Date: 20071115

Docket: T-1837-07

Citation: 2007FC1196

Ottawa, Ontario, Thursday, this 15th day of November 2007

PRESENT: MADAM PROTHONOTARY MIREILLE TABIB

BETWEEN:

PURDUE PHARMA

Applicant

- and -

PHARMASCIENCE INC. and
THE MINISTER OF HEALTH

Respondents

REASON FOR ORDER AND ORDER

[1] In this application for a prohibition order pursuant to the *Patented Medicines (Notice of Compliance) Regulations* (the "Regulations"), the Applicant seeks an order that this application be specially managed, and in the context of case management, that the Respondent Pharmascience Inc. ("Pharmascience") be scheduled to file its evidence before the Applicant's.

[2] It has been observed that proceedings under the *Regulations* are getting more and more complex and lengthy, both in terms of prosecution and in terms of hearing time, to the point where hearings on the merits taking place within the last six months of the 24-month statutory stay are becoming the rule rather than the exception, and where it is routine that hearings last three days or more. To the undersigned's knowledge, no such application appears to have been heard on the merits without having had to be designated as a specially managed proceeding and, more often than not, they have required significant interlocutory and scheduling hearings. Notices of allegations are getting lengthier, and in particular, allegations of invalidity are getting lengthier and more complex. Once an allegation of invalidity is made, an Applicant is almost compelled to file evidence, and its best evidence, on every single ground of invalidity alleged, whether or not the Respondent will ever lead evidence on that aspect. And whether or not the Respondent mounts an independent case on any of its invalidity allegations, it may still, and too often feels compelled to file evidence merely aiming to undermine, contradict or attack the credibility of the Applicant's affiants. Thus, secondary issues are often blown out of proportion, consuming the parties' and the Court's resources, and extending the time required for the hearing and determination of the application on its merits. Although fortunately many of those issues get abandoned prior to the hearing on the merits, they will still have contributed in multiplying the number of experts thought to be necessary by the parties, the time required to schedule and conduct their cross-examinations and often, the time and resources of the parties and of the Court in dealing with interlocutory motions arising from this evidence.

[3] Eventually, the issues in the vast majority, if not in all of the proceedings under the *Regulations* end up, by the time they get to a hearing, being substantially narrowed from what they originally were and from what they became in the course of prosecution. It is the process of getting there which is getting particularly longer and more exhausting of time and resources.

[4] Can there be a way to narrow the issues for hearing earlier? Can a disposition of the issues in the proceedings which is as just, but is less expensive and more efficient be achieved? The Applicant's present motion proposes that this be done by the simple expedient of reversing the order in which the Applicant and the Respondent are to serve and file their evidence.

[5] That idea is not new and was proposed by applicants and rejected by the Courts in the past (see: *Merck & Co. v. Nu-Pharm Inc. et al.* (2000) 7 C.P.R. (4th) 292 and *Bayer AG et al. v. Canada (Minister of National Health and Welfare)* (1993) 51 C.P.R. (3rd) 329).

[6] The case before me, I think, is different. In those earlier cases, the applicants were seeking the reversal essentially on arguments of what the *Regulations* contemplated, and on grounds of procedural fairness and prejudice. The just, least expensive and most efficient manner of proceeding with these complex litigations was not addressed in these matters. Case management, and the power of the case management Judge to give directions that are necessary for the just, most expeditious and least expensive determination of the proceedings on its merits do not appear to have

been considered in these cases (indeed, in the case of *Merck*, case management was not even in existence). Further, it is fair to say that proceedings under the *Regulations* had not, at that time, reached the same proportions as they have now reached. Also, the very idea of getting the parties to consider whether an inversion of the order in which some or all of the evidence is to be adduced has recently been raised by the Court in informal discussions between members of the Court and members of that particular Bar, as a possible way of rationalizing these proceedings.

