Federal Court  Cour fédérale

Date: 20191010

Docket: T-1434-14

Citation: 2019 FC 1271

BETWEEN:

PHARMASCIENCE INC.

Plaintiff

and

PFIZER CANADA ULC

Defendant

ORDER AND REASONS

O'REILLY J.:

I. Overview

[1] Since 2004, the Defendant, Pfizer, has held a patent for pregabalin, a pain medication sold under the brand name LYRICA. The plaintiff, Pharmascience, received a Notice of Compliance (NOC) in 2013 allowing it to market a generic version of pregabalin, PMS-pregabalin. Pharmascience had originally attempted to enter the pregabalin market in 2011 but was prevented from doing so when Pfizer sought an order under the Regulations prohibiting the Minister of Health from issuing Pharmascience an NOC (*Patented Medicines (Notice of Compliance) Regulations*, SOR/98-166, as amended SOR/93-133). Pfizer failed in its attempt to

obtain that order. Pharmascience then began this action for damages against Pfizer for the sales it allegedly lost during the period of time when it was kept off the market. Pharmascience relies on s 8(1) of the Regulations (all provisions cited are set out in an Annex).

[2] In response to Pharmascience's action, Pfizer alleges that Pharmascience is disentitled to damages because the hypothetical sales of PMS-pregabalin would have infringed Pfizer's patent. Pfizer alleges that any damages Pharmascience incurred should therefore be reduced or eliminated under s 8(5) of the Regulations, which gives the Court a broad discretion in calculating damages. Pfizer also maintains that Pharmascience should not be allowed to collect damages for improper conduct, namely, patent infringement, that falls within the doctrine of *ex turpi causa*—that a proceeding founded on a claimant's own wrongdoing should not succeed.

[3] In a motion filed on March 25, 2019, Pharmascience seeks a summary trial on the question of whether Pfizer's defence of *ex turpi causa* by reason of infringement is relevant to the assessment of damages. Pharmascience relies on the fact that Pfizer did not sue for infringement after Pharmascience obtained its NOC and evidence that Pfizer would not have done so if Pharmascience had entered the market in 2011.

[4] In addition to disputing the foundation of Pharmascience's motion, Pfizer argues that a summary trial is not the appropriate proceeding in which to decide the extent to which Pharmascience's damages should be reduced; that, it says, should be decided at trial.

[5] In my view, Pharmascience's motion should be granted. Pfizer's defence is not viable.

[6] There are two issues:

1. Can Pfizer assert potential infringement as a basis to reduce or eliminate Pharmascience's damages?
2. Is a summary trial appropriate?

II. Issue One - Can Pfizer assert potential infringement as a basis to reduce or eliminate Pharmascience's damages?

[7] Pfizer's main position is that it had the exclusive right, by virtue of its patent, to make, use, and sell its product. The fact that it did not enforce, and would not have enforced, that right by way of an infringement action does not, Pfizer says, diminish its legal position. The corollary of that proposition, according to Pfizer, is that Pharmascience cannot claim full compensation for hypothetical sales that it would have had no legal right to make.

[8] Pfizer contends that its position is well-supported in case law. In my view, the case law does not buttress Pfizer's position.

[9] Pfizer relies on *Apotex Inc v Merck & Co, Inc*, 2011 FCA 364. There, Merck's application for prohibition under the Regulations had been dismissed. Merck then began an infringement action against Apotex. The trial judge in that action found that some of Apotex's tablets would have infringed the patent, but also that Apotex had available to it a non-infringing process. The Federal Court of Appeal, in reasons authored by Justice John Evans, held that Apotex was entitled to damages for the delay in receiving its NOC, and remitted the calculation of damages to the trial judge. Justice Evans stated that the issue of infringement or *ex turpi causa* was a matter for the exercise of discretion under s 8(5) (para 37, 38).

[10] On redetermination, Justice Judith Snider (*Apotex Inc v Merck & Co, Inc*, 2012 FC 620) found that Apotex would have infringed the patent by making and selling lovastatin by a particular process. Apotex, she said, should not be able to recover damages for the hypothetical sale of lovastatin produced by the infringing process, based on the doctrine of *ex turpi causa*.

