Federal Court  Cour fédérale

Date: 20190703

Citation: 2019 FC 884

Ottawa, Ontario, July 3, 2019

PRESENT: Case Management Judge Mireille Tabib

BETWEEN:

Docket: T-1632-16

ELI LILLY CANADA INC., ELI LILLY AND COMPANY, LILLY DEL CARIBE, INC., LILLY, S.A. and ICOS CORPORATION INC.

Plaintiffs/Defendants by Counterclaim

and

APOTEX INC.

Defendant/Plaintiff by Counterclaim

AND BETWEEN:

Docket: T-1627-16

ELI LILLY CANADA INC., ELI LILLY AND COMPANY, LILLY DEL CARIBE, INC., LILLY, S.A. and ICOS CORPORATION INC.

Plaintiffs/Defendants by Counterclaim

and

MYLAN PHARMACEUTICALS ULC

Defendant/Plaintiff by Counterclaim

AND BETWEEN:

Docket: T-1631-16 (T-1639-16)

ELI LILLY CANADA INC., ELI LILLY AND COMPANY, LILLY DEL CARIBE, INC., LILLY, S.A. and ICOS CORPORATION INC.

Plaintiffs/Defendants by Counterclaim

and

TEVA CANADA LIMITED

Defendant/Plaintiff by Counterclaim

AND BETWEEN:

Docket: T-1623-16 (T-1624-16)

ELI LILLY CANADA INC., ELI LILLY AND COMPANY, LILLY DEL CARIBE, INC., LILLY, S.A. and ICOS CORPORATION INC.

Plaintiffs/Defendants by Counterclaim

and

PHARMASCIENCE INC. AND LABORATOIRE RIVA INC.

Defendants/Plaintiffs by Counterclaim

REASONS FOR ORDER

[1] The Plaintiffs, who will be referred to collectively as "Lilly" in these reasons, have sued Apotex Inc., Teva Canada Limited, Pharmascience Inc. and Laboratoire Riva Inc (the latter two, collectively referred to as PMS/Riva in these reasons), and Mylan Pharmaceuticals ULC, in independent actions for infringement of patents related to the drug tadalafil. Each of the Defendants has denied infringement and counterclaimed for a declaration of invalidity of the patents asserted against them.

[2] Although the actions (but for the PMS/Riva actions) have not been consolidated, they have been case managed together and are scheduled to proceed to trial beginning on December 2, 2019. The issues related to the construction and invalidity of the patents will be tried together in a common hearing, following which the infringement issues for each action will continue in four individual hearings.

[3] In early March 2019, slightly less than nine months before trial, Lilly announced its intention to amend each one of its actions to introduce what amounts to a new cause of action against each Defendant. The contested motions for leave to amend were formally filed in late April 2019, and were heard together in May 2019.

[4] For the reasons that follow, Lilly will be granted leave to amend its pleadings as requested, but on condition that all issues related to the newly added cause of action be

bifurcated and only be tried after the liability issues in the existing causes of action have been determined.

I. Procedural History and Context

[5] Lilly holds four patents in respect of the drug tadalafil, as used for the treatment of erectile dysfunction in men and other symptoms. These indications will be referred to in these reasons as "ED". Lilly sells and markets tadalafil in Canada for ED under the brand name Cialis. Tadalafil can also be used for the treatment of pulmonary arterial hypertension ("PAH"), but that use was known before the patents for ED were filed, and the compound tadalafil for that or any use other than ED is no longer protected by patents.

[6] The four patents at issue in these actions can briefly be described as follows:

> The '784 Patent, which expired on July 11, 2016, relates to the use of tadalafil to treat ED.
>
> The '684 Patent, which will expire on April 26, 2020, relates to a specific dosage form of tadalafil.
>
> The '948 Patent, which will also expire on April 26, 2020, relates to a specific formulation for tadalafil.
>
> The '540 Patent, which will expire on July 14, 2023, relates to a specific process for making tadalafil.

