Federal Court



Cour fédérale

Date: 20091217

Docket: T-1161-07

Citation: 2009 FC 1285

Ottawa, Ontario, December 17, 2009

PRESENT: The Honourable Madam Justice Snider

BETWEEN:

SANOFI-AVENTIS CANADA INC., SCHERING CORPORATION and SANOFI-AVENTIS DEUTSCHLAND GmbH

Plaintiffs

and

NOVOPHARM LIMITED

Defendant

AND BETWEEN:

NOVOPHARM LIMITED

Plaintiff by Counterclaim

and

SANOFI-AVENTIS CANADA INC., SCHERING CORPORATION and SANOFI-AVENTIS DEUTSCHLAND GmbH

Defendants by Counterclaim

Docket: T-1201-08

BETWEEN:

SANOFI-AVENTIS CANADA INC., SCHERING CORPORATION and SANOFI-AVENTIS DEUTSCHLAND GmbH

Plaintiffs

- and -

LABORATOIRE RIVA INC. and PHARMASCIENCE INC.

Defendants

AND BETWEEN:

LABORATOIRE RIVA INC. and PHARMASCIENCE INC.

Plaintiffs by Counterclaim

- and -

SANOFI-AVENTIS CANADA INC., SCHERING CORPORATION and SANOFI-AVENTIS DEUTSCHLAND GmbH

Defendants by Counterclaim

Docket: T-1357-09

BETWEEN:

APOTEX INC.

Plaintiff

and-

SCHERING CORPORATION, SANOFI-AVENTIS, SANOFI-AVENTIS DEUTSCHLAND GmBH and SANOFI-AVENTIS CANADA INC.

Defendants

REASONS FOR ORDER AND ORDER

[1] Sanofi-Aventis (Sanofi France), Sanofi-Aventis Canada Inc. (Sanofi Canada) and Sanofi-Aventis Deutschland GmbH (Sanofi Germany) (collectively Sanofi) have brought a motion to have three actions heard together with a common record. In each of the three actions, one or more of the Sanofi family of companies is named as Defendant. Each proceeding will require a calculation of damages under s. 8 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (*NOC Regulations*). A further common element is Canadian Patent No. 1,341,206 (the '206 Patent), a claim to the drug ramipril.

[2] For the reasons that follow, I have concluded that the motion for a joint hearing or a formal consolidation ought to be dismissed. I am, however, prepared to order that the three actions, while formally separate, be managed by the same case management prothonotary and heard consecutively by a single judge.

I. The Actions

- [3] In brief, the three actions in issue are as follows:
 - 1. T-1161-07: This file began as an action against Novopharm Limited (Novopharm) for infringement of the '206 Patent. Novopharm counterclaimed for, *inter alia*, damages pursuant to s. 8 of the *NOC Regulations*. By agreement, this part of the counterclaim was stayed pending the outcome of the main action. Court File No. T-1161-07 was heard together with Court File No. T-161-07, where Apotex Inc. (Apotex) was named as Defendant. By decision dated June 29, 2009, Sanofi's actions against both Apotex and Novopharm were dismissed (*Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2009 FC 676, 77 C.P.R. (4th) 99 (*Sanofi-ramipril*)). This decision is currently under appeal.
 - 2. T-1201-08: Sanofi also commenced an action against Laboratoire Riva Inc. (Riva) for infringement of the same '206 Patent. Riva counterclaimed for, *inter alia*, damages pursuant to s. 8 of the *NOC Regulations*. The parties have not proceeded further with this action presumably, because of the T-1161-07 action.

- 3. T-1357-09: Following the release of the decision in T-161-07 (which had been heard at the same time as T-1161-07), Apotex commenced this action claiming, *inter alia*, damages pursuant to s. 8 of the *NOC Regulations*.
- [4] Apotex supports this application and encourages the Court to order a formal consolidation of the three actions. The other plaintiffs Novopharm and Riva are strongly opposed to any form of consolidation. Schering Corporation, who is also named as a Defendant in the three actions, made limited representations on the motion.

