Federal Court  Cour fédérale

Date: 20190214

Dockets: T-1960-18
T-2093-18

Citation: 2019 FC 191

Ottawa, Ontario, February 14, 2019

PRESENT: Madam Prothonotary Mireille Tabib

Docket: T-1960-18

BETWEEN:

BAYER INC. AND BAYER INTELLECTUAL PROPERTY GMBH

Plaintiffs

and

TEVA CANADA LIMITED

Defendant

Docket: T-2093-18

AND BETWEEN:

BAYER INC. AND BAYER INTELLECTUAL PROPERTY GMBH

Plaintiffs

and

APOTEX INC.

Defendant

ORDER AND REASONS

[1] At issue before the Court is whether the trials in two separate actions instituted by the same Plaintiffs against two different generics pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 should be scheduled to be heard, in part, together and whether doing so offends the prohibition against joinder of actions set out in s 6.02 of the *Regulations*. For the reasons that follow, the Court determines that ordering the common invalidity issues in both actions to be heard together is in the interest of justice in the circumstances of this case and does not constitute a joinder of the actions.

[2] The Plaintiffs in both actions, Bayer Inc. and Bayer Intellectual Property GmbH (collectively referred to as "Bayer" in these reasons) instituted the first action, T-1960-18, against Teva Canada Limited on November 9, 2018, in response to a Notice of Allegation wherein Teva asserted that its proposed rivaroxaban product would not infringe any valid claims of Bayer's 2,547,113, 2,624,310 and 2,823,159 Patents. Less than one month later, on December 7, 2018, Bayer instituted the second action, T-2093-18, against Apotex Inc. in response to three Notices of Allegation asserting that Apotex's proposed generic rivaroxaban product would not infringe any valid claims of the same three patents.

[3] The *Regulations* require the Federal Court to hear and determine such actions within 24 months of their filing date. Guidelines for proceedings with these actions and meeting this tight schedule were issued by the Court in a Notice to the Parties and the Profession dated September 21, 2017. Pursuant to the guidelines, the undersigned was promptly designated Case Management Judge in the Teva action, and by order dated December 13, 2018, a schedule for all key steps in the action was fixed and two weeks were set aside, beginning September 14, 2020 for the trial of that action.

[4] The undersigned was also appointed Case Management Judge for the Apotex action. The first case management conference in that action was held on January 8, 2019, at which time a schedule was set that would see all key steps completed by the end of July 2020, and thus in time for a trial to be held at the same time as in the Teva action.

[5] The situation thus created is similar to the circumstances that gave rise to the decision in *Biogen Canada Inc. et al v Taro Pharmaceuticals Inc. et al* 2018 FC 1034. In that case, two actions by the same innovator, Biogen, were instituted under the *Regulations* against different generics, Taro and Apotex, in respect of the same medicine and the same patent, within slightly more than one month of each other. By the time the Court was ready to fix a schedule and a trial date in the Apotex action, the trial date in the Taro action had already been set. Biogen and Apotex consented to an order whereby the common invalidity issues in both actions would be heard together during the trial already scheduled for the Taro action, with the infringement allegations specific to the Apotex action being heard separately and at a later date.

[6] There was little disagreement between the parties in *Biogen* that hearing the common invalidity issues together would eliminate duplications, constitute sound use of judicial resources and achieve the just, most expeditious and least expensive determination of the issues in both actions. The Court explained those advantages as follows:

> [7] In pharmaceutical patent litigation, it has been the practice of the Court to assign, where reasonably possible, the same judge to hear matters involving the same patent and same medicine. The science and technology involved in such litigation is so complex that it requires considerable time and effort for a judge to acquire a working knowledge of the basic non-contentious scientific concepts that are required to determine the factual questions at issue. It is simply sound use of judicial resources for the Court to put that hard earned knowledge to work on subsequent cases that require it. A judge who is intimately familiar with the evidence adduced in one case will also have a keener sense of where the differences in the evidence adduced in a different case might justify a different result, without offending the principles of judicial comity and predictability.
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> [8] Following this practice, the Court would thus normally assign the same Judge to both the Taro and Apotex trials.
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> [9] Given that the invalidity issues in both actions are essentially the same, that counsel for Biogen are the same, that the same inventors will be called to testify to the same factual issues, that the two actions will be heard in the same period of time and that the judge should be the same, efficient use of the Court and the parties' time all but demands that the invalidity issues in both actions be tried together.

