Federal Court  Cour fédérale

Date: 20161208

Docket: T-953-16

Citation: 2016 FC 1359

Toronto, Ontario, December 8, 2016

PRESENT: Case Management Judge Kevin R. Aalto

BETWEEN:

VALEANT CANADA LP/
VALEANT CANADA S.E.C. AND
VALEANT PHARMACEUTICALS
LUXEMBOURG S.A.R.L.

Applicants

and

APOTEX INC. AND
THE MINISTER OF HEALTH

Respondents

ORDER AND REASONS

I. INTRODUCTION

[1] The Respondent, (Apotex) seeks an order dismissing the within application in its entirety pursuant to section 6(5)(b) of the *Patented Medicines (Notice of Compliance) Regulations* (the "*Regulations*"). The Applicants (Valeant) oppose striking the application essentially on the

ground that they have no burden or onus to prove anything on this motion and as they "have a right" to a hearing, the motion must be dismissed.

II. BACKGROUND

[2] Apotex delivered to Valeant a Notice of Allegation (NOA) in which Apotex alleged that its 1000 mg metformin tablets (the Apotex Tablets) would not infringe Valeant's 496 Patent. As described in the motion materials and the NOA, the 496 Patent relates to a pharmaceutical composition having a controlled-release coating formed from a "neutral ester copolymer without any functional groups" and "a poly glycol having a melting point greater than 55 C" where the coating is cured "at or above the melting point of the poly glycol".

[3] Apotex alleges in its NOA that it will not infringe the 496 Patent and further that the Apotex Tablets will not be using such a coating nor are they made in such a manner.

[4] Apotex advised Valeant in July, a few weeks after the application was commenced that it intended to bring this motion. Valeant did not seek to set a schedule for the exchange of evidence in the application. Rather, it engaged with Apotex on this section 6(5)(b) motion.

[5] In support of this motion, Apotex has filed three affidavits: 1) the affidavit of Lisa Ebdon, a law clerk, to which is attached various exhibits including the NOA and correspondence between the parties; 2) the affidavit of Duane Terrill, an Apotex employee, whose affidavit describes the contents of Apotex's ANDS for the Apotex Tablets; and, 3) the affidavit of Dr.

Ping I. Lee (Ping Affidavit), a professor of Pharmaceutics and Drug Delivery at the University of Toronto whose evidence is that the Apotex Tablets would not infringe the 496 Patent.

[6] More specifically, the Ping Affidavit notes that Dr. Ping was provided a copy of the 496 Patent (with the name of the owner and applicant redacted) and asked for an opinion on how the skilled person in the art would understand the 496 Patent and the essential element of its claims. Dr. Ping was also provided a copy of a similarly redacted regulatory submission and asked for an opinion on whether the formulation in the submission comprises all of the essential elements of the claims. The Ping Affidavit concludes that the formulation details provided in the regulatory submission will not contain or be made using the essential elements of the 496 Patent and that the Apotex Tablets do not comprise a coating or a pharmaceutical dosage that operates in the same manner as the dosage forms and coatings of the 496 Patent and its claims.

[7] Among other things, it is to be gleaned from the evidence that Apotex has provided to Valeant each and every document Valeant requested which was either referred to in the NOA or the ANDS. According to the evidence the documents demonstrate that the Apotex Tablets do not contain the essential claims of the 496 Patent. Much of the documentation was provided to Valeant prior to this application being commenced.

[8] The notice of application is of no assistance in understanding the position of Valeant or the grounds upon which it claims a prohibition order. The notice of application simply states "the Apotex Product infringes the 496 Patent" and "Apotex's allegations of non-infringement are not justified". No details other than these bald allegations are provided.

[9] Subsequent to the notice of application being commenced Valeant sought additional production pursuant to section 6(7) of the *Regulations*. Apotex provided all of the documentation requested.

[10] In a calculated strategic decision, Valeant chose not to file any evidence on this motion. Rather, it chose to engage with Apotex on this motion and did not seek an opportunity to file its evidence on the main application. It also did not cross-examine any of the Apotex witnesses. In sum, there is no evidence on this motion from Valeant save and except for the allegations contained in its notice of application.

III. Position of the Parties

[11] Apotex argues that this application is an abuse of process, is bereft of any chance of success and therefore the application should be struck. Apotex argues that the Court should exercise its discretion and the authority granted by the *Regulations* in s. 6(5)(b) to strike this application at this stage. Apotex argues that this application falls within the provisions of this section as the application is an abuse of process or is otherwise scandalous and vexatious.

