Federal Court  Cour fédérale

**Date: 20130510**

**Docket: T-825-06**

**Citation: 2013 FC 493**

**Ottawa, Ontario, May 10, 2013**

**PRESENT: The Honourable Mr. Justice O'Reilly**

**BETWEEN:**

**APOTEX INC.**

**Plaintiff**

**and**

**PFIZER CANADA INC.**

**Defendant**

## REASONS FOR JUDGMENT AND JUDGMENT

## I. Overview

[1] Apotex Inc claims that it incurred a loss as a result of being kept out of the market for a generic version of Pfizer Canada Inc's patented azithromycin tablets (under Canadian Patent No 1,314,876, "the '876 patent"). Pfizer's application to prohibit Apotex from entering the market was dismissed by Justice Judith Snider in 2003 (*Pfizer Canada Inc v Apotex Inc*, 2003 FC 1428). She concluded that Apotex's allegation that its tablets would not infringe the '876 patent was justified on the evidence.

[2] The actual period of liability and the quantum of damages are not in issue here. They will, if necessary, be determined in a separate proceeding. The sole issue before me is whether Apotex has a valid claim to damages.

[3] Apotex claims that it has met the requirements to receive compensation for its losses under s 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 by virtue of the fact that Pfizer lost its application for a prohibition order. Pfizer argues that Apotex is not entitled to damages because Apotex would have entered the market with material that infringed the '876 patent. Further, Pfizer contends that Apotex's allegation of non-infringement before Justice Snider misled both Pfizer and the Court in the earlier prohibition proceedings. Therefore, according to Pfizer, Apotex is disentitled to damages under the doctrine of *ex turpi causa non oritur actio* – no action can arise from wrongful conduct.

## II. The Legal Framework

[4] The *PMNOC Regulations* strike a balance "between the protection of intellectual property on the one hand and, on the other hand, the desire to reduce health care costs while being fair to those whose ingenuity brought the drugs into existence in the first place" (*Bristol-Myers Squibb Co v Canada (AG)*, 2005 SCC 26, [*Biolyse*] at para 2). The Regulations achieve this balance by creating a scheme under which generic drug manufacturers can gain entry to the market immediately after patents held by innovators expire. The underlying purpose of the Regulations is to prevent infringement of patents while permitting generic companies to work up and stockpile

inventory during the life of those patents. This purpose informs the interpretation of the Regulations – they must be construed in a manner "which goes no further than is necessary in order to prevent infringement since overshooting this objective would upset the other part of the balance . . . , namely the timely entry of cheaper generic drugs on the market" (*Merck Frosst Canada Ltd v Apotex Inc*, 2009 FCA 187 [*Alendronate*], at para 60).

[5] The Regulations provide measures that allow generic companies to assert claims of non-infringement or invalidity, and innovator companies to prevent generics from getting into the market at least until those claims are considered by the Court (s 6; provisions cited are set out in an Annex). The remedy of prohibition supplements the provisions of the *Patent Act*, RSC 1985, c P-4 – it exists "*in addition to* all of the usual remedies for patent infringement under the *Patent Act*" (*Biolyse*, at para 12, emphasis in original).

[6] In addition, in circumstances where an innovator's application for prohibition is unsuccessful, the Regulations grant a remedy to a generic company that was kept off the market while the issues of non-infringement or invalidity were before the Court. Section 8 states that an innovator (or, "first person") is liable to a generic (or, "second person") for "any loss suffered" between the date when the generic could otherwise have entered the market and the date on which the innovator's application for prohibition was dismissed. This remedy is available by way of an action in this Court by the generic against the innovator (s 8(2)). In determining the amount of damages, the Court must take into account "all matters that it considers relevant . . . , including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1)" (s 8(5)).

[7] Section 8 of the Regulations forms part of the balance described above. It protects generic companies who may have been drawn into unjustified or unduly prolonged prohibition proceedings. It operates as a kind of "counterweight" to the automatic injunction that keeps the generic companies out of the market while the matter is before the Court (see *Apotex Inc v Astrazeneca Canada Inc*, 2012 FC 559, at para 57). In this sense, s 8 and s 6 are closely connected. Indeed, "an award of damages under section 8 logically flows from the section 6 prohibition proceedings and would normally be adjudicated by the judge who hears the prohibition application" (*Alendronate*, above, at para 66).

[8] This case requires me to determine how proceedings under s 8 connect with the earlier s 6 proceedings. In particular, I must answer the following questions: Does the construction of the patent in the s 6 proceeding bind me as the judge hearing the s 8 claim? What is the significance of the original Notice of Application (NOA) – does it continue to shape the issues under s 8?

## III. Framing the Issues to be Decided

[9] To answer the questions set out above, I must consider two separate jurisprudential streams. I must first consider whether I am bound by the earlier s 6 decision of Justice Snider under the doctrine of *stare decisis* (or judicial comity). If so, I am bound by her construction of the '876 patent. I must also consider the relationship between the s 6 proceedings and this s 8 action. If this action is, essentially, an extension of the earlier application, then the original NOA delimits the issues that I can consider here.

[10] I have concluded that I am bound by Justice Snider's construction of the patent, and that the original NOA circumscribes the issues I can consider in this action.

1. *Stare decisis*

[11] The full Latin phrase from which the term *stare decisis* derives is *stare decisis et non quieta movere*, which means "to stand by decisions and not to disturb settled matters" (*Holmes v Jarrett*, [1993] OJ No 679 (Ont Ct J (Gen Div) [*Holmes*], at para 12). This doctrine serves important purposes in the administration of justice. It "promotes consistency, certainty and predictability in the law, sound judicial administration, and enhances the legitimacy and acceptability of the common law" (*R v Bedford*, 2012 ONCA 186, at para 56; see also *R v Neves*, 2005 MBCA 112, at para 90).

