

Federal Court



Cour fédérale

Date: 20140910

Docket: T-1310-09

Citation: 2014 FC 863

Ottawa, Ontario, September 10, 2014

PRESENT: The Honourable Mr. Justice Brown

BETWEEN:

**ABBVIE CORPORATION, ABBVIE
DEUTSCHLAND GMBH & CO., KG AND
ABBVIE BIOTECHNOLOGY LTD**

Plaintiffs

And

JANSSEN INC.

Defendant

ORDER AND REASONS

[1] This is a motion by AbbVie Corporation, AbbVie Deutschland GMBH & CO, KG and AbbVie Biotechnology Ltd [the Plaintiffs] for a show cause order under Rule 467 of the *Federal Courts Rules*, SOR/98-106 [the Rules] requiring Janssen Inc. [the Defendant] to appear before a Judge [the contempt trial judge] at a time and place to be fixed, to hear proof of certain acts of contempt allegedly committed by the Defendant, and be prepared to present any defence it may have in respect of such alleged contempt.

[2] More particularly, the Plaintiffs' motion requests:

1. an Order under Rule 467 requiring that Janssen Inc. appear before a Judge of the Federal Court in Toronto, at a time and place to be stipulated in the Order, to hear proof of the alleged acts of contempt described in Schedule "A" [of the Plaintiffs' Notice of Motion] and be prepared to present any defence that it may have in respect of such acts,
2. an Order that at the hearing referred to above AbbVie will seek, *inter alia*, the relief described in Schedule "B" [of the Notice of Motion]...

[3] Schedule "A" of the Notice of Motion recites the following alleged acts of contempt:

Schedule "A" – Alleged Acts of Contempt

1. On or about May 22, 2014, Justice Hughes gave a Judgment in this action and the judgment contained an Injunction against Janssen Inc. (the "**Injunction**"). On or about May 22, 2014, Justice Hughes issued his Reasons for Judgment.
2. The Injunction prohibited Janssen Inc. from communicating with certain physicians for the purpose of influencing the decision to initiate or continue certain treatment involving Stelara for treating psoriasis.
3. The Injunction prohibited Janssen Inc. from directly or indirectly detailing, promoting, or making any representations or claims respecting the use of Stelara for the treatment of psoriasis.
4. The Injunction contains a provision creating an exception to the Injunction in paragraph 1 of the Judgment where a physician has determined that providing Stelara for the treatment of psoriasis is "necessary". (the "necessity exception").
5. The Reasons made clear that the Court was relying on the "integrity of our medical profession" to abide by the necessity exception. Prior to the Injunction, there was no restriction by the Federal Court upon the prescribing of Stelara in Canada and no expectation by the Federal Court that physicians consider necessity before writing a prescription for Stelara. After the Injunction, this prior situation was changed and the Court began to rely on the integrity of doctors to implement the necessity exception.

6. Janssen Inc., by its senior officers and/or directors, was fully aware of the Injunction and the Reasons for Judgment.
7. Within days after the Injunction was pronounced, Janssen Inc. disobeyed the Injunction by implementing a campaign of directly communicating to hundreds of physicians to influence their decisions about whether to initiate or continue using Stelara for treating psoriasis.
8. Within days after the Injunction was pronounced Janssen Inc. also disobeyed the Injunction by implementing a campaign in which its detailers were instructed to detail, promote, and make representations and claims about Stelara for use in the treatment of psoriasis.
9. Within days after the Injunction was pronounced, Janssen Inc. acted in such a way as to interfere with the administration of justice and impair the authority and dignity of the Court by establishing the campaign that included actively telling physicians any one, or more, or all of the following:
 - (a) that “the injunction does not affect your ability to prescribe Stelara to your patients”; and
 - (b) that physicians were not required to make any change in their prescribing practices after the injunction; and
 - (c) that they could continue to prescribe Stelara as they did before the Injunction; and,
 - (d) that they should continue to prescribe Stelara as they did before the Injunction; and,
 - (e) that in respect of physicians prescribing Stelara it was “business as usual” despite the pronouncement of the Injunction, and
 - (f) That the product itself has not changed and there are no changes from a safety and efficacy standpoint.
10. The said campaign was deployed using the Stelara detailing force and required each detailer to visit and execute the campaign to the very same physicians that each detailer had been detailing for Stelara immediately before the Injunction.
11. Janssen Detailers were instructed to execute the campaign and deliver the above statements regardless of whether the

physician asked any questions about the Injunction, raised the issue of Stelara use at all, or even knew about the Injunction.

