Federal Court of Appeal | Cour d'appel fédérale

Date: 20170112

Docket: A-201-15

Citation: 2017 FCA 9

CORAM: **PELLETIER J.A.**
GAUTHIER J.A.
SCOTT J.A.

BETWEEN:

APOTEX INC.

Appellant
(Defendant)

And

ASTRAZENECA CANADA INC. and
AKTIEBOLAGET HÄSSLE

Respondents/Cross-Appellants
(Plaintiffs)

AND BETWEEN:

APOTEX INC.

Appellant
(Defendant)

And

ASTRAZENECA AB and
AKTIEBOLAGET HÄSSLE

Respondents/Cross-Appellants
(Plaintiffs)

Heard at Montréal, Quebec, on March 9, 2016.

Judgment delivered at Ottawa, Ontario, on January 12, 2017.

REASONS FOR JUDGMENT BY: GAUTHIER J.A.

CONCURRED IN BY: PELLETIER J.A.
SCOTT J.A.

Federal Court of Appeal | Cour d'appel fédérale

Date: 20170112

Docket: A-201-15

Citation: 2017 FCA 9

CORAM: **PELLETIER J.A.**
GAUTHIER J.A.
SCOTT J.A.

BETWEEN:

APOTEX INC.

Appellant
(Defendant)

And

ASTRAZENECA CANADA INC. and
AKTIEBOLAGET HÄSSLE

Respondents/Cross-Appellants
(Plaintiffs)

AND BETWEEN:

APOTEX INC.

Appellant
(Defendant)

And

ASTRAZENECA AB and
AKTIEBOLAGET HÄSSLE

Respondents/Cross-Appellants
(Plaintiffs)

REASONS FOR JUDGMENT

GAUTHIER J.A.

[1] Apotex Inc. (Apotex) appeals the decision of Justice Barnes of the Federal Court (2015 FC 322) as finally amended on July 15, 2015 (2015 FC 671). In its decision, the Federal Court found that certain claims (Claims 1, 5, 6, 13 and 19) of the Canadian Patent 1,292,693 (the 693 Patent) were valid and had been infringed by Apotex.

[2] The proceedings were bifurcated, so that the decision under appeal concerns only issues relating to liability. The Federal Court reserved the issue of costs. The respondents, AstraZeneca Canada Inc., AstraZeneca AB and Aktiebolaget Hässle (collectively, Astra) cross-appealed the Federal Court's decision on the issue of punitive damages, asserting that in the special circumstances of this case, the Federal Court should have recognized their right to claim such punitive damages.

[3] The 693 Patent in which Astra claims an interest pertains to pharmaceutical preparations containing omeprazole, a drug used in the treatment of gastrointestinal diseases. The 693 Patent has 19 claims, including 16 claims covering specific oral pharmaceutical preparations containing omeprazole, 15 of which are dependent on Claim 1. Claim 17 covers a process for making the said preparations , while Claim 18 covers a commercial package, which includes a claimed preparation (claims 1 to 16) and instructions for the use set out in Claim 19, which itself covers the use of a claimed preparation for the treatment of gastrointestinal diseases.

[4] After a 40-day trial, the Federal Court issued a 175-page decision (the Reasons) dealing with the construction of the patent, its validity (overbreadth, inutility and ambiguity), as well as infringement, the limitation period and whether it was appropriate to award punitive damages.

[5] In its appeal, Apotex does not challenge the Federal Court's findings that the subject matter of the claims at issue is novel and inventive (i.e. non-obvious). Apotex also concedes that if the Federal Court's construction is found to be valid, its pharmaceutical preparations containing omeprazole infringed the 693 Patent.

[6] I agree with Astra that this appeal, as well as the cross-appeal, involve no new principles of law and turn on their own facts. For the reasons that follow, in my view, the Federal Court made no reviewable errors in respect of the construction of the claims at issue and in concluding that these claims were valid. With respect to limitation period, I believe that with respect to the Federal Court file no. T 1890-11, the Federal Court erred in failing to properly consider whether a provincial time period shorter than six years did apply to some infringing activities of Apotex (see paragraphs 114-118,125 and 126 below). Finally, I believe that the cross-appeal should be dismissed.

I. CONTEXT

[7] To provide some context, I will set out, among other things, some facts and findings of the Federal Court that are not in dispute.

[8] The 693 Patent has a priority date of April 30, 1986; the application was filed in Canada on April 29, 1987; and was issued on December 3, 1991 (Reasons at para. 12). This means that it is subject to the application of the old *Patent Act*, R.S.C. 1985, c. P-4, which did not have a specific section dealing with the limitation period applicable to infringement actions unlike the current version of the *Patent Act* (*Act*), where, since 1993, section 55.01 provides that a six-year time limitation applies to acts of infringement.

[9] Claim 1, which is at the heart of the construction argument raised in this appeal, reads as follows:

> 1. An oral pharmaceutical preparation comprising: (a) a core region comprising an effective amount of a material selected from the group consisting of omeprazole plus an alkaline reacting compound, an alkaline omeprazole salt plus an alkaline reacting compound and an alkaline omeprazole salt alone; (b) an inert subcoating which is soluble or rapidly disintegrating in water disposed on said core region, said subcoating comprising one or more layers of materials selected from among tablet excipients and polymeric film-forming compounds; and (c) an outer layer disposed on said subcoating comprising an enteric coating.

[10] At the time the said patent was filed, it was known that omeprazole was a powerful inhibitor of gastric acid secretion and was useful to treat gastric and duodenal ulcers (Reasons at para. 5).

[11] But, as found by the Federal Court, omeprazole turned out to be a particularly difficult active pharmaceutical ingredient to formulate. It has very low solubility and is very acid and moisture sensitive. The solution found by the inventors was multifaceted in order to finely balance the incompatibility between alkalinity necessary for acceptable storage stability and the

preservation of the enteric coating necessary for good gastric acid resistance (Reasons at paras. 244, 253).

[12] The skilled person to whom this patent is addressed is someone with a university degree in natural sciences and practical experience in the development of pharmaceutical dosage forms: a skilled pharmaceutical formulator (Reasons at para. 225).

[13] Astra commercialized a preparation covered by Claim 1 under the brand name LOSEC. Meanwhile, in January 2004, Apotex obtained a Notice of Compliance (NOC), allowing it to market and sell its omeprazole product (sold under the brand name Apo-Omeprazole in Canada).

[14] The 693 Patent has been the subject of much litigation in Canada and in the United States and not only between these two parties. A few of the resulting decisions were considered by the Federal Court, such as *Astra Aktiebolag v. Andrx Pharmaceuticals, Inc.*, 222 F. Supp. 2d 423, affirmed 84 Fed. Appx. 76 (U.S. C.A. Fed. Cir. 2003) and *Omeprazole Patent Litigation, Re,* 490 F. Supp. 2d 381 (U.S. Dist. Ct. S.D.N.Y. 2007), affirmed 536 F. 3d 1361 (U.S. C.A. Fed. Cir. 2008), where the American courts had to determine whether various companies' omeprazole products (including Apotex's in the second wave of cases), infringed U.S. Patent 4,786,505, the American equivalent of the 693 Patent (Reasons at paras. 177-178). The Federal Court also referred to this Court's decision in *Apotex Inc. v. AB Hassle,* 2003 FCA 409, 312 N.R. 288 [*AB Hassle*], where Justice Rothstein, as he then was, had to construe Claim 1 of the 693 Patent in the context of a NOC regulations proceeding (Reasons at paras. 171-176).

[15] The Federal Court stated that it had no doubt that there were ways to make useful omeprazole preparations that would not fall within Claim 1 of the 693 Patent, as this proved to be the case for some defendants in the litigation proceedings which took place in the United States (Reasons at para. 275).

[16] Apotex looked for ways to work around the 693 Patent, and thought that it had succeeded by using a different process than the one covered by Claim 17 and described in the disclosure of the 693 Patent. Since the process it used was not known when the inventors filed their patent application, it was not, and could not have been, discussed in the disclosure of the 693 Patent.

[17] As found by the Federal Court, based on tests carried out by Astra's experts, Astra was able to ascertain the composition of Apotex's commercial preparation of omeprazole through testing performed in 2004 and 2011. These tests established, and the Federal Court accepted this evidence, that Apotex's product had a core containing omeprazole and an alkaline reacting compound (ARC), an outer enteric coat and a subcoat containing a methacrylic acid copolymer-povidone (MACP-PVP) complex (Reasons at paras. 303, 364).

