CITATION: Apotex Inc. v. Eli Lilly Canada Inc., 2021 ONSC 1588
COURT FILE NO.: CV-13-492419
DATE: 20210308

SUPERIOR COURT OF JUSTICE - ONTARIO

RE: APOTEX INC. and APOTEX PHARMACHEM INC., Plaintiffs

AND:

ELI LILLY CANADA INC., ELI LILLY AND COMPANY, ELI LILLY AND COMPANY LIMITED and ELI LILLY SA, Defendants

BEFORE: Paul B. Schabas J.

COUNSEL: Nando De Luca and Jerry Topolski, for the Plaintiffs

Marc Richard, Alex Gloor and Rebecca Stiles, for the Defendants

HEARD: December 3 and 4, 2020

REASONS FOR JUDGMENT

Introduction

[1] This is a motion for summary judgment brought by the defendants Eli Lilly Canada Inc. and related companies (collectively "Lilly") seeking to dismiss the action issued against them by the plaintiffs Apotex Inc. and Apotex Pharmachem Inc. ("Apotex"). Lilly submits that the action is barred by operation of the *Limitations Act, 2002*, S.O. 2002, c. 24, Sched. B. Alternatively, Lilly argues that Apotex is seeking relief for alleged harm beyond what is permitted by the *Patent Act*, R.S.C, 1985, c. P-4, and Regulations passed under it, which contain a regulatory scheme addressing the circumstances of this case, and that any damage caused to Apotex was due to operation of law, not actions by Lilly.

[2] The issues on this motion call on this Court to assess the merits of a position Apotex has been taking in a number of cases over the past decade. A manufacturer of generic drugs, Apotex has been alleging in several actions against innovator companies, including Lilly, that if a patent has, by operation of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 ("*PM(NOC) Regulations*"), kept Apotex out of the market, but the patent has subsequently been found invalid and void *ab initio*, then Apotex should be entitled to damages at common law and pursuant to the Ontario and English *Statutes of Monopolies*.[1] Additionally, as in this case, Apotex has also claimed damages under the

[1] *An Act concerning Monopolies, and Dispensation with penal laws, etc*., R.S.O. 1897, c. 323 (the Ontario *Statute of Monopolies*) and *An Act concerning Monopolies and Dispensation with Penal Laws, and the Forfeitures thereof*, 1624, 21 Jac. I, c.3 (the English *Statute of Monopolies*).

Trademarks Act, R.S.C. 1985, c. T-13, for false and misleading statements made by Lilly and other innovators in reliance on their patents when utilizing the *PM(NOC) Regulations.*

[3] Motions to strike these claims, which are novel, have largely been unsuccessful due to the low test the plaintiff must meet to defeat a motion to strike under Rule 21 of the *Rules of Civil Procedure*, R.R.O. 1990, Reg. 94, as judges have recognized that novel claims that are not obviously doomed to failure should be determined on a full record, which is usually at a trial.

[4] In this case, Apotex has sued Lilly for damages, including treble damages pursuant to the *Statutes of Monopolies*, arising from Lilly's patent for a drug called Olanzapine which was issued in 1998. Apotex seeks damages arising from Lilly registering its patent pursuant to the *PM(NOC) Regulations* and Lilly's subsequent commencement and pursuit of proceedings in the Federal Court of Canada pursuant to the *PM(NOC) Regulations*, which between 2006 and 2009 delayed the ability of Apotex to market its generic version of Olanzapine, known as Apo-Olanzapine. Although Lilly was successful in defending its patent in the proceedings against Apotex, in separate proceedings by another generic company, Novopharm Limited ("Novopharm"), in 2011 Lilly's patent was declared to be invalid, causing Apotex to eventually commence this action for damages in 2013.

[5] For the reasons that follow, the motion for summary judgment is granted. I conclude that summary judgment is appropriate in this case where there are few, if any, facts in dispute. Apotex is presumed to have put its best foot forward to justify its claims, and in my view a trial judge will be in no better position than I am to decide the issues.

[6] While I find that the action is not barred by the *Limitations Act, 2002*, I conclude that to the extent Apotex was kept out of the market, this was due to the operation of the *PM(NOC) Regulations* when Lilly was acting lawfully, pursuant to a patent issued in accordance with the *Patent Act*. In invoking the *PM(NOC) Regulations* Lilly relied on an existing patent which was presumed to be valid. Its actions were authorized by law, as Lilly was simply using the regulatory scheme established to address disputes over patents involving pharmaceutical drugs. The *Patent Act* and the *PM(NOC) Regulations* reflect a balancing of interests between protecting innovators and the public interest in allowing less expensive drugs to be available to the public. Patent law is "wholly statutory" and the Act and Regulations provide a complete code governing the issuance and use of patents, including available remedies when patents have been infringed and when they have been found to be invalid.

[7] The monopolies claim, in my view, has not merit. When it was enacted almost 400 years ago, the English *Statute of Monopolies* specified that the prohibition on monopolies did not apply to patents for new inventions. This is also the case in the Ontario *Statute of Monopolies*. Further, even if the patent could have authorized an unlawful monopoly, as it has now been declared invalid and void *ab initio*, Lilly is deemed to have never been granted a licence, patent or monopoly that is prohibited by the *Statutes of Monopolies*.

[8] I also conclude that Lilly has committed no wrongdoing that would give rise to liability under the *Trademarks Act* or at common law. Apotex led no evidence to support such

claims other than the facts that Lilly sought and obtained a patent for Olanzapine, and then invoked the *PM(NOC) Regulations* as it was entitled to do when it held that patent. Lilly did not engage in any unlawful conspiracy or make any false or misleading statements.

[9] Consequently, I am satisfied that there are no genuine issues requiring a trial, and I dismiss the action.

Background Facts

The 113 Patent and the Apotex Prohibition Proceedings

[10] On April 24, 1991, almost 30 years ago, Lilly filed an application for a patent for the drug Olanzapine, which was assigned the Patent Number 2041113 (the "113 Patent"). The drug, marketed by Lilly under the brand name ZYPREXA, was first approved for sale in Canada in 1996. Following a review of the application, on July 14, 1998 the 113 Patent was granted by the Commissioner of Patents pursuant to s. 27(1) of the *Patent Act*. It included 22 claims for exclusivity, including use of Olanzapine for the treatment of schizophrenia, anxiety and related disorders.

[11] Later in July 1998 Lilly filed a "Form IV: Patent List – Pertaining to Patented Medicines" pursuant to the *PM(NOC) Regulations* listing the 113 Patent with Health Canada (the "Form IV"). The Form IV identified the drug Olanzapine, marketed by Lilly under the brand name ZYPREXA, referred to the patent number, and described the therapeutic use of the drug as well as some other features, such as the dosage form and strength per unit. As a result, the drug was listed on the Patent Register maintained by the Minister of Health. The effect of this listing was that if another drug maker sought approval for a generic drug copying Olanzapine, the Minister of Health was prohibited from issuing a Notice of Compliance ("NOC") approving it for sale until the maker of the new drug addressed the 113 Patent, or until the patent expired, which would occur 20 years after the date of the application, on April 24, 2011.

[12] In December 2004 Apotex filed an Abbreviated New Drug Submission ("ANDS") with the Department of Health seeking approval of its generic drug, Apo-Olanzapine. In doing so Apotex relied on Lilly's submission for ZYPREXA and was required to address any patents listed on the Patent Register in respect of ZYPREXA.

[13] Following the procedures in the *PM(NOC) Regulations*, in December 2004 and March 2005 Apotex served notices on Lilly alleging that the 22 claims in the 113 Patent were invalid. The notice sent to Lilly dated December 16, 2004, signed by Dr. Bernard Sherman for Apotex, is approximately 140 pages long, and provides detailed factual and legal arguments in support of Apotex's allegations that all of the claims in the 113 Patent were "invalid, void and of no effect." In response, in January and May 2005, pursuant to the *PM(NOC) Regulations*, Lilly commenced proceedings in the Federal Court of Canada seeking orders prohibiting the granting of an NOC to Apotex for Apo-Olanzapine on the grounds that Apotex's allegations of invalidity were not justified (the "Apotex Prohibition Proceedings").

[14] The commencement of the Apotex Prohibition Proceedings meant that Apotex could not obtain an NOC for Apo-Olanzapine unless the proceedings, which were required to be concluded within 24 months, were determined in favour of Apotex. This is described as the "statutory stay" or "patent hold." As a result, although Apotex was advised on June 28, 2006 that Apo-Olanzapine was approved by the Minister of Health, it was denied an NOC due to the ongoing Apotex Prohibition Proceedings. Apotex claims it began to suffer damages on June 28, 2006, by being prevented from marketing its drug.

[15] Following a seven-day hearing, on April 27, 2007 Gauthier J. rejected Apotex's invalidity allegations: *Eli Lilly Canada Inc. v. Apotex Inc.*, 2007 FC 455. As required by s. 6(2) of the *PM(NOC) Regulations*, Gauthier J. issued an Order prohibiting the Minister from issuing Apotex an NOC (the "Gauthier Order"), effectively continuing the statutory stay or patent hold.

[16] An appeal of the April 27, 2007 decision of Gauthier J. was dismissed by the Federal Court of Appeal on February 5, 2008: *Apotex v. Eli Lilly*, 2008 FCA 44.

The Novopharm Proceedings

[17] At the same time as it was pursuing the Apotex Prohibition Proceedings, Lilly was also dealing with a challenge to the 113 Patent by Novopharm, which wished to obtain an NOC to market its version of Olanzapine, known as Novo-Olanzapine. Novopharm served its notice of allegations against the 113 Patent on June 20, 2005, and Lilly responded by commencing proceedings in the Federal Court pursuant to the *PM(NOC) Regulations* (the "Novopharm Prohibition Proceedings").

[18] In the Novopharm case, however, Lilly was not successful. In a decision by Hughes J. dated June 5, 2007 (less than two months after Gauthier J. ruled for Lilly against Apotex), the Court found that Lilly had not demonstrated that Novopharm's invalidity allegations were not justified and, accordingly, dismissed Lilly's application: *Eli Lilly Canada Inc. v. Novopharm Limited*, 2007 FC 596 (the "Hughes Order").