[4] The relief that the Plaintiffs may seek from the contempt trial court, if this matter proceeds to trial, are set out in Schedule B to their Notice of Motion:

Schedule “B” - Relief That AbbVie May Seek

1. An Order that Janssen Inc. has committed a civil contempt of the Judgment of Justice Hughes of the Federal Court of Canada dated May 22, 2014.
2. An Order forbidding any Janssen Inc. sales representative from any contact with dermatologists in Canada for the duration of the life of Canadian Letters Patent Number 2,365,281.
3. In the alternative to paragraph 2, an Order requiring Janssen Inc. to obtain monthly at its expense a report from IMS (or another third party supplier approved by the Court) which sets out the results of a survey of no less than 50 dermatologists from across Canada, which is designed to summarize the substance of all Janssen Inc. detailing efforts for Stelara which have been directed at such dermatologists in the previous month.
4. An Order that Janssen Inc. may purge its contempt by sending a letter to all Canadian dermatologists in the following words:

Dear Dr. ●,

On or after May 26, 2014, you may have been visited by your Janssen sales representative who may have delivered a message to you about the effect of an injunction issued by the Federal Court of Canada against Janssen in relation to Stelara.

That message may have included a suggestion that the Court injunction does not impact your ability to prescribe Stelara to your patients or that prescribing Stelara is “business as usual”.

Janssen is writing to you to correct that message.

The Federal Court of Canada has found that Stelara infringes a valid Canadian patent and, unlike before,

Stelara can be prescribed to new patients only in cases of necessity.

5. An Order that Janssen Inc. shall amend its BioAdvance form to provide a space for dermatologists to certify the existence of a medical need to prescribe Stelara that cannot be met by Humira.

[5] On this motion by the Plaintiffs, I am required to perform a gate-keeping function to determine what, if any, of the alleged acts of contempt the Defendant must defend itself against before a contempt trial judge. In this respect, Rule 467 establishes a two step process. The second step after the gate-keeping function, but only if ordered by this Court as gate-keeper, is an actual contempt trial before a contempt trial judge to take place at a later date.

[6] In order for a contempt trial to be granted, the Court must determine that, in the words of Rule 467(3) "... there is a *prima facie* case that contempt has been committed". Rule 467 states:

467. (1) Subject to rule 468, before a person may be found in contempt of Court, the person alleged to be in contempt shall be served with an order, made on the motion of a person who has an interest in the proceeding or at the Court's own initiative, requiring the person alleged to be in contempt

(a) to appear before a judge at a time and place stipulated in the order;

(b) to be prepared to hear proof of the act with which the person is charged, which shall be described in the order with sufficient particularity to enable the person to know the nature of the case against the

467. (1) Sous réserve de la règle 468, avant qu'une personne puisse être reconnue coupable d'outrage au tribunal, une ordonnance, rendue sur requête d'une personne ayant un intérêt dans l'instance ou sur l'initiative de la Cour, doit lui être signifiée. Cette ordonnance lui enjoint :

a) de comparaître devant un juge aux date, heure et lieu précisés;

b) d'être prête à entendre la preuve de l'acte qui lui est reproché, dont une description suffisamment détaillée est donnée pour lui permettre de connaître la nature des accusations portées contre elle;

person; and

(c) to be prepared to present any defence that the person may have.

(2) A motion for an order under subsection (1) may be made *ex parte*.

(3) An order may be made under subsection (1) if the Court is satisfied that there is a *prima facie* case that contempt has been committed.

(4) An order under subsection (1) shall be personally served, together with any supporting documents, unless otherwise ordered by the Court.

c) d'être prête à présenter une défense.

(2) Une requête peut être présentée *ex parte* pour obtenir l'ordonnance visée au paragraphe (1).

(3) La Cour peut rendre l'ordonnance visée au paragraphe (1) si elle est d'avis qu'il existe une preuve *prima facie* de l'outrage reproché.

(4) Sauf ordonnance contraire de la Cour, l'ordonnance visée au paragraphe (1) et les documents à l'appui sont signifiés à personne.

[7] It is important to note that the gate-keeping judge is not required to find actual contempt or deal with the merits of the contempt proceeding which is the job of the contempt trial judge. The gate-keeper judge is only to decide if there is: "a *prima facie* case that contempt has been committed".

[8] In my respectful opinion, a *prima facie* contempt has been committed, for the reasons that follow. Therefore, the Defendant must be tried by the contempt trial judge for those acts in respect of which a *prima facie* contempt has been committed as set out in Schedule "A" to these Order and Reasons. The relief the Plaintiffs may seek at the trial is set out in Schedule "B" to these Order and Reasons.

I. Background

[9] The Plaintiffs hold a patent for a medicine under Canadian Letters Patent Number 2,365,281 [the '281 patent]. The '281 patent is a biologic for the treatment of psoriasis in humans and was issued on or about September 9, 1999. The Plaintiffs also sell a medicine for the treatment of psoriasis called HUMIRA, which does not fall within any of the claims in issue in the '281 patent.