[12] Judges readily accept that this doctrine obliges them to follow decisions of higher courts. But the actual concept is broader than that – if a matter is settled, then it should not be disturbed. A matter may be settled if another judge, even of the same Court, has decided it. Generally, only if the material facts are different will the earlier decision not be considered binding on judges of the same Court (*Holmes*, above, at para 12).

[13] Perhaps to distinguish it from the idea that higher judgments are binding on lower judges, many judges prefer to describe this latter aspect of *stare decisis* as being one of "judicial comity" – where the earlier decision is not regarded as strictly binding so much as deserving of considerable respect (see, *eg, Glaxo Group Ltd v Canada (Minister of National Health and Welfare)* (1995), 64

CPR (3d) 65 (FCTD), at paras 10-12). As Justice Marc Noël of the Federal Court of Appeal has put it, "the doctrine of comity seeks to prevent the same legal issue from being decided differently by members of the same Court, thereby promoting certainty in the law" (*Apotex Inc v Allergan Inc*, 2012 FCA 308 [*Apotex Inc*], at para 43).

[14] Based on the idea that the law should be consistent and certain, this doctrine dictates that decisions of judicial colleagues should be followed "in the absence of strong reasons to the contrary" (*R v Northern Electric Co Ltd, et al*, [1955] 3 DLR 449 (Ont HCJ), at para 41). "Strong reasons to the contrary" does not simply mean better arguments. Justice Michael Phelan set out what this phrase actually means:

> (a) subsequent decisions have affected the validity of the impugned judgment;
>
> (b) it is considered that some binding authority in case law or some relevant statute was not considered; and
>
> (c) the judgment was unconsidered, a *nisi prius* judgment given in circumstances familiar with all trial judges, where the exigencies of the trial require an immediate decision without opportunity to fully consult authority. (*Altana Pharma Inc v Canada (Health)*, 2007 FC 1095, at para 36).

[15] Justice Noël expressed similar sentiments in *Apotex Inc*, above, when he stated that "the general view appears to be that the conclusions of law of a Federal Court judge will not be departed from by another judge unless he or she is convinced that the departure is necessary and can articulate cogent reasons for doing so. On this test, departures should be rare" (at para 48).

[16] *Stare decisis*, or judicial comity, has come up frequently in the context of the Regulations, because there are often multiple challenges to the same patent. Recently, Justice Roger Hughes reviewed the case law on the issue, and concluded that "the subsequent Court should respect the

decision of the earlier Court unless it is manifestly wrong or the jurisprudence has changed" (*Allergan Inc v Canada (Minister of Health)*, 2012 FC 767, at para 66).

[17] Regarding construction of patents, Justice Robert Barnes has stated that he felt bound by the construction given by Justice Hughes in an earlier proceeding, even where the evidentiary record was different (*Pfizer Canada Inc v Canada (Health)*, 2007 FC 446). Justice Hughes had been able to construe the patent without reference to the evidence, so his construction was binding, absent some basis for concluding that he was "manifestly wrong" (at para 31). Justice Hughes has also concluded that "where matters such as patent construction are considered having regard to the patent itself and not the evidence, or where the evidence is not different, the need for predictability and consistency remains" (*Eli Lilly Canada Inc v Novopharm Ltd*, 2007 FC 596, at para 63).

[18] Accordingly, based on the concepts of *stare decisis* and judicial comity, Justice Snider's construction of the '876 patent is binding on me unless it is, for strong reasons, necessary to depart from it. I have not been shown any reason to depart from Justice Snider's construction and, therefore, I am bound by it.

2. Recalling the Nature of the *PMNOC Regulations*

[19] The Regulations are a "comprehensive scheme" (*Apotex Inc v Canada (Minister of Health and Welfare)* (1993), 3 CPR ($4^{th}$) 1 (FCA), at para 28). Further, as discussed above, there is a close connection between ss 6 and 8 of the Regulations. They complement and counterbalance one another in the achievement of the overall equilibrium of the Regulations. In fact, these two

provisions are so closely connected that, generally, one judge will decide both the merits of a prohibition application and, if necessary, the question of damages.

[20] Accordingly, contrary to Apotex's submission, I cannot regard s 8 as creating a free-standing right of action, entirely separate from the s 6 proceedings. Such an interpretation would run counter to the characterizations of the Regulations laid out in the jurisprudence described above. It would, in effect, create a duplicative regulatory alternative to infringement and impeachment actions under the *Patent Act*, one completely disconnected from the rest of the scheme of the Regulations.

[21] In addition, to characterize s 8 proceedings in that way would unfairly expose first persons to allegations that could not have been anticipated when making the decision whether to apply for an order of prohibition under s 6. The prohibition application would have been founded on the issues raised in the original NOA and an assessment of whether they could be shown to be unjustified. It would be anomalous for the first person later to be faced, when assessing damages flowing from the prosecution of that application, with new and unforeseeable challenges. I see nothing in the Regulations that would permit a second person, by way of a s 8 action, to, in effect, serve a fresh NOA on the first person.

[22] It is clear that s 8(5) permits the judge to consider all relevant circumstances in determining the amount of damages. On its face, this provision gives the judge a broad discretion. However, given the relationship between ss 6 and 8, the judge hearing the s 8 action must, in my view, have regard to the issues put in play in the s 6 application. In my view, this means that entirely new allegations of non-infringement or invalidity are not "relevant" for purposes of s 8. The NOA

defined the issues in the s 6 application and, in my view, continues to define the limits of what is relevant for purposes of s 8.

