Federal Courts Reports

Recueil des décisions des Cours fédérales

2020 FCA 86

A-388-19

Apotex Inc. (*Appellant*)

v.

Bayer Inc. and **Bayer Intellectual Property GMBB** and **Teva Canada Limited** and **Taro Pharmaceuticals Inc.** and **Sandoz Canada Inc.** (*Respondents*)

A-389-19

Teva Canada Limited (*Appellant*)

v.

Bayer Inc. and **Bayer Intellectual Property GMBH** and **Apotex Inc.** and **Taro Pharmaceuticals Inc.** and **Sandoz Canada Inc.** (*Respondents*)

INDEXED AS: APOTEX INC. V. BAYER INC.

Federal Court of Appeal, Nadon, Pelletier and de Montigny JJ.A.—Toronto, January 13; Ottawa, May 14, 2020.

Patents — Practice — Appeals from Federal Court decision ordering that trial of common issues in Bayer Inc. et al. v. Taro Pharmaceuticals Inc. (T-435-19), Bayer Inc. et al. v. Sandoz Canada Inc. (T-806-19) be heard together with trial of common issues set for Bayer Inc. et al. v. Teva Canada Limited (T-1960-18), Bayer Inc. et al. v. Apotex Inc. (T-2093-18) — Previously, prothonotary issued order (Bayer No. 1) ordering that trial in Bayer Inc. et al. v. Teva Canada Limited (T-1960-18) be heard concurrently with trial in Bayer Inc. et al. v. Apotex Inc. (T-2093-18) in respect of all common invalidity issues; that trials would proceed separately in respect of all other issues — Respondents Bayer Inc., Bayer Intellectual Property GMBH (Bayer) market, sell in Canada drug product XARELTO®, anticoagulant containing active medicinal ingredient rivaroxaban; listed Canadian Patents Nos. 2547113; 2624310; 2823159; 2396561 ('561 patent) on Patent Register in connection with XARELTO® 10, 15, 20 mg strengths — Four actions commenced by Bayer against appellants Teva Canada Limited (Teva), Apotex Inc. (Apotex), against respondents Taro Pharmaceuticals Inc. (Taro), Sandoz Canada Inc. (Sandoz), stemming from service upon Bayer of notices of allegation (NOA) by four pharmaceutical generics pursuant to Patented Medicines (Notice of Compliance) Regulations — By NOAs, generics saying, inter alia, that patents at issue, excluding '561 patent, invalid — Whether Federal Court Judge making reviewable error in making impugned order — Impugned order infringing prohibition set out in Regulations, s. 6.02 pursuant to which no action may be joined to action commenced under s. 6(1) during period wherein Minister cannot issue notice of compliance under s. 7(1)(d) — Prothonotary's order in Bayer No. 1, like impugned order, violated s. 6.02 prohibition — Prothonotary of view that actions being joined synonymous with actions being consolidated, consequently, as section 6.02 only prohibiting actions being joined, not preventing her

from ordering that two actions be heard together — Prothonotary wrong in concluding as she did — Wording of prohibition capturing more than just consolidation of proceedings — Definitions of words "join", "réunir" examined; sufficiently broad to include order such as impugned order — While Judge not erring in regard to Federal Courts Rules, r. 105 (consolidation of proceedings), hearing together of four trials on common issues counter to prohibition found in s. 6.02 — Appeals allowed.

Practice — Parties — Joinder — Federal Court ordering that trial of common issues in Bayer Inc. et al. v. Taro Pharmaceuticals Inc. (T-435-19), Bayer Inc. et al. v. Sandoz Canada Inc. (T-806-19) be heard together with trial of common issues set for Bayer Inc. et al. v. Teva Canada Limited (T-1960-18), Bayer Inc. et al. v. Apotex Inc. (T-2093-18) — Previously, prothonotary issued order (Bayer No. 1) ordering that trial in Bayer Inc. et al. v. Teva Canada Limited (T-1960-18) be heard concurrently with trial in Bayer Inc. et al. v. Apotex Inc. (T-2093-18) in respect of all common invalidity issues; that trials would proceed separately in respect of all other issues — Whether Federal Court Judge making reviewable error in making impugned order — Federal Courts Rules, r. 105 giving Federal Court Judge discretion to make order made — Judge right to consider both r. 3, powers given to him under Rules, r. 385(1) — R. 105 relevant, applicable in present case — Court having to consider many factors before making order under r. 105, including whether prejudice will result — Nothing in legislation supporting appellant's argument for substantive protection of individual commercial interests of first or second generics to serve notices of allegation — Therefore, Judge not erring in not finding that order would cause prejudice to appellants — Also not erring in concluding that hearing of actions on common issues best solution for both parties, Court — However, Patented Medicines (Notice of Compliance) Regulations, s. 6.02 providing that no action may be joined to action commenced under s. 6(1) during period wherein Minister cannot issue notice of compliance under s. 7(1)(d) — Impugned order infringing prohibition set out in that provision — Federal Court decision set aside.

These were two appeals from a Federal Court decision ordering that the trial of common issues in *Bayer Inc. et al. v. Taro Pharmaceuticals Inc.* (T-435-19) and *Bayer Inc. et al. v. Sandoz Canada Inc.* (T-806-19) was to be heard together with the trial of common issues set for *Bayer Inc. et al. v. Teva Canada Limited* (T-1960-18) and *Bayer Inc. et al. v. Apotex Inc.* (T-2093-18). Previously, a prothonotary issued an order (*Bayer No. 1*) ordering that the trial in *Bayer Inc. et al. v. Teva Canada Limited (* T-1960-18) was to be heard concurrently with the trial in *Bayer Inc. et al. v. Apotex Inc.* (T-2093-18) in respect of all common invalidity issues and that, in respect of all other issues, the trials would proceed separately. The respondents Bayer Inc. and Bayer Intellectual Property GMBH (Bayer) market and sell in Canada the drug product XARELTO®, an anticoagulant that contains the active medicinal ingredient rivaroxaban, and has listed Canadian Patents Nos. 2547113 (the ′113 patent); 2624310 (the ′310 patent); 2823159 (the ′159 patent); and 2396561 (the ′561 patent) on the Patent Register in connection with XARELTO® 10, 15 and 20 mg strengths. The four actions commenced by Bayer against the appellants Teva Canada Limited (Teva) and Apotex Inc. (Apotex), and against the respondents Taro Pharmaceuticals Inc. (Taro) and Sandoz Canada Inc. (Sandoz), stem from the service upon Bayer of notices of allegation (NOA) by the four pharmaceutical generics pursuant to the *Patented Medicines (Notice of Compliance) Regulations* (Regulations). More particularly, by their NOAs, the generics say, *inter alia*, that the patents at issue, other than the ′561 patent which they do not challenge and which expires on December 11, 2020, are invalid.

The appellants Teva and Apotex submitted that the Federal Court Judge erred in making the impugned order joining their actions with the actions of the respondents on common issues and that, as a result, the Federal Court of Appeal should intervene. In support of their submission, the appellants made a number of arguments. In particular, they argued that the Court failed to consider the application of rule 105 of the *Federal Courts Rules* (Rules) and, as a result, it also failed to consider prejudice as a factor in its decision. The appellants said that, by failing to consider or refer to rule 105, the Federal Court Judge also erred in his approach to the issue of prejudice that could arise from the order, such as complexity, expenses and delay. The appellants also stated that they were poised to become the first movers in the generic rivaroxaban market because they were the first to serve their NOAs relating to their respective rivaroxaban products and that they should benefit from the first-movers advantage. Moreover, the appellants contended that the Federal Court erred in failing to consider sections 6.02, 6.08 and 6.09 of the Regulations.

The issue was whether the Federal Court made a reviewable error in making the impugned order.

Held, the appeals should be allowed.

Rule 105 gives the Court the power to consolidate two or more proceedings or to order that the proceedings be heard together or one immediately after the other. While the Federal Court Judge did not refer to rule 105 in making its determination, nothing turned on this omission. Nor did anything turn on the Federal Court's reliance on rule 3 and its inherent jurisdiction to control its proceedings. Rule 105 gave the Federal Court Judge the discretion to make the order that he made and, in making that order, there can be no doubt that the Judge was right to consider both rule 3 and the powers given to him under subsection 385(1) of the Rules. It had to be determined whether, in making the order that he did, the Judge erred in his exercise of the discretion afforded to him under rule 105. Rule 105, although not referred to by the Judge in his reasons, was relevant and applicable. Also, no special circumstances existed that would have permitted the Judge to dispense with compliance with rule 105. Consequently, whatever rights the parties had under rule 105 could not be dispensed with by the Judge even in the context of case management. In determining whether an order sought under rule 105 should be made, the Court must consider a number of factors, namely, the commonality of parties, issues, facts and remedies. The Court must also consider whether prejudice will result from the making of the order, a factor that carries great weight. These principles are not restricted to orders for consolidation but also apply to other rule 105 orders like the one under appeal. The appellants said that the Judge's order was prejudicial to them, more particularly, to the first generic that serves its NOA on a patentee by removing the incentive of first-mover advantage, and the order was therefore contrary to one of the intended purposes of the Regulations, which is to promote early generic market entry. Nothing in the legislation supported the appellants' argument for substantive protection of the individual commercial interests of the first generic or, in this case, the first and second generics, to serve NOAs. Canadian legislation in this area stands in contrast to the equivalent United States (U.S.) legislation, which grants to first movers in the U.S. the advantage sought by the appellants. While it may well have been preferable and fairer to first-movers to grant them the protection afforded to their U.S. counterparts, nothing in the Regulations supported the appellants' position that they are entitled to such an advantage in Canada. With respect to section 8 of the Regulations dealing with claims by generics, it will be left to the Federal Court or any other superior court to determine the extent of the loss claimed by a generic and, in doing so, the Court shall consider all matters that it considers relevant to this assessment. Consequently, it is open to the Court to consider whether the loss of market share is recoverable. Nevertheless, whether a generic can claim additional compensation under section 8 because it was the first mover, i.e. because it served its NOA first, was a question that did not need to be answered in these appeals. Therefore, the Judge did not err in not finding that his order would cause prejudice to the appellants. The Judge remained satisfied, for the reasons given in *Biogen Canada Inc. v. Taro Pharmaceutical Inc.*, that the Regulations do not bestow on the first generic to file an NOA any right to a prior hearing relative to any other interested party. There was no error in the prothonotary's reasoning in *Biogen*; thus, the Federal Court Judge's adoption of that reasoning was not an error.

With respect to the burden of proof under the Rules, rule 105 was applicable and the burden of proof rested with the parties seeking an order under that rule. However, burden of proof refers to a party's duty to establish facts in relation to a particular issue. If the party on whom the burden falls fails to furnish the requisite evidence, they will lose in regard to the point at issue. These circumstances were not present in the case at hand and, thus, where the burden of proof properly fell was ultimately immaterial. In the present case, the issue of prejudice turned on whether the legislation conferred a right to be heard first on the party that is first to serve its NOA. This was a purely legal question and the Judge required no evidence to make his determination. The Judge considered the parties' arguments and found that the legislation does not confer any such right, and, consequently, that the appellants would suffer no prejudice from an order requiring that their proceeding be heard in common with the respondents' on common issues. The Judge made no error in either of these determinations. In these circumstances, nothing turned on whether the Judge may have reversed the burden of proof. The appellants' argument on the burden of proof was therefore dismissed.

It was not an error on the part of the Judge not to consider section 6.08 of the Regulations. It was clearly open to Taro and Sandoz to agree, as they did, with the Judge's direction that the hearing of their actions should be joined to those of the appellants with respect to common issues. Although the Judge could have refused to make the impugned order, he was of the view that the joint hearing of the actions on common issues was the best solution for both the parties and the Court. His reasons did not reveal any error of principle nor did they reveal any palpable and overriding error.