[7] The parties in *Biogen* did not argue that a common trial of some issues would constitute a joinder of actions prohibited by s 6.02 of the *Regulations.* Taro, however, did object to the proposed common hearing on the basis that doing so might result in concurrent judgements, and the loss by it of the commercial advantage of being first to market with a generic version of its product. The Court considered Taro's arguments and concluded that an order directing the

common hearing of invalidity issues would not necessarily result in Apotex having its judgement at the same time as Taro, just as the converse would not guarantee that Taro would be first to come to market. In any event, the Court held that nothing in the *Regulations* entitled a generic that is first to send out a notice of allegation in respect of a particular medicine to be the first to obtain a judgement in an action taken pursuant to the *Regulations.*

[8] In the present case, both generics acknowledge that the interests of justice and sound use of resources dictate a similar result. The objection to a common hearing in this matter instead comes from the innovator, Bayer.

[9] Given Bayer's objection, the Court requested and received written submissions from Bayer and Apotex, and held a hearing by telephone conference, at which all parties, including Teva, appeared and made oral submissions.

[10] Although the Court had requested the parties' submissions as to "the scheduling of the trial", and had in the course of a previous case conference made specific reference to the order issued in *Biogen*, Bayer limited its written submissions to addressing a proposition whereby the actions would be consolidated, rather than partially heard together. Bayer's submissions give hardly any consideration to the advantages or disadvantages of a common hearing of issues, while expounding at length on the jurisprudential criteria to be met for a consolidation order and on the potential prejudice that would arise from a full consolidation of the actions and from uncertainties as to the modalities of the consolidation. Bayer's presentation of the issue as a choice between consolidation and the conduct of two fully independent trials also informs its

argument that this “consolidation” constitutes a joinder of action and is thus prohibited by s 6.02 of the *Regulations*.

[11] The power of the Court to determine how two or more proceedings pending before it are to be pursued or heard in relation to each other is set out in Rule 105, as follows:

105 The Court may order, in respect of two or more proceedings,	105 La Cour peut ordonner, à l’égard de deux ou plusieurs instances:
(a) that they be consolidated, heard together heard one immediately after the other;	a) qu’elles soient réunies, instruites conjointement ou instruites successivement;
(b) that one proceeding be stayed until another proceeding is determined; or	b) qu’il soit sursis à une instance jusqu’à ce qu’une décision soit rendue à l’égard d’une autre instance;
(c) that one of the proceedings be asserted as a counterclaim or cross-appeal in another proceeding.	c) que l’une d’elles fasse l’objet d’une demande reconventionnelle ou d’un appel incident dans une autre instance.

[12] Although the mechanisms of consolidation and of a common hearing are mentioned in the same sentence and are often thought to be functionally equivalent, they are quite different concepts with quite different consequences. The distinction has been noted by the Federal Court of Appeal in *Janssen Inc. v AbbVie Corporation et al.* 2014 FCA 176 at paras 7-8 and in *Venngo Inc. v Concierge Connection Inc.* 2016 FCA 209 at paras 7-9, citing with approval *Wood v. Farr Ford Ltd.*, [2008] O.J. No. 4092, 67 C.P.C. (6th) 23. The Ontario Superior Court of Justice’s decision in *Wood* concerns the application of Sub-rule 6.01(1) of the *Rules of Civil Procedure*,

R.R.O. 1990, Reg. 194, which, much like our Rule 105, provides for the consolidation of actions or for trials at the same time or one immediately after the other, in the following terms:

6.01(1) Where two or more proceedings are pending in the court and it appears to the court that,	6.01(1) Si plusieurs instances sont en cours devant le tribunal et qu'il appert au tribunal, selon le cas :
(a) they have a question of law or fact in common;	a) qu'elles ont en commun une question de droit ou de fait;
(b) the relief claimed in them arises out of the same transaction or occurrence or series of transactions or occurrences; or	b) que les mesures de redressement demandées sont reliées à la même opération ou au même événement ou à la même série d'opérations ou d'événements;
(c) for any other reason an order ought to be made under this rule,	c) qu'il est par ailleurs nécessaire de rendre une ordonnance en application de la présente règle,
the court may order that,	le tribunal peut ordonner :
(d) the proceedings be consolidated, or heard at the same time or one immediately after the other; or	d) soit la réunion des instances ou leur instruction simultanée ou consécutive;
(e) any of the proceedings be,	e) soit, l'une des mesures suivantes :
(i) stayed until after the determination of any other of them, or	(i) qu'il soit sursis à une instance jusqu'à ce qu'une décision soit rendue à l'égard de l'une des autres,
(ii) asserted by way of counterclaim in any other of them.	(ii) qu'une instance fasse l'objet d'une demande reconventionnelle dans l'une des autres.

[13] The Ontario Superior Court of Justice in *Wood* explained the distinction between consolidation and trial together as follows, at paragraphs 24 to 27:

> [24] Where two actions are consolidated, they become, and proceed as, one action. Thus, there is "one set of pleadings, one set of discoveries, one judgment, and one bill of costs": see The Civil Litigation Process, supra, p. 420.
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> [25] If two actions are ordered to be tried together, "the actions maintain their separate identity and there are separate pleadings, discoveries, judgments and bills of costs. But the actions are set down on the list one after the other to be 'tried in such manner as the court directs.' Usually, the trial judge will order that the evidence in one action is to be taken as evidence in the other action or actions. In this way both or all of the actions are tried together by the same judge or jury": see The Civil Litigation Process, ibid.
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> [26] Although it has been said that "[t]he difference between consolidation and an order directing the trial of actions together is more technical than real" (see The Civil Litigation Process, ibid.), I think the difference can be quite real if the matter is addressed promptly. Actions ordered tried together largely offer a savings of time and money, and enhanced convenience, at the trial stage. However, consolidation provides those features from an earlier stage in the proceedings, including: one set of pleadings, affidavits of documents, discoveries and pre-trial memoranda and one pre-trial.
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> [27] The existence of a second action also creates a risk that the two will proceed at different speeds, thereby leading to delay while the parties wait for the slower action to catch up.

[14] The distinction between consolidation, as contemplated by Bayer in its submissions, and the common hearing of the issues of invalidity, as ordered in *Biogen* and contemplated in this case, is thus the following: Under consolidation, both actions would become one single action, with only one set of discoveries, one trial, and, perhaps most importantly, one judgement. Under a common hearing of the invalidity issues, there will remain two separate actions; discoveries

may be coordinated if parties so consent, but need not be; the trials of both actions would proceed together, but only in respect of common issues, namely, claim construction and invalidity, for which the evidence would be adduced only once for the purposes of both; with respect to all other issues, including any issue of infringement, the trials would continue separately; finally, and just as importantly, two separate judgements would necessarily issue, each having binding effect only on the parties to which it relates, and each of which could even issue at different times. In *Biogen,* the precise dates and mechanism of the conduct of the trials allowed a hiatus of several weeks between the completion of the first trial and the resumption of the second, allowing for the potential issuance of judgements at different times:

> [17] Indeed, an order that the trials proceed concurrently on invalidity issues will not bifurcate the issues of the Apotex trial, but merely schedule the trial of the common invalidity issues to start, in the Apotex trial, at the same time as Taro's. Apotex's trial, as concerns all other issues, will then be adjourned to continue in April 2020, while Taro's trial will continue to its scheduled conclusion on March 13, 2020. Thus, the trial judge would be in a position, should she choose or be able, to issue a judgment in the Taro trial before completing the Apotex trial. Given that the evidence on invalidity will have been common, Apotex and Biogen might know the likely outcome of the Apotex trial on invalidity when the Taro judgment is issued, but that judgment will not be effective or binding, in and of itself, in respect of the Apotex action.