[23] I should point out, however, that Justice Snider concluded that Apotex's allegation of non-infringement was justified on the evidence. On that basis, she denied Pfizer's request for an order prohibiting the Minister from granting Apotex a Notice of Compliance (NOC). That conclusion, though, does not prevent the issue of infringement from being raised before me. Pfizer is entitled, now that Apotex's product is actually on the market and can be tested, to introduce evidence showing that Apotex may have actually infringed the '876 patent. Accordingly, I have received the parties' submissions and evidence on that issue, the details of which are set out below.

[24] Pfizer argues that its infringement evidence is sufficiently strong that it should defeat Apotex' s 8 action entirely, in keeping with the doctrine of *ex turpi causa*. I believe this argument was fully rejected by the Federal Court of Appeal in *Apotex Inc v Merck & Co, Inc,* 2011 FCA 364 [*Lovastatin*]. There, Justice John Evans concluded that Merck's *ex turpi causa* submissions were relevant to the court's exercise of discretion under s 8(5), not Apotex's entitlement to bring an action under s 8(1). He stated that "it is not necessary to read an *ex turpi causa* exception into subsection 8(1) in order to prevent patent infringers from unjustly recovering compensation from a first person" (at para 36). Instead, s 8(5) permits the court to consider all relevant circumstances, including evidence of infringement, in determining whether the second person's damages should be reduced or eliminated (at para 37).

3. Conclusion

[25] Apotex argues that Justice Snider's construction of the patent does not bind me. Further, it contends that s 8 of the Regulations creates a free-standing right of action, unhinged from the other provisions of the Regulations, most particularly s 6.

[26] I cannot agree with Apotex's submissions on these points. In my view, Justice Snider's decision is binding on me by virtue of the concepts of *stare decisis* and judicial comity. Even if that were not so, the overall scheme of the Regulations and the close connection between ss 6 and 8 suggest that the determination of damages flows from the s 6 application, and should be framed by the issues raised and decided in that proceeding. Further, the breadth of the word "relevant" in s 8 must be considered in light of the matters that were put in play in the s 6 application as framed by the NOA. The s 8 action should not be treated as a completely new and open-ended proceeding.

[27] Accordingly, as the original NOA stated that Apotex would not infringe the '876 patent, and made no reference to invalidity, I cannot now consider Apotex's new submissions about the invalidity of the '876 patent. Further, before Justice Snider, the parties agreed that the only claim in issue was claim 1 of the '876 patent, whose essential element she construed simply to be "crystalline azithromycin dihydrate" (AD). Having no strong reasons to conclude otherwise, that is the construction I will adopt.

[28] Apotex argued before me that the '876 patent relates to AD with non-hygroscopic properties that is substantially free of other crystalline forms. Therefore, according to Apotex, the '876 patent

does not cover mixtures of AD and other crystalline forms of azithromycin, any conversion from other crystalline forms of azithromycin to AD, or hygroscopic forms of AD.

[29] In its NOA, Apotex alleged that its tablets would contain azithromycin isopropanolate monohydrate (AIM). Here, Apotex argued that, if there is conversion from AIM to AD in its tablet product, this does not represent infringement of the '876 patent since the invention disclosed in that patent is a non-hygroscopic compound. Conversion from AIM to AD would require the introduction of water to AIM, which would indicate that Apotex's product was hygroscopic and, therefore, not within the '876 patent. Similarly, Apotex argued that the '876 patent does not extend to mixtures of AD with other compounds. Pfizer's evidence, discussed below, indicates that Apotex's product may contain a mixture of AIM and AD. This, Apotex suggests, would not amount to infringement of the '876 patent.

[30] Given the construction of the '876 patent I must apply, these arguments cannot be sustained. As mentioned, I am bound by Justice Snider's construction of the '876 patent and she found that the patent, particularly Claim 1, claims AD pure and simple. Therefore, any AD present in Apotex's product would infringe the '876 patent. Justice Snider also specifically found that any conversion from AIM to AD would amount to infringement. Accordingly, if Apotex's product contains AD, it has infringed the '876 patent and it is either disentitled to relief or its damages should be correspondingly reduced.

[31] In this action, Apotex bears the burden of proving the basis for its claim for damages. Pfizer accepts that it bears the burden of proving its defence of infringement by Apotex. Therefore, the main issues remaining to be determined are:

1. Has Apotex met the conditions for relief under s 8?
2. If so, has Pfizer proved that Apotex would have infringed the '876 patent if it had entered the market without having to invoke the Regulations?

[32] In addition, the following preliminary and procedural issues must be decided:

*(a) Admissibility of Pfizer's 2008 and 2009 tests of Apotex's tablets*

[33] Pfizer scientists carried out tests on Apotex's tablets in 2008 and 2009. Apotex argued that these tests are inadmissible because they constitute opinion evidence not introduced by way of a qualified expert. Apotex also argued that the tests are inadmissible because it was not invited to attend the testing to witness how it was carried out.

[34] Regarding the first objection, in my view, these tests are admissible, but only at face value. In other words, the measurements taken and recorded are admissible. These measurements were made by persons of sufficient skill to perform the tests summarized in the reports (see *AlliedSignal Inc v DuPont Canada Inc* (1998), 78 CPR (3d) 129 (FCTD), at paras 127-131, aff'd (1999), 86 CPR (3d) 324 (FCA)). However, the results have not been interpreted by a qualified expert (except, as discussed below, by Apotex's expert, Dr Michael John Zaworotko, Professor of Chemistry at the

University of South Florida. Dr Zaworotko gave his opinion in cross-examination after having been given only a few minutes to review the test results). Therefore, contrary to Pfizer's submissions, they do not constitute evidence that the tablets tested contained AD. Rather, the reports show results consistent with the possibility that the tablets contained some AD. This evidence is discussed in greater detail below.