The appellants' arguments on section 6.02 were well founded and the impugned order infringed the prohibition set out in that provision. Section 6.02 provides that no action may be joined to an action commenced under subsection 6(1) during the period wherein the Minister cannot issue a notice of compliance under paragraph 7(1)(d). What had to be determined is what the prohibition in section 6.02 of the Regulations meant in the context of the Rules—in other words, whether "joined" in section 6.02 of the Regulations is synonymous and strictly coextensive with "consolidated" in rule 105 or whether "joined" has a broader meaning. In *Bayer No. 1*, the Prothonotary ultimately ordered that the Teva and Apotex actions be heard together on common issues and found this order would not violate section 6.02 of the Regulations. A consolidation order would make matters extremely difficult for all concerned. The Prothonotary's reasons made it clear that consolidation of the two actions before her was, for all intents and purposes, not possible. It is, in most instances, simply not possible to consolidate multiple proceedings commenced under subsection 6(1) into one action because, *inter alia*, different parties are involved in each action and they are usually represented by different lawyers. Further, the issue of infringement is not necessarily the same in each action. Consequently, consolidation as a means of joining the actions is not a realistic approach. However, joining the actions for trial on common issues is possible and will usually be the preferred (and most expeditious) way of joining the actions so as to achieve the goal of simplifying matters and reducing the costs for the Court and for the parties. This is why, in regard to the rule 105 issue, no reviewable error on the part of the Judge was found. It was clear from the Prothonotary's reasons in *Bayer No. 1* that, in her view, actions being joined is synonymous with actions being consolidated. Consequently, as section 6.02 only prohibits actions being joined, it did not prevent her from ordering that the two actions before her be heard together. The Prothonotary was wrong in concluding as she did. The Prothonotary's order in *Bayer No. 1*, like the impugned order, violated the section 6.02 prohibition. The wording of the prohibition captures more than just the consolidation of proceedings as described by the Prothonotary in *Bayer No. 1*. The definitions of the words "join" and "*réunir*" were examined and those definitions supported a broader prohibition. They are sufficiently broad to include an order such as the impugned order. This suggested that the impugned order had in fact joined the four actions, within the meaning of the section 6.02 prohibition, in regard to the common issues. The fact that they were not joined in respect of all issues was irrelevant. While the French text for "consolidated" in rule 105 uses the same (French) word as is used for "joined" in section 6.02 of the Regulations, this did not support the proposition that the prohibition on actions being "joined" in section 6.02 of the Regulations is strictly limited to a prohibition on proceedings being "consolidated" in the narrow sense in which the Prothonotary had interpreted that word. The entire *raison d'être* of the section 6.02 prohibition is to promote the expediency of one action, and one action only, instituted pursuant to subsection 6(1), in the context of the 24-month time period within which that action is meant to be determined. Notwithstanding the fact that the Judge did not err in regard to rule 105, the hearing together of the four trials on the common issues was counter to the prohibition found in section 6.02. The effect of having the four actions heard together on the common issue would not only lengthen that trial but would inevitably delay the appellants' trials in regard to the infringement issue. Even if the determinations that joining actions means something more than just consolidation and joining is strictly synonymous and coextensive with consolidation were wrong, the impugned order, in its effects, resulted in a consolidation of the actions within the meaning ascribed to that term by the Prothonotary.

Finally, the Regulations do not require the Federal Court to render judgment within 24 months (section 6.09). While it is true that the Regulations prohibit the Minister from issuing a notice of compliance to a generic before the end of the 24-month period, they do not require the Federal Court to render judgment within that period. The Regulations make it clear that the burden of moving an action commenced under subsection 6(1) as efficiently as possible is on the parties, albeit with the help of the Court. Accordingly, although the 24-month period is a highly relevant consideration in

making orders under rule 105, it is not the only factor to be considered.

STATUTES AND REGULATIONS CITED

Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1589 (1984), S. 505(j)(4)(B)(IV).

Federal Court Rules, C.R.C., c. 663, RR. 1714-1718.

Federal Courts Rules, SOR/98-106, rr. 3, 55, 101, 102, 103, 104, 105, 106, 107, 213, 221, 342(1), 369, 385.

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, ss. 6(1),(3),(5)(*b*) (as am. by SOR/2006-242, s. 3; err. (E), Vol. 140, No. 23; SOR/2008-211, s. 3), 6.02, 6.08, 6.09, 6.1(1), 7(1)(d),(8), 8.

CASES CITED

APPLIED:

Biogen Canada Inc. v. Taro Pharmaceutical Inc., 2018 FC 1034; *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235; *Hospira Healthcare Corporation v. Kennedy Institute of Rheumatology*, 2016 FCA 215, [2017] 1 F.C.R. 331; *Apotex Inc. v. Merck & Co.*, 2003 FCA 438, 312 N.R. 273; *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533.

CONSIDERED:

Bayer Inc. v. Apotex Inc., 2019 FC 191, 164 C.P.R. (4th) 318; *Bayer Inc. v. Dr. Reddy's Laboratories Ltd.*, 2019 FC 1408; *Global Restaurant Operations of Ireland Ltd. v. Boston Pizza Royalties Ltd. Partnership*, 2005 FC 317, 38 C.P.R. (4th) 551; *John E. Canning Ltd. v. Tripap Inc.* (1999), 167 F.T.R. 93, 1999 CanLII 8029 (F.C.T.D.); *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 163, [2008] 1 F.C.R. 174; *Halifax (Regional Municipality) v. Canada*, 2008 FC 1159, 172 A.C.W.S. (3d) 818.

REFERRED TO:

Sanofi–Aventis Canada Inc. v. Novopharm Limited, 2009 FC 1285, 356 F.T.R. 235; *Ely Lilly and Co. v. Apotex Inc.*, 48 A.C.W.S. (3d) 31, [1994] 55 C.P.R. (3d) 429, 1994 CarswellNat 2072 (WL Can.) *sub. nom. Eli Lilly and Co. c. Novopharm Ltd.*, [1994] F.C.J. No. 680 (QL) (T.D.); *Apotex Inc. v. Wellcome Foundation Ltd.* (1993), 69 F.T.R. 178, 51 C.P.R. (3d) 480, 1993 CarswellNat 386 (WL Can.) (F.C.T.D.); *Mon-Oil Ltd. v. Canada* (1989), 26 C.P.R. (3d) 379, 27 F.T.R. 50 (F.C.T.D.) (WL Can.); *Janssen-Ortho Inc. v. Apotex*, 2009 FC 866, 180 A.C.W.S. (3d) 145; *Apotex Inc. v. Shire LLC*, 2017 FC 139, 161 C.P.R. (4th) 332; *Sivamoorthy v. Canada (Minister of Citizenship and Immigration)*, 2003 FCT 307, 121 A.C.W.S. (3d) 1125.

AUTHORS CITED

Hughes, Roger T. *Annotated Federal Court Act and Rules*, Markham, Ont.: Butterworths, 1998.

Larousse Langue Française, " *joindre*", " *jonction*", "*réunir* ", online: <www.larousse.fr/dictionnaires/francais>.

Merriam-Webster Dictionary, "consolidate", "join", online: <www.merriam-webster.com/dictionary>.

Regulatory Impact Analysis Statement, SOR/2017-166, *C. Gaz.* 2017.II.32.

APPEALS from a Federal Court decision (*Bayer Inc. v. Teva Canada Limited*, 2019 FC 1039, 169 C.P.R. (4th) 49) ordering that the trial of common issues in *Bayer Inc. et al. v. Taro Pharmaceuticals Inc.* (T-435-19) and *Bayer Inc. et al. v. Sandoz Canada Inc.* (T-806-19) was to be heard together with the trial of common issues set for *Bayer Inc. et al. v. Teva Canada Limited* (T-1960-18) and *Bayer Inc. et al. v. Apotex Inc.* (T-2093-18). Appeals allowed.

APPEARANCES

Harry Radomski and *Daniel Cappe* for appellant Apotex Inc.

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Melissa Binns for respondents Bayer Inc. and Bayer Intellectual Property GMBH.

Kavita Ramamoorthy and *Ben Wallwork* for respondent Taro Pharmaceuticals Inc.

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Fineberg Ramamoorthy LLP, Toronto, for respondent Taro Pharmaceuticals Inc.

Sprigings Intellectual Property Law, Toronto, for respondent Sandoz Canada Inc.

The following are the reasons for judgment rendered in English by

NADON J.A.:

I. Introduction and Procedural History

[1] Before us are two appeals of a decision (the order) of Pentney J. (the Judge) of the Federal Court (2019 FC 1039, 169 C.P.R. (4th) 49 [reasons]), dated August 1, 2019, wherein he ordered that the trial of common issues in *Bayer Inc. et al. v. Taro Pharmaceuticals Inc.* (T-435-19) and *Bayer Inc. et al. v. Sandoz Canada Inc.* (T-806-19) was to be heard together with the trial of common issues set for *Bayer Inc. et al. v. Teva Canada Limited* (T-1960-18) and *Bayer Inc. et al. v. Apotex Inc.* (T-2093-18).

[2] It should be pointed out that by order dated February 14, 2019 (2019 FC 191, 169 C.P.R. (4th) 318 [*Bayer No. 1*]), Prothonotary Tabib (the Prothonotary) had ordered that the trial in file T-1960-18 (*Bayer Inc. et al. v. Teva Canada Limited*) was to be heard concurrently with the trial in file T-2093-18 (*Bayer Inc. et al. v. Apotex Inc.*) in respect of all common invalidity issues and that, in respect of all other issues, the trials would proceed separately. I will hereinafter refer to the Prothonotary's order as *Bayer No. 1*.

[3] The respondents Bayer Inc. and Bayer Intellectual Property GMBH (Bayer) market and sell in Canada the drug product XARELTO®, an anticoagulant that contains the active medicinal ingredient rivaroxaban, and has listed Canadian Patents Nos. 2547113 (the ′113 patent); 2624310 (the ′310 patent); 2823159 (the ′159 patent); and 2396561 (the ′561 patent) on the Patent Register in connection with XARELTO® 10, 15 and 20 mg strengths.

[4] The four actions commenced by Bayer against the appellants Teva Canada Limited (Teva) and Apotex Inc. (Apotex), and against the respondents Taro Pharmaceuticals Inc. (Taro) and Sandoz Canada Inc. (Sandoz), stem from the service upon Bayer of notices of allegation (NOA) by the four pharmaceutical generics pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended on September 21, 2017 (the Regulations). More particularly, by their NOAs, the generics say, *inter alia*, that the patents at issue, other than the ′561 patent which they do not challenge and which expires on December 11, 2020, are invalid.

[5] I also note that on November 12, 2019, in *Bayer Inc. v. Dr. Reddy's Laboratories Ltd.*, 2019 FC 1408 (*Dr. Reddy's*), the Prothonotary dismissed a motion brought by another pharmaceutical generic for an order directing that the trial of its action, in regard to the issue of invalidity, be added to the trial of issues common to the four aforementioned actions.

[6] The appellants Teva and Apotex submit that the Judge erred in making the impugned order joining their actions with the actions of the respondents on common issues and that, as a result, we should intervene. In support of their submission, the appellants make a number of arguments.

[7] The appellants argue that the Court failed to consider the application of rule 105 of the *Federal Courts Rules*, SOR/98-106 (the Rules) and, as a result, the Court also failed to consider prejudice as a factor in its decision. Rule 105 provides that the Court may, in its discretion, order that two or more proceedings be "consolidated, heard together or heard one immediately after the other". Rule 105, according to the appellants, properly grants to the Federal Court the power that the Judge exercised in his order, that is, the power to determine how two or more proceedings pending before it are to be pursued or heard in relation to one another. The appellants argue the Judge erred by failing to make any reference to rule 105 and basing his order instead on the Court's inherent jurisdiction to control its proceedings and on rule 3, which states that the Rules are to be interpreted and applied "so as to secure the just, most expeditious and least expensive determination of every proceeding on its merits."

