Federal Court of Appeal | Cour d'appel fédérale

Date: 20160420

Docket: A-47-15

Citation: 2016 FCA 119

CORAM: **DAWSON J.A.**
TRUDEL J.A.
RENNIE J.A.

BETWEEN:

MYLAN PHARMACEUTICALS ULC

Appellant

and

ELI LILLY CANADA INC., ICOS CORPORATION and THE MINISTER OF HEALTH

Respondents

Heard at Ottawa, Ontario, on December 1, 2015.

Judgment delivered at Ottawa, Ontario, on April 20, 2016.

REASONS FOR JUDGMENT BY: RENNIE J.A.

CONCURRED IN BY: DAWSON J.A.
TRUDEL J.A.

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REASONS FOR JUDGMENT

RENNIE J.A.

I. Introduction

[1] This is an appeal from a decision of the Federal Court *per* Justice de Montigny (the judge) dated January 7, 2015 (2015 FC 17). In that decision, the judge allowed Eli Lilly's application for an order under section 6 of the *Patented Medicines (Notice of Compliance)*

Regulations, SOR/93-133 (Regulations) prohibiting a Notice of Compliance (NOC) from being issued to Mylan. Mylan had alleged that Eli Lilly's patent was invalid on the basis of obviousness-type double-patenting and for lack of utility due to no sound prediction. For the reasons that follow, I would dismiss the appeal.

II. Background

[2] The impugned patent (Canadian Patent No. 2,226,784 or the '784 patent) claims tadalafil and 3-methyl tadalafil (the two compounds) for the treatment of erectile dysfunction (ED). The patent comprises 28 claims, a subset of which are disputed in this appeal. Saliently, claim 18 claims the use of the two compounds via oral administration for the treatment of ED; claims 2, 4, 12, 14, and 15 (the remaining claims) are to the general use of the two compounds to treat ED, with no mention of oral administration.

[3] The impugned '784 patent had a priority date of July 14, 1995, Canadian filing date of July 11, 1996, and a publication date of February 6, 1997.

[4] Tadalafil and 3-methyl tadalafil are PDE V inhibitors. PDE V is an enzyme that breaks down the chemical cGMP (which causes erections via triggering smooth muscle relaxation) into GMP (which does not). Because PDE V prevents erections, a PDE V inhibitor has the effect of stimulating erections.

[5] Eli Lilly had previously acquired a patent that claimed, among other compounds, tadalafil. This earlier patent (Canadian Patent No. 2,181,377 or the '377 patent) had a priority

date of January 21, 1994 and a Canadian filing date of January 19, 1995. In the words of the judge, the '377 patent claimed "novel compounds, including tadalafil, pharmaceutical compositions, and the use of tadalafil in the treatment of various disorders where smooth muscle relaxation was thought to be beneficial, including cardiovascular disorders." The patent indicated that tadafafil was bioavailable for reducing systemic hypertension. It did not mention ED treatment specifically.

[6] On December 22, 1994 (after the priority date of the '377 patent, but before the priority date of the impugned '784 patent) Pfizer's American patent application WO 1994028902A1 (the '902 patent application) for sildenafil (another PDE V inhibitor) was published. Notwithstanding criticism of the equivalent Canadian patent (Patent 2,163,446) by the Supreme Court of Canada in *Teva Canada Ltd. v. Pfizer Canada Inc*. 2012 SCC 60, [2012] 3 S.C.R. 625 for inadequate disclosure of the particular chemical claimed by the patent, the '902 patent application did show that a PDE inhibitor could treat ED. There was evidence before the judge, however, that the information in the '902 patent application was a counterintuitive breakthrough and was initially met with scepticism.

[7] In early 1996 (after the priority date of the '784 patent, but a few weeks prior to its Canadian filing date) a study (the Boolell study) provided robust evidence, based on clinical trials, that the PDE V inhibitor sildenafil could be orally administered for effective treatment of ED. The judge found that this study stood for the broader proposition that a PDE V inhibitor could be administered orally for safe, effective treatment of ED.