[35] As Apotex's second objection also applied to evidence from Pfizer's expert, Dr Jerry Atwood, I will deal with it below.

*(b) Admissibility of Dr Atwood's evidence*

[36] Pfizer relied on the expert opinion of Dr Jerry Atwood, the Curators' Professor and Chairman of the Department of Chemistry of the University of Missouri-Columbia. Apotex argues that the results of Dr Atwood's tests, which were conducted while the litigation between the parties was ongoing, are inadmissible because Apotex should have been given notice and an invitation to witness those tests. This is particularly important, Apotex says, in the context of this case where the main question is whether Apotex's compound underwent a conversion to the patented AD. Conversion can occur in the course of the testing itself – due to heat, stress, or humidity – so it is important to know how the analysis was carried out. As mentioned, Apotex raised the same objection to Pfizer's 2008 and 2009 internal tests of Apotex's tablets.

[37] Apotex relied principally on the case of *Omark Industries (1960) Ltd v Gouger Saw Chain Co* (1964), 45 CPR 169 (Ex Ct) [*Omark*]. *Omark* deals specifically with testing done during the trial

– *pendente lite* (at para 204). Neither Dr Atwood's tests nor those earlier tests of Pfizer were conducted during the trial. As for tests carried out prior to trial, Justice Noël stated that tests conducted in the presence of the other party are "much more probative" than tests conducted *ex parte*. In other words, it is a matter going to weight, not admissibility.

[38] Apotex also relied on two subsequent cases in which tests were excluded based on the rationale in *Omark*. The first is *Merck & Co v Apotex Inc*, [1994] FCJ No 1898 (FCTD) [*Merck & Co*], at para 127, in which Justice Andrew MacKay found that the principle in *Omark* applied to testing both during and before trial. The second is *Halford v Seed Hawk Inc*, [2001] FCJ No 1631 (FCTD) [*Halford*], at paras 33, 37. There, Justice Denis Pelletier ruled inadmissible evidence relating to certain tests that were conducted in the absence of the other party.

[39] It is clear from *Omark* that the results of testing carried out during a trial are inadmissible unless the opposing party has been given an opportunity to witness the tests. The testing in *Omark* and *Merck & Co* was, indeed, conducted during the trial. In *Omark*, the evidence was, in any case, admitted because it related to measurements that could easily have been made by the opposing experts on their own. In *Halford*, however, the testing was done well before the trial.

[40] The rule, or practice, articulated in *Omark* is intended to ensure fairness between the parties (*Merck & Co Inc v Apotex Inc*, 2003 FC 1242, at para 7). Clearly, Apotex knew full well that Pfizer intended to conduct tests of its material. It provided samples to Pfizer for that very purpose. Had it wished to attend Pfizer's tests, Apotex could have asked to do so. Had Pfizer refused, there might well be an issue about the admissibility of Pfizer's tests. However, in these circumstances, where

Apotex had ample notice and knowledge of Pfizer's intentions, Apotex cannot now argue that Pfizer's evidence is inadmissible.

[41] Apotex raises the same objections regarding Pfizer's internal tests, all the more so because those tests were conducted by employees of Pfizer who, unlike independent experts, cannot be presumed to be impartial.

[42] In my view, these test results are also admissible. They were conducted well before trial and, in any case, are admissible only for the limited purpose described above.

## IV. The Factual Background

[43] Apotex served Pfizer with three NOAs in respect of three patents Pfizer had listed on the patent register for its azithromycin product called Zithromax®. In turn, Pfizer began proceedings to prohibit the Minister from issuing an NOC to Apotex. As mentioned, the application in respect of the '876 patent was dismissed by Justice Snider in 2003. A separate application relating to a second patent (No 2,148,071) was dismissed by Justice Richard Mosley in 2005. After receiving Apotex's third NOA in respect of the third patent (No 2,269,054), Pfizer decided not to commence further proceedings. As a consequence, the Minister granted Apotex its NOC on November 1, 2005.

[44] Apotex began this action under s 8 of the Regulations in 2006, seeking compensation for the losses it incurred for having been kept off the azithromycin market while Pfizer's applications were ongoing. As mentioned, Pfizer has defended itself by submitting that Apotex's product infringed the

‘876 patent by containing AD, the subject matter of the ‘876 patent.

[45] The purpose of this proceeding is to determine whether Apotex is entitled to compensation. If so, issues relating to the quantum of that compensation are to be determined in a further proceeding. That includes a determination of the period during which Apotex was kept off the market by virtue of Pfizer’s applications.

[46] The ‘876 patent was issued on March 23, 1993, and expired on March 23, 2010.The parties agree that the skilled person to whom the ‘876 patent is directed would have a bachelor’s degree in chemistry and two or three years’ experience in the field.

[47] As mentioned, the ‘876 patent relates to a crystalline form of azithromycin, a dihydrate version (AD), with non-hygroscopic properties. The patent describes how to make AD through the use of tetrahydrofuran and an aliphatic hydrocarbon as solvents. AD has benefits over the previously-known monohydrate version of azithromycin, whose hygroscopic tendencies made it unstable and difficult to formulate as a pharmaceutical product.

[48] Claim 1 of the ‘876 patent, the principal claim in issue, relates solely to the compound “crystalline azithromycin dihydrate,” to which I have been referring as AD.

[49] Claim 2 claims a method of preparing AD by crystallization from a mixture of tetrahydrofuran and an aliphatic hydrocarbon, in the presence of two molar equivalents of water.