[7] Three of those four patents, the use ('784), dosage form ('684) and formulation ('948) Patents, were listed on the Registry maintained by the Minister of Health under the *Patented Medicines (Notice of Compliance) Regulations* SOR/93-133 and were the subject of prohibition proceedings under the *PM(NOC)Regulations* against all defending generics in these actions. The

applications in respect of Apotex and Mylan eventually resulted in judgements concluding that the allegations of invalidity of the ‘784 Patent were not justified, but that those related to the invalidity of the ‘684 and ‘948 Patents (dosage and formulation) were justified. An order therefore issued prohibiting the issuance of Notices of Compliance for these generics to sell tadalafil for the treatment of ED until the expiration of the ‘784 Patent. The applications in respect of Teva, PMS and Riva were disposed of without judgement along the same lines.

[8] All Defendants obtained their NOC to sell tadalafil for the treatment of ED on July 12, 2016, the day immediately following the expiration of the ‘784 Patent, and immediately began selling tadalafil for that indication. Lilly promptly instituted these actions for infringement of its patents, asserting the ‘684, ‘948 and ‘520 Patents (dosage, formulation and process) against all four Defendants, and the ‘784 Patent against Apotex only. Apotex is the only one of the four Defendants that had, prior to the expiration of the ‘784 Patent, obtained a NOC in respect of tadalafil for the old indication of PAH. In its original Statement of Claim, Lilly alleged that Apotex’s tadalafil nominally approved for the treatment of PAH was instead being sold, promoted and used for ED, such that Apotex was infringing and inducing others to infringe the ‘784 Patent.

[9] As mentioned above, the actions were designated as specially managed proceedings and, while not consolidated, were managed together. Bifurcation orders were issued, severing the issues of liability and of compensation, and postponing discoveries and the trial related solely to compensation issues until after the trial and determination of the issues of invalidity and infringement. The parties cooperated and coordinated the oral discoveries of the corporate

representatives of Lilly and of the inventors so that they would be effective for all parties and for use in the common trial of the construction and invalidity issues. Discoveries in respect of infringement were conducted during the summer of 2018. Answers to undertakings were provided in October and November 2018. The trial dates were set in December 2018, and motions on refusals were heard and determined in January 2019.

[10] Lilly alleges that it conducted a comprehensive review of the pleadings at that time, leading it to propose the amendments at issue in these motions. Lilly asserts that the proposed amendments are based on information obtained during discoveries and will focus the issues at trial.

II. The Proposed Amendments

[11] Some of the amendments proposed by Lilly are not controversial and do indeed streamline and focus the issues at trial. The proposed amendments to which the Defendants have consented would:

> Remove all claims for infringement of the ‘948 Patent (formulation) against all Defendants.
>
> Remove the claim for infringement of the ‘540 Patent (process) against Mylan and PMS/Riva.
>
> Remove the claim for infringement of the ‘784 Patent (use) by reason of the sale of tadalafil for PAH by Apotex.

[12] This would leave a claim for infringement of the ‘684 Patent (dosage) against all Defendants and a claim for infringement of the ‘540 Patent (process) against Apotex and Teva only.

[13] The amendment that is vigorously contested would then add, against all Defendants, a new claim for infringement of the ‘784 Patent (use) by reason of the manufacturing, importing and stockpiling of tadalafil for ED prior to the expiration of the ‘784 Patent, and springboard damages flowing from that infringement.

[14] This new claim is different from the claim for infringement of the ‘784 Patent that was previously asserted solely against Apotex in respect of its infringement and inducing infringement through sales of the product that had been approved for PAH prior to the expiration of the ‘784 Patent. While that pre-existing claim will be removed, all Defendants would, if the amendment is permitted, now face a claim to the effect that they manufactured, imported and stockpiled tadalafil for the treatment of ED before the expiration of the ‘784 Patent.

[15] This cause of action is closely related to the causes of action already pleaded against the Defendants, in that it concerns the same product which the Defendants began selling on July 12, 2016 and in respect of which all Defendants allegedly infringe the ‘684 Patent and in respect of which Apotex and Teva allegedly infringe the ‘540 Patent. It is also related to the cause of action initially pleaded against Apotex in that it asserts the same patent that had previously been asserted against it. It is, however, clearly a new cause of action against all Defendants. Indeed, for all Defendants other than Apotex, it asserts an entirely new Patent; for all Defendants, including Apotex, it impugns conduct which was not previously the subject of any allegations at all.