[8] Eli Lilly applied for an order under subsection 55.2(4) of the *Patent Act*, RSC 1985, c P-4, and section 6 of the Regulations, prohibiting the Minister from granting a NOC to Mylan for a generic version of tadalafil. On December 21, 2012, Mylan filed a Notice of Allegation alleging that the '784 patent was invalid for lack of utility and obviousness-type double-patenting.

III. The decision below

[9] Mylan alleged that the claims at issue were invalid for obviousness-type double-patenting, and also that they were invalid for inutility on the basis of a lack of sound prediction.

[10] With regard to the double-patenting challenge, the judge determined that the relevant date on which the impugned patent was to be assessed was the priority date of the first ('377) patent (January 21, 1994). He found that the inquiry at the centre of obviousness-type double-patenting was whether the second patent's claims should have been included in the first patent. He also found that while the double-patenting analysis was to be a comparison of the claims of the two patents, the claims must be read in the context of the full patent; consequently, he interpreted the '377 patent as claiming tadalafil as a PDE V inhibitor even though its status as a PDE V inhibitor was only made clear in the specification.

[11] On the basis of this framework, the judge determined that at the priority date of the '377 patent, the use of PDE V inhibitors, such as the two compounds, to treat ED was patentably distinct from the '784 patent. Indeed, he noted that this factual finding was uncontroversial in the view of the parties' witnesses. In the alternative, the judge found that even at the priority date of the *second* patent, the '784 patent was still patentably distinct from the '377 patent. The '902

patent application, which had been published about six months prior to the '784 patent's priority date, did not sufficiently advance the common general knowledge held by the person ordinarily skilled in the art (the skilled person) such that the '784 patent was not patentably distinct.

[12] The judge also rejected the challenge to the utility of the patent. He concluded that the promise of the patent was the use of tadalafil and 3-methyl tadalafil to treat ED without reference to any particular mode of administration or the absence of toxicity or undue side effects. The judge found that in light of the experiments taught in the patent's disclosure, the common general knowledge and the disclosure of the '377 patent, there was a *prima facie* reasonable inference of utility for the claimed compounds.

[13] The judge also found that, in the alternative, even if the promise of the patent includes oral administration it was still soundly predicted. The judge determined that by combining the '377 patent's disclosure that demonstrated that tadalafil was an orally bioavailable PDE V inhibitor with the Boolell study's teachings that an orally bioavailable PDE V inhibitor could be used to treat ED, there was a *prima facie* reasonable inference of the utility of the oral administration of tadalafil. Having found that claim 18 was soundly predicted with regard to tadalafil, the judge determined that it was not necessary to make a similar finding with regard to 3-methyl tadalafil. The basis for this conclusion was that claim 18 was a *Markush* claim, and that *Markush* claims to a class of compounds have utility as long as at least one compound within the class has utility.

IV. Positions of the parties

[14] Mylan appeals the findings with regard to both obviousness-type double-patenting and sound prediction, limiting its arguments on appeal to the sound prediction of claim 18 and to obviousness-type double-patenting of the remaining claims.

[15] With regard to double-patenting, Mylan alleges that the judge erred in law by conducting the analysis as of the priority date of the '377 patent, and that *Whirlpool Corp. v. Camco Inc.*, 2000 SCC 67, [2000] 2 S.C.R. 1067 instead mandates using the *publication date of the later* (in this case, '784) *patent*. Mylan also contends that the judge committed a palpable and overriding error in finding that, at the '784 patent's priority date, the impugned patent was not invalid for obviousness-type double-patenting. Finally, Mylan argues that the nature of the inquiry for obviousness-type double-patenting should be akin to obviousness.

[16] Regarding sound prediction, Mylan argues that no skilled person would draw the inference of oral utility without specific *in vivo* tests on the two compounds which were claimed. Because there was no testing of 3-methyl tadalafil's oral bioavailability for any purpose, and no testing of the oral use of either compound to treat ED, claim 18 was not soundly predicted.

