

Federal Court



Cour fédérale

Date: 20160526

Docket: T-1478-15

Citation: 2016 FC 525

Toronto, Ontario, May 26, 2016

PRESENT: Case Management Judge Kevin R. Aalto

BETWEEN:

JANSSEN INC.

Applicant

and

**CELLTRION HEALTHCARE CO., LTD
AND MINISTER OF HEALTH**

Respondents

and

**THE KENNEDY TRUST FOR
RHEUMATOLOGY RESEARCH**

Respondent Patentee

AMENDED ORDER AND REASONS

[1] This is a motion brought by the Respondent, Celltrion Healthcare Co.Ltd. (Celltrion) to strike this application pursuant to section 6(5)(b) of the *Patented Medicines (Notice of*

Compliance) Regulations, SOR/93-133 as amended (the PMNOC Regulations). The Applicant, Janssen Inc. (Janssen) opposes the motion.

[2] The facts are somewhat unique. On January 15, 2014, Celltrion received a Notice of Compliance (NOC) for its drug called INFLECTRA (infliximab) for use in the treatment of rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis (collectively the RA Indications). Celltrion currently markets INFLECTRA in Canada with respect to those indications. At the time of filing its new drug submission on November 14, 2012 Celltrion did not have to address the patent in dispute (the 630 Patent).

[3] The 630 Patent is owned by the Respondent Patentee, The Kennedy Trust for Rheumatology Research.

[4] The 630 Patent was filed August 1, 1997 and will therefore expire on August 1, 2017. The 630 patent was granted on December 4, 2012 and is now listed on the Patent Register in connection with the drug REMICADE® (infliximab) sold by Janssen. It was listed on the register on December 6, 2012.

[5] In 2015, Celltrion then filed a Supplementary New Drug Submission (SNDS) seeking approval for additional uses for INFLECTRA in the treatment of diseases related to various forms of inflammatory bowel disease being Crohn's Disease; fistulising Crohn's Disease; and ulcerative colitis (collectively the IBD indications).

[6] On July 20, 2015 Celtrion served Janssen with a Notice of Allegation (NOA) pursuant to the *PMNOC Regulations* alleging that none of the intended uses (the IBD Indications) would infringe the 630 Patent. On September 2, 2015 Janssen commenced this application seeking a prohibition order.

[7] In its NOA, Celtrion sets out at length the reasons why it will not infringe the 630 Patent. Essentially, Celtrion alleges that none of the intended uses i.e. the IBD Indications are referred to in the claims of the 630 Patent and that the uses for which the 630 Patent is sold by Janssen are only the RA Indications. As noted, Celtrion has an NOC for the RA Indications. The RA Indications are not part of this application notwithstanding the arguments of Janssen.

I. The PMNOC Regulations

[8] The Court may strike an application in whole or in part pursuant to Section 6(5) of the *PMNOC Regulations* which reads as follows:

<p>6(5) Subject to subsection (5.1), in a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application in whole or in part</p> <p>(a) in respect of those patents that are not eligible for inclusion on the register; or</p> <p>(b) on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more</p>	<p>6(5) Sous réserve du paragraphe (5.1), lors de l'instance relative à la demande visée au paragraphe (1), le tribunal peut, sur requête de la seconde personne, rejeter tout ou partie de la demande si, selon le cas :</p> <p>a) les brevets en cause ne sont pas admissibles à l'inscription au registre;</p> <p>b) il conclut qu'elle est inutile, scandaleuse, frivole ou vexatoire ou constitue autrement, à l'égard d'un ou plusieurs brevets, un abus de</p>
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patents.

(5.1) In a proceeding in respect of an application under subsection (1), the court shall not dismiss an application in whole or in part solely on the basis that a patent on a patent list that was submitted before June 17, 2006 is not eligible for inclusion on the register.

procédure.

(5.1) Lors de l'instance relative à la demande visée au paragraphe (1), le tribunal ne peut rejeter tout ou partie de la demande pour la seule raison qu'un brevet inscrit sur une liste de brevets présentée avant le 17 juin 2006 n'est pas admissible à l'inscription au registre.

