Federal Court  Cour fédérale

Date: 20160609

Docket: T-1478-15

Citation: 2016 FC 651

BETWEEN:

JANSSEN INC.

Applicant

and

CELLTRION HEALTHCARE CO., LTD. AND MINISTER OF HEALTH

Respondents

and

THE KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH

Respondent Patentee

REASONS FOR JUDGMENT

HUGHES J.

[1] This proceeding arises from the provisions of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (*PMNOC Regulations*) wherein the Applicant Janssen Inc. (Janssen) seeks an Order prohibiting the Minister of Health from issuing a Notice of

Compliance to the Respondent, Celltrion Healthcare Co., Ltd until the expiry of Canadian Letters Patent No. 2 261 630 (the 630 patent). These reasons are briefer than I would otherwise have given since they must be given before June 10, 2016.

[2] In particular the matters before me arise from a motion made by Celltrion under the provisions of subsection 6(5)(b) of the *PMNOC Regulations* before Prothonotary Aalto of this Court to have this Application dismissed on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of the 630 patent. On May 10, 2016 the prothonotary gave an Order with Reasons, which was amended May 26, 2016. The Order reads:

> *1. The motion is granted and this application is struck.*
>
> *2. This Order is stayed for 30 days from the date of the Order.*
>
> *3. Celltrion is entitled to their costs of this motion and proceeding. Unless the parties can agree, Celltrion shall file its submissions on costs limited to 3 double spaced pages plus draft bill of costs within 15 days following the expiry of the stay. Janssen shall deliver their submissions limited to 3 pages double spaced within 10 days thereafter. Celltrion shall have 10 days to file reply submissions limited to 1 double spaced page.*

[3] The matter has now come before me in the form of several motions which are:

1. A motion by Janssen appealing that part of the prothonotary's Order granting Celltrion's motion and striking the application.

2. A motion by Janssen requesting that I vary paragraph 2 of the prothonotary's Order to read: *"This Order shall not take effect until all appeals are exhausted and this Order becomes final."*

[4] There was a further motion brought by Celltrion to permit the introduction of a second affidavit of Bon Joong Kim into the record. It is unclear whether this affidavit is already in the record. The prothonotary did not deal with this matter. I spoke to Counsel for the parties stating that I did not believe that it was necessary for me to deal with this motion. They agreed.

[5] Further, at the end of all the submissions by all Counsel at the hearing before me one of the Counsel for Celltrion rose and requested that I make certain orders respecting a stay or delay of any Order I would make herein on certain terms, some of which were unclear. I said that I would not hear such a request as it should have been made in writing just like all the other motions, and should not have been raised following the conclusion of all submissions by Counsel.

I. Background

[6] In order to give some context to these proceedings, especially as to timing issues, some background is needed.

[7] The 630 patent issued on December 4, 2012 from an application filed in the Canadian Patent Office with an effective filing date of August 1, 1997. The term of the 630 patent will

expire twenty years from the effective filing date, that is, on August 1, 2017, some thirteen and a half months from now.

[8] Celltrion received from the Minister of Health on January 15, 2014, a Notice of Compliance to sell a drug in Canada which it calls INFLECTRA (active ingredient called infliximab) for treatment of certain specific aliments namely rheumatoid arthritis, ankylosing spondylitis, psoriac arthritis and plaque psoriasis (collectively referred to as the RD indications). Celltrion filed its application for this Notice of Compliance on November 14, 2012 which is *before* the 630 patent issued therefor Celltrion did not have to address that patent as Janssen could not have, at that time, listed the patent under the *PMNOC Regulation*.

[9] Janssen has since brought a regular patent infringement action against Celltrion alleging infringement of the 630 patent, Celltrion denies infringement and challenges the validity of the patent. This action is scheduled to be heard by this Court starting September 12 of this year, that is, in about three months.

