Federal Court  Cour fédérale

Date: 20160108

Docket: T-1888-15

Citation: 2016 FC 31

Ottawa, Ontario, January 8, 2016

PRESENT: Madam Prothonotary Mireille Tabib

BETWEEN:

GILEAD SCIENCES, INC., GILEAD SCIENCES CANADA, INC., AND BRISTOL-MYERS SQUIBB & GILEAD SCIENCES LLC

Plaintiffs

and

TEVA CANADA LIMITED

Defendant

ORDER AND REASONS

[1] Teva Canada Limited brings this motion to strike the statement of claim of the plaintiffs Gilead Sciences Inc., Gilead Sciences Canada Inc. and Bristol-Myers Squibb and Gilead Sciences LLC (collectively "Gilead") on the basis that it fails to plead sufficient material facts to support an action for past infringement or to properly support a *quia timet* claim. Gilead argues that the facts it has pleaded are sufficient but , if not, that it should be given an opportunity to amend to plead further material facts, including facts that have been disclosed to it in the course

of discovery in a separate action involving Gilead Sciences Inc. and Teva. In order to do this, Gilead Sciences Inc. has sought to be relieved of the implied undertaking rule, pursuant to which it is prevented from using information obtained on discovery for any other litigation or purpose.

[2] The parties had agreed that both motions should be heard together. For the reasons that follow, I am satisfied that Gilead should be relieved of the implied undertaking rule. I have also concluded that Gilead's statement of claim, as it currently exists, fails to set out sufficient material facts to support an action for past or current infringement and that none of the amendments proposed by Gilead should be permitted in an attempt to cure that defect. With respect to the *quia timet* claim, the statement of claim, as currently framed, also fails to allege sufficient material facts but I am satisfied that the amendments proposed in Gilead's motion record, combined with further particulars as to the extent of the losses it would suffer, would be sufficient to sustain a *quia timet* claim, and that Gilead should be given an opportunity to make those amendments.

I. Confidentiality

[3] The discovery information at issue had been designated by Teva as confidential pursuant to a protective order issued in the relevant proceeding. That protective order governed the manner in which the parties were to treat information exchanged between them, but did not authorize them to file information under seal without first demonstrating to the Court that the information merits the protection of a confidentiality order. Teva has now made a motion for a confidentiality order in respect of the discovery information at issue. The need to uphold and enforce the implied undertaking rule would, by itself, justify the issuance of a confidentiality

order if Gilead's motion were dismissed. However, if Gilead were relieved of the implied undertaking rule, the evidence tendered by Teva on its motion is insufficient to support a confidentiality order. The evidence demonstrates only that Teva has always treated the information as confidential; it falls short of establishing that disclosure would likely cause serious harm to Teva. Teva has now abandoned its motion for a confidentiality order, but in order to protect the information from premature disclosure in case of a successful appeal of the order relieving Gilead from the implied undertaking rule, the discovery information shall remain under seal until all avenues of appeal of that order have been exhausted. For the same reasons, I have avoided discussing in these reasons the specifics of the discovery information at issue. It is sufficient, for these reasons to be intelligible, that the general nature of the information be disclosed.

II. Procedural background

[4] This action is part of a series of proceedings involving Canadian patents number 2,298,059 (the "059 Patent") and 2,261,619 (the "619 Patent"), owned by Gilead Sciences, Inc. and covering, respectively, the fumarate salt of tenofovir disoproxil ("TDF") and tenofovir disoproxil ("TD") itself. These antiviral drugs have been marketed in Canada by Gilead Sciences Canada, Inc. under the trademarks TRUVADA, ATRIPLA and VIREAD. The 059 Patent will expire on July 23, 2018, while the 619 Patent will expire on July 25, 2017.

[5] In late 2011 and 2012, Teva served on Gilead Notices of Allegation for products containing TDF which it compared to TRUVADA, ATRIPLA and VIREAD, against which both patents were listed. The Notices of Allegation alleged only the invalidity of the patents; they did

not contain allegations of non-infringement. Gilead responded by commencing applications under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 for orders prohibiting the Minister of Health from issuing Notices of Compliance to Teva for these products until the expiration of the 059 and 619 Patents (Court files T-8-12, T-280-12 and T-1708-12).