[7] I am satisfied that the Court has, in the context of case management, discretion to vary the order in which evidence of the parties on an application is to be served and filed if it is satisfied that it is necessary for the just, most expeditious and least expensive determination of the proceedings on its merits. That discretion is contemplated in Rule 385(1)(a). Additional support for this proposition, if needed, can be found in Rule 55, which allows the Court to vary a rule or dispense with compliance in special circumstances. An analogy may also be drawn with Rule 274, which sets out the order in which evidence is to be led at a trial, but specifically provides that the Court may direct otherwise.

[8] In my view, if such a reversal is to be contemplated or ordered, it must be for the purpose of achieving the least expensive and most expeditious determination of the issues on the merits in a manner that remains just. In other words, the goal and the precondition would be that is should not affect the substantive rights of the parties and the fairness of their procedural rights. The Court

being satisfied that such an order would achieve the just, most expeditious and least expensive determination of the proceeding is the primary requirement, and one which the moving party has the burden of establishing. Whether or not the order should be made in the circumstances remains a matter for the Court's discretion.

[9] The parties before me generally concurred that the present case involves particularly complex issues of construction and invalidity. There are, in addition, non-infringement issues. The Respondent's notice of allegation runs to 93 pages, alleges some 13 grounds of invalidity and further incorporates a notice of allegation previously issued by Novopharm with respect to the same drug, which itself gave rise to an extremely lengthy and complex prohibition application. (The application was eventually settled, but only after all evidence had been filed, including reply evidence).

[10] Having heard the parties' representations at length, and having personally been charged with the case management of the earlier application involving Novopharm, I consider that there is a distinct possibility, if both parties should obtain leave to have more than 5 experts each, and if motions for leave to file reply evidence are brought, that this matter will not be capable of being prosecuted with the 24-month period contemplated in the *Regulations*. On the record before me, if the litigation proceeds in the regular fashion, that may well happen.

[11] The Applicant submits that its proposal would effectively narrow the issues for determination at an early stage, reduce the likelihood that reply evidence will be needed, and ultimately prove more expeditious and less costly for both parties.

[12] As regards the non-infringement allegations, the Applicant concedes that the most important factor in narrowing the issues will be its own review of Pharmascience's formulation, dissolution and pharmacokinetic information, and its determination of which claims of the patent it intends to assert would be infringed. Until that is done, asking Pharmascience to file its evidence first would not narrow the issues and would instead force Pharmascience to file evidence on issues that may never be contested. The Applicant suggest that this initial narrowing of the non-infringement issues can be accomplished within some 21 days, by it receiving and reviewing Pharmascience's information and then advising, probably by way of an amended notice of application, which claims of the patent it asserts would be infringed. The Applicant goes on to suggest that if, from there, Pharmascience was required to file its evidence first, there would be an opportunity to further narrow the issues as Pharmascience might abandon some of its claims of non-infringement. The period of time required for the affidavits of both parties to be filed under this suggestion would be of 110 days, as opposed to 150 days under the schedule otherwise contemplated by the parties, a savings of 40 days. Although I agree that there would be some potential for the further narrowing of the issues anticipated by the Applicant, the bulk of the issues to be narrowed would be narrowed in any event under normal process. I am not certain that the potential additional narrowing would be substantial enough, and the savings in time substantial enough to justify forcing Pharmascience

to file its evidence on infringement first in the absence of its consent, especially since it appears to me that the non-infringement issues are much less voluminous and complex than the invalidity issues, and that the invalidity issues will likely dictate the pace at which this application can proceed.

[13] It is with respect to the invalidity issues that I can conceive of the most potential for narrowing the issues and gaining efficiencies in time and expenses. The Applicant conceded that with respect to allegations of lack of sound prediction and over-broadness, it would likely have to file factual evidence from the inventors before Pharmascience could be required to file its evidence. The Applicant asserts it would be able to do that within 30 days. The Applicant then believes that Pharmascience would reasonably require 90 days (including the initial 30 days), to serve and file its evidence on invalidity. As that would considerably narrow the issues, the Applicant believes that no more than 60 days, and conceivably less might be needed for it to file its evidence. The total time to file the parties' respective evidence would therefore be 150 days. That would not, in fact, be any different than if the Applicant filed its evidence first, in the usual manner. (The Applicant would require 90 days to file its evidence first and Pharmascience accepted that, subject to its review of the Applicant's evidence, it did not foresee that more than 60 days would be needed for it to file its evidence in response.).