[17] Eli Lilly contends that the judge ultimately reached the correct conclusion on both challenges to the patent.

[18] With respect to double-patenting, Eli Lilly argues that because PDE V inhibition is only mentioned in the patent's specification rather than its claims, the judge erred in reading PDE V

inhibition into the claims of the '377 patent. Notwithstanding this alleged error, however, Eli Lilly argues that the judge used the correct date for the double-patenting analysis and properly concluded that the patent was not invalid on this ground.

[19] Eli Lilly also submits that the obviousness-type double-patenting inquiry cannot be conducted according to the obviousness framework. It argues that to do so would make obviousness-type double-patenting a surrogate of the obviousness doctrine and circumvent the protections of section 28.3 of the *Patent Act*. Subsection 28.3(a) excludes from the prior art, which forms the basis of an obviousness challenge, any documents disclosed by the patentee in the year prior to filing.

[20] On the sound prediction issue, Eli Lilly's position is that the judge correctly concluded that the '902 patent application and the Boolell study provided a factual basis for a sound line of reasoning to predict the utility of claim 18 with regard to the two compounds.

V. Standard of review

[21] The standard of review established in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235 applies to appeals of NOC applications: *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2006 FCA 214, at para. 15, [2007] 2 F.C.R. 137. Findings of fact and mixed fact and law can only be reversed if there is a palpable and overriding error. Findings of law, including extricable questions of law on an issue of mixed fact and law, are reviewed on a correctness standard.

VI. Preliminary observations

[22] Before examining the grounds of invalidity under appeal, it is useful to briefly review three areas of patent law. The first is the distinction between prior art and common general knowledge. The second is the distinction between obviousness and double-patenting. Finally, a recapitulation of the various dates that are engaged by the issues on appeal completes the backdrop.

A. *Prior art and common general knowledge*

[23] Prior art is the collection of learning in the field of the patent at issue. It comprises any publically available teaching, however obscure or not generally accepted.

[24] The common general knowledge, in contrast, is the "knowledge generally known by persons skilled in the relevant art [skilled persons] at the relevant time": *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, at para. 37, [2008] 3 S.C.R. 265. Unlike the prior art, which is a broad category encompassing all previously disclosed information in the field, a piece of information only migrates into the common general knowledge if a skilled person would become aware of it and accept it as "a good basis for further action": *General Tire & Rubber Co. v. Firestone Tyre & Rubber Co.*, [1971] F.S.R. 417, (1972) R.P.C. 457 at 483 (C.A.).

[25] Prior art is used for specific purposes in patent law, such as to found an allegation that prior art anticipated the invention or rendered it obvious. The common general knowledge informs the way in which the claims and specifications are read, because it is to the skilled

person that the patent is addressed. Any inquiry in patent law that is performed from the perspective of a skilled person will import the common general knowledge.

B. *Obviousness-type double-patenting*

[26] The double-patenting doctrine holds that a claim is invalid if it constitutes patenting of an invention that has already been claimed in a previous patent. It is aimed at the problem of evergreening; extending the monopoly that was granted on the first patent by filing a new patent that does not offer a new invention to the public. As such, the doctrine of double-patenting prevents a patentee from violating the bargain at the heart of the patent system.

[27] In *Whirlpool*, the Supreme Court of Canada recognised two types of double-patenting. The first is "same-invention" double-patenting, which occurs when the claims of the second patent are outright "identical or coterminous" to the first. This is not alleged in this case. The second is "obviousness-type" double-patenting, which occurs when the second patent is not identical to the first, but is nonetheless not "patentably distinct" from the first.