II. Statutory Framework

- [5] Sanofi's motion for consolidation or joint hearing is based on Rule 105(a) of the *Federal Courts Rules*, SOR/98-106. Under Rule 105(a), Court may, in respect of two or more proceedings, order that they be consolidated, heard together or heard immediately after the other.
- [6] At this point in time, there has been (subject to the outstanding appeal in *Sanofi-ramipril*) resolution of the question of the validity of the '206 Patent. Each of the plaintiffs has undergone the complex application procedure of the *NOC Regulations*. We are now at the stage in the litigation where the assessment of damages under s. 8 is to be determined.
- [7] The three actions for damages are based on s. 8 of the *NOC Regulations*. Under s. 8(1)(b), if the innovator's NOC application to Court is withdrawn, discontinued, or dismissed by the Court,

"the first person is liable to the second person for any loss suffered during the period". Thus, the Court will be called upon to determine, for each action, the loss suffered by each of Novopharm, Riva and Apotex. At this point, the question of who is the proper "first person" has been the subject of further motions heard by the case management prothonotary; this question need not be resolved for purposes of this motion.

III. Analysis

A. Jurisprudence and Legal Principles

[8] A consolidation order under Rule 105 of the *Federal Courts Rules* is based on a number of policy objectives: "the avoidance of a multiplicity of proceedings and the promotion of expeditious and inexpensive determination of those proceedings" (*Global Restaurant Operations of Ireland Ltd. v. Boston Pizza Royalties Limited Partnership*, 2005 FC 317, 38 C.P.R. (4th) 551 (*Boston Pizza*), at para. 11; *John E. Canning Ltd. v. Tripap Inc.* (1999), 167 F.T.R. 93, 88 A.C.W.S. (3d) 543 at para. 27 (F.C.T.D.) (*Canning*)). For a patent trial, this eliminates the duplication of pre-trial preparations, including document production, examination of witnesses, and the length of the trial itself (*Apotex Inc. v. Wellcome Foundation Ltd.* (1993), 69 F.T.R. 178, 51 C.P.R. (3d) 480, at para. 7 (F.C.T.D.) (*Apotex-Wellcome*)). According to Justice Lemieux in *Canning*, these objectives further "the general interest of justice, its proper administration and the true interests of the parties" (above, at para. 26).

- [9] A number of relevant factors have been identified in the jurisprudence that may be taken into account in deciding whether the Court should exercise its discretion under Rule 105 (see *Boston Pizza*, above, at para. 11; *Canning*, above, at para. 27; *Knappett Construction Ltd. v. Canada (Minister of Labour)* (1999), 87 A.C.W.S. (3d) 30; [1999] F.C.J. No. 308 at para. 18 (F.C.T.D.) (*Knappett*); *Sivamoorthy v. Canada (MCI)*, 2003 FCT 307, 121 A.C.W.S. (3d) 1125 (*Sivamoorthy*); *Montana Band v. Canada* (1999), 182 F.T.R. 161, 93 A.C.W.S. (3d) 44 (F.C.T.D.) (*Montana Band*)). These factors include such matters as: commonality of parties, issues, facts and remedies; and, prejudice.
- [10] Under the notion of common facts and legal issues, Prothonotary Hargrave in *Fibreco Pulp Inc. v. Star Shipping A/S* (1998), 145 F.T.R. 125, 78 A.C.W.S. (3d) 437 (F.C.T.D.) (*Fibreco*), held that the rule for consolidation "does not require the separate causes of action to have completely common questions of fact or law, but only some commonality" (at para. 42).
- [11] With respect to prejudice, if the Court finds that one of the parties would suffer injustice or prejudice, this finding works against consolidation (*Boston Pizza*, above, at para. 11). Justice Rothstein (as he was then) held that the burden is on the party seeking consolidation to prove that the responding parties would not suffer appreciable prejudice or injustice (see *Eli Lilly and Co. v. Novopharm Ltd.* (1994), 55 C.P.R. (3d) 429, 48 A.C.W.S. (3d) 31 at para. 6 (F.C.T.D.) (*Eli Lilly*)). In *Apotex-Wellcome*, Justice Mackay agreed with the jurisprudence that the onus also rests on the moving party (often the defendant) to prove that continuing the actions separately would be an abuse of process or would prejudice the moving party (above, at para. 15; see *Mon-Oil Ltd. v. Canada*, (1989) 27 F.T.R. 50, 26 C.P.R. (3d) 379 (F.C.T.D.) (*Mon-Oil*); *Fruit of the Loom Inc. v.*

Chateau Lingerie Mfg. Co. Ltd. (1984), 79 C.P.R. (2d) 274). The moving party must prove a prejudice rather than a mere inconvenience (*Apotex-Wellcome*, above, at para. 15).