[9] The approach to be applied on a motion pursuant to section 6(5) of the *PMNOC Regulations* has been usefully summarized in a number of cases but most recently in *Bayer Inc. v. Pharmaceutical Partners of Canada Inc.*, 2015 FC 388. In that decision Prothonotary Roger R. Lafrenière made the following observations regarding the purpose and application of section 6(5) of the *PMNOC Regulations*, he stated as follows:

[16] The purpose of s. 6(5) is to enable the Court to expeditiously dispose of unmeritorious applications by first persons which have no chance of succeeding at hearing. The parties agree that dismissal of an application pursuant to subsection 6(5)(b) is an extraordinary remedy. Such relief will only be granted when the application is “clearly futile” or it is “plain and obvious” that the application has no chance of success: *Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 163 [Sanofi-Aventis] at para 28 and 36. The moving party bears the entire burden of proof in a s. 6(5)(b) motion: *Pfizer Canada Inc v Apotex Inc*, 2009 FC 671 at para 33.

[17] A second person may move under s. 6(5)(b) to dismiss a first person's application on the basis that the first person's affidavit evidence is insufficient to prove the second person's allegations of infringement are not justified: *Novopharm Limited v Sanofi-Aventis Canada Inc*, 2007 FCA 167 [Novopharm], at para 13. In order to make such a determination, the motions judge must be able to make the necessary findings of fact, viewed in the light most

favourable to the first person, and apply the law to the facts.

[18] A motion to dismiss will only be granted where it is apparent that there is no arguable case on the merits of the application. The court is not justified in embarking on anything resembling a trial of the action on conflicting affidavits in order to evaluate the strength of either party's case.

II. Positions of the Parties

A. Janssen

[10] For its part, Janssen relies upon a plethora of cases which are argued to stand for the proposition that where there are complex issues of statutory interpretation, where there are issues involving the construction of the claims of a patent and the like, it should all be allowed to proceed to a hearing to be dealt with on a full record. Among the many cases cited by Janssen, all of which have been considered, are the following: *Safilo Canada Limited v. Contour Optik Inc.*, 2004 FC 1534; *Procter & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)*, 2003 [1 F.C. 402] (CA).

[11] Janssen also argues that on a section 6(5) motion there is no burden on Janssen and that the entire burden rests with Celltrion to demonstrate that the application is plainly and obviously without the slightest chance of success. For that proposition Janssen cites among others *Pfizer Canada Inc. v. Apotex Inc.*, 2009 FC 671. That point was made by Janssen in part in response to the fact that little evidence was filed by Janssen in response to this motion. Janssen argues as they have no burden they are not required to file any evidence in support of their position and therefore rely upon Celltrion's motion record, cross-examinations, and the Notice of Application.

[12] Janssen casts this motion as being extremely complicated with several novel issues for determination. In particular, Janssen argues that there are at least 5 significant and different issues in play in this application, several of which involve questions of statutory interpretation and issues of law and fact which simply cannot be determined on an interlocutory motion such as this, without the benefit of a full record.

[13] Janssen argues that the evidence filed by Celltrion on this motion, being an affidavit of Bon Joong Kim, a Regulatory Affairs employee at Celltrion (Kim Affidavit) and Dr. Steven Sullivan (Sullivan Affidavit), a gastroenterologist, do not provide evidence that is of any assistance on this motion. Janssen argues that the evidence of these two individuals is of no assistance to the Court in construing the claims of the 630 Patent. The Kim Affidavit speaks to regulatory issues and the timing of new drug submissions and the NDS and the approvals for which Celltrion seeks for INFLECTRA. The Sullivan Affidavit addresses the differences between the RA Indications and the IBD Indications and notes that gastroenterologists diagnose and treat diseases referred to in the IBD Indications which are medically distinct from the RA Indications. Further, it is a rheumatologist who would prescribe INFLECTRA for diseases referred to in the RA Indications.

[14] Even though it argued it had no burden, Janssen did file two affidavits in response to the Celltrion evidence. Janssen filed an affidavit of Jane P. Castoris, the President of Regulatory Solutions Inc. (the Castoris Affidavit), a consultant in the pharmaceutical, natural health product and medical device industry and the affidavit of Dr. Janet E. Pope (Pope Affidavit), a rheumatologist.