[10] Celltrion, in its application for a Notice of Compliance filed on November 14, 2012, sought a Notice which included not only the RA indications, which were ultimately approved as aforesaid, also but for use in treating diseases related to various forms of inflammatory bowel disease such as Crohn's Disease, fistulising Crohn's Disease and Ulcerative Colitis (the IBD indications). The IBD indications were not approved in Celltrion's original application. Therefore Celltrion filed a supplementary application in mid-2015 with the Minister of Health seeking approval for use of INFLECTRA in treating the IBD indications (sometimes referred to

by Celltrion as the SNDS indications). By the time this 630 patent had been granted and listed by Janssen under the provisions of the *PMNOC Regulations*. Thereafter Celltrion was required to address the 630 patent under those *Regulations*. Respecting its IBD indications, Celltrion sent a Notice of Allegation to Janssen on or about July 20, 2015 which triggered the present proceedings brought about by a Notice of Application filed by Janssen on September 2, 2015.

[11] These proceedings are Case Managed by Prothonotary Aalto. He ordered production of certain materials to be made by Celltrion but otherwise no evidence intended to be used in the ultimate hearing of these proceedings has been filed by any party.

[12] On November 23, 2015, Celltrion brought a motion under subsection 6(5)(b) of the *PMNOC Regulations* requesting that Janssen's Application herein be dismissed. It filed in support of its motion affidavits from Bon Joong Kim, Dr. Stephen Sullivan, and Kelsie Edwards. Janssen opposed the motion and, in its Memorandum of Fact and Law requested that the motion be dismissed and such further and other Order that the Court deems just. It said:

> *110. Celltrion has not met it burden, which is to show that for every legal and factual issue in this motion, it is certain to succeed and Janssen has no chance of success. Janssen therefore respectfully requests: (a) an Order dismissing Celltrion's motion with costs payable forthwith on a Column V scale, with all disbursements; and (b) such further and other Order that this Honourable Court deems just.*

[13] Janssen cross-examined Celltrion's affiants Kim and Sullivan and filed the affidavits of Donald Elrich, Janet Pope and Jane P. Costas , each of whom was cross-examined.

[14] The Case Management Judge, Prothonotary Aalto, heard the motion on February 17, 2016 and on May 10, 2016 rendered his Order with Reasons, Amended on May 26, 2016 as aforesaid.

[15] Counsel are agreed that at no time, during the hearing before Prothonotary Aalto or otherwise did any party, nor did the prothonotary, raise the issue of a stay of any Order to be granted. The matter was never raised nor addressed.

[16] I will now turn to the motions before me.

II. Janssen's Motion on Appeal to Set Aside the Prothonotary's Order Dismissing the Application

[17] Prothonotary Aalto dismissed Janssen's Application for a prohibition Order under the *PMNOC Regulations* in its entirety. Janssen wants that Order to be set aside on this appeal.

[18] Subsection 6(5) of the *PMNOC Regulations* states that "the court" may dismiss an application. This means that either a Prothonotary or a Judge may hear and determine such a motion. In this case it was a Prothonotary. While there is well developed jurisprudence as to how a Judge hearing an appeal from an Order or Judgment of a Prothonotary is to approach such an appeal it is clear that, in cases such as this, where the Order brings about a final determination of the matter, particularly when, as in the case here, the matter has been determined largely on a question of law, that the Judge hearing the appeal should approach the matter *de novo*. Justice

Stratas of the Federal Court of Appeal addressed the matter in *Bayer Inc. v. Fresenius Kabi Canada Ltd.*, 2016 FCA 13 particularly at paragraphs 6 and 7:

> *[6] Housen would be the controlling authority but for the fact that this is an appeal from a Rule 51 appeal. In appeals from a Rule 51 appeal, the standard of review is different. We may interfere with the Federal Court's decision where the Federal Court had no grounds to interfere with the Prothonotary's decision or, in the event such grounds existed, if the decision of the Federal Court was arrived at on a wrong basis or was plainly wrong: Z.I. Pompey Industrie v. ECU-Line N.V., 2003 SCC 27, [2003] 1 S.C.R. 450 at paragraph 18, citing this Court's decision in Jian Sheng Co. v. Great Tempo S.A., [1998] 3 F.C. 418 (C.A.), per Décary J.A., at pp. 427-28. In this case, when the Federal Court sat in appeal under Rule 51 from the Prothonotary, it employed the standard of review in Aqua-Gem, not the normal appellate standard of review in Housen.*
>
> *[7] I have previously suggested that these different standards of review have outlived their usefulness and that the general standard of review for civil appeals set out in Housen, above, should apply: Apotex Inc. v. Bristol-Myers Squibb Company, 2011 FCA 34, 91 C.P.R. (4th) 307 at paragraphs 6-9. In addition to the reasons I offered in that case, I note that Housen postdates Aqua-Gem and, on its terms, was intended to state the standard of review for all civil appeals: see Imperial Manufacturing Group Inc. v. Decor Grates Incorporated, 2015 FCA 100 at paragraph 22. As for the Supreme Court's later articulation of the standard of review in Pompey, above, the more recent Supreme Court case of Hryniak v. Mauldin, 2014 SCC 7, [2014] 1 S.C.R. 87 may have overtaken it. There, the Supreme Court encouraged courts to take steps to make procedures simpler and more accessible. We have applied this philosophy elsewhere in our standard of review jurisprudence with a view to simplifying and unifying as much as possible the standard of review for civil appeals: Turmel v. Canada, 2016 FCA 9; Imperial Manufacturing, above.*

[19] Since the issues here essentially turn on questions of law, I will approach the matter *de novo*.

[20] Janssen's Counsel raised several matters in his memorandum and very ably argued the matter before me. Essentially Janssen's arguments are:

i. It has a fairly arguable case to make as to the constitution of the *PMNOC Regulations*, particularly subsection 5(2);

ii. The evidence, presented on this motion, shows that there is some possibility of infringement of the 630 patent.

iii. Celltrion has a heavy burden to meet on a motion to strike on Application under subsection 6(5)(b) of the *PMNOC Regulations* and has not met that burden.

iv. Given that it has a fairly arguable case to make, the threshold for dismissing an application is sufficiently high such that Janssen should be afforded an opportunity to make its arguments based on a full record on a full hearing of the matter.

[21] I will address those arguments:

(i) Construction of Subsection 5(2) of the *PMNOC Regulations*

[22] Subsection 5(2) of the *PMNOC Regulations* reads as follows:

> *If a second person files a supplement to a submission referred to in subsection (1) seeking a notice of compliance for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient and the supplement directly or indirectly compares the drug with, or makes reference to, another drug that has been marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall, in the supplement, with respect to each patent on the register in respect of the other drug,…*

[23] That subsection follows from subsection 4(1), 4(3) and 4(3)(c) of the *PMNOC Regulations* which provide that a party such as Janssen may add a patents to the list of patent respecting a drug for which there has been a change consisting of a new use:

> ***4 (1)*** *A first person who files or who has filed a new drug submission or a supplement to a new drug submission may submit to the Minister a patent list in relation to the submission or supplement for addition to the register.*
>
> **…**
>
> ***(3)*** *A patent on a patent list in relation to a supplement to a new drug submission is eligible to be added to the register if the supplement is for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, and*
>
> *…*
>
> ***(c)*** *in the case of a change in use of the medicinal ingredient, the patent contains a claim for the changed use of the medicinal ingredient that has been approved through the issuance of a notice of compliance in respect of the supplement*.

[24] Janssen's Counsel submits that a party such as Celltrion is obliged by subsection 5(2) of the *PMNOC Regulations* to address a patent which relates to a drug whether or not the patent claims a new or different use for the drug. In other words it is the drug, not the use, that triggers compliance, hence a two year holding period, with the *PMNOC Regulations*.

