. an identifiable portion of a molecule) that contains five or six hydroxyl groups. Teva thus says that [ ] is a [ ] alcohol because there are [ ] hydroxyl groups on the alcohol moiety [ ]. In other words, Teva and its experts contend that for purposes of classifying the type of alcohol that [ ] is, the skilled person would count only the [ ] hydroxyl groups on the alcohol moiety of the molecules [

].

[29] Apotex and its experts, on the other hand, assert that the skilled person would understand pentahydric and hexahydric alcohols to include only those alcohols comprised of molecules that contain a total of five or six hydroxyl groups. They thus contend that the skilled person would count all the hydroxyl groups in a molecule for purposes of classifying it and, accordingly, that the skilled person would understand [

] is not pentahydric [or hexahydric] alcohol. They therefore say that the Apotex Products do not infringe the 310 Patent as they do not contain a pentahydric or hexahydric alcohol.

V. Principles Applicable to Claims Construction

[30] In assessing the parties' respective positions on this issue, the first step to be undertaken is the construction of the relevant Claims in the 310 Patent. The case law teaches in this regard that construing the claims in a patent is the necessary first step in an infringement analysis as the

claims define the invention and the limits of the monopoly conferred by a patent (see e.g. *Whirlpool Corp v Camco Inc.*, 2000 SCC 67, [2000] 2 SCR 1067 at para 43 [*Whirlpool*]; *Free World Trust v Electro Sante Inc*., 2000 SCC 66, [2000] 2 SCR 1024 at para 31 [*Free World Trust*]; *Pfizer Canada Inc. v Canada (Minister of Health)*, 2005 FC 1725, 144 ACWS (3d) 938 [*Pfizer 1*] at para 10; *Novo Nordisk Canada Inc. v Cobalt Pharmaceuticals Inc.*, 2010 FC 746, 86 CPR (4th) 161 at para 89; *Alcon Canada Inc. v Cobalt Pharmaceuticals Company*, 2014 FC 149, 117 CPR (4th) 323 [*Alcon v Cobalt*] at para 18).

[31] The principles of claims construction are well-settled and were laid out by the Supreme Court in *Whirlpool* and *Free World Trust*. There, the Court indicated that patent claims are to be construed in an informed and purposive manner, with the claims being read in the context of the patent as a whole through the eyes of a person of ordinary skill in the art (or skilled person). Justice Hughes aptly summarized these principles in *Pfizer 1* at paras 32-53. He restated those principles in *Hughes & Woodley, Patents*, 2nd ed, looseleaf (Canada: LexisNexis Canada Inc, 2005-2014) at 310-11 [*Hughes & Woodley*] as follows:

> (1) Who construes the claim?
>
> The Court construes the claims, not an expert witness.
>
> (2) When are the claims construed?
>
> At the outset, before deciding issues of infringement and validity.
>
> (3) As of what date are the claims construed?
>
> As of the date of publication, except for patents issuing from applications filed before October 1, 1989, in which case it is the date of issue and grant.
>
> (4) What are the criteria for construction?

> The claim must be given a purposive construction. It is an objective exercise as to what a person skilled in the art would have understood the inventor to mean.

(5) What resources may be used for construction?

> The claim is to be read in the context of the rest of the specification, assisted by an expert witness, in order to understand the context of the invention described and the particular meaning of terms used in the patent. The expert is not to displace the Court in the role of the person who is to interpret the claims.

(6) Through whose eyes is the construction made?

> Through the eyes of the ordinary person skilled in the art. An ordinary person is one who operates on the basis of common knowledge in the trade, possessing ordinary skills and without any special "in house" knowledge.

(7) What is to be made of the resulting construction?

> The literal meaning of the claim may be expanded or limited. There may be a self-inflicted wound committed by the inventor in drafting the claim.

(8) A finding of ambiguity is to be avoided if at all possible.

[32] Here, as noted, the sole construction issue that is relevant to infringement is how the terms "pentahydric alcohol" and "hexahydric alcohol" are to be construed as Claims 2 and 31 of the 310 Patent include compositions including at least 60% by weight of such alcohols.

VI. The Experts' Evidence on Construction

[33] Turning first to Teva's experts, their evidence establishes that, prior to formulating their opinions on construction, each was given a copy of Apotex' NOA and portions of Apotex'

ANDS by counsel for Teva. Thus, before they formulated their opinions on construction, each Teva expert was aware that the Apotex Products contained [ ] and that the party who wished to retain them took the position that the Apotex Products infringed the 310 Patent.

[34] Their affidavits moreover reveal that the Teva experts undertook the construction of the terms "pentahydric or hexahydric alcohols" with [ ], the allegedly infringing substance, in mind.

[35] More specifically, Dr. Atwood offers in his affidavit a definition of the terms "pentahydric" and "hexahydric" and an explanation for what constitutes an "alcohol" but does not specifically say what the skilled person would understand the terms, when used together, to mean, except with reference to [ ].

[36] He states as follows in this regard:

> 22. "Penta" and "hexa" refer to five and six, respectively.
>
> […]
>
> 26. The term "alcohol" generally refers to an organic molecule having at least one hydroxyl (-OH) group, although the term "alcohol" is also generally used to refer to the hydroxyl group itself.

[37] Then, after discussing nomenclature and sugar alcohols generally, he states as follows:

> 29. In addition to mannitol, sorbitol and xylitol (the polyols exemplified in the 310 Patent), other sugar alcohols have been approved for use in the food and pharmaceutical industries. [ ] is classified as a sugar alcohol. It is a [

].

> 30. The skilled person would understand that although glucose contains five hydroxyl groups [ ] glucose is not considered to be an "alcohol" or "polyol" because it also contains an aldehyde group. This is a simple matter of nomenclature taught in undergraduate organic chemistry classes. However, because [ ] is considered to be an "alcohol" that contains a [ ] the skilled person would clearly understand [ ] to be included within the group of pentahydric and hexahydric alcohols contained in the 310 Patent.

[38] Drs. Byrn and Weiner's affidavits (which are very similar to each other on the construction point) offer a more fulsome construction for the terms "pentahydric", "hexahydric" and "alcohol", but also tie their construction of these terms in the 310 Patent to [ ].

[39] Dr. Byrn says as follows:

> 20. "Pentahydric" would be understood to refer to five hydroxyl 9-OH) groups. "Hexahydric" would be understood to refer to six hydroxyl groups.
>
> 21. The term "alcohol" would be understood to be an organic compound having at least one hydroxyl group on the alcohol moiety or alcohol molecule but which does not contain carbon-oxygen functional groups such as carboxylic acids, aldehydes, or ketones.

[40] He then goes on to discuss [ ] and concludes as follows on the issue of construction of the terms used in the 310 Patent:

> 28. A skilled person would understand that when a compound contains a polyhydric moiety and a sugar moiety, determining whether it is a pentahydric or hexahydric alcohol is done on the basis of the number of hydroxyl groups on the polyhydric moiety. The skilled person would not include the –OH groups attached to

> the glucose moiety in determining the class of polyhydric alcohol to which it belongs.
>
> 29. [
>
>].

[41] Similar reasoning and language are contained in paras 21 to 26 of Dr. Weiner's affidavit.