[19] The Hughes Order allowed the Minister of Health to issue an NOC to Novopharm on June 6, 2007. However, as the Hughes Order only decided the specific issues raised in the Novopharm Prohibition Proceedings, and did not declare the 113 Patent invalid, Lilly immediately commenced an infringement action in the Federal Court against Novopharm claiming that Novopharm's manufacture, use and sale of Novo-Olanzapine was nevertheless infringing the 113 Patent. Novopharm counterclaimed, seeking a declaration that the 113 Patent was invalid (the "Novopharm Infringement Proceedings").

[20] An appeal of the Hughes Order was dismissed by the Federal Court of Appeal on November 6, 2007: *Eli Lilly Canada Inc. v. Novopharm Limited*, 2007 FCA 359.

[21] The Novopharm Infringement Proceedings were decided, initially, by O'Reilly J. on October 5, 2009: *Eli Lilly v. Novopharm*, 2009 FC 1018. O'Reilly J. declared "the claims of the '113 patent in issue" to be invalid (the "O'Reilly #1 Decision").

[22] However, the O'Reilly #1 Decision was overturned in part by the Federal Court of Appeal on October 5, 2009 and remitted back to O'Reilly J. for further consideration: *Eli Lilly Canada Inc. v. Novopharm Limited*, 2010 FCA 197. This led to another decision, released on November 10, 2011, in which O'Reilly J. again found the 113 Patent to be invalid: *Eli Lilly Canada Inc. v. Novopharm Limited*, 2011 FC 1288 (the "O'Reilly #2 Decision"). An appeal of this decision was dismissed by the Federal Court of Appeal on September 10, 2012 (*Eli Lilly Canada Inc. v. Novopharm Limited*, 2012 FCA 232) and an application for leave to appeal to the Supreme Court of Canada was dismissed on May 16, 2013: *Eli Lilly Canada Inc. v. Novopharm Ltd.*, [2012] S.C.C.A. No. 471.

[23] In again finding the 113 Patent invalid, O'Reilly J. relied on the "Promise Doctrine." He concluded that the 113 Patent over-promised as "the evidence available to Lilly in April 1991 did not demonstrate that olanzapine could meet the promise of the '113 patent that it would provide markedly superior clinical treatment of schizophrenia with a better side effects profile than other known antipsychotics": O'Reilly #2 Decision, at para. 210. Ironically, in 2017, the Supreme Court of Canada held that the "Promise Doctrine" was "unsound": *AstraZeneca Canada Inc. v. Apotex Inc*., 2017 SCC 36, [2017] S.C.R. 943, at para. 36.

[24] O'Reilly J.'s work on the matter continued, as Novopharm (which became Teva Canada Limited ("Teva")) subsequently sought damages from Lilly under s. 8 of the *PM(NOC) Regulations* for the time period that its Novo-Olanzapine drug was kept off the market due to the pursuit of the Novopharm Prohibition Proceedings by Lilly. O'Reilly J. released a lengthy judgment awarding damages to Teva on January 30, 2017: *Eli Lilly Canada Inc. v. Teva Canada Limited*, 2017 FC 88 (the O'Reilly #3 Decision").

Further proceedings in the Federal Court involving Apotex

[25] As a result of the O'Reilly #1 Decision invalidating the 113 Patent, an NOC was issued to Apotex for Apo-Olanzapine on October 9, 2009, and Apotex began to market its drug to the public. This date marks the end of the period in which Apotex allegedly suffered damage from the inability to market its drug.

[26] Immediately following the O'Reilly #1 Decision, Apotex sought reconsideration of the Gauthier Order, asking Gauthier J. to set aside her order in the Apotex Prohibition Proceedings and to retroactively dismiss Lilly's application. Apotex sought this relief so that it could seek damages resulting from the "statutory stay" or "patent hold" under s. 8 of the *PM(NOC) Regulations*.

[27] Gauthier J. dismissed Apotex's motion on September 24, 2010: *Eli Lilly v. Apotex*, 2010 FC 952. In dismissing the motion, Gauthier J. stated at paras. 32-33:

> It is undisputable that the current version of section 8 was meant to clarify the legislator's intent. When it was adopted after full consultation, it would have been easy to add − had this been Parliament's intent − that the generic was to be indemnified if the patent listed was ever declared invalid. Instead, Parliament chose to focus on all possibilities that could happen in the normal course of a prohibition proceeding (dismissed, discontinued, reversed in appeal, *etc*.).

> The Court sees no good reason for changing the *status quo* by giving Apotex an opportunity that had ceased to exist when the Federal Court of Appeal confirmed the 2007 order. Apotex had a full opportunity to raise all possible allegations in respect of the invalidity of the '113 patent in its NOA. It also had the right to seek expungement from day one. In balancing the issue of fairness, I do not believe that the balance is in favour of Apotex here.

[28] In fact, three years before Gauthier J. commented that Apotex "had the right to seek expungement from day one", on November 13, 2007 Apotex had commenced an impeachment action in the Federal Court seeking to invalidate the 113 Patent. However, that action was not pursued and Apotex eventually discontinued it on June 13, 2013, after the Supreme Court of Canada denied leave to appeal from the O'Reilly #2 Decision.

[29] Not to be outdone, Lilly commenced an infringement proceeding against Apotex on October 26, 2011, but this was also not pursued and was discontinued on June 6, 2013, after the Supreme Court ruling.

[30] Although the 113 Patent had in any event expired on April 24, 2011, Apotex filed a copy of the O'Reilly #2 Decision with the Patent Office on November 5, 2013.

[31] One month later, on December 4, 2013, Apotex's appeal of Gauthier J.'s dismissal of its motion for reconsideration to set aside the Gauthier Order was dismissed by the Federal Court of Appeal: *Apotex Inc. v. Eli Lilly Canada Inc*., 2013 FCA 282. An application for leave to appeal to the Supreme Court of Canada was dismissed on April 24, 2014: *Apotex Inc. v. Eli Lilly Canada Inc*., [2014] S.C.C.A. No. 43.

Commencement of this action and the pleadings

[32] Apotex commenced this action against Lilly on November 7, 2013, just under two years after the O'Reilly #2 Decision of November 10, 2011.

[33] The Statement of Claim asserts three bases for liability, each of which is predicated on the *in rem* finding in the O'Reilly #2 Decision that, as Apotex puts it, "the 113 Patent is and always has been invalid, void and of no effect and, accordingly, should have never been issued."

[34] First, Apotex pleads breaches of the *Statutes of Monopolies*, stating that "had the 113 Patent not been improperly issued, Lilly would not have been able to list the 113 Patent on the Patent Register" and pursue the Apotex Prohibition Proceedings which delayed the issuance of the NOC to Apotex for over three years. Apotex therefore says that "it has been hindered, grieved, disturbed and disquieted by occasion and pretext of the '113 Patent and is entitled to treble damages" under the *Statutes of Monopolies*.

[35] Apotex's second claim, under s. 7 of the *Trademarks Act*, arises from listing the 113 Patent on the Patent Register. Apotex asserts that Lilly made false and misleading representations that it held a valid patent when it completed the listing in Form IV, and that this tended to discredit and cause damage to Apotex.

[36] The third claim is that the defendants, all Lilly-related companies, conspired to restrain trade and to monopolize the Olanzapine market by, among other things, "the procurement of an invalid patent, the listing of the 113 Patent on the Patent Register and prosecution of the prohibition proceedings under the *PM(NOC) Regulations*, and the prosecution of an infringement action under the *Patent Act*."

[37] Although Apotex also pleaded relief pursuant to s. 8 of the *PM(NOC) Regulations*, it discontinued that claim in light of the Gauthier Order following Apotex's unsuccessful attempt to have it reconsidered.

[38] A motion to strike out the action under Rule 21 was brought by the defendants in 2016, but due to findings in other cases that I discuss below which permitted similar actions to go forward, the motion was abandoned when it came on for a hearing on September 13, 2016.

[39] The defendants have filed statements of defence pleading, among other things, that Lilly "is not the cause and/or did not cause any of the damages," and asserting that any damages were caused by operation of the *Patent Act* in issuing the patent, the *PM(NOC) Regulations*, and the Gauthier Order. Lilly also pleads that the *Statutes of Monopolies* and the *Trademarks Act* have no application, and deny any common law conspiracy, pleading that any steps Lilly took were authorized by law. In addition, the defendants plead ss. 4 and 5 of the *Limitations Act, 2002*, in support of the action being statute-barred.

[40] This motion for summary judgment by the defendants was commenced on January 24, 2020. Affidavits were exchanged which are not contentious and which attached supporting documents addressing the history of the 113 Patent, proceedings related to it, and similar proceedings. There were no cross-examinations.

Issues on this motion

[41] The defendants move for summary judgment on two grounds:

> (1) that the action is barred by s. 5 of the *Limitations Act, 2002* as the facts relied upon by Apotex to ground its claims were discovered more than two years before this proceeding was commenced; and
>
> (2) any harm allegedly suffered by Apotex was caused by operation of the *PM(NOC) Regulations* and a court order, and that damages are not recoverable other than pursuant to s. 8 of the Regulations.

[42] While the second ground is framed narrowly, it requires the Court to consider the merits of Apotex's claims of an unlawful monopoly, false statements and conspiracy arising from the finding that the 113 Patent is invalid and, pursuant to s. 62 of the *Patent Act*, void *ab initio*.

Appropriateness of Summary Judgment

[43] Rule 20.04(1)(a) of the *Rules of Civil Procedure* states that "the court shall grant summary judgment if, … the court is satisfied that there is no genuine issue requiring a trial with respect to a claim or defence." The word "requiring" was added in 2010. At that time Rule 20 was also amended to provide judges with the discretion to use additional fact-finding powers designed to expand the scope and use of summary judgment.

[44] In *Hryniak v. Mauldin*, 2014 SCC 7, [2014] 1 S.C.R. 87 ("*Hryniak*"), the Supreme Court of Canada addressed the issue of summary judgment, including when it is appropriate and the test to be met. Karakatsanis J. summarized the Court's position as follows, at para. 4:

> In my view, a trial is not required if a summary judgment motion can achieve a fair and just adjudication, if it provides a process that allows the judge to make the necessary findings of fact, apply the law to those facts, and is a proportionate, more expeditious and less expensive means to achieve a just result than going to trial.

[45] At para. 49 of *Hryniak* Karakatsanis J. continued:

> There will be no genuine issue requiring a trial when the judge is able to reach a fair and just determination on the merits on a motion for summary judgment. This will be the case when the process (1) allows the judge to make the necessary findings of fact, (2) allows the judge to apply the law to the facts, and (3) is a proportionate, more expeditious and less expensive means to achieve a just result.

