Federal Court of Appeal | Cour d'appel fédérale

Date: 20220804

Dockets: A-31-21 (lead file)
A-32-21

Citation: 2022 FCA 142

CORAM: **DE MONTIGNY J.A.**
LOCKE J.A.
MONAGHAN J.A.

Docket: A-31-21

BETWEEN:

PHARMASCIENCE INC.

Appellant

and

BRISTOL-MYERS SQUIBB CANADA CO. and BRISTOL-MYERS SQUIBB HOLDINGS IRELAND UNLIMITED COMPANY

Respondents

Docket: A-32-21

AND BETWEEN:

PHARMASCIENCE INC.

Appellant

and

BRISTOL-MYERS SQUIBB CANADA CO.,

BRISTOL-MYERS SQUIBB HOLDINGS IRELAND UNLIMITED COMPANY, and PFIZER INC.

Respondents

Heard at Toronto, Ontario, on June 22, 2022

Judgment delivered at Ottawa, Ontario, on August 4, 2022.

REASONS FOR JUDGMENT BY: LOCKE J.A.

CONCURRED IN BY: DE MONTIGNY J.A.
MONAGHAN J.A.

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REASONS FOR JUDGMENT

LOCKE J.A.

I. Background

[1] This decision results from four consolidated appeals from a decision of the Federal Court (2021 FC 1, *per* Zinn J.) concerning four actions under the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133. Those actions, brought by the respondents, Bristol-Myers Squibb Canada Co., Bristol-Myers Squibb Holdings Ireland Unlimited Company and Pfizer Inc. (collectively, BMS), against the appellants, Pharmascience Inc. (PMS) and Sandoz Canada Inc. (Sandoz), concerned the validity of certain claims in two BMS patents: Canadian Patent Nos. 2,461,202 (the 202 Patent) and 2,791,171 (the 171 Patent). The Federal Court rejected all of the appellants' validity attacks, and found both patents valid.

[2] Shortly before the hearing in this Court, Sandoz filed notices of discontinuance in respect of its appeals (Court File Nos. A-33-21 and A-34-21). Accordingly, only PMS's appeals (Court File Nos. A-31-21 and A-32-21) remain in dispute, and only the issues PMS has raised remain to be decided.

II. Patents in Suit

[3] The patents in suit concern an anticoagulant product for treating thrombosis marketed by BMS as ELIQUIS. The active pharmaceutical ingredient of ELIQUIS is apixaban, which works by blocking certain clotting proteins in the blood. Apixaban is a selective inhibitor of the enzyme Factor Xa (FXa). It avoids the difficulties with warfarin, which was previously used to treat thrombosis.

[4] The 202 Patent describes a large number of FXa inhibitors, including apixaban. The claims in issue of the 202 Patent are directed specifically to apixaban itself, and to its use in the treatment of thromboembolic disorders. The 202 Patent was filed on September 17, 2002, published on April 3, 2003, and issued on July 12, 2011. It is set to expire on September 17, 2022.

[5] A single prior art reference is relevant to many of the validity attacks on the 202 Patent: Canadian Patent No. 2,349,330 (the 330 Patent). The 330 Patent, also owned by BMS, describes a vast number of compounds as FXa inhibitors. Apixaban falls within the very broad scope of compounds contemplated by the 330 Patent, but is not identified therein. The 330 Patent (which has now expired) was published on July 6, 2000, before the claim date of the 202 Patent and more than one year prior to its filing date. Accordingly, the 330 Patent is citable against the 202 Patent as prior art for the assessment of anticipation (lack of novelty) and obviousness (lack of inventiveness). The 330 Patent is also relevant to PMS's double patenting argument. Moreover,

it is relevant to the debate as to whether the 202 Patent is a valid selection patent over the 330 Patent, as the genus patent.

[6] The other patent whose validity is in issue is the 171 Patent. It is directed to formulations of apixaban tablets. It was filed on February 24, 2011, published on September 1, 2011, and issued on August 29, 2017. It is set to expire on February 24, 2031. Many of the validity issues surrounding the 171 Patent concern the fact that the claims in issue define characteristics of particle size and dissolution rate, but are not limited to any particular means of achieving those characteristics.

[7] The 171 Patent explains that applying the claimed characteristics results in formulations of apixaban that lead to consistent human *in vivo* dissolution. As explained by BMS, an oral medicine must be dissolved in the gastrointestinal tract before it can be absorbed by the body. The rate of absorption of a medicine may be limited by the rate at which it dissolves or by the rate at which the dissolved medicine permeates across intestinal membranes. If the dissolution rate is at least as high as the permeation rate, the medicine will behave in the body as if the medicine was administered as pre-dissolved liquid solution. This is called solution-like behaviour, and is ideal for optimizing absorption and minimizing variability.

III. Standards of Review and Issues in Dispute

[8] The parties agree that the standards of review to be applied by this Court are as defined in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235: correctness on questions of law and

palpable and overriding error on questions of fact or of mixed fact and law in which there is no extricable issue of law. Unsurprisingly, the parties disagree on the application of these standards in this case.