III. The Defendants’ Objections

[16] The Defendants oppose the addition of the new cause of action in respect of the ‘784 Patent on the basis that it discloses no reasonable cause of action. Some of the Defendants also raise issues that are specific to the proposed allegations against them, such as that the proposed pleading fails to allege sufficient material facts and that some of the facts alleged have no basis in fact or are incapable of being proven. Finally, all of the Defendants argue that in any event, the amendment comes impermissibly late, after the parties have committed to a course of action that may not be changed, and would cause them prejudice that cannot be compensated in costs.

[17] There is no dispute between the parties as to the law applicable to motions to amend and the relevant case law need not be reviewed in these reasons. Lilly has the burden of showing that its amendments should be allowed. Any of the objections raised by the Defendants, if established, would justify refusing leave to amend.

IV. Analysis

A. *Do the amendments disclose a reasonably arguable case?*

[18] All four Defendants essentially argue that, because the ‘784 Patent is a “use” patent for a known compound, infringement of the patent cannot be established in relation to their product, even if it was designed to be sold and used for the treatment of ED, because infringing use by patients during the period of validity of the patent cannot be established. They argue that none of them sold or could sell their product in Canada until the expiration of the ‘784 Patent, and that no case for infringement of the’784 Patent can possibly be made out since use of tadalafil to treat ED was, by then, no longer protected by patent.

[19] While the Defendants raise an interesting argument, it is not one that has previously been recognized by jurisprudence on similar facts, and the Court is not satisfied that it is plain and obvious that the proposed new claim can not succeed.

[20] The Defendants articulate their argument around general principles and dicta drawn from five cases, none of which are directly on point. The Defendants begin their analysis with the description and label used by all parties for the '784 Patent as being a "use" patent, and then default to the decision of this Court in *Solvay Pharma v Apotex* 2008 FC 308 at 136, which they say sets out the principle that infringement of a "use" claim requires an act of infringement to be completed by the direct infringer, in accordance with the seminal case of *Weatherford Canada Limited et al. v Corlac Inc.* FCA 2011 to 28, at paragraph 162. They round off the argument by pointing to the Federal Court's decision in *Bristol-Myers Squibb Canada et al. v Apotex Inc.* 2017 FC 1061, which they assert used the same approach in respect of the assessment of infringement of claims to pharmaceutical compositions for use in the treatment of certain disorders. They argue that these are essentially "use" claims in a different form. They hold up the *Bristol-Myers Squibb* decision as justifying the same approach (of requiring proof of direct infringing use by an end user), "so as not to artificially extend the monopoly held by the patent holder by effectively transforming all pharmaceutical patents into compound patents, meaning that the patentee would monopolize the drug itself even where it is not protected by the patent" (*Bristol-Myers Squibb*, above, at para 33).

[21] The Defendants claim further support for their position from chosen excerpts from the Supreme Court's decision in *Monsanto Canada Inc. v Schmeiser* 2004 SCC 34. They cite

portions of paragraph 49 to the effect that the issue is "what the defendant does,… not what he intends" to support their argument that it is irrelevant that they might, prior to the expiry of the '784 Patent, have made, possessed or stockpiled tadalafil with the intention that it eventually be used to treat ED, because no infringement actually took place (through use by a patient during the period of validity of the patent). They rely on the definition of "use" found at paragraphs 35 and 36 of *Monsanto* as being the question "did the defendant's activity deprive the inventor in whole or in part, directly or indirectly, of the full enjoyment of the monopoly conferred by law?" Again, since no use could be made of the tadalafil they possessed prior to the expiration of the '784 Patent, they could not infringe by mere possession of the compound. Finally, they rely on the case of *MediaTube Corp. v Bell Canada* 2017 FC 6, at para 223 to show that infringement by possession cannot occur where the actions described in the patent (e.g., actual use for ED by a patient in this case) are not performed, because the benefits of the purported invention (use in ED, as distinct from the composition itself) are not taken.

[22] The Court has no doubt that a reasonably arguable defence can be raised as to whether the making and/or possession, for the purpose of eventual sales, of a product intended for a particular use constitutes infringement of a claim for "a compound for" that particular use, where it is clear that sales and use of the product would only take place after the expiration of the patent. However, the Court is not satisfied that the cases cited by the Defendants support that defence, much less that they are determinative of the issue.

[23] The Defendants' argument relies on the erasure of any distinction between claims drafted as "a composition for use in the treatment of" and those drafted as "use of a composition in the

treatment of", and the conflation of all use-limited claims as claims for the use of a pharmaceutical composition by a patient. If that conflation is accepted, then any infringement of the claims of the '784 Patent by generics must necessarily be by inducement and, using the tripartite test elaborated in *Weatherford*, necessarily require infringing use by the end-user of the product.

