Federal Court  Cour fédérale

Date: 20140916

Docket: T-2792-96

Citation: 2014 FC 883

Vancouver, British Columbia, September 16, 2014

PRESENT: Prothonotary Roger R. Lafrenière

BETWEEN:

MERCK & CO.,
MERCK FROSST CANADA & CO.,
MERCK FROSST CANADA LTD.,
SYNGENTA LIMITED,
ASTRAZENECA UK LIMITED AND
ASTRAZENECA CANADA INC.

Plaintiffs

and

APOTEX INC.

Defendant

REASONS FOR ORDER AND ORDER

[1] The Defendant, Apotex Inc. (Apotex) has moved for leave to file an amended Responding Statement of Issues.

[2] Apotex wishes to argue before a referee appointed pursuant to Rule 153 of the *Federal Courts Rules* that the Plaintiffs are not entitled to any damages for infringement of their patent because, after issuance of the liability judgment against Apotex and exhaustion of Apotex's appeals, but before the hearing of the damages reference, the Supreme Court of Canada rendered a decision in another proceeding rejecting one of the principles upon which the trial judge relied in finding that the Plaintiffs' patent had been validly issued. Apotex also seeks leave to allege that the Plaintiffs have breached specific provisions of the *Competition Act*, such as to disentitle them to damages.

[3] The motion is opposed by the Plaintiffs on the grounds that the proposed amendments are untimely, prejudicial and disclose no reasonable issue that can be dealt with at this stage of the proceeding.

[4] For the reasons that follow, I conclude that the motion for leave to amend should be dismissed in its entirety.

Facts

(A) *Background*

[5] The facts, gleaned from the pleadings and various judgments referred to by the parties, are summarized below.

[6] The Plaintiffs, Merck & Co. Inc. (Merck US), Merck Frosst Canada & Co., Merck Frosst Canada Ltd. (Merck Canada and collectively, "Merck") and Syngenta Limited, Astrazeneca UK Limited (Astrazeneca UK) and Astrazeneca Canada Inc. (Astrazenca Canada and collectively, "Astrazeneca"), commenced the underlying action against Apotex for infringement of Canadian Letters Patent No. 1,275,350 (the '350 Patent) on December 19, 1996.

[7] The '350 Patent is one of six patents divided out of, and claiming priority from, a single patent application bearing serial number 341,340 (the '340 Application). The '350 Patent was issued pursuant to subsection 36(2) of the operative *Patent Act* RS, c P-4, which provided that a divisional application could (and in some cases must) be filed if the patent application describes and claims more than one invention. Subsection 36(4) allowed divisional applications filed in accordance with subsection 36(2) to claim priority from the date of the relevant patent application.

[8] The '340 Application claimed the invention of a large class of compounds that included enalapril, enalprilat and lisinopril, each of which was asserted to be useful for the stated purpose of treating hypertension. The '350 Patent claimed a smaller class of compounds selected from the larger class in the '340 Application (including lisinopril) and specifically claimed lisinopril itself in Claim 2.

[9] The Plaintiffs alleged in their Statement of Claim, as amended, that Apotex infringed Claims 1, 2 and 5 of the '350 Patent. Apotex in turn counterclaimed alleging invalidity of the '350 Patent.

[10] On July 24, 2000, Madam Prothonotary Roza Aronovitch ordered bifurcation of the issues of liability and damages (the Bifurcation Order) on consent of the parties, so as to leave discovery and the calculation of the quantum of damages or profits to a later time.

(B) *The Liability Trial*

[11] The trial of the liability phase of the action commenced on January 9, 2006 before Mr. Justice Roger Hughes. At the trial, one of Apotex's arguments was that the '350 Patent was void because Merck had breached the fundamental requirement in the *Patent Act* that every patent must disclose a useful invention to the public. More specifically, Apotex claimed that Merck US obtained six patents, including the '350 Patent, in exchange for disclosure of a single invention in the '340 Application.

[12] Apotex argued that, since Merck only disclosed one invention in the '340 Application, it was only entitled to one patent. According to Apotex, the '350 Patent did not disclose a separate invention and was therefore not properly issued pursuant to subsection 36(2) of the *Patent Act*.