[9] The patent validity issues remaining in dispute are as follows:

A) For the 202 Patent:

i. Status as a Selection Patent;

ii. Anticipation, Obviousness, and Double Patenting; and

iii. Insufficiency,

B) For the 171 Patent:

i. Obviousness;

ii. Ambiguity; and

iii. Overbreadth.

[10] These various issues are addressed in turn in the paragraphs below. In short, I conclude that the appeals remaining in dispute should be dismissed.

IV. Analysis

A. *Status of the 202 Patent as a Selection Patent*

[11] PMS argues that, since apixaban falls within the scope of the compounds already disclosed in the 330 Patent, the disputed claims of the 202 Patent relating to apixaban can be valid only if it is an inventive selection over the 330 Patent. PMS asserts that the Federal Court never made a clear finding as to whether the 202 Patent is a selection patent. It argues that this failure reflects a lack of understanding of the 202 Patent and its factual context. PMS also argues that the Federal Court erred in failing to recognize (i) that the 202 Patent did not indicate a special advantage, and (ii) the requirement that a selection patent disclose the special advantage of the selection (because the special advantage is the invention, and a patent must disclose its invention).

[12] PMS's assertion that the Federal Court never made a clear finding that the 202 Patent is a selection patent does not lead to a conclusion that the Federal Court misunderstood the nature of the 202 Patent. Neither does the disagreement between the parties on the requirement to disclose the special advantage of the selection lead to a conclusion that the Federal Court erred on the issue. At paragraphs 106 and 107 of its reasons, the Federal Court indicated clearly that the requirements for a selection patent (as set out in *In re I. G. Farbenindustrie A. G.'s Patents* (1930), 47 R.P.C. 289 (Ch. D.), and quoted in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, [2008] 3 S.C.R. 265 at paragraph 10 (*Sanofi*)) were met, and that the 202 Patent does disclose special advantages of apixaban. The Federal Court cited testimony from Sandoz' expert Dr. Gleason and BMS's expert Dr. Weitz that a skilled person reading the 202 Patent, "would understand that apixaban was singled out from the genus of compounds [disclosed in the 330 Patent] because, while the genus had the potential to be useful in treating thromboembolic disorders, apixaban was selected in the 202 Patent because it was useful." (Original emphasis.) The

Federal Court also found at paragraph 79 of its reasons that "the skilled person reading the 330 Patent would understand that not all of the claimed compounds would be useful in treating and preventing thromboembolic disorders."

[13] PMS criticizes the Federal Court for focusing on apixaban simply having been singled out, without considering the absence of any comparison of apixaban to the genus compounds. PMS notes that the 202 Patent describes apixaban among a large number of other compounds, and that Example 18 therein merely describes how to make apixaban, without discussing its advantages. PMS argues that the only basis for the Federal Court's conclusion that apixaban has any special advantages over other compounds described in the 330 Patent is the focus on apixaban in the claims. It argues that reliance on the claims as support for the validity of those same claims improperly assumes the conclusion.

[14] In my view, there was evidence on which the Federal Court was entitled to, and did, rely to conclude that the 202 Patent does disclose a special advantage of apixaban over the genus of compounds described in the 330 Patent. There was no error in considering the claims, as part of the specification, in determining how a skilled person would understand the 202 Patent as a whole. There was also no error in finding that a special advantage was disclosed by inference. There was no need for the 202 Patent to provide an explicit comparison of apixaban to any other particular compound falling within the scope of the 330 Patent. I find no palpable and overriding error in the Federal Court's conclusion that the 202 Patent disclosed a special advantage.

[15] At the end of the day, the 202 Patent gave the public something useful it did not have with the 330 Patent: an FXa inhibitor that is effective as a treatment for thromboembolic disorders.

B. *Anticipation, Obviousness and Double Patenting of the 202 Patent*

[16] The subjects of anticipation, obviousness and double patenting are dealt with together because PMS acknowledges that the analysis of double patenting in this case is the same as that for obviousness, and PMS does not address the issue of anticipation separately from obviousness.

[17] PMS's main argument on these issues is similar to that discussed in the previous section: that the Federal Court erred in finding that the 202 Patent discloses an invention, i.e. the special advantage of apixaban over the compounds described in the 330 Patent (the 330 Patent being citable prior art). As discussed above, I find no palpable and overriding error in the Federal Court's conclusion that the 202 Patent does disclose a special advantage.

[18] PMS also argues that the Federal Court's obviousness analysis was inadequate because, having identified the proper steps in paragraph 84 of its reasons, it failed to follow those steps in its analysis. Specifically, PMS notes that the Federal Court did not "identify the inventive concept" of the claims in issue. Neither did it identify differences between the state of the art and the inventive concept. Instead, the Federal Court jumped to the final step of asking whether the differences constitute steps that would have been obvious to a skilled person.

[19] The Federal Court noted, at paragraph 86 of its reasons, the experts' testimony that, "the skilled person reading the 330 Patent would expect that only a small percentage of the compounds therein described would be effective FXa inhibitors and useful to treat thromboembolic disorders." In paragraph 87 of its reasons, the Federal Court concluded that the evidence showed that the "discovery of apixaban was the result of hard work, innovative thinking and a bit of good luck."