[46] Apotex has raised the *Statutes of Monopolies* and *Trademarks Act* in a number of other cases, several of which have been the subject of motions to strike under Rule 21 of the *Rules of Civil Procedure* for disclosing no reasonable cause of action. See, e.g., *Apotex Inc. v. Eli Lilly and Company*, 2012 ONSC 3808, 111 O.R. (3d) 683 (J. Macdonald J.); *Apotex Inc. v. Eli Lilly and Company et al*., 2015 ONSC 5396 (Dunphy J.); *Apotex Inc. v. Merck & Co., Inc.*, unreported, 20151005 (K.P. Wright J.); *Apotex Inc. v. Schering Corporation*, 2016 ONSC 3407 (Dunphy J.); *Apotex Inc. v. Pfizer Ireland Pharmaceuticals et al*., 2016 ONSC 4966 (Lederman J.).

[47] On a motion to strike, the moving party must meet a high test: whether "it is plain and obvious, assuming the facts pleaded to be true, that the pleading discloses no reasonable cause of action" or that "the claim has no reasonable prospect of success": *R. v. Imperial Tobacco Canada*, 2011 SCC 42, [2011] 3 S.C.R. 45, at para. 17 ("*Imperial Tobacco*"). The Supreme Court has directed that courts be especially cautious before striking out novel claims, observing at para. 21 of *Imperial Tobacco* that "[a]ctions that yesterday were deemed hopeless may tomorrow succeed….The approach must be generous and err on the side of permitting a novel but arguable claim to proceed to trial."[2]

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[2] An early attempt to plead the Ontario *Statute of Monopolies*, R.S.O. 1897, c. 323 in respect of an invalid patent occurred in 1960. That pleading also survived a motion to strike on the basis that the claim was "novel" and that it

[48] Apotex argues that the issues raised are novel and therefore should be resolved at a trial, citing *2462192 Ontario Ltd. v. Paramount Franchise Group Inc.*, 2019 ONSC 2962, at para. 39, and *Romano v. D'Onoforio* (2005), 77 O.R. (3d) 583 (Ont. C.A.). However, what concerned the Court in those cases was that the legal issue required a "full appreciation of the factual matrix" which in both cases required additional evidence.

[49] On this motion for summary judgment, the parties are sophisticated, well-represented and have filed evidence of the factual matrix – evidence which is not in dispute. Both parties are well aware of the requirement to put their best foot forward on the issues. As the Court of Appeal stated in *Toronto-Dominion Bank v. Hylton*, 2012 ONCA 614, at para. 5:

> A party moving for summary judgment has the evidentiary burden of showing there is no genuine issue for trial. Once this burden is discharged the responding party must prove that its defence has a real chance of success. Each party must put its best foot forward to establish whether or not there is an issue for trial. The court is entitled to assume that the record contains all the evidence the parties would present at trial. [Emphasis added]

[50] In oral argument, counsel for Apotex agreed that there are sufficient facts before the Court to decide the issues, but nevertheless submitted that because the law is unsettled, the case should go to trial. When pressed on this, counsel for Apotex could not identify additional evidence that would be presented to a trial judge to obtain a better appreciation of the claims by the plaintiffs, or of the defences raised by Lilly which has chosen to bring this motion.

[51] Apotex points to three other cases in which it is raising similar monopoly claims, one of which involves Lilly, in which judges declined to permit summary judgment motions to proceed. Each of those brief procedural rulings, however, turned on the particular circumstances of those cases, including the stage of the litigation, the number of issues raised including factual issues, and whether summary judgment would actually resolve the action or just some of the issues. In two of those three cases the validity of the patents was still in issue: *Apotex Inc. v. Merck*, unreported, August 31, 2016; *Apotex Inc. v. Schering Corporation*, 2019 ONSC 299, at para. 3. This action is quite different. The validity of the patent has been determined. Apotex failed in the underlying Apotex Prohibition Proceedings and it cannot pursue a claim for damages under s. 8 of the *PM(NOC) Regulations*. The evidence has been exchanged and is not in dispute.

[52] Apotex also objects to the use of the summary judgment rule asserting that this is "but the latest attempt by Lilly to delay the orderly progress of the action." This is a surprising submission given that it is Lilly that has brought the motion to dismiss the action, having previously abandoned its motion to strike the claim under Rule 21. Indeed, it was Apotex that sought to delay this motion when it objected to it proceeding in a "virtual" hearing by Zoom during the COVID-19 pandemic – an objection I dismissed: *Apotex Inc. v. Eli Lilly Canada Inc.*, 2020 ONSC 7460.

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could not be concluded "at this stage of litigation that appellants' action cannot possibly succeed": *Gilbert Surgical Supply Co. v. F. W. Horner Ltd.* 1960 CarswellOnt 25 (Ont. C.A.) at 20.

[53] As Myers J. aptly observed in *2287913 Ontario Inc. v. Blue Falls Manufacturing Ltd*., 2015 ONSC 7982, at para. 10, "[s]ummary judgment lies best when the moving party is able to identify a discrete, neat, gating issue that might be resolved on a motion to thereby save the parties the cost and delay associated with going to trial on a number of other issues."

[54] Here, Lilly raises two "gating issues" that are well-suited to summary judgment.

[55] First, the court is asked whether the declaration of invalidity in the O'Reilly #2 Decision is a pre-requisite to Apotex's action. This affects whether the limitation period only began to run from the date of that decision, as Apotex alleges, or whether it began to run on some earlier date – perhaps much earlier – when Apotex indisputably had grounds to challenge the validity of the 113 Patent. If this is decided in favour of Lilly, the action is at an end.

[56] There is no dispute that Apotex alleged invalidity under the *PM(NOC) Regulations* in December 2004, leading to the Apotex Prohibition Proceedings. Apotex alleged invalidity again when it commenced its impeachment action in 2007. Apotex puts forward no additional facts that require assessment by a trial judge, but simply argues that the *in rem* declaration of invalidity, which did not occur until the O'Reilly #2 Decision, is an essential element of its claims. There are, therefore, no facts in dispute that require a trial on this issue, making it appropriate to consider on a motion for summary judgment.

[57] Second, Lilly raises what is described as the causation issue – submitting that any damage to Apotex by being prevented from marketing its Apo-Olanzapine drug between June 28, 2006 and October 9, 2009, was due to the operation of the *PM(NOC) Regulations* and the Gauthier Order made pursuant to the Regulations, and not due to any wrongdoing by Lilly. The wrongdoing alleged by Apotex is that Lilly obtained and acted on an invalid patent by invoking the operation of the *PM(NOC) Regulations*. Again, the facts are not in dispute. Apotex's case is based on events recorded in pleadings and court documents from this and other actions, and other documents. Lilly's evidence is similarly based on documents addressing the history of the 113 Patent and the Apotex and Novopharm litigation discussed above.

[58] The causation issue, therefore, deals with whether steps indisputably taken by Lilly under the *Patent Act* and the *PM(NOC) Regulations* became actionable once the 113 Patent was declared invalid. The resolution of this issue does not require the court to make findings of fact on contentious issues, let alone use the expanded fact-finding powers added to Rule 20 in 2010.

[59] In short, a trial judge will be in no better position than me to determine the issues raised, which will either end the action or narrow the remaining issues. This is precisely what summary judgment is intended to achieve.

The *Limitations Act, 2002* Issue

[60] Section 4 of the *Limitations Act, 2002* states that, "[u]nless this Act provides otherwise, a proceeding shall not be commenced in respect of a claim after the second anniversary of the day on which the claim was discovered."

[61] Section 5(1) of the *Limitations Act, 2002* addresses when a claim is "discovered." It states:

> A claim is discovered on the earlier of,
>
> (a) the day on which the person with the claim first knew,
>
> (i) that the injury, loss or damage had occurred,
> (ii) that the injury, loss or damage was caused by or contributed to by an act or omission,
> (iii) that the act or omission was that of the person against whom the claim is made, and
> (iv) that, having regard to the nature of the injury, loss or damage, a proceeding would be an appropriate means to seek to remedy it; and
>
> (b) the day on which a reasonable person with the abilities and in the circumstances of the person with the claim first ought to have known of the matters referred to in clause (a).

[62] The Supreme Court of Canada has stated that a limitation period begins running when "the material facts on which [the cause of action] is based have been discovered or ought to have been discovered by the plaintiff by the exercise of reasonable diligence": *Central Trust Co. v. Rafuse*, [1986] 2 S.C.R. 147, at p. 224, quoted with approval more recently in *Pioneer Corp. v. Godfrey*, 2019 SCC 42, at para. 31. See also *Lawless v. Anderson*, 2011 ONCA 102, at paras. 22-23.

[63] Lilly's position on this issue is simply stated: all material facts giving rise to the causes of action were known to Apotex many years ago, and more than two years before this action was commenced on November 7, 2013.

[64] Undoubtedly, Apotex was well aware of the 113 Patent by no later than sometime in 2004 when it had formed its belief that all claims in the 113 Patent were invalid, as contained in Dr. Sherman's detailed letter to Lilly on December 16, 2004. That letter, signed almost nine years before this action was commenced, alleged that "all of [the 113 Patent's] claims (claims 1 - 22) are invalid, void and of no effect."

[65] Material facts supporting Apotex's claims include that Lilly procured an invalid patent, listed it on the Patent Register, commenced and prosecuted the Apotex Prohibition Proceedings, and failed to "permit Apotex to come to market following the decision of Hughes J. dated June 5, 2007." All of these events occurred well before November 7, 2011. Indeed, the Apotex Prohibition Proceedings were concluded by the Federal Court of Appeal on February 5, 2008, more than five years before this action was commenced. In addition, six years prior to commencing this action, on November 13, 2007 Apotex commenced an impeachment action in the Federal Court seeking a declaration that the 113 Patent was invalid, an action it discontinued in June 2013. Finally, the 113 Patent expired on April 24, 2011, and therefore any wrongful acts premised on the existence of the 113 Patent, and any harm to Apotex, would not have occurred after that date, which is more than two years prior to the commencement of the action.