[15] In short, then, an order of consolidation results in the joinder of two actions into one, including, necessarily, a single trial, while an order that two actions be heard together results in a joint trial, but not otherwise in the joinder of the actions. The general prohibition against joinder set out in s. 6.02 of the *Regulations* reads as follows:

6.02 No action may be joined to a given action brought under subsection 6(1) during any period during which the Minister shall not issue a notice of compliance because of paragraph 7(1)(d) other than:	6.02 Aucune action ne peut être réunie à une action donnée intentée en vertu du paragraphe 6(1) durant la période pendant laquelle le ministre ne peut délivrer d'avis de conformité en raison de l'alinéa 7(1)d), sauf :
(a) another action brought under that subsection in relation to the submission or supplement in that given action; and	**a)** une autre action intentée en vertu de ce paragraphe relativement à la présentation ou au supplément visé dans cette action donnée;
(b) an action brought in relation to a certificate of supplementary protection that is added to the register after the filing of the submission or supplement in that given action, if the patent that is set out in that certificate of supplementary protection is at issue in that given action.	**b)** toute action relative à un certificat de protection supplémentaire ajouté au registre après le dépôt de la présentation ou du supplément visé dans cette action donnée, si le brevet mentionné dans ce certificat de protection supplémentaire est en cause dans cette action donnée.

[16] On a plain reading of the provision, its application is limited to the joinder of actions. To read the provision as prohibiting the common trial of one of more actions would require interpreting the word "action" as including both the action as a whole and the trial of an action as a severable component, so that the provision reads "No action and no trial of an action may be joined to a given action or to the trial of a given action […]". Not only would that strain the ordinary meaning of the words used, but it is not justified for the purpose of giving effect to the purpose or intent of the regulatory scheme.

[17] The rationale for the prohibition against joinder is explained as follows in the Regulatory Impact Analysis Statement issued with the amended *Regulations* (Canada Gazette Part I, Vol. 151, No. 28 at 3321):

> The limit on joinder is necessary to restrict the number of issues in dispute to facilitate resolution within 24 months. It is also necessary to avoid further complicating the assessment of damages arising from delayed market entry.

[18] The features of a joinder of actions (or of a later consolidation), such as a single set of pleadings and discoveries and a single judgement, may in ordinary actions be found advantageous, but in the context of actions brought under the *Regulations*, they are more likely to be the source of the complications which Bayer cites as prejudicial and which s 6.02 of the *Regulations* seeks to avoid. Given the speed at which actions proceed under the *Regulations*, achieving a single set of pleadings following consolidation requires amendments to existing pleadings. Each generic will most likely have its own lawyers and its own views of construction and invalidity issues, complicating the crafting of a single responding pleading and eventually, of a single judgement; the need to coordinate availabilities across three sets of counsel for all discoveries and interlocutory proceedings may be cumbersome and inefficient, and the imposition of conflicting confidentiality provisions by each generic in respect of technical or scientific data pertaining to its own product can greatly complicate the exchange of discovery evidence, of expert reports and the conduct of the trial; ancillary or procedural issues raised by one generic but not the other may also lead to cumulative delays. The necessity for consolidated actions to proceed to a single trial and result in a single judgement also gives rise to a significant risk that the determination of the issues in respect of one generic's submissions would be unduly

delayed by complications caused by another generic, giving rise to the complications in the assessment of damages from delayed market entry to which the RIAS refers.

[19] Conversely, simply directing a common trial of some issues does not create the same complications, and reading s. 6.02 as also preventing common trials would have no effect in restricting the issues in dispute or facilitating the resolution in 24 months.