[20] It is indeed curious that the Federal Court cited a series of steps to be followed in an obviousness analysis, but did not then address each of those steps in its analysis. However, I find the Federal Court's reasoning understandable. Reading the reasons as a whole, it seems clear that the Federal Court saw the inventive concept to be the selection of apixaban from among the other compounds falling within the scope of the 330 Patent. It also seems clear that it saw the difference between the inventive concept and the state of the art as being an effective FXa inhibitor useful in treating thromboembolic disorders, rather than a compound that merely had the potential to be useful. I see no reviewable error in the Federal Court's failure to discuss separately each of the steps in its obviousness analysis. I also see no error in the Federal Court's conclusion that the disputed claims of the 202 Patent are not invalid for obviousness.

[21] It is also curious that the Federal Court found, in paragraph 86 of its reasons, that "[i]t would not be obvious to the skilled person that apixaban was included in the 330 Patent…" Read in isolation, this passage could suggest that the Federal Court found that a skilled person would not know that apixaban was within the scope of the compounds described in the 330 Patent. It is difficult to understand what evidence would support such a finding. However, in the context of the reasons as a whole, it seems clear that what the Federal Court intended to express was that it

would not be obvious to the skilled person to consider apixaban among the multitude of compounds described in the 330 Patent. That finding was open to the Federal Court. Moreover, the Federal Court immediately added that, in any case, it would not be obvious that apixaban was an effective FXa inhibitor useful in treating thromboembolic disorders.

C. *Insufficiency of the 202 Patent*

[22] The crux of PMS's argument of insufficiency is the fact that, at the date the application for the 202 Patent was filed, it did not indicate that the focus of the invention was apixaban. Neither did it do so at the date of publication. The application, as filed and as published, described and claimed a large number of compounds, and did not focus on apixaban. At best, apixaban was merely one of over one hundred examples that are described in the 202 Patent. The claims focusing on apixaban were not introduced until years later, shortly before the 202 Patent issued.

[23] PMS notes the requirement of paragraph 27(3)(a) of the *Patent Act*, R.S.C. 1985, c. P-4, that a patent specification must "correctly and fully describe the invention and its operation or use as contemplated by the inventor". Since the validity of the 202 Patent must depend on it being a selection patent, PMS argues, the focus on apixaban must be the invention. Accordingly, the 202 Patent did not describe an invention, and hence did not comply with paragraph 27(3)(a), either at the filing date or at the publication date. PMS argues that the 202 Patent is invalid because the date for determining sufficiency is the publication date. In support of that date, PMS cites the discussion of the issue by Justice Roger T. Hughes in *Novartis Pharmaceuticals Canada Inc. v. Teva Canada Limited*, 2013 FC 283, at paragraphs 179-188 (*Zoledronate*). The decision in

Zoledronate was affirmed by this Court without comment on sufficiency (2013 FCA 244). Justice Hughes considered whether the sufficiency of a patent should be determined as of the filing date, the publication date, or the issue date. After reviewing Canadian and U.K. authorities on the issue, he expressed a preference for the publication date on the basis that "[t]hat is the date that the person applying for the patent has committed to claims for the invention in a manner available to the public."

[24] PMS acknowledges that subsection 27(6) and section 38.2 of the *Patent Act* contemplate amendments to a patent application prior to issuance to put it into compliance with the requirements for a valid patent. However, PMS notes that, pursuant to subsection 38.2(2), such amendments may not "add matter that cannot reasonably be inferred from the specification or drawings contained in the application on its filing date." PMS argues that the introduction of new claims that define an invention that was not defined in the application as originally filed is impermissible because such an invention could not be reasonably inferred from the application as filed. Just as the Supreme Court of Canada found in *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 (*AZT*), that it was unfair to the public to file a patent application that was neither demonstrated nor soundly predicted to be useful at the time of filing, PMS argues that it is equally unfair to the public to file a patent application that does not describe the invention therein.

[25] PMS criticizes the Federal Court in the present case for assessing sufficiency based on the claims of the 202 Patent as issued (rather than as filed or as published), and for doing so

without having either followed the *Zoledronate* decision, or construed the requirements of subsection 27(3) of the *Patent Act* in the context of the patent regime and of the 202 Patent.

[26] I note first that no formal, contextual statutory interpretation of subsection 27(3) of the *Patent Act* was done in *Zoledronate* either. I note also that the discussion in *Zoledronate* concerning the date for determining sufficiency is *obiter dicta*. The patent in issue in that case had been filed under the pre-1989 *Patent Act*, such that it was not published until its issuance. Therefore, it was not necessary in *Zoledronate* to distinguish between the publication date and the issue date.

[27] I note also that the U.K. authorities cited by Justice Hughes rely on the wording of the patent statute in that jurisdiction. For the purposes of the 202 Patent, this Court should focus on the wording of Canada's *Patent Act* and Canadian authorities. I note further that Justice Hughes did not tie his reason for choosing the publication date as the relevant date for determining sufficiency to the *Patent Act* or any Canadian jurisprudence. Rather, he referred to publication being when the applicant first publicly commits to claims defining the invention. It is not clear to me that such a public commitment should be the basis for considering the claims that were pending at that time rather than the claims as issued.