[12] Inconsistency in findings of fact does not necessarily constitute prejudice. The question of consolidation was before the Court in *Mon-Oil*, above, where the defendant had brought a motion to consolidate three separate actions with different plaintiffs but the same defendant. In dismissing the motion, Justice Cullen stated as follows:

Certainly, for the defendant, it would be more convenient, and administratively easier to consolidate/join the actions or require that they be heard consecutively in a pre-determined order. However, that is clearly not the test, and is a long way from meeting the heavy onus. Inconsistent findings of fact may well occur but vigilant counsel and a vigilant court can minimize that possibility, and in any event is not a sufficient ground to warrant consolidation.

These three actions are moving forward at their own pace as determined by counsel for the plaintiffs and counsel for the defendant. To consolidate the three actions would seriously hinder one plaintiff where action is practically ready for trial, whereas another is barely off the starting block. This delay could very well result in a significant loss to certainly one plaintiff if its worst fears are realized.

[13] In oral argument, Apotex argued that the Court of Appeal in *Apotex Inc. v. Janssen*Pharmaceutica Inc. et. al. (1997), 72 C.P.R. (3d) 179 at 181 (F.C.A.) (Apotex-Janssen) altered the test for consolidation as stated in *Mon-Oil*. Justice Décary stated:

We wish to add that the Court's time and resources would be better used if counsel arranged for joint hearing of applications, actions or appeals dealing with some common question of law or fact instead of each insisting in having his or her own separate day in court. Counsels' failure to do so impedes the development of a coherent case law and obliges the Court of Appeal to apply, sometimes reluctantly, the principle of *stare decisis*.

- [14] I do not agree that *Apotex-Janssen* has the effect asserted by Apotex. The comments of the Court of Appeal do not effectively relieve the moving party of its burden to establish prejudice on its part, and no prejudice to an opposing party. All one can take from this decision is that, wherever possible, parties should strive to have similar matters heard together. However, the Court of Appeal did not direct that consolidation should take place when a party could be prejudiced. These passing comments do not change the principles of *Mon-Oil*.
- [15] A final consideration is Rule 3 of the *Federal Courts Rules*. As taught by this Rule, the Rules including Rule 105 are to be "interpreted and applied so as to secure the just, most expeditious and least expensive determination of every proceeding on its merits". In the context of a motion to consolidate or hear together, an important question to keep in mind is this: Would consolidation provide the most efficient resolution of the matters in issue?
- [16] In sum, for this particular motion, the following questions are significant:
 - 1. Are there common parties?
 - 2. Are there common legal and factual issues?
 - 3. Will any of the parties suffer prejudice or injustice from the consolidation?
 - 4. Will consolidation provide the most efficient resolution of the matters in issue?

- [17] Based on these principles, I now turn to the facts of the case.
- B. Application of Law to Facts

(1) Common Parties

- [18] The three actions all involve different plaintiffs, Novopharm, Riva and Apotex. This fact argues against consolidation, although not strongly so.
- [19] For the most part, the defendants are common to the three actions. Novopharm argues that, if consolidation were to occur, it would have to litigate against defendants unrelated to its s. 8 claim. Apotex has made s. 8 claims against Sanofi (France) when Novopharm has not done so. This difference in defendants is minor and could likely be managed in a joint or consolidated trial.

(2) Common Legal and Factual Issues

[20] There is no question that each of Novopharm, Riva and Apotex is seeking compensation with respect to s. 8 of *NOC Regulations*. Moreover, each claim is in respect of the same patented drug – the '206 Patent to ramipril. That, of course, does not necessarily assist Sanofi and Apotex in this motion (to formally consolidate or hear together) unless the factual and legal underpinnings are so intertwined that one action ought not to proceed without the others.