[15] The Castoris Affidavit provided evidence regarding references in the Celltrion SNDS to studies involving the RA Indications in seeking approval for the new IBD Indications. Further, it contains opinions regarding the leveraging of RA information from the original NDS with respect to safety in the SNDS. Having reviewed both the Celltrion NDS and SNDS, the Castoris Affidavit concludes that the drug product used to treat RA patients, for which Celltrion has an NOC, is the same drug that is used to treat IBD patients.

[16] The Pope Affidavit discusses the prescribing practices with respect to INFLECTRA by Canadian rheumatologists and whether there is an overlap in prescribing practices for patients with both rheumatoid arthritis and gastrointestinal diseases. As a rheumatologist her evidence is to the effect that there is some overlap between treatment of the RA Indications and the IBD Indications in a few patients. Janssen also makes much of the fact that the product labelling for Celltrion's drug product will be the same, regardless of which indication the drug will be prescribed. The Pope Affidavit refers to a small number of patients who suffer from both RA and IBD diseases and might receive INFLECTRA for these diseases. However, it is clear from the Pope Affidavit that rheumatologists treat patients with RA with the use of infliximab for RA, while gastroenterologists treat patients with IBD diseases with the use of infliximab. They are prescribed by different specialists, for different uses, in different doses, and administered in the case of RA with methotrexate.

[17] Janssen argues that based on the evidence before the Court, Celltrion has not and cannot meet the high burden on a motion under s. 6(5)(b). Relief under s. 6(5)(b) should only be

granted in exceptional circumstances [see for example *Nycomed GmbH v Canada (Health)*, 2008 FC 330].

[18] Further, as it is necessary on this motion to interpret the *PMNOC Regulations*, summary motions are not the venue to determine complex issues of statutory interpretation. For that proposition they cite *Apotex Inc. v Merck & Co. Inc.*, 2004 FC 1452. However, that case is distinguishable as it deals with interpretations relating to section 8 and was an action not an application. They also cite jurisprudence that suggests that proper interpretation of sections of the *PMNOC Regulations* should only be made in circumstances where there is clear cut authority to support the interpretation or clear cut authority to strike. They argue that the facts of this case do not give rise to the remedy sought on the motion.

[19] The first statutory interpretation issue which Janssen raises relates to section 5(2) of the *PMNOC Regulations*. Section 5(2) provides as follows:

5(2) 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.

(emphasis added)

5(2) Dans le cas où la seconde personne dépose un supplément à la présentation visée au paragraphe (1), en vue d'obtenir un avis de conformité à l'égard d'une modification de la formulation, d'une modification de la forme posologique ou d'une modification de l'utilisation de l'ingrédient médicinal, lequel supplément, directement ou indirectement, compare celle-ci à une autre drogue commercialisée sur le marché canadien aux termes de l'avis de conformité délivré à la première personne et à l'égard duquel une liste de brevets a été présentée — ou y fait renvoi —, cette seconde personne doit, à l'égard de chaque brevet ajouté au registre pour cette autre drogue, inclure dans son supplément

[20] Janssen argues that the relevant comparison for section 5(2) of the *Regulations* is between the generic drug and the innovator drug. On the basis of their analysis of section 5(2) Janssen's position is that it is the **drugs** that must be compared, not the **uses** of the drugs. On this basis alone Janssen argues that Celltrion's approach to interpreting the section must fail [see *Apotex Inc. v Canada (Minister of Health)*, 2004 FC 650 and *AstraZeneca Canada Inc. v Canada (Minister of Health)*, [2006 2 FCR 560].

[21] However, these cases relied upon by Janssen are not directly on point. The *Apotex* case was a judicial review proceeding dealing with the eligibility for the listing of a patent. The Court

found that the issues raised in the judicial review properly belonged as part of prohibition proceedings and specifically refrained from deciding on the correct interpretations of the *PMNOC Regulations*. The Court did observe that in section 5 (1) of the *PMNOC Regulations* that it is drugs that are referred to and not uses of a product. However, the section relied upon by Celltrion, section 5 (3), specifically refers to “use of the drug”.