[66] Apotex, however, argues that the claim was not "discoverable" until the O'Reilly #2 Decision. That *in rem* declaration, which found the 113 Patent to be invalid and void *ab initio*, Apotex asserts, is an essential element of each of its causes of action. As the O'Reilly #2 Decision was not released until November 10, 2011, and the action was commenced within two years of that date, on November 7, 2013, Apotex submits that the action was commenced within two years in accordance with ss. 4 and 5 of the *Limitations Act, 2002*.[3]

[67] This issue has arisen in other Apotex and related litigation. In *Apotex Inc. v. Schering Corporation*, 2018 ONCA 890, 143 O.R. (3d) 321, a case raising similar monopolies claims, the Court of Appeal agreed that the validity of the patent is "central" to the plaintiff's case. Nordheimer J.A. stated at para. 31:

> The respondent's claim is a novel one, as the motion judge himself characterized it. It is evident, however, that in order to have any prospect of success, the respondent will have to establish that the monopoly that the appellants enjoyed in the market for Ramipril was an unlawful one. If the monopoly was the result of a valid patent, and thus was a monopoly authorized by law, there does not appear to be any way for the respondent to succeed in its claim. Thus, it would appear to be beyond debate that the invalidity of the 206 Patent is an essential element of the claims advanced here. Indeed, it is arguable that an invalid patent is an essential element of any claim of this type: see *Actavis Pharma Co. v. Alcon Canada Inc.*, 2016 ONSC 7151 and the cases referred to therein. [Emphasis added.]

[68] In *Actavis Pharma Co. v. Alcon Canada Inc*. ("*Actavis*"), cited by Nordheimer J.A. above, the plaintiff made similar monopolies claims; however, unlike this case there had not been an *in rem* declaration of invalidity of the patent in issue. Rather, the plaintiff was pursuing damages under s. 8 of the *PM(NOC) Regulations* after having succeeded in the prohibition proceeding brought by the defendant under s. 6 of the Regulations, and also sought relief under the *Statutes of Monopolies* in order to request treble damages. The defendants took the position that claims under the *Statutes of Monopolies* should be struck out under Rule 21.

[69] In *Actavis*, Akbarali J. agreed that an *in rem* declaration of invalidity was an essential element of a claim under the *Statutes of Monopolies.* She followed *Apotex Inc. v. Eli Lilly and Company*, 2015 ONSC 5396, in which Dunphy J. described a declaration of invalidity as the "trigger" for such a claim. This was also the holding of the Federal Court of Appeal in *Apotex Inc. v. Warner Lambert Company LLC*, 2012 FCA 323, which held that a declaration of invalidity was a necessary precondition to an action for damages under the *Statutes of Monopolies.* As declarations of invalidity of patents are within the exclusive jurisdiction of the Federal Court under s. 20 of the *Federal Courts Act*, R.S.C. 1985, c. F-7, it is necessary to obtain that declaration before actions for damages can proceed in the

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[3] While it might be argued that the declaration of invalidity occurred with the O'Reilly #1 Decision on October 5, 2009, and time began to run from that date, when it was overturned by the Federal Court of Appeal in 2010 the validity of the patent was restored and the clock was, effectively, re-set pursuant to operation of s. 62 of the *Patent Act.*

Superior Court in Ontario which, unlike the Federal Court, has jurisdiction to grant damages under the *Statutes of Monopolies*.

[70] In striking out the monopolies claims in *Actavis*, Akbarali J. put the point concisely at para. 17:

> A statement of claim must disclose a presently existing, legally recognized claim against the defendant: *Gevaert v Arbuckle* (1998), 1998 CanLII 14925 (ON SC), 26 CPC 4th 207 (Ont Gen Div) at para. 18. At the moment, the most that can be said about the plaintiff's claims under the *Statutes of Monopolies* is that they may arise if the declaration of invalidity is sought and granted. In argument, counsel for the defendants agreed that, if a declaration of invalidity is sought and granted by the Federal Court, any limitation period under the *Statutes of Monopolies* would begin to run at that time, and that no limitation period has yet begun to run. There is thus no prejudice to the plaintiff if its claims are struck. [Emphasis added]

[71] Lilly argues, however, that Apotex confuses what is necessary to *prove* a claim with what is necessary to *bring* a claim. Lilly points out that all the facts necessary to bring an action based on an invalid patent were known to Apotex long ago, at least as early as Dr. Sherman's December 2004 letter when Apotex first asserted the invalidity of the 113 Patent, and therefore Apotex did not need to wait for the O'Reilly #2 Decision declaring the patent to be invalid.

[72] Lilly notes that actions for false statements under s. 7 of the *Trademarks Act* involving invalid patents have gone forward without a declaration of invalidity. As McHaffie J. recently stated in *Fluid Energy v. Exaltexx*, 2020 FC 81, at para. 49: "It has long been recognized that a false allegation that a competitor infringes a patent may fall within subsection 7(a): *S&S Industries Inc v Rowell*, [1966] SCR 419 at pp 422, 424-425, 429-432. This is so even if the falsity of the allegation may not be established until later, such as after a finding that the patent is invalid: *S&S Industries* at p 425."

[73] Apotex has itself made allegations under the *Statutes of Monopolies* and the *Trademarks Act* in respect of patents which have not been declared invalid.

[74] In *Sanofi-Aventis Canada Inc. v. Apotex Inc.* (T-161-07), Apotex sought damages under s. 7 of the *Trademarks Act* in a counterclaim which also sought a declaration of invalidity. However, in that case the alleged false and misleading statements went well beyond the mere registration of a patent under the *PM(NOC) Regulations*.

[75] In *Apotex Inc. v. Merck & Co., Inc.* (an unreported decision of Wright J. of the Ontario Superior Court of Justice dated October 5, 2015), Apotex had been successful in prohibition proceedings brought by Merck in the Federal Court under s. 6 of the *PM(NOC) Regulations*, but this did not result in an *in rem* declaration of invalidity. Apotex then commenced an action in this Court seeking damages pursuant to s. 8. Apotex also included a request for "a declaration that Apotex's manufacture, use and sale of dorzolamide and dorzolamide-containing products do not and have not infringed the '211 Patent … because

said patent is and always has been invalid," so that Apotex could seek damages under the *Statutes of Monopolies*.

[76] Wright J. permitted the action to go forward, finding persuasive Apotex's argument that the prohibition proceeding in the Federal Court had made a finding of invalidity. Further, according to Wright J., the Federal Court's exclusive jurisdiction to make *in rem* adjudications as to the validity of patents did not oust the Superior Court's general jurisdiction to determine disputes between parties, "including the granting of declarations as to patent infringement." Consequently, the action was allowed to proceed. A motion for leave to appeal Wright J.'s decision was dismissed by Sachs J.: *Apotex Inc. v. Merck & Co.*, (unreported, March 18, 2016 (Div. Ct.).

[77] In the meantime, perhaps out of an abundance of caution, on September 21, 2015 Apotex commenced a proceeding against Merck in the Federal Court for an *in rem* declaration of invalidity. That action, however, was stayed with the consent of Apotex by Prothonotary Milczynski on June 20, 2016, in favour of allowing the action in this Court, with its claim for a declaration of invalidity, to proceed first. The action later settled. While interesting, the decision of Wright J. arose in different circumstances from this case and did not address the specific issue before me.

[78] With some reluctance, I accept Apotex's position and conclude that the action is not out of time and should not be dismissed pursuant to ss. 4 and 5 of the *Limitations Act, 2002*. I say with some reluctance because limitations laws are intended to prevent new and seemingly endless litigation over matters that happened long ago. They prevent claimants from sitting on their rights or litigating in stages: see, e.g., *Johar v. College of Veterinarians of British Columbia*, 2020 BCSC 1085 at paras. 153-169; *Lawless v. Anderson*, 2011 ONCA 102, at para. 36; *Beniuk v. Leamington (Municipality)*, 2020 ONCA 238, 150 O.R. (3d) 129, at para. 75. The presence of these concerns is obvious in this case as the validity of the 113 Patent was put in issue as early as 2004 and has been the subject of numerous actions and applications as summarized above.

[79] Nevertheless, I must accept that a declaration of invalidity of the 113 Patent is an essential element of the action under the *Statutes of Monopolies*, as stated by Nordheimer J.A. in the Ontario Court of Appeal in *Apotex Inc. v. Schering Corporation*, at para. 31. The *in rem* finding of invalidity of the 113 Patent, therefore, is not just necessary to confirm or prove the allegations made by Apotex but is a precondition to bringing the action. That declaration can only come from the Federal Court, which occurred when the O'Reilly #2 Decision was released on November 10, 2011. The declaration of invalidity is a "material fact" that was not, and could not be, known to Apotex until that date.

[80] I observe that the conclusion I have reached is similar to the approach taken in malicious prosecution and negligent investigation cases which also require a judicial finding in favour of an accused before the limitation clock begins to run, even though all the facts supporting the malicious conduct may have been known to the claimant for many years. As the Supreme Court of Canada observed in *Hill v. Hamilton-Wentworth Regional Police Services Board*, 2007 SCC 41, [2007] 3 S.C.R. 129, at 97-98:

> As discussed above, the loss or injury as a result of alleged police negligence is not established until it is clear that the suspect has been imprisoned as a result of a wrongful conviction or has suffered some other form of compensable harm as a result of negligent police conduct. The wrongfulness of the conviction is essential to establishing compensable injury in an action where the compensable damage to the plaintiff is imprisonment resulting from a wrongful conviction. In such a case, the cause of action is not complete until the plaintiff can establish that the conviction was in fact wrongful. So long as a valid conviction is in place, the plaintiff cannot do so.
>
> It follows that the limitation period in this case did not start to run until December 20, 1999 when Mr. Hill, after a new trial, was acquitted of all charges of robbery. [Emphasis added.]

