Federal Court  Cour fédérale

Date: 20141113

Docket: T-1161-13

Citation: 2014 FC 1076

BETWEEN:

TAKEDA CANADA INC. AND TAKEDA GMBH

Applicants

and

THE MINISTER OF HEALTH AND MYLAN PHARMACEUTICALS ULC

Respondents

REASONS FOR ORDER

TABIB P.

[1] In the context of this proceeding under the *Patented Medicines (NOC) Regulations* (SOR/93-133), Mylan seeks a confidentiality order that would designate as confidential – and therefore shield from public disclosure – portions of its Notice of Allegations ("NOA"), as well as detailed evidence in support of the NOA.

[2] This is not the first time a generic drug manufacturer has sought to have its NOA declared confidential. In *Pfizer Canada Inc. v Novopharm Limited*, 2010 FC 668, Novopharm

had sought a confidentiality order in respect of its NOA, on the argument that such an order was necessary to protect its first-to-market position. The Court examined all aspects of the test applicable to a confidentiality order pursuant to Rule 151 of the *Federal Court Rules*, as further explained by the Supreme Court of Canada in *Sierra Club of Canada v Canada (Minister of Finance)*, 2002 SCC 41, and found that Novopharm had failed to establish every branch of that test. Yet, Mylan comes to this Court, on the very same argument and on no better evidence than was tendered by Novopharm in *Pfizer*, seeking to protect the factual basis of its NOA from disclosure to its competitors.

I. Background

[3] By letter dated May 15, 2013, Mylan served upon the Applicants Takeda Canada Inc. and Takeda GMBH ("Takeda") a Notice of Allegations, as contemplated by section 5 of the *PM(NOC) Regulations*, in relation to the drug pantoprazole magnesium. Mylan's NOA alleges that the patents owned by Takeda and listed against Takeda's own TECTA-brand pantoprazole magnesium tablets would not be infringed by Mylan's product, and that one of the patents is invalid for, *inter alia*, anticipation and obviousness.

[4] The NOA sets out Mylan's construction of the patents, claim by claim, stating the essential element of each claim and alleging that the Mylan compound will not contain one of those elements or will not be made in that particular way. Very occasionally, the NOA goes on to state what the Mylan compound would in fact contain or how it would in fact be made, but only in the very broadest of terms. The passages of the NOA which Mylan seeks to keep confidential

include both the claim construction and the information as to what its compound would or would not contain and how it would or would not to be made.

[5] As to invalidity, the NOA alleges that the patent is anticipated and made obvious by, inter alia, a specific piece of prior art. The NOA asserts that Mylan has commissioned an independent expert to reproduce this prior art process to support that allegation, and the results of this testing are included in Annex to the NOA. Mylan seeks to keep the specific prior art process it has reproduced and the results of the testing confidential.

[6] The notation "CONFIDENTIAL" appears on every page of the NOA. However, there is no evidence on the record that Mylan had, prior to serving it, sought or obtained from Takeda any assurance that Takeda would treat the NOA or the information contained therein in a confidential fashion.

[7] Takeda commenced this application for a prohibition order pursuant to section 6 of the *PM(NOC) Regulations* on June 28, 2013. Takeda's Notice of Application does not repeat or set out Mylan's non-infringement allegations, but in respect of the testing, it states, at paragraph 34:

> Mylan alleges that Example 10 of WO 114 necessarily produces pantoprazole magnesium dihydrate. However, this example says nothing about producing a dihydrate of pantoprazole magnesium. Mylan alleges that it performed testing which confirms said allegation. […].

[8] Thus, the specific allegation to the effect that it is Example 10 of WO114 that necessarily produces pantoprazole magnesium dihydrate, and the allegation that Mylan performed tests to confirm that allegation were publicly disclosed by the filing of Takeda's Notice of Application.

[9] Paragraph 66 of the Notice of Application also states:

> Takeda denies Mylan's allegation that the Mylan letter [NOA] is confidential and that it should be subject to any Protective Order granted by this Honorable Court.