[28] Invalidity on the basis of obviousness-type double-patenting is not the same as invalidity on the basis of obviousness. Obviousness is directed at the question of whether an "invention" (in the legal sense) exists at all. Obviousness-type double-patenting has a different policy justification; the prevention of evergreening an existing patent through what would otherwise be a valid patent but is, in effect, an extension of the patent that has already been granted: *Merck & Co., Inc. v. Pharmascience inc.*, 2010 FC 510, at para. 124, 368 F.T.R. 1. Some of the

differences are contested issues in this appeal, but a few uncontroversial distinctions between the two variants of the doctrine can be noted.

[29] In an obviousness challenge, any piece of prior art, including a collection of works, can be cited as rendering the impugned patent obvious and therefore not patentable: *Sanofi-Synthelabo* at paras. 67-71. By contrast, in an obviousness-type double-patenting challenge, only the earlier patent can be cited as rendering the impugned patent not patentably distinct; any other prior art is only relevant insofar as it contributes to the common general knowledge of the skilled person.

[30] Finally, in an obviousness challenge, subsection 28.3(a) of the *Patent Act* provides that any information disclosed by the patentee within a year prior to the filing cannot be cited as prior art that renders the patent obvious. This effectively gives the patentee a one-year grace period before filing in which it can make disclosures without worrying that those disclosures will be the basis of an obviousness attack. Double-patenting is not subject to subsection 28.3(a), which is what allows the earlier patent to be cited if it was published within a year of the filing date of the impugned patent.

C. *The relevant dates*

[31] Borrowing in large measure from *Hughes and Woodley on Patents*: The Honourable Mr. Justice Roger T. Hughes, Dino Clarizio & Neal Armstrong, 2d ed, looseleaf, (Toronto: LexisNexis Butterworths, 2005), it is useful to revisit some of the key terms on which this appeal turns:

a) The *filing date* is the date on which the patent application is filed with the Canadian Patent Office.

b) The *priority date* is the date on which an earlier patent application disclosing the same invention was filed by the patentee – either in Canada or (much more often) in a country that is party to a relevant patent treaty or convention to which Canada is also a party. A priority date only applies at the request of the patentee, and the patent must be filed in Canada within 12 months of the priority date.

c) The *claim date* is the priority date if there is one; otherwise the claim date is the filing date.

(The above concepts (a and b) are governed by section 28.1 of the *Patent Act*. Though the various iterations of the *Patent Act* complicate matters slightly, a general statement can be made that novelty and obviousness are both assessed as of the claim date).

d) The *publication date* is the date on which the application for a patent is first open to the public for inspection. The prospective patentee has the right to delay this up to 18 months after the claim date. This is governed by section 10 of the *Patent Act*. The patent becomes citable prior art as of the publication date; the publication date is also the date for claims construction.

VII. Analysis

[32] One issue in dispute between the parties is whether the substance of the analysis of obviousness-type double-patenting is the same as that for obviousness and what date is to be used for conducting the analysis.

[33] Mylan submits that the Court should apply the well-settled test for obviousness, with the earlier patent taking the place of the prior art. Under this construct, the question for the Court is whether a skilled person would consider the impugned patent obvious in light of the earlier patent, with the earlier patent taking the place of the prior art generally, or whether there was an inventive step that makes the impugned patent non-obvious. This approach differs from

straightforward obviousness in terms of what prior art is considered, but the central inquiry is the same.

[34] Eli Lilly argues that this is incorrect, and that the inquiry is instead whether the second invention constitutes an improper extension of the original patent. For his part, the judge framed the question as whether what was claimed in the second patent could or should have been included in the first patent.

[35] I do not see a substantive distinction between the two approaches. They are not inconsistent and are, in effect, reformulations of the same inquiry. When one says "the second patent is an impermissible extension of the first" or "the claims of the second patent should have been included in the first", those statements, in essence, ask whether there is an inventive step from the first patent to the second.