[13] In his decision dated April 26, 2006 and reported as *Merck & Co Inc v Apotex Inc*, 2006 FC 524 (CanLII), (2006), 53 CPR (4th) 1 (the Liability Judgment), Mr. Justice Hughes held that Apotex's argument was barred by issue estoppel because it could have been raised in earlier litigation relating to the patent for enalapril, which was also divided out of the '340 Application. Despite this conclusion, he proceeded to consider whether the '340 Application disclosed more than one invention.

[14] Mr. Justice Hughes concluded, albeit with strong reservations, that each claim in the '340 Application disclosed a separate invention. He considered himself bound by two decisions of Mr. Justice Thurlow in the Exchequer Court which were upheld by the Supreme Court of Canada and involved patents similar to the '340 application: *Boehringer Sohn, CH v Bell‑Craig Ltd* [1962] Ex.CR 201; aff'd 1963 CanLII 67 (SCC), [1963] SCR. 410 [*Boehringer*] and *Hoechst Pharmaceuticals of Canada Ltd et al v Gilbert & Company et al* [1965] 1 Ex CR 710; affd 1965 CanLII 52 (SCC), [1966] SCR 189 [*Hoechst*]. Mr. Justice Hughes reasoned as follows at paragraph 116:

> Were I to approach the matter without jurisprudential constraints, I would readily find that the '340 application is directed to but one invention, a class of compounds, of which individual compounds such as lisinopril are but illustrative. However, *Boehringer* and *Hoechst*, supra, oblige me to find otherwise, on the slender basis that there was, in the '340 application not only examples but also specific claims to the individual compounds enalapril, enalaprilat and lisinopril, each of which, on the theory of those cases, is a different invention from the class. A higher court may be persuaded otherwise however, for jurisprudential integrity in this Court, I must find that the '340 application discloses separate inventions to each of the class, to lisinopril, to enalapril and to enalaprilat.

[15] Based on the above findings, and for other reasons, Mr. Justice Hughes rendered judgment declaring the '350 Patent to be valid and infringed by Apotex, awarding damages to the Plaintiffs and directing a hearing to quantify those damages.

(C) *Events Subsequent to Liability Judgment*

(i) Appeal to FCA and Leave to Appeal to SCC

[16] The Liability Judgment was appealed by Apotex to the Federal Court of Appeal. On October 10, 2006, the appeal was dismissed: *Merck & Co Inc v Apotex Inc,* 2006 FCA 323. The Court of Appeal disagreed with Mr. Justice Hughes' finding that Apotex's argument was barred by issue estoppel, but endorsed his reliance on *Boehringer* and therefore upheld the finding that the '340 Application disclosed more than one invention.

[17] Leave to appeal to the Supreme Court of Canada was dismissed on May 10, 2007: *Apotex Inc v Merck & Co Inc* [2006] SCCA No 507.

(ii) Damages Reference

[18] On March 22, 2010, the Plaintiffs filed a requisition to fix the time and place of the Reference, with Merck and Astrazeneca each delivering a Statement of Issues. Apotex filed its responding Statement of Issues on September 7, 2010.

[19] By Order of the Chief Justice dated April 13, 2012, the hearing of the Reference is scheduled to take place on January 12, 2015 for a duration of twenty-five days.

(iii) Teva *v Pfizer*

[20] On April 8, 2012, the Supreme Court of Canada released its decision in *Teva Canada Ltd v Pfizer Canada Inc* [2012] 3 SCR 625 [*Teva*]. The issue before the Court in *Teva* was the sufficiency of the disclosure in a patent claiming a large number of compounds, including the molecule sildenafil, that were allegedly effective for the treatment of erectile dysfunction (the '446 Patent). The claims in the '446 Patent were structured as "cascading claims" where

each claim concerned progressively smaller groups of compounds and the last two claims each related to an individual compound. For example, Claim 1 involved over 260 quintillion compounds: para 73. The ‘446 patent disclosed that one of the claimed compounds had induced penile erection in impotent males during testing but did not disclose which compound had been tested.

[21] Teva had argued at trial that the disclosure in the ‘446 Patent was not sufficient because a person skilled in the art would not know which of the claimed compounds was the useful invention. However, Mr. Justice Michael Kelen in *Pfizer Canada Inc v Novopharm Limited*, 2009 FC 638 and Federal Court of Appeal in *Novopharm Limited v Pfizer Canada Inc*, 2010 FCA 242, relying on the decision in *Boehringer*, both held that each claim in the ‘446 Patent disclosed a separate invention. Since the claim for sildenafil was considered its own invention, the issue of finding the useful invention amid the plethora of claimed compounds did not arise.