[18] It is no longer disputed that Apotex's omeprazole product contains a distinct structural layer of polymeric film that is present on the core between the core and the enteric coating. The Federal Court found that this layer is substantially continuous (the minor imperfections have no functional significance), and inert (Reasons at para. 364). It serves as an effective barrier between the core and the enteric coating, and in almost every instance, exceeds a thickness of 2 microns (Reasons at paras. 364-365).

[19] This layer under the enteric coating is formed by a chemical reaction between the enteric coating MACP and the core excipient PVP when the enteric coating is applied to the pellet cores during manufacture (Reasons at para. 303). This is referred to in the Reasons as an *in situ* subcoating as opposed to a subcoating that is sprayed, painted, compressed or otherwise applied individually during the manufacturing process. As will be further explained, a main issue before us is whether the Federal Court properly interpreted the words of Claim 1 before concluding that such a layer is a "subcoating … disposed on the core" within the ambit of the said claim.

[20] The Federal Court found that Apotex could have done testing similar to that performed by Astra's experts before putting its omeprazole product on the market to see if its product could infringe Claim 1 of the 693 Patent because it exhibits all the essential elements of the claimed pharmaceutical preparations covered by the said patent. Instead, Apotex appeared satisfied that it would not so infringe because it had used a different process than the one described in the patent, which in its view, only covers preparations where the separating layer between the core and the enteric coat is applied during the manufacturing process before the enteric coating is applied.

[21] Both parties acknowledged before the Federal Court that there was nothing inventive about the process described in the disclosure of the 693 Patent or claimed in Claim 17 except that it had never been used to make the particular pharmaceutical preparations claimed in the 693 Patent. Indeed, the parties had agreed that the inventive concept of the claims was a formulation of omeprazole containing an alkaline core, an inert subcoating and an enteric coating which provides good long-term storage stability and gastric acid resistance (Reasons at para. 226). As

mentioned at paragraph 5 above, the Federal Court's findings that the invention was not obvious and not anticipated are not challenged in this appeal.

[22] The facts relevant to Astra's cross appeal and its claim that Apotex should pay punitive damages can be briefly summarized as follows.

[23] Astra alleges that Apotex was deceptive in the context of a settlement obtained in an earlier NOC proceeding involving the 693 Patent (Federal Court file no.T-1446-93). Dr. Sherman, the Chairman of Apotex, testified under oath in the NOC proceeding that the Apotex omeprazole product contained dibasic sodium phosphate as an ARC, a component exemplified in the 693 Patent, whereas unbeknownst to Astra, Apotex substituted magnesium hydroxide as its ARC in its New Drug Submission to the Minister in order to avoid another patent of Astra's that claimed dibasic sodium phosphate as a stabilizing agent (1,388,377 Patent). Apotex failed to advise Astra of this substitution when it clearly knew that its testimony on this point was inaccurate (Reasons at paras. 382-383, 386).

[24] Instead of summarizing in a distinct section, the Federal Court decision and the various findings relevant to the issues in dispute in this appeal, I will do so when reviewing each issue individually. This will avoid unnecessary repetition.

II. The issues

[25] In the appeal, the issues are:

1) Did the Federal Court err in construing the 693 Patent, and if so, then it erred in finding that Apotex's omeprazole product infringed Astra's 693 Patent?

2) If the Federal Court did not err in its construction, did the Federal Court err in finding:

   (i) That the disclosure was sufficient?

   (ii) That Claim 1 was not overbroad and not ambiguous? and,

   (iii) That utility had been either demonstrated or soundly predicted?

3) Did the Federal Court err in concluding that a six-year limitation period applied to all of Apotex' infringing activities?

[26] In the cross-appeal, the only issue is whether the Federal Court erred in declining to award punitive damages to Astra.

[27] As acknowledged by Apotex at the hearing before us, because Apotex's argument on proper construction feeds into the validity arguments, the issue relating to the construction of the patent is the most important one.

[28] The standards of review applicable to those issues are those set out in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235. With respect to the issues set in paragraphs 25(2) and (3) above, absent an extricable error of law, Apotex must establish that the Federal Court made a palpable and overriding error.

[29] While it was argued that the standard of review for patent construction is palpable and overriding error, the Supreme Court has consistently applied correctness: *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67 at para. 76, [2002] 2 S.C.R. 1067 [*Whirlpool*], and *Sanofi-Aventis v. Apotex Inc.*, 2013 FCA 186 at paras. 32-33, 447 N.R. 313 [*Plavix*].

[30] However, the Federal Court is entitled to deference in respect of its appreciation of the expert evidence as to how a person of ordinary skill in the art would understand specific wording. For example, while the Federal Court noted that the expert evidence did not provide much in the way of specialized usage in respect of the words "disposed on" (Reasons at paras. 170-175), this was not so in respect of the meaning of the word "inert" (Reasons at paras. 193-194).

III. ANALYSIS

A. Construction

[31] The Federal Court summarized the applicable principles of claim construction at paragraphs 160-167 of the Reasons. Apotex does not dispute that the Federal Court correctly articulated those principles. Rather, it argues that the Federal Court adopted a fettered, results-oriented construction, by beginning its analysis by asking whether Claim 1 covered preparations having a "subcoating that forms *in situ*". Apotex also submits that by focusing on whether Claim 1 as a whole related to a product on the one hand, or to a process on the other, the Federal Court improperly fettered its consideration of the wording of the claim. Thus, in Apotex's view,

although the Federal Court articulated the appropriate principles of law, it paid lip service to these principles. In other words, the Federal Court improperly applied them.

[32] Apotex also insists that the Federal Court erred by relying on this Court's findings in *AB Hassle* since in that case, and the American cases cited by the Federal Court, the evidentiary record was different and in any event, those courts also erred by failing to give appropriate weight to the disclosure and the nature of the invention described therein when they construed Claim 1 of the 693 Patent or its American equivalent.

[33] Apotex argues that as a result of the above-mentioned errors in the Federal Court's approach, specifically its failure to properly consider the disclosure in the patent and give it appropriate weight in performing its purposive analysis, the Federal Court failed to appropriately construe the words "subcoating" "disposed on", "selected from", and "inert". In Apotex's view, the Federal Court also failed to construe Claim 1 as it would have been understood by a person skilled in the art in 1991. Apotex claims that the Federal Court erred because one cannot include within the scope of the monopoly claimed that which the inventors had not disclosed to the public in the 693 Patent.

[34] Apotex raises a number of other arguments that I do not intend to discuss for they simply have no merit. I will illustrate this with two examples.

[35] Apotex says that the Federal Court replaced the words "selected from" by the word "comprising". When one reads paragraph 284 of the Reasons on which Apotex relies for this

alleged “error of law” (Apotex’s Memorandum of Law at para. 55, footnote 68), the word “comprising” is used exactly as found in Claim 1. It is not meant to replace “selected from”. The Federal Court, having reached the stage where it was in its Reasons, had looked at the composition of Apotex’s omeprazole pellets. As such, the Federal Court was not required to fully quote or give a contextual meaning to the latter part of Claim 1(b) since what was as a matter of fact before it, was a layer made of a MACP-PVP complex. Apotex also submits that the Federal Court erred in interpreting “subcoating” as not including a gelatine capsule. This is not relevant to this appeal where obviousness and anticipation are no longer in issue. Moreover, I raised this during the hearing and did not get any satisfactory answer as to why it was necessary for this Court to determine this issue in order to deal with this appeal.

[36] That said, I now turn to a few findings of the Federal Court that are at the heart of Apotex’s main argument. First, the Federal Court found that Claim 1 and its dependent claims are product claims that are not limited to preparations made by the processes expressly referred to in the disclosure (Reasons at paras. 173, 178, 179, 183).

[37] The Federal Court also held that the expression “disposed on” is not a term of art used by the skilled person to whom the patent is addressed. This expression was not given a special meaning in the disclosure where it is used only once at page 5 of the 693 Patent. Thus, there was no clear particular meaning attributed to this expression by the inventors (Reasons at paras. 170, 179-181, and 189 *in fine*). It found that the objective reader would understand that “the purposive use of a general term to define the product would be insufficient to import a process limitation” (Reasons at para. 179 *in fine*). Read in context, I understand the Federal Court to say that the

expression refers to the relative position or spatial arrangement of the subcoating in the finished preparations covered by the product claims (i.e. in the completed tablets or pellets containing omeprazole).