[42] On cross-examination, all three Teva experts confirmed that they reviewed portions of Apotex' ANDS and NOA and were aware that the Apotex Products contained [ ] before they formulated their opinions on construction (Atwood affidavit at para 7 AR, p 51-52, Cross-examination Questions 314-317 AR, p 2253; Byrn affidavit at para 11 AR, p 208; Byrn Cross-examination Questions 221 and 321 AR, pp 2467, 2468 and 2473; Weiner affidavit at para 10 AR, p 271, Cross-examination Questions 117-120 AR, pp 2562-2563).

[43] Apotex' experts, on the other hand, were never given a copy of the Apotex NOA and were given portions of the Apotex ANDS only after they had formulated their opinions on construction. This is made clear in their affidavits.

[44] Dr. Hopfenberg says as follows at paras 10 to 13 of his affidavit:

> 10. Mr. Richard Naiberg of Goodmans LLP, counsel for Apotex Inc. ("Apotex"), provided me with a copy of Canadian Letters Patent No. 2,232,310 ("310 Patent", a copy of which is attached as Exhibit 2), and the documents referenced in the 310 Patent, as follows: GB 1,003,686 ("GB 686", a copy of which is attached as Exhibit 3) and WO 95/11016 ("WO 016", a copy of which is attached as Exhibit 4).

11. Mr. Naiberg then asked me to:

(a) Examine the 310 Patent and state my opinion as to:

(i) Who is the person of ordinary skill in the art to whom the 310 Patent is addressed?

(ii) How would the person of ordinary skill in the art at April 10, 1997 understand the disclosure of the 310 Patent and claims 2 and 31 thereof? And

(iii) Would the person of ordinary skill in the art understand the 310 Patent to promise any specific useful property or properties for its subject matter, and if so identify it or them.

(b) Provide some background information about the subject matter of the 310 Patent, as would have been known to the person of ordinary skill in the art as of April 10, 1997.

12. After forming my opinions with respect to these matters, I was provided with a copy of what I am advised by Mr. Naiberg is an excerpt from Apotex's Abbreviated New Drug Submission ("ANDS excerpt", a copy of which is attached as Exhibit 5) for Apo-rasagiline.

13. I was asked by counsel to review the ANDS excerpt and answer the following question: Is Apo-rasagiline a pharmaceutical composition that falls within the scope of claim 2 and/or claim 31 of the 310 Patent?

[45] Likewise, Dr. Palmieri deposes as follows at paras 19 to 21 of his affidavit:

19. Counsel provided me with copies of the following documents:

a) Canadian Letters Patent No. 2,232,310 (the "310 patent"), a copy of which is attached as **Exhibit "C"** and

b) The documents cited in the 310 patent, namely GB 1,003,686 ("GB686") and WO 95/11016 ("WO11016"), copies of which are attached **as Exhibits "D"** and **"E"**, respectively.

20. Counsel then asked me to provide my opinion on the following questions:

a) Who is the "skilled person" to whom the 310 patent is addressed?

b) What would the skilled person understand the 310 patent to be describing as of April 10, 1997?

c) What would the skilled person understand claims 2 and 31 of the 310 patent to cover as of April 10, 1997?

d) What, if anything, would the skilled person understand the 310 patent to be promising in respect of the utility of its subject matter?

e) If the 310 patent promised any specific utility, was this utility demonstrated prior to September 18, 1996?

f) If the 310 patent promised any specific utility, did the inventors have and disclose in the patent a factual basis and line of reasoning for a sound prediction of this promised utility?

g) Do claims 2 and 31 of the 310 patent cover compositions that do not have the promised utility, if any?

h) Do claims 2 and 31 of the 310 patent include compositions that were not indicated to have been invented or disclosed in the patent?

i) What would the skilled person understand by the term "stable" as it was used in the 310 patent?

j) Does the 310 patent teach the skilled person how to prepare compositions that meet the promised utility, if any?

k) Are there any differences between the inventive concept of each of claims 2 and 31 of the 310 patent and the common general knowledge/state of the art as of September 20, 1995 that the person to whom the 310 patent is addressed, without viewing the 310 patent, would have needed to exercise inventive ingenuity to overcome?

21. After providing my opinion on these questions, counsel provided me with a copy of portions of Apotex's Abbreviated New

> Drug Submissions ("ANDS") for its Apo-Rasagiline product, which are attached to my affidavit as Exhibit "F". Counsel asked me to provide my opinion as to whether the Apo-Rasagiline product falls within claims 2 and/or 31 of the 310 patent?

[46] Thus, neither of the Apotex experts was aware that [ ] was contained in the Apotex Products when they formulated their opinions on how to construe the terms in the 310 Patent.

[47] Their opinions on construction, not surprisingly, make no reference to [ ]. Dr. Hopfenberg offers the following as to how he believes the skilled person would interpret the terms "pentahydric and hexahydric alcohols" in the 310 Patent:

> 30. An alcohol is an organic compound having at least one hydroxyl (-OH) group. Alcohols may contain more than one –OH group, in which case they are known as polyhydroxyl or polyhydric alcohols or polyols. Polyhydric alcohols may also be identified more specifically according to the number of hydroxyl (-OH) groups in the molecule. Polyhydric alcohols with five –OH groups are called pentahydric alcohols; those alcohols with six –OH groups are called hexahydric alcohols.
>
> […]
>
> 49. As discussed above, the person of ordinary skill in the art understands the term "pentahydric or hexahydric alcohols" to be a polyhydric alcohol having five or six –OH groups, respectively. Since the inventors specifically reference and exemplify those polyhydric alcohols that have five or six hydroxyl groups and no others, the person of ordinary skill in the art would not understand claim 1 (or claims 2 or 31) to include any polyhydric alcohols have a greater than six or less than give hydroxyl groups.
>
> 50. The person of ordinary skill in the art would assume that the specification of the pentahydric and hexahydric alcohols was intentional and that polyhydric alcohols with more than six or less than five hydroxyl groups would not function in the same way to achieve the same improved stability as promised for pentahydric or hexahydric alcohols. Thus, the skilled person understands that no other polyhydric alcohol can be substituted for a pentahydric or

> hexahydric alcohol in the formulations of claim 1 of the 310 Patent.

[48] Dr. Palmieri, for his part, says as follows:

> 67. An alcohol is a molecule that contains a carbon atom to which is attached a hydroxyl (-OH) group, namely an oxygen atom (O) attached to a hydrogen atom (H). The hydroxyl group (-OH) is the functional group that defines the compound as an alcohol.
>
> 68. The term "pentahydric" would refer to an alcohol having 5 hydroxyl (-OH) groups and the term "hexahydric" would refer to an alcohol having 6 hydroxyl (-OH) groups. "Typically" says the patent, "the alcohol used in accordance with the invention is a member selected from the group of mannitol, xylitol and sorbitol.
>
> 69. The skilled formulator would understand that mannitol, xylitol and sorbitol are each closely-related, simple, straight chain alcohols that share similar properties and uses in formulations.
>
> 70. Mannitol, sorbitol and xylitol have very similar structures. Mannitol and Sorbitol each consist of a chain of 6 carbon atoms with a single hydroxyl group (-OH) on each carbon atom and have the [same] chemical formula and the same molecular weight (182.17 g/mol). Xylitol has 5 carbon atoms with a hydroxyl group (-OH) on each carbon atom with a somewhat lesser molecular weight (152.15 g/mol).
>
> […]
>
> 126. The term pentahydric or hexahydric alcohol has the meaning ascribed to this term above. The skilled formulator would understand the phrase "comprising at least 60% by weight of the total composition" to mean that the weight of the at least one pentahydric or hexahydric alcohol makes up about 60% of the total tablet. For example, if the total tablet weight is 100 mg, then the weight of the pentahydric or hexahydric must be at least about 60 mg.