[10] Takeda requested from Mylan further documents and information as to the composition and method of manufacture of Mylan's product, and as to the testing it had performed. The parties agreed to the wording of a protective order to govern, as between them, the manner in which information designated as confidential was to be treated. The Protective Order was issued on consent on August 28, 2013, following which Mylan communicated to Takeda the requested documents and information. The Protective Order defines the information that each party may unilaterally designate as confidential in a non-limitative fashion, but does not permit the parties to file under seal any information so designated unless the parties formally apply for and obtain a confidentiality order. The Protective Order further provides, at paragraph 14 (c), that it does not apply to information which "was in the possession of a Party prior to the commencement of this proceeding other than by virtue of a Court order containing terms respecting the preservation of confidentiality of information […]".

[11] The parties served on each other their affidavit evidence. All affidavits were designated as confidential, in their entirety. In September 2014, Mylan announced its intention to make a motion for leave to file further evidence in reply to the affidavits served by Takeda. As that motion would have to be supported by the affidavits exchanged by the parties, Mylan brought the present motion for a confidentiality order.

II. The test to be applied:

[12] Rule 151 of the *Federal Courts Rules* reads as follows:

151. (1) On motion, the Court may order that material to be filed shall be treated as confidential.	151. (1) La Cour peut, sur requête, ordonner que des documents ou éléments matériels qui seront déposés soient considérés comme confidentiels.
(2) Before making an order under subsection (1), the Court must be satisfied that the material should be treated as confidential, notwithstanding the public interest in open and accessible court proceedings.	(2) Avant de rendre une ordonnance en application du paragraphe (1), la Cour doit être convaincue de la nécessité de considérer les documents ou éléments matériels comme confidentiels, étant donné l'intérêt du public à la publicité des débats judiciaires.

[13] The Supreme Court of Canada, in *Sierra Club* above, has elaborated further on the criteria to be considered in applying Rule 151, as follows:

> 53 […] A confidentiality order under Rule 151 should only be granted when:
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> (a) such an order is necessary in order to prevent a serious risk to an important interest, including a commercial interest, in the context of litigation because reasonably alternative measures will not prevent the risk; and
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> (b) the salutary effects of the confidentiality order, including the effects on the right of civil litigants to a fair trial, outweigh its deleterious effects, including the effects on the right to free expression, which in this context includes the public interest in open and accessible court proceedings.

[14] The Supreme Court added that "three important elements are subsumed under the first branch of this test", which elements have been summarized as follows in *Pfizer*, above:

> 9 […]
>
> (i) the risk in question must be real and substantial, in that the risk is well grounded in the evidence, and poses a serious threat to the commercial interest in question;
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> (ii) in order to qualify as an "important commercial interest", the interest in question cannot merely be specific to the party requesting the confidentiality order, the interest must be one which can be expressed in terms of a public interest in maintaining confidentiality; and
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> (iii) the Court must consider not only whether reasonable alternatives to a confidentiality order are available, but must also restrict the order as much as is reasonably possible while preserving the commercial interest in question.

[15] The Supreme Court further specified, under the heading of "necessity" in the first branch of the test, that it was a strict requirement that the applicant for a confidentiality order demonstrate that the information in question is, in fact, confidential:

> 60 Pelletier J. noted that the order sought in this case was similar in nature to an application for a protective order which arises in the context of patent litigation. Such an order requires the applicant to demonstrate that the information in question has been treated at all relevant times as confidential and that on a balance of probabilities its proprietary, commercial and scientific interests could reasonably be harmed by the disclosure of the information: AB Hassle v. Canada (Minister of National Health and Welfare) (1998), 83 C.P.R. (3d) 428 (F.C.T.D.), at p. 434. To this I would add the requirement proposed by Robertson J.A. that the information in question must be of a "confidential nature" in that it has been "accumulated with a reasonable expectation of it being kept confidential" as opposed to "facts which a litigant would like to keep confidential by having the courtroom doors closed" (para 14).
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> [Emphasis added]

III. Application of the Test to this Case:

[16] The kind of information at issue on this motion can be divided in three categories. There is, first, the basic information relating to the composition and method of manufacture of Mylan's product and to Mylan's testing of anticipatory art, as that information is set out in the NOA. There is also the additional information as to the details of the testing performed by Mylan's expert on the allegedly anticipatory prior art, contained in the August 28, 2013 affidavit of Dr. Jerry Atwood (the "Atwood fact affidavit"). Finally, there is the more detailed information relating to the composition and method of manufacture of Mylan's product, drawn from Mylan's Abbreviated New Drug Submission and Drug Master File (the "ANDS Information"), that was requested and provided after the issuance of the Protective Order.