[8] The appellants say that, by failing to consider rule 105, the Judge also erred in his approach to the issue of prejudice that could arise from the order. Prejudice, according to the appellants, is the most important factor for the Court to consider in determining whether it should exercise the powers set out in rule 105. The appellants argue that while the onus of showing that the order would not be prejudicial to them should have been on the respondents, the Judge inappropriately reversed the burden of proof by requiring that the appellants themselves demonstrate that they would be prejudiced by the order.

[9] With regard to the prejudice that would, in their view, result from the order, the appellants' arguments are as follows. They say that they were poised to become the

first movers in the generic rivaroxaban market because they were the first to serve their NOAs relating to their respective rivaroxaban products.

[10] The appellants say that Taro and Sandoz, on the other hand, were on track to become late entrants in the generic rivaroxaban market because they delayed the service of their respective NOAs for a considerable length of time after the appellants had served theirs. By reason of the tardiness of their NOAs, Bayer's actions against Taro and Sandoz were only commenced in March and May 2019, respectively—months after Bayer commenced actions against the appellants Teva and Apotex in November and December 2018, respectively.

[11] The appellants further say that because of the 24-month stay imposed by the Regulations, their actions must be determined by the Federal Court by November 9 and December 7, 2020, respectively. The Taro and Sandoz actions, on the other hand, need not be determined until the spring of 2021.

[12] The parties have provided us with a table (Apotex's memorandum of fact and law, at paragraph 30; Teva's memorandum of fact and law, at paragraph 15), summarizing the relevant dates of the four proceedings:

Defendant	**NOA Served**	**Statement of Claim**	**24 months**
Teva	Sept. 28, 2018	Nov. 9, 2018	Nov. 9, 2020
Apotex	Oct. 23, 2018	Dec. 7, 2018	Dec. 7, 2020
CA 561 Patent Expiry Dec. 11, 2020			
Taro	Jan. 23, 2019	Mar. 8, 2019	Mar. 8, 2021
Sandoz	Apr. 2, 2019	May 17, 2019	May 17, 2021

[13] Thus, the appellants say that if they are successful, they will enter the market on December 11, 2020, upon the expiry of the ′561 patent which, as I indicated earlier, none of the parties have challenged.

[14] According to the appellants, as matters stood prior to the order, in the event their defences to Bayer's actions against them were successful, they would have shared the "first-mover advantage" in the rivaroxaban market. The appellants argue that the effect of the Judge's order is that they will lose their first-mover advantage and that Taro and Sandoz "will be able to jump the queue and enter the rivaroxaban market simultaneously with the first movers, Apotex and Teva (if successful)." (Apotex's memorandum of fact and law, at paragraph 5).

[15] The appellants go on to say that the first-mover advantage is a significant and substantial advantage in the context of the generic pharmaceutical market and that its loss constitutes an irreparable harm, adding that if generics are denied this advantage, there will be no incentive to pursue timely market entry.

[16] On that basis, the appellants criticize the Judge for dismissing out of hand the prejudice they say they will suffer. The Judge's focus was fixed, wrongly in the appellants' view, on whether procedural efficiencies would be gained from a common trial on invalidity. The appellants say that, had the Judge properly considered the issue of prejudice, he must have concluded that Taro, Sandoz and Bayer failed to establish that the appellants would not be prejudiced by a joint hearing or that the respondents would be prejudiced by separate hearings.

[17] The appellants also point out that another effect of the Judge's order is to add complexity and expenses to their proceedings and that additional delay will likely occur because of the involvement of two additional parties.

[18] Finally, the appellants contend that the Judge erred in failing to consider sections 6.02, 6.08 and 6.09 of the Regulations.

II. The Federal Court Decision

[19] After setting out the background of the issue before him, the Judge turned to the appellants' arguments and in particular to their argument concerning prejudice, which he summarized at paragraphs 7 to 10 of his reasons:

> In this case, however, Teva and Apotex argue that they will be prejudiced in several ways if Taro and Sandoz are added as defendants to the hearing of common issues. First, as noted earlier, they submit that Taro and Sandoz did not align the service of their NOAs on Bayer with the expiry of the 561 Patent, and thus they have ceded a potential commercial advantage. Adding Taro and Sandoz now as defendants to the common hearing would allow them, in effect, to "leapfrog" the expected sequence of events within the 24-month timeline fixed by the *Regulations*, and thereby re-gain the commercial advantage they have lost.
>
> In addition, Teva and Apotex note that the initial schedules for their actions were fixed by the Case Management Judge before the statements of claim were even issued in the Taro and Sandoz matters. The four actions, therefore, are at very different points in the schedule, which must work within the very tight timelines set by the *Regulations*. They argue that adding the two latecomers now will inevitably add complexity, cost, and delay to the trial preparation currently underway, as well to the actual the [sic] trial of common issues.
>
> Teva and Apotex contend that they have worked to collaborate on preparation for the trial of common issues, and to align their pleadings. This involves a certain added time and expense to their efforts, but it may also lead to some savings for each of them, or at the least the possible sharing of costs associated with trial preparation and the trial itself. Tentative dates have already been set for the hearing, and trial preparations are well underway.
>
> Teva and Apotex further submit that any additional costs to Bayer associated with not adding Taro and Sandoz to the trial of common issues is simply the result of the decision taken by Bayer to launch these actions against all four defendants, and are a natural consequence of the scheme set out in the *Regulations.*

[20] The Judge then set out, at paragraphs 11 to 18 of his reasons, the arguments of Taro, Sandoz and Bayer for why he should order the four actions heard together on common issues.

[21] Beginning at paragraph 21 of his reasons, the Judge gave his own explanation for why the order should be made. First, he relied on rule 3 of the Rules. The Judge stated that the principles set out in rule 3 render two considerations particularly relevant in the context of the Regulations: first, the 24-month deadline within which matters must be determined, and, second, the balance of interests as between innovators and generics, their respective commercial interests and the public interest, as reflected in the Regulations.

[22] The Judge then specifically addressed the appellants' first-mover argument. He rejected the appellants' submission that the Court should be guided by the Regulations to protect any sort of first-mover advantage. In so concluding, the Judge adopted the reasons of the prothonotary in *Biogen Canada Inc. v. Taro Pharmaceutical Inc.*, 2018 FC 1034 (*Biogen*), namely, that there is no guarantee that any party's action will proceed before that of any other, and the Court is not bound to deal with cases in any sequence dependant upon which actions were first in time. In the Judge's view, the primary consideration in the action before him was "the interests of justice for all of the parties in the particular circumstances of these cases" (reasons, at paragraph 24).

[23] The Judge then went on to consider what he believed to be the circumstances relevant to the determination he had to make. First, he made it clear that there were persuasive arguments on both sides of the question. He highlighted the fact that the appellants and Bayer had been proceeding diligently so as to abide by the schedule already set by the Prothonotary and that this had required considerable efforts on their part.

[24] In making these comments, the Judge recognized that adding Taro and Sandoz to the appellants' proceedings would necessarily add complexity to the preparation and conduct of the trial of common issues. The Judge added that the respondents had no absolute right to participate in the appellants' trial and that they would not be prejudiced if their common issues were not heard with those of the appellants. The Judge recognized that Taro and Sandoz could actually benefit from "going second" rather than being included in the appellants' trial.

[25] However, the Judge then made the point that Taro and Sandoz had caught up to the appellants' trial preparations and thus no delay was likely to result from adding them to the appellants' proceedings. He also made the point that hearing the four cases together on the common issues would result in savings of time and expenses to Bayer and to the Court "by avoiding two or possibly three trials on issues which are common to all of the proceedings" (reasons, at paragraph 26).

[26] The Judge did not agree with Bayer's argument that if Taro and Sandoz were not added to the trial on common issues, Bayer would be prejudiced by having to deal with "duplication and potential overlap in trial preparations for separate hearings on similar legal and factual questions, occurring in roughly the same time frame" (reasons, at paragraph 28). The Judge stated that, having made the decision to launch four separate actions, Bayer could not claim undue prejudice for having to manage a number of separate proceedings during the same time frame.

[27] On the basis of these considerations, the Judge concluded that the interests of justice required that the Taro and Sandoz trials be heard together with the appellants' on the common issues. Notwithstanding that greater efforts would be required by the

parties to bring the matter to fruition, it was clear to the Judge that the Taro and Sandoz proceedings were in a position to proceed in accordance with the schedule established by the Prothonotary for the appellants' proceedings. The Judge was also satisfied that it was in the interests of justice that the evidence in respect of the four actions be heard prior to the determination of the common issues of validity and claim construction. In the Judge's view, the most effective and efficient way of avoiding different rulings on these issues was to add Taro and Sandoz as defendants in the trial of common issues.

III. Legislation

[28] The following provisions of the Rules and of the Regulations are relevant to the determination of this appeal.

Federal Courts Rules, SOR/98-106

General principle

3 These Rules shall be interpreted and applied so as to secure the just, most expeditious and least expensive determination of every proceeding on its merits.

…

Varying rules and dispensing with compliance

55 In special circumstances, in a proceeding, the Court may vary a rule or dispense with compliance with a rule.

…

Consolidation of proceedings

105 The Court may order, in respect of two or more proceedings,

(a) that they be consolidated, heard together or heard one immediately after the other;

(b) that one proceeding be stayed until another proceeding is determined; or

(c) that one of the proceedings be asserted as a counterclaim or cross-appeal in another proceeding.

…

Consolidation of appeals

342 (1) Unless the Court orders otherwise, where more than one party appeals from an order, all appeals shall be consolidated.

…

Powers of case management judge or prothonotary

385 (1) Unless the Court directs otherwise, a case management judge or a prothonotary assigned under paragraph 383(c) shall deal with all matters that arise prior to the trial or hearing of a specially managed proceeding and may

(a) give any directions or make any orders that are necessary for the just, most

expeditious and least expensive determination of the proceeding on its merits;

…

(d) subject to subsection 50(1), hear and determine all motions arising prior to the assignment of a hearing date.

Patented Medicines (Notice of Compliance) Regulations, SOR/93-133

Right of Action

6 (1) The first person or an owner of a patent who receives a notice of allegation referred to in paragraph 5(3)(a) may, within 45 days after the day on which the first person is served with the notice, bring an action against the second person in the Federal Court for a declaration that the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) would infringe any patent or certificate of supplementary protection that is the subject of an allegation set out in that notice.

…

(3) The second person may bring a counterclaim for a declaration

(a) under subsection 60(1) or (2) of the *Patent Act* in respect of any patent claim asserted in the action brought under subsection (1); or

(b) under 125(1) or (2) of that Act in respect of any claim, asserted in the action brought under subsection (1), in the patent set out in the certificate of supplementary protection in question in that action.

…

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

(a) another action brought under that subsection in relation to the submission or supplement in that given action; and

(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.

…

6.08 An action brought under subsection 6(1) may, on the motion of a second person, be dismissed, in whole or in part, 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 or certificates of supplementary protection.

6.09 Every first person, second person and owner of a patent shall act diligently in carrying out their obligations under these Regulations and shall reasonably cooperate in expediting any action brought under subsection 6(1) or a counterclaim brought under subsection 6(3) to which they are a party.

6.1 (1) An action brought under subsection 6(1) shall be a specially managed proceeding in

accordance with the *Federal Courts Rules*.