[25] Prothonotary Aalto dealt with this argument at paragraphs 20 to 26 of his Reasons. I agree with his reasoning and adopt it as my own

[26] The Supreme Court of Canada, Binnie J. for the Court has given careful consideration to an argument such as Janssen raises, in *Bristol-Myers Squibb Co. v. Canada (Attorney General)*,

[2005] 1 SCR 533. While the provisions of the *PMNOC Regulations* at the time and with which he was dealing were somewhat different the approach to the matter is completely analogous and pertinent to the interpretation argued by Janssen. Binnie J wrote at paragraphs 53, 61 and 66 to 68:

> *53 Secondly, it is not every use of the patented invention that will trigger the NOC Regulations. Section 55.2(4) is specifically directed to preventing infringement by persons who use "the patented invention" for the "early working" exception and the "stockpiling" exception set out earlier in ss. 55.2(1) and 55.2(2). That is all the Governor in Council is authorized to regulate. (The stockpiling exception was repealed by S.C. 2001, c. 10, s. 2(1); assented to June 14, 2001.)*
>
> *...*
>
> *61 The text of s. 5(1.1) closely tracks the language of s. 4(1). It is a reciprocal provision in the sense that s. 4(1) sets up the patent list that the person subject to s. 5(1.1) must circumnavigate. Section 5(1.1) should therefore receive a similarly purposive interpretation. The word "submission" should also be construed so as to fulfill the purposes laid out in s. 55.2(4) of the Patent Act.*
>
> *...*
>
> *66 The broad interpretation urged by BMS would lead to an absurd result. The "medicine" in the drug to which the patent list relates need not itself be patented, or indeed owe anything to the ingenuity of the "first" person. It could be a "medicine" whose usefulness was discovered by somebody else (as in the case of paclitaxel) or something in the public domain as common as penicillin. So long as such "medicine" shows up as a component, however minor, in the chemical composition of the drug to which the patent list relates, the "second person" (including an innovator who is seeking to manufacture a new and useful drug) is barred from proceeding to market by the automatic statutory freeze, and this "bar" will continue for so long as the patent list holder can evergreen its product by resort to patentable improvements to other components or additions, be they ever so minor. This would stifle competition and innovation in the pharmaceutical industry and produce a result at odds with what the regulator was trying to achieve.*

> *67 The "plain meaning" adopted by the Federal Court of Appeal in this case would suggest that s. 5(1.1) is ultra vires the regulation-making power which, as noted earlier, only authorizes regulations "necessary for preventing the infringement of a patent by any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) [the 'early working' exception] or (2) [the 'stockpiling' exception — now repealed]". While there are other similarities between the Biolyse product and the BMS product, the decision of the Federal Court under s. 5(1.1) rests entirely on the presence of paclitaxel in both the BMS and the Biolyse products.*
>
> *68 The interpretation put forward by BMS should be rejected, based not only on the limiting language of s. 55.2 of the Patent Act but on the more fundamental objection that on such a view a "first person" could extend its monopoly far beyond the scope of any possible quid pro quo its own skill and ingenuity have contributed to the public.*

[27] Thus, in a case such as the present one, where a patent claims a particular use of a drug it is that use that must be compared with the intended use by the generic and not just the drug.

[28] Here Janssen's Counsel concedes that every claim of the 630 patent claims the use of the drug for RA indications Celltrion already has a Notice of Compliance for RA indications and needs not to address those indications in its Supplementary application which is directed to IBD indications and not RA.

[29] Plainly and simply Janssen's application is, to use the words of subsection 6(5)(b) of the *PMNOC Regulations*, scandalous, frivolous, vexations and an abuse of process respecting the 630 patent.

(ii) Does the Evidence on the Motion Show Some Possibility of Infringement of the 630 Patent.