[22] The Supreme Court of Canada allowed Teva’s appeal, holding that Teva had established its allegation that the ‘446 Patent was not valid. In addressing the nature of the invention, Mr. Justice Lebel, writing for the Court, stated that the Exchequer Court’s decision in *Boehringer* had been misinterpreted. He went on to say at para 57:

> It does not stand for the proposition that every claim in a patent application is a separate invention. Rather, as Teva points out (A.F., at paras. 106-9), the court in *Boehringer* reached the conclusion that each claim in the patent in question concerned a separate invention only after considering the specification as a whole. The court did not purport to establish a broad proposition that in every case, each claim in a patent application concerns a

> separate invention. Such a proposition would be contrary to the scheme of the Act.

[23] Mr. Justice Lebel made specific reference to the decision of the Federal Court of Appeal on appeal from the Liability Judgment (what he referred to as "*Apotex ACE*") and commented as follows at paras 63 and 64:

> [63] In *Apotex ACE*, the Federal Court of Appeal varied the Federal Court's decision in part, but upheld the conclusion that separate claims disclose separate inventions. However, as I have stated, this broad conclusion is contrary to the provisions of the Act and must be rejected.
>
> [64] It is possible, as in *Boehringer*, for each claim in a patent to disclose a separate invention. Where this issue is raised, however, individual patents must be considered on a case-by-case basis. In my view, the approach Teva advocates for at para. 119 of its factum is useful in this case: ". . . the specification as a whole must be examined to determine whether sildenafil and the other compounds claimed in the patent are linked so as to form a single general inventive concept". This is consistent with this Court's comment in *Consolboard*, at p. 520: "We must look to the whole of the disclosure and the claims to ascertain the nature of the invention and methods of its performance...."

(iv) Virgin v Zodiac

[24] On July 3, 2013, the United Kingdom Supreme Court released its decision in *Virgin Atlantic Airways Limited v Zodiac Seats UK Limited* [2013] UKSC 46 [*Virgin Atlantic*]. In that case, Zodiac Seats UK Limited (Zodiac) was held to have infringed a patent for reclining airline seats held by Virgin Atlantic Airways Ltd. (Virgin). This finding was upheld on appeal and leave to appeal to the Supreme Court was refused. However, after Zodiac's appeal rights expired but before Virgin's damages were assessed, the patent in suit was amended by the European Patent

Office (EPO) on the basis that it was invalid in its original form. The effect of this amendment was that the patent that Zodiac was found to have infringed was deemed to have never existed.

[25] The issue before the UK Supreme Court was whether, during the inquiry as to damages, Zodiac was entitled to contend that there had been no damages because the patent was subsequently amended and Zodiac's seats did not infringe the amended patent. Both concurring judgments held that Zodiac was permitted to rely on the subsequent amendment of the patent (and the invalidity of the unamended patent) despite the fact that the very argument that the EPO relied on to require the patent amendment had been rejected in the UK proceedings.

[26] The UK Supreme Court reasoned that, although Zodiac was potentially bound by cause of action estoppel and/or issue estoppel concerning the invalidity and infringement of the patent over the prior art, and bound by a finding of abuse of process regarding other prior art that it could potentially raise, it was not estopped from relying upon the fact that the patent had been revoked, since that fact was not available at the time of the first decision. Accordingly, the UK Supreme Court held that Zodiac was entitled to rely upon the fact of the patent's amendment in the EPO on the damages inquiry.

[27] As Lord Neuberger noted at para 52, it would be fundamentally unfair to grant damages as if the unamended patent remained valid:

> Absent special factors, principle, fairness and commercial sense support the view that the fact that the patent in issue had been revoked was a point which the alleged infringer should have been entitled to rely on in the assessment…to deny the alleged infringer the ability to raise it would be to give effect to a monopoly right which the patentee never should have had.