[17] The latter category can be analyzed and dealt with summarily. The first and second categories will discussed together at greater length below.

A. The ANDS Information:

[18] I am compelled by precedent to recognize, in respect of the ANDS Information, an interest in confidentiality which qualifies as an important interest under the *Sierra Club* test. It is the public interest in ensuring that generics provide full and complete information to the Minister when applying for a NOC, to allow the Minister to properly assess the safety and efficacy of drugs, without fear that this information would become public as a result of a request for disclosure under sub-section 6(7) of the *PM(NOC) Regulations*. Both the case law and sub-section 6(8) of the *PM(NOC) Regulations* recognize that this general public interest, which is

entirely separate and independent from a generic's market position, is seriously at risk where disclosure of the details of an ANDS beyond what is set out in a NOC must be made in the context of prohibition proceedings, and that the benefits of the protection of a limited confidentiality order outweigh the public interest in open and accessible court proceedings. The Federal Court of Appeal in *AB Hassle v Canada (Minister of National Health and Welfare)*, [2000] F.C.J. No. 283, in a concise analysis at paragraphs 4 to 6, reiterated that the perceived confidentiality of information was a cornerstone of the regulatory scheme, which should be honoured and maintained to the extent possible. It also cited precedents recognizing that while a generic must provide in its NOA a detailed statement of the factual basis for non-infringement to allow the innovator to identify the grounds raised, decide whether to begin prohibition proceedings and define the issues, full disclosure was not expected to be made until proceedings were commenced and confidentiality could be assured by a protective order. The Federal Court of Appeal finally noted that the 1998 amendments to the *PM(NOC) Regulations* now expressly state, in subsection 6(8), that "a document produced under subsection (7)" -- i.e. any portion of the submission for a notice of compliance filed by the second person relevant to the disposition of the issues in the proceedings -- "shall be treated confidentially". As a result, the Court of Appeal endorsed the principle that confidentiality orders can issue to protect ANDS information in NOC proceedings, but cautioned that the Courts must restrict their application to what is strictly necessary to strike a balance between this recognized confidentiality interest and the need for public scrutiny of the Court process.

[19] The ANDS Information was voluntarily provided by Mylan to Takeda, rather than under compulsion of a motion under subsection 6(7), and subsection 6(8) therefore does not directly

apply. However, the reasoning of the Court of Appeal in *AB Hassle* stands for the proposition that where it appears that information from an ANDS would have been compellable pursuant to sub-section 6(7) and is voluntarily produced under an agreement or an order providing for confidentiality of that information between the parties, there is a presumption that the information meets the criteria for a limited confidentiality order of the kind discussed in *AB Hassle*. I note in any event that Mylan has, on this motion, submitted an affidavit which establishes that that Mylan voluntarily complied with Takeda's request for documents from its ANDS and DMF in order to avoid a motion under section 6(7) of the Regulations, that the ANDS Information is of a confidential nature, was at all time treated by Mylan as confidential and that Mylan had a reasonable expectation that it would be kept confidential.

[20] I am satisfied that the proposed Confidentiality Order presents appropriate limits and safeguards, and that it should be issued in respect of the ANDS Information.

[21] I now turn to the other two categories of information, being the NOA and the Atwood fact affidavit.

B. The NOA and the Atwood Fact Affidavit

(1) The condition precedent: Is the information in fact confidential?

[22] Mylan, whose burden it was on this motion to demonstrate that it had treated the information as confidential at all relevant times and had a reasonable expectation of

confidentiality, failed to adduce any such evidence in respect of the NOA. That alone is fatal to Mylan's motion as it concerns the NOA.

[23] In any event, in view of the decision in *Pfizer*, above, I do not see how a generic could reasonably expect the Court to recognize the confidentiality of a NOA. The Court in *Pfizer* noted that the absence of a prior request for an agreement by the innovator to treat the NOA as confidential raised a serious question as to the generic's reasonable expectation that its NOA would be kept confidential, even if unilaterally marked as confidential. The Court also inferred that the absence of a provision in the *PM(NOC) Regulations* relating to the confidentiality of NOAs, contrasted with the express provision of confidentiality of additional information drawn from ANDSs, suggested that NOAs should not be treated as confidential.