[38] With respect to the word "inert", the Federal Court preferred the evidence of Astra's expert (Dr. Bodmeier) to that of Apotex's expert (Dr. Kibbe). In the context of Claim 1, the Federal Court held that this term of art would not be understood as requiring the complete absence of any chemical reaction whatsoever, as submitted by Apotex's expert. It would be understood by skilled formulators as meaning that the subcoating components should not interfere with the function of the enteric coating and the stability of the omeprazole core (Reasons at paras. 138, 190-195).

[39] As for the meaning of "subcoating" in the claims, the Federal Court considered the expert evidence as to how this would be understood. It noted that most of the parties' arguments were largely matters of grammar and context where expert opinions add little, if any, interpretative value (Reasons at para. 170). The Federal Court found that the use of the term "subcoating" in Claim 1 would be understood as one or more layers that are substantially continuous with a thickness that is sufficient to achieve its purpose (Reasons at paras. 196-208).

[40] There was no real dispute before the Federal Court as to the meaning of "selected from". This is an expression that is often used in claims and is well understood. The Federal Court considered the argument made by Apotex that the term connotes a choice (Reasons at para. 169(b)). The Federal Court did not have to comment on this further considering its overall view

that, when read in context, the wording of Claim 1 does not limit it to preparations made by the process referred to in the disclosure and claimed at Claim 17.

[41] As the issue of construction of the patent is to be reviewed on the correctness standard, I have performed my own analysis of the 693 Patent. I have thus considered, as proposed by Apotex, what the invention is by reading the full specification. For the reasons that follow, I do not agree with Apotex's suggestion that the invention is to keep the core and the enteric coating separated at all times (my emphasis), meaning from the start of the manufacturing process up until the time the products or preparations claimed are completed and ready for storage and then used to treat gastrointestinal diseases.

[42] That said, it is appropriate to first say a few words about the arguments raised by Apotex as set out in paragraphs 31 and 32 above.

[43] To argue that the Federal Court paid lip service to the principles it properly articulated because it refers to the problem confronting it (does the invention cover subcoating that forms *in situ*) in the construction section of its reasons shows a misunderstanding of the Federal Court's reasons. So is the view that somehow the Federal Court failed to have regard to the actual wording of the claims simply because it viewed the 693 Patent as a product claim. This is especially so when one considers that it is Apotex itself, in its post-trial submissions, who framed the construction issue as whether or not the claims cover an *in situ* reaction product (Appeal Book, Vol. 5 at pages 699, 706). I am certainly not prepared to infer anything on this basis. It would be like concluding that Justice Binnie was paying lip service to a principle he enunciated

in *Whirlpool* because he commented on the construction issues facing the Court in the section of his reasons dealing with infringement. Should we infer from this that the learned judge erred in law by ignoring that construction should be assessed first without an eye on validity and infringement? Although it may have been preferable for the Federal Court to use Apotex's exact words, it is clear from its description of the construction issues (Reasons at paras. 163-167, 169(a) and (g)) that the Federal Court well understood the issues before it. The words used were meant to convey the main issue raised by Apotex, namely, that the wording of the claim, whether a product claim or not, does not cover a layer (under the enteric coat, i.e. subcoat) applied using a process that was unknown at the relevant time.

[44] Furthermore, identifying the type of claim one construes as a product claim (including a product by process claim) or a process claim versus a use claim or a hybrid claim, has always been part of the construction analysis in Canada as well as anywhere else in the world that I am aware of. This includes the United States, Australia, the United Kingdom and the European Union. It is a most basic principle of patent drafting that a court must consider. It has been done as a matter of course by the Supreme Court of Canada (see *Whirlpool*, *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902 [*Monsanto*], *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 to name a few). Moreover, it is very clear from a fair reading of the Reasons that the Federal Court did not view this characterization as a final or complete answer to the construction of Claim 1. It fully considered the wording of the claim itself and the competing views offered by the parties and their experts as to how Claim 1 would be understood by a skilled person. Moreover, the Federal Court made it clear during the trial that determining whether Claim 1 was a claim for a product with 3 structural elements was not a full

answer to the construction issue before it, for one still had to give meaning to the wording used such as “disposed on” (Appeal Book, Vol. 6, Trial Transcripts, Cross-Examination of Dr. Kibble at page 24224).

[45] Finally, the Federal Court properly considered this Court’s decision in *AB Hassle*, noting that it was not a binding precedent as it was issued in the context of a NOC proceeding and that it would not have hesitated to differ if Apotex’s position had been persuasive. The Federal Court simply found that this was not so (Reasons at paras.175-178).

[46] Returning to my analysis, the applicable principles of construction are well-established and the Federal Court properly summarized them. In both *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 [*Free World*] and *Whirlpool*, the Supreme Court of Canada made it clear that patents are to be construed purposively rather than literally.

[47] The “key” to purposive construction is the identification by the court, with the assistance of the skilled reader, of the particular words and phrases in the claim that describe what the inventor considered to be “essential elements of his invention” (*Whirlpool* at para. 45; and *Free World* at para. 31). The intention of the inventor is not to be assessed subjectively (meaning that the testimony of the inventor as to what he or she had in mind is irrelevant). The intention is derived from the wording of the claims read in context harmoniously with its purpose. The Supreme Court made it abundantly clear that the objective intention of the inventor is to be found within the four corners of the patent. This means that a later patent such as Astra’s Patent No. 2,186,037 cannot be used to establish such intention or the meaning of a word. In this particular

case, there was no debate that the *in situ* process at issue, whether or not it can be called an *in situ* coating process, was not part of the common general knowledge in 1991 or before. Thus, there is no need to refer to any post-art evidence in that respect.

[48] It is trite law that a court will consider the disclosure when it construes the claims. I considered the disclosure as it may help to determine if the inventor gave a particular meaning to an expression or word in the claim by adopting a special lexicon. However, the disclosure cannot be used "to enlarge or contract the scope of the claim as written and thus understood" (*Whirlpool* at para. 52 *in fine*; see also Justice Rothstein's comment in the seminal decision of *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*., 2008 SCC 61 at para. 77 *in fine*, [2008] 3 S.C.R. 265). It must be recalled that predictability (that is fairness to the public, including the competitor of the patentee), demands that primacy of the claim's language be maintained (*Free World* at paras. 39-41). It is fairness to the inventor that is achieved by interpreting the claims in an informed and purposive manner. It is thus somewhat surprising that in this case, it is the competitor who insists on giving the disclosure more weight than that allegedly given to it by the Federal Court in order to restrict the scope of the claim as written at this stage when one should not be concerned with validity (i.e. for example whether the disclosure is insufficient or the claims overbroad) or infringement.

[49] Turning to the 693 Patent, the disclosure generally follows the usual pattern adopted by patent agents to describe the invention. After describing the field of the invention (page 1, at lines 3-7), it sets out the background of the invention, which, as mentioned earlier, includes that omeprazole was known for its powerful inhibitory action, and the problems encountered in

formulating a pharmaceutical dosage form that will prevent degradation of the omeprazole by preventing it from coming into contact with acidic gastric juice as well as the acidic compounds of enteric coatings, which may be used to remedy the first problem. It then notes at lines 15-16 of page 2 that "in order to enhance the storage stability the cores which contain omeprazole must also contain alkaline reacting constituents" (see for example page 1 at lines 16-17, 29-32; page 2 at lines 7-13).

[50] At page 3, lines 5-6, the disclosure mentions that "under the circumstances, there has been a demand for the development of new enteric preparations of omeprazole with better stability". The disclosure then goes on to describe various prior art, where preparations including one or several layers over the core would not solve the two problems encountered in formulating omeprazole preparations.

[51] At page 4, the inventors state: "[t]he object of the present invention is to provide an enteric coated dosage form of omeprazole, which is resistant to dissolution in acid media and which dissolves rapidly in neutral to alkaline media and which has a good stability during long-term storage". It goes on to state the following:

> [c]ores containing omeprazole mixed with alkaline compounds or an alkaline salt of omeprazole optionally mixed with an alkaline compound are coated with two or more layers, whereby the first layer/layers is/are soluble in water o (sic) rapidly disintegrating in water and consist(s) of non-acidic, otherwise inert pharmaceutically acceptable substances. This/these first layer/layers separates/separate the alkaline core material from the outer layer, which is an enteric coating. The final, enteric coated dosage form is treated in a suitable way to reduce the water content to a very low level in order to obtain a good stability of the dosage form during long-term storage.