[10] It should be noted that this case differs from other patent infringement actions. As the Court stated in its reasons for the permanent Injunction, the public version being *AbbVie Corporation v Janssen Inc*, 2014 FC 489 [Injunction Reasons]:

[15] What makes this case different from the usual patent case is that the Plaintiffs do sell a product in Canada which is competitive with the Defendant's STELARA product, it is called HUMIRA, but it does not fall within the scope of the '281 patent claims at issue. Other than the Defendant, nobody sells a product in Canada that comes within the scope of the claims at issue. Further, there appears to be a medical need that at least a portion of psoriasis sufferers in Canada require the Defendant's STELARA product for the effective treatment of their condition.

[16] Thus, the Court is required to balance on the one hand, the rights of a patentee to the exclusive use of their claimed invention, including the right to control, by licence, others who wish to use the claimed invention, with the commercial desire of the Defendant to sell the infringing drug and, with a medical need by some members of the Canadian public to have continued access to the infringing drug.

[11] To revert to the history of matters, after the Plaintiffs obtained their '281 patent, the Defendant developed an IL-12 antibody it calls STELARA, which is also used for the treatment of psoriasis in humans. The Defendant launched STELARA in 2009.

[12] Although they differ in some respects, the two drugs (HUMIRA and STELARA) are equally effective in the treatment of psoriasis, and between them have the majority market share in Canada.

[13] As of January 2014, the Defendant's STELARA also received Health Canada approval for the treatment of psoriatic arthritis. Psoriatic arthritis is usually dealt with by doctors specializing in rheumatology, while psoriasis is dealt with by dermatologists. It is possible that STELARA would be used to treat psoriatic arthritis, but STELARA is not on any provincial formulary for that purpose. See Injunction Reasons at paragraphs 26-28.

[14] After the launch of STELARA in Canada, litigation ensued in which the Plaintiffs alleged patent infringement by and other claims against the Defendant.

[15] This litigation was partially concluded at the trial level of this Court when, on January 17, 2014, it concluded that claims 143 and 222 of the '281 Patent are valid, and further, that these Plaintiffs' patent claims were infringed by the Defendant through the promoting, offering for sale, and selling in Canada of the drug STELARA for the treatment of psoriasis. See *AbbVie Corporation v Janssen Inc*, 2014 FC 55 [Infringement and Validity Reasons].

[16] The Infringement and Validity Reasons required a further decision in respect of the injunctive and other relief sought because the litigation was bifurcated into infringement/validity and remedy components.

[17] Thereafter, on May 22, 2014, the Court issued its Injunction Reasons, *supra*, and the permanent injunction itself [the Injunction], compliance with which is now at issue.

[18] The Injunction as set out in its entirety states:

UPON THIS COURT HAVING MADE a finding of validity and infringement of Claims 148 and 222 of Canadian Letters Patent 2,365,281 on January 17, 2014; and

UPON THIS COURT HAVING ORDERED that the Plaintiffs' claims for injunctive relief be tried commencing May 12, 2014 at Toronto;

UPON reading the evidence submitted and hearing the witnesses brought before me on May 12, 13 and 14, 2014;

AND UPON hearing the submissions of Counsel for the Plaintiffs and the Defendant;

AND for the Reasons Provided:

THE COURT ADJUDGES AND ORDERS THAT:

[1] The Defendant Janssen Inc., its officers, directors, servants, agents, employees, all those with whom it acts in concert, and all those over whom it exercises control (hereinafter Janssen) is hereby enjoined until the expiry of Canadian Letters Patent No. 2,365,281 from making, using, selling, offering for sale, or promoting the use of a product, in Canada, for the treatment of psoriasis; which product falls within the scope of either or both of claims 143 and 222 of said patent; and, in particular, the product which it calls STELARA.

[2] The injunction set out in paragraph 1, above, shall not prohibit Janssen from:

- A. doing any act solely intended to provide STELARA to a patient who, on the date hereof, has already received at least one injection of STELARA as a treatment for psoriasis and remains on such treatment by the prescription of that person's own physician; and
- B. doing any act solely intended to provide STELARA for the treatment of psoriasis to a person who has

not previously received STELARA for that purpose, provided that such person's own physician has determined that such treatment is necessary for that purpose.

Provided that Janssen shall not communicate directly or indirectly with any such physician for the purpose of influencing the decision to initiate or continue such treatment.

[3] For greater certainty and without restricting the generality of the injunction provided herein:

- A. Janssen shall not, directly or indirectly, detail, advertise, promote or make any representations or claims, in Canada, respecting the use of STELARA for the treatment of psoriasis;
- B. Janssen shall terminate all advertising in all media published, broadcast, or received in Canada respecting the use of STELARA for psoriasis; and
- C. Janssen shall not commence any Phase IV clinical trial in Canada respecting the use of STELARA for psoriasis unless required to do so by law.