…

Notice of Compliance

7 (1) The Minister shall not issue a notice of compliance to a second person before the latest of

…

(d) the day after the expiry of the 24-month period that begins on the day on which an action is brought under subsection 6(1);

…

(8) As long as the Federal Court has not made a declaration referred to in subsection 6(1), it may shorten or extend the 24-month period referred to in paragraph (1)(d) if it finds that a party has not acted diligently in carrying out their obligations under these Regulations or has not reasonably cooperated in expediting the action.

8 (1) A second person may apply to the Federal Court or another superior court of competent jurisdiction for an order requiring all plaintiffs in an action brought under subsection 6(1) to compensate the second person for the loss referred to in subsection (2).

(2) Subject to subsection (3), if an action brought under subsection 6(1) is discontinued or dismissed or if a declaration referred to in subsection 6(1) is reversed on appeal, all plaintiffs in the action are jointly and severally, or solidarily, liable to the second person for any loss suffered after the later of the day on which the notice of allegation was served, the service of which allowed that action to be brought, and of the day, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations.

…

(5) If the Federal Court or the other superior court orders a second person to be compensated for a loss referred to in subsection (2), the court may, in respect of that loss, make any order for relief by way of damages that the circumstances require.

(6) In assessing the amount of compensation — including any apportionment of that amount between the plaintiffs who are liable under subsection (2) — the court shall take into account all matters that it considers relevant to the assessment of the amount or the apportionment, including any conduct of the parties that contributed to delay the disposition of the action.

IV. Issues

[29] The only issue in these appeals is whether the Judge made a reviewable error in making the impugned order.

V. Analysis

A. *Standard of Review*

[30] I agree with the parties that the standards of review enunciated by the Supreme Court of Canada at paragraphs 26 to 28 of *Housen v. Nikolaisen*, 2002 SCC 33, [2002]

2 S.C.R. 235 (*Housen*) are the standards applicable in the present matter. This Court, at paragraphs 66 to 79 of *Hospira Healthcare Corporation v. Kennedy Institute of Rheumatology*, 2016 FCA 215, [2017] 1 F.C.R. 331, confirmed that any discretionary decision of a prothonotary or a judge of the Federal Court, as is the case here, is to be reviewed on the *Housen* standards.

[31] Consequently, questions of fact and mixed questions of law and fact are subject to the palpable and overriding error standard while questions of law and mixed questions, where there is an extricable principle of law, are subject to the correctness standard.

B. *The Rule 105 issue and prejudice*

[32] As I indicated earlier, the appellants criticize the Judge for having failed to consider rule 105, for having reversed the burden of proof applicable under that rule and for having summarily dismissed their argument regarding prejudice.

[33] I begin my discussion of this issue by saying that it does not appear that Taro, Sandoz or Bayer made a motion under rule 105 requesting that their actions be heard together with those of the appellants on common issues. Rather, it appears that, during the course of the case management of the four actions, the Judge—who, in addition to being a case management judge for the actions alongside the Prothonotary, was also the judge designated to hear the actions—directed by way of a letter dated June 20, 2019 that the appellants provide him, by the end of the business day on Friday June 21, 2019, with their position on the "possible involvement of Taro and Sandoz as parties in the hearing of common issues previously ordered in regard to Apotex and Teva".

[34] In response to the Judge's directive, the appellants submitted, on June 21, 2019, a brief response, reserving their right to elaborate more fully or to add to their submissions at the Case Management Conference scheduled for June 24, 2019.

[35] On June 24, 2019, prior to the case management conference, Taro filed a brief response to the appellants' submission of June 21, 2019.

[36] The case management conference was held on June 24, 2019, during which the issue of the joint hearing of the four actions on common issues was debated by the parties. The result of this debate is the Judge's order of August 1, 2019, the subject of these appeals.

[37] I turn now to review the legislative context within which the Judge made the order under review. Rule 105 gives the Court the power to consolidate two or more proceedings or to order that the proceedings be heard together or one immediately after the other.

[38] Subsection 6.1(1) of the Regulations states that any action brought under subsection 6(1) thereof is a specially managed proceeding in accordance with the Rules. Thus, rule 385, which sets out the powers of a case management judge or prothonotary, was applicable to each of Bayer's actions. Paragraphs 385(1)(a) and (d) [of the Rules], which I reproduce once again for the sake of convenience, provide as follows:

Powers of case management judge or prothonotary

385 (1) Unless the Court directs otherwise, a case management judge or a prothonotary assigned under paragraph 383(c) shall deal with all matters that arise prior to the trial or hearing of a specially managed proceeding and may

(a) give any directions or make any orders that are necessary for the just, most expeditious and least expensive determination of the proceeding on its merits;

…

(d) subject to subsection 50(1), hear and determine all motions arising prior to the assignment of a hearing date.

[39] The wording of paragraph 385(1)(a) is similar to that of rule 3, on which the Judge relied for his order. Both rules provide that the Court must ensure that its orders and directions lead not only to a just outcome, but to the most expeditious and least expensive determination of the proceedings on their merits.

[40] The Regulations thus provide for the case management of any action commenced under subsection 6(1), and the Rules provide the case management judge or prothonotary with discretion to make any order for the just, most expeditious and least expensive determination of proceedings. However, the question remains how exactly the powers granted to a case management judge under subsection 385(1) [of the Rules] are to be exercised. In considering the exercise of his or her powers, a case management judge must remain cognizant of rule 55, which provides that, only in special circumstances may the Court "vary a rule or dispense with compliance with a rule". In my view, there are no special circumstances in the present matter that would allow the Court to vary or dispense with compliance of any rule and, in particular, rule 105. More particularly, the 24-month stay provided for at paragraph 7(1)(d) of the Regulations does not constitute a special circumstance.

[41] However, although I agree with the appellants that the Judge did not refer to rule 105 in making his determination, I am satisfied that nothing turns on this omission. Neither, in my view, does anything turn on the Judge's reliance on rule 3 and the Court's inherent jurisdiction to control its proceedings. The fact is that rule 105 gave the Judge the discretion to make the order that he made and, in making that order, there can be no doubt that the Judge was right to consider both rule 3 and the powers given to him under subsection 385(1) [of the Rules]. The question we must decide is whether, in making the order that he did, the Judge erred in his exercise of the discretion afforded to him under rule 105.

[42] As the foregoing makes clear, I am satisfied that rule 105, although not referred to by the Judge in his reasons, was relevant and applicable. I am also satisfied that no special circumstances existed that would have permitted the Judge to dispense with compliance with rule 105. Consequently, whatever rights the parties had under rule 105 could not be dispensed with by the Judge even in the context of case management. In support of this view, I rely on this Court's decision in *Apotex Inc. v. Merck & Co.*, 2003 FCA 438, 312 N.R. 273, where the Court dealt with an order of a prothonotary made pursuant to rule 3 and paragraph 385(1)(a) which was subsequently confirmed by a judge of the Federal Court. By his order, the prothonotary dismissed the appellant's motion to compel answers on discovery with respect to questions that the respondent

had refused to answer during examination for discovery. In finding that the judge and prothonotary had erred in concluding as they did, this Court, per paragraph 13 of the reasons of Strayer J.A., explained its understanding of rule 3 and rule 385:

> In my view, however, in the present case there has been an error of principle which has fettered the exercise of discretion by the prothonotary, and his decision has been confirmed by the motions judge. I do not understand Rule 385 to authorize a case management judge or prothonotary, in giving directions that are necessary for the "just, most expeditious and least expensive determination of the proceeding on its merits" to enable them to deny a party the legal right to have questions answered on examination for discovery which are relevant to the issues in the pleadings. That right is not merely "theoretical" (as the prothonotary put it) but is clearly spelled out in Rule 240 and I do not take the general words of Rule 385(1)(a) or of Rule 3 to be sufficient to override that specific right. I would also observe that the word "just" which appears in both these rules relied on by the respondents and the decision-makers below confirms that justice is not to be subordinated to expedition. A person who is a party to a civil action is entitled to ask any question on discovery that is relevant to the issue: that is a matter of justice to him, subject of course to the discretionary power of the prothonotary or a judge to disallow the question where it is abusive for one of the reasons mentioned above. No such findings have been made in this case. [My emphasis.]

[43] Thus, this Court found that, as justice was not to be subordinated to expedition, the appellant was entitled to obtain answers to questions that were relevant to the issues raised by the pleadings, and the prothonotary had erred by invoking rules 3 and 385 to dismiss the appellant's motion. Similarly, in the present matter, the Judge could not rely on rules 3 and 385 to abrogate any rights the appellants were entitled to under rule 105.

[44] With this in mind, I turn now to a brief review of the jurisprudence pertaining to rule 105 to assist in determining whether the Judge erred in exercising his discretion under that rule.

[45] The jurisprudence makes clear that the purpose of an order under rule 105 is "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 Ltd. Partnership*, 2005 FC 317, 38 C.P.R. (4th) 551 (*Global Restaurant*), at paragraph 11; *John E. Canning Ltd. v. Tripap Inc.* (1999), 167 F.T.R. 93, 1999 CanLII 8029 (F.C.T.D.) (*John E. Canning*), at paragraph 27.

[46] In determining whether an order sought under rule 105 should be made, the Court must consider a number of factors, namely, the commonality of parties, issues, facts and remedies. The Court must also consider whether prejudice will result from the making of the order (*Sanofi–Aventis Canada Inc. v. Novopharm Limited*, 2009 FC 1285, 356 F.T.R. 235, at paragraph 9). In a number of decisions, the Federal Court has held that no order of consolidation should be made where prejudice would result from the order. It is also well established that the onus rests with the moving party to show that it would not be abusive or prejudicial to make the order sought (*Global Restaurant*; *Ely Lilly and Co. v. Apotex Inc.*, 48 A.C.W.S. (3d) 31, [1994] 55 C.P.R. (3d) 429, 1994 CarswellNat 2072 (WL Can.) (F.C.T.D.), at paragraph 6; *Apotex Inc. v. Wellcome Foundation Ltd.* (1993), 69 F.T.R. 178, 51 C.P.R. (3d) 480, 1993 CarswellNat 386 (WL Can.) (F.C.T.D.) (*Wellcome*), at paragraph 15; *Mon-Oil Ltd. v. R.* (1989), 26 C.P.R. (3d) 379, 27 F.T.R. 50, 1989 CarswellNat 153 (WL Can.) (F.C.T.D.), at paragraph 4). Thus, it is clear that, while prejudice is not the only consideration relevant to a determination

under rule 105, it carries great weight. To this, I would add that the nature and severity of the prejudice are of obvious relevance.

[47] In my view, the above principles are not restricted to orders for consolidation but also apply to other rule 105 orders like the one under appeal where it is determined that two or more proceedings are to be heard together on all issues or on common issues only. I see no basis for distinguishing between consolidation orders and orders like the impugned order in this regard.

[48] Another important aspect of the rule 105 case law that I wish to briefly draw attention to is that rule 105 issues typically arise following the filing of a motion for one of the forms of relief provided for under that Rule. Thus, in general, when relief under rule 105 is at issue, an evidentiary record is constituted by the parties for the purpose of supporting their arguments for or against. Practically, what this means is that parties are given a reasonable amount of time and a reasonable opportunity to put forward their case on the propriety or impropriety of a rule 105 order.

[49] While the case law supports the proposition that a judge may, in appropriate circumstances, on his or her own initiative and without a formal motion, make an order for any form of relief available under rule 105, I would counsel the greatest caution in respect of this practice. I consider my view to be echoed in the Federal Court's "NOTICE TO THE PARTIES AND THE PROFESSION - INFORMAL REQUEST FOR INTERLOCUTORY RELIEF" dated August 25, 2017. This notice makes clear that, with respect to interlocutory relief, including the consolidation of proceedings, parties must bring formal motions before the Court unless the request is by consent or is not opposed. This supports, in my view, the general principle that rule 105 relief should only be granted following the formal filing of motions, unless such relief is by consent or is unopposed, in which case informal letters will suffice. Finally, I would advise parties, such as the appellants in the present matter, to always either insist that a motion be brought by those seeking a rule 105 order or, where a judge intends to make such an order of his or her own motion, to indicate to the judge that sufficient time is required to prepare submissions and to constitute, if necessary, an evidentiary record.