[52] To understand the 693 Patent, it is important to take into account that, as mentioned at page 5 of the disclosure and as further confirmed by the independent Claim 1 and Claim 17, there are two aspects to the invention. The first aspect is the oral pharmaceutical preparation comprising the elements found in Claim 1. Indeed, the exact wording of that claim is found at lines 4-13 of page 5 of the disclosure. It is the only place where the expression “disposed on” is used in the disclosure.

[53] The second aspect of the invention is a process for preparing the oral preparation of the invention, which comprises coating. Again, the wording of the disclosure at lines 14-25 of page 5 is exactly the same as that of Claim 17.

[54] It is also important to mention that in the detailed description that follows from pages 5a to 9 (and most of the disclosure thereafter), the two aspects of the invention are intermingled. The second line of page 9 of the disclosure makes it clear that the drafter describes the two aspects of the invention under each of the subtitles of the detailed description and that the process used to make the core, the separating layer and the enteric coating layer (all subtitles in the disclosure) are conventional techniques. This has the advantage of also providing details that enable the public to make the oral preparation of the invention as required by law while at the same time providing support for Claim 17 (see subsection 34(1) of the old *Patent Act*). It also confirms the unity of the invention in that the process described in the disclosure and later claimed, in and of itself, is not inventive.

[55] To illustrate the intermingling discussed above, at pages 6 and 7 of the disclosure, one learns how the subcoating layer described on page 5 (particularly element (b)) is used to separate "the omeprazole containing alkaline reacting cores ... from the enteric coating polymer(s) containing free carboxyl groups, which otherwise causes degradation/discolouration of omeprazole during the coating process or during storage" (see page 6 at lines 3-6), and how "the separating layer(s) can be applied to cores – pellets or tablets - by conventional coating procedures" and that the material used is "chosen among the pharmaceutically acceptable, water soluble, inert compounds or polymers used for film-coating applications such as, for instance sugar, polyethylene glycol …, or the like" (see page 6 at lines 25-34). The disclosure then goes on to discuss the thickness of the separating layer, which may vary depending on the preparations (for example tablets versus pellets), and the method used to prepare them (see page 6 at lines 34-36, page 7 at lines 6-7). Another example is found at lines 16-17 of page 7, where again, when discussing the enteric coating layer, the drafter indicates that it "is applied on to the sub-coated cores by conventional coating techniques".

[56] At page 8, lines 11-14, the disclosure makes it clear that "[w]ithout this separating layer the resistance towards gastric juice would be too short and/or the storage stability of the dosage form would be unacceptably short".

[57] On page 9, there is a brief explanation of how one would use a preparation of the invention and administer it to treat conditions for which omeprazole is known as an active medicinal ingredient.

[58] Several examples of preparations made by known techniques, including comparative examples with preparations that do not include a subcoating layer, are found at pages 10 to 27 of the disclosure. Apotex put a lot of emphasis on these examples, going so far as to say, in answer to a question from the Bench, that were it not for these examples, there may not have been a problem construing the claims. This is followed by a discussion of the preferred embodiments of the process claimed and lessons learned from the testing. Then at page 29, there is a brief description of biopharmaceutical studies (administration of a preparation to human volunteers). As required by law, the specification ends with 19 claims. As mentioned earlier, 16 of those claims cover oral pharmaceutical preparations, while Claim 17 covers a coating process to make them. Claim 18 covers a commercial package, which includes a claimed preparation for the use covered in Claim 19.

[59] Like Justice Rothstein in *AB Hassle* before me, I have given much detail about the disclosure (although I could not reproduce all the passages highlighted by Apotex) rather than simply saying that I have read it carefully more than once, despite the fact that it is clearly not always essential to do so in one's reasons.

[60] Having considered the specification as a whole, I am satisfied that the invention is a pharmaceutical preparation (such as a tablet or pellets) having a specific structure in order to provide good long-term stability and gastric acid resistance.

[61] The elements of this structure are the three elements described in Claim 1, which the inventors clearly viewed as essential.

[62] With respect to the word “subcoating”, it is defined in the claim itself as one or more layers made of one of the selected materials described in the product claims. As the word itself indicates, this or these layers are under the enteric coating (thus subcoating). The evidentiary record and the disclosure support the Federal Court’s finding that it would be understood by the skilled person that these layers are substantially continuous, with a thickness appropriate to their purpose. It is not the role of this Court to reweigh the evidence in that respect. It was also open to the Federal Court to conclude as it did with respect to the meaning of the word “inert”. Contrary to what Apotex suggested, that expression in section (b) of Claim 1 refers to the state of the layer or layers in the finished oral pharmaceutical preparation.

[63] I am satisfied that the expression “disposed on”, which expression is not a term of art, meant to describe the position or spatial arrangement in the final structure of the claimed preparations. I agree with the Federal Court that the disclosure does not attribute a particular meaning such as “coated” or “applied” to this expression. In my view, it is telling that this non-technical expression is used instead of words like “coated” or “applied” when describing this aspect of the invention at page 5. The drafter chose to use a different expression than when describing how one can make these preferred embodiments and the process claimed throughout the disclosure. This construction is perfectly in harmony with the purpose of the invention as noted by Justice Rothstein at paragraph 23 of *AB Hassle* referred to in the Reasons at paragraph 173. It is also in line with the inventive concept agreed upon by the parties and used by the Federal Court in its unchallenged findings that the invention was new and not obvious.

[64] There is no impermissible redundancy as suggested by Apotex. When the adjective "disposed" is used to denote a position, it must necessarily be qualified by words such as "on", "above", "under" or "over". The particular position of each essential element of the structure of these new preparations is repeated not only by use of the words "disposed on" in sections (b) and (c) of Claim 1, but also by using the words "subcoating", "outer layer… comprising an enteric coating". This is not unusual. Patents are rarely regarded as fine examples of English writing nor are they meant to be read as such by the person skilled in the art. In my view, the language of Claim 1 as a whole makes it very clear that the position of each element of the final product is essential.

[65] Given the undisputed factual findings of the Federal Court with respect to the structure of Apotex's omeprazole preparation and my conclusion that the Federal Court was correct in construing Claim 1 as not including a process limitation, the Federal Court's findings in respect of infringement should stand.

IV. Validity

[66] I will thus now discuss the argument that the Federal Court erred in finding that the claims at issue were valid. As was mentioned during the hearing before us, many of the arguments raised in respect of sufficiency, overbreadth and ambiguity overlap. Thus, like the Federal Court, I will treat them under the same heading while I will treat the argument with respect to utility separately.

A. Sufficiency, overbreadth and ambiguity

[67] The Federal Court found that the 693 Patent imparts useful and sufficient information to the person of skill to craft an omeprazole formulation that would be expected to solve problems the inventors encountered. In its view, the fact that some routine stability and gastric acid resistance testing would still be required to know if a particular formulation with the structural features of Claim 1 actually worked as expected did not mean that Claim 1 was overbroad or unclear (Reasons at para. 278).

[68] The Federal Court found that by following the instructions in the specifications, and with routine testing and some adjustments if necessary, the skilled formulator is able to obtain a useful formulation (Reasons at para. 279).

[69] The Federal Court noted at paragraph 281 of the Reasons that the fact that the person skilled in the art needs to apply some basic knowledge or routine testing to work the invention is not fatal because the essential framework of the invention is provided. In that respect, the Federal Court referred to *Burton Parsons Chemicals, Inc. v. Hewlett-Packard (Canada) Ltd.*, [1976] 1 S.C.R. 555, 54 D.L.R. (3d) 711 [*Burton Parsons*], which was been analyzed in a more recent decision by the same judge: *Delp v. Fresh Headies Internet Sales Ltd.*, 2011 FC 1228, at paras. 13-19 [*Delp*].

[70] The Federal Court also dealt with Apotex's argument that some materials or constituents falling within the possible selections referred to in Claim 1 could be highly reactive and would

not work. The Federal Court found that the requirement that the subcoating be inert directs the skilled person away from highly reactive components, and that such a person would also know that water and heat are undesirable and would therefore seek to minimize and control them (Reasons at paras. 276, 277). Thus, the claim is not overbroad when considering how it would be understood by the skilled person.