[22] The *AstraZeneca* case is not helpful to Janssen as it was a case dealing with the bioequivalence of drugs and not uses of drugs.

[23] Janssen raises two other statutory interpretation issues. One of those issues deals with the argument that Celltrion has not compared its drug to the drug named in the 630 Patent. Rather, Celltrion and its NOA has only addressed the IBD Indications and not dealt with the RA Indications. That issue flows into the third statutory interpretation issue which Janssen relates to the “register freeze” exception in the *PMNOC Regulations*. Celltrion did not have to address the 630 Patent with respect to its original ANDS because that was filed prior to the listing of the 630 Patent on the register. Now that the 630 Patent has been registered, the *PMNOC Regulations* require Celltrion to address the 630 Patent.

[24] Finally, Janssen argues that there is no evidence before the Court which would assist in the construction of the claims of the 630 Patent. The 630 Patent has 42 claims which deal with various pharmaceutical compositions and medicaments as being useful for various purposes. To that end, in order for this application to be bereft of any chance of success it is argued that the Court must find that the Celltrion drug will not infringe the 630 Patent claims. To that end,

Janssen has cited many authorities for the proposition that while construction of patent claims is a determination to be made by the Court it should be made on the basis of guidance by expert opinions [see for example *Unilever PLC v Procter and Gamble Inc.*, [1995 FCJ 1005; *Bayer Inc. v Cobalt Pharmaceuticals*, 2015 FCA 116]. In the *Bayer* case, Justice Davis Stratas did observe:

[17] Overall, a court nearly always reads a patent through goggles supplied by the experts whom the judge considers to be credible and accurate. Because of that, in practice, the standard of review of palpable and overriding error will often apply. This Court has acknowledged this practical reality for a while now:

While the construction of a patent is for the court, it is not initially to be undertaken simply in the manner a court would construe an ordinary contract or a statute, for example, but with the knowledge of the skilled artisan to the extent that such knowledge is revealed by expert evidence accepted at trial. In short, construction turns heavily on the evidence of a person skilled in the art.

(*Unilever PLC v. Procter & Gamble Inc.* (1995), 61 C.P.R. (3d) 499 at pages 506-07, 184 N.R. 378 (Fed. C.A.))

[25] Notably, Justice Stratas uses the phrase “nearly always”. There are circumstances where the Court does not need the goggles supplied by an expert. In my view, this is one of those circumstances where expert evidence is not required as is further discussed below.

[26] While Janssen raised other arguments, these are the main issues raised.

B. Celltrion

[27] For its part, Celltrion argues that this application can only relate to the allegations of non-infringement in the NOA and that those allegations deal only with the IBD Indications. Celltrion

argues that the *PMNOC Regulations* support this approach in that section 5(2)(b)(iv) provides as follows:

5(2)(b)(iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the supplement is filed. (emphasis added)

This means, as Celltrion argues, that the IBD indications cannot infringe the claims of the 630 Patent since all of the claims of the 630 Patent are directed to the treatment of the RA Indications. Further, Celltrion notes that Janssen in the Notice of Application does not assert that the IBD Indications infringe the claims of the 630 Patent.

[28] As noted above, there was a consensus within the evidence on the motion that the RA Indications and the IBD Indications are medically distinct. Patients who would ordinarily receive Celltrion's drug and are suffering from RA would be referred to a rheumatologist for treatment while those suffering from any of the IBD diseases would be referred to a gastroenterologist. Janssen endeavoured to demonstrate that there could be an overlap of patients receiving the Celltrion drug for both RA and IBD issues. However, those patients are *de minimis* as on the cross-examinations only one scenario was identified and it was acknowledged that there were not many patients who suffer from both.

[29] Celltrion further argues that the *PMNOC Regulations* are designed to prevent infringement and find support for that interpretation in *Bristol-Myers Squibb Co. v Canada (Attorney-General)*, 2005 SCC 26 wherein the Court stated:

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.)

[30] For purposes of the disposition this is a sufficient summary of Celltrion’s arguments.