[11] It is important to note, however, that Merck had clearly asserted its patent rights by way of its infringement action against Apotex.

[12] Pfizer also points to a decision of Justice Robert Barnes where he dealt with a similar issue: *AstraZeneca Canada Inc v Apotex, Inc*, 2017 FC 726. Justice Barnes reviewed the history of the proceedings before him, noting that at the time of the original s 8 action, AstraZeneca had an outstanding infringement claim against Apotex. In the s 8 action (2012 FC 559), Justice Hughes found that, if AstraZeneca were to succeed in the infringement claim, the presiding judge could factor the s 8 damages into the remedy imposed in that action. Justice Hughes concluded that it would be "unconscionable" to hold up the s 8 proceeding pending the infringement trial. As a result, the issue of infringement was effectively irrelevant to the s 8 action. Justice Hughes' decision was upheld on appeal (2013 FCA 77).

[13] AstraZeneca ultimately succeeded in proving infringement (*AstraZeneca v Apotex*, 2015 FC 322) and it fell to Justice Barnes in 2017 to calculate Apotex's damages pursuant to s 8(5). He concluded that Apotex was not entitled to damages because, given its infringement, it "suffered no loss by being kept out of the marketplace . . ." (para 219).

[14] Again, it was clear that AstraZeneca had asserted its patent rights in its successful infringement claim against Apotex.

[15] Another case on which Pfizer relies is *Apotex Inc v AstraZeneca Canada Inc*, 2018 FC 181. There, Justice George Locke, before his appointment to the Federal Court of Appeal, found that it was undisputed that Apotex's product infringed an AstraZeneca patent, which was ultimately found to be valid (2017 SCC 36). Accordingly, in effect, Apotex was claiming under s 8 "compensation for loss as a result of being prevented from infringing AstraZeneca's valid patent" (para 96). Justice Locke found that the infringement, or *ex turpi causa*, was an important factor within s 8(5) that could not be overlooked. Otherwise, Apotex would be allowed to receive compensation "for profits it never could have rightly made" (para 97).

[16] I note, once again, that AstraZeneca asserted the undisputed question of infringement within the s 8 proceeding.

[17] Pfizer's authorities suggest to me that infringement is a factor that can and should be taken into account in assessing the quantum of s 8 damages, but only where infringement has been asserted and proved, or is not disputed. Otherwise infringement is not relevant to s 8, even when an infringement action is pending. I also note that the issues of infringement and *ex turpi causa* are treated in these cases as being essentially the same thing. The terms are used interchangeably. That is not to say that there can be no difference between them; rather, there is simply no need to distinguish them where the alleged turpitude is patent infringement. For present purposes, therefore, I need not consider them separately.

[18] In my view, the case before me is akin to *Apotex Inc v Sanofi-Aventis*, 2012 FC 553, aff'd 2014 FCA 68, aff'd 2015 SCC 20, on which Pharmascience relies. There, the question at trial was whether Sanofi would have opposed the listing of Apotex's product for certain off-label uses. If not, Apotex could have entered the market for those indications during the relevant period and would be entitled to compensation for any lost sales. Justice Judith Snider found that Apotex would have made sales for the contested indications without any objection from Sanofi. In addition, she noted that if Sanofi believed Apotex was infringing its patents, it could have begun an infringement action. In fact, Sanofi did not commence any infringement suits after Apotex and other generics had entered the market.

[19] At the Federal Court of Appeal, Justice Robert Mainville noted that Sanofi had not enforced its patents or opposed the entry of generics into the market:

> If Sanofi is not enforcing its HOPE patents in the real market, and is allowing the sale of generic versions of ramipril for HOPE indications in the real market without any serious opposition, I fail to understand why the situation should be deemed different in the hypothetical market. To the extent the hypothetical market is intended to reflect the real market, sales in the hypothetical market should be treated in the same way as sales in the real market" (para 133; while Justice Mainville dissented in the Federal Court of Appeal, the majority agreed with him on this point).