[6] While the prohibition proceedings were still pending, Teva, in August 2012, served and filed a statement of claim in Court file T-1529-12, seeking a declaration that the 619 and 059 Patents are invalid, void and of no force and effect. That action does not make any allegation or seek any declaration with respect to the non-infringement of the patents, but it does allege that Teva Canada is an interested party because it wishes to import, make, use and sell in Canada TDF or products containing TDF. The discovery transcripts that Gilead seeks to use were constituted in that impeachment action in October 2013, after the hearing of the prohibition proceedings, but before a judgment was rendered.

[7] On December 20, 2013, this Court granted an order prohibiting the Minister of Health from issuing an NOC to Teva until after the expiry of the 619 Patent in each of Court files T-8-12, T-280-12 and T-1708-12, but dismissed all applications in respect of the 059 Patent. As a result, the Minister of Health could issue NOCs to Teva as early as July 25, 2017, the date of expiry of the 619 Patent.

[8] Notwithstanding this decision, Teva continued to prosecute its impeachment action in Court file T-1529-12 in respect of both patents. The trial was set to begin on March 2, 2015. Discoveries were completed and expert reports were exchanged in 2014. On December 17, 2014,

less than three months prior to the expected start of the trial, Teva served and filed a notice of discontinuance of the action in T-1529-12, but in relation to the 059 Patent only. The pleadings themselves were not amended.

[9] Due to the unforeseen and serious illness of one of Teva's main expert witnesses in mid-February 2015, the trial, initially scheduled to begin on March 2, 2015, had to be adjourned. It is now scheduled to take place beginning on November 28, 2016.

[10] On November 9, 2015, Gilead instituted the present action, seeking a declaration that Teva has in the past and will in the future infringe the 059 Patent. Teva immediately demanded particulars in respect, *inter alia*, of the allegations of past and current infringement, as well as the allegations that Teva intends to come to market with products containing TDF as early as July 25, 2017. In response, Gilead declined to provide further particulars of the circumstances of the past, current or future infringement, prompting Teva to bring the present motion to strike.

[11] Gilead has, in parallel, also filed a motion to consolidate this action with the action in T-1529-12 so that they be heard together in November 2016. That motion is scheduled to be heard shortly by the Judge designated to preside over the trial in Court file T-1529-12, if Gilead's action survives this motion to strike.

III. Gilead's motion to be relieved of the implied undertaking rule

[12] As mentioned above, Gilead has in this matter made a general allegation to the effect that Teva intends to and will import, make, use and sell in Canada products containing TDF prior to

the expiry of the 059 Patent, and as early as July 25, 2017. Teva, by its motion to strike, has put Gilead to the task of pleading the specific material facts upon which this allegation is based or see its statement of claim struck. Gilead wishes to use a portion of the discovery transcript constituted in the T-1529-12 impeachment action to meet that challenge.

[13] Teva specifically alleges in the T-1529-12 impeachment action that it is an interested person because it wishes to import, make, use and sell in Canada TDF or products containing TDF and because it must "either successfully impeach the relevant claims and/or succeed in an application under the *PM (NOC) Regulations* in order to sell the Teva Products prior to the expiry of the 619 Patent and the 059 Patent". The discoveries in that action were conducted at a time where the 059 Patent was still very much at issue. The examination on discovery addressed Teva's intentions, as well as what it had done to act on those intentions, including the approvability status of its submissions for NOCs with the Minister of Health.