[81] Akbarali J. noted the rationale behind this approach in *Actavis* in explaining why the monopolies claim should not proceed even though the action for damages under s. 8 of the *PM(NOC) Regulations* would go forward, stating at para. 18:

> Of course, the s. 8 action will continue. Striking the claims under the *Statutes of Monopolies* thus runs the risk that, if the *Statutes of Monopolies* claims are brought again if a declaration of invalidity is granted by the Federal Court, there could be two proceedings in this court dealing with the same factual matters – this proceeding under s. 8 and another under the *Statutes of Monopolies.* Such a result raises the spectre of inconsistent findings. While I am troubled by this risk, I have concluded it is preferable to the risks of attempting to prosecute a novel action for damages when all the elements of the claim are not present. These risks include that the litigation will be expanded to encompass factual and legal issues, and in particular as they relate to damages under the *Statutes of Monopolies*, that may never need to be addressed if the declaration of invalidity is never granted. As such, there may be greater inefficiency in allowing the *Statutes of Monopolies* claims to proceed than in requiring them to be brought anew if and when the declaration of invalidity is granted. [Emphasis added]

[82] Justice Akbarali's comments accord with the final part of s. 5(1)(a)(iv) of the *Limitations Act, 2002*, which requires "that, having regard to the nature of the injury, loss or damage, a proceeding would be an appropriate means to seek to remedy it." As Laskin J.A. observed, "one reason why the legislature added 'appropriate means' as an element of discoverability was to enable courts to function more efficiently by deterring needless litigation": *407 ETR Concession Company Limited v. Day*, 2016 ONCA 709, 133 O.R. (3d) 762, at para. 48. Further, Laskin J.A. noted at para. 34 that "when an action is "appropriate" depends on the specific factual or statutory setting of each individual case." See also *Presidential MSH Corporation v. Marr Foster & Co. LLP*, 2017 ONCA 325, 135 O.R. (3d) 321, at paras. 17-18.

[83] The conclusion I have reached applies to each of the three causes of action pleaded by Apotex. While, arguably, the conspiracy and *Trademarks Act* claims might not depend, entirely, on the invalidity of the 113 Patent, I am satisfied that, as pleaded, the claims are

all derived from and based on the finding of invalidity in the O'Reilly #2 Decision, and therefore I conclude that the action is not barred by the *Limitations Act, 2002*.

Causation

The pleading

[84] Lilly's second basis for seeking summary judgment is that the cause of any harm Apotex suffered from being kept out of the market from June 28, 2006 to October 9, 2009, was due to "the operation of law and the Gauthier Order." In particular, Lilly argues that it obtained and acted pursuant to a then-valid patent and invoked legal rights under the *Patent Act* and the *PM(NOC) Regulations*, which only give rise to liability for damages under s. 8 if prohibition proceedings are unsuccessful. Any exposure to damages beyond s. 8 would, Lilly argues, "drastically upset Parliament's statutory regime."

The statutory context: the Patent Act *and the* PM(NOC) Regulations

[85] Patents are granted in Canada under the authority of the *Patent Act*. They are issued after an application for a patent for a new "invention", as defined in the Act, has been reviewed and approved by the Commissioner of Patents pursuant to s. 27. Once issued, and unless revoked or voided, s. 42 states that a patent grants to its owner "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction." [emphasis added]

[86] Section 43(2) of the *Patent Act* states that "[a]fter the patent is issued, it shall, in the absence of any evidence to the contrary, be valid and avail the patentee and the legal representatives of the patentee for the term mentioned in section 44 or 45, whichever is applicable". In this case, as the application for the 113 Patent was made after October 1, 1989, the patent was granted for a term of 20 years from the filing date (s. 44).

[87] Section 54 of the *Patent Act* provides rights to patent holders to enforce their exclusivity by commencing infringement actions. A patent holder may seek damages sustained as a result of an infringement under s. 55 of the *Patent Act*.

[88] Proceedings may be brought by the Attorney General or "any interested person" to impeach a patent and have it declared invalid or void (s. 60(1)). Section 62 of the *Patent Act* provides in such circumstances that "[a] patent, or part of a patent, that is voided by a judgment shall be and be held to have been void and of no effect, unless the judgment is reversed on appeal as provided in section 63." [emphasis added] In addition, a person may bring an action for a declaration that something "does not or would not constitute an infringement" of a patent (s. 60(2)). However, the *Patent Act* does not provide for an award of damages against a patent holder if the patent is found to be invalid or void. This is the case even if the patent is voided due to untrue or misleading information provided by the applicant for the patent, even if "wilfully made for the purpose of misleading" (s. 53(1)).

[89] Section 20 of the *Federal Courts Act*, R.S.C. 1985, c F-7, highlights the broad jurisdiction of the Federal Court over patents. It provides that the Federal Court has "exclusive original

jurisdiction" over conflicting patent applications and "in all cases in which it is sought to impeach or annul any patent of invention…." Accordingly, only the Federal Court can make an *in rem* declaration of invalidity.

[90] The safety, efficacy and approval of drugs for marketing in Canada is governed by the *Food and Drugs Act*, R.S.C. 1985, c. F.27. A drug cannot be marketed unless and until the Minister of Health issues an NOC under the *Food and Drug Regulations*, C.R.C. 1978, c. 870, C.08.004. Innovators must submit a New Drug Submission ("NDS"), which is usually very detailed and the result of extensive research and development, in support of their request for an NOC. Generic companies, however, may submit to the Minister of Health an ANDS where they seek an NOC for a drug that is the "pharmaceutical equivalent" of a previously approved drug.

[91] In 1993 Parliament amended the *Patent Act* and promulgated the *PM(NOC) Regulations* to address the development of generic drugs. This included enacting s. 55.2 of the *Patent Act*, which provides that "[i]t is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product." This provision allows for the "early working," or development, of copycat drugs despite the existence of patents.

[92] The *PM(NOC) Regulations* established a regulatory scheme to address the application of patents to generic companies taking advantage of the "early working" exception to develop copycat drugs. The scheme was concisely summarized by Binnie J. in *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560, at para. 17 ("*AstraZeneca*"):

> The general scheme of the NOC Regulations is to create a Patent Registry within the Department of Health in which an innovator drug company like AstraZeneca may have patents listed relevant to its various drug submissions for regulatory approval (s. 4). A generic manufacturer that is not prepared to await the expiry of what are alleged to be the relevant patents must challenge their validity or applicability to its proposed product (s. 5). The challenge is to be embodied in a notice of allegation, which will generally trigger an application in the Federal Court by the patent owner to prohibit the issuance of a NOC based on (in its view) the relevance, validity and applicability of the listed patents (s. 7). The unusual feature of the NOC Regulations is that mere initiation by the patent owner of its application for prohibition freezes ministerial action for 24 months unless the prohibition proceedings are earlier disposed of, which seems to be rare (s. 7(1)(e)). As pointed out in the majority judgment in *Biolyse* [*Bristol-Myers Squibb Co. v. Canada (Attorney General)*, [2005] 1 S.C.R. 533, 2005 SCC 266] (at para. 24):
>
> > [U]nder this procedure, the court hearing the prohibition application has no discretion to lift the stay even if it thinks the innovator's case for interim relief is weak. Nor does the court have a discretion to leave the contending parties to their remedies under the *Patent Act*. The "[generic

> manufacturer]"'s application for a NOC simply goes into deep-freeze until the statutory procedures have played themselves out. For these reasons, Iacobucci J. described the regime as "draconian" in *Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare)*, 1998 CanLII 792 (SCC), [1998] 2 S.C.R. 193, at para. 33.

[93] It has been observed that the *PM(NOC) Regulations* reflect "an attempt to strike a balance between the need for patent protection on the one hand and the timely entry of lower priced drugs on the market, on the other": *Apotex v. Eli Lilly*, 2011 FCA 358 at para. 18; see also *Apotex Inc. v. Eli Lilly and Company* (2015), 125 O.R. (3d) 561, 2015 ONCA 305 at para. 27. In *AstraZeneca*, at para. 12 Binnie J. described the *PM(NOC) Regulations* as the balancing of the "sometimes conflicting objectives" of enabling safe and effective medicines to come to market with the patent system which, "in exchange for disclosure to the public of an invention, including the invention of a medication, the innovator is given the exclusive right to its exploitation for a period of 20 years."

[94] Although the listing of a patent on the Patent Registry may delay approval by the Minister, s. 55.2 of the *Patent Act* and the *PM(NOC) Regulations* provide several advantages to generic manufacturers. The "early working" of the drug is estimated to accelerate market entry by three to five years: see Regulatory Impact Analysis Statement ("RIAS"), (October 2006), *Canada Gazette*, Part II, Vol. 140, No. 21, p. 1510. Section 8 of the *PM(NOC) Regulations* provides that a generic company may obtain damages for the "deep freeze" if it defeats the patentee's clams in the prohibition proceeding. As I have noted above, this right to seek damages against the patent holder does not otherwise exist under the *Patent Act*, where the only result of a successful challenge to a patent is a declaration of invalidity. Successfully defending a prohibition proceeding often also provides a generic company with the advantage of a period of exclusivity over the generic market for the drug at issue.[4]

[95] On the other hand, the successful defence of a prohibition proceeding brought under s. 6 of the *PM(NOC) Regulations* in force at that time did not result in an *in rem* declaration of invalidity, but only determined the validity of the allegations made by the generic company which provoked the proceeding.[5] This is illustrated in the context of this case when Novopharm, even though it was successful in the Novopharm Prohibition Proceedings and obtained an NOC, immediately faced an infringement proceeding brought by Lilly. Nor did Novopharm's success before Hughes J. allow Apotex to obtain its NOC.

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[4] The *PM(NOC) Regulations* also provide a number of procedural advantages, including requiring the patentee to bring a prohibition proceeding within 45 days of receiving a notice of allegation, and if the proceedings are not completed within two years the generic company is entitled to receive the NOC. The burden of proof is on the innovator company to rebut allegations of invalidity. The *PM(NOC) Regulations* in force at the time did not give innovator companies the ability to appeal negative decisions, but only permitted appeals by generics.

[5] The *PM(NOC) Regulations* were amended in 2017. They now provide innovators with a right of appeal. In addition, proceedings may now proceed by way of an action permitting discovery, and the court may make final determinations on patent infringement and validity, avoiding multiple proceedings: *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, 2017*, RIAS, (July 15, 2017) *Canada Gazette*, Part I, Vol. 151, No. 28.

[96] Under the *PM(NOC) Regulations*, prohibition applications under s. 6 may be brought to the Federal Court or to "any other superior court of competent jurisdiction." In practice they are brought in the Federal Court where judges are familiar with patent claims and infringement issues. Both the Federal Court and the provincial superior courts also have jurisdiction to award damages under s. 8 of the *PM(NOC) Regulations*, which is why actions for damages, coupled with the novel monopolies claims, such as this one, have proceeded in Ontario's Superior Court of Justice.

***By operation of law: the "complete code" of the* Patent Act *and* PM(NOC) Regulations**

[97] The Supreme Court has stated that patent law is "wholly statutory": *Apotex v. Sanofi-Synthelabo Canada Inc*., 2008 SCC 61, [2008] S.C.R. 265, at para. 12 citing *Synthon B.V. v. SmithKline Beecham plc*, [2006] 1 All E.R. 685, [2005] UKHL 59, at paras. 57-58 ("*Synthon B.V.*"). As Judson J. put it in *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49, at p. 57: "There is no inherent common law right to a patent. An inventor gets his patent according to the terms of the *Patent Act*, no more and no less."