[12] Apotex relies upon *Toronto (City) v C.U.P.E., Local 79*, [2003] 3 S.C.R. 77 for the proposition that courts should control their process to ensure that matters which come before it do not bring the administration of justice into disrepute; and that matters which are litigated do not violate "such principles as judicial economy, consistency, finality and the integrity of the administration of justice" [*Toronto, supra*, para 37].

[13] Apotex further argues that this case is an abuse of process as Valeant has chosen not to provide to Apotex or to the Court any evidence to justify that the proceeding should be allowed to proceed. As the premise of the *Regulations* is to prevent infringement [see, for example, *Sanofi-Aventis Canada Inc. v Novopharm Ltd.* 2007 FCA 167], in the absence of any evidence of infringement the application is an abuse of process.

[14] Valeant's position is best summarized in two paragraphs of its written representations as follows:

> 3. Apotex chose to bring this application before delivery of any of Valeant's evidence without even seeking a schedule for the delivery of such evidence. As a result, it must convince the Court that there is no possibility of any evidence being adduced by Valeant that would give it any chance of success. In other words, Apotex must satisfy this Court that no witness could possibly provide evidence in support of the application. The Court does not have any information before it to make such a determination. The law is clear that any doubt in this regard must be resolved in favour of Valeant.
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> 5. Valeant has the right, as the applicant, to have its application heard. It has no obligation to respond to Apotex's evidence on this motion, thereby giving Apotex and its witnesses two opportunities to make their case. The *Regulations* and the *Federal Courts Rules* give Valeant the opportunity and the right to lead its evidence and have its case on the merits determined at a full hearing of the application.

[15] Implicit in these submissions are several assumptions or arguments that require comment. First, there is an assumption that Apotex should have awaited the filing of Valeant’s evidence on the application. Second, there appears to be a suggestion that Apotex had some onus to obtain a scheduling order. Third, there is absolutely no onus of any kind whatsoever on Valeant to

produce any evidence on this motion. Fourth, Apotex has the burden of demonstrating that there is no possible witness anywhere that might support Valeant's case. Fifth, Valeant has a right to a hearing on the merits. Sixth, Apotex by bringing such a motion will obtain two opportunities to make their case. Seventh, Valeant has no obligation to respond to the case of Apotex on the motion.

[16] Each of these positions of Valeant is wrong or vastly overstated as discussed below.

IV. IV. Issue and Analysis

[17] The issue on this motion is whether the Court should dismiss this application as an abuse of process or on the ground that it is scandalous or vexatious.

[18] As noted, the purpose of the *Regulations* is to prevent infringement and to that end provides to a patentee a two year moratorium on the generic manufacturer entering the market. However, the *Regulations* do provide to a generic manufacturer a remedy in section 6(5) and, more specifically, section 6(5)(b) which provides as follows:

6(5) Subject to subsection (5.1), in a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application in whole or in part	6(5) Sous réserve du paragraphe (5.1), lors de l'instance relative à la demande visée au paragraphe (1), le tribunal peut, sur requête de la seconde personne, rejeter tout ou partie de la demande si, selon le cas :
. . .	

(b) on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents.	b) il conclut qu'elle est inutile, scandaleuse, frivole ou vexatoire ou constitue autrement, à l'égard d'un ou plusieurs brevets, un abus de procédure.

[19] This Court may strike an application if it falls into any of these categories: abuse of process, scandalous, frivolous, or vexatious. In my view, for the reasons that follow, this application is an abuse of process and ought to be struck.

[20] Primarily, it is an abuse of process as Valeant has deliberately chosen not to provide to Apotex or to the Court any evidence to justify why the proceeding should be allowed to proceed.

[21] Valeant argues that Apotex should have awaited the filing of Valeant's evidence on the application before bringing this motion. The simple answer to this submission is that there is nothing in section 6(5) which prevents a generic manufacturer from bringing a section 6(5) motion at any time.