[49] Both Apotex experts were provided with the Apotex ANDS for purposes of formulating their opinions on infringement. Drs. Hopfenberg and Palmieri offer the opinion that [ ] is

not a pentahydric or hexahydric alcohol because it contains [ ] hydroxyls, all of which must be counted for purposes of classification. They both also offer critiques of the views expressed by the Teva experts.

[50] In this regard, Dr. Hopfenberg points out a disagreement between the Teva experts. He notes that Dr. Atwood offered a different interpretation from Drs. Byrn and Weiner, and tied his construction to the number of carbon atoms in the molecule or moiety as opposed to the number of hydroxyls. Dr. Hopfenberg expresses the view that this is an error. It appears that Dr. Hopfenberg is correct in this assertion as all the other experts for both sides concur that the relevant atoms for purposes of classifying something as a pentahydric or hexahydric alcohol are the hydrogen and oxygen atoms that comprise the hydroxyl groups. Indeed, Teva did not seek to defend Dr. Atwood's reference to carbon as being correct.

[51] Dr. Hopfenberg also offers in his affidavit an extract from the International Union of Pure and Applied Chemistry (IUPAC) Compendium of Chemical Terminology to counter the construction offered by Teva's experts. He states as follows at paras 65 to 68 of his affidavit:

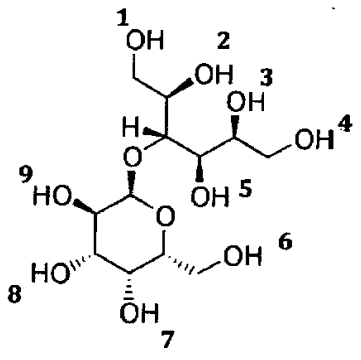
> 65. However, Dr. Weiner's description overlooks the important distinction between a molecule and a moiety. The person of ordinary skill in the art understands that an alcohol is a complete molecule and a moiety is part of a molecule.
>
> 66. The IUPAC defines "moiety" as follows:[4]
>
> > In physical organic chemistry moiety is generally used to signify part of a molecule, e.g. in an ester R1COOR2 the alcohol moiety is R2O. The term should not be used for a small fragment of a molecule. [emphasis added]
>
> 67. This statement, from the IUPAC "Gold Book", indicates that a molecule containing a moiety that is a remnant of an alcohol

> (because a hydrogen atom is "subsumed" in the formation of the ester) is not understood to be an alcohol. Rather, the molecule is understood to be an ester.
>
> 68. The person of ordinary skill in the art reading the 310 Patent would understand that the claim terms "pentahydric alcohol" and "hexahydric" alcohol" refer unequivocally to entire, individual molecules, and not to a selected "part of a molecule" that contains a pentahydric or hexahydric moiety.

[52] The other Apotex expert, Dr. Palmieri, makes reference in his affidavit to two patents for other substances in support of his view that [ ] is not a pentahydric or hexahydric alcohol.

[53] The first of these is U.S. Patent 3,234,151 [the U.S. 151 Patent], issued in February 1966 for products produced from lactositol, [ ] The 151 Patent states that lactositol is the "trivial or common name of the nonahydric alcohol obtained by the reduction of lactose under nonhydrolyzing conditions. Its proper chemical name is 4-O-β-D-galactosyl-D-glucitol" [emphasis added] (Exhibit "M" to the Palmieri affidavit, Applicant's Application Record, AR, p 2168).

[54] In his affidavit, Dr. Palmieri provides the chemical structure for lactositol as follows:

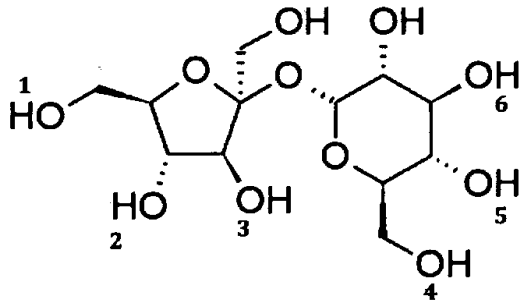


Lactositol – nonahydric alcohol

[55] The other patent to which Dr. Palmieri refers in his affidavit is U.S. Patent 6,204,300 [the U.S. 300 Patent]. It was issued on March 20, 2001 and filed on January 29, 1999 (with a foreign priority date of February 6, 1998). The U.S. 300 Patent pertains to low resistance urethane foam, which is made in part from a polyol (or alcohol with multiple hydroxyl groups). The 300 Patent describes the alcohols that may be used to make the invention in the following terms:

> The alcohol that may be used as the initiator includes monohydric or polyhydric alcohol including monohydric alcohol such as methanol or ethanol; dihydric alcohol such as ethylene glycol and propylene glycol; trihydric alcohol such as glycerine and trimethylol-propane; tetrahydric alcohol such as pentaerythritol; hexahydric alcohol such as sorbitol; and octahydric alcohol such as saccharose. (Exhibit N to Palmieri affidavit AR, p 2195)
>
> [emphasis added]

[56] In his affidavit, Dr. Palmieri provides the chemical structure for saccharose as follows:



Saccharose – octahydric alcohol

[57] Dr. Palmieri opines that because lactositol and saccharose [ ] contain alcohol groups but are classified based on the total number of hydroxyls in the molecule, [ ] cannot be a pentahydric or hexahydric alcohol. He opines that, just as is done with lactositol and saccharose, one must count all the hydroxyl groups in [ ] for classification

purposes. When one does this, according to Dr. Palmieri, one must conclude that [ ] is a [ ] and not a pentahydric or hexahydric alcohol.

[58] Dr. Palmieri also makes another point in his affidavit, saying that the skilled formulator would appreciate that [ ] is quite different in structure from mannitol, sorbitol and xylitol as it contains a greater number of reactive hydroxyl groups. He therefore offers the view that [ ] would not be seen by the skilled person as coming within the group of pentahydric or hexahydric alcohols because there is no reason to believe that [ ] would function the same way as the alcohols named in the 310 Patent. He buttresses this argument with reference to the entries for [ ] in the 2006 edition of the *Handbook of Pharmaceutical Excipients*, R.C. Rowe, P.J. Sheskey, S.C. Owen, ed, 5th ed (Chicago: Pharmaceutical Press, 2006) [the Handbook], noting that [ ] was not contained in earlier edition of the Handbook and that the 2006 extract does not list sorbitol, mannitol or xylitol as substances related to [ ].