[50] In this vein, I note that in the present matter, the respondents argue that even if the appellants were successful in convincing the Court with respect to their first-mover argument, they should nevertheless fail because they have not adduced any evidence regarding the approvability of their respective drug submissions. More particularly, the respondents say that the appellants have not put forward, *inter alia*, evidence regarding their manufacturing ability to supply the market, nor have they provided any evidence with regard to their intention to sell their products. Had I been persuaded by the appellants' first-mover argument (I will shortly explain why I have not been persuaded), I would have been inclined to return the matter to the Judge with a direction that he allow the appellants to constitute an evidentiary record with regard to their ability to go to market by the end of December 2020. I would be so inclined because, in the circumstances, no motion was brought forward for an order under rule 105 and the appellants were only given a very short time to respond to the Court's direction. However, because of my conclusion that the appellants cannot succeed on their first-mover argument, it is not necessary to make such a direction.

[51] I now turn to the errors that the appellants say were made by the Judge.

[52] The appellants say that the Judge's order is prejudicial to them. More particularly, they say that the order is prejudicial to the first generic that serves its NOA on a patentee "by removing the incentive of first-mover advantage," and the order "is therefore contrary to one of the intended purposes of the Regulations (which is) to promote early generic market entry." (Teva's memorandum of fact and law, at paragraph 10). In other words, the appellants take the position that, as the first-mover advantage promotes early generic market entry and hence early provision of generic drugs to the public, which is one of the purposes of the Regulations, this advantage should not be compromised.

[53] The difficulty with this proposition, as I see it, is that there is nothing in the Regulations nor the Regulatory Impact Analysis Statement, SOR/2017-166, (2017) *C. Gaz.*, Part II, Vol. 151., No. 1, pages 32–52 (RIAS) that supports the appellants' position. The RIAS, at page 33, sets out the Government's patent policy in the following terms:

> The Government's pharmaceutical patent policy seeks to balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower-priced generic competitors. The Regulations were intended to reflect this balance by enabling summary legal proceedings that would address patent concerns without unduly delaying access to generic medicines. Over time, the Regulations became less effective, in part because litigants commenced further litigation under the *Patent Act* (the Act) when unsatisfied with summary proceeding rulings.

[54] It is clear that the appellants are correct in saying that one of the goals of the Regulations is to promote early generic market entry, or, in other words, to prevent undue delay in the public's access to generic medicines. However, the fact remains that nothing in the legislation supports the appellants' argument for substantive protection of the individual commercial interests of the first generic or, in this case, the first and second generics, to serve NOAs.

[55] Canadian legislation in this area stands in contrast to the equivalent United States (U.S.) legislation, the *Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1589 (1984) (the Hatch Waxman Act of 1984), section 505(j)(4)(B)(IV), which grants to first movers in the U.S. the advantage now sought by the appellants. While it may well have been preferable and fairer to first-movers, as the appellants argue, to grant them the protection afforded to their U.S. counterparts, nothing in the Regulations supports the appellants' position that they are entitled to such an advantage in Canada.

[56] Before concluding on this issue, I will address an argument made by the appellants with respect to section 8 of the Regulations. The appellants point out that, pursuant to section 8 as it read prior to the 2017 amendments, when a patentee made an application under subsection 6(1) that ended in the generic's favor, the generic could only claim damages for losses suffered during a specified period. The beginning date for that period was the date upon which a notice of compliance (NOC) would have been issued in the absence of the Regulations. The end date for the recoverable period was the date the application proceedings concluded—essentially, the date on which the generic became capable of entering the market. Conversely, under the new Regulations, there is no end date for generics' recoverable period. According to the appellants, this change from the old to the new Regulations was intended to account for

a generic's loss of first-mover advantage that occurs when a patentee brings proceedings, and translates into a permanent loss of market share for the generic. The appellants add that case law on the predecessor provision to section 8 also recognized the existence of a first-mover advantage.

[57] I do not consider that section 8 supports the appellants' argument that they are entitled to a first-mover advantage by reason of having filed their NOAs earlier than the respondents. Both versions of section 8 were meant, in my view, to allow generics to seek compensation for losses suffered during the period they were kept out of the market by reason of an ultimately unsuccessful or discontinued proceeding (an application under the previous regime and an action under the amended regime) brought against them by a patentee under the Regulations.

[58] Under section 8, as it read prior to the 2017 amendments, the end date for claiming damages was the date on which the subsection 6(1) application proceedings came to an end. Under the current section 8, and more particularly pursuant to subsection 8(2), claims by generics are no longer limited to losses occurring prior to the close of proceedings. Generics can now claim for all losses suffered as a result of late market entry that occur after the later of the two dates specified in subsection 8(2). Those dates are the date on which the generic's NOA was served and the date on which an NOC would have been issued in the absence of the Regulations.

[59] Pursuant to subsections 8(1), 8(5) and 8(6), it will be left to the Federal Court or any other superior court to determine the extent of the loss claimed by a generic and, in doing so, the Court shall consider all matters that that it considers relevant to this assessment. Consequently, it is open to the Court to consider whether the loss of market share is recoverable.

[60] I agree with the respondents that a common hearing with Taro and Sandoz does not affect the appellants' rights to make their claim under section 8. In other words, if the appellants succeed in their defences to the actions taken by Bayer, they will not be prevented from arguing that, in the absence of the Regulations, they could or would have entered the market first and hence that they are entitled to compensation for their loss.

[61] Ultimately, however, whether or not a generic can claim additional compensation under section 8 because it was the first mover, i.e. because it served its NOA first, is a question we need not answer in these appeals. I will say, though, that since subsection 8(2) of the Regulations provides that losses can be claimed from the later of either the date on which a NOA was served and the date on which a NOC would have been issued in the absence of the Regulations, the Regulations clearly contemplate circumstances wherein the first generic to serve its NOA is not the first generic to receive the Minister's approval of its drug product.

[62] Thus, although an argument can be made on the basis of section 8 that the first-mover advantage is a relevant consideration for the assessment of damages, it does not follow, as the appellants argue, that they are also entitled to be heard first. As I have said, nothing in the Regulations supports the appellants' claim to a right of first hearing.

[63] Finally, I wish to point out that a determination under section 8 of the loss suffered by a generic is not based on any real world market launch but on entirely

hypothetical circumstances, as it seeks to determine what would have happened but for the commencement of an action by a patentee under the Regulations.

[64] In light of the above, I cannot conclude that the Judge erred in not finding that his order would cause prejudice to the appellants. The Judge was certainly alive to the appellants' first-mover argument and acknowledged, at paragraph 23 of his reasons, that "the balance of interests and the commercial realities underlying the regime set out in the *Regulations* is a relevant background consideration in this case". Nevertheless, the Judge remained satisfied, for the reasons given by the prothonotary in *Biogen*, that the Regulations do not bestow on the first generic to file an NOA any right to a prior hearing relative to any other interested party. In *Biogen*, the prothonotary made the following statements at paragraphs 11 to 13 of her reasons:

> Taro's objections are not based on any perceived substantive or procedural prejudice it might suffer from a common trial, but on the perception that doing so will result in concurrent judgments, resulting for Taro in a loss of the commercial advantage of being first to market with a generic fampidrine product.
>
> I find, however, that in the circumstances of this case, ordering the common invalidity issues to proceed to trial concurrently would not have the effect of depriving Taro of any commercial or strategic rights conferred on it by the *Regulations*.
>
> Being the first to send out a Notice of Allegations in respect of a particular medicine does not entitle a generic to be the first to obtain a judgment in an action taken pursuant to the Regulations, or guarantee it that result.

[65] I have not been persuaded by the appellants that the reasons given by the prothonotary in *Biogen* do not apply equally in this case. On my understanding of the Regulations and of rule 105, I cannot detect any error in the prothonotary's reasoning in *Biogen*, nor, therefore, do I find any error in the Judge's adoption of that reasoning.

C. *The Burden of proof under Rule 105*

[66] I now turn to the appellants' arguments concerning the burden of proof under rule 105.

[67] The appellants say that there was a heavy onus on the respondents to show that separate hearings would be prejudicial to them and that no prejudice would be caused to the appellants by the making of the order. However, in the appellants' view, the Judge instead placed the burden of proof on them, which he would not have done if he had properly considered rule 105.

[68] As I have already indicated, rule 105 was applicable and the burden of proof rests with the parties seeking an order under that rule. However, burden of proof refers to a party's duty to establish facts in relation to a particular issue. If the party on whom the burden falls fails to furnish the requisite evidence, they will lose in regard to the point at issue. These circumstances are not present in the case at hand and thus where the burden of proof properly fell is ultimately immaterial.

[69] In the present case, the issue of prejudice turned on whether the legislation confers a right to be heard first on the party that is first to serve its NOA. This is a purely legal question and the Judge required no evidence to make his determination. The

Judge considered the parties' arguments and found that the legislation does not confer any such right, and, consequently, that the appellants would suffer no prejudice from an order requiring that their proceeding be heard in common with the respondents' on common issues. I have found the Judge made no error in either of these determinations. In these circumstances, nothing turns on whether the Judge may have reversed the burden of proof.

[70] The appellants' argument on the burden of proof is therefore dismissed.

D. *Sections 6.02, 6.08 and 6.09 of the Regulations*

(1) *Section 6.08 of the Regulations*

[71] Given the respondents' argument about inconsistent decisions and abuse of process, the appellants submit that the Judge also erred by failing to consider section 6.08 of the Regulations which provides that the Court may, on the motion of a generic, dismiss an action commenced by a patentee under subsection 6(1) where the action "is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of the process in respect of one or more patents or certificates of supplementary protection." In the appellants' view, section 6.08, considered in light of the jurisprudence pertaining to former paragraph 6(5)(*b*) of the Regulations, provides a mechanism by which duplication or inconsistent decisions may be avoided when multiple proceedings have been brought, as is the case here.

[72] The appellants remind us of this Court's pronouncements on the former paragraph 6(5)(*b*) of the Regulations in *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 163, [2008] 1 F.C.R. 174 (*Sanofi-Aventis*). In that case, this Court held that a generic could bring a motion under that provision for abuse of process where a patentee, having been unsuccessful in an application to prevent the Minister from issuing a NOC to a generic because its patent was found to be invalid, seeks to relitigate the same issues against another generic.

[73] There can be no doubt, the appellants submit, that *Sanofi-Aventis* and related case law sought to prevent inconsistent decisions on the same issues. As section 6.08 is not substantially different than former paragraph 6(5)(*b*), it follows that it would be open to Taro and Sandoz, in the event that the appellants' defences to Bayer's actions are successful, to file motions under section 6.08 requesting that Bayer's actions against themselves be dismissed.

[74] This leads the appellants to say that the Judge erred in failing to consider section 6.08, particularly in light of the fact that the Judge expressed his concern that failing to make the impugned order could give rise to the possibility of inconsistent decisions.

[75] The appellants also point, as alternative remedies for Taro and Sandoz, to rules 213 and 221 of our Rules, which deal respectively with motions to strike and for summary judgment.

[76] Thus, it is the appellants' position that, considering the availability of section 6.08 of the Regulations as well as rules 213 and 221, it was unreasonable, and thus a failure by the Judge in the exercise of his discretion, to find that the hearing together of the four

actions on common issues was the most preferable and efficient means to ensure the interests of justice and the protection of the interests of the parties and of the Court.