[4] For greater certainty, and without restricting the generality of the injunction provided herein:

- A. Janssen is not precluded from communicating, by email, facsimile transmission, or postal service, information required by law to be disseminated by it;
- B. Janssen may continue to operate its BioAdvance programme for existing and new patients described in paragraph 2, above;
- C. Janssen may continue to operate its GRASP programme for psoriatic arthritis;
- D. Janssen's Medical Information Group may respond to enquiries about STELARA;
- E. Janssen is not precluded from compliance with requests made by Health Canada; and

F. Janssen product representatives, also known as detailers, are not precluded from detailing the use of STELARA for use in treatment of psoriatic arthritis to rheumatologists.

[5] The Plaintiffs are entitled to recover their costs from the Defendant on the basis as set out in the Reasons.

[19] It is important to note that the Injunction contains exceptions from the broad application outlined in paragraph 1, which exceptions are set out in paragraph 2. Subparagraph 2A “solely” allows the Plaintiffs to provide STELARA to existing patients by the prescription of that person’s own physician. Subparagraph 2B “solely” allows the Plaintiffs to provide STELARA to new patients provided that such person’s own physician has determined that such treatment is necessary for that purpose. The exceptions in paragraph 2 are subject to the narrowing proviso with which paragraph 2 concludes. As noted above, these exceptions were added because STELARA would be more effective for some patients. These exceptions were included out of a general concern that patients not be deprived of the Defendant’s ‘281 patent infringing treatment for psoriasis. As the Court stated in its Injunction Reasons:

[51] Here, however, there are some patients in Canada for whom there is no alternative to STELARA in the effective treatment of their psoriasis. Another consideration is that of the treating physician, Dr. Shear, in his opinion letter (Tab C, Exhibit D-22) said “*we need options*”. He argued that a physician should have a reasonable opportunity to switch from one product to another, so as to determine which product may best serve the particular needs of a particular patient.

[20] Therefore this Court rejected an outright injunction. Instead, the Court held in essence that the decision to prescribe STELARA for psoriasis to existing and new patients should be

made by each patient's physician uninfluenced by marketing actions, claims, representations and the like, by the Defendant. This Court stated in its Injunction Reasons:

[66] I propose to have faith in the integrity of our medical profession in Canada. New patients may be prescribed STELARA, provided that such patient's own physician has determined that prescribing STELARA is necessary for treatment of the patient's psoriasis. I will not require that the physician sign a form or check off a box. I appreciate that this provision does not have the rigour of the method urged by the Plaintiffs; however, I view that rigour to be overly restrictive and too skeptical of the integrity of our doctors. I have included a provision prohibiting Janssen from trying to influence the decisions of such doctors. [Emphasis added]

[21] The Court addressed in its Injunction Reasons an issue central to the current motion, namely what the Defendant's pharmaceutical sales staff (called detail persons, or detailers) are prohibited from doing:

XI. Marketing and Promoting STELARA

[67] Central to the issue of the marketing and promotion of STELARA for the treatment of psoriasis in Canada is the role of persons called product representatives or "detail" persons. The evidence of Drs. Lynde and Shear illustrated the role of such persons, as did the evidence of Mr. Manning and Mr. Nitert.

[68] Drs. Lynde and Shear explained that they gained most of their information about a drug such as STELARA from a product monograph, scientific literature, meetings, conferences, and discussions with peers. Janssen has a Medical Information Specialist on staff who can answer technical inquiries from doctors about such a drug. The Plaintiffs do not seek to restrain the dissemination of, or access to, technical information or this sort.

[69] A "detail" person, of whom Janssen employs a number, is essentially a sales representative. "Detail" persons visit doctors several times a year, as explained by Mr. Nitert in cross-examination, Volume 3, pages 465 to 473. Their function is to execute the marketing strategy of Janssen. They are paid a salary and, if they meet certain sales quota – for instance, for STELARA – they are paid a bonus. They are not allowed to give information beyond that contained in a product monograph. They may "leave

behind” literature that promotes the product, but does not go beyond the monograph. As Dr. Shear said in cross-examination, at Volume 2, page 273, someone who is working for the marketing department must be considered as part of the marketing strategy.

[70] In cross-examination, Volume 3, pages 470 to 472, Mr. Nitert explained that not every dermatologist is as diligent as Drs. Lynde and Shear, and may require the assistance of a detail person to “*shape their own decisions*”.