VII. Teva's Objection to Additional Evidence Offered by Dr. Palmieri

[59] Teva argues that the U.S. 151 and 300 Patents as well as the [ ] extract from the 2006 version of the Handbook, and all references to them in Dr. Palmieri's affidavit, are inadmissible because they were not mentioned in Apotex' NOA. It submits that the case law of this Court and of the Federal Court of Appeal establishes that a respondent in this sort of application cannot rely on any fact, document or argument that was not disclosed in its NOA, relying in this regard on *AB Hassle v Canada (Minister of National Health and Welfare)* (2000), 7 CPR (4th) 272, [2000] FCJ No 855 at paras 21-24; *Bayer Inc v Cobalt Pharmaceuticals Co*, 2013 FC 1061, 121 CPR (4th) 14 [*Bayer*] at paras 34-37; *Alcon Canada Inc v Apotex Inc*, 2014

FC 791, [2014] FCJ No 952 at paras 75 and 94-95; *Alcon v Cobalt* at paras 14 and 135; *Merck & Co. v Pharmascience Inc.*, 2010 FC 510, 85 CPR (4th) 179 [*Merck v Pharmascience*] at para 96; *Pfizer v Canada*, 2008 FC 500, 167 ACWS (3d) 984 [*Amlodipine*] at para 88; and *Bristol-Myers Squibb Canada Co. v Mylan Pharmaceuticals ULC*, 2012 FC 1142, 107 CPR (4th) 75 at para 63. As the U.S. 151 and 300 Patents and the extract from the 2006 version of the Handbook were not mentioned in Apotex' NOA, Teva says they should be struck from the record and ought not to be considered by me.

[60] Not surprisingly, Apotex disagrees. While recognizing that the case law and subsection 5(3)(a) of the PMNOC Regulations do require a party to disclose all facts and arguments it intends to rely on in its NOA, Apotex argues that an exception to this requirement has been recognised in those situations where a respondent is replying to arguments made by the applicant in their evidence. It points in this regard to the decisions in *AstraZeneca AB v Apotex Inc.*, 2005 FCA 183, 39 CPR (4th) 289 [*Omeprazole 1*]; *Pfizer v Novopharm*, 2005 FCA 270, 141 ACWS (3d) 636 [*Pfizer 2*]; *Fournier Pharma Inc. v Canada*, 2004 FC 1718, 136 ACWS (3d) 349 [*Fournier*]; *Merck v Alcon*, [2000] FCJ No 785, 8 CPR (4^{th}) 87 [*Merck Frosst*]; and *AstraZeneca AB v Apotex Inc.*, 2004 FC 313, 33 CPR (4th) 97 [*Omeprazole 2*], where respondents were allowed to file materials to address unanticipated arguments made by the applicants or their experts. Apotex says that it is merely countering Teva's position that [ ] is a pentahydric alcohol, which is characterized as a "fantastical argument" and not something that it could have anticipated. Apotex thus asserts that its situation is on all fours with those in *Omeprazole 1*, *Pfizer 2*, *Fournier*, *Merck Frosst*, and *Omeprazole 2* and therefore says that the disputed documents are properly before me.

[61] I disagree with Apotex, and in spite of the colourful language used by its counsel to describe Teva's position, do not believe Teva's arguments were unanticipated. In this regard, the 310 Patent claims an invention centred on the alleged stabilizing properties of pentahydric or hexahydric alcohols when combined with rasagiline. Apotex asserted in its NOA that its Products did not infringe the 310 Patent, and when it made this assertion knew that its Products contained [ ]. It therefore was asserting that [ ] is not a pentahydric or hexahydric alcohol. Apotex staked this position out in its NOA where it stated:

> No claim of the 310 Patent will be infringed by the making, constructing, using or selling of APO-Rasagiline tablets since APO-Rasagiline tablets will not contain an alcohol selected from the group consisting of pentahydric and hexahydric alcohols. More specifically, APO-Rasagiline tablets will not contain mannitol, xylitol and sorbitol or any other pentahydric and hexahydric alcohol, as these terms would be understood by a person skilled in the art of the 310 Patent. (AR, p 1150)

[62] Thus, Apotex' case, from the inception, involved the assertion that [ ] is not classified as a pentahydric or hexahydric alcohol. The defence of Teva to the opposite effect is one that Apotex clearly had to anticipate as it is only if [ ] is such an alcohol that the 310 Patent would be infringed.

[63] The disputed documents are directed toward proving that [ ] should not be classified as a pentahydric or hexahydric alcohol. This is precisely the position that Apotex advanced in its NOA. It therefore follows that the disputed documents ought to have been disclosed in the NOA: they are material evidence in support of an issue that Apotex was well aware of when it drafted its NOA.

[64] As Teva correctly notes, the case law recognizes that by virtue of subsection 5(3)(a) of the PMNOC Regulations, a party seeking an NOC through the filing of an ANDS must disclose in its NOA the material facts, arguments and documents it intends to rely on so as to allow the patentee the opportunity to make an informed decision as to whether to seek a prohibition order. Because commencing such a proceeding may expose the patentee to damages under section 8 of the PMNOC Regulations, both this Court and the Federal Court of Appeal have held that a respondent in an application such as this cannot seek to rely on material documents that were not disclosed in its NOA, in circumstances where it possessed sufficient information when it filed the NOA to know that the documents would be relevant to its position.

[65] For example, in *Bayer*, Justice Hughes stated at paras 34-37:

> It has been firmly established by the Court of Appeal that the second person, a generic such as Cobalt, has an obligation in its Notice of Allegation to raise all the facts and legal arguments upon which it relies in support of its allegations. It cannot craft new arguments, or raise new allegations or new facts or new prior art documents not set out in the Notice of Allegation. (*AB Hassle v Canada (Minister of National Health and Welfare)* (2000), 7 CPR (4th) 272, at paras 21-24; *Proctor & Gamble Pharmaceuticals Canada, Inc v Canada (Minister of Health)*, 2002 FCA 290, at paras 21-26.
>
> While this may seem draconian since, undoubtedly, new matters may be raised as experts are consulted and evidence emerges, it is equally draconian for the first person who decides to institute proceedings to face shifting allegations and facts. The process is in need of change, but no interested person seems to be pressing for that change.
>
> As matters stand now, the Court must reject arguments based on facts or documents not set out in the Notice of Allegation nor can the Court address new allegations.
>
> I repeat the words of Stone JA in *AB Hassle, supra* where he wrote at paragraph 21 that the Notice of Allegation must set forth the legal and factual bases for the allegations in a sufficiently complete

> manner so as to enable the first person (here Bayer) to assess its course of action in response to the allegations.

[66] In *Merck v Pharmascience*, he added (at para 96):

> In this sense, the Notice of Allegation is like a pleading. Once a second party has taken a position as to fact or law, it cannot be seen to resile from that position. This is particularly so since a Notice of Allegation cannot be amended once Court proceedings have been commenced.

[67] While it is true that the case law recognises an exception to the disclosure requirement where the respondent is replying to unexpected arguments made by the patentee in its evidence, contrary to what Apotex argues, the situation here is markedly different from those cases where this exception was found to be applicable. In each of *Omeprazole 1 and 2*, *Pfizer 2*, *Fournier* and *Merck Frosst*, relied on by Apotex, the applicants raised new arguments regarding infringement that were more than merely responsive to the claims made in the NOA because they raised new factual issues.

[68] For example, in *Omeprazole 1*, *Pfizer 2* and *Fournier*, the applicants argued that the respondents' products might have degraded, thereby creating compounds that fell within the scope of the disputed claims. This was a new, positive defence to an allegation of non-infringement and not an issue that the respondents could have anticipated. Likewise, in *Omeprazole 2*, the applicant, in a use claim, raised the assertion that the respondent was instructing patients or doctors to use the allegedly infringing product for a use claimed in the patent, through wording in the product monograph, thereby raising new assertions that the respondent was not required to anticipate. Similarly, the evidence filed by the applicants in

Merck Frosst, regarding the nature of gels, was new and not purely a denial of the position staked out by the respondents in their NOA.