[36] The Supreme Court of Canada in *Whirlpool* indicated that the substance of a double-patenting inquiry – like obviousness – is whether there is "invention" or "ingenuity" in the move from the first patent to the second: *Whirlpool* at paras. 66-67. Moreover, because the doctrine exists to prevent the evergreening of patents with uninventive additions, examination of whether the changes in the second patent are or are not inventive is directly linked to the policy considerations that underlie the doctrine. Finally, while not dispositive, the use of the label "obviousness" for this type of double-patenting indicates that a similar analytical process is appropriate.

[37] This, in execution, requires consideration of the claims of the second patent against the claims of the first patent. The distinction from an obviousness inquiry is nuanced, but doctrinally important. As noted by Hughes J. in *Merck v. Pharmascience*, at para. 124:

> What is important to keep in mind is that the exercise required in the inquiry as to whether there is double patenting is that the claims of the earlier patent owned by the same patentee as the latter must be compared with the claims of the latter to see if they are "identical or co-terminus", or whether the latter is "obvious" in view of the former. Therefore, the exercise is somewhat different than that of dealing with obviousness of a patent having regard to the art that would have been known to a person skilled in the art as of the relevant time. The exercise respecting double patenting is to present the notional person skilled in the art with the claims of the first patent and inquire whether what is claimed in the second patent was "identical or co-terminus" with the first or would have been obvious in light of the earlier patent. The inquiry must not bother with any inquiry as to whether the earlier patent would have come to the attention of the notional person skilled in the art. Nor does the inquiry extend to the validity or otherwise of the claims of the earlier patent. Nor does the inquiry extend to "prior art" beyond the earlier patent, as Binnie J. wrote at paragraph 67 of *Whirlpool*, the inquiry is whether a second patent can be justified unless the claims exhibit "novelty or ingenuity" over the first patent.
>
> [Emphasis in original]

[38] Although formulated in slightly different language, this analysis may be traced back to, and is consistent with, *Commissioner of Patents v. Fabwerks Hoechst Aktiengeselschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49 and its focus on whether the second patent contains a new or inventive element or process beyond that claimed in the first.

[39] In my view, the judge erred in referring to the specification when construing the claims of the '377 patent. The rules of patent construction preclude reference to the specification when the

claims are clear, and also improper if it varies the scope of the claims: *Hughes and Woodley on Patents*, p. 312:

> In construing a patent, the claims are the starting point. The claims alone define the statutory monopoly and the Patentee has a statutory duty to state, in the claims, what he invention is for which protection is sought. In construing the claims, recourse to the rest of the specifications is (1) permissible to assist in understanding the terms used in the claims; (2) unnecessary where the words and plain and unambiguous and (3) improper to vary the scope or ambit of the claims.

[40] In this case, the '377 patent unambiguously claims the compound tadalafil, without any comment on its use as a PDE V inhibitor. In these circumstances, the judge's reliance on *Sanofi-Synthelabo*, at paragraph 77 is misplaced. Rothstein J.'s comments regarding the patent specification were in the specific context of construing the inventive concept of a selection of patent for the purposes of an obviousness analysis, not in the context of claims construction. *Sanofi-Synthelabo* makes it clear that construing the inventive concept is a distinct analysis from claims construction.

[41] Paragraphs 76-77 of *Sanofi-Synthelabo* are helpful on this point. First, at paragraph 76, Rothstein J. construed the claims of the patent and found that they constitute "the dextro-rotatory isomer", a compound. Rothstein J. *then* moved to the obviousness inquiry and the inventive concept of this claim. It was only at this latter stage of the analysis that Rothstein J. referenced the specification, observing that "[a] bare chemical formula in a patent claim may not be sufficient to determine its inventiveness."