[24] I am satisfied that in the circumstances of this case, Mylan did not treat the information contained in the NOA as confidential at all relevant times, because it voluntarily included it in a letter sent to Takeda, with no reasonable expectation of it being kept confidential. Indeed, Takeda, in its Notice of Application, could and did publicly set out some of the details of the NOA which Mylan asserts should benefit from a confidentiality order, and expressly denied Mylan's right to claim confidentiality over the NOA. Mylan's own conduct in consenting to the drafting of both the Protective Order and the present proposed Confidentiality Order, pursuant to which confidentiality does not apply to information that came into the possession of a party prior to the commencement of the application, tends to confirm that it never expected its NOA to remain confidential.

[25] Mylan has provided some evidence in respect of its expectations of confidentiality in respect of the Atwood fact affidavit. Specifically, the affidavit of Brad Jenkins, one of Mylan's lawyers, states that the Atwood fact affidavit was designated as confidential prior to being delivered to Takeda, pursuant to the Protective Order issued by the Court on August 28, 2013, which order "provided that […] the Atwood Fact Affidavit […] could be treated as confidential". That statement is true, but only insofar as the definition of what may be designated as confidential in that order is expressly said not to be limited to the specific information identified therein, and therefore allows a party to designate as confidential anything at all, subject only to the exclusions found in paragraph 14. The Protective Order does not make any mention of the Atwood fact affidavit, or even more generally of a party's independent testing of publicly available prior art. Mr. Jenkins stops short of stating that he, or anyone at his firm or at Mylan, expected the Atwood fact affidavit to be kept confidential. I also note that the affidavit of David E. Blais, general counsel for Mylan Pharmaceuticals ULC, is entirely silent as to the confidential nature of the Atwood fact affidavit or as to Mylan's expectations that it would be kept confidential.

[26] I am not satisfied that Mylan had any real expectation that the Atwood fact affidavit would be kept confidential, and find that even if Mylan had such expectations, they were not reasonable for two reasons. First, the Federal Court in *Pfizer* recognized that the very strong public interest in openness as regards allegations of invalidity of a patent weighed significantly against a finding of confidentiality:

> 30 Where an NOA raises legitimate questions regarding the validity of one or more patents, another significant factor that weighs against the view that the entire NOA should be treated as a confidential document is that a patent effectively confers a statutory monopoly on the patent holder, in the sense that the patent holder is shielded from competition for the life of the patent. This provides the basis for a strong public interest in transparency and openness with respect to (i) the allegations contained in an NOA, (ii) the basis for those allegations, and (iii) the proceedings involving those allegations.

[27] Given those comments, Mylan could not reasonably expect that the Court would recognize the confidentiality of the Atwood fact affidavit. Secondly, Mylan's motion record itself recognizes the significance of the Atwood fact affidavit to the determination of the issues before the Court and the public interest in its disclosure. What Mylan seeks to achieve by this motion is not recognition of the information's inherent confidentiality, but that its inevitable publication be delayed until the hearing of the application on its merits. This speaks to a hope or a wish for secrecy, but not of a reasonable expectation of confidentiality.

[28] In any event, the Atwood fact affidavit contains no information of a confidential nature. As mentioned above, Takeda has already publicly disclosed, in its Notice of Application, Mylan's allegation that Example 10 of WO 114 was reproduced to prove that it produces pantoprazole magnesium dehydrate and therefore anticipates Takeda's Patent. Once that is made public, there can be nothing original or worthy of protection in the details of such testing, since the testing must, by necessity, strive to reproduce the example as any person skilled in the art would, armed with nothing more than the common general knowledge.

[29] Given my conclusion that Mylan has failed to satisfy the condition precedent for a confidentiality order in respect of the NOA and the Atwood fact affidavit, there is no need for me to consider or determine the other criteria of the *Sierra Club* test. However, given Mylan's insistence that the decision in *Pfizer* supports its argument that a generic's market position is a matter of substantial public interest, and that this interest outweighs the public interest in open and accessible Court proceedings, I feel compelled to address some of its arguments.

(2) Is Mylan's "first-to-market" position an important interest as contemplated in *Sierra Club*?

[30] Mylan cites its expectation of being the first to market a generic version of pantoprazole magnesium as the important commercial interest justifying its request for a confidentiality order.