[71] Apotex argues that the disclosure of the 693 Patent is insufficient because if the preparation includes a layer made *in situ*, there is no teaching as to how to make it. This is particularly so considering that the concept of an *in situ* formed layer was not known in the state of the art in 1991.

[72] Also, Apotex claims that the Federal Court erred in applying *Burton Parsons* given that the testing required to determine if a layer formed *in situ* would not have been considered to be routine at the relevant time. The Supreme Court of Canada in *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60 at paras. 72-79, [2012] 3 S.C.R. 625 [*Teva*], teaches that the patent cannot require the public to conduct experiments to understand the scope of the invention. Here, according to Apotex, this is exactly what would be required to determine if a preparation made using the *in situ* method provided a layer that came within the parameters of Claim 1. These are Apotex's principal arguments on insufficiency which I will deal with after identifying its arguments on overbreadth and ambiguity.

[73] Apotex also submits that the claims of the 693 Patent are overbroad because the inventors do not disclose, nor made a preparation, where the separating layer was made using an *in situ*

process. Apotex submits that Claim 1 is overbroad because it does not include an essential element of the invention, namely the need to ensure that the enteric coating is kept out of contact with the omeprazole core at all times.

[74] Finally, Apotex states that Claim 1 is ambiguous because the public does not know with certainty where it may safely go without infringing the patent. Apotex asserts that the 693 Patent fails to teach what falls inside or outside of the patent for a variety of reasons.

[75] Simply because Apotex argued one construction issue over another does not make the language of Claim 1 ambiguous.

[76] It is telling that what may arguably be the wrong interpretation according to Apotex is not only supported by expert evidence but also by all courts that have had to construe Claim 1 of the 693 Patent or its American equivalent. We have all come to the same conclusion as to its meaning and ambit. How could this claim be ambiguous when read with a mind willing to understand? In my view, this claim is not ambiguous.

[77] The Federal Court found as a fact, and which was open to it, that Apotex could have determined if its pellets of omeprazole had the essential elements of Claim 1. Instead, it chose to simply rely on its view that the claim could not be infringed if it used a process not described in the disclosure despite the fact that Dr. Sherman suspected that a layer separated the alkaline core from the enteric coating. The fact that Dr. Sherman did not consider this layer as a subcoating within the ambit of Claim 1 is of no moment. Infringement need not be intentional and there is

no requirement that the disclosure contain details of tests to be carried to determine if one infringes. With this last comment, I now turn to Apotex's argument on sufficiency, that is whether the disclosure adequately describes the invention so as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use.

[78] There is no dispute that the disclosure enables the person skilled in the art to practise the invention as described in Claim 1. What Apotex is really saying is that the invention must also describe, in sufficient detail, all processes that can be used at any time during the life of the 693 Patent to make the invention.

[79] It is well established in patent law that when one claims a new and inventive product, an inventor is only required to enable the person skilled in the art to work the invention. He or she need only describe one method or process for making it (see for example *Cobalt Pharmaceuticals Company v. Bayer Inc.*, 2015 FCA 116 at para. 68, 474 N.R. 311). Thus, in my view on the law as it stands, the Federal Court made no palpable and overriding error in finding that the information contained in the 693 Patent is sufficient.

[80] Apotex relies on *Teva* to say that the invention was not properly or sufficiently described if one were to use the *in situ* process, which only became known and which Apotex only used several years after the 693 Patent was issued. This is not the teaching of the Supreme Court in *Teva*. Indeed, that case is distinguishable, given that the problem in *Teva* was that the inventor had not disclosed what his invention was because only one compound in the various claims

worked and the disclosure did not say which one did. Thus, it could not be said that the inventor had properly described his invention in order to meet the requirements of subsection 27(3) of the *Act*. In the present case, all experts agreed that by following the teachings of the 693 Patent, they would expect the formulations (products) claimed in Claim 1 to have the advantages set out in the said patent.

[81] Apotex's reliance on the House of Lords' decision in *Biogen Inc. v. Medeva plc* (1996), [1997] R.P.C. 1 (H.L.) [*Biogen*], is also misplaced. Indeed, in that case, the reason Lord Hoffman held that the disclosure was insufficient was because of the hybrid nature of the claim and the nature of the invention. In that case, the inventor could not claim a product because the DNA molecule (Dane particle) he had made was not new. He could not claim the process because the process itself was also known; thus, he had to draft the claim to describe the product he was trying to monopolize partly through the way it worked and partly through how it was made.

[82] As indicated above, the 693 Patent is a product claim describing the essential elements of the final structure of the product, thus the nature of the claims in the 693 Patent are not at all similar to the one dealt with in *Biogen*. In fact, Apotex's argument is more akin to the one that was raised, also by relying on *Biogen*, in *Generics (UK) Limited v. H. Lundbeck*, [2008] EWCA Civ 311, affirmed [2009] UKHL 12 [*Lundbeck*].

[83] In that case, the inventor had claimed escitalopram, an enantiomer (a product claim). This was the active medicinal ingredient in an antidepressant sold under the brand name Cipralex. The inventive step supporting the claim was the method that had been developed to separate this

enantiomer. Since the enantiomer itself (i.e. the product) had never been made, it was new and non-obvious (process was inventive). As such, the inventor was entitled to claim the product. The competitor in that case had developed a new method for separating the enantiomer and contested the validity of the patent on the basis that it did not teach the method it was using and thus was insufficient to support the product claim. This argument was rejected by the Court of Appeal of the United Kingdom (*Lundbeck CA*) and by the House of Lords. Obviously, I should not be taken to say that the facts of this case are on all fours with the one before us. But there are two reasons why it is still relevant to explain why Apotex's argument is flawed.

[84] First, in *Lundbeck CA*, Lord Hoffmann, then sitting with the panel of the Court of Appeal, explains the teachings of *Biogen* and second, both the Court of Appeal and the House of Lords had to determine the sufficiency of the enabling disclosure, having regard to the development of a superior method of preparing the claimed product (escitalopram), which was not known at the time the patent was published and which was evidently not described in the disclosure.

[85] It is particularly clear from Lord Hoffman's reasons that the law applicable in the United Kingdom with respect to this aspect of sufficiency has not changed since 1949 (the new European concept of technical contribution is not relevant here). Pursuant to section 72(1)(*c*) of the United Kingdom's *Patents Act 1977* (U.K.), 1977, c. 37, the English Court may revoke a patent on the ground that the "specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art". Thus, it is on par with the statutory requirement set out in subsection 34(1) of the old *Patent Act* (subsection

27(3) of the *Act*). Lord Hoffmann and Lord Jacob, well recognized for their vast experience in patent law, both acknowledged that new product claims embrace all methods of producing that product and that a disclosure will be sufficient if the inventor describes one method for obtaining the product. There is simply nothing more required to meet the sufficiency requirement.

[86] Although Lord Hoffmann was sympathetic to the view expressed by the defendant, he could not concur and stated at paragraph 27:

> [27] I can understand and sympathise with the judge's instinctive reaction to the inherent breadth of a product name…. [b]ut in my opinion his reasoning is not justified either by the statute or the authorities. In an ordinary product claim, the product is the invention. It is sufficiently enabled if the specification and common general knowledge enables the skilled person to make it. <u>One method is enough.</u>
>
> [My emphasis]

[87] In first instance ([2007] EWHC 1040), Justice Kitchin's finding that the patent was insufficient was entirely based upon the decision of the House of Lords in *Biogen.* In *Lundbeck CA*, Lord Hoffmann reviewed the House of Lords' decision in *Biogen* and concluded the following at paragraphs 35 and 41:

> [35] In my opinion, therefore, the decision in *Biogen* is limited to the form of claim which the House of Lords was there considering and cannot be extended to an ordinary product claim in which the product is not defined by a class of processes of manufacture. …
>
> [41] What the judge has done is to make the requirements for sufficiency under section 72(1)(c) differ according to the nature of the inventive step. If it is to 'describe a new and non-obvious compound which has a beneficial effect', the judge acknowledges (at paragraph 263) that one way of making it will be sufficient. But the case is otherwise if the inventive step is to find a way of making an obvious compound. In my opinion, however, there is nothing in section 72(1)(c) which connects the requirements of sufficiency to the inventive step. What needs to be disclosed sufficiently to enable it to be performed is *the*

> *invention* as defined in the claim. That remains the same, whatever may have been the invented step.