[14] The implied undertaking of confidentiality prevents the use of information obtained in discovery from being used other than in the litigation in which it was disclosed. The rationale behind the rule is twofold. First, the rule exists to protect the privacy interests of the persons being examined in the face of compulsory discovery, achieving a balance between the public interest in getting at the truth in a civil action and the preservation of the rights of the "reluctant participants" in litigation, by ensuring that the invasion of privacy is limited to satisfying the sole purpose of that litigation. Second, the rule encourages parties to provide a more complete and candid discovery, again, furthering the interest of justice by giving them some assurance that the documents and answers will not be used for a purpose collateral or ulterior to the proceedings

(*Juman v Doucette*, 2008 SCC 8, at paras 23 to 26; *Sanofi-Aventis Canada Inc. et al v Apotex Inc.* 2008 FC 320, at paras 16 and 17). The rule is not however absolute and the Court retains the power to relieve persons of the obligation where it is in the interest of justice to do so.

[15] The Supreme Court decision in *Juman v Doucette,* above, establishes at paragraph 32 that an application for relief "requires an applicant to demonstrate to the court on the balance of probabilities the existence of a public interest of greater weight than the values the implied undertaking rule is designed to protect". Teva argues that this statement sets a higher standard than that which had been previously applied by the courts. I cannot agree with this interpretation. In the discussion that follows paragraph 32, the Supreme Court explicitly recognizes existing provincial rules of practice as aptly codifying the common law on the issue and goes on to cite some case law which it considers provides useful guidance to the exercise of the court's discretion. At paragraph 38, the Supreme Court expressly states that the categories of superior public interests it discusses are not meant to be fixed.

[16] One of the categories of superior public interests recognized by the Supreme Court in *Juman* is where the deponent has given contradictory testimony about the same matters in successive or different proceedings. The Supreme Court reasons that "[a]n undertaking implied by the Court (or imposed by the legislature) to make civil litigation more effective should not permit the witness to play games with the administration of justice […] Any other outcome would allow a person accused of an offense [w]ith impunity [to] taylor his evidence to suit his needs in each particular proceeding". Gilead essentially argues that the same superior public

interest is at play here, but involving the litigation positions taken by Teva as a party, rather than the testimony given by an individual witness or accused. I agree.

[17] Where it suited its purpose, as plaintiff in the T-1529-12 impeachment action, Teva publicly described itself as an interested party on the basis of express allegations of an intent to come to market with products containing TDF prior to the expiry of the subject patents. It is fair to say that any facts that may have been disclosed on discovery by Teva to flesh out or support these allegations were proffered to advance Teva's own interests in that litigation. Now that it is sued by at least one of the same parties on the basis of that very same stated intention, with full knowledge of the facts and testimony it has previously given to support those allegations, Teva takes the position that Gilead "cannot meet the requirements for a *quia timet* action", "have no basis upon which to allege that Teva will launch TDF products", "are only speculating that Teva will launch or intends to launch TDF products", "have no knowledge as to whether Teva will or will even be capable to carry out the alleged activities" and "have no material facts showing that Teva intends to and can in fact launch infringing product if and when it receives regulatory approval". According to Gilead, the position taken by Teva can only be sustained by reliance on the implied undertaking rule: Had the evidence Teva gave on discovery been adduced at trial or not been protected by the implied undertaking rule, it would show ample basis, in the form of admissions by Teva, to conclude that it can and will launch TDF products prior to the expiration of the 059 Patent. In the circumstances, the implied undertaking would permit Teva to play games with the administration of justice and to tailor its litigation position to suit its needs in each particular proceeding.

[18] The circumstances here are quite different from those in *Juman*, *Carbone v De La Rocha*, [1993] OJ No 1113 or *Goodman v Rossi* [1995] OJ No 1906. In those cases, the discovery evidence sought to be used against the disclosing witness was reluctantly provided, and revealed facts that would never have come to the knowledge of the requesting party outside the context of discovery and the compulsion or encouragement to full and frank disclosure the implied undertaking rule seeks to promote. Here, the discovery evidence went to support a factual allegation voluntarily and publicly made by Teva for its own interest. The information was not of a nature to hurt Teva's case or support Gilead's defence; as such, had Teva refused to answer discovery questions pertaining to its status as an interested person, the sanction would likely have been, not compulsion or the striking of its pleadings, but the inability to introduce trial evidence establishing that information without leave of the court, pursuant to rule 248. Indeed, in preparation for the trial, Teva formally requested that Gilead admit its status as an interested person and served on Gilead a "will say" statement to the effect that a representative of Teva would testify that "Teva will come to market immediately upon receipt of a Notice of Compliance from Health Canada for the Teva Products."