[20] An appeal to the Supreme Court of Canada was dismissed: 2015 SCC 20.

[21] The *Apotex v Sanofi* case stands for the proposition that the absence of obstacles to market entry in the real world should prevail in the but-for world; if a generic manufacturer could have made sales without objection from the patentee, those sales should be considered in the calculation of the generic's losses.

[22] Here, that proposition means that Pfizer's non-opposition to Pharmascience's entry into the market in the real world should be reflected in the calculation of damages owed to Pharmascience in the but-for world. In that hypothetical, but-for world, Pharmascience would not have been prevented from marketing and selling its product and it would have suffered losses as a result. Accordingly, Pfizer's defence of *ex turpi causa* by reason of infringement is not legally viable to the issue in these proceedings, the calculation of Pharmascience's damages from being excluded from the pregabalin market.

[23] As has been stated in the case law, including in the *Apotex v Sanofi* case, the but-for world should reflect, to the extent possible, what happened in the real world. The but-for world is not reality, but it is virtual reality. It must take account of what real actors would have done in real-life situations.

[24] The features of the but-for world are frequently determined by asking what would have happened if the patentee had not begun prohibition proceedings. Here, in that scenario, Pharmascience would have entered the market, made sales, and earned profits. Pfizer would not have intervened by way of an infringement action. Potential infringement, therefore, should not now stand in the way of Pharmascience's claim for damages.

[25] In the result, therefore, I find that Pharmascience has shown that Pfizer's defence of *ex turpi causa* by reason of infringement is not relevant to an assessment of Pharmascience's damages. Pfizer cannot assert that defence in this proceeding as a basis to reduce or eliminate Pharmascience's damages.

III. Issue Two – Is a summary trial appropriate?

[26] Pfizer argues that the calculation of damages must be conducted at trial, not on a motion for summary trial. Of course, Pfizer is basing its position on the assumption that alleged infringement by Pharmascience is relevant to damages, a position I have already rejected.

[27] Having been able to conclude, based on the record before me, that Pfizer's putative defence *ex turpi causa* by reason of infringement is not legally relevant in this proceeding, it follows that a summary trial is an appropriate means of making that determination. In addition, deciding the issues in this fashion will obviate the need to hear evidence and arguments on the issues of infringement and invalidity during the damages hearing.

IV. Conclusion and Disposition

[28] Pfizer's defence *ex turpi causa* by reason of infringement is not relevant to the main issue in this action – Pharmascience's claim for damages. A summary trial is an appropriate means of making that determination. Therefore, I will grant Pharmascience's motion, with costs.

ORDER IN T-1434-14

THIS COURT ORDERS that the motion is granted, with costs.

"James W. O'Reilly"
Judge

OTTAWA, ONTARIO
October 10, 2019

Annex

Patented Medicines (Notice of Compliance) Regulations, SOR/98-166, as amended SOR/93-133	*Règlement sur les médicaments brevetés (avis de conformité),* DORS/93-133
Notice of Compliance	Avis de conformité
8 (1) A second person may apply to the Federal Court or another superior court of competent jurisdiction for an order requiring all plaintiffs in an action brought under subsection 6(1) to compensate the second person for the loss referred to in subsection (2).	8 (1) La seconde personne peut demander à la Cour fédérale ou à toute autre cour supérieure compétente de rendre une ordonnance enjoignant à tous les plaignants dans l'action intentée en vertu du paragraphe 6(1) de lui verser une indemnité pour la perte visée au paragraphe (2).
…	[…]
(5) If the Federal Court or the other superior court orders a second person to be compensated for a loss referred to in subsection (2), the court may, in respect of that loss, make any order for relief by way of damages that the circumstances require.	(5) Lorsque la Cour fédérale ou l'autre cour supérieure ordonne que la seconde personne soit indemnisée pour la perte visée au paragraphe (2), elle peut rendre toute ordonnance qu'elle juge indiquée pour accorder réparation par recouvrement de dommages-intérêts à l'égard de cette perte.

FEDERAL COURT

SOLICITORS OF RECORD

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