Motion to Amend

[28] On January 30, 2014, Apotex filed the present motion for leave to amend its Statement of Issues to argue that the same result as in *Virgin Atlantic* should apply in the present case, as well as to amend paragraph 26 to identify the provisions of the *Competition Act* which Apotex alleges the Plaintiffs have breached. The proposed amendments are reproduced below:

> 3. Hughes J.'s conclusion that the '350 Patent was valid was based upon his application of a principle or rule of law he understood to hold that separate claims in a patent constitute separate inventions distinct from the inventive concept of the patent as a whole.
>
> 4. The 350' Patent issued from an application voluntarily divided out of the parent '340 application ("340 Application"). The '340 Application claimed the invention of a large class of compounds that included enalpril, enalprilat and lisinopril, each of which was asserted to be useful for the stated purpose of treating hypertention. The '350 Patent claimed a smaller class of compounds selected from the larger class in the '340 Application in claim 1, including lisinopril, and specifically claimed lisinopril itself in claim 2.
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> 5. Hughes J. determined that there was nothing in the '340 Application to suggest that the class of compounds claimed in the '350 Patent, including lisinopril, constituted a separate invention distinct from the class claimed in that application. Hughes J. concluded that the inventors of the '350 Patent had only made a single invention that was directed to all the compounds claimed in the '340 Application.
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> 6. However, Hughes J. felt bound by judicial precedent to hold that the subject matter of each of the claims of the '350 Patent constituted discrete inventions. But for the principle or rule of law he felt bound to apply, Hughes J. would have found that the subject matter of the '350 Patent did not constitute an invention distinct from the invention of the class of compounds claimed in the parent '340 Application, and which comprised the subject matter of Canadian Letters Patent Nos. 1,275,349, 1,300,313 and 1,308,313, all of which issued to the Plaintiff, Merck & Co. Inc.
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> 7. The Court of Appeal upheld Hughes J. decision that each claim constituted a separate invention and thus that the '350 Patent monopolized the specific class of compounds it claimed including lisinopril, as a separate invention distinct from the invention of the larger class of compounds claimed in the '340 Application.
>
> …

10. During the pendency of this phase of the action addressing the Deferred Issues, the Supreme Court of Canada released its judgment in *Teva Canada Ltd v Pfizer Canada Inc* (2012 SCC 60) ("*Teva*"). In *Teva*, the Supreme Court of Canada determined that there is no rule of law which holds that separate claims in a patent constitute separate inventions distinct from the inventive concept of the patent as a whole. In reaching that conclusion, the Supreme Court of Canada explicitly referred to the Liability Judgment, and unequivocally rejected the principle that both Hughes J. and the Court of Appeal had relied upon in concluding that the '350 Patent had been validly issued.

11. As a consequence of the Supreme Court of Canada's decision in *Teva*, and the decision of the UK Supreme Court in *Virgin Atlantic Airways Ltd v Zodiac Seats UK Ltd* 2013 UKSC 46 (*"Virgin"*), the legal and factual foundation of this enquiry concerning the Deferred Issues no longer exists. In *Virgin*, the UK Supreme Court determined that where, subsequent to a finding of patent infringement but prior to the rendering of a money judgment in respect thereof, the underlying patent is invalidated, there is no basis to recover damages for infringement.

12. Apotex states that the same result should apply in the within case. The inquiry in respect of the Deferred Issues is premised on the existence of a validly issued patent comprising an invention distinct from the invention of the entire class of compounds claimed in the '340 Application. Apotex states as a fact that, since the decision of the Supreme Court of Canada in *Teva* has determined that the only basis for holding that the '350 Patent could have been lawfully granted is wrong in the law, the Plaintiffs could not and did not suffer any damage as a result of any activities of Apotex.

13. In the alternative, any inquiry into the damages allegedly suffered by the Plaintiffs must take into account the fact that the subsequent decision of the Supreme Court in *Teva* has determined that the invention claimed in the '350 Patent could not form the subject matter of a separate patent at the time of the alleged infringement. It is trite law that a patent that has been determined to be invalid is void *ab initio*, and a patent that should not have been granted cannot have been infringed. As a matter of law and equity, the Plaintiffs should not be rewarded by any measure of damages that does not take into account the fact that the patent in question could not have been infringed when the activities of Apotex that form the basis of the Deferred Issues inquiry were carried out.