[77] In my view, these arguments must fail. First, it is not a foregone conclusion that the principles set out in *Sanofi-Aventis*, which dealt with the former Regulations, will find identical application under the current Regulations, as the purpose of proceedings commenced under subsection 6(1) of the current Regulations differs from the purpose of proceedings commenced under the former Regulations.

[78] Second, had the trials of Taro and Sandoz not been joined to those of the appellants, and had the appellants' defences to Bayer's actions been successful, Taro and Sandoz would likely have had to wait before they could bring a motion under section 6.08. This is because the Apotex and Teva judgments would, in all probability, have been appealed to this Court. Hence, no motion under section 6.08 could have been brought prior to the determination of the appeals.

[79] The appellants' arguments with regard to the Judge's failure to consider section 6.08, properly understood, are that Taro and Sandoz should have delayed the trial of their actions until decisions were rendered in the appellants' cases. While it is no doubt true that Taro and Sandoz could have chosen to wait—assuming that Bayer, notwithstanding the 24-month period, was willing to go along with this—they were under no obligation to delay the hearing of their actions. I cannot see on what possible basis the Judge could have ordered them to wait upon the outcome of the appellants' hearing. Such a course of action would be contrary to the obligation of diligence in the prosecution of an action imposed by section 6.09.

[80] Lastly, in the circumstances, it was clearly open to Taro and Sandoz to agree, as they did, with the Judge's direction that the hearing of their actions should be joined to those of the appellants with respect to common issues. Although the Judge could have refused to make the impugned order, he was of the view that the joint hearing of the actions on common issues was the best solution for both the parties and the Court. His reasons, as I have already said, do not reveal any error of principle nor do they reveal any palpable and overriding error. More particularly, I conclude that it was not an error on the part of the Judge not to consider section 6.08 of the Regulations.

(2) *Sections 6.02 and 6.09*

[81] Section 6.02 of the Regulations provides that no action may be joined to an action commenced under subsection 6(1) during the period wherein the Minister cannot issue a NOC under paragraph 7(1)(d). The RIAS, at page 37, explains the prohibition and its purpose as follows:

> Limitations on joinder
>
> During the 24-month period in which the Minister is prohibited from issuing a NOC, the Regulations prohibit joinder of any action, other than an action in relation to an allegation of the second person included in a submission or supplement in the main action or an action in respect of a CSP that sets out a patent at issue in the main action. This, in appropriate circumstances, allows for joinder of (i) separate actions brought by a first person and a patent owner in response to the same Notice of Allegation (NOA), and (ii) separate actions brought in response to multiple NOAs that address different patents but are served in respect of the same submission. Other actions, such as an action alleging infringement of a

> patent that cannot be litigated under the Regulations, may not be joined. 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. If the 24-month period has expired or otherwise does not apply by operation of the Regulations, the Court is free to order joinder where appropriate. [My emphasis.]

[82] As for section 6.09, it provides that the parties to an action commenced under subsection 6(1) shall be diligent in respect of their obligations under the Regulations and that they are to cooperate in expediting the action, failing which the Court may, pursuant to subsection 7(8), shorten or extend the 24-month period referred to in paragraph 7(1)(d).

[83] With respect to section 6.02, the appellants, echoing the RIAS, say that the purpose of the prohibition on actions being joined is to ensure that actions under the Regulations are decided within the 24-month period and to prevent complicating the assessment of damages under section 8.

[84] The appellants then refer to the Prothonotary's decision in *Bayer No. 1* (see paragraph 2 of the present reasons) ordering the appellants' actions heard together on common issues. More specifically, the appellants point to the Prothonotary's explanation of the difference between a consolidation order and the one that she would be making. The appellants agree with the Prothonotary that many of the features of consolidation elucidated by the Prothonotary—common pleadings, common schedule, common discoveries and common trial, to name a few—are inimical to actions brought under the Regulations. The appellants say the effect of these features is to create a variety of complications. These include difficulty in coordinating discoveries and interlocutory proceedings across multiple sets of counsel, the fact that ancillary or procedural issues raised by one generic but not the other may lead to delay, and the complications that must accompany attempting a single trial resulting in a single judgment, which will also extend to any subsequent section 8 trials.

[85] The appellants argue, however, that the above deleterious features of consolidation are also present in the impugned order. More particularly, they say that, as a result of the Judge's order, Taro and Sandoz must abide by the schedule ordered in the appellants' actions, that the parties must coordinate and cooperate to meet the deadlines of that schedule and that, as a result, common discoveries and common motions have become necessary. This, the appellants say, became inevitable because five parties are involved in the trial of common issues and because of the compressed timelines imposed by the different dates of expiry of the automatic stay imposed by the Regulations.

[86] The appellants note that the Judge recognized in his reasons that adding the Taro and Sandoz trials to theirs would add complexity and time to the preparation and conduct of the trial of common issues. The appellants say that these concerns have been heightened still further by reason of trial-scheduling constraints facing counsel. The appellants were also concerned by the possible addition of an action by Dr. Reddy's Laboratories Ltd. to the trial of common issues (as I indicated at paragraph 5 of these reasons, the Prothonotary dismissed a motion seeking that this action be heard with those of the four other generics with regard to common issues).

[87] At paragraph 100 of its memorandum of fact and law, Apotex makes the following submission:

> At some point, the timing and number of the actions to be heard together results in proceedings that are said to be heard together in fact being closer to consolidation. Apotex submits that this is such a case. Accordingly, Apotex submits the Order Below offends the principles and purpose underlying section 6.02 of the *Regulation*s such that appellate intervention is warranted.

[88] With respect to section 6.09, the appellants argue that the provision creates obligations of diligence and cooperation only in relation to parties to one's own action commenced under subsection 6(1). The appellants then point out that section 6.02 prohibits other actions being joined to their own action. The appellants observe that the impugned order has nevertheless imposed on them obligations of diligence and cooperation in relation to parties to another action. The appellants submit that this reality is reflected in the Judge's remarks, found at paragraph 33 of his reasons, where he says:

> First, although adding new defendants will no doubt add a degree of complexity and require some greater efforts to coordinate as between counsel, it is evident that Taro and Sandoz are now ready to proceed in accordance with the schedule previously established for Teva and Apotex. I note that whatever extra burden is imposed, it will be shared by all of the parties, and I have confidence that the experienced counsel representing all of the parties in these matters can collaborate to ensure that the matters proceed in accordance with this schedule. It may be that Taro and Sandoz may incur extra burdens or expenses by having to meet this schedule, but they have agreed to do so. [My emphasis.]

[89] In the end, the appellants say that the impugned order has complicated their actions and increased the time and expense that will be required to see them through. In their view, the result of the order is unfairly prejudicial and does not properly balance the interests of the parties.

[90] The respondents do not agree with the appellants' position.

[91] First, the respondents say that the appellants did not raise sections 6.02 and 6.09 before the Judge and therefore this Court should not consider their arguments based on those sections. Second, they say that by reason of rule 3, paragraph 385(1)(a) and rule 105 [of the Rules], the Court is entitled to make orders such as the impugned order on its own motion. Third, they rely on the Prothonotary's reasons in *Bayer No. 1*, wherein the Prothonotary held that section 6.02 does not prevent orders for joint trials of common issues. More particularly, the respondents refer to paragraphs 16, 21 and 22 of those reasons where the Prothonotary says:

> On a plain reading of the provision [section 6.02 of the Regulations], 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.
>
> …
>
> 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.
>
> 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.

[92] With respect to section 6.09, the respondents say that the appellants are not involved in the conduct of their actions nor are they required to adhere to any schedule imposed in their actions, adding that, to the contrary, it is them, Taro and Sandoz, that are to align themselves to the timing and issues of the appellants' actions. The respondents say that the addition of their trials to the appellants' imposes no limits on the appellants' rights.

[93] The respondents conclude by saying that "the parties have been coordinating for months and have conducted common discoveries. There has been no complaint of additional burdens by [the appellants]" (Taro's memorandum of fact and law, at paragraph 133).

[94] For the reasons that follow, I conclude that the appellants' arguments on section 6.02 are well founded. In other words, I am satisfied that the impugned order infringes the prohibition set out in that provision.

[95] Before explaining why I so conclude, I wish to say that I see no reason why we should not consider the appellants' arguments concerning sections 6.02 and 6.09, as the respondents urge. First, the appellants' arguments, as I understand them, do not require any evidence to support them. Second, as I have previously indicated, the appellants were given short notice to respond to the Federal Court's direction regarding the addition of the Taro and Sandoz trials to theirs on common issues. Thus, I am satisfied that, in the circumstances, it is fair and proper to hear these arguments.

[96] I begin by saying that section 6.02 of the Regulations prohibits any action from being joined to an action commenced under subsection 6(1) during the 24-month period provided for at paragraph 7(1)(d). The explanation for this prohibition, which can be found at page 37 of the RIAS, reproduced hereinabove at paragraph 81, is to facilitate the resolution of actions commenced under subsection 6(1) within the 24-month period and to avoid complicating the assessment of damages under section 8. I note that the prohibition terminates upon the expiry of the 24-month period.

[97] Rule 105, which is at the heart of these appeals, does not explicitly speak of the joining of actions but of consolidation of proceedings and the hearing of two or more

proceedings together or one immediately after the other. However, rule 105 is nevertheless located in a section of the Rules comprising rules 101 to 107, the heading of which is “Joinder”. Rule 101 deals with “Joinder of claims”, rule 102 deals with “Multiple persons joined as parties”, rule 103 with “Misjoinder and nonjoinder”, rule 104 with “Order for joinder or relief against joinder”, rule 105 with “Consolidation of proceedings”, rule 106 with “Separate determination of claims and issues” and, finally, rule 107 deals with “Separate determination of issues”.

[98] I note that before the amendments to the Rules in 1998 (the Rules came into force on April 25, 1998), the only Rules that dealt with joinder were Rules 1714 to 1718 [of the *Federal Court Rules*, C.R.C., c. 663]. The word “consolidation” did not appear in those Rules. I should also point out that in the previous Rules, there was no rule similar to rule 105. As observed by Roger T. Hughes, former Justice of the Federal Court, in his *Annotated Federal Court Act and Rules* (Markham, Ont.: Butterworths, 1998), at page 11,149, “Rule 105 had no counterpart in the previous *Federal Court Rules* although the Court did, on occasions, consolidate proceedings or order that trials be heard together or one after the other”. As an example of the author’s statement, see the Federal Court’s decision *per* MacKay J. in *Wellcome*.

[99] The question that we must determine in these appeals is what the prohibition in section 6.02 of the Regulations means in the context of our Rules. Does the statement in section 6.02 of the Regulations that “[n]o action may be joined” only prohibit proceedings from being “consolidated” within the meaning of rule 105, as the Prothonotary found, or does the prohibition apply more broadly to other arrangements for multiple proceedings? In other words, is “joined” in section 6.02 of the Regulations synonymous and strictly coextensive with “consolidated” in rule 105, or does “joined” have a broader meaning?

[100] In order to answer this question, I will first address the Prothonotary’s reasons in *Bayer No. 1* where she ordered that the Teva and Apotex actions be heard together on common issues. At paragraph 1 of her reasons, the Prothonotary set out the questions before her, i.e. whether the Teva and Apotex actions (T-1960-18 and T-2093-18) should be heard together on common issues and whether such an order would be in breach of the prohibition in section 6.02 of the Regulations. The Prothonotary ultimately ordered that the Teva and Apotex actions be heard together on common issues and found this order would not violate section 6.02.

[101] I should point out that, as in the present matter, it does not appear that a motion under rule 105 was brought before the Court in *Bayer No. 1*. Although the appellants, Teva and Apotex, did not object to the Prothonotary’s order, Bayer objected on the grounds that the order would infringe the prohibition set out in section 6.02.