[98] Apotex argues that it is an overstatement to say patent law is entirely statutory, citing common law developments such as the concepts of "obviousness" and "double patenting," the right to sue those who induce infringements of patents, and that patents are exigible in the context of creditors' relief under provincial legislation. However, each of these examples is, in the words of Lord Walker in *Synthon B.V.*, simply "judge-made doctrine [which] has over the years done much to clarify the abstract generalities of the statutes and to secure uniformity in their application." As Lord Walker continued at para. 58 (quoted with approval by Rothstein J. in *Apotex v. Sanofi-Synthelabo*, at para. 12), "it is salutary to be reminded, from time to time, that the general concepts which are the common currency of patent lawyers are founded on a statutory text, and cannot have any other firm foundation."

[99] One feature of the "wholly statutory" nature of patent law is the limited forms of relief which can be sought. Until the *PM(NOC) Regulations* were promulgated, there was no basis upon which a patent holder could be found liable for damages, and the Regulations only permit a limited damages claim. Attempts by Apotex and other generic companies to obtain expanded relief such as disgorgement of the innovator's profits based on claims of unjust enrichment have failed, and amendments to the *PM(NOC) Regulations* in 2006 confirmed that generic companies are not entitled to recover innovator's profits: see, e.g., *Apotex Inc. v. Abbott Laboratories Ltd. et al*. 2013 ONSC 356, aff'd., 2013 ONCA 555 at para. 6; *Apotex Inc. v. Eli Lilly and Company*, 2013 ONSC 5937, aff'd 2015 ONCA 305 (CanLII)), leave to appeal refused [2015] S.C.C.A. No. 29; and the *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/2006-242.

[100] In *DBC Marine Safety Systems Ltd. v. Canada*, 2008 FCA 256, Richard C.J. stated at para. 2:

> The regime for patent applications is firmly established by the Patent Act and the Patent Rules. Together, the various legislative provisions set out a complete code

> governing the duties of an applicant for a patent, the consequences of a failure to comply with those duties, and the steps that may be taken to avoid those consequences. [Emphasis added.]

[101] In two decisions, the Federal Court of Appeal has treated the *PM(NOC) Regulations* as a complete code dealing with damages which may flow from invoking the Regulations. In *Apotex Inc. v. Merck & Co. Inc*., 2009 FCA 187, Noël J.A. (as he then was) rejected arguments that Apotex could claim profits of the innovator, or that it should be entitled to seek the remedies available to a patentee whose patent has been infringed.

[102] Subsequently, in *Apotex v. Eli Lilly*, 2011 FCA 358, Noël J.A. again rejected the argument that a generic could seek disgorgement of profits, as that is not permitted by s. 8 of the *PM(NOC) Regulations*. Although the Federal Court may have jurisdiction to provide such equitable relief under s. 20(2) of the *Federal Courts Act*, Noël J.A. stated at para. 23 that the section "cannot be used to grant a remedy which section 8 was intended to exclude…unless a cause of action independent of the operation of section 8 is alleged." Justice Noël does not explain what "independent" causes of action he had in mind; however, it can be inferred that they would involve separate, independent wrongdoing as he went on to say that if the claim for disgorgement arose simply from the dismissal of the prohibition proceedings the action would be unfounded.

[103] In Ontario, the "complete code" issue has been raised on some Rule 21 motions. In *Apotex Inc. v. Abbott Laboratories Ltd. et al.*, 2013 ONSC 356, Quigley J. rejected a claim for disgorgement as part of a s. 8 proceeding, stating at para. 152:

> Apotex has argued that the legislation does not oust prior rights and it assumes that there was a pre-existing cause of action, but that cannot be the case in these circumstances. A generic drug manufacturer has no right to patent-related restitution based on unjust enrichment or otherwise that has no statutory background or foundation. Here, the background or foundation and the only source of the entitlement is to be found entirely in the statutory framework that Parliament created, and as is plain from its language, both initially and as amended, and from the Federal Court of Appeal's decision in Eli Lilly, that framework constitutes a complete code and does not leave room for any stand-alone equitable remedies. [Emphasis added.]

[104] The decision of Quigley J. was upheld by the Ontario Court of Appeal in a brief endorsement which included the following (*Apotex Inc. v. Abbott Laboratories, Limited*, 2013 ONCA 555) at paras. 5-6:

> In its factum, the appellant argues more broadly that, despite the Patent Regulations, it should be entitled to pursue an unjust enrichment claim for disgorgement of the respondents' profits or revenues.
>
> In our view, the simple answer to that argument is that the profits or revenues earned by the respondents for which the appellant claims disgorgement are due to the operation of the regulatory scheme of the Patent Regulations. The respondents'

> right to be in the market to the exclusion of the appellant and therefore to earn its profits or revenues is that provided for by the Patent Regulations. Those Regulations constitute a valid juristic reason for the respondents' profits and revenues for the period in question. This precludes the appellant's claim for disgorgement. [Emphasis added.]

[105] The Divisional Court agreed with this approach in *Apotex Inc. v. Eli Lilly and Company*, 2013 ONSC 5937. In that case, as in this one, the underlying patent had been declared invalid and Apotex had claimed that Eli Lilly had therefore "made representations which were materially false and misleading when it listed its patent on the patent register." In allowing the appeal and striking out the claim, the Court stated at para. 8:

> While it may be possible to assert a claim that is totally independent of the regulatory regime governing patents, the amended statement of claim in this case does not disclose such a claim. It is therefore plain and obvious that the amended statement of claim discloses no reasonable cause of action based on unjust enrichment. [Emphasis added.]

[106] An appeal of the decision of the Divisional Court was dismissed by the Ontario Court of Appeal. Feldman J.A. agreed that Apotex could not claim disgorgement of profits or unjust enrichment under s. 8 of the *PM(NOC) Regulations*, and that any such claim would have to arise from a "stand-alone cause of action": *Apotex Inc. v. Eli Lilly and Company*, 2015 ONCA 305, 125 O.R. (3d) 561, at para. 53; leave to appeal refused, [2015] S.C.C.A. No. 291. Feldman J.A. also warned at paras. 57 and 60 that "overcompensation should be avoided in this regulatory context" which reflects "a compromise between the interests of the public in encouraging research and development of new patentable drugs and in encouraging generics to market drugs at lower prices."

[107] At para. 35 of her decision, Feldman J.A. summarized the positions of courts on the "complete code" issue, observing that the Federal Court of Appeal and the Divisional Court agreed that the *Patent Act* and the *PM(NOC) Regulations* were a complete code, but stated that the British Columbia Court of Appeal had rejected it in *Low v. Pfizer Canada Inc*., 2014 BCSC 1469 ("*Low*"). The *Low* decision cited by Feldman J.A., however, was not an appellate decision, but a decision of the British Columbia Supreme Court. That decision was subsequently appealed to the British Columbia Court of Appeal. In a detailed and persuasive judgment, Garson J.A. concluded that the *Patent Act* and the *PM(NOC) Regulations* constitute a comprehensive statutory scheme for addressing disputes between innovator and generic companies: *Low v. Pfizer Canada Inc*., 2014 BCCA 506, at paras. 48 and 69. As Garson J.A. stated at para. 71:

> The Patent Regulatory Regime involves a balancing of interests through the implementation of legislative policy choices. As the Court stated in *Teva v. Pfizer Canada Inc.*, [2012 SCC 60] the patent system is based on a *quid pro quo*. It provides an incentive for disclosing a new invention in the form of a limited monopoly, such that society can benefit from that knowledge. In the context of patented medicines, the notice of compliance system acts as an accountability mechanism. In *Apotex Inc. v. Eli Lilly Canada Inc.*, the Federal Court of Appeal

> described the *PM(NOC) Regulations* (and s. 8 in particular) as "an attempt to strike a balance between the need for patent protection on the one hand and the timely entry of lower priced drugs on the market, on the other" (at para. 18). In my view, it is not for this Court to upset the balance that Parliament has struck by expanding the scope of available remedies. [Emphasis added]

[108] This conclusion is supported by the general principles to be applied in determining whether Parliament intended to create a complete or exclusive code. As stated in *Sullivan on the Construction of Statutes*, 5th ed. (Markham: Ont.: LexisNexis Canada, 2008), at page 441:

> The intent to create an exclusive code may be expressly stated in the legislation or it may be implied from reading the legislation and its relevant context. When an enactment duplicates the common-law, offers a comprehensive regulation of a matter or implements a specific legislative policy choice, the courts are likely to infer that it was meant to be exhaustive. This inference may also be based on implied exclusion, the presumption against a tautology or the unsatisfactory state of the common-law. [Emphasis added.]

[109] The existence of a "complete code" has been recognized by the Supreme Court of Canada in another highly regulated context. In *Gladstone v. Canada*, 2005 SCC 21, [2005] 1 S.C.R. 325, the Court refused to require the government to pay interest on money it had received from the sale of fish it had seized under the *Fisheries Act*, R.S.C. 1970, c. F-14. Although the *Fisheries Act* expressly provided for the return of any proceeds realized on the sale of seized property, it did not provide for interest or any other amount to be paid. The Court held, at para. 9, that management and control of commercial fishing was a "highly regulated field" where the statutory scheme created "a comprehensive framework for dealing with issues arising from seizure." The *Fisheries Act* therefore constituted "a complete code dealing with the return of seized property," and interest lost was unrecoverable due to the "operation of the Act."

[110] In light of the "wholly statutory" nature of patent law, which is highly regulated and contains detailed provisions with limited remedies, and which reflects a balancing of interests and policy choices by Parliament, the case for a complete code is compelling.

[111] Furthermore, even if Lilly was motivated by an improper motive – on which there is no evidence - its actions in invoking the *PM(NOC) Regulations* would still not be wrongful. This was the conclusion of the Ontario Court of Appeal in *Harris v. GlaxoSmithKline et al*., 2010 ONCA 872, 106 O.R. (3d) 661 ("*Harris*"), a class action by consumers who claimed that the patent holder had misused the *PM(NOC) Regulations* to delay entry of a less expensive generic into the market. Moldaver J.A. (as he then was) held that this could not amount to a conspiracy. As he put it at paras. 45-46:

> The PM(NOC) Regulations permitted GSK to do just that. GSK was entitled to defend the validity and scope of its patents. The fact that a patent confers on its owner the power to exclude others certainly has economic implications. But, as GSK points out, those implications are necessarily consequential and, in any event, intended by Parliament and thus not unlawfully anticompetitive.