[19] The discovery evidence at issue is the kind of information which Teva would most likely have disclosed to Gilead even in the absence of the implied undertaking rule, as it needed to do so to advance its own case. Teva confirmed, in its will-say statement, its intention to adduce evidence of that same nature at the trial. Upholding the implied undertaking rule in the circumstances would merely permit Teva to delay the public disclosure of information it has continuously intended to use at trial, and by doing so, delay Gilead's ability to use it. Teva is using the implied undertaking rule to play games with the administration of justice, by asserting

in one proceeding that it will lead evidence at trial of its intent to market TDF products in Canada prior to the expiration of the 619 and 059 patents, while at the same time alleging that there exists no factual basis to support that same allegation when made by Gilead. I find that the public interest in preventing the use of the implied undertaking rule for this purpose must, in this case, be given greater weight than the values the implied undertaking rule is designed to protect, in part because in giving the discovery evidence at issue, it is clear that Teva was not a "reluctant litigant" giving evidence by compulsion or out of a duty to give complete and candid discovery, and not in need of the protection offered by the implied undertaking.

[20] I further note that the Supreme Court in *Juman* recognized at paragraph 35 that "where discovery material in one action is sought to be used in another action with the same or similar parties and the same or similar issues, the prejudice to the examinee is virtually nonexistent and leave will generally be granted". While the present action includes additional parties, such as Gilead affiliates and Bristol-Myers Squibb, these additional plaintiffs claim under the patentee pursuant to section 55 of the *Patent Act*, RCS 1985, c P-4 and are therefore "similar parties". And while the present action is for patent infringement rather than impeachment, and therefore based on different causes of action, these causes of action are clearly related. More importantly, the narrow issue of whether Teva intends to and will come to market prior to the expiration of the 619 and/or 059 Patents is not just similar, it is the same. Teva cannot claim that they are distinct merely because the current action concerns only the 059 Patent while the T-1529-12 action no longer concern that Patent: At the time discovery was given, the 059 Patent was directly at issue.

IV. Teva's motion to strike

[21] Gilead's statement of claim, as currently written, only alleges past or current infringement in the vaguest and broadest of terms: "Teva has since prior to November 3, 2011 imported and/or manufactured pharmaceutical compositions including acceptable excipients comprising TDF (…)", "Teva manufactures TDF, or causes TDF to be manufactured (…)". As mentioned earlier, Teva promptly sought but was refused particulars of the facts upon which Gilead relies to support these allegations. The case law is clear that an infringement action that fails to set out sufficient material facts by which a defendant is alleged to have infringed a patent and relies solely on bald conclusions of infringement or on the mere fact that a defendant pharmaceutical company has sought regulatory approval to market a medicine constitutes an abuse of process and should be struck (*Apotex Inc. et al v Allergan Inc. et al*, 2011 FCA 134; *Astrazeneca Canada Inc. v Novopharm Ltd.*, 2010 FCA 112).

[22] As currently framed, it is plain and obvious that Gilead's allegations of past or current infringement must be struck. The question then becomes whether the amendments proposed by Gilead to cure this defect should be allowed.

[23] The proposed amendments are of two kinds. The first relies on Teva's stated intention to enter the Canadian market as soon as it obtains an NOC to conclude that Teva must have "necessarily stockpiled sufficient quantities of finished product". The second relies on the discovery evidence in Court file T-1529-12, said to contain admissions of infringing activities. I agree with Teva that the proposed new allegations of the first kind are entirely speculative. Even assuming that it is reasonable to infer from Teva's stated intent that Teva has available to it sufficient quantities of finished product, there is simply no reasonable basis, either in the