[28] Yet another key point is that *Zoledronate* is not the only decision at the level of the Federal Court that has commented on the question of the relevant date for determining patent sufficiency. In *Merck & Co. v. Apotex Inc.*, [1994] F.C.J. No. 1998 (QL), 59 C.P.R. (3d) 133 (F.C.T.D.) at paragraphs 115-120, Justice W. Andrew MacKay reviewed some of the same

Canadian authorities that were reviewed in *Zoledronate*, and concluded that it was the patent specification at the date of issuance that was relevant. He explained that, until a patent has issued, it is simply a pending application that is subject to amendment. Justice Hughes' analysis in *Zoledronate* did not address Justice MacKay's view.

[29] Both sides note the following passage from the Supreme Court of Canada in *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623, 25 C.P.R. (3d) 257 at 1638 (S.C.C.) (*Pioneer Hi-Bred*):

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

[30] The clear concern in this passage is that the patentee meet its side of the patent bargain by providing a specification that permits a skilled person, after expiration of the patent, "to use the invention as successfully as the inventor could at the time of his application." There is no suggestion that the specification must meet that requirement at the application date, and cannot be amended during prosecution to comply. There is likewise no suggestion in the text of section 27, or elsewhere in the *Patent Act*, that a patent specification cannot be amended during prosecution to meet the

requirement for sufficiency. Indeed, amendments within the confines of subsection 27(6) and section 38.2 are explicitly contemplated.

[31] It is important to draw a distinction between the date for determining sufficiency and the claims to be considered in that determination. As BMS notes, it is well understood that other questions of patent validity are determined as of a date prior to issuance, but such determinations are based on the claims of the issued patent, not the claims as they stood at some prior date. For example, the novelty and inventiveness of a patented invention are generally determined, in accordance with sections 28.2 and 28.3 of the *Patent Act*, as of the claim date. However, there is no doubt that it is the issued claims that are relevant to that determination, not the claims that were pending before the Patent Office at the claim date. The same approach applies to utility, which is determined as of the filing date (*AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36, [2017] 1 S.C.R. 943 at para. 55), and to claim construction, which is determined as of the publication date (*Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at para. 31(e)(ii)). These issues, too, are based on the claims of the issued patent.

[32] Even in *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625 (*Sildenafil*), which found the patent in issue invalid for insufficiency, it was the specification as issued that was considered, not the specification as it appeared at some prior date.

[33] This approach is consistent with the text of subsection 27(3) of the *Patent Act*. PMS notes that subsection 27(3) identifies the requirements of the "specification", and argues that subsection 27(2) indicates that it is the specification as filed that must meet those requirements. However,

such an argument does not withstand scrutiny. Firstly, it would effectively read out subsection 27(6), which contemplates amendments to bring the application into compliance with the sufficiency requirements. Secondly, a similar argument would seem to apply to the requirements for novelty (the opposite of anticipation) and inventiveness (the opposite of obviousness). Sections 28.2 and 28.3, which address these issues, both refer to requirements for "[t]he subject-matter defined by a claim in an application for a patent." PMS's focus on the specification as filed for determining sufficiency would also imply a focus on the claims as filed for anticipation and obviousness, since the relevant provisions mention "a claim in an application". I can see no reason that the approach that PMS urges for sufficiency would not apply similarly to anticipation and obviousness. However, as indicated above, there is no doubt that anticipation and obviousness are assessed based on the issued claims, not those pending prior to issuance.

[34] In my view, the concerns expressed by the Supreme Court of Canada in *AZT* with regard to patent applications filed prior to any demonstration or sound prediction of utility do not apply similarly to the question of sufficiency. At paragraph 70 of *AZT*, the Court stated:

> …Normally, it is sufficient if the specification provides a full, clear and exact description of the nature of the invention and the manner in which it can be practised: H. G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions* (4th ed. 1969), at p. 167. It is generally not necessary for an inventor to provide a theory of *why* the invention works. Practical readers merely want to know that it does work and how to work it. In this sort of case [in which the invention is the discovery of a new use of a known compound], however, the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly… [Original emphasis]

[35] At paragraph 80, in response to an argument by Glaxo/Wellcome that patent utility should be determined as of the date the patent is challenged, the Court wrote:

> In my view, with respect, Glaxo/Wellcome's proposition is consistent neither with the Act (which does not postpone the requirement of utility to the vagaries of when such proof might actually be demanded) nor with patent policy (which does not encourage the stockpiling of useless or misleading patent disclosures). Were the law to be otherwise, major pharmaceutical corporations could (subject to cost considerations) patent whole stables of chemical compounds for all sorts of desirable but unrealized purposes in a shot-gun approach hoping that, as in a lottery, a certain percentage of compounds will serendipitously turn out to be useful for the purposes claimed. Such a patent system would reward deep pockets and the ingenuity of patent agents rather than the ingenuity of true inventors.

[36] It is not disputed before this Court that, in the present case, BMS had demonstrated the utility of apixaban prior to the filing date of the 202 Patent. Utility is not in issue. This is not a case of a speculative patent application. Moreover, subsection 27(6) and section 38.2 of the *Patent Act*, while limiting the matter that can be added to a patent application by way of amendment, do permit amendments, and without restriction as to whether such amendments might buttress the sufficiency of the specification.