[42] Moreover, when Rothstein J. assessed obviousness-type double patenting later in the judgment, he did not consider the patent's specification in construing the claims. At paragraph 108, he stated:

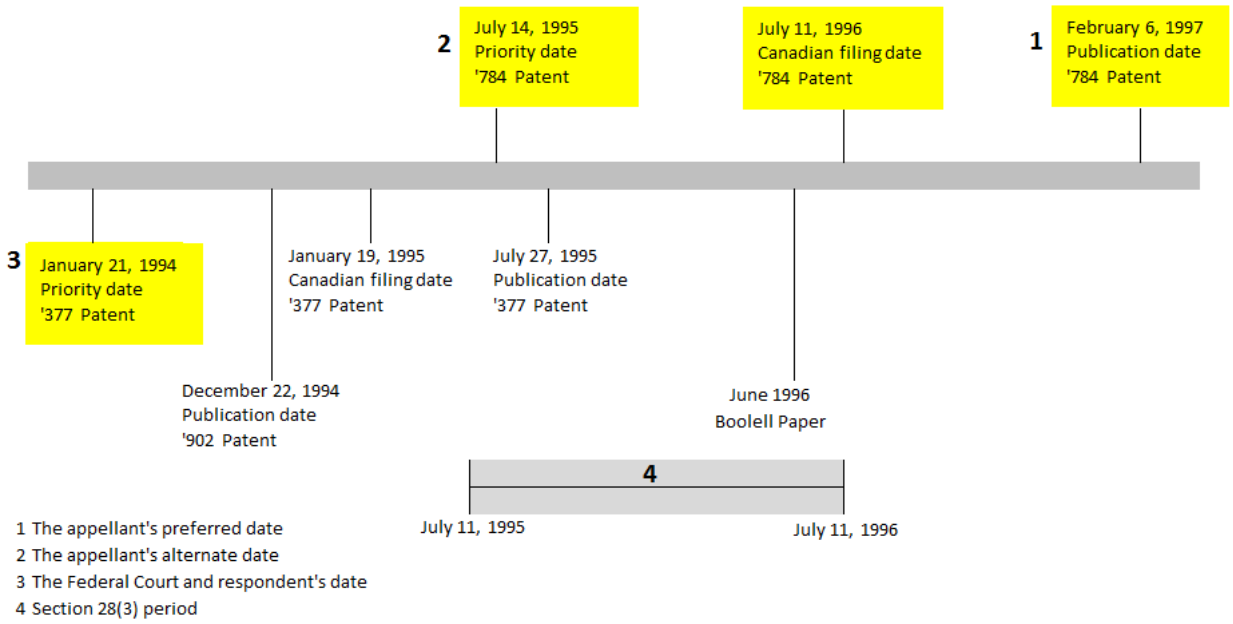
> Apotex argues that the focus in a double patenting challenge is on the claims of the two patents rather than on the disclosure. I agree. In *Whirlpool*, Binnie J. stated, at para. 63:
>
> > It is clear that the prohibition against double patenting involves a comparison of the claims rather than the disclosure, because it is the claims that define the monopoly.

[43] To conclude, as there was no ambiguity in the claims here, there could be no recourse to the specification. However, this error is one of no consequence, as its effect was to impose a higher burden on Eli Lilly. The judge came to the correct conclusion with respect to obviousness-type double patenting.

[44] Having settled on the essential methodology, I turn to the question as to the date at which the inquiry is to be conducted. The consequences associated with the selection of any date are considered by Professor N. Siebrasse in "*Sufficient Description, Observations on Canadian patent case, Disagreement on Date for Assessing Obviousness-type Double Patenting*" (14 August 2015),: <http://www.sufficientdescription.com/2015/08/disagreement-on-date-for-assessing.html>, where he concludes that the law is unsettled and that the point is a difficult one, a proposition with which I agree.

[45] There are three possible dates from which obviousness-type double-patenting may be assessed. The first date is the priority date of the first patent. The middle date is the priority date

of the second patent, which in this case is *after* Pfizer's '902 patent application was published. The last possible date is the publication date of the second patent, by which point the Boolell study was also publically available and well-known. The timeline, and choices, is reflected below:



[46] The parties broadly agree on the consequences of each date being the appropriate one. If the first date (the priority date of the '377 patent) is correct, the respondent will almost surely succeed; Mylan did not argue in its factum or oral argument that double-patenting could be established based on the '377 patent alone. If the last date is correct (the publication date of the '784 patent), the appellant will almost surely succeed, as the Boolell study renders the contributions of the '784 patent non-inventive. Eli Lilly, in oral argument, did not seriously contend otherwise. If the middle date is correct (the '784 patent priority date), then there is an evidentiary dispute as to whether the judge erred in finding no double-patenting.