[30] Janssen refers to evidence provided in cross-examination of one of its affiants, Dr. Pope who treats patients with rheumatoid arthritis (RA) at questions 153 to 157:

> *153. Q. And of the 25 or so patients that you say you treat with Remicase how many of them have Crohn's disease?*
>
> *A. That I'm treating in RA…*
>
> *154. Q. Yes.*
>
> *A. …with Remicase? I know one patient has Crohn's and rheumatoid arthritis. And it's actually GI is treating her with Remicade. I had her before she got Crohn's on a different biological drug and she developed Crohn's. She was on Etanercept which does not working Crohn's, so she was switched over to Remicade by the GI doctor. So I wouldn't be a prescribing physician of biological drugs in Crohn's.*
>
> *155. Q. So one of the 25 patients?*
>
> *A. Well, that's one I can think of.*
>
> *156. Q. Okay. And how many of the Inflectra patients have Crohn's?*
>
> *A. Of my two or three?*
>
> *157. Q. Yes.*
>
> *A. Zero.*

[31] There is lacking any evidence to show that Celltrion, whether in its proposed product monograph, which is in the record, or otherwise induced any doctor or patient to use the product at issue to treat both RA and IBD indications in the same patient.

[32] The Federal Court of Appeal in *AB Hassle v. Canada (Minister of National Health and Welfare*, 2002 FCA 421 has addressed a situation such as that presented here. It held that a generic cannot be prevented from obtaining a Notice of Compliance solely on the basis that it will sell the drug where there was a likelihood that someone may use it for a patented use. Mere sale of the drug, without more does not trigger the *PMNOC Regulations*. Sexton JA, for the Court, wrote at paragraphs 56 and 57:

> *[56] The Appellants relied on the following passage from Genpharm at paragraphs 47 to 50 to argue that Genpharm should be applied to the present appeal:*
>
> *The point is that use claims referred to in subparagraph 5(1)(b)(iv) contemplate use, not just by the generic producer, but by patients as well, and that infringement will result by patients using a medicine sold by a generic producer, even if there is no inducement or procurement by the generic producer.*
>
> *The scheme of the Regulations seems obvious. If a generic producer sells a product and infringement by anyone using the product results, that is the infringement the Regulations are intended to preclude. There is no suggestion that the generic producer must have induced or procured patients or others to infringe the patent.*
>
> *For this reason, I am satisfied that in the case of use claims, it is not necessary for a patentee to demonstrate that a generic producer's actions will induce or procure patent infringement by patients or others. Provided that the generic producer cannot establish that no claim for the use of the medicine would be infringed by patients or others by its selling of its product, it will not satisfy the justification test in subsection 6(2) of the Regulations and a prohibition order must be made.*
>
> *In this case, if a patient used the Genpharm product for osteoporosis, the use claims of P & G's 376 Patent would be infringed. It would be Genpharm's selling of its product that would result in the infringement. Here, the evidence is overwhelming that it is not only probable, but inevitable, that Genpharm's Gen-etidronate product would, if notices of compliance issue, be used for the treatment of osteoporosis in the cyclical regimen that constitutes the invention under the 376 Patent. [my emphasis]*

> *It should be emphasized, however, that the Court made these statements after having concluded that the evidence in Genpharm overwhelmingly demonstrated that the actions and intentions of Genpharm would inevitably lead to an infringement. Because no such conclusion can be reached in the case before us, the Genpharm case can be distinguished on that basis. I do not view Genpharm as being authority for the proposition that mere sale by a generic, without more, of a medicine subject to a use patent is sufficient to constitute infringement for the purpose of subparagraph 5(1)(b)(iv).*
>
> *[57] Thus Apotex cannot be prevented from obtaining a NOC solely on the basis that it will sell omeprazole. If it were otherwise, then serious policy issues would arise. If there was any likelihood that a patient would consume a generic product for a patented use, then the generic product would not be approved. This would prevent new uses from being approved for existing drugs because there is always the possibility that someone somewhere will use the drug for the prohibited, patented purpose. This would result in a real injustice: since a generic company cannot possibly control how everyone in the world uses its product, the prevention of the generic from marketing the product would further fortify and artificially extend the monopoly held by the patent holders. The patent holder would, therefore, effectively control not just the new uses for the old compound, but the compound itself, even though the compound itself is not protected by the patent in the first place. The patent holders, as a result, would obtain a benefit they were not meant to have. In the end, society would be deprived of the benefit of new methods of using existing pharmaceutical medicines at a lower cost.*