III. Analysis and Conclusion

[31] This motion consumed that better part of two days and was akin to arguing a full PMNOC Application on its merits. Because it is a PMNOC Application with the attendant two year time limitation, it is necessary to issue these reasons for decision without fully canvassing the extensive arguments of both parties in this decision. In my view the reasons herein adequately deal with the positions of the parties.

[32] Thus, for these brief reasons the motion is granted but on specific terms as noted below.

[33] In my view many of the arguments of Janssen, while at first blush seemingly substantial, on balance do not stand up to scrutiny.

[34] It is to be remembered that the underlying premise of the *PMNOC Regulations* is to prevent infringement. What is unique about this case is that Celltrion currently has an NOC for the RA Indications. It remains in effect and no Court has been asked to set it aside.

[35] The Claims of the 630 Patent on their face without any need for expert evidence, speak specifically and directly to and only to the RA Indications. For example, Claim 17 contains the following “. . . for use in performing adjunctive therapy with a medicament comprising methotrexate **on an individual suffering from rheumatoid arthritis . . .**” [emphasis added]. This language referring to the RA Indications is found throughout the 630 Patent. There is no reference in the Claims to anything other than the RA Indications.

[36] However, in a preamble to the Claims, the 630 Patent does speak to Crohn’s Disease in addition to the RA Indications as follows:

Therefore, in one embodiment, the invention relates to a method of treating and/or preventing rheumatoid arthritis in an individual comprising co-administering an anti-TNF antibody or a fragment thereof and methotrexate to the individual in therapeutically effective amounts. In a second embodiment, the invention relates to a method of treating and/or preventing Crohn’s disease in an individual comprising co-administering an anti-TNF antibody or a fragment thereof and methotrexate to the individual in therapeutically effective amounts. In a third embodiment, the invention relates to a method of treating and/or preventing other autoimmune diseases and/or acute or chronic immune disease associated with a transplantation in an individual, comprising co-administering an anti-TNF antibody or a fragment thereof and methotrexate to the individual in therapeutically effective amounts.

[37] Notwithstanding this reference the claims are the fence-posts surrounding any possible viable or valid claim for infringement of a patent. The claims of the 630 Patent only speak to and address rheumatoid arthritis. Thus, it is not necessary to have expert evidence to construe the claims of the 630 Patent. It is sufficient to read the claims of the 630 Patent which, given a plain and ordinary construction on their face, relate only to the RA Indications not any indications beyond the RA Indications. They do not in any way discuss nor allude to the IBD

Indications. Thus, notwithstanding counsel's efforts to convince the Court otherwise, Celltrion, if it were to obtain an NOC for its SNDS, could not infringe the claims of the 630 Patent.

[38] This alone should be sufficient to dispose of the motion. However, Janssen raises issues concerning the application and interpretation of the *PMNOC Regulations*. In particular, whether the *PMNOC Regulations* dictate that a generic manufacturer must relate the drug and not the intended uses of the drug. As noted above, Janssen relies upon *Apotex* for this proposition. However, on a careful reading of the case it did not deal with this issue and the comment regarding relating drugs to drugs is a comment made in passing by the trial judge and is *obiter*.

[39] There is no doubt the *PMNOC Regulations* refer in section 5 (2) make reference to "drug" and not uses of the drug, save and except that the word "drug" in section 5(2)(b)(iv) specifically refers to "for which the supplement is filed" and further in section 5 (3)(b)(i) to "use of the drug in respect of which the submission or supplement has been filed". In my view, given that the *PMNOC Regulations* have as their underlying objective the prevention of infringement, it only makes contextual sense that if a submission refers to uses of a drug that do not infringe and on the plain and ordinary meaning of the claims of the patent those uses do not infringe it should be the end of the matter. Section 5(3) makes specific reference to the use of the drug.

[40] While Janssen argues that interpretations of the *PMNOC Regulations* should not be made on motions but on a full record before the hearing judge, there was no indication of what or, if any, additional evidence might be made available before the hearing judge. In my view, there is no need for expert evidence to provide the Court with a view of the claims through a person

skilled in the art. The *PMNOC Regulations* will not change and the facts relating to the claims in issue will not change. That is, the NDS relates to IBD Indications and the claims of 630 Patent only cover the RA Indications.