[71] The injunction provided herein is intended to permit the dissemination of scientific and medical information, while restraining marketing activity by detail persons. [Emphasis added]

[22] The Defendant achieved its successful market penetration by STELARA because it is safe and effective and because it was marketed as such. The Defendant’s marketing of STELARA as both safe and effective was made through the Defendant’s detailers. There is no doubt this marketing contributed to the commercial success of STELARA.

[23] The Defendant markets other medical products by way of personal visits by their detailers to physicians, including another medicine for psoriasis called REMICADE. And while it is not listed on any provincial formulary, the Defendant’s STELARA has been approved for psoriatic arthritis in addition to psoriasis.

[24] Therefore, marketing meetings between detailers and physicians could legitimately concern the Defendant’s medicines other than STELARA. Specifically, marketing meetings between the Defendant’s detailers and dermatologists concerning REMICADE for psoriasis are not affected by the Injunction.

[25] The Defendants appear to have ceased many commercial activities associated with its drug STELARA, following the issuance of the Injunction.

[26] That said, the problematic area for the Defendant's detailers is what references, if any, the Defendant's detailers could make to dermatologists about STELARA in light of the Injunction.

[27] Within two or three days following the issuance of the Injunction, the Defendant summoned an urgent two-day meeting of all its sales and marketing staff involved in promoting and marketing STELARA to dermatologists. The Defendant described this meeting and resulting operation as an "immediate" and "proactive" measure. At this meeting, the Defendant delivered to its salespeople (detailers) a "script", i.e. a scripted statement to be used by the Defendant's detailers. The Defendant instructed its detailers to use this script [Script 1] in their discussions with dermatologists.

[28] The Defendant describes the role of Script 1 and the job of its detailers in its Written Representations of the Responding Party:

46. Following the injunction compliance meeting, the sales representatives were permitted to return to the field, *but only with respect to Remicade and not Stelara*.

47. It was recognized that dermatologists would undoubtedly make inquiries of Janssen's representatives who had previously been responsible for detailing Stelara if these representatives no longer mentioned that product without further explanation. It was also recognized that some explanation would be needed to ensure that doctors would know that their questions about Stelara could still be answered by Janssen Medical Information, as the injunction provides. To explain the change, the representatives (now only Remicade representatives) provided information about the

injunction to the dermatologists on their first post-injunction visit. This was in order “to be able to deal with this change”.

[29] Script 1 is central to this motion (along with its implementation) and states in full:

PRIVILEGED & CONFIDENTIAL

STELARA[®] Injunction Script

Subject to ongoing legal and regulatory review

Not for external distribution

Date last updated: Monday, May 26, 2014

Status: FINAL

This script is for notifying dermatologists about the injunction and/or for use in response to questions about STELARA[®]. Questions that cannot be answered using the information in this statement should be forwarded to Medical Information, who will direct the call to the appropriate person.

A recent legal case regarding patent infringement between AbbVie and Janssen has led to a court order limiting my ability to speak with you about STELARA[®]. Due to my legal obligation related to this situation, I am limited in what I can discuss. Please rest assured that if you do have questions I am not able to answer, I will put you in contact with someone who will be able to provide more information.

It is important to note that this court order does not impact your ability to prescribe STELARA[®] to your patients. The product itself has not changed and there are no changes from a safety and efficacy standpoint. The court order does not impact the BioAdvance[®] program.

If you have further questions about this, please contact Janssen Medical Information at 1-800-567-3331. Based on the nature of your questions, they will be able to direct your question to the appropriate person.

[30] The Defendant's witness Jason Nitert was cross-examined on a motion to stay the Injunction. He described what the Defendant intended and instructed detailers to do upon the conclusion of the two-day meeting as follows:

Q. Okay. What was the very specific instruction about the proactive injunction statement?

A. That they were to deliver it immediately, going into their next visit with the dermatologist.

Q. And what was the statement?

A. I don't have it verbatim, but basically the essence of the statement was that a decision was made and there is a legal injunction in place that basically precludes the representative from facilitating any exchange of information on Stelara. There was another aspect of that statement that spoke to...that there was no change to the availability of the product, and there was no change to the safety or efficacy of the product.

Q. Was there not also a statement that the injunction doesn't require doctors to change their prescribing practices?

A. That is correct.

Q. And to your knowledge, Janssen's sales reps were instructed to go out and tell doctors that there [*sic*] would be required to be no change to their prescribing practices?

A. Yes, there was no change to their ability to prescribe Stelara.

Q. No change to their ability and no need to change their practices?

A. Correct.

Q. Business as usual, correct?

A. In terms of that, yes.

[31] The Injunction does not prevent physicians from prescribing STELARA to either their new or existing patients, instead the Defendant's actions are greatly restrained the Injunction. In

note that the Defendant was not restrained, in the case of existing patients treated with STELARA, from “doing any act solely intended to provide STELARA to a patient who, on the date hereof, has already received at least one injection of STELARA as a treatment for psoriasis and remains on such treatment by the prescription of that person’s own physician”.