[33] Justice Mactavish made similar finding in her decision in *Lundbeck Canada Inc. v. Ratiopharm Inc.*, 2009 FC 1102 at paragraphs 367-369:

> [367] Based upon all of the above considerations, the applicants argue that because of the nature of the Canadian market for memantine, infringement of the '492 patent will inevitably occur as physicians will prescribe, pharmacists will dispense, and patients will use ratiopharm's memantine product in combination therapy.
>
> [368] This may well be the case. Indeed, the circumstantial evidence suggests that ratiopharm's ratio-MEMANTINE product may indeed end up being used in combination with

> acetylcholinesterase inhibitors for the treatment of Alzheimer's disease, thereby infringing the '492 patent. ratiopharm may expect this to happen. However, it is ratiopharm's actions and not its expectations that are the issue before me.
>
> [369] The parties agree that the fact that there may be downstream infringement is not enough, on its own, to show infringement by inducement. Indeed, as Justice Gauthier observed in Aventis Pharma Inc. v. Pharmascience Inc. 2006 FC 861, 51 C.P.R. (4th) 161, even if it can be shown that infringement by others "is highly probable, if not inevitable", that will not be enough to establish that an allegation of non-infringement is not justified: see para. 31.

[34] I find that there is insufficient evidence to conclude that there is any basis for a finding of infringement by Celltrion of the 630 patent.

(iii) Celltrion's Burden

[35] Janssen argues that Celltrion has a very heavy burden to meet in securing a dismissal of an application under subsection 6(5)(b) of the *PMNOC Regulations*. I agree, but the burden is not an impossible one. I will address this matter further in issue (iv) which follows, however I am satisfied that Celltrion has met that burden.

(iv) If the Case is Fairly Arguable, Should the Matter go to a Further Hearing?

[36] There is no doubt that applications under the *PMNOC Regulations* were intended to proceed in a summary fashion and, were that the case, a Court should be inclined not to entertain motions to dismiss before a full hearing. Regrettably applications under these *Regulations* have become, quite literally, a nightmare for the parties and the Court. Masses of evidence by way of

affidavits, exhibits, transcripts of cross-examination and otherwise fill boxes submitted in the record. Finely tuned arguments pursuing the minutest and arcane points of law are put forward by extremely able and aggressive Counsel. The Court is required, within a few weeks or even days, to deliver Judgment together with or followed by thorough Reasons. Therefore, unlike many other types of summary applications, there is a good incentive to determine whether the case is appropriate for early disposition provided that early disposition is clearly established as appropriate. The Court should not incentivize such applications as routine.

[37] The Supreme Court of Canada in *Hryniak v. Mauldin*, [2014] 1 SCR 87 has asked for a culture change whereby the Court's resources should be applied in a proportionate way as to achieve a fair and just result, a trial or full hearing is not always required. Karakatsanis J. for the Court wrote at paragraphs 31 to 33 (albeit in regard to Ontario summary judgment rules but the principles are equally applicable here):

> *[31] Even where proportionality is not specifically codified, applying rules of court that involve discretion "includes . . . an underlying principle of proportionality which means taking account of the appropriateness of the procedure, its cost and impact on the litigation, and its timeliness, given the nature and complexity of the litigation": Szeto v. Dwyer, 2010 NLCA 36, 297 Nfld. & P.E.I.R. 311, at para. 53.*
>
> *[32] This culture shift requires judges to actively manage the legal process in line with the principle of proportionality. While summary judgment motions can save time and resources, like most pre-trial procedures, they can also slow down the proceedings if used inappropriately. While judges can and should play a role in controlling such risks, counsel must, in accordance with the traditions of their profession, act in a way that facilitates rather than frustrates access to justice. Lawyers should consider their client's limited means and the nature of their case and fashion proportionate means to achieve a fair and just result.*
>
> *[33] A complex claim may involve an extensive record and a significant commitment of time and expense. However,*

> *proportionality is inevitably comparative; even slow and expensive procedures can be proportionate when they are the fastest and most efficient alternative. The question is whether the added expense and delay of fact finding at trial is necessary to a fair process and just adjudication.*

[38] Thus in this case while Janssen's Counsel has made several arguments, I find as has Prothonotary Aalto, that these arguments are destined not to succeed. There is nothing further that could be presented to the Court at a full hearing that would alter the conclusions reached here. Dismissal of the Application is the appropriate remedy.