[102] After referring to rule 105, the Prothonotary indicated that consolidation and common hearings are different concepts, and the section 6.02 prohibition only prohibits the former. The Prothonotary reviewed a number of decisions of this Court (the cases to which the Prothonotary refers all appear to be decisions made by rule 369 judges and not by a panel of this Court) and of the Ontario Superior Court of Justice in regard to its equivalent of rule 105, before explaining, at paragraphs 14 and 15 of her reasons, the distinction between consolidation and common hearings:

> 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 …
>
> 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…. [My emphasis.]

[103] After reproducing section 6.02 of the Regulations, the Prothonotary opined that the prohibition was limited to the joinder of actions which, it is clear from the above, she interpreted as being synonymous with consolidation under rule 105. In other words, in the Prothonotary's view, the section 6.02 prohibition is limited to a prohibition on consolidation as that term is described by the Prothonotary at paragraph 14 of her reasons. In her view, to extend the prohibition to common trials of two or more actions would "strain the ordinary meaning of the words used" and "is not justified for the purpose of giving effect to the purpose or intent of the regulatory scheme" (*Bayer No. 1*, at paragraph 16).

[104] At paragraph 18 of her reasons, the Prothonotary went on to explain why the consolidation of two or more actions brought under subsection 6(1) of the Regulations would render proceedings extremely complicated. She said that consolidation would require amendments to existing pleadings, that each generic having its own lawyers with their own views regarding the common issues would complicate the crafting of a single pleading and that the need to coordinate availabilities between three sets of counsel in respect of discoveries and interlocutory proceedings would be cumbersome and inefficient. She also pointed to the difficulties arising from confidentiality provisions required by each generic in respect of technical or scientific data pertaining to their own product, noting that this would lead to complications with regard to discovery evidence, expert reports and the conduct of the trial.

[105] I agree entirely with the Prothonotary that a consolidation order would make matters extremely difficult for all concerned. In fact, in my view, the Prothonotary's reasons make it clear that consolidation of the two actions before her was, for all intents and purposes, not possible. In other words, I am satisfied that, should one of the parties have made a motion to consolidate the two actions in *Bayer No. 1*, or, for that matter, the four actions before the Judge in the decision under review, the motion would no doubt have been dismissed.

[106] The five actions that have been instituted by Bayer against five generics (including the generic in *Dr. Reddy's* referred to at paragraph 5 of the present reasons) are typical of what happens when generics seek to enter the market with drugs that are bio-equivalent to a patentee's. More particularly, by way of their respective

NOAs, generics will allege that their drugs do not infringe the patentee's patent and/or that the patent is invalid. As a result, the patentee will commence an action under subsection 6(1) of the Regulations challenging each NOA, as Bayer has done in the present matter. The present scenario is no different from what used to occur under the former Regulations, albeit under the former Regulations the patentee commenced its challenge of a generic's NOA by way of an application to prohibit the Minister from issuing a NOC.

[107] In my opinion, it is, in most instances, simply not possible to consolidate multiple proceedings commenced under subsection 6(1) into one action because, *inter alia*, different parties are involved in each action and they are usually represented by different lawyers. Further, the issue of infringement is not necessarily the same in each action. Consequently, consolidation as a means of joining the actions is not a realistic approach. However, joining the actions for trial on common issues is possible and will usually be the preferred (and most expeditious) way of joining the actions so as to achieve the goal of simplifying matters and reducing the costs for the Court and for the parties. This is why, in regard to the rule 105 issue, I have been unable to find a reviewable error on the part of the Judge.

[108] I note that rule 102, which allows two or more persons to join in one proceeding as plaintiffs, applicants or appellants where there is a common issue of law or fact or where the relief claimed arises from substantially the same facts, provides that this can only be done where the persons are represented by the same solicitor. I believe this supports my view that consolidation under rule 105, with regard to actions commenced under subsection 6(1) of the Regulations, would only be possible if all generics were represented by the same counsel. Rule 102 makes shared counsel a precondition to joinder of parties because otherwise there would be no defensible reason for parties to seek, or the Court to grant, the joinder—it would confer no benefit as it must give rise to more complications than it could possibly resolve. This is also what I mean when I say that consolidation of subsection 6(1) actions under the Regulations is not possible, for all intents and purposes, without common counsel, because the practical difficulties that it would occasion are utterly prohibitive of such an arrangement. It would simply never happen. In other words, where there are multiple proceedings pursuant to subsection 6(1) and the parties are represented by different lawyers, consolidation will never be the means taken by the Court to advance those proceedings.

[109] On the other hand, the Prothonotary was satisfied that the order that she was making was the most efficient way to manage the two actions. More particularly, she was so satisfied because the actions would remain separate and therefore no amendments to the existing pleadings would be required, discoveries and interlocutory motions would not need to be coordinated between counsel and confidentiality restrictions would not be jeopardized. She also stated that "[e]ach action may proceed at its own pace towards the common trial dates" (*Bayer No. 1*, at paragraph 20). Thus, in the Prothonotary's view, joining the cases for trial of common issues avoided all of the complications resulting from consolidation.

[110] As I have observed, it is clear from the Prothonotary's reasons in *Bayer No. 1* that, in her view, actions being joined is synonymous with actions being consolidated. Consequently, as section 6.02 only prohibits actions being joined, it did not prevent her from ordering that the two actions before her be heard together. I am of the opinion that

the Prothonotary was wrong in concluding as she did. In other words, it is my view that the Prothonotary's order in *Bayer No. 1*, like the impugned order, violates the section 6.02 prohibition. I am satisfied that the wording of the prohibition captures more than just the consolidation of proceedings as described by the Prothonotary in *Bayer No. 1*.

[111] Let me say that if, as the Prothonotary found, the word "joined" in section 6.02 of the Regulations is merely coextensive with the word "consolidated" in rule 105, and has no broader meaning, then, in my view, the section 6.02 prohibition is completely useless. I simply cannot see what actions brought under subsection 6(1) of the Regulations would ever be consolidated in the manner described by the Prothonotary. The two actions in *Bayer No. 1* and the four actions now before us in these appeals would never have been consolidated for the reasons given by the Prothonotary in *Bayer No. 1* and for the reasons which I have also expressed hereinabove. Accordingly, I cannot accept that the prohibition in section 6.02 only prevents the consolidation of actions, as this would mean the provision merely tilts at windmills.

[112] At this point, it will be useful to turn to the dictionaries for the definitions of the words "join" and "*réunir*"—the latter being the word used in the French text of section 6.02 for the word "join":

> **JOIN:** transitive verb
>
> **1a**: to put or bring together so as to form a unit // *join* two blocks of wood with glue
>
> **b**: to connect (separated items, such as points) by a line
>
> **2:** to put or bring into close association or relationship // two people *joined* in marriage

(SOURCE: Merriam-Webster, "*Merriam-Webster Dictionary*" (last visited April 20, 2020) online: (*Merriam-Webster.com*) < www.merriam-webster.com/dictionary>).

> ***RÉUNIR*:** (verbe transitif) (de unir):
>
> 1. *Rapprocher des choses séparées de façon à les mettre en contact, à les joindre: Réunir deux bouts de ficelle par un nœud*.
>
> 2. *Raccorder, faire communiquer des choses entre elles: Réunir plusieurs villes par une voie rapide*.
>
> 3. *Rattacher officiellement un pays, une région à un autre*.
>
> 4. *Rassembler, regrouper des éléments pour constituer un tout: Réunir les papiers nécessaires à une demande*.

(SOURCE: Société Éditions Larousse, "*Larousse Langue Française*" (last visited April 20, 2020) online: (*Larousse.fr*) < www.larousse.fr/dictionnaires/francais).

[113] The English text of section 6.02 prohibits actions from being "joined" while the French text prevents *la réunion d'actions* ("*[a]ucune action ne peut être réunie à une action donnée intentée en vertu du paragraphe 6(1)*"). As I have just explained, if the sole purpose of these words is to prevent the consolidation of proceedings in the manner described by the Prothonotary, then they serve no purpose. In my view, the above definitions of "join" and "*réunir*" support a broader prohibition.

[114] Neither of these words suggest that the meaning of joining actions is confined to turning two or more proceedings into one. Rather, they suggest that actions are joined whenever they are brought together, connected or brought into close association. Although I am prepared to concede that one could interpret these words to include the joining of more than two proceedings into one, their meanings are clearly not limited to that understanding and are sufficiently broad to include an order such as the impugned order. This suggests, in my view, that the impugned order has in fact joined the four actions, within the meaning of the section 6.02 prohibition, in regard to the common issues. The fact that they have not been joined in respect of all issues is irrelevant.

[115] I make one further comment on the text of section 6.02 before moving to consider the purpose of that provision. It may be observed that "*réunir*", which serves as the French version of the word "join" in section 6.02 of the Regulations, is the same word used for "[consolidate[d]]" in rule 105 of the Rules. This could be said to support the Prothonotary's position that the prohibition on actions being "joined" in section 6.02 exclusively prohibits the "consolidation" of actions commenced under subsection 6(1), and nothing more. The following three observations are sufficient, in my view, to dispose of any such argument, were it to be made.

[116] First, the use of "*réunir*" for "join" appears in the Regulations, whereas the use of "*réuni*" for "consolidate" appears in the Rules. I am far from certain as to whether using the French word "*réunir*" for the English words "join" and "consolidate" appearing in two different pieces of legislation signifies any intent on the part of the legislature to equate the definitions of the English words. Second, I note that "consolidate", in the Rules, is variously translated as "*réunir*" in rule 105 and "*joindre*" in subsection 342(1) [of the Rules]. Finally, although, for the sake of coherence, I have discussed "consolidation" in these reasons in the same sense in which that term is used by the Prothonotary, I wish to emphasize that it is not at all settled that "consolidation" bears the meaning attributed to it by the Prothonotary at paragraph 14 of her reasons in *Bayer No. 1*. This is apparent when one consults either the term's dictionary definition or its interpretation in the case law on rule 105.

[117] The *Merriam-Webster Dictionary* defines "consolidate" to mean the following:

> **CONSOLIDATE:** *transitive verb*:
>
> 1: to join together into one whole: UNITE // *consolidate* several small school districts
>
> 2: to make firm or secure: STRENGTHEN // *consolidate* their hold on first place // He *consolidated* his position as head of the political party
>
> 3: to form into a compact mass // The press *consolidates* the fibers into board.

[118] None of these definitions necessarily entail, with respect to the constituent components of a thing that has been consolidated, the loss of identity and wholesale assimilation that is part and parcel of the Prothonotary's interpretation of the term "consolidate". These definitions would also capture, in my view, less complete associations between the constituent components of a thing consolidated. The same can also be said of the words "*jonction*" and "*joints*" which appear in subsection 342(1) [of the Rules]. These words being the French equivalents of the words "consolidation" and "consolidated". The words "*jonction*" and "*joindre*" are defined as follows:

***JONCTION**: nom féminin:*

1. Action de joindre, d'unir deux choses séparées: Opérer la jonction par un pont.

2. Action de se joindre, de se réunir, en parlant de groupes, de troupes en mouvement: Les deux manifestations firent leur jonction sur la place.

…

***JOINDRE:** (verbe transitif):*

1. Assujettir deux choses l'une à l'autre par un moyen quelconque: Joindre deux bouts de ficelle par un nœud.

2. Rapprocher deux choses de telle sorte qu'elles se touchent: Joindre les talons.

3. Établir une liaison, une communication entre deux lieux: Joindre deux agglomérations par une nouvelle voie routière.

4. Ajouter quelque chose (à quelque chose d'autre), le mettre dedans, avec: Joindre un timbre (à sa lettre) pour la réponse.