[37] The real debate here should be whether the addition of claims specific to apixaban introduced new matter to the specification of the 202 Patent that could not reasonably be inferred from the application as filed. PMS argues that the focus on apixaban could not be inferred from the application as filed because nothing in the original application highlighted apixaban. Unfortunately, this specific issue was not argued before the Federal Court, and therefore it reached no conclusion on it. BMS argues that this new issue should not be considered for the first time on appeal. There may be some merit to BMS's position since there is no alleged error by the Federal Court on this issue for this Court to consider, and it is difficult to know what other evidence or arguments might have been made before the Federal Court if the issue had been raised. In any case, I would not be inclined to find that claims to apixaban are not reasonably

inferable from the original application for the 202 Patent. The description of apixaban, and how to make it, in Example 18 would seem to be sufficient to support the introduction of claims thereto despite the broad range of compounds originally claimed. It is common for patent applications to be filed claiming a broad range of embodiments described in the disclosure, only to be significantly narrowed prior to issuance. The situation might be different if the issued claims concerned a compound that BMS had not described in the original application, but BMS had clearly focused on apixaban (among other compounds) prior to the filing date.

[38] Aside from the failure to include claims specific to apixaban in the original application, PMS also argues that the 202 Patent is insufficient for failing to disclose any special properties of apixaban over other compounds falling within the scope of the 330 Patent, which would be necessary for a valid selection patent. Without such a disclosure, PMS argues, the public received nothing in return for a second monopoly on apixaban. I disagree. As indicated at paragraph 15 above, the public received an FXa inhibitor that is effective as a treatment for thromboembolic disorders. There is no requirement for a selection patent to discuss the special advantages of the selection over the genus in any particular way. As discussed in the passage from *Pioneer Hi-Bred* quoted in paragraph 29 above, it is necessary to describe the invention and define the way it is produced or built. The Federal Court found that these requirements were met, and I see no error of law or palpable and overriding error of fact or of mixed fact and law that would permit this Court to interfere with that finding.

D. *Obviousness of the 171 Patent*

[39] I turn now to the issues concerning the validity of the 171 Patent. The first issue is obviousness.

[40] Section 28.3 of the *Patent Act* provides that

Invention must not be obvious	**Objet non évident**
28.3 The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science to which it pertains, having regard to	**28.3** L'objet que définit la revendication d'une demande de brevet ne doit pas, à la date de la revendication, être évident pour une personne versée dans l'art ou la science dont relève l'objet, eu égard à toute communication :
…	[…]
(b) information disclosed before the claim date … in such a manner that the information became available to the public in Canada or elsewhere. [Emphasis added.]	**b)** qui a été faite par toute autre personne avant la date de la revendication de manière telle qu'elle est devenue accessible au public au Canada ou ailleurs.[non souligné dans l'original]

[41] There is no dispute concerning the legal test applied by the Federal Court in assessing obviousness. In paragraph 120 of its reasons, the Federal Court identified the approach set out in *Sanofi* at paragraph 67:

> It will be useful in an obviousness inquiry to follow the four-step approach first outlined by Oliver L.J. in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*, [1985] R.P.C. 59 (C.A.). This approach should bring better structure to the obviousness inquiry and more objectivity and clarity to the analysis. The *Windsurfing* approach was recently updated by Jacob L.J. in *Pozzoli SPA v. BDMO SA*, [2007] F.S.R. 37 (p. 872), [2007] EWCA Civ 588, at para. 23:

In the result I would restate the *Windsurfing* questions thus:

(1) (a) Identify the notional "person skilled in the art";

(b) Identify the relevant common general knowledge of that person;

(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;

(3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

It will be at the fourth step of the *Windsurfing/Pozzoli* approach to obviousness that the issue of "obvious to try" will arise. [SCC's emphasis.]

[42] The Supreme Court of Canada expanded on the issue of "obvious to try" in the subsequent paragraphs as follows:

i. When Is the "Obvious to Try" Test Appropriate?

[68] In areas of endeavour where advances are often won by experimentation, an "obvious to try" test might be appropriate. In such areas, there may be numerous interrelated variables with which to experiment. For example, some inventions in the pharmaceutical industry might warrant an "obvious to try" test since there may be many chemically similar structures that can elicit different biological responses and offer the potential for significant therapeutic advances.

ii. "Obvious to Try" Considerations

> [69] If an "obvious to try" test is warranted, the following factors should be taken into consideration at the fourth step of the obviousness inquiry. As with anticipation, this list is not exhaustive. The factors will apply in accordance with the evidence in each case.
>
> 1. Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
>
> 2. What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
>
> 3. Is there a motive provided in the prior art to find the solution the patent addresses?
>
> [70] Another important factor may arise from considering the actual course of conduct which culminated in the making of the invention. It is true that obviousness is largely concerned with how a skilled worker would have acted in the light of the prior art. But this is no reason to exclude evidence of the history of the invention, particularly where the knowledge of those involved in finding the invention is no lower than what would be expected of the skilled person.