[88] Lastly, Lord Hoffman stated:

> [40] … *Biogen* should therefore not be read as casting any doubt upon the proposition that an inventor who finds a way to make a new product is entitled to make a product claim, even if its properties could have been fully specified in advance and the desirability of making it was obvious.

[89] Lord Justice Jacob agreed that *Lundbeck*'s appeal should be allowed for the reasons given by Lord Hoffman. He added, at paragraph 52, in respect of the issue of sufficiency that:

> [52] … There is a very short answer to this point. The claim is to the (+) enantiomer. That is novel and non-obvious. If one asks the straightforward question 'Does the patent enable the skilled man to make it?' the answer is an equally straightforward: 'Yes.' So, in the language of Art 83, the patent discloses 'the invention in a matter sufficiently clear and complete for it to be carried out'.

[90] I conclude from the paragraphs reproduced above that the teachings of *Biogen* are simply not as wide as argued by Apotex. It is telling in my view that Apotex has been trying all along to construe Claim 1 as a hybrid claim (i.e. a product claim whose ambit is restricted by its language to a particular way of making it).

[91] I now turn to the issue of having to do routine testing to obtain a useful preparation. It is again trite law that routine testing is acceptable as part of enablement (how to work the invention). Inasmuch as an inventor need not provide for all methods for making a product, he or she need not provide for detailed technical support in respect of new methods that are not discussed in the disclosure. If a competitor or a member of the public decides to use a method not described in a patent to make a product that is covered by the claim, he or she must find the

necessary information to do so successfully elsewhere. That person may even invent a new method and obtain a patent for this invention, but he or she will still need a licence to use the teaching of the patent claiming the product. Here, the facts are undisputed. Apotex's product did have the essential elements set out in Claim 1.

[92] Finally, in my view, Apotex's argument that Claim 1 is overbroad (see paragraph 73 above) has no merit. As mentioned, I do not agree that keeping the enteric coating and the core separate during the manufacturing process is an essential element of the invention claimed in Claim 1.

[93] I will now deal with the last issue raised in respect of the validity of the 693 Patent: its utility or lack thereof.

B. *Utility*

[94] Apotex says that the Federal Court erred in confusing "the identity of the utility with the degree of confidence the inventors had in asserting such utility at the filing date" (statement made by Apotex at the hearing before us). In Apotex's view, the inventors had not demonstrated the utility of the preparations embraced by Claim 1, first because three of the formulations tested during the development process leading to the invention failed and second, because they never experimented to demonstrate that a preparation made using an *in situ* process worked.

[95] According to Apotex, Astra had to rely on sound prediction; but the inventors simply could not predict anything about a preparation where the separating layer was formed *in situ* by

reaction as they had never even conceived of such a process. Also, the examples in the 693 Patent instructed that putting the enteric coat directly on the core did not yield the results that provided the advantage "promised".

[96] Here again for the most part, Apotex combines its earlier argument on the proper construction of Claim 1 and its understanding of what the examples in the disclosure were meant to establish. Having rejected these arguments earlier, I cannot agree that they somehow become relevant when assessing utility.

[97] To say that an inventor must demonstrate the utility of a preparation made by a process that was not known when he or she claimed a product makes no sense.

[98] The Federal Court was satisfied on the evidence (this included Apotex's expert, Dr. Kibbe) that a formulation meeting the essential structural elements of Claim 1 would be expected to provide good gastric acid resistance and long-term storage stability (Reasons at para. 282). I understand this to mean that, whether or not the 693 Patent contains a promise that such result could be achieved (an issue that need not be decided here), a skilled person would expect the formulation to effectively provide those advantages based on the information provided in the 693 Patent.

[99] This also means that the inventors had disclosed a sound factual basis to predict that the preparations having the essential elements of Claim 1 would be useful.

[100] While I agree that using the word “demonstrated” in paragraph 282 may not have been the most appropriate choice of words, it does not persuade me that the Federal Court made a palpable and overriding error in concluding that the claims were not invalid on this ground. The Federal Court is certainly also entitled to a fair reading of its Reasons by a mind willing to understand.

[101] The last point to cover is one that was not raised by Apotex in its written submissions to the Federal Court. It was barely mentioned during its oral arguments before that court. Before us, Apotex argued that Dr. Lovgren, one of the six inventors, acknowledged that three of the numerous formulations tested (not by him) in 1981 (FBS 136-1 and FBS 136-2) and in 1982 (FBS 183-2) (see notations of lab notes on pages 7819 and 7996 included at tab 90 of Apotex’s compendium) did not yield the desired threshold of gastric acid resistance of 85% or above after exposure to gastric fluids for two hours. Apotex did not situate these tests in the long and complex process leading to the invention as described in the Reasons where the Federal Court deals with “obviousness” (see Reasons at paras. 263-272). These findings are not contested in this Appeal.

[102] It is quite telling that Apotex’s experts did not comment on this evidence, nor does it appear to have been raised by Apotex in the cross-examination of Dr. Bodmeier. With respect to FBS 136-1 and -2, Dr. Lovgren said that the failure was explained in the material but he was not given an opportunity to give this explanation during his cross-examination since Apotex’s counsel cut it short. At the hearing before us, Astra mentioned a problem with the equipment. As

for FBS 183-2, the test could have failed for a number of reasons; this is why skilled formulators always conduct tests. Even a good cook can fail at making a sauce.

[103] In such circumstances, it appears that the Federal Court did not feel the need to make any explicit findings in that respect and I am not prepared to conclude that it made a palpable and overriding error in so doing.

[104] This concludes my review of the arguments with respect to validity. In my view, Apotex has not established any reviewable error that would justify this Court's intervention with respect to the Federal Court's finding that the claims at issue are valid.

V. Time limitation

[105] It is important to recall here that none of the Federal Court's findings with respect to acts of infringement were contested in this appeal (except for the construction issue and its potential impact on the finding of infringement). The only issue in the Notice of Appeal that relates to infringing acts is the applicable limitation period as found by the Federal Court (see Notice of Appeal at 19, subparagraph 26(l)). In that respect, Apotex only challenges the time limitation applicable to certain products which were made, sold and delivered in Ontario and to which in its view a two year limitation should apply. It also contests that the exportation of infringing products means that a six years limitation will apply. Such arguments are only relevant in the Federal Court action instituted in 2011 in file no.T-1890-11. Indeed time limitation is not relevant to claims in the action instituted in 2004 (file no T-1409-04) the year Apotex received its NOC for the infringing omeprazole products.

[106] The Federal Court described very generally how Apotex operated at the relevant time in paragraphs 389 and 390 of its Reasons. It concluded that since 2004 (and up to the expiration of the 693 Patent in 2008), Apotex not only directly infringed the 693 Patent by making and selling its omeprazole product in Canada, but it also infringed by inducing infringement by its customers (Claims 1, 5, 6, and 13) and by end-users throughout Canada (Claim 19) (Reasons at para. 391).

[107] The relevant portion of the Reasons dealing with limitation period is short, but so was the written argument presented at the end of the trial on this point. Apotex had the burden of establishing all the facts necessary for the Federal Court to make a finding that a limitation period shorter than six years applied to all or some of the infringing activities for which Astra claimed a monetary remedy. The damages would then be quantified at the second stage of the proceedings. Apotex produced only one witness, Mr. Fahner, to explain how Apotex operates and how and where its products were made, sold and distributed.

[108] The Federal Court held that on the facts of this case, a six year limitation applied to all acts of infringements by Apotex. As mentioned, in its memorandum, Apotex argues that the Federal Court erred in law in finding that a six-year time limitation applied in respect of infringement acts involving its omeprazole products that were manufactured, sold and distributed in or exported from Ontario. Apotex does not refer to any evidence at all in the short portion of its memorandum dealing with this ground of appeal (one page and a half, starting at page 29) nor did it do so in its oral argument. It appears that Apotex viewed this issue as a pure question of law.