5. Associer son action, son effort, etc., à ceux de quelqu'un d'autre: Joindre sa voix à celles de l'opposition.

…

8. Décider d'instruire ou de juger en même temps deux ou plusieurs causes pendantes devant un tribunal. [My emphasis.]

(SOURCE: Société Éditions Larousse, "*Larousse Langue Française*" (last visited April 20, 2020) online: (*Larousse.fr*) <https://www.larousse.fr/dictionnaires/francais>).

[119] I note that one of the definitions of "*joindre*" is "*[d]écider d'instruire ou de juger en même temps deux ou plusieurs causes pendantes devant un tribunal*" which I translate as meaning deciding to hear or determining at the same time two or more proceedings pending before the Court. This is precisely what has happened here by reason of the impugned order, i.e., four actions are in the process of being heard at the same time in respect of common issues.

[120] Neither does the case law unambiguously support the Prothonotary's interpretation of "consolidate". A motion for hearing two applications together was considered a motion for consolidation in *Janssen-Ortho Inc. v. Apotex*, 2009 FC 866, 180 A.C.W.S. (3d) 145 (see paragraph 4), as was a motion requesting that actions be heard together or sequentially in *John E. Canning* (see paragraphs 34 and 37). Each of the various types of relief provided for under rule 105 was referred to as a "form of consolidation" in *Halifax (Regional Municipality) v. Canada*, 2008 FC 1159, 172 A.C.W.S. (3d) 818 (see paragraphs 13–14). Still other cases order the consolidation of evidence (*Global Restaurant*) and refer to orders for joint or simultaneous hearings as orders for "partial" or "quasi" consolidation (*Apotex Inc. v. Shire LLC*, 2017 FC 139, 161 C.P.R. (4th) 332; *Sivamoorthy v. Canada (Minister of Citizenship and Immigration)*, 2003 FCT 307, 121 A.C.W.S. (3d) 1125).

[121] My point, in this brief overview of the jurisprudence, is that the definition of "consolidated" in the context of rule 105 is not as cut and dry as may be supposed from reading the Prothonotary's reasons. However, it is not necessary for deciding the issues now before this Court to seek to resolve this definitional ambiguity. The preceding discussion simply illustrates that, even if it should be pointed out that the French text for "consolidated" in rule 105 uses the same (French) word as is used for "joined" in section 6.02 of the Regulations, this does not support the proposition that the prohibition on actions being "joined" in section 6.02 of the Regulations is strictly limited to a prohibition on proceedings being "consolidated" in the narrow sense in which the Prothonotary has interpreted that word.

[122] Having analyzed the wording of section 6.02 of the Regulations, I now turn to consider more closely the purpose of the prohibition. The entire *raison d'être* of the section 6.02 prohibition is to promote the expediency of one action, and one action only, instituted pursuant to subsection 6(1), in the context of the 24-month time period within which that action is meant to be determined. My meaning in saying that the prohibition is concerned with the expediency of one action only becomes clear when the purpose of the prohibition is contrasted with the purpose of paragraph 105(a) [of the Rules]. The various forms of relief available under paragraph 105(a) seek to promote the most expedient and least expensive determination of multiple proceedings before the Court that share similar issues. In other words, in making an order under rule 105, a judge or a prothonotary seeks to achieve the most efficient and inexpensive way of dealing with two or more proceedings, both in the interest of the parties and of the Court. Not so with section 6.02 of the Regulations. Section 6.02 is exclusively concerned with the progress of a single action to ensure it is determined within the 24-month deadline that applies to it. The concerns that animate an order under paragraph 105(a)—efficiencies and cost savings across multiple parties in multiple proceedings, and as they apply to the court—have no bearing on section 6.02 of the Regulations, the singular focus of which remains exclusively on determining that single action before its peculiar deadline. Thus, to make an order under rule 105 for the arrangement of multiple proceedings that would result in time and cost savings for multiple parties and the court would still be contrary to the purpose of the section 6.02 prohibition if that arrangement made it at all less likely that any single action brought pursuant to subsection 6(1) would be determined within its 24-month deadline.

[123] The proposition that section 6.02 (and, indeed, the wider Regulations) is peculiarly concerned with the most expedient conclusion of each discreet action commenced under subsection 6(1) in its own right is reinforced, in my view, by the existence of section 6.09. This provision translates the abstract goal of expedient proceedings that finds expression in many statutes and rules into concrete legal obligations on parties to subsection 6(1) actions to act diligently and to cooperate with all other parties to the action. This is an exceptional provision that applies, as the appellant pointed out in its submission, only as between parties to the same action commenced under subsection 6(1).

[124] In the present case, the purpose of the section 6.02 prohibition must be considered from the perspective of the appellants, who served their NOAs at the earliest point in time. A rule 105 order ordering any sort of arrangement of the appellants' proceedings with the respondents' proceedings may well result in efficiencies and cost savings when one considers the multiplicity of proceedings that would otherwise take

place. This is not, however, the concern of section 6.02. The concern of that provision is whether the rule 105 order could possibly result in the appellants' actions exceeding their 24-month deadlines. A rule 105 order for common hearings in particular might not cause the appellants' actions to exceed their respective deadlines—but it might, and such an order certainly would not shorten the timeline for the determination of the appellants' actions. For this reason, not only does a prohibition on common hearings fit easily within the meaning of the words used in section 6.02, such a prohibition is entirely consistent with the purpose of the prohibition.

[125] Thus, notwithstanding my conclusion that the Judge did not err in regard to rule 105, in my view, the hearing together of the four trials on the common issues is counter to the prohibition found in section 6.02. More particularly, I have no doubt that ordering that four cases be tried together on the issue of invalidity is counter to the *raison d'être* of the prohibition in that, as the Judge himself recognized at paragraph 35 of his reasons, "[a]dding two defendants to the trial of the common issues will likely add some time to that trial." Needless to say, the effect of having the four actions heard together on the common issue will not only lengthen that trial but will inevitably delay the appellants' trials in regard to the infringement issue. More particularly, Teva's trial (Teva being the first generic to serve its NOA on Bayer) with regard to infringement will only proceed in October 2020, i.e. a number of weeks after the completion of the trial of the common issues. Thus, I am satisfied that the impugned order runs afoul of the prohibition in section 6.02.

[126] Even if I were wrong in my view that joining actions means something more than just consolidation, and joining is, in fact, strictly synonymous and coextensive with consolidation, I am nonetheless satisfied, as Apotex submits at paragraph 100 of its memorandum of fact and law, that the impugned order, in its effects, results in a consolidation of the actions within the meaning ascribed to that term by the Prothonotary. While it is true, in theory, as the Prothonotary says at paragraph 20 of her reasons in *Bayer No. 1*, that because the actions remain separate each party is entitled to its own discovery and interlocutory motions, the reality is otherwise. Indeed, it appears from counsel's representations at the hearing and from the memoranda before us that discoveries and pre-trial motions have proceeded, with respect to the common issues, as if the parties were part of the same action. In other words, the four generics have participated in joint discoveries and joint pre-trial motions which is what the Prothonotary in *Bayer No. 1* said would result if the actions were consolidated.

[127] While it appears that the discoveries were conducted by all parties upon consent, I suspect that the appellants were not truly given the option of conducting their own discoveries, i.e. without the presence of Taro and Sandoz. As the appellants point out in their submissions, the Judge expected that Taro and Sandoz would abide by the common schedule already set for the appellants' trial and also expected that the parties would coordinate and cooperate to meet the fixed deadlines (reasons, at paragraphs 35 and 36). I also find it telling that the Prothonotary herself, though professing the parties' freedom to arrange separate discoveries where a joint trial is ordered, nevertheless recognized at paragraph 22 of her reasons in *Bayer No. 1* that "[t]he 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."

[128] In my view, had the appellants conducted their discoveries separately from those conducted by Taro and Sandoz, this would have made it very difficult for Taro and Sandoz to meet the deadlines fixed for the appellants' trial. Thus, I doubt very much that the Federal Court would have appreciated being advised by the appellants that they refused to cooperate with Taro and Sandoz in regard to the examinations on discovery or in regard to any motion arising from the common issues. I therefore do not believe that the appellants were truly free to arrange their proceedings as they saw fit.

[129] Hence, it has come to pass that the four actions have had common discoveries and, as these appeals show, have and will continue to have joint motions with regard to the common issues. In other words, it appears to me that, by reason of the impugned order, the proceedings, in respect of the common issues, are advancing as if they were one. The order has given rise to the very complications that, in the Prothonotary's view, justify a prohibition against consolidation: the parties have had to "coordinate availabilities across [four] sets of counsel for all discoveries and interlocutory proceedings" resulting in a "cumbersome and inefficient" manner of proceeding (*Bayer No. 1*, at paragraph 18).

[130] I note that the Judge also recognized that adding the Taro and Sandoz actions to the common hearing would add complexity to the preparation and the conduct of the trial of the common issues (reasons, at paragraph 24) and that it would also likely increase the time required to conduct the trial (reasons, at paragraph 35).

[131] Consequently, I am satisfied that the impugned order has, in effect, consolidated the four actions with respect to the common issues.

[132] Before concluding on this issue, I wish to address the remarks made by the Prothonotary at paragraph 3 of her reasons in *Bayer No. 1* where she states that the Federal Court must hear and determine subsection 6(1) actions prior to the expiry of the 24-month period. In my view, the Regulations do not require the Federal Court to render judgment within 24 months. While it is true that the Regulations prohibit the Minister from issuing a NOC to a generic before the end of the 24-month period, they do not require the Federal Court to render judgment within that period. I am not saying that the Federal Court should not attempt to meet the 24-month deadline, but that is a vastly different proposition from the one that the Prothonotary, and the parties in their submissions, put forward. I also note that the Judge subscribed to the Prothonotary's view at paragraph 36 of his reasons where he indicated that "all of the parties and the Court are required to work within a very short 24-month time frame in order to get these matters ready for hearing, and then to complete the trial, and to write and issue the decision" adding that it was "an inherent part of the current arrangement set out in the *Regulations*."

[133] What the Regulations in fact provide is that the parties to a subsection 6(1) action must be diligent (section 6.09 thereof)—with the help of the Court through case management—in ensuring that the proceedings move as expeditiously as possible and must cooperate in attempting to have the action determined within the 24-month period. Consequently, it is my view that, in case-managing these cases, judges should bear in mind that they are not positively duty-bound to decide them within the 24-month period. I wish to be clear that I am not suggesting that the 24-month guideline be dealt with flippantly. However, it should be recognized that disposing of cases within 24 months remains a goal—not an obligation on the Court. It bears recalling that even if, in a given

case, judgment is rendered by the Federal Court in the 24-month period, appeals taken from such a judgment do not extend the stay period. As the Supreme Court of Canada said, albeit in regard to the Regulations as they read prior to the 2017 amendments, in *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533, at paragraph 23:

> …. Commencement of the application for prohibition automatically triggers a 24-month statutory freeze that stops the Minister from issuing a NOC unless within that period the prohibition application is finally disposed of by the court … In practice the prohibition proceedings can easily drag on beyond the initial 24-month period.

[134] Thus, the Regulations make it clear that the burden of moving an action commenced under subsection 6(1) as efficiently as possible is on the parties, albeit with the help of the Court. Accordingly, although the 24-month period is highly a relevant consideration in making orders under rule 105, it is not the only factor to be considered. Otherwise, the Court would have to neglect many of its other litigants in favor of the pharmaceutical industry. If it was Parliament's intention that the Federal Court decide these cases within the 24-month period, it should have said so.

VI. Conclusion

[135] For the above reasons, I would allow the appeals, set aside the decision of the Federal Court dated August 1, 2019 (2019 FC 1039) and grant the appellants their costs in regard to the appeals and the motions for leave to appeal.

PELLETIER J.A.: I agree.

DE MONTIGNY J.A.: I agree.