proposed amended pleadings or in the discovery transcript, to infer that Teva has actually, in Canada, either made or stockpiled commercial quantities of infringing product. In similar circumstances, in *Teva Canada Limited v Novartis AG*, (Federal Court file T-2021-10, August 12, 2011, now reported at 2016 FC 18) I held that "[a]vailability is not synonymous with actual possession; taken in context, the word "available" connotes more readily that the product can be obtained than that it is in actual possession. This is to be contrasted with the facts that were alleged in the case of *Allergan Inc. et al v Apotex Inc. et al* unreported, Federal Court file T-1267-10, November 9, 2010, affirmed at 2011 FCA 134, where it was specifically alleged that Apotex had indicated in its filing with the US FDA that it had made and used the product in Canada and that Apotex had been issued a tentative approval to manufacture the product in Canada." The present case is indistinguishable. The proposed amendments amount to no more than bald speculation and ought not to be allowed.

[24] With respect to Gilead's request to amend to plead alleged admissions of infringement made by Teva in the course of discovery in T-1529-12, I am satisfied that the proposed amendments mischaracterize the discovery evidence and that it would accordingly not be in the interest of justice to allow them to salvage Gilead's claim for past or current infringement. A fair reading of the discovery transcript shows that Teva has not admitted to any activity beyond the regulatory requirements for the preparation and filing of its ANDS, which are specifically exempted by section 55.2 of the *Patent Act*. It was held in *Eli Lilly Canada Inc. et al v Nu-Pharm Inc.*, 2011 FC 255 that allegations of such conduct are not sufficient to validly sustain an action for past or current infringement.

[25] I now turn to Gilead's allegations of future infringement. The case law generally recognizes and applies the following criteria for validly initiating a *quia timet* proceeding alleging patent infringement, as set out in *Connaught Laboratories Limited v SmithKline Beecham Pharma Inc.* [1998] FCJ No 1851: "the statement of claim must allege a deliberate expressed intention to engage in activity the result of which would raise a strong possibility of infringement; the activity to be engaged in must be alleged to be imminent and the resulting damage to the plaintiff must be alleged to be very substantial if not irreparable; and, finally, the facts pleaded must be cogent, precise and material. It is not sufficient that they be indefinite or speak only of intention or amount to mere speculation."

[26] In its current form, Gilead's statement of claim relies on the allegations made by Teva in T-1529-12 of an expressed intention to market TDF products prior to the expiry of the 059 and 619 Patents, and on the procedural circumstances unique to this matter, including Teva's institution of an impeachment action whilst prohibition proceedings were ongoing, the results of the prohibition proceedings pursuant to which Teva may receive an NOC as early the expiry of the 619 Patent, or earlier if it is successful on the impeachment action, and Teva's decision to discontinue the impeachment action in respect of the 059 Patent and pursue it in respect of the 619 Patent, notwithstanding the results of the prohibition proceedings. The statement of claim, as it currently stands, is however silent as to Teva's ability to carry out its professed intention, including with respect to the approvability status of its ANDS. This fact situation is very similar to that which existed in *Teva Canada Limited v Novartis AG*, above: Teva had, in an impeachment action, stated that it was an interested party because it intended to market imatinib tablets in Canada and that in order to do so prior to the expiry of the subject patent, it had to

either successfully impeach the relevant claims of the patent or succeed in an application under the *PM (NOC) Regulations*, both of which it was endeavoring to do at a time where the patent only had a few years left to run before expiration. As in the present case, the statement of claim for the *quia timet* claim did not contain allegations as to the approvability status of Teva's imatinib product. I held in that case that while Novartis had met the expressed intention criterion, it had failed to meet the temporal aspect of the criteria:

> (…) Although Teva argued that the exact timing of Teva coming to market remained subject to a corporate decision being taken, the allegations of an expressed intent, of an ability to begin possibly infringing activities, combined with the recent conduct of Teva, convey a sense of purpose and urgency speaking to much more than a mere possibility. In the circumstances, the allegations of the Counterclaim are more than sufficient to meet that criterion. Indeed, it seems that these allegations of expressed intent were precisely those that were found missing in *Connaught Laboratories*.
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> It is on the last criteria on of the *Connaught Laboratories* test that Novartis' allegations fail. Novartis does not allege that Teva's application for an NOC has been approved and/or is on "patent hold" awaiting simply the resolution of the prohibition proceedings or the expiration of the patent. Teva therefore argues that the alleged imminence of the infringement is speculative, as it is contingent upon it obtaining an NOC from Health Canada.
>
> That specific argument was found to be determining in *Pfizer Research and Development Co. N.V./S. A. v. Lilly ICOS LLC*, (2003) 20 7C. P. R. (4th) 86:
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> > "The Plaintiffs have not demonstrated the temporal aspect of the criteria for commencing a *quia timet* action. Neither party has control over when, or if, the government will issue regulatory approval for its product. In my opinion, the Plaintiffs have not pleaded facts to support its allegation that the Defendants' allegedly infringing activities are imminent. This motion for an order striking out the Amended Statement of Claim in its entirety is granted as the Plaintiffs have failed to properly plead a *quia timet* action; it is plain and obvious that

> the pleading discloses no reasonable cause of action."
>
> This decision was further cited and applied in *Astrazeneca Canada Inc. v. Novopharm Limited, supra*. I am bound to follow these precedents.

[27] I find that, even without the amendments proposed by Gilead, the statement of claim does, through cogent, precise and material facts, allege a deliberate expressed intention to engage in activity that would raise a strong possibility of infringement. However, without the proposed amendments, Gilead's statement of claim suffers from the same fatal defect as Novartis' did: Absent allegations to the effect that Teva's application for an NOC is approvable and that an NOC will issue as soon as the 619 Patent expires or is declared invalid, the statement of claim lacks sufficient material facts to show that the infringement is imminent; the infringement remains speculative, contingent upon whether and when Health Canada might approve the submissions for an NOC.

[28] As mentioned, the status of Teva's ANDS was the subject of discoveries in T-1529-12, and Gilead, having now been relieved of the implied undertaking rule, proposes to amend its statement of claim to plead material facts going to that issue. I am satisfied that the discovery evidence, and the amendments proposed, are sufficiently cogent, precise and material to satisfy the criterion of imminence, and that Gilead should be allowed to make the proposed amendments.

[29] As an alternative argument, in the event it were not relieved of the implied undertaking rule, Gilead argued at the hearing that the following factual circumstances permit a reasonable

inference that Teva's submissions are approvable: Under the *PM (NOC) Regulations*, Teva was required to have filed its ANDS prior to or concurrently with the service of its Notices of Allegation, such that the ANDS would have been submitted at the latest in 2012; the *PM (NOC) Regulations*' timeframes contemplate that a decision as to approvability will usually be made within two years, such that Teva would necessarily now know if its submissions have been approved; given that Teva continues to pursue its impeachment action and to maintain that it intends to come to market as soon as the 619 Patent expires or is declared invalid, Teva must necessarily have been advised that its ANDS is approvable and on patent hold. I agree that those circumstances together, while not conclusive of the issue, would form a sufficiently cogent, precise and material set of facts from which one could reasonably infer and conclude that at least one of Teva's ANDS is on patent hold, awaiting simply the expiration of the 619 Patent or its impeachment. Even if I had been wrong in allowing Gilead to rely on the discovery evidence to amend its pleadings, I would have permitted it to amend to raise the circumstances discussed above as material facts showing that Teva will come to market with TDF products at least as early as July 2017.

[30] Although a case so framed would be circumstantial and may be open to challenge, Gilead, at this stage, is not required to do more than plead a reasonably arguable case. Care must be taken that motions to strike for failure to plead material facts not be turned into a show cause hearing where a plaintiff is required to prove its case, especially where, as here, the moving party is not relying on any evidence of its own.

[31] Finally, I am satisfied that the probability that infringement will occur in July 2017 is sufficiently imminent to justify a *quia timet* action. The purpose of a *quia timet* action is to stop an event before it happens. Given that streamlined infringement actions may now be heard and determined in two years, it is neither premature nor pointless to institute such an action 22 months before the occurrence of the event to be avoided. To ask that a plaintiff wait until the event is so imminent that there is not enough time to reasonably bring the proceeding to conclusion would be to doom such actions to failure to achieve their goal or to impose unreasonably tight schedules on the parties and the Court.