[24] There is however jurisprudence that recognizes a difference between the two kinds of claims. That jurisprudence acknowledges that a claim for use of a compound in treating a disorder is not susceptible of direct infringement by a pharmaceutical manufacturing company, and that infringement of such claims necessarily must be based on inducement. Yet these cases also do recognize that claims drafted as "a composition for use in the treatment of" can be construed as claiming a specific product, and are therefore susceptible of direct infringement by a maker of generic medicines. The Federal Court of Appeal's decision in *AB Hassle et al v Canada (Minister of National Health and Welfare)* 2002 FCA 42, which was cited and followed in both *Solvay Pharma* and *Bristol-Myers Squibb*, above, is a case in point. The Court of Appeal, at para 5 of the decision, describes the patent at issue as follows:

> The '668 patent held by Hassle contains three claims, each relating to use of the compound, Omeprazole as follows:
>
> 1. In the manufacture of a medicament for the treatment of Campylobacter infections.
>
> 2. In the treatment of Campylobacter infections.
>
> 3. In a pharmaceutical preparation for use in the treatment of Campylobacter infections.
>
> (Emphasis added)

[25] The Federal Court of Appeal then summarizes, in paragraphs 12 to 14 of its decision, the key findings of the trial judge in respect of direct infringement, as follows:

> 12 In his decision, O'Keefe J. made four factual findings. Firstly, he found that there was no evidence that Apotex will directly infringe the Appellants' '668 patent. According to O'Keefe J., the Appellants had not adduced evidence that successfully established an infringement of the first claim, which claims the exclusive right to use omeprazole for the manufacture of a medicine for the treatment of Campylobacter infections. Therefore, under the first claim, the manufacture by Apotex only falls within the exclusive domain of the patent holder if the medicine is being manufactured for the treatment of Campylobacter infections, and Apotex alleges in its NOA that it is not manufacturing the medicine for this limited treatment.
>
> 13 As for the second claim, he found that the Appellants had conceded that it is impossible for Apotex, as a company itself, to use omeprazole to treat a Campylobacter infection. Therefore, Apotex does not and will not directly infringe the second claim of the '668 patent.
>
> 14 With respect to third claim, he held that the claim is limited by the wording "for use in the treatment of Campylobacter infections". Therefore, pharmaceutical preparations of omeprazole for uses other than the treatment of Campylobacter infections would not infringe the '668 patent.
>
> (Emphasis added)

[26] The appeal was not concerned with these findings, but with the findings of fact and law in relation to indirect infringement and whether at law, it was necessary to show that Apotex, by its actions, implicated itself in the infringement of third parties. It is in that context that the Federal Court of Appeal in *AB Hassle* wrote the dictum cited by the Court in *Bristol-Myers Squibb*, above, as to the importance of properly applying the test for induced infringement, so as

not to artificially extend the monopoly held by patent holders by transforming all pharmaceutical patents into compound patents.

[27] Indeed, the case of *Bristol-Myers Squibb* on which the Defendants rely does recognize the distinction between pure use claims and compounds for use claims. The decision was issued in the context of an application for a prohibition order under the prior version of the *PM(NOC) Regulations*, on a motion to dismiss brought pursuant to paragraph 6(5)(b). The reasons describe the independent claims of the patent as follows: “Claim 16 is for "[t]he use of aripiprazole in the treatment of, or for the production of a medicament effective in the treatment of, a disorder of the central nervous system (…)” and “Claim 36 is for "[a] pharmaceutical composition comprising aripiprazole, and an acceptable diluent or excipient, for use in the treatment of a disorder of the central nervous system(…)”. Having set out these two independent claims, however, the Court then only ever mentions claim 16 in its analysis. This incongruity may explain why the Judgement was reversed on consent on appeal (Unreported, Judgment of the Federal Court of Appeal in file no A-386-17, dated January 25, 2018). This discrepancy however hardly matters for the purpose of this discussion, as claim 16 includes claims for the direct use of the composition and for its use in a medicament for use in treatment. What is of particular relevance is that the Court’s analysis is separated in two distinct parts: “A. Evidence of direct infringement” and “B. Evidence of induced infringement”.