…

> 26. Apotex states that the Plaintiffs agreed whether tacitly or overtly, not to compete in the Lisinopril market in Canada so as to maintain an artificial price for their Lisinopril, in contravention of section 45, 47 and 61 of the *Competition Act* in force at all material times. Accordingly, by reason of their anti-competitive behaviour, they are each disentitled from claiming damages, or in the alternative, are disentitled from claiming damages at the profit margin calculated based on the selling prices maintained by the Plaintiffs.

Status of the Proceeding

[29] At the time Apotex's motion was brought, oral and documentary discovery for the purpose of the reference on damages was ongoing. Second round examinations for discovery were completed, however, answers to undertakings given at these examinations had yet to be exchanged and motions to compel questions refused or taken under advisement had yet to be scheduled.

[30] Over the course of the discovery process, the claim being advanced by the Plaintiffs was particularized as follows:

(a) The lost profits that AstraZeneca Canada and Merck Canada would have earned on the sales of the additional lisinopril containing products;

(b) AstraZeneca U.K.'s lost profits on the sales of bulk lisinopril and lisinopril tablet formulations to AstraZeneca Canada;

(c) AstraZeneca U.K.'s lost royalty income from the toll manufacturing of bulk lisinopril by a subsidiary;

(d) The portion of additional dividends representing the lost profits from additional sales of bulk lisinopril by Merck's Irish manufacturing facility to Merck Canada;

(e) The royalties Merck U.S. says would have been earned by a subsidiary on the sales of Merck Canada's Prinivil products, and AstraZeneca Canada's Zestril products, from their respective "replacement" sales;

(f) The difference in the price Merck Canada would have charged for its Prinil and Prinzide products but for the presence of Apotex's lower-priced infringing products ("price suppression"); and

(g) A reasonable royalty on Apotex's exports of infringing lisinopril formulations.

[31] Although the Plaintiffs have not quantified their respective claims for damages, it is expected to total several hundred million dollars. Apotex disputes the Plaintiffs' entitlement to, and the alleged quantum of, the alleged heads of damages described above.

Principles Governing Motions for Leave to Amend

[32] The hearing of the Apotex's motion consumed the best part of two days. Much of the argument centered on the role and the limits of the discretion of the Court on a motion for leave to amend under Rule 75 of the *Federal Courts Rules*.

[33] The parties agree that the basic principle of amendment remains that set out in *Canderel Ltd v Canada* (1993), 1993 CanLII 2990 (FCA), [1994] 1 FC 3, 157 NR 380 (CA) [Canderel]. Leave to amend should be allowed for the purpose of determining the real questions in controversy between the parties, provided that it would serve the interests of justice, and that allowing the amendment would not result in an injustice to the other party not capable of being compensated by an award of costs.

[34] It is also common ground between the parties that an amendment must be refused if it would not survive a motion to strike. A claim will only be struck if it is plain and obvious, assuming the facts pleaded to be true, that the pleading discloses no reasonable cause of action: *Odhavji Estate v Woodhouse*, 2003 SCC 69 (CanLII), 2003 SCC 69, [2003] 3 SC. 263, at para 15; *Hunt v Carey Canada Inc*, 1990 CanLII 90 (SCC), [1990] 2 SCR 959, at p 980.

[35] In *R v Imperial Tobacco Canada Ltd*, 2011 SCC 42 (CanLII), 2011 SCC 42 [*Imperial Tobacco*] at para 21, the Supreme Court of Canada reminded lower courts that motions to strike should be a "tool that must be used with care" in order to allow the law to naturally evolve. Apotex submits that the same cautious approach should be taken by the Court when dealing with a motion for leave to amend. According to Apotex, the case will only be beyond doubt if the proposed amendment has no "possible prospects of success" because it is "so incontestably bad" and "devoid of any merit" that it does not advance an argument that is even worth considering. I disagree that the bar should be set so low.