[50] Claim 3 is a variation on Claim 2 in which the hydrocarbon is hexane.

[51] Claim 4 is a further, more detailed variation on Claim 2.

[52] Claim 5 claims a pharmaceutical composition comprising an antibiotic effective amount of non-hygroscopic AD, mixed with a pharmaceutically acceptable diluent or carrier.

## V. Issue One – has Apotex met the conditions for relief under s 8?

[53] Apotex must meet two requirements. First, it must show that Pfizer's application under s 6(1) was dismissed. Second, it must have suffered a loss during the period it was kept off the market by virtue of the Regulations (*Lovastatin*, above, at paras 34-35).

[54] Apotex succeeded in defeating Pfizer's application for an order prohibiting Apotex from obtaining an NOC for AIM. This is sufficient to entitle it to compensation for the loss suffered during the period of time it was kept off the market, from the date on which it would otherwise have been able to obtain an NOC (here August 13, 2003) to the date on which it actually obtained its NOC (November 1, 2006). This entitlement is subject, of course, to Pfizer's submission that Apotex would have entered the market with material that infringed the '876 patent, notwithstanding Justice Snider's conclusion that Apotex's allegation of non-infringement was justified on the evidence before her. That is the main issue.

VI. Issue Two – has Pfizer proved that Apotex would have infringed the '876 patent if it had entered the market without having to invoke the Regulations?

[55] There is no direct evidence that Apotex used any bulk material that contained AD, manufactured any tablets that contained AD, or put into the marketplace any tablets that contained AD. Pfizer's infringement claim is based primarily on inferences to be drawn from tests of bulk material not intended to be used in the manufacture of tablets, and of tablets made from non-infringing material. In my view, this evidence is insufficient to prove infringement by Apotex. I will now summarize and review the various categories of evidence.

1. Pfizer's three internal tests in 2006, 2008, and 2009

[56] In 2006, Pfizer tested Apotex's tablets through Solid State Nuclear Magnetic Resonance Spectroscopy (SSNMR) and reported that they contained 96% AIM, and 4% other azithromycin polymorphs. There was no detectable amount of AD. Dr Zaworotko's opinion is that there were actually no other azithromycin polymorphs in the tablets; rather, the results showed that minor changes in the crystalline structure of AIM caused it to show an SSNMR spectrum similar to other polymorphic forms. Since there were no other solvates present that would suggest a transformation to other polymorphs, there is no evidence that the tablets contained anything other than AIM. Similarly, the isopropanol content was inconsistent with the presence of AD. Other tests – Powder X-Ray Diffraction (PXRD), and infrared spectroscopy – confirmed that there was no AD present.

[57] Dr Zaworotko's opinion was based on his extensive knowledge of crystallography, including the various forms of azithromycin crystals, as well as their structure and characteristics.

[58] Pfizer's in-house scientists also tested some of Apotex's tablets in 2008 and 2009. As mentioned, Apotex objected to this evidence on the grounds that it constituted opinion evidence supplied by non-experts. In my view, this evidence came from experienced scientists who were conducting routine tests. They were not expressing expert opinions. Rather, as skilled persons, they were simply describing the results of tests that fell well within their skill sets to conduct. However, the evidence contained in these reports and in the accompanying testimony amounts merely to the results themselves. There is no opinion evidence before me from Dr Atwood interpreting those results. The only expert opinion on those tests was Dr Zaworotko's, provided after he had been given only a few minutes to review them.

[59] An SSNMR test on an Apotex tablet in 2008 generated results consistent with there being about 30% AD in it, and about 70% AIM or other, similar polymorphs. A PXRD test was also consistent with the presence of some AD, as well as other polymorphic forms of azithromycin. The GC test indicated that the tablet contained 2.1% isopropanol. A Karl Fischer Titration (KFT) test for water content showed 8.7 mg of water per tablet. According to Dr Zaworotko, this data resembled the results obtained by Dr Atwood in his testing of Apotex tablets, as discussed below. His opinion was that the SSNMR and PXRD data was insufficient evidence that AD was present in the tablet. Further, the isopropanol content was consistent with the presence of a polymorph of AIM, not AD.

[60] In 2009, an SSNMR test on another tablet showed results consistent with about 33% AD, and the remainder AIM; a corresponding PXRD test was consistent with the presence of some AD and other azithromycin polymorphs. Again, Dr Zaworotko regarded this test as showing that two crystal forms of azithromycin were present in the tablet, but there was not enough evidence to demonstrate that one of them was AD.

2. Tests of bulk Apotex material

[61] Later tests led to Pfizer's submission in this case that Apotex infringed the '876 patent. In 2012, Pfizer's expert, Dr Atwood, tested 13 lots of Apotex raw material. He conducted an array of analyses – PXRD, SSNMR, KFT, Differential Scanning Calorimetry (DSC), Thermogravimetric Analysis (TGA), and Proton Solution Nuclear Magnetic Resonance Spectroscopy ($^1$H-NMR). He believed that these tests were the most probative, noting that they "overlap, so that one technique will provide confirmation of the results from another technique."

[62] Dr Atwood concluded that nine lots of Apotex raw material consisted mainly of the patented AD, not Apotex's AIM. He labelled these samples as "Group I". The other four, "Group II", consisted of a mix of AD and AIM. He reached his conclusion by referring to the expected values for AD and AIM in the prior art. He was not asked whether the AD he found in Apotex's material was the same AD as patented by Pfizer. However, according to the prior art, AD has a unique crystal structure. Dr Atwood was unaware of any crystalline forms that are isostructural with AD. Accordingly, he opined that the AD in Apotex's material was the same as Pfizer's.