[14] The distinction between the two manners of proceeding would be felt in the following manner: Pharmascience represented at the hearing that the evidence it currently contemplates bringing on the invalidity issues and the infringement issues together could likely be adduced by no more than five experts. On the other hand, the Applicant, having had the experience of litigating this particular patent as against Novopharm, and even considering the recent case law limiting the number of experts to five per side without leave of the Court, indicates that it is more likely than not that it will require more than five experts, in order to put its best foot forward on all thirteen grounds of invalidity raised in the notice of allegation. The Applicant accepted however, that if Pharmascience were to file its evidence first and limits itself to five experts, it would not only be far more difficult for it to justify being granted leave to adduce more than five experts, but that it might not be necessary at all, as this would necessarily imply a narrowing of the issues.

[15] Yet, Pharmascience indicated at the hearing that if the Applicant filed its evidence first and was granted leave to adduce the evidence of more than five experts, it would be very likely that Pharmascience itself would need and seek leave to file the evidence of more than five experts, as well as additional time to do that.

[16] I conclude from this that it is indeed more likely than not that if Pharmascience were to file its evidence first, it would serve to substantially narrow the issues to be litigated in this matter and that it is likely that fewer expert witnesses would be needed. The fewer the experts and the

narrower the issues, the more limited the risk that reply evidence will be sought or allowed. Also, experts are notably busy, and securing their availabilities for cross-examination represents the bulk of the time usually provided for cross examinations. The fewer the experts, the less time will be necessary to coordinate, schedule and conduct their cross-examinations. This results in a less expensive determination of the issues as well as a more expeditious one.

[17] Of course, there can be no certainty in this, especially since both parties can, in the circumstances of this particular case and depending on the order in which they would be filing their evidence, argue with some justification that motions for leave to file reply evidence are likely to be required and might delay the scheduling and completion of cross-examinations of experts. Nevertheless, I remain convinced that in the circumstances of this case, it is more likely than not that reversing the order in which evidence is to be brought, at least with respect to invalidity issues, would substantially narrow the issues and lead to a just, less expensive and more expeditious resolution of the issues in this application. There is, to this, an important caveat: The savings in time and expenses can only, in my view, be achieved to their full extent if both parties are committed to this process and embrace it fully, so as to extend to each other the cooperation and transparency necessary to this purpose. Indeed, the very complexity of the issues and the awkwardness created by the partial reversal needed to deal with the allegations of non-infringement, lack of sound prediction and over-broadness, would require a high degree of cooperation between the parties.

[18] Unfortunately, Pharmascience forcefully objects to the idea that there should be a reversal of the order in which evidence is to be filed unless the Applicant provides the following counterparts: 1) That Pharmascience be allowed, as of a right, to file reply evidence; and 2) That the Applicant abandon and undertake not to rely on arguments raised in its notice of application as to the insufficiency of the notice of allegation. The Applicant will not make these concessions and I do not think its position is unreasonable. It must therefore be taken that Pharmascience objects to the Applicant's proposed order of proceeding. Pharmascience's objection – and the nature of the concessions it seeks – are such that in the circumstances, imposing a reversal of the order of evidence for part or all of the evidence would not foster that climate of cooperation necessary to realize the full benefit of efficiencies of time. Such savings of time and expense that would then result from reversing the order of evidence would likely be less considerable, and militates against imposing it on Pharmascience.