[36] One of the Court's functions is to act as gatekeeper and to ensure that its resources are utilized fairly, with a view towards judicial economy so that meritorious claims can be dealt with in an efficient manner. This means adopting a robust approach to the striking of pleadings which do not have a reasonable chance of success, as was reinforced by the Supreme Court of Canada in *Imperial Tobacco*, at paras 19-20:

> [19] The power to strike out claims that have no reasonable prospect of success is a valuable housekeeping measure essential to effective and fair litigation. It unclutters the proceedings, weeding out the hopeless claims and ensuring that those that have some chance of success go on to trial.
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> [20] This promotes two goods -- efficiency in the conduct of the litigation and correct results. Striking out claims that have no reasonable prospect of success promotes litigation efficiency, reducing time and cost. The litigants can focus on serious claims, without devoting days and sometimes weeks of evidence and argument to claims that are in any event hopeless. The same applies to judges and juries, whose attention is focused where it should be -- on claims that have a reasonable chance of success… .

[37] This trend towards simplifying proceedings as soon as it is reasonable and fair was reiterated by the Supreme Court of Canada in *Hryniak v Mauldin*, 2014 SCC 7, a summary judgment case calling for "a culture shift...in order to create an environment promoting timely and affordable access to the civil justice system...moving the emphasis away from the conventional trial in favour of proportional procedures tailored to the needs of the particular case." Striking pleadings or denying amendments that have no reasonable prospect of success is consistent with this new culture.

[38] In determining whether a novel claim has a "reasonable prospect" of success, many factors must be examined. The clarity of the factual pleadings is important, as well as the existence of case law discussing the same or similar causes of action is relevant. The courts must be careful not to inhibit the development of the common law by applying too strict a test to novel claims. However, as was stated by the Alberta Court of Appeal in *O'Connor Associates Environmental Inc v MEC OP LLC*, 2014 ABCA 140: "the courts must resist the temptation to send every case to trial, even if some legal analysis is needed to determine if a claim has any reasonable prospect of success…". The courts accordingly have a duty to carefully assess the reasonableness or viability of a plea and separate the wheat from the chaff.

[39] Pleadings may also be struck on the basis of other enumerated grounds under subsection 221(1) of the *Federal Courts Rules*. These include pleadings that would prejudice and delay the fair trial of the action. The same considerations apply to proposed amendments.

ANALYSIS

[40] It is axiomatic that the onus on a motion for leave to amend remains on the moving party to persuade the Court that there is a "reasonable prospect" that the claim or defence will succeed.

[41] According to Apotex, the Supreme Court of Canada in *Teva* rejected the alleged rule of law applied by Mr. Justice Hughes in the Liability Judgment and upheld by the Federal Court of Appeal, holding that it would be contrary to the scheme of the *Patent Act*. In its proposed amended Statement of Issues, Apotex seeks to plead facts that it claims are relevant to the assessment of the Plaintiffs' damages. Apotex maintains that its pleading is consistent with the

UK Supreme Court's recent decision in *Virgin Atlantic* where the defendant was permitted to raise the revocation of the patent in answer to the damages assessment notwithstanding that the patent had been found to be valid and infringed.

[42] Apotex submits that it should be permitted to assert that the same result as in *Virgin Atlantic* should apply in this case. The fact that the Supreme Court of Canada specifically rejected the legal foundation of the Liability Judgment that the '350 Patent was properly issued goes to the frailties of the '350 Patent and is said to be relevant to any assessment of what the Plaintiffs actually lost as a result of the infringement found at trial.

[43] Apotex seeks leave to argue before the Referee that the legal conclusion of the Supreme Court of Canada in *Teva* should be a factor considered in quantifying the Plaintiff's claim for damages. Apotex wishes to assert that, in fixing a just and appropriate award, it would be improper for the Referee not to take into account all the circumstances with regard to the '350 Patent. Apotex submits that the key principle in *Virgin Atlantic* is that a court tasked with assessing damages should not blind itself to subsequent events relevant to the patent at issue and should instead consider all relevant circumstances to avoid an absurd result.

[44] No matter how Apotex couches its argument, the essence of the proposed amendments constitutes a collateral attack on Mr. Justice Hughes' ruling that the '350 Patent is valid and infringed by Apotex. The issue of the patent's validity has been finally adjudicated in the Plaintiff's favour. By the proposed amendments, Apotex seeks to do an end run around the

Liability Judgment, which was appealed unsuccessfully all the way to the Supreme Court of Canada.

[45] Both *res judicata* (also known as estoppel by *res judicata* or cause of action estoppel) and issue estoppel prevent Apotex from re-opening the question of the validity of the '350 Patent as the same question was finally determined as between the parties: *Danyluk v Ainsworth Technologies Inc* [2001] 2 SCR 460 at 489-90.