[109] In my view, this is not so. Section 39 of the *Federal Courts Act*, R.S.C. 1985, c. F-7 provides:

39. (1) Except as expressly provided by any other Act, the laws relating to prescription and the limitation of actions in force in a province between subject and subject apply to any proceedings in the Federal Court of Appeal or the Federal Court in respect of any cause of action arising in that province.	39. (1) Sauf disposition contraire d'une autre loi, les règles de droit en matière de prescription qui, dans une province, régissent les rapports entre particuliers s'appliquent à toute instance devant la Cour d'appel fédérale ou la Cour fédérale dont le fait générateur est survenu dans cette province.
(2) A proceeding in the Federal Court of Appeal or the Federal Court in respect of a cause of action arising otherwise than in a province shall be taken within six years after the cause of action arose.	(2) Le délai de prescription est de six ans à compter du fait générateur lorsque celui-ci n'est pas survenu dans une province.

[110] It is not clear to me that the Federal Court's findings were solely based on its allegedly wrong interpretation of this provision and its view that subsection 39 (2) was designed "to facilitate a judicial forum for the one –time resolution of disputes that concern activity crossing provincial boundaries and international borders" (Reasons at para. 397).

[111] The Federal Court appears to have found that in this case there were evidentiary problems. It could not conclude that the cause of action in respect of any infringing products arose solely in Ontario. The Federal Court appears to have accepted Astra's argument that the cause of action in respect of each such products could not be parsed into pieces, given that infringing sales in one province could also constitute an infringement in another if the same

product was resold or reshipped or where there was downstream inducement in other provinces (Reasons at paras. 396-397).

[112] If the Federal Court's conclusion that the six-year limitation applied to all infringement acts at issue was based on its reading that the words "a cause of action arising otherwise than in a province" in subsection 39(2) as though they said "all causes of action, any of which arose otherwise than in a single province", I agree that the Federal Court erred in its interpretation. Indeed having regard to the text of subsection 39(1) and to provincial jurisdiction over property and civil rights and that each act of infringement constitutes a distinct cause of action, such an interpretation is unreasonable.

[113] While I understand and am sympathetic to the practicality of such an interpretation (confirmed by the amendment made in 1993 to the *Patent Act*), where the law is set out in a statute, a court must articulate the law as it is defined in that statute. Here the statute requires an inquiry into the place where each cause of action arose.

[114] For the purposes of the limitation analysis, the critical fact is that, following the jurisprudence of this Court, a cause of action arises in a province if all the elements of the cause of action occur in that province: see *Canada v. Maritime Group Canada Inc.*, [1995] 3 F.C. 124 (C.A.) at para. 9, *Plavix* at para. 105. Hence the provincial limitation period would apply to acts of infringement which are limited to a single province. Thus a sale by Apotex, from its Toronto office, to a distributor located in Ontario would be subject to the Ontario limitation period since the sale constitutes the act of infringement. Similarly a sale by Apotex, from its Toronto office,

to a distributor in another province would be subject to the provincial limitation period applicable to the province where the sale occurred. To that extent, the Federal Court's judgement would have to be modified to reflect the possibility that some transactions would be subject to the applicable provincial limitation period.

[115] The issue becomes more complex when considering Apotex's liability for inducing infringement by others. These are distinct acts of infringements (thus distinct causes of action). To determine where the cause of action for this type of infringement arose, one must consider the well-established three-prong test that one must meet to establish a cause of action for infringement by inducement. That test was described as follows in *Corlac Inc. v. Weatherford Canada Inc.*, 2011 FCA 228, 42 N.R. 49:

> [162] It is settled law that one who induces or procures another to infringe a patent is guilty of infringement of the patent. A determination of inducement requires the application of a three-prong test. First, the act of infringement must have been completed by the direct infringer. Second, the completion of the acts of infringement must be influenced by the acts of the alleged inducer to the point that, without the influence, direct infringement would not take place. Third, the influence must knowingly be exercised by the inducer, that is, the inducer knows that this influence will result in the completion of the act of infringement: *Dableh v. Ontario Hydro*, [1996] 3 F.C. 751, paras. 42, 43 (C.A.), leave to appeal refused, [1996] S.C.C.A. No. 441; *AB Hassle v. Canada* (Minister of National Health and Welfare), 2002 FCA 421, 22 C.P.R. (4th) 1, para. 17 (C.A.), leave to appeal refused, [2002] S.C.C.A. No. 531; *MacLennan v. Les Produits Gilbert Inc.*, 2008 FCA 35, 67 C.P.R. (4th) 161, para. 13.

[116] To the extent that the elements of inducing infringement require an infringing act by a third party, the cause of action can only be said to arise in a province if both of Apotex's inducement and the third party's own act of infringement occurred in the same province. In those cases, the provincial limitation period would apply. If the infringing act is a resale, then both the

inducement and the resale would have to occur in the same province. In any other case, the six year limitation in subsection 39(2) would apply.

[117] Further complications are introduced by the Federal Court's finding that Apotex induced infringement of Claim 19 which claims use of the patented product to treat gastrointestinal disorders. Once again, the use by the ultimate infringer, the patient, and Apotex's acts of inducement would have to occur in the same province in order for the provincial limitation period to apply. In any other case, the six year limitation in subsection 39(2) would apply.

[118] To summarize, I believe that the Federal Court erred in precluding the possibility that provincial limitation periods might apply to specific acts of infringement. I do not believe that the possibility that a single transaction might comprise multiple acts of infringement changes the position. The Federal Court appears to have concluded that because a single sale to a distributor might be an infringement by sale, an infringement by inducement to re-sell, and an inducement to infringement by use, the possibility that some of those infringements might occur other than in a province justified the application of the six year limitation period to all the acts of infringement. I do not believe this is correct.

[119] This will be a very fact intensive inquiry which is no doubt one of the reasons Parliament chose to amend the Act to provide for a uniform limitation period. Unfortunately, the Federal Court will have to undertake this onerous task.

[120] Turning to products exported by Apotex, Apotex made no detailed submissions before the Federal Court. It simply stated that it reserved its right to challenge the time limitation set out in *Plavix* as this decision was under appeal before the Supreme Court of Canada. After the written submissions were made to the Federal Court, Apotex discontinued its appeal before the Supreme Court of Canada. The Federal Court was therefore bound to follow our Court's decision in *Plavix*.

[121] Although the final amended order included "export" as an infringing act (see paragraph 1 of the Order dated July 15, 2015), the Federal Court does not discuss this aspect of Apotex's infringing activities in its Reasons dealing with time limitation except for a mention that Apotex's commercial activity was national and international in scope.

[122] Apotex challenges our Court's decision in *Plavix* on the basis that it failed to consider its own case law in *Beloit Canada Ltd. v. Valmet-Dominion Inc.*, [1997] F.C.J. No 48 at para. 56-79 (*sub nom. J.M. Voith GmbH v. Beloit Corp.*)(1997), 73 C.P.R. (3d) 321 at 341-348 [*Beloit*] and had misinterpreted and applied the decision of the Supreme Court of Canada in *Markevich v. Canada*, 2003 SCC 9, [2003] 1 S.C.R. 94 [*Markevich*].

[123] Apotex's argument before us was brief. I would note that while Apotex is free to challenge this Court's decision in *Plavix*, it cannot do so on the basis that we improperly concluded that exportation constituted infringement. That question was conceded by Apotex: see *Plavix* at para. 85-88. The only issue in *Plavix* was the applicable limitation period. That said, the argument made by Apotex does not meet the test set out in *Miller v. Canada (Attorney General)*,

2002 FCA 370, 220 D.L.R. (4th) 149. Our Court in *Plavix* fully considered *Markevich* and it referred to *Beloit* at paragraph 108 to support a different point. Moreover, in *Beloit*, our Court never addressed the issue of exportation as this aspect was never raised by the parties before it. I thus see no reason to reconsider our previous decision on this point. This is especially so, considering that, as mentioned earlier, the time limitation applicable to all acts of infringement has now been included in the *Act* for more than 20 years and it is difficult to imagine that there are more than a few, if any, cases remaining involving patents subject to the old *Patent Act*. The more interesting question in my view, which is not before us today and which was not before our Court in *Plavix*, is whether exportation *per se* is a distinct act of infringement. But as mentioned, Apotex has chosen not to raise this issue in its Notice of Appeal.

[124] To conclude this section, it appears to me that the Federal Court had to determine whether any provincial limitation period(s) applied in respect of any of the infringing products for which Astra claims damages in accordance with subsection 39(1) and paragraphs 114-118 above. The Federal Court could not simply apply the six-year limitation set out in subsection 39(2) to all infringing activities of Apotex.