> Viewed through that lens, GSK submits, correctly in my view, that the appellant "cannot convert the legitimate interest of a patentee in protecting (and monetizing) its intellectual property rights into anti-competitive monopoly practices in order to conjure up the improper predominant purpose required for the tort of conspiracy".

[112] At para. 47, Justice Moldaver went on to quote with approval the words of the motions judge, Perell J., who stated (at para. 86 of his reasons):

> The resort to a NOC Proceeding is a part of the ordinary competition between innovators and generic manufacturers. The case law establishes that provided that there are no unlawful acts, an ordinary commercial transaction with the predominant purpose of advancing one's own economic interests does not constitute a conspiracy even though a party or a third party may suffer an economic loss.

[113] Justice Moldaver also agreed with Perell J.'s conclusion, at para. 50 (para. 94 of Perell J. decision):

> In the case at bar, GSK's NOC Proceedings were not contrary to law or to statute. GSK's NOC Proceedings were the opposite of unauthorized; they were proceedings that GSK was entitled to bring. In other words, they were acts that GSK was at liberty to commit. The NOC Proceedings are actually a response to NOC's initiated by Apotex and two other generic manufacturers. GSK has a statutory right to show that the generic manufacturer's allegations are "not justified." [Emphasis added.]

[114] This was also the conclusion of Rothstein J.A. (as he then was) in responding to the concern raised by generics that patent holders could invoke the *PM(NOC) Regulations* to protect their exclusivity in the market for an additional two years even when the patent was clearly ineligible to block the generic, or would be found invalid. As Rothstein J.A. stated in *Apotex Inc. v. Canada (Minister of National Health and Welfare)* (2000), 181 D.L.R. (4th) 404, 2000 CanLII 14856 (FCA), at para. 28*, "*there is a comprehensive scheme provided in the Regulations which specifically addresses ineligible patents on the Register and the costs, loss and damage suffered by generic manufacturers arising from such ineligible patents being included on the Register." [Emphasis added]

[115] This reasoning is applicable to this case. The claims made by Apotex arise from the patent regime and Lilly's exercise of rights it had under the 113 Patent. While Apotex attempts to dress up Lilly's acts in seeking a patent and listing the 113 Patent on the Patent Register as wrongful due to the subsequent voiding of the patent, Lilly was exercising rights which exist under the *Patent Act*. Absent a "stand alone cause of action" or a claim "totally independent of the regulatory regime," to use the language of the Ontario Court of Appeal and the Divisional Court, in my view the *Patent Act* and the *PM(NOC) Regulations* constitute a "complete code" which precludes causes of action arising from the operation of that code.

[116] To accept Apotex's argument that it may nevertheless pursue the causes of action it has pleaded would, as Lilly argues, "drastically upset Parliament's statutory regime." I would add that it would undermine it. Exposing a party to liability for damages simply because it

successfully obtained a patent and exercised its rights based on its presumptive validity would remove one of the key benefits of the patent regime, which exists to foster and encourage innovation by protecting inventions for the benefit of the inventor for a limited period of time.

[117] Without the *PM(NOC) Regulations*, there would have been nothing standing in the way of Apotex obtaining an NOC for its Apo-Olanzapine drug once it became approvable by the Minister of Health on June 28, 2006. Apotex pleads exactly this in para. 32 of its Statement of Claim, where it states: "The ANDS for Apo-olanzapine became approvable under the FDA Regulations on or about June 28, 2006. In the absence of the PMNOC Regulations, Apotex would have been issued an NOC for its product at that time." [Emphasis added]

[118] The fact that Lilly was not required to list the 113 Patent on the Patent Register, or to commence and pursue the Apotex Prohibition Proceedings, including obtaining and defending the Gauthier Order, does not affect the conclusion that any damages are caused by operation of law. Pursuant to s. 43(2) of the *Patent Act*, the 113 Patent was presumed valid when Lilly listed it on the Patent Register and when it pursued the prohibition proceedings against Apotex and Novopharm. These were steps, as Perell J. put it in *Harris v. GlaxoSmithKline*, approved by Moldaver J.A., such acts "were the opposite of unauthorized" and were acts that Lilly "was at liberty to commit."[6]

[119] Although s. 62 of the *Patent Act* provides that a patent "that is voided by a judgment shall be and be held to have been void and of no effect," this does not rewrite history. Rather, it prevents a patent holder from pursuing, or continuing to pursue, any actions for patent infringement that it otherwise might have had under the patent. But it does not create, retrospectively, the benefit asserted by Apotex that a patent holder is liable for acts that it had a right to take while the patent was extant.[7]

[120] Apotex finds itself, no doubt unhappily, in the position that it cannot even pursue damages pursuant to s. 8 of the *PM(NOC) Regulations* because it was unsuccessful in the Apotex Prohibition Proceedings before Gauthier J., but that is the way the law works. As Gauthier J. stated in dismissing Apotex's motion for reconsideration (*Eli Lilly Canada Inc. v. Apotex Inc*., 2010 FC 952), at para. 32, "it would have been easy to add − had this been Parliament's intent − that the generic was to be indemnified if the patent listed was ever declared invalid. Instead, Parliament chose to focus on all possibilities that could happen in the normal course of a prohibition proceeding (dismissed, discontinued, reversed in appeal, etc.)."

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[6] For the same reasons, Lilly was also entitled to refuse to consent to Apotex receiving an NOC following the Hughes Order in 2007 as the patent continued to be presumptively valid – a point implicitly conceded by Apotex in arguing that the O'Reilly #2 Decision in 2011 was a necessary precondition to all of its claims.

[7] More generally, in the absence of some independent wrong a party should not be subject to liability and damages, other than for costs, for bringing an action to protect what it believes to be its legal right. If there are to be exceptions to that principle, they must be clearly legislated. An example of this can be found in the Anti-SLAPP law, *Courts of Justice Act*, R.S.O. 1990, c. C.43, s. 137.1, which exposes a plaintiff to damages if an action is brought that infringes the defendant's freedom of expression and the plaintiff cannot satisfy the test to allow it to continue.

[121] Accordingly, as the *Patent Act* and the *PM(NOC) Regulations* constitute a "complete code" and the actions alleged to have caused harm to Apotex were authorized by law and flowed from the operation of law, the action should be dismissed.

Are the causes of action tenable?

[122] Consideration of the "novel" causes of action supports the conclusion reached above. A close examination of the claims confirms that none of them constitute "stand alone" claims that are "totally independent of the regulatory regime." Further, even if the claims could be pursued, they have no support in the evidence or the law.

The monopolies claim

[123] Apotex's monopoly claim is based on the Ontario and English *Statutes of Monopolies*. As the 113 Patent has been declared to be void *ab initio*, the claim asserts that Lilly had an unlawful monopoly arising from an invalid patent, and that Apotex has been "hindered, grieved, disturbed and disquieted by occasion of the 113 Patent." Thus, Apotex asserts, it is entitled to "treble damages" pursuant to s. 4 of the *Statutes*.

[124] The English *Statute of Monopolies, "An Act concerning Monopolies and Dispensations with penal Lawes and the Forfeyture thereof* ", 1624 Jac. 1, c. 3, has an important place in English history. It is an example of Parliament limiting the power of the monarch which led, just a couple of decades later, to the English Civil War and the execution of Charles I. It was passed in response to perceived abuses by the Crown, notably by Elizabeth I and James I, who issued "letters patent" or licenses, to operate monopolies for trade in certain goods, trade routes, and to operate particular industries, all in return for revenue paid to the Crown.[8]

[125] Patents were also issued for new inventions at the time, but it was the monopolies over economic activity that were the source of grievances and which led to the passing of the Act. This is seen in the Act itself, which in s. 5 excluded patents for new inventions - or "new Manufactures" as they were called in the 17th century - which could be granted for a period of 21 years. In contrast, other monopolies, commissions, licences or grants of authority were declared "utterlie void and of none effecte" by s. 1 of the Act and, pursuant to s. 4, give rise to treble damages where someone is "hindered, grieved, disturbed or disquieted" by such a monopoly.

[126] The English legislation was enacted, or re-enacted, by the Ontario Legislature in 1897, in *An Act concerning Monopolies and Dispensation with penal laws, etc*., R.S.O. 1897, c. 323, in virtually identical, although slightly modernized, language.

[127] There are a number of questions about the application and validity of the *Statutes of Monopolies*, some of which were discussed by Dunphy J. in *Apotex Inc. v. Eli Lilly and Company et al*., 2015 ONSC 5396. One question is whether the English Act of 1624 was

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[8] See Chris Dent, "'Generally Inconvenient': The 1624 *Statute of Monopolies* as Political Compromise" (2009) 33 Melbourne UL Rev 415, for a very thorough article on the circumstances surrounding the enactment of the statute.

received as part of the laws of Upper Canada (now Ontario) in 1792 by the *Property and Civil Rights Act*, R.S.O. 1990, c. P.29. Another question is whether the Ontario Act can apply to the circumstances of this case which would involve finding an unlawful monopoly arising from an invalid patent for a new invention, as "patents of invention and discovery" are a matter of federal jurisdiction: *Constitution Act, 1867*, s. 91(22).

[128] Yet another question is the federal jurisdiction over monopolies as legislated by Parliament under the *Competition Act*, R.S.C. 1985, c. C-34. Alleged abuses of patent rights are dealt with under s. 32 of that Act, which may also oust any application of the *Statutes of Monopolies* to patents. The Ontario Court of Appeal touched on this in *Harris* at para. 18 as the claim in that case, which pleaded common law torts, made "numerous references to GSK's 'monopoly' and the 'supra-competitive' prices it was able to charge." Justice Moldaver stated at para. 18 that "[i]n considering the rights of patentees, it is essential to differentiate between a monopoly, in the anti-competitive, unlawful sense of the word, and an intellectual property right, such as a patent." He noted that the exercise of intellectual property rights is not anti-competitive, a point confirmed in s. 79(5) of the *Competition Act* which states that "an act engaged in pursuant only to the exercise of any right or enjoyment of any interest derived under the [. . .] *Patent Act* [. . .] is not an anti-competitive act."