[47] I am convinced that the publication date of the later patent (the last date) is not the appropriate one. Contrary to the appellant's submissions, I do not read *Whirlpool* as the controlling authority on this point.

[48] As noted by the judge, *Whirlpool* was an obviousness case and did not turn on the correct date for a double-patenting analysis. The Court found the expert evidence before the judge insufficient to support a finding of obviousness-type double patenting. Further, the discussion arose in the context of the date for construction of claims under the old act and the Court settled on the publication date. Thus, while strictly *obiter*, Binnie J.'s observation at paragraph 67 that the inquiry is whether a second patent can be justified unless the claims exhibit "novelty or ingenuity" over the first patent, places the focus on the publication date of the first patent. At the risk of repetition, I note as well the interpretation of *Whirlpool* by Hughes J. in *Merck v. Pharmascience*, at para. 124, subsequent to *Whirlpool*, that:

> The exercise respecting double patenting is to present the notional person skilled in the art with the claims in the first patent and inquire whether what is claimed in the second patent was "identical or co-terminus" with the first or would have been obvious in light of the earlier patent […] Nor does the inquiry extend to "prior art" beyond the earlier patent.

[49] The next question is therefore whether the publication date of the later patent (the '784 patent) is nonetheless the correct date in light of the principles underlying double-patenting doctrine. I conclude that it is not. Specifically, it would be inappropriate to use any date after the claim date of the second patent (whether in a particular case the claim date is the same as the priority date – as it is here – or the filing date).

[50] As Professor Siebrasse notes, using a date after the claim date would also mean that a court assessing an obviousness-type double-patenting claim would consider prior art beyond what section 28.3 allows the Court to consider when assessing classical obviousness. Contrast this with the fact that the double-patenting doctrine allows a challenger to circumvent the one year grace period in subsection 28.3(a). That circumvention is acceptable because a consideration of the patentee's prior patent documents is precisely what the doctrine mandates the Court to undertake. However, there is no equivalent reason to allow a challenger alleging obviousness-type double-patenting to point to prior art after the claim date, while not allowing the same to a challenger alleging obviousness.

[51] This eliminates the possibility of the third date – the '784 patent publication date – being correct. As such, the Boolell study cannot be considered by the skilled person when assessing double-patenting. The scenario in which the appellant Mylan succeeds uncontroversially should be eliminated.

[52] This leaves the first date, on which the appellant Mylan uncontroversially fails, and the middle date, on which there is an evidentiary dispute. It is not necessary to determine the question of which of these dates is the appropriate one. This is because, on the facts of this case, even if the correct date is the more appellant-friendly middle date, I find that the judge did not err in finding that there was no double-patenting. As I will explain, there was no change in the common general knowledge between the first date and the middle date.

[53] Specifically, I find that the judge committed no reviewable error in concluding that the ‘784 patent was patentably distinct even in light of the ‘902 patent application. I agree with the appellant that the fact that the Supreme Court of Canada criticised the Canadian equivalent to the ‘902 patent application for lack of disclosure of the specific compound claimed (sildenafil) is irrelevant to the broader issue of what the ‘902 patent application taught about PDE V inhibitors as a general class. However, the judge accepted evidence that the ‘902 patent application’s teachings about the use of PDE V inhibitors to treat ED were counterintuitive and met with initial skepticism. As such, the skilled person would not have unhesitatingly accepted the teachings of the ‘902 patent application as true; they were not part of the common general knowledge. The judge correspondingly did not commit a palpable and overriding error in concluding that, even as the common general knowledge stood after the ‘902 patent application, the ‘784 patent was patentably distinct over the ‘377 patent.