[32] However, with respect to new patients, subparagraph 2B of the Injunction appears to have had a very different effect. The Defendant was exempted from the general prohibitions of paragraph 1 (against “making, using, selling, offering for sale, or promoting the use of” STELARA for psoriasis) but only in respect of: “B. doing any act solely intended to provide STELARA for the treatment of psoriasis to a person who has not previously received STELARA for that purpose, provided that such person’s own physician has determined that such treatment is necessary for that purpose”. Paragraph 2 contained a further and concluding proviso: “Provided that Janssen shall not communicate directly or indirectly with any such physician for the purpose of influencing the decision to initiate or continue such treatment.”

[33] Following a complaint by the Plaintiffs, the Defendants proposed that Script 1 be amended approximately one month later, by which time it is probable that the Defendant’s detailers had met with all of their client dermatologists. The amended script [Script 2] reads as follows:

PRIVILEGED & CONFIDENTIAL

STELARA® Injunction Script

Subject to ongoing legal and regulatory review

Not for external distribution

Date last updated: Wednesday, July 2, 2014

Status: FINAL

This script is for notifying dermatologists about the injunction and/or for use in response to questions about STELARA[®]. Questions that cannot be answered using the information in this statement should be forwarded to Medical Information, who will direct the call to the appropriate person.

A recent legal case regarding patent infringement between AbbVie and Janssen has led to a court order limiting my ability to speak with you about STELARA[®]. Due to my legal obligation related to this situation, I am limited in what I can discuss. Please rest assured that if you do have questions I am not able to answer, I will put you in contact with someone who will be able to provide more information.

It is important to note that this court order permits your existing Stelara patients (those that have already received at least one injection of Stelara) to continue to receive Stelara. Patients who have not previously received Stelara for the treatment of psoriasis may receive Stelara if you determine that Stelara is necessary for the treatment of their psoriasis.

The product itself has not changed and there are no changes from a safety and efficacy standpoint. The court order does not impact the BioAdvance[®] program.

If you have further questions about this, please contact Janssen Medical Information at 1-800-567-3331. Based on the nature of your questions, they will be able to direct your question to the appropriate person.

[34] Script 1, and amended Script 2, together with Defendant's actions in relation to meetings between the Defendant's detailers and dermatologists form the basis for the Plaintiffs' contempt allegations.

II. Positions of the parties

A. *The Plaintiffs' position*

[35] The Plaintiffs say that the Court issued the permanent Injunction against the Defendant in respect of its drug STELARA for use in the treatment of psoriasis and that:

- a) Paragraph 1 enjoins the Defendant company, its officers, directors, servants, agents, employees, all those with whom it acts in concert, and all those over whom it exercises control, from making, using, selling, offering for sale, or promoting STELARA for use in treating psoriasis until the expiry of the '281 patent.
- b) Paragraph 2 creates two exceptions to the broad injunction set out in paragraph 1:
 1. STELARA can continue to be prescribed to a patient by their own physician where the patient was already receiving STELARA for the treatment of psoriasis at the date of the Injunction; and
 2. STELARA can be initiated in a new patient for the treatment of psoriasis provided that the patient's own physician has determined that such treatment is necessary for that purpose.
- c) Paragraph 2 also prohibits the Defendant from any direct and indirect communication with any physician prescribing STELARA for use in psoriasis for the purpose of "influencing" the physician's decision to initiate or continue such treatment. It does this in the proviso with which paragraph 2 concludes.

- d) Paragraph 3 prohibits the Defendant from directly or indirectly detailing, advertising, promoting, or making representations or claims in Canada about the use of STELARA for psoriasis.

[36] The Defendant's proactive communications campaign mandated its pharmaceutical sales representatives (detailers) to immediately communicate with dermatologists across Canada. The Defendant's detailers were instructed to, and did deliver, a proactive message to Canadian dermatologists that with regard to their prescribing of STELARA, it was "business as usual".

[37] By delivering its proactive message, the Plaintiffs state that the Defendant acted contrary to Paragraphs 2 and 3 of the Injunction. Moreover, it is significant to note that the Defendant did not deliver its proactive message by way of a letter, email, or through its Medical Science Liaison department. Instead, the Defendant mobilized the very sales force that had been detailing STELARA for the last 5 years and whose role it was to shape the decision of the physicians. They were instructed to go to the very dermatologists with whom they had forged relationships over many years. And they did so in the face of the Injunction prohibiting all detailing.

[38] Moreover, key employees of the Defendant were aware of and had actual copies of the Injunction yet they instructed their detailers to immediately deliver a proactive message contrary to the express terms of the Injunction. The communications campaign was not limited to circumstances where physicians asked questions or sought information about the Injunction.