[69] Here, on the other hand, Teva's expert evidence to the effect that [ ] is a pentahydric alcohol is merely responsive to Apotex' claim that it is not. Accordingly, this case does not fall within the exception to the disclosure requirements noted in *Omeprazole 1* at para 11; *Pfizer 2* at paras 16-18; *Fournier* at para 60; or *Merck Frosst* at para 11.

[70] Thus, the disputed documents ought to have been disclosed by Apotex in its NOA. Because they were not so mentioned, the disputed documents and all references to them in Dr. Palmieri's evidence must be struck from the record. I have accordingly not considered them in making this decision.

VIII. Assessment of the Parties' Respective Positions on the Construction of the Terms "Pentahydric or Hexahydric Alcohols"

[71] Having determined what portion of the expert evidence on the construction issue is properly before me, I turn next to the assessment of that evidence. Both parties make several arguments as to why their experts' evidence ought to be preferred.

A. *Teva's arguments regarding why its experts' evidence should be preferred*

[72] Teva argues that I should prefer its expert evidence because its experts' knowledge of chemical nomenclature, which is at the heart of the construction issue, is superior to that of Apotex' experts. It also suggests that the independence of Drs. Hopfenberg and Palmieri should

be questioned because the opinions they offered on other issues are so erroneous that I ought to conclude both were functioning as advocates for Apotex' position rather than as independent experts.

[73] The opinions in question involved two issues: first, the interpretation of the words "at least 60% by weight" in Claim 1 of the 310 Patent by both Drs. Hopfenberg and Palmieri and, second, the interpretation of Claim 31 of the 310 Patent mentioned by Dr. Hopfenberg in paragraph 52 of his affidavit.

[74] With respect to the former point, both Apotex experts offer the view in their affidavits that the words "at least 60% by weight" in Claim 1 should be understood as meaning approximately 60% or more by weight, which would result in Example 1 in the 310 Patent falling within the scope of Claims 2 and 31. This Example arguably does not demonstrate the alleged stabilizing effect of pentahydric or hexahydric alcohols on rasagiline solutions, which in turn may suggest that the Patent fails for lack of demonstrated or soundly predicted utility. Teva argues that interpreting the unambiguous phrase "at least 60%" to include compositions including 58.9% alcohol so as to include Example 1 within the scope of Claim 1 is a results-driven conclusion that can only be explained by Dr. Hopfenberg and Dr. Palmieri's desire to support Apotex' positions. It says that this interpretation is not supportable and, indeed, is contradicted by the decision in *Eli Lilly and Co. v Apotex Inc.*, 2009 FC 991, 80 CPR (4th) 1 at paras 155-156, where Justice Johanne Gauthier indicated that the words "at least" are clear and unambiguous and mean what they say, namely, no less than the mentioned amount.

[75] In terms of the second interpretative issue, Dr. Hopfenberg stated in para 52 of his affidavit that the person of ordinary skill in the art understands Claim 31 of the 310 Patent to cover any composition having at least 1.56 mg of rasagiline. The Claim, however, does not use the words "at least" and, rather, is limited to compositions having this amount of rasagiline. Teva thus says that Dr. Hopfenberg misspoke in para 52 of his affidavit and, indeed, so admitted during his cross-examination (at Question 348, AR, p 2669). It argues that this should undercut his credibility.

[76] As for the relative expertise of the Apotex experts, Teva notes that Dr. Hopfenberg has only authored two papers in the last twenty years and suggests he now works primarily as a legal consultant, noting he has previously testified on Apotex' behalf. As for Dr. Palmieri, Teva notes that he has only a formulator's knowledge of chemistry and suggests that he admitted on cross-examination that he would defer to those with the type of expertise possessed by the Teva experts to determine the correct nomenclature for a chemical and, thus, deferred on the very interpretive issue that is at the centre of the infringement claim.

B. *Apotex' arguments regarding why its experts' evidence should be preferred*

[77] Apotex contests these arguments, noting that the alleged lack of independence was not put squarely to its experts on cross-examination and, accordingly, cannot be now asserted by Teva due to the rule in *Browne v Dunne* (1893), 6 R 67 (UK, HL). That rule requires a party seeking to impugn a witness' credibility by calling independent evidence to put the evidence to the witness on cross-examination (see in this regard Alan W. Bryant, Sidney N. Lederman and

Michelle K. Fuerst, eds, *The Law of Evidence in Canada*, 4th ed (Markham, ON: LexisNexis, 2014 (Sopinka) at p. 1184).

[78] Apotex also says that even if the positions advanced by its experts on the impugned interpretive issues surrounding "at least" are without merit, that is no reason to disregard the rest of their evidence as the case law is replete with examples of situations where expert testimony is rejected on one point but accepted on others. It points to *AstraZeneca Canada Inc. v Apotex Inc.*, 2014 FC 638, [2014] FCJ No 671 [*Omeprazole 3*] at paras 235 and 321 as an example of a situation where this occurred.

[79] Apotex also submits that a review of the cross-examinations of Drs. Atwood and Byrn demonstrates that both were unduly combative and failed to concede obvious points without repeated questioning. Apotex argues that I should infer a lack of objectivity or independence from this attitude, especially in light of the fact that Drs. Atwood and Byrn have almost invariably provided opinions on behalf of patentees. It therefore argues that I should prefer the evidence of its experts.

[80] Apotex further asserts that Teva and Dr. Atwood conceded that [ ] was not a pentahydric or hexahydric alcohol in the context of a motion they brought to obtain further information about the Apotex Products. In his affidavit filed in support of that motion, Dr. Atwood said that it was necessary for him to obtain disclosure regarding all the contents of the Apotex Product for purposes of his infringement opinion as [ ] may degrade and, if this

occurs, would produce mannitol and sorbitol. He concluded as follows in para 17 of that affidavit:

> Information in Apotex' ANDS which discloses the identity and quantity of the impurities in the [ ] used in Apotex' rasagiline product, as well as information on the identity and quantity of the impurities in Apotex' rasagiline product itself, would be necessary and important to assess Apotex' allegation that its rasagiline product does not infringe the claims of the '310 Patent and in particular the allegation that its proposed rasagiline product will not contain mannitol, xylitol and sorbitol or any other pentahydric or hexahydric alcohol.

[81] Apotex argues that this is effectively a concession by Teva and Dr. Atwood that in the absence of such degradation, the Apotex Products do not infringe the 310 Patent by merely containing [ ] as otherwise, one cannot say that the additional disclosure was necessary to determine if the Apotex Products infringe the 310 Patent. Apotex notes that at the point Teva requested the additional disclosure it knew the Apotex Products contained [ ]. It argues that the request for additional disclosure thus was premised on the belief that [ ] was not a pentahydric or hexahydric alcohol as otherwise, no additional information would have been required by Teva to determine if the Apotex Products infringed the 310 Patent.

[82] Apotex asserts that the position taken by Teva regarding the necessity of obtaining further disclosure should lead me to apply the doctrine of election or approbation and reprobation, which would estop Teva from arguing that [ ] is a pentahydric alcohol. It asserts in this regard that the situation is on all fours with that in *Apotex v AstraZeneca Canada Inc.*, 2012 FC 559, 215 ACWS (3d) 722 [*Omeprazole 4*], where my colleague, Justice Hughes, found this equitable doctrine prevented the respondent from taking the position that Apotex was

a "second person" within the meaning of the PMNOC Regulations, when it had adopted the opposite position in earlier proceedings.