[19] I recognize that there is an undeniable tactical advantage accruing to the party, whoever it might be, who files its evidence second. That party not only gets to file its evidence in substantially the way it had anticipated to present and shape it, but has the added advantage of having the opportunity to adapt it so that it best opposes its opponent's; in the absence of any independent evidence of its own, that party also has the opportunity of weakening and attacking directly its opponent's evidence and mining its credibility. These are tactical advantages, which although legitimate, are neither substantive nor procedural. Such tactical advantages, it is hoped at least, should not in the end determine the outcome of the proceedings.

[20] For better or for worse, the procedure contemplated by the Rules for dealing with applications under the *Regulations* results in the respondent having this tactical advantage and it seems to me that in order to deprive it of this advantage without its consent, substantial savings in time, expense and resources, both of the Court and of the parties would have to be expected.

[21] As mentioned above, this matter involves issues of infringement, lack of sound prediction and inutility for which evidence should be adduced in the normal order; reversal would therefore apply to only part of the evidence, a procedure which is, as yet, unfamiliar to the Court and the parties and might for that reason and absent exemplary cooperation between the parties, require more interlocutory interventions by the Court.

[22] Taking the above into consideration, as well as the fact that the notion of reversing the order of evidence for some or all the issues in NOC proceedings is still a novel idea, which some respondents may not have considered when they served their notices of allegation and therefore may not be prepared to address, I will not exercise my discretion to set a schedule that would see Pharmascience's evidence filed first. This is not to say the Court might not in future choose to exercise its discretion differently, even in similar circumstances.

[23] I will note, however, that Pharmascience's position and argument speak of it being more concerned with preserving the tactical advantage it enjoys from filing its evidence in response to the

Applicant's than to narrowing the issues in dispute at an early stage, so as to reduce the number of experts, the expenses thereof, and likely reduce the time required to bring this application to a hearing. It is, I think, a choice that Pharmascience has a right to make, but at the same time, the consequences of that choice should not be visited solely on the Applicant and on the Court. The *Regulations* impose a very short timeframe for the determination of these applications, and in attempting to shoehorn into that timeframe proceedings which are developing the complexity of full-blown patent impeachment actions, the Court is too often required to schedule, hear and determine complex motions under unreasonable pressure of time, to say nothing of the hearing on the merits. When matters are delayed, it is the Applicant who must justify an extension of the period of statutory stay, or lose its opportunity that a prohibition order might issue. The Applicant further faces the threat of section 8 damages for a longer period of time if its application is ultimately dismissed. If and when these issues should come up for determination in relation to these proceedings, I would think it appropriate that the Court review the manner in which this application in fact proceeded, and consider what impact Pharmascience's choice might have had.

ORDER

IT IS ORDERED THAT:

1. This proceeding shall continue as a specially managed proceeding.

2. Subject to further order or direction of the case management Judge or Prothonotary, the schedule for the further steps to be taken in this proceeding shall be as follows:

   (a) The Applicant's evidence shall be served and filed no later than 97 days following the date on which Pharmascience complies with the order for disclosure dated November 14, 2007, in which the period of the Christmas recess is to be computed.

   (b) The Respondent's evidence shall be served and filed no later than 60 days from the date of service of the Applicant's evidence.

   (c) Cross-examinations on affidavits shall be completed no later than 90 days from the date of service of the Respondent's evidence.

   (d) The Applicant has leave to serve and file a requisition for hearing immediately after completion of the cross-examinations on affidavits and shall in any event do so no later than 10 days following completion of the cross-examinations on affidavits.

(e) The Applicant's record shall be served and filed no later than 45 days following completion of the cross-examinations on affidavits.

(f) The Respondent's record shall be served and filed no later than 45 days following service of the Applicant's record.

3. Costs of this motion shall be in the cause.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

NAME OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	T-1837-07
STYLE OF CAUSE:	Purdue Pharma v. Pharmascience Inc. and the Minister of Health
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	November 1, 2007
REASONS FOR ORDER:	MADAM PROTHONOTARY MIREILLE TABIB
DATED:	November 15, 2007

APPEARANCES:

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