[22] Valeant's second argument that Apotex brought this motion "without even seeking a schedule for the delivery of such evidence [Valeant's]" is somewhat astonishing given that Valeant complains of an attempt by Apotex to reverse the onus on Valeant on this motion. This submission amounts to placing an onus on a respondent to move the matter forward by seeking a schedule from the Court for the delivery of evidence. Where in the *Regulations* is there any suggestion that a respondent must seek a schedule for evidence to be delivered? Perhaps because all proceedings under the *Regulations* are case managed that this changes the process. It does

not. It is Valeant's application and Valeant has the onus to move the matter forward. Their evidence is due 30 days after initiating the application unless in the context of case management another schedule for delivery of evidence is established. Valeant did nothing to seek a schedule for evidence. It cannot now complain that Apotex had some obligation to press for a schedule. That onus was on Valeant. There was absolutely nothing to stop Valeant from delivering its evidence at any time prior to this motion being heard. Having made the calculated strategic decision not to deliver any evidence either in support of the application or in response to the motion it must live with the consequences.

[23] As well, notably, when establishing the schedule for the hearing of this motion, Valeant sought sufficient time to allow it the opportunity to file evidence and to cross-examine. It has done neither. This motion could have been heard much earlier.

[24] Valeant's third point is that it has no onus to put evidence forward on this motion. To require it to do so in Valeant's view is to turn this motion into a summary judgment motion which reverses the onus. Such is not the case. It is not sufficient for a party to commence an application without any grounds set out in the application to support its case. The grounds for infringement in the application are nothing more than a conclusion that the Apotex Product will infringe. There is no indication of what claims of the patent; no indication of how the infringement will occur; no reference to anything concrete other than the bald, empty statement that Apotex will infringe. On its face it is bereft of any chance of success. It should therefore be struck.

[25] The fourth point raised by Valeant is that Apotex has the burden of demonstrating that there is no possible witness anywhere that might support Valeant's case. This vastly overstates the burden on this motion. It raises the burden to something beyond a reasonable doubt. All that is required is for Apotex to demonstrate on the record before the Court that the application is bereft of any chance of success. Apotex has led evidence to demonstrate that the Apotex Product does not infringe. There is no evidence of any sort from Valeant to demonstrate that this application is not bereft of any chance of success. This is not a reversal of burden scenario. If the application contained information from which it could reasonably be inferred that there was some substance to the allegation of infringement then this application would not be bereft of any chance of success.

[26] Fifth, Valeant argues that it has a "right" to a hearing on the merits on a full record. This statement is partially correct. Valeant is entitled to a hearing provided that the application as a whole is not bereft of any chance of success. Valeant could not point to anything that allows this application to continue which would give it a "right" to a hearing. A litigant has a right to a hearing where there is some merit to the application. That is not the case here. The Court is a gatekeeper of its process [see, for example, *Hryniak v Mauldin*, 2014 SCC 7] and should winnow out at an early stage those cases that have no chance of success. The "right" to a hearing is a qualified right.

[27] It cannot be that an innovator has an unfettered right to bring an application and have it heard where it provides no indication of any arguable case for its application. Such an approach is offensive to the conduct of proceedings under the *Regulations* and to proceedings generally.

The *Regulations* provide a complete code for pursuing the opportunity to prohibit a generic from obtaining an NOC. Those *Regulations* are premised on the fact that an innovator has grounds for asserting its position. It receives as part of the bargain created by the *Regulations* a 24 month injunction against a generic from entering the market and the right to continue to sell its product unhindered by competition from the generic product. This valuable right cannot be given in the absence of some reasonable basis for the application being brought. It cannot be that any innovator can simply commence an application to gain its 24 month benefit and say to the Court and the generic that it has a right to a hearing and will demonstrate whatever case it has in due course.

[28] Sixth, Valeant argues that Apotex by bringing such a motion will obtain two opportunities to make their case to the detriment of applicants. That is, a generic, with relative impunity can simply bring a section 6(5) motion to finesse out the case of the applicant. If they are unsuccessful then they get a second opportunity to bolster their case and fill in the gaps. By virtue of this Valeant argues that requiring an applicant to respond with evidence to a section 6(5) motion would open the floodgates to all generic manufacturers to bring such motions which would clog the Court.

[29] The argument being that generics would all want to get a "free" look at the evidence of the innovator by bringing such a motion and get another opportunity to cross-examine. In my view, there are several answers to this argument. First, this is not a summary judgment motion and the innovator is not being asked to put its "best foot forward" [see, for example, *Moroccanoil Israel Ltd. v Lipton*, 2013 FC 667]. It is only being asked to show on the record that there is

some reasonable basis for bringing the application apart from the statement that it had a right to do so. That does not require it to put forward a bevy of expert reports or to put all its case together. Intellectual property disputes are rife with ingenious ways to put some evidence before the Court without exposing someone to cross-examination. For example, an affidavit of a law clerk attaching a draft expert affidavit or, more to the point, drafting a notice of application which sets out clear grounds for the application and not simply empty boilerplate and conclusions without material facts. The second answer is that the floodgates argument is really the opposite. If innovators can get away with empty boilerplate and no material facts to support any basis for the application, they would do so in every case which wold result in clogging the Court with more section 6(5) motions.