[39] The Plaintiffs state that the communications campaign outlined above attracts liability in contempt because:

- (a) It was a communication with physicians designed to influence the physicians' decisions to initiate or continue Stelara. It was a disobedience of the Injunction contrary to Rule 466(b).
- (b) It was detailing, promoting and making representations or claims in Canada respecting the use of Stelara for the treatment of psoriasis. It was a disobedience of the Injunction contrary to Rule 466(b).
- (c) It encouraged physicians to treat the Injunction as if it had no effect on their prescribing practices and to continue prescribing Stelara just as they had been prior to the Injunction, without regard to the "necessity" proviso imposed by the Court. It was an interference with the orderly administration of justice, impaired the authority and dignity of the Court, and was a contempt of Court subject to sanction under Rule 466(c).

[40] The Plaintiffs state that the Defendant implemented the immediate proactive communications campaign with full knowledge of the Injunction and the Reasons for the Injunction, in a considered, deliberate and wilful manner, and with full knowledge and approval from the highest ranking Canadian employees of the Defendant.

[41] In light of the foregoing, the Plaintiffs seek an Order under Rule 467(1) requiring that the Defendant appear before a Judge, at a time and place to be fixed in the order, to hear proof of certain acts of contempt and be prepared to present any defence it may have in respect of such acts.

B. *Position of the Defendant*

[42] The Defendant states that it has complied with both the letter and the spirit of the Injunction, and that the Plaintiffs have failed to make out a *prima facie* case of contempt. The Defendant claims that it is undisputed that the use of STELARA for treating psoriatic arthritis or any condition other than psoriasis does not infringe the patent claims that are the subject of this case. Indeed, the Injunction expressly permits the Defendant to promote STELARA for treating psoriatic arthritis to rheumatologists. The Injunction also has no effect on promotion of drugs to dermatologists other than STELARA, including the Defendant's REMICADE product, for the treatment of psoriasis or any other condition. As the Defendant admitted in its Motion for a Limited Post-Trial Injunction, it was never intended to interfere with physician prescribing practices:

In this motion, AbbVie does not ask the Court to interfere in physician prescribing practices nor to do anything that might be alleged to affect patient choice or well-being. AbbVie is not seeking an Order to remove Stelara from the market at this time.

[43] The Defendant goes on to say that the terms of the Injunction explicitly authorize the Defendant to continue certain activities, including the communication of information required by law to be disseminated by it, responding to enquiries about STELARA through the Defendant's Medical Information Group, and complying with requests made by Health Canada.

[44] Moreover, as soon as the Injunction issued, the Defendant states that it took immediate, deliberate and effective steps to comply with both its letter and spirit. Janssen immediately ordered all nine of its dermatology sales representatives to cease all contacts with dermatologists, flew them to Toronto, and instructed them as to how to comply with the Injunction. Following

two days of training, the sales representatives were allowed to return to the field for the purpose of contacting dermatologists with respect to the use of REMICADE, but were instructed to refer all questions about the use of STELARA (even non-infringing uses) to the Defendant's Medical Information Group.

[45] The Defendant states that Script 1 was prepared to inform physicians of the existence of the Injunction and to advise them that their inquiries about STELARA should be addressed to the Defendant's Medical Information Group. Sales representatives were instructed to follow Script 1, and not to say anything else about STELARA. The Defendant states that the Plaintiffs' contempt motion focuses almost entirely on the first two sentences of the second paragraph of Script 1, however, it is important to examine the full context. The entire text of Script 1 is set out at paragraph 29 above.

[46] The Defendant states that the contents of Script 1 are true and are not prohibited explicitly or implicitly by the Injunction. By using Script 1, the Defendant states that it ensured that its sales representatives would not "detail, advertise, promote or make any representations or claims, in Canada, respecting the use of STELARA for the treatment of psoriasis," or otherwise "communicate ... with any such physician for the purpose of influencing the [physician's] decision to initiate or continue such treatment" (see Injunction, paragraphs 2 and 3A) while at the same time ensuring compliance with the provisions of the Injunction that specify that the Injunction does not "prohibit Janssen from ... doing any act solely intended to provide STELARA to a patient who ... has already received ... STELARA as a treatment for psoriasis" or who has not previously received STELARA for psoriasis but whose physicians have

“determined that such treatment is necessary for that purpose.” (See Injunction, paragraph 2A and B.)