III. Prothonotary Aalto's Order Staying his Order for 30 Days.

[39] Prothonotary Aalto stayed his Order for 30 days. There was a concern as to whether the time should be calculated from the date of his original Order, May 10, 2016 or his Amended Order of May 26, 2016. In a Direction to the parties he said that May 10, 2016 was the operative date.

[40] Therefor the hearing of the matters before me was held on June 8, 2016 and I have delivered these Reasons and my Judgment on June 9, 2016.

[41] While the result may seem harsh the point has been made in other decisions that a party in Janssen's position suffers no irreparable harm (even if that were a criterion). Janssen, by instituting an Application to the Court under the *PMNOC Regulations* gains a 24 month delay in the issuance of a Notice of Compliance to a party such as Celltrion. Dismissal of the application brings that delay to an end but leaves a party such as Janssen with all the usual remedies such as

a patent infringement action. In fact Janssen has launched such an action and trial is scheduled to begin three months from now.

[42] Rothstein JA wrote in *Janssen-Ortho Inc. v. Canada (Minister of Health)*, 2004 FCA 168 at paragraph 6:

> *[6] In my opinion, this Court's decision in Bristol-Myers Squibb Canada Inc. v. Canada (Attorney General), [2001] F.C.J. No. 16 (C.A.), is dispositive of the matter. In that case, it was decided that when an action for patent infringement is available, the inability of a patent holder to access the automatic stay provisions in the Patent Medicines (Notice of Compliance) Regulations did not constitute irreparable harm. That is precisely the situation here.*

[43] As I have said, it is common ground that the issues of a stay was not raised by Prothonotary Aalto, nor any of the parties.

[44] Had the matter been raised, Prothonotary Aalto would have had to consider the decision of Sharlow JA in *Janssen-Ortho Inc. v. Apotex Inc.*, 2009 FCA 250 where she held that, in circumstances under the *PMNOC Regulations* the same as the circumstance here, where there has been an Order dismissing an application there is nothing to stay; the Order cannot be stayed. She wrote at paragraphs 18 to 22.

> *[18] Apotex points out, correctly, that the order of Prothonotary Aalto is an order dismissing a claim that he found to be unmeritorious. It does not require anybody to do anything. It merely puts an end to Janssen's attempt to stop the Minister from doing something that she is required to do because of her statutory mandate, namely, issuing a notice of compliance to Apotex upon being satisfied that the applicable requirements of the Food and Drug Regulations, C.R.C., c. 870, have been met. On that basis, Apotex argues that no stay is possible.*

[19] Counsel for Janssen conceded that he had been unable to find any case in which a court had granted a stay of an order that does not require anything to be done, but he argues that such a stay is possible as a matter of law. He points out that the expected exercise by the Minister of her statutory mandate to issue a notice of compliance to Apotex (assuming the applicable regulatory requirements are met) is an inevitable outcome of the order of Prothonotary Aalto. The fact is, however, that the Minister is compelled to act because of the Food and Drug Regulations, not because of Prothonotary Aalto's order.