[31] The Court extensively discussed this issue at paragraphs 38 to 46 of the reasons in *Pfizer*. The Court concedes, at para 40, that: "[f]irms' concerns with their market positions […] lie at the very root of our market-oriented economy and, arguably, are a matter of substantial public interest". However it addresses that argument in detail, and ultimately concludes that Novopharm's competitive position was personal to Novopharm and did not therefore qualify as an important interest under the *Sierra Club* test:

> 46 That said, it is not clear that the Supreme Court intended the aforementioned language at page 546 of Sierra Club, above, to stand for the proposition that a firm's market position can be characterized as an important commercial interest, as contemplated by the second element in the first part of the test established in that decision. Therefore, I am unable to conclude that Prothonotary Milczynski's conclusion on this point was clearly wrong.

[32] Mylan's situation appears, on the record before me, to be no different than the situation of Novopharm or of any other generic. Mylan failed to bring evidence of circumstances or considerations that would bring a generic's interest in being first-to-market to a level that transcends its own personal interest. Where Mr. Blais' affidavit speaks of the incentive created by the anticipation of being first-to-market, the incentive he describes is to engage in activities "which are necessary to challenge patents listed on the Patent Register". Since challenging the patents is essential to Mylan's wish to be the first to enter the market, Mylan's argument is circular, and goes back to its own personal commercial interest. I do not accept Mylan's argument that there is a general public interest in challenging patents which must be fostered. Indeed, in enacting section 60 of the *Patent Act*, R.S.C., 1985, c. P-4, pursuant to which only interested persons can sue to impeach a patent, Parliament has indicated that the personal interest of those who are affected by the monopoly created by a patent is not only a sufficient incentive to mount such challenges, but a necessary requirement. In any event, as proceedings under the *PM(NOC) Regulations* are summary and do not result in the invalidation of patents, any alleged public interest in encouraging generics to challenge patents would not be served by allowing generics to keep the grounds for their challenge secret.

[33] Mylan's argument also appears to suggest, but provides no cogent basis to establish, that there is a public interest in encouraging generics to avail themselves of the mechanism provided in the *PM(NOC) Regulations* to gain entry into the market prior to the expiration of registered patents, and that the prospect of being first to market, or a close second, is an important incentive without which generics would not go to the expense of preparing and serving NOAs. While it is understandable that a generic's primary goal would be to be first-to-market, there is no evidence

that the prospect of being a distant second, third or fourth on the market provides insufficient rewards for generics to invest in drafting and serving NOAs. Indeed, the sheer volume of NOC litigation before this Court involving NOAs served by multiple generics in respect of the same patent is testament to the contrary.

[34] Finally, Mylan argues that there is a public interest "in ensuring that all information, including Mylan's ANDS/DMF and the Atwood affidavit, that is relevant and important to the central issues in this application is placed before the Court" and in "protecting the right to a fair hearing". The public interest in fair hearings and complete records is not in doubt. However, it is not in play in this matter. There is no evidence or suggestion that the unavailability of a confidentiality order to protect the NOA or the detailed evidence in support of invalidity allegations would lead Mylan, or has ever led any generic, to forego serving a NOA or fully presenting its evidence or its case.

(3) Is the risk real and substantial, well grounded in evidence and does it pose a serious threat?

[35] Even had I accepted Mylan's argument that a generic's first-to-market status has a public interest dimension, Mylan, like Novopharm before it in *Pfizer*, has failed to a establish that there is a "real and substantial" risk that disclosure of its NOA or of the Atwood fact affidavit would pose a "serious threat" to its alleged first-to-market position.

[36] The only specific evidence on record on this issue is found in paragraph 11 of Mr. Blais' affidavit, and is to the effect that: "There are currently no other proceedings pending in this

Court relating to pantoprazole magnesium, the drug at issue in this proceeding. To my knowledge, no other generic drug company has yet taken steps to develop a generic version of pantoprazole magnesium tablets." Mr. Blais' affidavit otherwise appears to proceed on the assumption - not otherwise grounded in evidence – that Mylan's competitors are in fact interested in marketing and developing their own pantoprazole magnesium product and that the only thing preventing them from doing so is their inability to come up with the ideas that underlie Mylan's NOA, that is, the construction of the relevant patents, the basic composition and method of manufacture of a compound that would fall outside the claims as construed, and the idea that example 10 of WO114 is anticipatory because it produces pantoprazole magnesium dehydrate.