[43] There is also no dispute concerning the information considered by the Federal Court in assessing obviousness. In fact, PMS relies on the description of the relevant common general knowledge at paragraph 129 of the Federal Court's reasons. This includes the following facts:

A. 2.5 and 5 mg doses of apixaban are Class III drugs in the Biopharmaceutics Classification System (BCS) having high solubility and low permeability (meaning they are slow to be absorbed by the body once they are dissolved);

B. Drug dissolution is expected to be irrelevant to absorption in BCS Class III drugs;

C. Particle size reduction is not a recognized formulation strategy for BCS Class III drugs like apixaban;

D. The target dissolution rate for reliable solution-like behaviour for a BCS Class III drug, which was significantly higher than that claimed in the claims in issue of the 171 Patent.

[44] PMS also notes that the Federal Court accepted its summary of the approach that a formulator takes in the drug development process (see paragraph 126 of the reasons). This incudes conducting studies of various characteristics of the drug, seeing solution-like behaviour as ideal for immediate-release tablets, determining the point at which the drug goes into solution, experimenting with different methods and media, testing characteristics like dissolution, absorption and bioavailability throughout the process, and adjusting proposed formulations accordingly.

[45] Moreover, PMS does not, in its argument in chief, take issue with the Federal Court's description of the inventive concept (that tablets having the claimed characteristics of particle size and dissolution rate provide consistent solution-like behaviour) or the differences between the state of the art and the inventive concept (as described at paragraphs 131 to 138 of the Federal Court's reasons). The Federal Court noted that BMS discovered the point at which *in vitro* tablet dissolution started to affect one indicator of absorption of apixaban. The Federal Court also noted that BMS discovered that formulations made with large particles of apixaban resulted in less than optimal exposure.

[46] PMS argues that, based on the facts as found by the Federal Court, it should have concluded that the claims in issue of the 171 Patent are invalid for obviousness in that the invention was necessarily obvious to try. PMS criticizes the Federal Court's analysis of the fourth step in the obviousness analysis as incomplete and conclusory.

[47] The Federal Court's conclusion on the issue of whether differences between the state of the art and the inventive concept require a degree of invention is set out in paragraphs 139 and 140 of the reasons, reproduced here:

> [139] Given the significant differences between the state of the art concerning BCS Class III drugs like apixaban, and the findings of the inventors, which were directly contrary to them, I have no hesitation in finding that a degree of invention was required to achieve the differences noted above.
>
> [140] Further, I also have no hesitation in finding that what BMS did was not obvious to try. In *Sanofi* at paras 65 and 66 the Supreme Court held that the "obvious to try" test works only where it is very plain or more or less self-evident that what is being tested ought to work. In light of the prior art and common general knowledge, I am unable to find any evidence that convinces me on a balance of probabilities that it was more or less self-evident to try to obtain the invention, given the differences between the invention and the state of the art.

[48] Though paragraph 139 itself does not elaborate on the conclusion that "a degree of invention was required" to achieve the claimed formulations, that paragraph clearly relies on the analysis in the paragraphs that precede it, including the findings mentioned in paragraphs 43 to 45 above. Reading its reasons as a whole, the Federal Court effectively explained that the claimed formulations in the 171 Patent are inventive because a skilled but uninventive apixaban formulator would not have thought to reduce particle size to improve absorption, or to target the significantly lower dissolution rate of the claims in issue.

[49] These conclusions were open to the Federal Court and were not excluded by the Federal Court's description of how a formulator would be expected to proceed. As noted by the Federal Court, even PMS's expert Dr. Laskar acknowledged that the skilled person would not have expected reduced particle size of a BCS Class III drug like apixaban to increase bioavailability (see paragraph 137 of the Federal Court's reasons), or that solution-like behaviour would be observed with a significantly lower dissolution rate (see paragraph 132 of the Federal Court's reasons). In my view, these unexpected results would not necessarily have been revealed by the drug development process described at paragraph 126 of the Federal Court's reasons. That description is general enough that it does not necessarily follow that the inventors would have ignored the common general knowledge and taken steps that would have revealed the inventive concept.

[50] I do not accept PMS's argument that the Federal Court in this case made the same error as described in *Tetra Tech EBA Inc. v. Georgetown Rail Equipment Company*, 2019 FCA 203 (*Tetra Tech*). At paragraph 63 of *Tetra Tech*, this Court found that the Federal Court had erred in law by failing to consider how a skilled person would have responded to the prior art. Here, the Federal Court clearly considered what would and would not have occurred to the skilled person, and what such a person would have done.

[51] The Federal Court's conclusions concerning inventiveness are also not contradicted by the finding at paragraph 145 of its reasons, in discussion of insufficiency and overbreadth, that there was no evidence that the testing required to work the invention was more than routine trial

and experimentation. The routineness of testing required to put an invention into practice once it has been identified is not necessarily determinative of the obviousness of the invention itself.

[52] Moreover, I do not read the passage "I am unable to find any evidence" in paragraph 140 of the Federal Court's reasons as contradicting the analysis that preceded it (as PMS urges). The Federal Court was referring not to a complete absence of evidence, but rather to the absence of evidence that convinced it "on a balance of probabilities that it was more or less self-evident to try to obtain the invention." That conclusion was open to the Federal Court.