[20] Janssen relies on the following excerpt from RJR – MacDonald Inc. v. Canada (A.G.), [1994] 1 S.C.R. 311 (per Justice Sopinka and Justice Cory, writing for the Court) at page 329:

> *We are of the view that the Court is empowered, pursuant to both s. 65.1 [of the Supreme Court Act] and r. 27 [of the Rules of the Supreme Court of Canada], not only to grant a stay of execution and of proceedings in the traditional sense, but also to make any order that preserves matters between the parties in a state that will prevent prejudice as far as possible pending resolution by the Court of the controversy, so as to enable the Court to render a meaningful and effective judgment. The Court must be able to intervene not only against the direct dictates of the judgment but also against its effects. This means that the Court must have jurisdiction to enjoin conduct on the part of a party in reliance on the judgment which, if carried out, would tend to negate or diminish the effect of the judgment of this Court.*

[21] The Court would have entered the motion for a stay even without its statutory authority. The following appears at page 332:

> *Finally, if jurisdiction under s. 65.1 of the Act and r. 27 were wanting, we would be prepared to find jurisdiction in s. 24(1) of the Charter. A Charter remedy should not be defeated due to a deficiency in the ancillary procedural powers of the Court to preserve the rights of the parties pending a final resolution of constitutional rights.*

[22] I am not persuaded that RJR – MacDonald establishes that the order of Prothonotary Aalto in this case may be stayed. What

> *was being sought in RJR – MacDonald was a stay of a judgment of the Quebec Court of Appeal declaring that certain provisions of the Tobacco Products Control Act, R.S.C. 1985, c. 14 (4th Supp.) were valid. After the judgment, regulations were enacted under Tobacco Products Control Act that, if enforced, would impose costly obligations on the parties asserting the constitutional challenge. It was in those circumstances that the Supreme Court of Canada determined that it had the jurisdiction to stay the judgment of the Quebec Court of Appeal, even though it was in form a declaratory judgment.*

[45] Similar remarks were made by Sharlow JA in *Bristol-Myers Squibb Canada Inc. v Canada (Attorney General)*, docket A-721-00, dated January 9, 2001 and Boivin J (as he then was) in *Apotex Inc. v Sonofi-Aventis*, docket T-644-09, December 16, 2011.

[46] Therefore I will allow the appeal in respect of this matter and set aside paragraph 2 of Prothonotary Aalto's Order granting a 30 day stay.

IV. Janssen's Motion to Extend the Stay Until All Appeals Have Been Disposed

[47] As I have previously discussed, a stay is simply not available in these circumstances. If it were I certainly would not grant a stay in these terms requested by Janssen as the effect, as a practical matter would be to keep this proceeding alive well past the statutory limit of two years (September 2, 2017) and even after the expiry of the term of the 630 patent (August 1, 2017). Pragmatically no appeal can be heard by the Federal Court of Appeal, together with a leave application to the Supreme Court of Canada, before those dates.

[48] Janssen cannot, in effect keeps its statutory injunction alive, without ever addressing the merits of the case, by obtaining the stay such as it wishes.

V. Conclusion and Costs

[49] In conclusion I affirm Prothonotary Aalto's Order dismissing the application and set aside that part of his Order granting a stay. I will not grant a stay on any terms.

[50] As to costs, both in respect of the motions before me and before Prothonotary Aalto invite submissions of no more than five (5) pages from Celltrion within ten (10) days from the date of this Order. Janssen should submission of no more than five (5) pages within ten (10) days from receipt of Celltrion's submission. Upon my receipt of both submission I will make a determination as to costs.

[51] I commend all Counsel for their preparation of the material and arguments made before me. I also commend Ryan Coe a judicial assistant in the Toronto Federal Court Office in his prompt and attentive preparation of these reasons.

"Roger T. Hughes"
Judge

Toronto, Ontario
June 9, 2016

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1478-15
STYLE OF CAUSE:	JANSSEN INC. v CELLTRION HEALTHCARE CO., LTD. AND MINISTER OF HEALTH AND THE KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	JUNE 8, 2016
REASONS FOR JUDGMENT:	HUGHES J.
DATED:	JUNE 9, 2016

APPEARANCES:

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Warren Sprigings Dale Schlosser Christopher Tan	FOR THE RESPONDENTS CELLTRION HEALTHCARE CO., LTD.
Andrew Skodyn James S.S. Holtom	FOR THE RESPONDENT PATENTEE THE KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH

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