[28] The Court conducts its analysis in respect of <u>direct</u> infringement by looking at whether the product Apotex intended to make was indicated or would be approved for the patented use, and concludes, at paragraph 27:

> (…) Simply put, if Apotex does not manufacture Apo-Aripiprazole for the claimed uses, but rather, manufactures Apo-Aripiprazole solely for the unclaimed use, there can be no direct infringement of claim 16.

[29] The Court in *Bristol-Myers Squibb* therefore did consider and address the possibility that direct infringement could be made out by the manufacturing of a product for a claimed use, independent of any induced infringement. It is only in the second part of the analysis, dedicated to induced infringement, that the Court applies the tripartite test developed in *Weatherford,* requiring evidence of a completed act of infringement by a direct infringer, and refers to the policy concerns expressed in *AB Hassle* as to the artificial extension of a monopoly for a compound. The decision in *Bristol-Myers Squibb* does not support the conflation and application of the tripartite inducement test to claims drafted as a "composition for use".

[30] The Defendants' reliance on *Solvay Pharma,* above, is not helpful. The paragraph they cite (para 136) may be worded generally as setting out the test applicable to establish "infringement of a use claim", but it is clear that it did not intend to extend the test to direct infringement of use-limited product claims. Indeed, only two claims were at issue in *Solvay Pharma*. They are set out in paragraph 26 of the decision, and both are worded as "Use of the pharmaceutical composition (…) for the regulation of [a disorder]" and "Use of the pharmaceutical composition (…) for treating [a disorder]". The only mode of infringement alleged or addressed in these reasons was infringement by inducement.

[31] It is also noteworthy that Courts in Canada have in the past considered and construed claims drafted as "composition for use in the treatment of (…)", or "Swiss-type claims", for the

purpose of determining their validity in light of the jurisprudential prohibition against patenting claims for methods of medical treatment (see *Hospira Healthcare Corporation v Kennedy Trust for Rheumatology Research*, 2018 FC 259 and cases cited at paragraph 143 of that decision). Many of these cases have concluded that such claims can be construed as claiming "vendible products" and be valid. It is, clearly, arguable that a claim for a vendible product can be directly infringed by making, importing or stockpiling the product, even if no sales or use by a consumer have occurred.

[32] Indeed, while the decision in *Monsanto* does establish that mere possession does not always equate to infringement, and that as a general rule, intention is irrelevant to infringement, it also clearly recognizes that possession of a patented product "with a view to trade" or in commercial circumstances may amount to infringing use (see discussion at paras 52 to 56).

[33] To the extent it is reasonably arguable that the asserted claims of the '784 Patent are for vendible products (and the Defendants have not argued that, as a matter of construction, they cannot), the Court is satisfied that a reasonably arguable case for direct infringement through the importation, manufacture or stockpiling of that product can be made out in the absence of an allegation that infringing use of the product has been made by a direct infringer.

B. *Do the proposed amendments plead sufficient material facts to support the causes of action alleged?*

[34] Apotex and Mylan have argued that, even if one accepts that direct infringement of the ‘784 Patent can be made out without infringing use by a patient, some of the proposed amendments should be denied because they fail to plead sufficient material facts.

[35] Mylan, in particular, argues that the allegations of importation and stockpiling prior to the expiration of the patent are bare conclusions of fact, without sufficient particulars, and are merely inferences based on the date of its first sale of tadalafil, and that the allegation of stockpiling is insufficiently defined in terms of how the alleged activities interfered with Lilly’s monopoly. The Court is satisfied that in the particular circumstances of this case, Lilly’s allegation of stockpiling can, without more, be understood as an allegation of possession for commercial sales. As discussed above, the Supreme Court’s decision in *Monsanto* supports the conclusion that such conduct may disclose a reasonable cause of action. The Court is also satisfied that, to the extent the allegations of importing and possession for commercial sales prior to the expiration of the Patent are based on inference drawn from the date of first sales, from the commercial practices described in the excerpts from the discovery of Mylan to which Lilly has referred in support of its motion, and from the fact that Mylan clearly began engaging in commercial sales on the day immediately following the expiration of the Patent, a reasonable argument can also be made that these allegations are sufficient to support the conclusions urged.