[129] Justice Moldaver also cited with approval *Canada (Competition Act, Director of Investigation and Research) v. Warner Music Canada Ltd.*, 1997 CanLII 3725 (C.T.), at p. 9, where the tribunal stated that "[t]he right granted by Parliament to exclude others is fundamental to intellectual property rights and cannot be considered to be anticompetitive." Justice Moldaver continued at para. 20:

> While the normal exercise of an intellectual property right is not an "abuse of dominance" under the *Competition Act*, Parliament was alive to the fact that those rights can be used inappropriately. Section 32 of the Act gives the Federal Court broad remedial powers to address the use of intellectual property rights in ways that "unduly lessen" competition. This reflects recognition that intellectual property rights can be used in unlawfully anti-competitive ways. What then is the nature of a drug patent? It is a time-limited, statutorily-authorized monopoly on the production and sale of certain medicines. <u>The patent-holder's right to exclude others is fundamental to the nature of the patent, but those anticompetitive characteristics are dealt with in the statutory scheme of the *Competition Act*</u>.[Emphasis added]

[130] These foundational issues were not argued before me, although some were pleaded in the Statement of Defence. However, it is not necessary for me to address them in light of my conclusion that, assuming the *Statutes* are valid and may be applicable, they do not support Apotex's position.

[131] On this summary judgment motion, to support its argument that it has been "hindered, grieved, disturbed, or disquieted" by the 113 Patent, Apotex simply relies on the documentary evidence that Lilly obtained and relied on what turned out to be an invalid patent. It was, however, a patent for a new invention which is not prohibited by the *Statutes of Monopolies*.

[132] Additionally, if the patent is void *ab initio*, as Apotex emphasizes, then it is treated as having never existed. Apotex, however, wants it both ways, saying that Lilly never had a patent, but that Apotex was harmed by the patent. This cannot be right. If Apotex wants to say the patent never existed, then Lilly was never granted a monopoly, let alone an unlawful monopoly, and the prohibition has no application. If one is going to rewrite history, it should at least be done consistently.[9]

[133] Finally, although this claim under the *Statutes of Monopolies* has been described as "novel," it has arisen in the past, and been dismissed.

[134] Over a century ago, in *Peck v. Hindes* (1898), 15 RPC 113 (Q.B.D.), an attempt to invoke the English Act in somewhat similar circumstances was considered and rejected in England. After an infringement action had been discontinued due to the realization that the patent could not be validly invoked, an action was brought against the patent holder for having brought the infringement action, relying on s. 4 of the English *Statute of Monopolies*. After reviewing the 1624 Act and observing that patents for new inventions were excluded from it, Mathew J. observed, at p. 127, that the Act "applies in its terms to invalid and improper exercises of the Royal Prerogative, and not to Letters Patent which were perfectly legitimate and protected by law," and concluded, on p. 128, "that the Statute of Monopolies does not apply."

[135] The holding in *Peck v. Hindes*, is consistent with my conclusions above. The Act excludes patents for new inventions from the prohibition on monopolies. Further, the purpose of the Act was to prevent "invalid and improper" grants of monopolies by the Crown. As I have stated, if the 113 Patent is void *ab initio*, then it is deemed never to have been granted.

[136] The holding in *Peck v. Hindes* is an early illustration of the operation of the "patent bargain" described by the Supreme Court in *Teva Canada Ltd. v. Pfizer Canada Inc*., 2012 SCC 60, [2012] 3 S.C.R. 625, at para. 32, in which "the inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge." To obtain the patent, the applicant must satisfy various statutory requirements under s. 27 of the *Patent Act*, and the patent holder must then be prepared to defend the patent if an application to impeach it is brought, or a notice of allegation is served under the *PM(NOC) Regulations*. But to retroactively make a patent holder's actions wrongful and be liable for damages beyond those provided in the Regulations, including treble damages, if the patent is found to be invalid, would upset that bargain and undermine the objectives of the Act.[10]

[137] Accordingly, I find that the monopolies claim pleaded by Apotex has no merit, and that Apotex has raised no genuine issue requiring a trial on that basis.

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[9] I observe that, unlike Apotex, Lilly did not seek to rewrite history and ask for reconsideration of the invalidation of the 113 Patent following the discarding of the promise doctrine by the Supreme Court in *AstraZeneca* in 2017. If that could be revisited, Lilly could then seek damages for infringement. Of course, the law does not work this way.

[10] A short and helpful comment on these issues is by Sam Sokoloff, "Can a 400 year old statute disrupt Canadian patent law?" online: 2020) WJLS: https://ojs.lib.uwo.ca/index.php/uwojls/announcement/view/114.

Trademarks Act

[138] Apotex relies on s. 7(a) of the *Trademarks Act*, which is breached when a party (i) makes a false or misleading statement; (ii) which tends to discredit the business, wares or services of a competitor; and (iii) results in damage. Apotex also pleads s. 7(d) of the *Trademarks Act* which requires a finding that a party made use, in association with goods or services, of any description that is false in a material respect and likely to mislead the public as to the character, quantity or quality of the goods or services.

[139] In its Statement of Claim Apotex says that "in listing the '113 Patent on the Patent Register, Lilly either explicitly or implicitly made statements and represented that:

> (a) the '113 Patent was valid and enforceable;
>
> (b) Lilly had the exclusive right to the subject matter of the claims of the '113 Patent;
>
> (c) the '113 Patent was eligible for and properly listed on the Patent Register;
>
> (d) the listing of the '113 Patent on the Patent Register was with the agreement and consent of Lilly U.K. because such agreement and consent was necessary to do so; and
>
> (e) any person, including Apotex, who filed a submission for an NOC in respect of an olanzapine solution on the basis of a comparison to ZYPREXA, would, before being able to receive an NOC for same, have to first address the '113 Patent."

[140] On this motion, Apotex led no evidence on this issue other than the Form IV, and in argument counsel confirmed that Apotex simply relied on the Form IV completed by Lilly in support of this claim. As I have noted, however, the Form IV is a very straightforward document which identifies the drug, dosage form, brand name, that it is for human use, that it is taken orally and lists some of the therapeutic uses. It provides the patent number, the filing date, the date the patent was granted, and the expiry date. The holder of the patent certifies that this information is correct. That is all.

[141] There is nothing untrue or false in any material respect, let alone disparaging or discrediting of Apotex, in the Form IV. At the time it was completed, Lilly did have the 113 Patent for Olanzapine. That is essentially all that was stated. The Form IV made no reference to Apotex, directly or indirectly, or to any other entity. In short, Apotex has raised no genuine issue requiring a trial on this cause of action.

[142] This claim also suffers from the same flaw as the monopolies claim, in that it seeks to make Lilly liable for doing something it had a right to do when it held a presumptively valid patent. As the Federal Court stated in *Excalibre Oil Tools Ltd. v. Advantage Products Inc*., 2016 FC 1279, at para. 281 ("*Excalibre*"):

> Section 43(2) of the *Patent Act* states that issued patents are presumed valid, absent evidence to the contrary. Patentees are entitled to assert that they have rights flowing from a valid patent. [Emphasis added]

[143] In *Excalibre* and other cases that have sought damages under the *Trademarks Act*, the facts involved patent holders writing cease and desist letters to alleged infringers or to others that were threatening and which tended to discredit the goods of a competitor. As Manson J. stated at para. 282 of *Excalibre*:

> It is important to distinguish between cease and desist letters that are informative and letters that are threatening. In *Supertek*, above [*E Mishan & Sons, Inc v Supertek Canada Inc*, 2016 FC 986], Mr. Justice Roger Hughes contrasted the situation in *S&S* [*S & S Industries Inc v Rowell*, [1966] SCR 419], where the false and misleading statements consisted of a cease and desist letter threatening litigation that never came to pass, with the situation in *M&I Door Systems Ltd v Indoro Industrial Door Co Ltd* (1989), 25 CPR (3d) 477 (FCTD), where the cease and desist letter was more informative than threatening. Informative letters set out a patentee's rights and provide information that will enable the recipient to understand what may constitute infringement. Threatening letters contain explicit or veiled threats that the recipient will be sued if they do not change a particular course of conduct.

[144] *Excalibre* and the cases cited in it do not support application of the *Trademarks Act* to a patent holder of a pharmaceutical drug doing what Lilly did in this case, which was to complete a Form IV to place the 113 Patent on the Register. In doing so, Lilly was simply exercising its legal right based on the then existing patent. As with the commencement of the Apotex Prohibition Proceedings, the listing of the patent was "the opposite of unauthorized" and an act Lilly "was at liberty to commit."

Conspiracy

[145] Apotex's final cause of action is common law conspiracy, in which it is alleged that the defendants "agreed amongst themselves to," among other things, "monopolize in Canada the manufacture and sale of olanzapine," fix monopolistic prices, preclude competition, procure an invalid patent, list the 113 Patent on the Patent Register, pursue litigation under the *PM(NOC) Regulations*, and pursue an infringement action against Apotex.

[146] Apotex has led no evidence of this conspiracy to support a "stand alone" cause of action, or at all. It has pointed to no agreements or conduct to support these allegations other than what Lilly had the right to do: apply for a patent and, once it was obtained, list it on the Patent Register and pursue proceedings under the *PM(NOC) Regulations*. There is no evidence, or even suggestion, of improper conduct by Lilly in obtaining the 113 Patent. Apotex simply relies on the fact that many years later the 113 Patent was found to be

invalid.[11] As Perell J. put it, cited with approval by Moldaver J.A. in *Harris*, at para. 47, "[t]he case law establishes that provided that there are no unlawful acts, an ordinary commercial transaction with the predominant purpose of advancing one's own economic interests does not constitute a conspiracy even though a party or a third party may suffer an economic loss."

[147] Again, Apotex raises no genuine issue requiring a trial.

Conclusion

[148] The motion for summary judgment is granted and the action shall be dismissed. If the parties cannot agree on costs, counsel for Lilly may provide me with brief written submissions within three weeks of the release of these Reasons, and counsel for Apotex shall provide any responding submissions two weeks later.

Paul B. Schabas J.

Date: March 8, 2021

[11] I note that even if Apotex could point to some improper or misleading statement by Lilly in its application for the 113 Patent, the *Patent Act* addresses that situation in s. 53(1) dealing with untrue or misleading statements. This too, supports the "complete code" argument.