[32] The only criterion left to be considered is that of "substantial, if not irreparable harm". Clearly, while allegations of irreparable harm would satisfy that criterion, irreparable harm is not a requirement and allegations of substantial harm will be sufficient. The case law does not offer further guidance as to what harm would be substantial enough to justify a *quia timet* claim.

[33] The statement of claim currently only alleges that Gilead will be deprived of the statutory exclusivity to its invention, that it will suffer damages in excess of $50,000 and that Teva will make a profit.

[34] Any proven act of infringement constitutes a deprivation of the patent holder's exclusivity rights. Given that the Court in *Connaught Laboratories* expressly included harm as a necessary requirement for a *quia timet* claim of patent infringement, it is clear that it did not contemplate the deprivation of exclusivity rights as constituting, of itself, either irreparable or substantial harm. And while a patentee may choose to claim profits made by the infringer, the

profits of an infringer do not necessarily constitute harm to the patentee, whatever their magnitude. Thus, the only allegation of harm left in Gilead's statement of claim is that it will suffer damages in excess of $50,000 (a figure which likely is not intended as indicative of the magnitude of the damages, but that the action should not proceed as a simplified proceeding). The allegation is, obviously, not precise or cogent enough to meet the requirements set out in *Connaught*. The amendments proposed by Gilead do not include any further particulars as to the magnitude of the expected loss. While Teva has generally asked for particulars of paragraph 49 of the original statement of claim (which sets out the consequences that would result from the intended infringement by their nature), it has asked no particulars of paragraph 51 (which confirms that expected damages will exceed $50,000). Given the substantial costs involved in prosecuting such complex actions, I expect that, given an opportunity to provide a better particularized estimate of the damages Gilead expects to suffer should Teva infringe the 059 Patent, the figure would be far in excess of $50,000. I am satisfied that Gilead should be afforded an opportunity to amend its statement of claim to particularize the monetary loss it might suffer from the alleged further infringement, with leave to Teva to argue that the particularized amount remains insufficient to meet the criterion of "substantial, if not irreparable" harm.

V. Costs

[35] Gilead has been successful on its motion to be relieved of the implied undertaking rule, and should have its costs of that motion. On Teva's motion to strike, success being divided, there shall be no costs.

ORDER

THIS COURT ORDERS that:

1. Gilead is relieved of the implied undertaking rule in respect of the excerpts of discovery transcripts identified in its motion record.

2. The discovery transcripts and the information they contain shall remain sealed until the exhaustion of all avenues of appeal of paragraph 1 of this order, whereupon, unless the Court orders otherwise, they will be unsealed.

3. Gilead's statement of claim, insofar as it alleges past or current infringement, is hereby struck, without leave to amend.

4. Gilead shall amend its statement of claim to remove allegations of past or current infringement and to add the amendments set out in the proposed amended statement of claim included in its motion record, with the exception of sub-paragraphs 7A(a) and (b), the words between parenthesis in sub-paragraph 7A(c), the words that start after the first use of the word "admitted" and end with the second use of the word "admitted" in paragraph 45(A), and paragraph 45B.

5. Gilead shall also amend its statement of claim to add particulars of the amount of damages it expects to suffer if Teva enters the market with the "Teva Products" prior to the expiry of the 059 Patent.

6. Teva shall have leave to reapply to strike the statement of claim on the basis that the particulars to be provided fail to allege sufficient material facts of substantial harm.

7. Costs of Gilead's motion to be relieved of the implied undertaking rule shall be payable by Teva to Gilead.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1888-15
STYLE OF CAUSE:	GILEAD SCIENCES, INC., GILEAD SCIENCES CANADA, INC., AND BRISTOL-MYERS SQUIBB & GILEAD SCIENCES LLC v TEVA CANADA LIMITED
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