[37] The problem here is the same as was noted in *Pfizer*, above: the quality and emulation-worthiness of Mylan's work product cannot simply be assumed; it must be grounded in evidence:

> 35 In reaching her conclusion on this point, Prothonotary Milczynski found that there were a number of significant problems with Novopharm's argument that a failure to designate its NOA as confidential would pose a serious threat to an important commercial interest, as contemplated by the first element of the first part of the test set forth in Sierra Club, above. Specifically, she noted the following:
>
> First, there is no evidence of a serious risk to Novopharm's commercial advantage with respect to its market position and what it hopes to be the timing of its market entry. Novopharm assumes it will succeed on all five patents in issue in this case and makes assumptions about how its and ratiopharm's hearings will be scheduled by the Court. Novopharm may or may not be first or a close second on the market. There is also no evidence other than its own confidence in the quality of its work product to suggest that other generics will be lining up to copy any part of the Novopharm NOA, particularly when there is no evidence that ratiopharm's NOA has attracted such keen attention (or evidence that ratiopharm's NOA should not warrant it).
>
> [Emphasis added]

[38] Mylan's assumption that it will be first-to-market and will maintain that position for a significant length of time, if only it can shield its NOA from its generic competitors' eyes, also ignores the possibility that other generics might already (unbeknownst to Mylan because of the inherent confidentiality of ANDS filings) have submitted ANDSs to the Minister and received approval, and the possibility that Takeda might meet Mylan's entry in the market with the launch of an authorized generic, a scenario well documented in section 8 cases (see, for example, *Apotex v Sanofi-Aventis*, 2014 FCA 68, at para 58, *Teva Canada Ltd v Pfizer Canada Inc*, 2014 FC 248 at para 94). A confidentiality order would do nothing to protect Mylan from either of these scenarios.

(4) Is there a significant public interest in the information at issue?

[39] Mylan relies on the following well-known passage of *AB Hassle*, above, to minimize or dismiss any real or significant public interest in the information it seeks to protect:

> 7 Let us not be naive. There is little, if any, public interest in knowing the specific content of drug processes and no one can seriously argue that the issuance of protective orders of the type at issue in NOC proceedings imperils the principle of open justice. The parties themselves may challenge the true confidentiality of specific documents by the very terms of the orders and the Court will always be prepared to hear challenge by a third party, whether or not the terms of the order so provide.

[40] Mylan's reliance on this passage is not justified in the circumstances of this case.

[41] First, the Federal Court of Appeal's comments are expressly directed to the "specific content of drug processes", i.e., the details found in the ANDS and not the basic allegations of the NOA or the parties' case on invalidity. Neither the NOA nor the evidence on invalidity was

protected by a confidentiality order in *AB Hassle*. As also mentioned above, this Court in *Pfizer* expressly noted the strong public interest in questions regarding the validity of patents.

[42] Further, given the significant increase in NOC litigation this Court has seen since these words were written in 2000, and the consequent developments of the law applicable to these cases, especially in the areas of issue estoppel and abuse of process, the public interest in openness can be seen as going beyond mere curiosity as to the details of drug processes. This Court noted, in *Pfizer Canada Inc v Canada (Minister of Health)*, 2008 FC 11 (the "Quinapril decision":

> 38 NOC proceedings are flooding the Court system at a rate which, roughly calculated, at the current pace, means that three proceedings are instituted for each one disposed of by the Court. The NOC Regulations require that the proceedings be disposed of by the Court within 24 months from institution barring consent of the parties to an extension. Rarely is such consent, except for perhaps a few weeks, forthcoming. The Court accepts the challenge. However, where essentially the same matters as were previously disposed of are raised again, the Court must come to grips with the question as to whether there is an unnecessary waste of the Court's resources.
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> […]
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> 43 Thus, in the context of NOC proceedings, in particular this one, it is entirely appropriate to consider whether the resources of the Court and the Minister are being unduly taxed by a generic that raises essentially the same questions as were raised by another generic in previous proceedings, and failed. The Court must be mindful that the generic always has the remedy of a proceeding to challenge the validity of a patent in the usual way. The Court is also mindful that, if a different question is raised as to validity in subsequent proceedings, that question should be considered as it was, for instance, in *Eli Lilly Canada Inc. v. Novopharm Ltd.*, [2007] F.C.J. No. 800, 2007 FC 596, previously discussed.
>
> [Emphasis added]