[83] In the alternative, if I do not agree, Apotex asserts that, at the very least, I should interpret the evidence given by Dr. Atwood as undermining his credibility as he failed to disclose the position he now takes regarding the classification of [ ] in his earlier affidavit filed in support of the disclosure motion. Apotex asserts that there either was a failure of candour by Dr. Atwood in his earlier affidavit or his current views on the nature of [ ] were formulated later, thereby demonstrating the tenuous nature of his opinion.

[84] In addition to the foregoing, Apotex makes three other arguments in support of its submission that its expert evidence ought to be preferred.

[85] It first argues that the care it took to "blind" its experts to the contents of its Products when they formulated their opinions on construction should result in their being granted greater weight as they could not be results-driven, in contrast to the Teva experts. Apotex asserts in this regard that the required principles of claims construction, as laid out by the Supreme Court of Canada in *Whirlpool* and *Freeworld Trust*, mandate that the construction exercise should be carried out uninfluenced by knowledge of the invention claimed in the patent. Apotex argues that only its experts proceeded in this fashion whereas the Teva experts did not. It says that this is an important reason to prefer its experts' evidence, as, indeed, my colleague Justice Rennie recently held in *Omeprazole 3*.

[86] Secondly, Apotex asserts that counsel for Teva improperly interfered with its cross-examination of Dr. Atwood in cutting off questions related to Dr. Atwood's affidavit filed in support of its motion for disclosure that were equally pertinent to his affidavits filed in support of Teva's prohibition application. Apotex asserts that this is a further reason why I should disregard or give less weight to Dr. Atwood's evidence.

[87] Finally, Apotex submits that the construction offered by its experts makes much more sense in light of the wording of the 310 Patent. It argues in this regard that the specification speaks to the addition of "alcohols" to the mixture to produce the claimed invention and that, when used in this sense, an alcohol must mean the entire molecule as one cannot add a moiety or part of a molecule to a mixture. It argues that the term "alcohol" as used or incorporated in Claims 1, 2 and 31 must be given a similar meaning and accordingly must mean the entire substance to be added. It thus says that the terms "pentahydric or hexahydric" must modify the term alcohol (taken to mean the entire substance) and, therefore, that its interpretation is to be preferred.

C. *Analysis*

[88] While I find some of the arguments advanced by Apotex unconvincing, I do prefer the evidence given by Apotex' experts as to the construction of the terms "pentahydric or hexahydric alcohol" for five reasons.

[89] The first reason I prefer Apotex' position flows from the wording of the 310 Patent, itself, and from the analysis of it given by the Apotex experts. In this regard, as the case law

teaches, the construction exercise is to be carried out from the point of view of the skilled person to whom the patent is addressed. As noted, in this case, that person is a skilled formulator, with a university degree in a field related to chemistry, chemical engineering or pharmacy. I agree with Drs. Palmieri and Hopfenberg that the skilled person would read the 310 Patent with a view to understanding what ingredients are to be included in the formulation to produce a stable rasagiline formulation and that when read in this sense, the term "alcohol" would be understood as denoting a substance because the 310 Patent states at several points that what is to be added to the composition is an "alcohol". This can only be a substance as opposed to a moiety as one can only add a substance to the composition. That the term "alcohol" means the substance to be added to the composition is evident from the way the term "alcohol" is used in the specification at several points. For example, it provides:

> The patent further discloses the use of the subject compounds in admixture with a variety of substances including various alcohols such as a benzyl alcohol, stearyl alcohol, and methanol." Lines 14-16 AR, p 12
>
> In accordance with the invention it was surprisingly found that the stability of formulations comprising PAI can be significantly improved by the incorporation of relatively large amounts of certain alcohols. Lines 8-10 AR, p 13
>
> …there is provided a pharmaceutical composition comprising…at least 60% by weight of at least one alcohol being a member selected from the group of pentahydric and hexahydric alcohols. Lines 11-17 AR, p 13
>
> Preferably the composition comprises at least 70% of said at least one alcohol. Lines 20-21 AR, p 13

[90] I further concur with Apotex that the meaning to be given to the term "alcohol" in Claims 1, 2 and 31 must be the same as the meaning given to the term "alcohol" as used elsewhere in the 310 Patent. There is no reason to interpret the terms differently and every reason to interpret

them in a similar fashion as the entire Patent makes clear that the inventors mean the same thing when they refers to an "alcohol" in the specification and the Claims. Thus, when the term "alcohol" is used in Claim 1 and 2 (and incorporated by reference into Claim 31 through its reliance on Claim 2), the term "alcohol" means a substance.

[91] I further agree with Apotex that the terms "pentahydric or hexahydric", as used in both the Claims and the specification, modify the term "alcohol" and thus refer to the entire substance. Therefore, the required five or six hydroxyls must exist in the entire substance and not only in a part of the molecule. I therefore concur with Drs. Palmieri and Hopfenberg when they conclude that the skilled person would understand the terms pentahydric and hexahydric alcohols, as used in the relevant Claims as "unequivocally meaning" the entire molecule and not a part or moiety of a molecule.

[92] As noted by the Apotex experts, this interpretation is further supported by the fact that the only alcohols referred to in the 310 Patent as coming within the scope of the class of pentahydric or hexahydric alcohols are those which contain 5 or 6 hydroxyls in the entire molecule.

[93] This interpretation is also supported in my view by the IUPAC definition of "moiety" cited by Dr. Hopfenberg at para 66 of his affidavit, which distinguishes between the nomenclature for a substance and a moiety. From this definition it is clear that a substance may be an alcohol and may also contain an alcohol moiety, or may be another type of compound, such as an ester, and still contain an alcohol moiety. Thus, when one uses the term "alcohol" to

denote the entire substance, one is required to consider all the hydroxyls included on the entire molecule as Dr. Hopfenberg opines.

[94] Secondly, I agree that the manner in which the experts were retained and instructed in this case provides a reason to prefer the evidence of the Apotex experts over that of the Teva experts. Because they did not know what alcohol Apotex had used in its Products when they conducted their construction exercise, their interpretation was undertaken in accordance with the direction from the Supreme Court of Canada, requiring that the construction exercise be uninfluenced by concerns over infringement or invalidity. The Teva experts, on the other hand, conducted their construction of the terms with a view to the potentially infringing substance. This is evident from the terms of their affidavits, which indicate that the molecular structure of [ ] was factored into the construction exercise.

[95] Like Justice Donald Rennie found in *Omeprazole 3*, I believe that in this case as well, the fact that the allegedly infringing substance was disclosed to the Teva experts before they conducted their construction of the Claims means their interpretation is to be afforded lesser weight. At para 321 of that decision, Justice Rennie wrote:

> First, Apotex's experts' disbelief in a fear of racemisation facing the skilled chemist is more credible because its experts more closely emulated the perspective of the skilled person. Drs. Jacobsen and Danheiser (for Apotex) had mandates that allowed them to opine on the state of the art, in the words of the Supreme Court of Canada, "viewed without any knowledge of the alleged invention as claimed" (*Sanofi-Synthelabo Plavix*, at para 67), while both Drs. Davies and Armstrong (for AstraZeneca) did not. More specifically, the Apotex experts were "blinded" from the 653 for their initial reports addressing whether and how the enantiomers of omeprazole could be obtained. By contrast, Dr. Davies has given extensive evidence in prior esomeprazole litigation, while Dr.