[125] That being said, this Court is not in a position to determine if the evidence produced during the first stage of the trial was sufficient for the Federal Court to even make such a determination. I note that the Bifurcation Order dated August 3, 2012 does not specifically deal with the time limitation issues. It would certainly have been preferable to do so. It may well be that these issues were discussed during case management or trial management and the Federal Court is better equipped to deal with such matters.

[126] Considering that the Federal Court still has to deal with the second stage of the proceedings, it is best in my view to leave the decision as to how the determination mentioned above should be done and on the basis of what evidence to the Federal Court.

VI. Astra's Cross-Appeal

[127] Astra was seeking punitive damages or solicitor/client costs, or both, on the basis that Apotex had been deceptive in the context of the settlement obtained in earlier NOC proceedings (T-1446-93) involving the 693 Patent (Reasons at para. 382).

[128] The Federal Court reviewed the relevant evidence (Reasons at paras. 382-386), and referred expressly to the prior decision of Justice Kelen of the Federal Court in *Astrazeneca Canada Inc. v. Canada (Minister of Health)*, 2004 FC 1278, affirmed 2005 FCA 58, on which Astra relied heavily to argue that punitive damages would be the more appropriate remedy. The Federal Court determined that it could properly condone the inappropriate behaviour of Apotex by issuing an appropriate costs award, and that the actual amount of costs would be left to be argued another day, in accordance with the parties' request in that respect.

[129] At paragraph 386 of its Reasons, the Federal Court wrote:

> [386] If the evidence before me had established that Apotex's undisclosed substitution of one ARC for another was a material factor in the settlement of the earlier NOC proceeding, a good case for punitive damages would have been made out. That evidence is lacking here. I am also not satisfied that Apotex deliberately misrepresented its omeprazole formulation to deceive AstraZeneca. There does not appear to have been any particular advantage gained by Apotex misrepresenting its intended ARC to AstraZeneca. However, when the error was identified, Apotex failed in its duty to inform AstraZeneca. Both Dr. Niebergall and Dr. Sherman were careless about the accuracy of their sworn evidence and

> remiss in not correcting the record at the first available opportunity. The need for scrupulous accuracy and fair dealing under the NOC system is manifest. Parties must understand that carelessness and a lack of absolute candour cannot be condoned. These are matters which may bear on the issue of costs. The parties request that costs be held in reserve. I will, therefore, hear from them at a later point about the significance, if any, of this evidence to the award of costs.

[130] Astra argues that the Federal Court misapprehended the law as it required proof of "intentional deception" to justify an award of punitive damages and wrongly focused on Astra's position rather than Apotex's behaviour. Astra adds that the Federal Court made inconsistent findings of fact given that it had acknowledged at paragraph 382 of its Reasons that Apotex had originally changed the ARC in its formulation from dibasic sodium phosphate (as represented by Dr. Sherman) to magnesium hydroxide to avoid another patent (referred to in the Reasons as the 377 Patent).

[131] Finally, Astra submits that the Federal Court erred in finding that there was no particular advantage gained by Apotex in misrepresenting the ARC it used in T-1446-93 because some years later it was able to obtain the dismissal of another NOC proceeding instituted by Astra and the Japanese owner of the 377 Patent in *Astra Pharma Inc. v. Canada (Minister of National Health and Welfare)*, [2000] F.C.J. No. 1426, 99 A.C.W.S. (3d) 1044 [*Astra Pharma*]. Astra contends that ultimately this dismissal enabled Apotex to obtain a NOC in 2004 and be the first generic to reach the market with a generic version of LOSEC.

[132] First, I do not read the first sentence of paragraph 386 of the Reasons as evidence that the Federal Court did not understand the law applicable to punitive damages which it is presumed to know. Rather, I understand the Federal Court to simply be referring to its own state of mind with

respect to the facts of this particular case, noting that it would have been more inclined to grant punitive damages had Astra established that Apotex's representation of its use of dibasic sodium phosphate was a material factor in the settlement (this finding of fact is not challenged).

[133] I have also not been persuaded that it is implicit that the Federal Court misunderstood the law simply because it made findings in respect to facts which are not legally required to as a prerequisite to the exercise of its discretion to award punitive damages The findings of fact made by the Federal Court were relevant to its assessment of the severity and nature of Apotex's behaviour and it was entitled to consider these two issues in exercising its discretion. Punitive damages, although allowable in patent infringement cases, are still awarded only in exceptional cases (*Bell Helicopter Textron Canada Limitée v. Eurocopter, société par actions simplifiée*, 2013 FCA 219 at para. 184, [2013] F.C.J. No. 1043). The Federal Court was thus entitled to make some findings of fact that explained its view on the evidence presented.

[134] Second, I cannot agree with Astra's assertions that the Federal Court made inconsistent findings of fact. At paragraph 386 reproduced above, the Federal Court was reviewing whether there was an advantage gained by Apotex in misrepresenting its formula when the inaccurate evidence was presented. This is logically linked to the Federal Court's previous statement that it was not satisfied that Apotex had the intention to mislead Astra at the time the facts were misrepresented. This had nothing to do with the issue as to why Apotex changed its formula sometime in 1995, well before Dr. Sherman gave his evidence. At the time, the 377 Patent had not been included on the patent list (see *Astra Parma* at para. 3). Considering the complex and

long road between the day Dr. Sherman filed his evidence and 2004, it was open to the Federal Court to discard Astra's submissions on this point.

[135] This Court should not intervene lightly with the Federal Court's weighing of the evidence and its assessment of which of the remedies sought is the most appropriate. I note that if Astra still feels that this is relevant it will, at the hearing on costs, have the opportunity to make the point that its proceedings in T-2026-99 were instituted on the basis of the formula disclosed by Dr. Sherman and were ultimately dismissed with costs when Apotex satisfied the court that it was not using dibasic sodium phosphate in the formula submitted to the Minister.

[136] To conclude, I have not been persuaded that this is a case where this Court can intervene because the Federal Court misconstrued the law or made a palpable and overriding error in assessing the facts.

VII. CONCLUSION

[137] In light of the foregoing, I propose that the appeal be allowed in part. I would vary paragraph 8 of the judgment of the Federal Court as amended by the Order dated July 15, 2015 as follows:

> 8) With respect to Court file number T-1890-11 only:
>
> a) It is declared that AstraZeneca AB is statute barred from obtaining relief for any infringing activity and any activity constituting inducing infringement that took place before November 22, 2005 and AstraZeneca AB's claims for relief in respect of such activity before November 22, 2005 are dismissed; and
>
> b) Provincial limitation periods shall apply to any infringing activity and any activity constituting inducing infringement coming within the principles set out in paras. 114-118 of the reasons (2017 FCA 9); and

Notwithstanding this modification, Astra has largely been successful in this appeal, I would therefore grant 90% of its costs of the appeal.

[138] I also propose to dismiss the cross-appeal with costs to Apotex.

"Johanne Gauthier"
J.A.

"I agree
J.D. Denis Pelletier J.A."

"I agree
A.F. Scott J.A."

NAMES OF COUNSEL AND SOLICITORS OF RECORD

APPEAL FROM A JUDGMENT OF THE FEDERAL COURT DATED March 16, 2015, NOs. T-1409-04 and T-1890-11 (2015 FC 322)

DOCKET:	A-201-15
STYLE OF CAUSE:	APOTEX INC. V. ASTRAZENECA CANADA INC. AND AKTIEBOLAGET HÄSSLE AND BETWEEN APOTEX INC. v. ASTRAZENECA AB and AKTIEBOLAGET HÄSSLE
PLACE OF HEARING:	MONTRÉAL, QUEBEC
DATE OF HEARING:	MARCH 9, 2016
REASONS FOR JUDGMENT BY:	GAUTHIER J.A.
CONCURRED IN BY:	PELLETIER J.A. SCOTT J.A.
DATED:	JANUARY 12, 2017

APPEARANCES:

Harry B. Radomski Richard Naiberg Ben Hackett	FOR THE APPELLANT
Gunars Gaikis Lynn Ing	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Goodmans LLP Toronto, Ontario	FOR THE APPELLANT
Smart & Biggar Toronto, Ontario	FOR THE RESPONDENTS