[53] With regard to the Federal Court's conclusion that the invention of the 171 Patent was not obvious to try, PMS argues that the Federal Court erred in defining the legal test. Specifically, PMS criticizes the statement, at paragraph 140 of the reasons, that "the 'obvious to try' test works only where it is very plain or more or less self-evident that what is being tested ought to work." In this regard, PMS cites my reasons in *Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology Research*, 2020 FCA 30 at paragraph 90 (*Hospira*), in which I stated as follows:

> It should be noted that, whereas being "more or less self-evident to try to obtain the invention" (per *Sanofi* at para. 66) is a requirement for obviousness to try, being "more or less self-evident that what is being tried ought to work" (per *Sanofi* at para. 69) is not a requirement but merely a factor to be considered.

[54] PMS argues that the Federal Court incorrectly treated "more or less self-evident that what is being tested ought to work" as a requirement rather than one of several factors to be considered.

[55] There are two principal reasons that I am not convinced that the Federal Court erred in this regard. The first is that the Federal Court did not misquote *Sanofi*. Though the Supreme Court of Canada did indeed characterize "more or less self-evident to try to obtain the invention" as a requirement in paragraph 66 and "more or less self-evident that what is being tried ought to work" as a factor in paragraph 69, it gave mixed signals on the point (see my discussion in *Apotex Inc. v. Janssen Inc.*, 2021 FCA 45 at paragraph 36). At paragraph 65, it stated that, "the 'obvious to try' test will work only where it is very plain or … more or less self-evident that what is being tested ought to work." This is what the Federal Court stated in the impugned passage at paragraph 140. It is also notable that, later in the same paragraph, the Federal Court cited the proper requirement of "more or less self-evident to try to obtain the invention."

[56] The second reason that I am not convinced that the Federal Court erred on the issue of obviousness to try is that it adequately considered the other relevant factors (as listed at paragraph 42 above), albeit without identifying them as such. It noted that it took some seven years to develop the patented formulation (see paragraph 6 of the reasons), and it rejected PMS's argument that BMS's story of the invention was revisionist history (see paragraph 125 of the reasons). The Federal Court also appears to have understood the critical importance of finding a practical formulation of apixaban in order to make it into a commercial product, and noted that the common general knowledge pointed away from the approach described in the 171 Patent.

[57] PMS also argues, in the alternative, that the Federal Court erred in defining the inventive concept of the 171 Patent. Specifically, PMS argues that

A. The inventive concept should be defined by the text of the claims (*Hospira* at para. 94), but the reference to solution-like behaviour in the statement of the inventive concept at paragraph 130 of the Federal Court's reasons is unsupported by the claims in issue; and

B. A single overarching inventive concept should link all of the claims of a patent (*Sildenafil* at para. 64, *Apotex Inc. v. Shire LLC*, 2021 FCA 52 (*Shire*) at paras. 77 and 86), but claim 2 of the 171 Patent (which is not in issue) does not include any limitation to dissolution rate.

[58] I find no merit in either argument. With regard to the first, I reject the submission that the Federal Court improperly imported solution-like behaviour to the inventive concept. Paragraph 130 of the Federal Court's reasons concluded that the inventive concept of the 171 Patent is its teaching that, if the particle size is no greater than as defined therein, and the dissolution rate is at least as high as defined therein, "then the tablets will provide consistent solution-like exposures." I read the reference to "solution-like exposures" as a statement of the reason that the inventive concept is useful, not a separate element thereof. At paragraph 127 of its reasons, the Federal Court noted BMS's submission that, "[i]f you make those tablets in the way that the 171 Patent instructs, you are guaranteed to obtain tablets that provide consistent solution-like exposures." Nothing in the Federal Court's analysis suggests that it read in solution-like behaviour (or solution-like exposures) as a separate element of the inventive concept.

[59] Turning now to the second alternative argument on inventive concept, the authorities cited by PMS are clear that different claims may have different inventive concepts: see *Sildenafil* at para. 64, *Shire* at para. 87. Accordingly, I see no error in the Federal Court concluding that dissolution rate was an element of the inventive concept of the claims in issue of the 171 Patent, even if that element is omitted in another claim. Indeed, the Federal Court would have fallen into error if it had not included dissolution rate as part of the inventive concept when considering allegations of obviousness of the claims in issue, since these claims explicitly include dissolution rate as an element.

E. *Ambiguity of the 171 Patent*

[60] Subsection 27(4) of the *Patent Act* provides that "[t]he specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed."

[61] The basis for invalidity due to ambiguity is that the patent must give adequate notice to the public as to what activities are claimed as exclusive to the patentee: *Western Oilfield Equipment Rentals Ltd. v. M-I LLC*, 2021 FCA 24 at para. 121. A claim may be invalid for ambiguity if it uses language that is avoidably ambiguous or obscure: *Unilever PLC v. Procter & Gamble Inc.*, [1995] F.C.J. No. 1005 (QL), 61 C.P.R. (3d) 499 at para. 31 (F.C.A.). However, a claim is likely not invalid if the phrase in issue "can be interpreted using grammatical rules and common sense": *Mobil Oil Corp. v. Hercules Canada Inc.*, [1995] F.C.J. No. 1243 (QL), 63 C.P.R (3d) 473 at para. 22 (F.C.A.). A claim that can be interpreted in more than one way, such that it would be impossible for the skilled person to know in advance whether or not something

would be within the claims, is ambiguous: *Apotex Inc. v. Hoffmann-La Roche Ltd.*, [1989] F.C.J. No. 321 (QL), 24 C.P.R. (3d) 289 at 299 (F.C.A.). However, a claim is not invalid simply because it is not a model of concision and lucidity: *Pollard Banknote Limited v. BABN Technologies Corp.*, 2016 FC 883 at para. 137; *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2005 FC 1725 at para. 52; *Letourneau v. Clearbrook Iron Works Ltd.*, 2005 FC 1229 at para. 37.