[43] The Federal Courts in *Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 163, *Eli Lilly Canada Inc v Novopharm Ltd*, 2007 FC 596, the Quinapril decision, above, and *Allergan Inc v Canada (Minister of Health)*, 2012 FC 767, amongst others, have applied sub-section 6(5)(b) of the *PM(NOC) Regulations* and the doctrines of issue estoppel, abuse of process and judicial comity to curb re-litigation of invalidity issues by both innovators and generics. Essentially, this jurisprudence is to the effect that where a determination has previously been made in respect of an allegation of invalidity found in a generic's NOA, the Court, when seized of the same allegation made by a different generic, should be cautious about making a different determination unless there is "better evidence or more appropriate argument". Those same principles have also been held applicable to non-infringement allegations (*Nycomed Canada Inc v Novopharm Ltd*, 2008 FC 454).

[44] These principles were developed and must be applied to safeguard the public's right to equitable access to the Courts, and weigh very heavily in favour of public disclosure of the details of the allegations, of the evidence and of the Court's assessment of that evidence. Given the disproportionate share of the Court's resources used by NOC proceedings, and the growing realization that judicial resources are not endless and must be shared equitably among all litigants, there is a clear public interest in ensuring that unnecessary duplications are not concealed or allowed to proliferate under a shroud of secrecy.

[45] Finally, while Mylan has been unable to establish that its NOA would attract particular attention among generics, the strong desire displayed by Mylan and other generics to keep their NOAs confidential does speak to the keen interest generics do have in litigation resulting from

others' NOAs. Mylan's broad assertion that "the public" has no interest in the information at issue in NOC litigation fails to take into account that the generic pharmaceutical industry forms part of "the public". That industry's interest cannot be discounted as illegitimate, or driven solely by a competitor's desire to peer into a litigant's proprietary information to gain a commercial or competitive advantage. Other generics' interest in the details of the allegations and evidence in NOC proceedings is legitimate, as the Court's decisions on NOC proceedings are susceptible of having precedential value, or of giving rise to arguments of issue estoppel, abuse of process or judicial comity, and therefore, of affecting the outcome of these other generics' NOAs. For better or for worse, the *PM(NOC) Regulations* have established a process whereby the allegations of non-infringement or invalidity made by generic drug manufacturers must be assessed by the Courts, and not by administrative tribunals. Other generics therefore do have a legitimate interest in the Court's practices, proceedings and decisions that cannot be discounted or ignored when considering the public interest in open and accessible Court proceedings involving the *PM(NOC) Regulations*.

IV. Conclusion

[46] Mylan has failed to establish, in respect of its NOA, of the information set out in the NOA and of the evidence in support of its allegations of invalidity, that the information was treated as confidential or benefited from a reasonable expectation of confidentiality, and that alone is fatal to its motion. Mylan also failed to establish that a confidentiality order would be necessary to prevent a real and substantial risk of serious harm to its hope or desire to be first to market, that such a hope is an important interest which qualifies for consideration under the *Sierra Club* test or that such an interest would counterbalance the very strong legitimate public

interest in openness as regards all aspects of proceedings under the *PM(NOC) Regulations*. A confidentiality order will therefore issue, but only in respect of the ANDS Information not otherwise disclosed in the NOA.

"Mireille Tabib"
Prothonotary

Ottawa, Ontario
2014-11-13

FEDERAL COURT

SOLICITORS OF RECORD

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APPEARANCES:

CHRISTOPHER VAN BARR KIERNAN MURPHY	FOR THE APPLICANTS
VINCENT DE GRANDPRÉ GEOFFREY LANGEN	FOR THE RESPONDENT MYLAN PHARMACEUTICALS ULC
NO APPEARANCE	FOR THE RESPONDENT MINISTER OF HEALTH

SOLICITORS OF RECORD:

GOWLING LAFLEUR HENDERSON LLP Barristers and Solicitors Ottawa, Ontario	FOR THE APPLICANTS
OSLER, HOSKIN & HARCOURT LLP Barristers and Solicitors Ottawa, Ontario	FOR THE RESPONDENT MYLAN PHARMACEUTICALS ULC
William F. Pentney Deputy Attorney General of Canada Ottawa, Ontario	FOR THE RESPONDENT MINISTER OF HEALTH