> Armstrong, to a lesser extent, has also addressed the '653 patent in a prior case.

Similar reasoning pertains in this case.

[96] On this point, I disagree with Teva that all that counsel did when it provided its experts with extracts from the Apotex ANDS and NOA at the outset was to alert them to the issues that were relevant and thus to focus their analyses on "where the shoe pinches". Teva argues in this regard that the case law recognises that arguments and evidence need to be directed to the point in dispute or, "where the shoe pinches", relying on *Shire Biochem Inc. v Canada (Minister of Health)*, 2008 FC 538, 67 CPR (4th) 94 at para 22 [*Shire Biochem*]. However, the decision in *Shire Biochem* does not stand as authority for the proposition that it is proper to construe a patent with the infringing substance in mind, but, rather, only for the common sense notion that to be useful evidence and arguments in a case must be directed toward the issues that arise. Teva could easily have directed its experts' attention to these issues by posing the question whether the terms "pentahydric or hexahydric alcohols" as used in the 310 Patent would connote a molecule or a moiety to the skilled person, without alerting the experts to the fact that the potentially infringing substance was [ ].

[97] Thus, the way in which the experts were instructed and retained in this case provides a second reason to prefer the evidence of Apotex' experts.

[98] Thirdly, I find that the fact that Dr. Weiner's affidavit sets out incorrect diagrams for [ ], in erroneously depicting the carbon-hydroxyl bonds at para 25 (AR, p 275) by

reversing their stereochemistry, undercuts his credibility. This is not a mere typographical error as counsel for Teva argues. Nor does the fact that this affidavit was penned by counsel (who presumably mis-copied the diagrams) lessen this error; if anything it makes it more telling as in such circumstances the expert witness must be doubly circumspect to ensure the accuracy of the material that is being placed before the Court. This provides a further reason for according lesser weight to Dr. Weiner's affidavit.

[99] Fourthly, the fact that Dr. Atwood misspoke at para 29 of his affidavit and defined a hexahydric alcohol as a 6-carbon alcohol undercuts his credibility as this assertion is contradicted by all the other experts who concur that a hexahydric alcohol is one with six hydroxyl groups.

[100] Fifthly, I concur with Apotex that counsel for Teva improperly prevented counsel for Apotex questioning Dr. Atwood on points that were material to his opinion. In this regard, counsel refused to allow Dr. Atwood to answer questions directed towards Dr. Atwood's state of mind when he prepared the affidavit he filed in support of Teva's disclosure motion. Such questions are relevant to the strength of Dr. Atwood's opinion on construction and to when he developed the view that [ ] is not a pentahydric or hexahydric alcohol, which issue is at the heart of the dispute between the parties in respect of infringement. The refusals were as follows:

> 348 Q. You knew the structures of the compounds? I think you just told me that you drew these?
>
> A. I did.
>
> 349 Q. Knowing the name of the compounds, the structures of them, you still considered it was necessary to have information—further information—to assess Apotex' allegation?

A. Yes. I wanted to have as complete information as possible with regard to this constituent, which was [ ].

350 Q. In fact, you said that was necessary. That's what you so swore to our court.

A. Yes, to give a complete and full evaluation.

351 Q. Oh, no, I don't think you said that. You said it was necessary, right?

A. I said it was necessary. I'm pointing out that the report which I subsequently have in front of us is as complete and accurate as I could make it. I needed the information which is requested in this particular affidavit in order to be able to produce the final document.

352 Q. In your April 2013 affidavit you do not give the opinion that [….] in Apotex' tablet is a pentahydric or hexahydric alcohol?

REF DR. KLEE: You're not going to cross-examine Dr. Atwood on this affidavit.

BY MR. BRODKIN

353 Q. I take that refusal. You did not offer the opinion that [ ] were pentahydric alcohols?

REF DR. KLEE: Refused

BY MR. BRODKIN

354 Q. You didn't offer the opinion that Apotex' tablets infringe any claim to the 310 because they contain the [ ]?

REF DR. KLEE: Refused

[101] In my view, Teva's refusal to allow Dr. Atwood to answer these questions renders Dr. Atwood's testimony less valuable as was held in somewhat similar circumstances in *Pfizer Canada Inc. v Apotex Inc.*, 2005 FC 1421, 43 CPR (4th) 81 at para 90 and *AstraZeneca AB v Apotex Inc.*, 2007 FC 688, 60 CPR (4th) 199 [*Omeprazole 5*] at para 67. Moreover, Apotex was not required to move to compel answers to these questions, particularly in an application such as

the present which is to be heard in a summary fashion. Apotex, therefore, is entitled to rely on the improper refusals in support of its argument to accord lesser weight to Dr. Atwood's evidence (see, in this regard, *Smithkline Beecham Pharma Inc. v Apotex Inc.*, [1998] FCJ No 1412, 83 ACWS (3d) 178 at paras 5-6; *Indcondo Building Corporation v Steeles-Jane properties Inc.*, [2001] OJ No 3316, 14 CPC (5th) 117 (Ont Sup Ct) at para 7).

[102] Thus, for these reasons, I prefer the evidence of Apotex' experts over that offered by Teva's experts on the interpretive issue that is relevant to infringement in this case, namely, what is meant by the terms "pentahydric or hexahydric alcohols" incorporated into Claims 2 and 31 of the 310 Patent.

[103] It is evident, therefore, that I am unconvinced by several of the other arguments made by the parties regarding why I should prefer the evidence of their experts.

[104] As concerns Teva's arguments in this regard, the alleged errors made concerning the interpretation of the words "at least" in the 301 Patent do not mean that I must discount the other evidence offered by the Apotex experts. As Apotex argues, even if they were mistaken in their interpretations on this point, this would not undermine their experts' credibility completely as their testimony may well be accepted on some points but rejected on others. I moreover note in this regard that if the Apotex experts erred on this point, it is a much different error than the one made by Dr. Byrn, as theirs involved an interpretation that Teva challenges whereas in Dr. Byrn's case he signed off on an affidavit drafted by counsel that contained a fundamental error in the representation of the chemical substance at the heart of this litigation.

[105] In addition, at least in the case of Dr. Palmieri, the alleged weakness in his interpretation and the suggestion that he was acting as an advocate for Apotex as opposed to fulfilling the role of an independent expert was not put to him on cross–examination. While not, strictly speaking, a violation of the rule in *Browne v Dunne*, the failure to cross-examine on these points undercuts Teva's argument regarding Dr. Palmieri's lack of independence.

[106] Nor am I convinced by Teva's assertions regarding the alleged lack of expertise of Drs. Palmieri and Hopfenberg. The fact that Dr. Hopfenberg has acted frequently as an expert witness and has published very little in the past several years does not necessarily disqualify him from providing relevant and reliable expert evidence. Moreover, his training and fields of study are related to the issues that arise in this application, and I therefore reject the attack on his expertise.