[36] Mylan, like Apotex, also takes issue with some of the broader conclusory statements or declaratory relief set out in the proposed amended pleading, arguing that they are unsupported by the evidence adduced on discovery. The Court having determined that the proposed amendments generally disclose a reasonable arguable case, it is wasteful of the Court’s time to ask it to parse

the details of the language used to describe that cause of action with a view to surgically excising a word here or there or dictating how it should be worded. To the extent the Defendants are of the view that the formulation of the propose amendments is ambiguous or unclear, they may seek particulars at the appropriate time.

[37] Both Apotex and Mylan argue that the proposed amendments to the effect that their allegedly infringing tablets have the same size, shape and colour as Lilly's Cialis tablets disclose no reasonable cause of action, Lilly having withdrawn previous allegations of trademark infringement and passing off based of such allegations. The Court is satisfied that a reasonable argument can be made that these allegations support Lilly's claim that the impugned products constitute a "vendible product" for the treatment of ED.

[38] Finally, Mylan objects to the proposed addition of a claim for elevated or punitive damages based on the issuance of a prohibition order for the '784 Patent. While Mylan's argument is compelling, given that that there is no allegation or suggestion that Mylan's conduct breached the prohibition order, the categories of what constitutes conduct that justifies the award of punitive or elevated damages remain open. The Court is not satisfied that it is plain and obvious that the act of engaging in infringing conduct, if established in that particular context, cannot arguably be considered the "something more" that is required to give rise to punitive damages. The allegations, further, are clearly circumscribed and are unlikely to give rise to protracted or abusive discoveries.

C. *Is the lateness of the amendment likely to cause prejudice?*

[39] As mentioned above, the disputed amendments would add an entirely new cause of action, less than nine months prior to trial. While the Court will not lightly deny a party leave to amend to raise an arguable cause of action, neither will it permit a party to prejudice, embarrass or delay the proper conduct of litigation through the last minute addition of new causes of action, especially where they are the product of deliberate or negligent conduct. As noted by the Federal Court of Appeal in *Bristol-Myers Squibb Company et al v Apotex Inc et al* 2011 FCA 34, at para 37:

> Complex, high-stakes intellectual property proceedings are governed by procedural rules aimed at fairness, full and timely disclosure, and efficiency. Purposeful, strategic conduct involving non-disclosure, non-clarification or inaction, as the Prothonotary and the Federal Court judge found here, disrespects these rules and their aims. Those who disrespect the rules and their aims can hardly expect courts to smile upon them when they look for a favourable exercise of discretion under those rules.

[40] Doing justice between the parties here will require balancing the parties' legitimate substantive and procedural right against each other's and the public interest in the judicious and efficient use of Court resources. The timeliness of the motion and the parties' conduct leading up to the amendments are relevant factors to be taken into consideration.

[41] The Court does not subscribe to the Defendants' view that Lilly engaged in reprehensible or abusive conduct, that it improperly held off proposing its amendments or strategically chose to "lay in the weeds" to gain a tactical advantage from late amendments. However, neither does the Court agree with Lilly's position that the amendments were brought in a timely fashion.

[42] While Lilly might have guessed from publicly available information that the Defendants might have been importing, manufacturing or stockpiling product they eventually sold for ED prior to the expiration of the ‘784 Patent, facts elevating what was mostly speculation to a reasonably arguable case were obtained progressively through the course of this litigation. On the record before it on this motion, the Court is satisfied that facts sufficient to form the basis of the proposed new cause of action were known to Lilly at least as early as the Fall of 2018, and probably even during the Summer of 2018. While nothing indicates that Lilly deliberately sat on its rights, its failure to act earlier speaks to lack of diligence in assessing those facts with a view to forming and disclosing an intention to assert the cause of action flowing from them. It has not been suggested that the Defendants obfuscated or delayed Lilly’s ability to uncover the relevant facts. In the circumstances, the prejudicial consequences of Lilly’s delay, where they cannot be avoided or mitigated, should be allowed to fall on Lilly rather than on the Defendants.

[43] Even assuming that discoveries on the new cause of action are minimal or could be truncated given the discoveries already conducted by Apotex in respect of the ‘784 Patent, expecting a defendant to plead to and be ready to proceed to trial on a new cause of action for patent infringement in less than nine months would be unprecedented. Asking a defendant to do so at the same time as it is preparing to go to trial on a relatively tight schedule, in an ongoing patent infringement action, is clearly unreasonable. The removal of the allegations relating to one or two patents previously at issue might alleviate some of the burden of preparation for the existing trial, and free up a little bit of time to address the new cause of action, but the disruption the late amendment would cause clearly outweighs any relief the removal of issues relating to some of the patents would bring.