[46] The law as to *res judicata* is well stated by Middleton J.A. of the Ontario Court of Appeal in *McIntosh v Parent* [1924] 4 DLR 420, at p 422:

> "When a question is litigated, the judgment of the Court is a final determination as between the parties and their privies. Any right, question, or fact distinctly put in issue and directly determined by a Court of competent jurisdiction as a ground of recovery, or as an answer to a claim set up, cannot be re-tried in a subsequent suit between the same parties or their privies, though for a different cause of action. The right, question, or fact, once determined, must, as between them, be taken to be conclusively established so long as the judgment remains.

[47] The doctrine of issue estoppel has consistently been applied by the courts, including in *Virgin Atlantic*, at para 27:

> If this case is to be determined according to these general principles of the modern law, there can, I think, be little doubt about the answer. The Court of Appeal decided, before the result of the opposition proceedings in the EPO, that in its unamended form the patent was valid and infringed. It follows that Zodiac are estopped from asserting on the enquiry as to damages that in its unamended form the patent was invalid or was not infringed. This estoppel is a true cause of action estoppel. The Court of Appeal has determined in favour of Virgin issues essential to the existence of the cause of action for infringement of the unamended patent, which are the basis of the claim for damages.

[48] The same reasoning would apply in the present case. All questions of fact, law and mixed fact and law from the decision of Mr. Justice Hughes, as affirmed by the Federal Court of Appeal, are *res judicata* and Apotex is estopped from asserting otherwise.

[49] I agree with the Plaintiffs that whether the Supreme Court subsequently changed the law upon which the Liability Judgment was based is irrelevant. A change in the law is not a sufficient basis to re-open previously decided cases: *Regie des rentes du Quebec v Canada Bread Company Ltd*, 2013 SCC 46 at para 55, *AB Hassle v Apotex Inc*, 2008 FC 184 at paras 39-40, aff'd 2008 FCA 416, *Metro Can Construction Ltd v Canada*, 2001 FCA 227 at paras 4-5.

[50] Special circumstances may operate to restrict the application of the issue estoppel rule, and allow a party to re-litigate what would, absent those special circumstances, be estopped: *Apotex Inc v Merck & Co*, 2002 FCA 210 at para 29. However, no special circumstances have been pleaded by Apotex in its proposed amendments.

[51] Apotex places great reliance on *Virgin Atlantic*. The decision is based, however, on a peculiar aspect of European patent law which has no parallel in Canada.

[52] The United Kingdom is subject to a unique patent regime where two independent bodies, the English Courts and the EPO, both have jurisdiction over European patents. Virgin sued Zodiac in the UK for infringing its European patent for airplane seats. The English Court of Appeal held the patent valid and infringed. The Technical Board of Appeal (TBA) of the EPO, a body independent of the United Kingdom Courts but having parallel jurisdiction over European

patents, which also apply in the UK, subsequently ruled that the same patent was invalid *in rem* and amended it, also with *in rem* and retrospective effect.

[53] The UK Supreme Court concluded that there were two related reasons why Zodiac could not be precluded from relying on the decision of the TBA on the enquiry as to damages. One was that Zodiac was relying on the more limited terms of a different patent which, by virtue of the decision of the TBA, had to be treated at the time of the enquiry as the only one that has ever existed. The other was that Zodiac was not seeking to reopen the question of validity determined by the Court of Appeal. Zodiac was relying on the mere fact of amendment, not on the reasons why it happened. Because the EPO had jurisdiction to amend the patent with retrospective effect, the amendment was a new fact, which the English Court was obliged to recognize. Nothing in *Virgin Atlantic* affects Canadian patent law or the doctrine of *res judicata*.

[54] Apotex suggests that, in light of the *Teva* decision, Mr. Justice Hughes would have ruled that the ‘350 Patent is invalid as an improper divisional. However, such a result is speculation, at best. Mr. Justice Hughes ruled that even if the ‘350 Patent had been improperly divided from the parent ‘340 application, this was not a ground of invalidity. Nothing in *Teva* changes the law on divisional patents and nothing in *Teva* affects the validity of the ‘350 Patent or the liability of Apotex for its infringement.