[63] According to Dr Zaworotko, the certificates of analysis of the material that Apotex received from its supplier, Alembic, show that it contained AIM exclusively. That material arrived in bags sealed under nitrogen within sealed drums. Apotex scientists removed four samples from each drum. They tested two samples and set aside two others in case they were needed for future purposes. They placed these samples in screw-cap bottles and then returned the bulk material that was to be used to manufacture tablets to bags sealed under nitrogen within sealed drums.

[64] Apotex's tests, including tests for water content, isopropanol content and PXRD data, consistently showed that the bulk material was AIM and did not contain AD. If the bulk material was stored longer than 30 days before it was put into tablets, Apotex conducted a further test. None of these tests showed the presence of any AD. (I note that some bulk material, when tested, contained too little isopropanol. However, when retested, the isopropanol level in the material fell within the expected range. The most parsimonious explanation for this irregularity, according to Dr Zaworotko, was that a lab error was made on the particular date when the tests for isopropanol were made.)

[65] There is no evidence that water might have been introduced during the tableting process, which could have caused a conversion of AIM to AD. No water was used in the preparation of Apotex's tablets, except during the coating of the tablets, and no water reached the tablets' core. In fact, there is no evidence that there was any conversion of AIM to AD during the manufacturing process.

[66] In 2005, Health Canada raised with Apotex some concerns about the stability of its product and asked for further evidence regarding any conversion of AIM to AD. Apotex responded with evidence of further testing showing no conversion. Health Canada granted Apotex a NOC for its product on November 1, 2005.

[67] Dr Zaworotko's evidence, interpreting the certificates of analysis for Apotex's bulk material, was that the PXRD pattern, in combination with the requisite amounts of isopropanol and water, proves that the bulk material was AIM.

[68] Dr Zaworotko agreed with some of Dr Atwood's findings regarding the bulk material, but disputed whether they showed that Apotex's raw material or tablets actually contained AD. In particular, he noted that Dr Atwood tested raw material that had been stored for several years under less than ideal conditions. Those samples were kept in screw-top bottles whose seal would not be tight enough to prevent an exchange of isopropanol for water, resulting, potentially, in a conversion of some AIM to AD, or to another crystalline form of azithromycin. Pfizer did not ask to test any of Apotex's bulk material that was actually used to manufacture tablets.

[69] Some of the bulk material Dr Atwood tested in 2012 and found to be substantially pure AD had been tested by Apotex in 2007 and 2008 and found to be AIM. This suggests, according to Dr Zaworotko, that it was AIM that was used in the production of Apotex's tablets, while the material that was kept in bottles, and not to be used for manufacture, underwent some form of conversion. Support for this theory lies in the fact that some of the bulk material that Dr Atwood found to contain substantially pure AD was used to manufacture tablets that he concluded only contained a

"detectable" amount of AD. It is likely, therefore, that the poorly stored bulk material underwent some form of transformation but that it was actually pure AIM that was used to make the tablets. A reverse transformation from AD to AIM could not be explained.

[70] While Dr Zaworotko, like Dr Atwood, was aware of only one crystal form of AD, he felt it was likely that the hydrate was polymorphic. Given the promiscuous nature of azithromycin (about two dozen crystal forms are known), one would expect it to form multiple polymorphs, solvates and hydrates. While another dihydrate has not been reported in the literature, that does not mean it cannot, or does not, exist.

3. 2012 tests of Apotex tablets

[71] Dr Atwood tested three lots of Apotex tablets in 2011 and 2012. His PXRD analysis showed that the tablets had peaks common to both Groups I and II of the bulk material, indicating that they contained both AD and AIM. His SSNMR analysis showed that the tablets contained AIM, as well as a detectable amount of AD. His other tests were consistent with the tablets containing AIM. In the Conclusion section of his expert report, Dr Atwood expresses no overall opinion about the content of the tablets, although his summary describes the tablets as mixtures of AD, AIM, and "other compounds with varied ratios of azithromycin, isopropanol, and/or water". His tabular results, the final exhibit to his expert affidavit, describe the tablets as AIM with a detectable (but unquantified) amount of AD.

[72] Dr Atwood agreed that his tests showed the content of the material he tested on the day of the testing in 2012. They did not give direct proof of the tablets' contents at any earlier point in time, including, of course, during the period before the expiry of the '876 patent in March 2010. Therefore, Dr Atwood's tests do not provide direct evidence to support Pfizer's claim of infringement.

[73] Dr Zaworotko disputed Dr Atwood's results, particularly whether Apotex's tablets had been shown to contain AD. Given that azithromycin is known for its tendency to form a variety of polymorph crystals, Dr Zaworotko believes that what Dr Atwood may have detected was a previously unidentified polymorph of AIM, not easily distinguished from AD. The tablets contained a significant amount of AIM and isopropanol, and only a small amount of some other crystal. In fact, the PXRD patterns, SSNMR spectra, and $^{1}$H NMR data for the tablets were consistent with a large quantity of isopropanol in the tablets, which would be inconsistent with any significant transformation to AD. Rather, it is likely that any conversion would be to another crystalline form that, despite a similar PXRD pattern and SSNMR spectrum to AD, is, in fact, a polymorph of AIM or another solvate.

[74] Dr Zaworotko points out that Dr Atwood's opinion does not include any explanation as to how the tablets could acquire water in order to convert to AD. The exchange of isopropanol for water could occur in the bulk material that Dr Atwood tested because it was stored in screw-cap bottles whose seal was permeable. However, that material was not used to make tablets. The bulk material used for manufacture, according to all the evidence, was pure AIM and the tablets

produced were placed into impermeable blister packs. In order for AD to form in the tablets, a source of water would be required.