[44] Lilly has attempted to minimize the significance of the task of preparing to meet the new cause of action by pointing to the fact that Apotex has already mounted and invalidity counterclaim on the ‘784 Patent and that the other Defendants have already litigated that patent in the context of prohibition proceedings under the *PM(NOC)Regulations*. These attempts are ill-conceived.

[45] Apotex’s litigation choices and strategies in respect of the ‘784 Patent were informed by the specific acts of infringement alleged against it. One cannot assume that, faced with an allegation of infringement for different conduct, it would have made the same choices. In addition, the proposed amendments assert claim 23 of the ‘784 Patent, related to packaging, that is on its face of a different nature from the other asserted claims and that has never been litigated between any of the parties. As regards the Defendants other than Apotex, it is not entirely accurate to say that all of them have litigated the ‘784 Patent in the context of prohibition proceedings. In the case of Teva, PMS and Riva, proceedings were stayed or deadlines were extended, on consent, pending the determination of the Apotex and Mylan applications, and never proceeded to the exchange of expert evidence. In any event, strategies adopted in the context of the summary application process under the previous *PM(NOC)Regulations* regime can be significantly different to those that are appropriate to full-blown infringement actions. Nor is it fair to demand of the Defendants to retroactively consent to be bound and guided by the litigation strategies adopted by Apotex. Fairness requires that they be given an opportunity to make their own assessment of the defence strategy adopted by Apotex and time to implement a strategy that might differ from the one followed by Apotex. Permitting the proposed amendments with a view to bringing them to trial in December 2019 clearly does not allow sufficient or

reasonable time for the Defendants to do so and would cause significant disruption to their trial preparation. The Court is satisfied that permitting the amendments so that liability issues arising from them can proceed to trial in December 2019 would cause prejudice to the Defendants that cannot be compensated in costs.

[46] That conclusion, however, does not mean that the amendments must be refused, if other procedural means can be implemented to avoid that prejudice and protect all parties' rights.

[47] Delaying the trial to allow the Defendants time to properly defend against the new cause of action, as Lilly belatedly suggested, is not practicable or in the interest of justice. Scheduling the trials of these actions as one common hearing of construction and invalidity issues, followed by four individual hearings on infringement issues over a total of eight weeks, given the number of parties involved and their counsel's trial schedules in other matters, has not been an easy task. An adjournment at this time would unacceptably delay the hearing of those portions of the trial that are essentially ready for trial by several years. Lilly's current suggestion that the trial simply be adjourned to the Fall of 2020 presumptuously assumes that common dates of availability between the Court and the parties can be wished into existence to meet its needs when earlier attempts had failed. Indeed, as the Case Management Judge, the undersigned is aware that Lilly's request for a trial as early as possible was accommodated over the Defendants' preference for a more leisurely schedule, because dates that would match the Court's schedule and the parties' availabilities could not be found in 2020.

[48] In a case management telephone conference convened to schedule the hearing of the motions to amend, the Court raised the possibility of deferring all new issues of liability and compensation related to the ‘748 Patent to the already bifurcated quantification stage of the trials, assuming the Court concluded that the proposed amendments raised an arguable cause of action.

[49] While the Defendants vigorously argued that the amendments should simply be refused, none have provided reasons why allowing the amendments, on condition that discoveries and the trial of the issues thereby raised be bifurcated to proceed alongside any issue of quantification remaining to be determined following the first phase of the action, might cause them prejudice.

[50] Indeed, refusing leave to amend would not have the effect of relieving the Defendants from the cloud of litigation surrounding the ‘784 Patent, as some of the Defendants have suggested. The Court having determined that the proposed amendments raise a reasonable cause of action, nothing would prevent Lilly, if leave to amend was not granted, to assert the very same claim in a new action. That action could proceed through discovery and to a trial in roughly the same timeframe as the quantification part of the present actions. The time, effort and expenses the parties have already spent on discoveries in these actions and that may have relevance to the issue raised in the proposed amendments would however be lost, unless the parties were to agree to waive the implied undertaking rule and be able to make binding use of discovery evidence obtained in the present actions for the purpose of the new ones. Absent such agreement, the Court anticipates repeated procedural skirmishes as to what can or cannot fairly be used, be deemed binding on the other or be construed as abusive of the Court’s process. Findings of fact

made in the liability phase of the current actions that may have relevance to the new action would, of course, be binding in future litigation between the same parties, but what of evidence adduced at the trial of these actions that may have relevance to the new cause of action but did not crystallise in a particular finding of fact? In the second phase of a bifurcated action, that evidence can be used, but not in a separate but related proceeding, even as between the same parties.