[107] Likewise, I find the attack on Dr. Palmieri's expertise to be unconvincing. Contrary to what counsel for Teva asserts, Dr. Palmieri did not concede during cross-examination that he lacked expertise to provide reliable testimony on the issues covered in his affidavit, and counsel for Teva has stretched his testimony far beyond what was said. In this regard, the questions asked and answers given on this point during his cross-examination were as follows:

> 321 Q. … I'd like to return, though, to the maltitol entry.
>
> A. Maltitol solution?
>
> 322 Q. The maltitol solution entry, yes. Thank you. And I'd like you to confirm for me that the synonym for maltitol known as alpha-D-glucopyranosyl-1,4D-glucitol is the same?
>
> MR. NAIBERG: As what?
>
> MR. NORRIE: As [ ].

THE WITNESS: The synonym for the entry of maltitol solution describes it as 1,4-D-glucitol, whereas the entry in the USP for [ ], but…

MR. NORRIE:

323 Q. So there's the possibility that the [ ]?

A. I'm not certain. As a formulator, I'm not certain.

324 Q. You're not an expert in chemistry?

A. I have a formulator's understanding of chemistry.

325 Q. But you don't have particular expertise in the chemistry and nomenclature of compounds?

A. That is correct.

326 Q. And you would defer to someone who was a chemist—

MR. NAIBERG: For what purpose?

MR. NORRIE: For—I hadn't completed my question.

MR. NAIBERG: Please complete it.

MR. NORRIE:

327 Q. You would defer to someone who was an expert in chemistry when it came to identifying a compound such as this and determining the conventional nomenclature?

MR. NAIBERG: What do you mean by conventional? And again, I said, when I interrupted you, when I thought you were finished, for what purpose and what context are you talking about?

MR. NORRIE: The nomenclature that's conventional for chemists, naming compounds and putting them into entries such as these ones that we've been reviewing.

THE WITNESS: As a formulator, I concern myself with common or trivial names. If I wanted to confirm that one chemical name was the same as another chemical name, I would defer to my chemistry nomenclature expert.

328 Q. The term [ ] is not a common term in use in the literature that a formulator reads?

> A. The term—well, the phrase [ ] is not a common term, is not something that a formulator uses in their everyday work. However, it's quite clear, I think, to a formulator that [ ] would mean [ ]. (AR, p 2731)

[108] In the forgoing exchange, Dr. Palmieri says only that he would defer to a chemist on issues of nomenclature in the context of confirming if a trivial name was equivalent to the formal name for a compound. The questions were moreover posed in connection with maltitol, a different compound from that at issue here. Thus, the passage cannot be read as constituting an admission by Dr. Palmieri that he would defer to a chemist to confirm what the skilled person would understand by the terms "pentahydric and hexahydric alcohols". His testimony on the construction issue as set out in his affidavit is therefore not shaken by this exchange, contrary to what Teva argues.

[109] I also find two of the arguments made by Apotex unconvincing. In this regard, in the first place, I am unconvinced by the generalized attacks on Drs. Atwood and Byrn's credibility levied by Apotex. The mere fact that they have almost always testified on behalf of patentees does not render their evidence inherently unreliable as was noted by Justice Snider in *Teva Canada Ltd. v Apotex Inc.*, 2013 FC 141, 109 CPR (4th) 1 at para 36, cited by Teva. Nor can I infer a hostile attitude from a bare review of the transcript, as counsel for Apotex would have me do. While there are several points in the cross-examination of each expert where it appears that each was unduly reticent to provide answers, I am unprepared to find them to be uncooperative in the absence of an ability to evaluate their *viva voce* testimony.

[110] Secondly, the attacks made by Apotex on Dr. Atwood based on the prior affidavit he swore in the context of the disclosure motion are without merit. Contrary to what Apotex asserts, the positions taken by Teva and Dr. Atwood on that motion are not incompatible with the positions advanced on this application. As Teva correctly notes, the disclosure motion might have led to discovery of additional grounds of infringement, but this is not incompatible with the arguments made in this application. Thus, Teva is not estopped from making these arguments.

[111] Thus, I am persuaded by most of Apotex' arguments and for the foregoing reasons, prefer the evidence of Drs. Palmieri and Hopfenberg to that given by Drs. Atwood, Byrn and Weiner in respect of the manner in which the terms "pentahydric or hexahydric alcohol" as incorporated into Claims 2 and 31 of the 310 Patent, are to be construed. I therefore find the terms "pentahydric and hexahydric alcohols" to mean alcohols that are comprised of molecules having five or six hydroxyls, or in the words of Dr. Palmieri:

> 67. An alcohol is a molecule that contains a carbon atom to which is attached a hydroxyl (-OH) group, namely an oxygen atom (O) attached to a hydrogen atom (H). The hydroxyl group (-OH) is the functional group that defines the compound as an alcohol.
>
> 68. The term "pentahydric" would refer to an alcohol having 5 hydroxyl (-OH) groups and the term "hexahydric" would refer to an alcohol having 6 hydroxyl (-OH) groups. (AR p 1810).

IX. Infringement

[112] As counsel for both parties noted, infringement in this case is determined by the construction given to the terms "pentahydric and hexahydric alcohols". As I have construed those terms to mean alcohols that contain in total five or six hydroxyl groups, it follows that the Apotex Products do not infringe the 310 Patent as they contain only [ ] more than 60% by

weight, and the [ ].

Therefore, the Apotex Products do not infringe the 310 Patent and this application for an order in the nature of prohibition must accordingly be dismissed.

[113] Given this determination, it is not necessary for me to address the other arguments advanced by the parties concerning validity and, indeed, both concurred that I ought not to do so by way of *obiter dicta*.

[114] Thus, for these reasons, this application will be dismissed.

X. Costs

[115] Both parties agreed that costs should follow the event based upon the formulation that has been applied by Justice Hughes in cases of this sort (see e.g. *Apotex Inc. v Syntex Pharmaceuticals International Ltd.*, 2009 FC 494, 76 CPR (4th) 325 at para 88; *Eli Lilly Canada Inc. v Apotex Inc.*, 2008 FC 142, 63 CPR (4th) 406 at para 188 [*Raloxifene*]; and *Pfizer Canada Inc. v Pharmascience Inc.*, 2013 FC 120, 111 CPR (4th) 88 at para 218).

[116] I agree and accordingly have determined that Apotex is entitled to its reasonable costs assessed at the mid-point of Column IV of Tariff B to the *Federal Courts Rules*, SOR/98-106. Reasonable fees shall include a second counsel for attendance at the hearing. Expert fees are awarded but may not exceed fees of senior counsel for equivalent time involvement. Fees or disbursements for attending or defending cross-examinations shall be limited to one counsel, including for costs of travel. If applicable, business class airfare is reasonable, but only for trans-

Atlantic flights. The parties shall attempt to agree on quantum of costs. Should the parties be unable to agree, they may refer this matter to an assessment officer.

[117] Finally, I want to express my thanks to counsel for both parties for the helpful nature of their submissions.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. U.S. Patents 151 and 300 and the Extract from the 2006 version of the Handbook, which are attached as Exhibits M, N and P to the Palmieri affidavit, and all references to them in that affidavit, are struck;

2. This application is dismissed with costs in favour of Apotex, to be calculated in accordance with paragraph 115 of these Reasons; and

3. If the Minister of Health issues an NOC to Apotex for the Apotex Products, Apotex shall advise the Court of this fact within 48 hours of the issuance of the NOC to allow for release of a non-redacted version of the Judgment and Reasons in this matter.

"Mary J. L. Gleason"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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