- [21] Sanofi and Apotex each argue that the overall generic market for ramipril will be the focus of all of the claims. Accordingly, they assert that consolidation (or at least joint hearings) will ensure that there is a common evidentiary record and, thus, consistent decisions.
- [22] On the other hand, there will be major factual differences. The s. 8 claims deal specifically with the individualized damages that arise with respect to each generic pharmaceutical "second person". Each of Apotex, Riva and Novopharm will bear the burden of proving its losses for the applicable length of time, and will bring its own financial situation to the table for consideration by the Court.
- [23] The Court will be required to evaluate each claim separately. While consolidation does not call for completely common factual or legal situations (*Fibreco*, above), in my view, the records will be significantly different in each action. There may be common evidence, related to the operation of the market for ramipril, to all three actions. Actions of a generic who is not party to one action may impact on the assessment of damages in that action. In my view, these are evidentiary matters that can be dealt with in the context of each the action without joining or consolidating it with the other two.
- [24] On balance, I view this factor as not supporting consolidation.

(3) <u>Prejudice</u>

[25] Of all of the factors, the issue of potential prejudice is the most significant. It must be remembered that there is a two-pronged onus on the moving party (Sanofi) to prove that: (a) it will suffer prejudice under the *status quo* of separate hearings; and, (b) the responding parties will not suffer prejudice if consolidation occurs (see *Boston Pizza*, above; *Eli Lilly*, above; *Apotex-Wellcome*, above).

[26] In Sanofi's submissions:

At the heart of these proceedings is how this Court should assess damages under s. 8 of the *Regulations* in circumstances of multiple generic entry. A fundamental issue will be identifying the appropriate 'but for' universe. Is each generic entitled to have its damages assessed independent of the activities of any other generic? Alternatively, is the Court required to make a finding on a single 'but for' universe and allocate damages accordingly?

- [27] Sanofi alleges that if proceedings are heard separately, there is a potential for contradictory or inconsistent findings with respect to the "but for" market share determinations. Apotex supports Sanofi in this position and goes even further in arguing that Apotex will be prejudiced if it is not allowed complete access to the discovery of all witnesses.
- [28] Neither Sanofi nor Apotex have persuaded me that they would be prejudiced by the continuation of separate trials. I first observe that Sanofi's view of the necessity of a "but for" market share determination is strongly challenged by Novopharm. At this stage, Sanofi and Apotex hold a view of how damages can be proven that is not accepted by the party whose burden it is to prove its damages. If Novopharm is correct, there will be no need for all generics to prove

individual shares of some hypothetical "but for" market and no prejudice to Sanofi by not joining the actions. Even if Sanofi and Apotex are correct, the individual trial of Novopharm can still proceed with Sanofi tendering whatever evidence on the "but for" market that it feels is necessary to refute the claims of Novopharm. Apotex, in its action, can litigate its claim on whatever basis it wishes and, once again, Sanofi can defend. In any one of the three actions, Sanofi may obtain evidence from other generics through subpoenas. Apotex may do the same in its action.

- [29] In my view, the prejudice to Novopharm and Riva, should the consolidation occur, would outweigh the problems of not consolidating.
- [30] I would also find that Sanofi has not discharged its burden to prove that Riva, in particular, will not suffer prejudice from the consolidation. Riva, during oral submissions, argued that consolidation would not help to expedite its s. 8 claim, and would come at a heavy cost for Riva, a smaller generic pharmaceutical company. I agree. Neither Sanofi nor Apotex has addressed the prejudice that would befall Riva. As was taught by jurisprudence in *Mon-Oil*, *Boston Pizza* and *Eli Lilly*, the onus is on Sanofi, the moving party, to prove that it would suffer prejudice without a consolidation or a joint hearing, and that other parties would not suffer injustice or prejudice. Sanofi has not come close to meeting this burden.