[51] As mentioned earlier in these reasons, the proposed amendments, while raising a new cause of action, are very much related to the facts at issue in the present actions. Forcing Lilly to bring its new claim for infringement by way of a separate action rather than by way of conditional amendment to the ongoing actions seems not only wasteful of work already done, but potentially invites further and entirely avoidable controversy as to procedural and evidentiary issues. Granting it leave to amend on condition of bifurcation, on the other hand, permits the efficient use of resources for all concerned.

[52] Lilly for its part argued that imposing a bifurcation condition to its amendments would be prejudicial to it, as it would delay by some six years the trial of that cause of action. Lilly's argument is based on the provision of the bifurcation orders, as they currently stand, which provide that discovery on matters relating solely to the bifurcated quantification issues may not be had until the determination of the liability issues, including any appeals. Lilly thus assumes that the determination of the liability phase, including appeals and any leave to appeal to the Supreme Court, would take at least two years and that a further two and a half to three years would be needed for the remaining bifurcated issues to be brought to trial.

[53] Lilly's assumptions are, in the circumstances, not justified. Given that its proposed claim under the '784 Patent is not contingent upon the determination of the liability issues in respect of the other patents, there is no basis upon which the start of discoveries pertaining to that claim should be delayed beyond the end of the trials on the current actions. As some of the Defendants have pointed out in their submissions, the nature of Lilly's proposed new claims, which focusses on how the Defendant's pre-expiry activities might have interfered with Lilly's monopoly and include springboard damages in respect of acts of infringement carried out prior to the expiry of the '784 Patent but leading to losses suffered after the expiration, may very well command a different view of the benefits of bifurcating the liability and infringement in respect of that Patent. Losses or profits attributable to the alleged infringement of the '784 Patent may be coextensive with those attributable to the alleged infringement of the '684 or '540 Patents. It may accordingly very well be that the provision restricting discoveries in respect of the quantification issues for all patents until the exhaustion of all appeals should be revisited in light of the addition of this new claim.

[54] The Court also notes that, even if it were to accept Lilly's arguments that it would suffer prejudice if the Court only allowed its amendments on condition that they be litigated and tried after the completion of the currently scheduled trial, the alleged prejudice is not greater than the prejudice that would befall the Defendants if they were forced to proceed to trial on the new issues beginning in December 2019. As mentioned above, in the circumstances, given that Lilly is the party whose lack of diligence caused the late amendments, it is only fair that it should be the party to shoulder the burden of prejudice that cannot be mitigated or avoided.

[55] Finally, while it is the Court's belief that it would be more efficient, less expensive and less likely to lead to sterile procedural or evidentiary debates if Lilly's new claim was brought as part of the existing action, even if it means deferring it to after the currently scheduled trial, Lilly is free to choose a different course of action. If Lilly considers the conditions imposed for permitting the amendments to be too onerous, it may choose to forego acting on the leave granted, and bring its claim as a new action. The Court cannot force Lilly to amend, or prevent it from bringing a fresh action as a way of asserting a new cause of action. All the Court can do is to impose the bifurcation as a condition to granting leave to amend, in order to prevent a prejudice being caused to the Defendants in these actions.

V. Costs

[56] Success being divided, costs will be in the cause.

"Mireille Tabib"

Case Management Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1632-16, T-1627-16, T-1631-16 AND T-1623-16
STYLE OF CAUSE:	ELI LILLY CANADA INC., ELI LILLY AND COMPANY ET AL. v. APOTEX INC. ELI LILLY CANADA INC. ET AL. v. MYLAN PHARMACEUTICALS ULC ELI LILLY CANADA INC. ET AL. v. TEVA CANADA LIMITED ELI LILLY CANADA INC. ET AL v. PHARMASCIENCE INC.
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