[75] Again, in Dr Zaworotko's opinion, it is therefore more likely that the transformation observed by Dr Atwood was from AIM to another type of azithromycin, not AD. He also found support for this explanation in Pfizer's own 2006 testing of AIM, in which the analyst noted the presence of other forms of azithromycin, not AD, in Apotex's tablets.

[76] Pfizer tendered no evidence in response to Dr Zaworotko's evidence.

4. Has Pfizer met its burden of proving infringement?

[77] In my view, Pfizer has not established infringement of the '876 patent. The evidence, in summary, amounts to the following:

- The bulk material Apotex used to manufacture tablets did not contain any AD.
- The bulk material that Apotex kept as retained samples, in screw-top bottles, may have contained AD. If it did, the most likely explanation for its appearance was the exchange of isopropanol for water through the permeable cap.
- Tests of tablets reveal that:
    - in 2006, Apotex's tablets contained no AD;
    - in 2008, 2009, and 2012, Apotex's tablets contained AIM and a small amount of another crystal that is probably not AD.

[78] This evidence supports only the *possibility* that Apotex's tablets may have contained some small amount of infringing material before the expiry of the '876 patent. It is insufficient to support

a conclusion, on a balance of probabilities, that Apotex's tablets did contain infringing material. Therefore, Apotex's s 8 claim cannot be defeated entirely, either on the basis that its damages should be reduced to zero under s 8(5), or according to the doctrine of *ex turpi causa*. The evidence before me, however, may be relevant to the amount of compensation that is appropriate under s 8(5), a matter to be determined separately.

## VII. Conclusion and Disposition

[79] Apotex has met the conditions for relief under s 8 of the Regulations. Pfizer has not established that Apotex is disentitled, based either on infringement of the '876 patent or the doctrine of *ex turpi causa*, to compensation for its losses. Therefore, Apotex's claim is allowed with costs; the quantum of compensation will be determined in a subsequent proceeding.

## JUDGMENT

**THIS COURT'S JUDGMENT is that:**

1. The plaintiff's claim for compensation under s 8 of the Regulations is allowed, with costs;

2. The assessment of compensation will be carried out in a subsequent proceeding.

"James W. O'Reilly"

Judge

Annex

*Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133

RIGHT OF ACTION

**6.** (1) A first person may, within 45 days after being served with a notice of allegation under paragraph 5(3)(*a*), apply to a court for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of a patent that is the subject of the notice of allegation.

(2) The court shall make an order pursuant to subsection (1) in respect of a patent that is the subject of one or more allegations if it finds that none of those allegations is justified.

(3) The first person shall, within the 45 days referred to in subsection (1), serve the Minister with proof that an application referred to in that subsection has been made.

(4) Where the first person is not the owner of each patent that is the subject of an application referred to in subsection (1), the owner of each such patent shall be made a party to the application.

(5) Subject to subsection (5.1), in a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application in whole or in part

(*a*) in respect of those patents that are not eligible for inclusion on the register; or

(*b*) on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents.

(5.1) In a proceeding in respect of an application under subsection (1), the court shall

*Règlement sur les médicaments brevetés (avis de conformité)*, DORS/93-133

DROITS D'ACTION

**6.** (1) La première personne peut, au plus tard quarante-cinq jours après avoir reçu signification d'un avis d'allégation aux termes de l'alinéa 5(3)*a*), demander au tribunal de rendre une ordonnance interdisant au ministre de délivrer l'avis de conformité avant l'expiration du brevet en cause.

(2) Le tribunal rend une ordonnance en vertu du paragraphe (1) à l'égard du brevet visé par une ou plusieurs allégations si elle conclut qu'aucune des allégations n'est fondée.

(3) La première personne signifie au ministre, dans la période de 45 jours visée au paragraphe (1), la preuve que la demande visée à ce paragraphe a été faite.

(4) Lorsque la première personne n'est pas le propriétaire de chaque brevet visé dans la demande mentionnée au paragraphe (1), le propriétaire de chaque brevet est une partie à la demande.

(5) Sous réserve du paragraphe (5.1), lors de l'instance relative à la demande visée au paragraphe (1), le tribunal peut, sur requête de la seconde personne, rejeter tout ou partie de la demande si, selon le cas :

*a*) les brevets en cause ne sont pas admissibles à l'inscription au registre;

*b*) il conclut qu'elle est inutile, scandaleuse, frivole ou vexatoire ou constitue autrement, à l'égard d'un ou plusieurs brevets, un abus de procédure.

(5.1) Lors de l'instance relative à la demande visée au paragraphe (1), le tribunal ne peut

not dismiss an application in whole or in part solely on the basis that a patent on a patent list that was submitted before June 17, 2006 is not eligible for inclusion on the register.

(6) For the purposes of an application referred to in subsection (1), if a second person has made an allegation under subparagraph 5(1)(*b*)(iv) or (2)(*b*)(iv) in respect of a patent and the patent was granted for the medicinal ingredient when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent, or by their obvious chemical equivalents, it shall be considered that the drug proposed to be produced by the second person is, in the absence of proof to the contrary, prepared or produced by those methods or processes.

(7) On the motion of a first person, the court may, at any time during a proceeding,

(*a*) order a second person to produce any portion of the submission or supplement filed by the second person for a notice of compliance that is relevant to the disposition of the issues in the proceeding and may order that any change made to the portion during the proceeding be produced by the second person as it is made; and

(*b*) order the Minister to verify that any portion produced corresponds fully to the information in the submission or supplement.

(8) A document produced under subsection (7) shall be treated confidentially.