[55] Try as it might, Apotex cannot escape the fact that it is bound by the Liability Judgment. The only issue remaining to be determined in the present proceeding is the quantum

of damages which Apotex must pay because of its violation of the Plaintiffs' intellectual property rights.

[56] The Referee's mandate is to assess the quantum of damages owing on the basis that the '350 Patent is valid and has been infringed as has been finally determined by this Court. The Referee has no authority to decide otherwise as the scope of a Reference is strictly limited by the terms of the referring order: *Society of Composers, Authors & Music Publishers of Canada v 960122 Ontario Ltd*, 2003 FCA 256 at paras 21-22. Moreover, the Referee may not vary or broaden the terms of the Reference as delineated by the referring court.

[57] Even if it were open to Apotex to now seek a declaration regarding the validity of the '350 Patent, a damages reference is not the appropriate forum to do so. To allow such issues to be raised at this time would essentially convert the Reference into a reconsideration of the matters that have been finally adjudicated as between the parties.

[58] For the above reasons, the proposed amendments should not be allowed on the grounds that they constitute an improper collateral attack of the Liability Judgment, including the validity of the '350 Patent and the Plaintiffs' entitlement to damages. It is plain and obvious that Apotex's proposed amendments disclose no issue that is relevant to determining the quantum of damages. Alternatively, the Referee has no jurisdiction to entertain such questions.

[59] The additional proposed amendments to allege a criminal violation of the *Competition Act* must suffer the same fate, but for different reasons.

[60] Apotex seeks a declaration from the Referee that the Plaintiffs have acted "in contravention of subsection 45, 47 and 61 of the *Competition Act*". Apotex is effectively seeking a declaration from the Referee that the Plaintiffs have engaged in price-fixing (section 45) and bid-rigging (section 47). Apotex submits that the Plaintiffs' contravention of the *Competition Act* is a factor to be considered in assessing the Plaintiffs' damages. I disagree.

[61] The fact that the Plaintiffs did not move to strike the allegations of anti-competitive behaviour as they presently stand in Apotex's Statement of Issues does assist Apotex. The onus remains on Apotex to establish that it is just and appropriate to amend the allegations.

[62] I agree with and adopt the objections raised by the Plaintiffs at paras 70 to 74 of their Outline of Argument filed on April 3, 2014. Beyond the fact that the plea is deficient, the claim appears to be statute-barred. In any event, whether there has been a violation of the *Competition Act* requires the determination of a legal question which ought properly be brought by way of action under section 36 of the *Act*. The allegations certainly cannot be grafted onto a damages reference.

[63] I should also add that no explanation has been provided why Apotex is seeking to make such serious allegations against the Plaintiffs at this late stage of the proceeding. If the amendments were allowed, discoveries would have to be re-opened, with the attendant delays, which may place the hearing dates of the reference in jeopardy. Any further delay in this 18 year old case would work a serious prejudice to the Plaintiffs.

[64] In the circumstances, I do not consider it in the interests of justice to grant leave to amend paragraph 26 of the Statement of Issues.

CONCLUSION

[65] For the above reasons, I conclude that leave to amend Apotex's Responding Statement of Issues should be denied.

[66] Finally, at the conclusion of the hearing, counsel agreed that costs fixed in the amount of $5,000.00 should be awarded to any party that was entirely successful on the motion. In the circumstances, costs shall be granted to the Plaintiffs.

ORDER

THIS COURT ORDERS that:

1. The motion is dismissed.

2. Costs of the motion, hereby fixed in the amount of $5,000.00, inclusive of disbursements and taxes, shall be paid by the Defendant to the Plaintiffs.

"Roger R. Lafrenière"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-2792-96
STYLE OF CAUSE:	MERCK & CO., MERCK FROSST CANADA & CO., MERCK FROSST CANADA LTD., SYNGENTA LIMITED, ASTRZENECA UK LIMITED AND ASTRAZENECA CANADA INC. v APOTEX INC.
PLACE OF HEARING:	TORONTO, ONTARIO MONTRÉAL, QUEBEC
DATE OF HEARING:	MARCH 14, 2014 APRIL 7, 2014
REASONS FOR ORDER AND ORDER:	LAFRENIÈRE P.
DATED:	SEPTEMBER 16, 2014

APPEARANCES:

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