[41] Notwithstanding the very forceful arguments of counsel for Janssen, I am not persuaded that the issue relating to the interpretation of the *PMNOC Regulations* should go to a hearing. In these circumstances, giving a purposive interpretation to the *PMNOC Regulations*, the uses to which the drug will be put and the determination of any possibility of claim infringement is the aim of the section noted above. This outcome, in my view, fits the admonition of the Supreme Court of Canada in the recent case of *Hryniak v Mauldin* [2014] 1 R.C.S. 87 wherein Justice Karakatsanis stated at paras 1 2:

Ensuring access to justice is the greatest challenge to the rule of law in Canada today. Trials have become increasingly expensive and protracted. Most Canadians cannot afford to sue when they are wronged or defend themselves when they are sued, and cannot afford to go to trial. Without an effective and accessible means of enforcing rights, the rule of law is threatened. Without public adjudication of civil cases, the development of the common law is stunted.

Increasingly, there is recognition that a culture shift is required in order to create an environment promoting timely and affordable access to the civil justice system. This shift entails simplifying pre-trial procedures and moving the emphasis away from the conventional trial in favour of proportional procedures tailored to the needs of the particular case. The balance between procedure and access struck by our justice system must come to reflect modern reality and recognize that new models of adjudication can be fair and just.

[42] Janssen argues that the proposed monograph for Celltrion's drug product also refers to the RA Indications and therefore it will infringe Claims 1-42 of the 630 Patent. The problem

with this argument is that Celltrion already has an NOC for the use of its drug for the RA Indications. The RA Indications do not come into play in this proceeding. Janssen has an infringement action ongoing against Celltrion for the RA Indications. That is a separate action but does not impact this proceeding.

[43] Notably, Janssen in this application does not allege that the IBD Indications infringe the claims of the 630 Patent. That is because based on a plain reading of the claims the IBD Indications are not referred to and in any event would not infringe. There is simply no evidence of infringement before the Court on this motion. The highest at which Janssen can put an argument of infringement is in para. 105 of its written representations wherein it is argued that:

However, Celltrion's argument [that there is no infringement] is also at odds with the claims of the 630 Patent that relate to pharmaceutical compositions and manufactures of medicaments. For these claims, even assuming Celltrion's construction, Celltrion would be infringing because it would be making INFLECTRA for use in RA, which was then sold and used for RA. That is direct infringement.

[44] However, given that Celltrion already has an NOC for the RA Indications, that argument does not stand up to scrutiny. While there are other arguments raised, in my view, those arguments would not affect the end result and these reasons are sufficient to dispose of the matter.

[45] In all of the circumstances, I am not persuaded that this matter should proceed to a hearing. In coming to this conclusion I have considered and reviewed the relevant jurisprudence relating to the section 6 (5) motions and to the many cases dealing with striking proceedings

including *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 959 and *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.*, [1995] 1 FC 588 (C.A.). However, given the ramifications of this decision, I will stay the effect of this order for 30 days to allow Janssen to take whatever steps they deem appropriate.

ORDER

THIS COURT ORDERS that:

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.

"Kevin R. Aalto"

Case Management Judge

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

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DATED: MAY 10, 2016

APPEARANCES:

Andrew Skodyn
Melanie Baird

FOR THE APPLICANT
JANSSEN INC.

Warren Sprigings
Christopher Tan

FOR THE RESPONDENT
CELLTRION HEALTHCARE CO., LTD.

SOLICITORS OF RECORD:

Lenczner Slaght Royce Smith
Griffin LLP
Barristers

FOR THE APPLICANT
JANSSEN INC.

Sprigings Intellectual Property Law
Barristers & Solicitors

FOR THE RESPONDENT
CELLTRION HEALTHCARE CO., LTD.

Department of Justice
William F. Pentney Q.C.

FOR THE RESPONDENT
THE MINISTER OF HEALTH

Lenczner Slaght Royce Smith
Griffin LLP
Barristers

FOR THE RESPONDENT PATENTEE