[30] Finally, Valeant argues that it has no obligation to respond to the case of Apotex on the motion. For the reasons discussed above this argument also falls flat.

[31] In *Toronto, supra*, the Supreme Court of Canada made clear that courts must control their own process and winnow out those cases which are abusive. In my view, this is such a case.

[32] Counsel for the parties, during the course of argument, provided an extensive tour of the various cases in this Court and the FCA which have considered section 6(5). Those cases include the following among others: *Bayer Inc. v Pharmaceutical Partners*, 2015 FC 388 (Proth.); *Novopharm Limited v Sanofi-Aventis Canada Inc.*, 2007 FCA 167; *Astra Pharma Inc. v Canada (Minister of National Health and Welfare)*, [2000] 9 C.P.R. (4th) 69 (F.C.T.D.); *Jannsen Inc. v Celltrion Healthcare Co.*, 2016 FC 525 (Proth) aff'd 2016 FC 651.

[33] For purposes of these reasons, while these authorities have been reviewed and considered there is no reason to further dissect these decisions. The purport of them is that the Court should exercise its discretion to strike an application where there is no arguable case on the merits of the application that is demonstrated on the section 6(5) motion. As was stated by Prothonotary Roger Lafrenière in *Bayer*:

> [16] The purpose of s. 6(5) is to enable the Court to expeditiously dispose of unmeritorious applications by first persons which have no chance of succeeding at hearing. The parties agree that dismissal of an application pursuant to subsection 6(5)(b) is an extraordinary remedy. Such relief will only be granted when the application is "clearly futile" or it is "plain and obvious" that the application has no chance of success: *Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 163 [*Sanofi-Aventis*] at para 28 and 36. The moving party bears the entire burden of proof in a s. 6(5)(b) motion: *Pfizer Canada Inc v Apotex Inc*, 2009 FC 671 at para 33.
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> [17] A second person may move under s. 6(5)(b) to dismiss a first person's application on the basis that the first person's affidavit evidence is insufficient to prove the second person's allegations of infringement are not justified: *Novopharm Limited v Sanofi-Aventis Canada Inc*, 2007 FCA 167 [*Novopharm*], at para 13. In order to make such a determination, the motions judge must be able to make the necessary findings of fact, viewed in the light most favourable to the first person, and apply the law to the facts.
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> [18] A motion to dismiss will only be granted where it is apparent that there is no arguable case on the merits of the application. The court is not justified in embarking on anything resembling a trial of the action on conflicting affidavits in order to evaluate the strength of either party's case.

[34] I agree with this statement of the law. The facts in *Bayer*, while not entirely on point, are instructive. In that case the respondents filed no evidence and relied entirely on the evidence filed by Bayer in the man proceeding including two expert affidavits. No cross-examinations were conducted. No additional evidence was filed by Bayer. As found by Prothonotary

Lafrenière the facts were not in dispute. Similarly, here there are no facts in dispute. Valeant has not filed evidence of any sort and relies entirely on the notice of application and its "right" to a hearing. Valeant has not responded to the Apotex evidence.

[35] On this basis there is no arguable case made out by Valeant and as such it is bereft of any chance of success and must be struck.

[36] The Court is grateful to counsel for their very helpful arguments. At the conclusion of the hearing, counsel for Apotex requested that the issue of costs be reserved and that the Court receive further submissions respecting costs. Thus, as Apotex has been successful on this motion, unless the parties are unable to resolve the issue of costs the parties shall provide written submissions limited to five pages plus any draft bill of costs. Apotex shall deliver their submissions on or before January 13, 2016. Valeant shall respond on or before January 31, 2017.

ORDER

THIS COURT ORDERS that:

1. This application is struck.

2. Apotex shall have their costs of the motion and the application. If the parties are unable to agree upon costs the parties shall provide written submissions limited to five pages plus any draft bill of costs. Apotex shall deliver their submissions on or before January 13, 2017. Valeant shall respond on or before January 31, 2017.

"Kevin R. Aalto"
Case Management Judge

FEDERAL COURT

SOLICITORS OF RECORD

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