[20] Because a joint trial order does not otherwise join the actions, the drawbacks of consolidations are avoided. The actions remaining separate, there is no call for amendments, and there is no increase in the number of issues in dispute in each action. Because each action stands to be adjudicated separately, each may be adjudicated in accordance with and based only on the issues raised in each, without risk of complicating the assessment of damages arising from delayed market entry. Discoveries and interlocutory motions need not be coordinated across all counsel, and confidentiality restrictions are respected. Each action may proceed at its own pace towards the common trial dates, accommodating unique issues that may arise without resulting in cumulative delays. And because the actions remain separate and are not inextricably bound as consolidated actions must be, should one of them encounter such complications that its trial must be delayed, that too can be accommodated without impacting the action that remains on track for the scheduled trial dates.

[21] Interpreting the *Regulations* as removing the Court's ability to schedule parts of trials in common may even be counterproductive to achieving the *Regulations'* aim of determining actions within 24 month the aims.

[22] As mentioned in the passage of *Biogen* cited above, the common trial of issues in these complex cases constitutes the most efficient use of the Court and the parties' time and resources. Where, as here, two actions raising the same invalidity issues in respect of the same patents are instituted and must be resolved within a scant month of each other, prohibiting the Court from ordering the common trial of these issues would force the Court to hear essentially duplicate trials within a month of each other, requiring the same lawyers, the same inventors and perhaps the same experts to make themselves available for trial for twice the amount of time as a joint trial would require, increasing the difficulty of finding common availability dates and leading to unnecessary delays in scheduling. Ensuring the same Judge's availability for both trials in the time permitted by the *Regulations* may also prove impossible, leading to the loss of the efficiencies that come from assigning the same Judge and potentially increasing the time required for adjudication. The prospect of a joint trial also serves as an incentive for the parties in the two actions to coordinate and hold joint discoveries of inventors, eliminating potential delays in attempting to schedule repeated attendance of multiple inventors at two sets of discoveries.

[23] In conclusion, the Court is satisfied that ordering the trial of common invalidity issues in the two actions to proceed at the same time does not offend the letter, purpose or intent of s. 6.02 of the *Regulations.*

[24] The reasons provided above also lead to the inescapable conclusion that such an order will also lead to the just, most expeditious and least expensive determination of the issues in both actions on their merits, and meet the interest of justice.

[25] The arguments made by Bayer in its written submissions to the effect that "consolidation" would cause it prejudice are simply not applicable to a joint trial. Bayer's argument that ordering a joint trial of issues would be prejudicial to it because it would "unfairly" give Teva and Apotex the advantage and opportunity of pooling resources while it would be left to take on two opponents simultaneously is unpersuasive, especially coming from a well-heeled multinational corporation represented by experienced counsel.

[26] While trial dates have been set aside for the Teva action beginning on September 14, 2010 for two weeks, they have yet to be formally fixed; a trial Judge has yet to be assigned and the availabilities of Bayer and Apotex in the period before and after the Teva dates have yet to be canvassed. Accordingly, while the Court will order that the common invalidity issues in both actions be tried together, the precise dates of the start, adjournment, resumption and end of the common and individual portions of the trials will be fixed by the judicial administrator in consultation with the parties and the Case Management Judge.

ORDER

THIS COURT ORDERS that:

1. The trial in Court file T-1960-18 will be heard concurrently with the trial in T-2093-18, in respect of all common invalidity issues, at a time and place and for a duration to be fixed by the judicial administrator in consultation with the parties and the Case Management Judge.

2. The trials in Court file T-1960-18 and T-2093-18 in respect of all other issues will proceed separately at times and places and for durations to be fixed by the judicial administrator in consultation with the parties and the Case Management Judge.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1960-18
STYLE OF CAUSE:	BAYER INC. AND BAYER INTELLECTUAL PROPERTY GMBH v TEVA CANADA LIMITED
AND DOCKET:	T-2093-18
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