(4) Efficiency

[31] I do not doubt that consolidation or some other common procedure can provide for overall efficiencies in an action. The validity and infringement issues in *Sanofi-ramipril* are a fine example.

However, I do not believe that this is one of those cases. Rather than efficiency, I am concerned that the result of consolidation or a joint hearing, in this case, would result in a situation close to procedural paralysis.

- [32] Sanofi and Apotex both argue that it would be against principles of expediency and conservation of court resources to have different judges deal with the common background of these three s. 8 claims. I do not disagree. However, the added complexity of a joint or consolidated trial would tend to neutralize any theoretical advantage of such a proceeding.
- [33] With at least four parties, whose interests are not always aligned, one can be certain that there will be difficulty in managing each and every procedural step. At the pre-trial stage, there will be a multiplicity of motions, all of which will require the submissions of four sets of counsel. Since actions for damages necessarily deals with financial information, the likely disputes on maintenance of confidentiality will be hard fought. A trial management conference, even on the simplest of matters, will require coordination of all parties rather than two. The issues related to discovery will require resolution by all parties and almost certainly require many trips to the case management prothonotary or judge. At a consolidated or joint trial, up to four sets of witnesses and experts will be heard. Issues of admissibility and confidentiality will be complex. Finally, there is the possibility of another generic company commencing a s. 8 claim with respect to ramipril.
- [34] A common concern of Sanofi and Apotex is the possibility of inconsistent findings in the three cases. This potential problem could be effectively managed by having the cases heard separately, but consecutively by one judge. Furthermore, I can see considerable advantage to having

all three cases managed by the same case management prothonotary or judge. While dismissing the motion, as advanced by Sanofi or Apotex, I am prepared to exercise my discretion to order that both of these steps be taken.

C. Common Discovery Transcripts

[35] Sanofi asks the Court to order that all transcripts from examinations for discovery in all three actions be made available to each of the parties in the actions. Apotex goes even further in its request that there be common discoveries in the actions, even if the files are not consolidated. I see no advantages to so ordering.

IV. Conclusion

- [36] In conclusion, I am not prepared to allow the motion that seeks full consolidation (as requested by Apotex) or hearing together (as requested by Sanofi). However, I can see substantial merit in having the three proceedings heard one after the other, by the same judge. Further, common case management of all three would be an essential element to the overall efficiency of the trials. In this way, the benefits of full consolidation could be achieved without the risks described above.
- [37] One problem, identified by Novopharm, remains. Novopharm submits that it would be ready to proceed to trial and seeks a trial date of September 2010. Novopharm also argues that it would be prejudiced by a delay while the other two actions get up to speed. It is true that the Novopharm action is procedurally ahead of the other two. It is questionable whether the other two

plaintiffs (Riva and Apotex) would be ready to proceed to trial as of September 2010. However, this potential problem disappears because the Court is likely unable to accommodate a three-week trial any sooner than early 2011. Thus, the parties to the other two actions would have sufficient time to prepare for their trials, which would follow the Novopharm trial.

THIS COURT ORDERS that:

- Pursuant to Rule 105(a) of the *Federal Courts Rules*, Court files T-1161-07,
 T-1201-08 and T-1357-09 are to be assigned to a single judge to be heard consecutively; and
- 2. The motion of Sanofi is otherwise dismissed, with costs fixed in the amount of \$2,000.00 to each of Novopharm and Riva.

"Judith A. Snider"	
Judge	_

FEDERAL COURT SOLICITORS OF RECORD

DOCKET: T-1161-07; T-1201-08; T-1357-09

STYLE OF CAUSE: SANOFI-AVENTIS CANADA et al. v. NOVOPHARM

(T-1161-07)

SANOFI-AVENTIS CANADA et al v.

LABORATOIRE RIVA and PHARMASCIENCE INC.

(T-1201-08)

APOTEX INC. v. SANOFI-AVENTIS CANADA et al

(T-1357-09)

PLACE OF HEARING: TORONTO, ONTARIO

DATE OF HEARING: NOVEMBER 30, 2009

REASONS FOR ORDER

AND ORDER: SNIDER J.

DATED: DECEMBER 17, 2009

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