(9) In a proceeding in respect of an application under subsection (1), a court may make any order in respect of costs, including on a solicitor-and-client basis, in accordance with the rules of the court.

rejeter tout ou partie de la demande pour la seule raison qu'un brevet inscrit sur une liste de brevets présentée avant le 17 juin 2006 n'est pas admissible à l'inscription au registre.

(6) Aux fins de la demande visée au paragraphe (1), dans le cas où la seconde personne a fait une allégation aux termes des sous-alinéas 5(1)*b*)(iv) ou 5(2)*b*)(iv) à l'égard d'un brevet et que ce brevet a été accordé pour l'ingrédient médicinal préparé ou produit selon les modes ou procédés de fabrication décrits en détail et revendiqués dans le brevet ou selon leurs équivalents chimiques manifestes, la drogue qu'elle projette de produire est, en l'absence d'une preuve contraire, réputée préparée ou produite selon ces modes ou procédés.

(7) Sur requête de la première personne, le tribunal peut, au cours de l'instance :

*a*) ordonner à la seconde personne de produire les extraits pertinents de la présentation ou du supplément qu'elle a déposé pour obtenir un avis de conformité et lui enjoindre de produire sans délai tout changement apporté à ces extraits au cours de l'instance;

*b*) enjoindre au ministre de vérifier si les extraits produits correspondent fidèlement aux renseignements figurant dans la présentation ou le supplément déposé.

(8) Tout document produit aux termes du paragraphe (7) est considéré comme confidentiel.

(9) Le tribunal peut, au cours de l'instance relative à la demande visée au paragraphe (1), rendre toute ordonnance relative aux dépens, notamment sur une base avocat-client, conformément à ses règles.

(10) In addition to any other matter that the court may take into account in making an order as to costs, it may consider the following factors:

(*a*) the diligence with which the parties have pursued the application;

(*b*) the inclusion on the certified patent list of a patent that should not have been included under section 4; and

(*c*) the failure of the first person to keep the patent list up to date in accordance with subsection 4(7).

**8.** (1) If an application made under subsection 6(1) is withdrawn or discontinued by the first person or is dismissed by the court hearing the application or if an order preventing the Minister from issuing a notice of compliance, made pursuant to that subsection, is reversed on appeal, the first person is liable to the second person for any loss suffered during the period

(*a*) beginning on the date, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations, unless the court is satisfied on the evidence that another date is more appropriate; and

(*b*) ending on the date of the withdrawal, the discontinuance, the dismissal or the reversal.

(2) A second person may, by action against a first person, apply to the court for an order requiring the first person to compensate the second person for the loss referred to in subsection (1).

(3) The court may make an order under this section without regard to whether the first person has commenced an action for the infringement of a patent that is the subject matter

(10) Lorsque le tribunal rend une ordonnance relative aux dépens, il peut tenir compte notamment des facteurs suivants :

*a*) la diligence des parties à poursuivre la demande;

*b*) l'inscription, sur la liste de brevets qui fait l'objet d'une attestation, de tout brevet qui n'aurait pas dû y être inclus aux termes de l'article 4;

*c*) le fait que la première personne n'a pas tenu à jour la liste de brevets conformément au paragraphe 4(7).

**8.** (1) Si la demande présentée aux termes du paragraphe 6(1) est retirée ou fait l'objet d'un désistement par la première personne ou est rejetée par le tribunal qui en est saisi, ou si l'ordonnance interdisant au ministre de délivrer un avis de conformité, rendue aux termes de ce paragraphe, est annulée lors d'un appel, la première personne est responsable envers la seconde personne de toute perte subie au cours de la période :

*a*) débutant à la date, attestée par le ministre, à laquelle un avis de conformité aurait été délivré en l'absence du présent règlement, sauf si le tribunal estime d'après la preuve qu'une autre date est plus appropriée;

*b*) se terminant à la date du retrait, du désistement ou du rejet de la demande ou de l'annulation de l'ordonnance.

(2) La seconde personne peut, par voie d'action contre la première personne, demander au tribunal de rendre une ordonnance enjoignant à cette dernière de lui verser une indemnité pour la perte visée au paragraphe (1).

(3) Le tribunal peut rendre une ordonnance aux termes du présent article sans tenir compte du fait que la première personne a institué ou non une action pour contrefaçon du brevet visé par la

of the application.

(4) The court may make such order for relief by way of damages or profits as the circumstances require in respect of any loss referred to in subsection (1).

(5) In assessing the amount of compensation the court shall take into account all matters that it considers relevant to the assessment of the amount, including any conduct of the first or second person which contributed to delay the disposition of the application under subsection 6(1).

demande.

(4) Le tribunal peut rendre l'ordonnance qu'il juge indiquée pour accorder réparation par recouvrement de dommages-intérêts ou de profits à l'égard de la perte visée au paragraphe (1).

(5) Pour déterminer le montant de l'indemnité à accorder, le tribunal tient compte des facteurs qu'il juge pertinents à cette fin, y compris, le cas échéant, la conduite de la première personne ou de la seconde personne qui a contribué à retarder le règlement de la demande visée au paragraphe 6(1).

**FEDERAL COURT**

**SOLICITORS OF RECORD**

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| **DOCKET:** | T-825-06 |
| **STYLE OF CAUSE:** | APOTEX INC.<br>v<br>PFIZER CANADA INC. |
| **PLACE OF HEARING:** | Toronto, Ontario |
| **DATE OF HEARING:** | September 4-7; 10-13; 18-19, 2012 |
| **REASONS FOR JUDGMENT AND JUDGMENT:** | O'REILLY J. |
| **DATED:** | May 10, 2013 |

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| | |
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