A. ***Utility of claim 18***

[54] Mylan also challenges claim 18 on the basis that it lacks utility. Specifically, Mylan alleges that while the oral administration of tadalafil to treat ED may have been soundly predicted, the oral administration of 3-methyl tadalafil was not. This is because while the ‘377 patent (demonstrating oral bioavailability and PDE V inhibition) could be combined with the Boolell study (teaching that an orally bioavailable PDE V inhibitor could treat ED) in the case of tadalafil, the ‘377 patent only showed such oral bioavailability for tadalafil and not 3-methyl tadalafil.

[55] Utility need not be demonstrated at the time a patent is filed; it is enough for the claimed utility to be soundly predicted by the filing date. Sound prediction has three requirements, a factual basis for the prediction, an articulable and sound line of reasoning and proper disclosure: *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77, at para. 70, [2002] 4 S.C.R. 153. If all of these are present, a "*prima facie* reasonable inference of utility" can be reached: *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197, at para. 85, [2012] 1 F.C.R. 349.

[56] After finding that claim 18 with regard to tadalafil was soundly predicted, the judge did not consider whether the use of 3-methyl tadalafil to treat ED orally was also soundly predicted. He reasoned that the status of the claim as a *Markush* claim rendered it unnecessary to determine whether each compound claimed would work. However, a *Markush* claim requires that each compound in the claimed class, not merely one of the compounds, have utility: *Abbott Laboratories v. Canada* (Minister of Health), 2005 FC 1095, at paras. 23-27, 30 C.P.R (4^{th}) 20. Assuming, without deciding, that claim 18 was indeed a *Markush* claim, the judge thus erred, but it is an error of no consequence.

[57] There was evidence before the judge which indicated that 3-methyl tadalafil was soundly predicted. In particular, the reply affidavit of Dr. Brock provided a factual basis and a sound line of reasoning sufficient to ground a sound prediction. Dr. Brock noted both the Boolell study's demonstration that PDE V inhibitors could be used to treat ED and also the broad variety of tetracyclic derivatives that were identified as orally bioavailable PDE V inhibitors in the '377 patent. The latter fills in, via a general statement, the factual premise (that 3-methyl tadalafil as a tetracyclic derivative was an orally bioavailable PDE V inhibitor) which Mylan alleges is

missing. Dr. Brock further understood that a skilled person would be able to infer the oral administration of both compounds to treat ED. There was no guarantee of success, but the doctrine of sound prediction does not require guarantees. A *prima facie* reasonable inference of success existed.

[58] Finally, I note that even if a different view were taken as to the validity of claim 18, it would have no effect on the disposition of this appeal. Claim 18 is a dependent claim comprising a subset of the subject matter claimed by the remaining claims. Because, as I have determined above, the remaining claims survive the double-patenting challenge, claim 18 fences off no monopoly that is not entirely subsumed within their scope.

VIII. Conclusion

[59] In conclusion, the judge committed no reversible errors in finding that the impugned patent was not invalid for either obviousness-type double-patenting or a lack of utility. Accordingly, I would dismiss the appeal with costs.

"Donald J. Rennie"

J.A.

“I agree
Eleanor R. Dawson J.A.”

“I agree
Johanne Trudel J.A.”

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

APPEAL FROM A JUDGMENT OF THE FEDERAL COURT DATED JANUARY 7, 2015 (2015 FC 17) DOCKET T-296-13

DOCKET:	A-47-15
STYLE OF CAUSE:	MYLAN PHARMACEUTICALS ULC v. ELI LILLY CANADA INC., ICOS CORPORATION and THE MINISTER OF HEALTH
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	DECEMBER 1, 2015
REASONS FOR JUDGMENT BY:	RENNIE J.A.
CONCURRED IN BY:	DAWSON J.A. TRUDEL J.A.
DATED:	APRIL 20, 2016

APPEARANCES:

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