[62] PMS argues, as it did before the Federal Court, that the claims in issue of the 171 Patent are invalid for ambiguity because they define particle size as "measured by laser light scattering", but do not specify whether the dispersion method used in such measurement should be wet or dry. PMS argues that different results are obtained depending on the dispersion method that is used.

[63] The Federal Court cited Sandoz' expert Dr. Kibbe for the conclusion that a formulator would know how to measure particle size (see paragraph 151 of the reasons). The Federal Court also cited BMS's expert Dr. Davies for the conclusion that, done properly, there is no difference between the wet and dry dispersion methods (see paragraph 152 of the reasons). PMS disputes the Federal Court's characterization of Dr. Davies' evidence, saying that he merely stated that results using wet dispersion correlated well with those using dry dispersion.

[64] In addition to raising the issue of whether the Federal Court misstated Dr. Davies' evidence, PMS also argues that the Federal Court incorrectly considered ambiguity from the perspective of whether the skilled person could work the invention (which is relevant to

sufficiency rather than ambiguity). Finally, PMS argues that the Federal Court improperly read in wet dispersion to claims that do not include such a limitation.

[65] I am not convinced that the Federal Court erred in its analysis of ambiguity. It is true that the passage cited by the Federal Court from Dr. Davies' evidence does not clearly support the statement that there is no difference between the wet and dry dispersion methods. However, Dr. Davies did state that skilled formulators would know that dry dispersion could cause particle attrition (which could lead to inaccurate results), and wet dispersion would be less likely to cause attrition. He also referred to the importance of employing the dry dispersion method accurately, and he stated that either wet or dry dispersion could be used (see paragraph 68 of BMS's memorandum of fact and law on the 171 Patent).

[66] Moreover, the Federal Court found that a skilled formulator, if in doubt about which method to use, would consult the 171 Patent and find that it describes the use of wet dispersion, and would employ that method (see paragraph 152 of the reasons). This finding was open to the Federal Court because there was evidence to support it.

[67] The foregoing is a full answer to the allegation that the skilled formulator would not be able to determine whether a tablet fell within the claims in issue.

[68] Likewise, I am not convinced that the Federal Court erred by considering ambiguity from the perspective of whether the skilled person could work the invention, or by reading wet dispersion into the claims. The Federal Court clearly understood that the claims refer to

measurement by laser light scattering, by whichever method provides an accurate result. It also understood that wet dispersion was more likely to yield accurate results. It did not limit the claims to wet dispersion. The Federal Court's discussion of the appropriate dispersion method was concerned with the issue of whether one can determine if a tablet falls within the scope of the claims in issue. Any overlap with issues of how to work the invention is incidental and not indicative that the Federal Court erred in law.

F. *Overbreadth of the 171 Patent*

[69] The nature of PMS's argument on overbreadth of the 171 Patent is not entirely clear. By letter dated June 17, 2022 following the discontinuance of Sandoz' appeals, the parties confirmed that PMS would not be making arguments that only Sandoz had made. Since PMS's argument on overbreadth of the 171 Patent at paragraph 125 of its memorandum of fact and law is limited to relying on Sandoz' arguments, it would seem at first glance that PMS is no longer pursuing this issue. However, the same letter identified overbreadth as one of the grounds of invalidity of the 171 Patent that remains live.

[70] PMS did not address this issue in its oral submissions, except to confirm that it remains in dispute. Accordingly, I focus on Sandoz' argument as set out in paragraphs 74 to 78 of its memorandum of fact and law. The root of this argument is that there are factors other than particle size that affect dissolution rate, but the 171 Patent does not disclose what they are. Sandoz' argument was that the claims in issue are invalid for overbreadth because the dissolution rate threshold is a mere desired result that is not limited to what was invented and what was disclosed.

[71] First, I reject the argument that dissolution rate is the desired result. As clearly stated in the 171 Patent and by the Federal Court, the desired result is solution-like behaviour in the body. The claims provide thresholds for particle size and dissolution rate that the inventors discovered can guarantee solution-like behaviour. There was no obligation for the 171 Patent to describe factors other than particle size that could affect dissolution rate unless the skilled reader would need that information to put the invention into practice. It does not appear that PMS is arguing that the skilled reader would need such information. Moreover, such a flaw, if it were present, would seem to relate to the sufficiency of the 171 Patent, rather than overbreadth.

V. Conclusion

[72] For the foregoing reasons, I would dismiss PMS's appeals with costs.

"George R. Locke"
J.A.

"I agree.
Yves de Montigny J.A. "

"I agree.
K.A. Siobhan Monaghan J.A. "

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

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