[47] The Defendant argues that the sentences in Script 1 that the Plaintiffs put in issue, far from being the basis of a contempt motion it says, are entirely faithful to the letter and spirit of the Injunction. The Injunction expressly recognizes the public interest in maintaining the availability of STELARA for Canadian patients who need it, including both current and future psoriasis patients. Script 1 does no more than fairly inform dermatologists of STELARA’s continued availability for such patients and the fact that STELARA’s safety and efficacy has not changed – information vital to prescribing physicians – while respecting the injunction’s prohibition against detailing and promoting it for use in treating psoriasis patients. This balance was contemplated by the Injunction, which explicitly authorizes physicians to prescribe STELARA, a one-of-a-kind drug, to all patients for whom it was necessary to treat their relentless illness.

[48] Indeed, the Defendant states that the Court recognized the public interest in not impacting a physician’s ability to prescribe STELARA to patients when it rejected the Plaintiffs’ attempts to limit the physicians’ ability to prescribe STELARA only to those patients who had failed on HUMIRA.

[49] In conclusion, the Defendant argues that the Plaintiffs fail to demonstrate the *prima facie* case that it must prove, and are attempting to use this contempt proceeding for its own

commercial purposes to expand the injunction far beyond the scope of the Court's order. The Defendant requests that the Plaintiffs' motion be dismissed.

III. Legal framework

[50] I accept the Defendant's submission that the test for a show cause order or *prima facie* finding of contempt as requested in the current motion is (i) "whether there is a *prima facie* case that the actions of the alleged contemnor have been committed and that they constitute contempt deserving of sanction of this Court" and (ii) whether "it is clear from the record that the alleged violation is such that it does not deserve to be punished". As the Federal Court of Appeal held, "[t]o so satisfy the Court, the alleging party must show a *prima facie* case of wilful and contumacious conduct on the part of the contemnor" (*Chaudhry v Her Majesty the Queen*, 2008 FCA 173 [*Chaudhry*] at para 6).

[51] A good summary of the law in this connection is found in *Direct Source Special Products Inc v Sony Music Canada Inc*, 2005 FC 1362 [*Direct Source*] at para 4, with which I agree and to which both parties refer:

A motion for a show cause order has been brought in this case by the Defendant against the Plaintiff and against Plaintiff's counsel. On such motion, in order to grant the show cause order sought, the Court must determine only the threshold issue of whether the evidence establishes a *prima facie* case that the actions of the alleged contemnor have been committed and that they constitute contempt deserving of sanction of this Court. A motion for a show cause order is not the time or place to argue the merits of the contempt proceeding or what may be valid defences. The exception is in those cases where it is clear from the record that the alleged violation is such that it does not deserve to be punished.

[52] In addition, I agree with the Plaintiffs that there are different modalities by which contempt may be committed. Indeed this is expressly recognized by the Rules as may be seen in the differing provisions of Rule 466. Rule 466(b) describes contempt to disobey an order of the Court, while Rule 466(c) addresses contempt by interfering with the orderly administration of justice, or to impairing the authority or dignity of the Court. Each is engaged in this motion. However these two modalities differ somewhat.

[53] Under Rule 466(b), a party will be in contempt if it “disobeys a process or order of the Court”, such as the terms of an injunction. The test for establishing contempt under Rule 466(b) is set out in *Canada (Human Rights Commission) v Warman*, 2011 FCA 297 at paras 35-36 and 53, and is as follows:

- a) The order must state clearly and unequivocally what should and should not be done; and
- b) Knowing of the order, the alleged contemnor deliberately and wilfully disobeyed the court order.

[54] The test for contempt under Rule 466(c) is set out in *Merck & Co v Apotex Inc*, 2003 FCA 234 paras 50, 73 [*Merck*], and is as follows:

- A. The order and the reasons for judgment are clear and unambiguous; and,

- B. Knowing of the order and the reasons, the alleged contemnor deliberately and wilfully interfered with the administration of justice, or impaired the authority or dignity of the court (for Rule 466(c)).

[55] I agree with the Plaintiff's submissions that pursuant to *Merck*, at para 54, quoting *Baxter Travenol Laboratories of Canada Ltd v Cutter (Canada) Ltd*, [1983] 2 SCR 388, a party may also commit an act that is "technically not a breach of an injunction" but that still constitutes contempt "because it would tend to obstruct the course of justice" and to "completely [...] defeat [the] injunction". The same authority supports the proposition that "[c]ontempt in relation to injunctions has always been broader than actual breaches of injunctions".

[56] I also note that frustrating the purpose of an injunction may be contempt pursuant to Rule 466(c) as set out in *Microsoft Corp v 9038-3746 Quebec Inc*, 2007 CF 1235 at paras 21-27. Therefore, even if this Court were to hold that there are technical arguments as to why there was no *prima facie* breach of the Injunction, it may find *prima facie* contempt based on the acts to frustrate or defeat the effects of the Injunction.

IV. Findings

[57] With these points in mind, I propose to review each of the "Alleged Acts of Contempt" set out in Schedule "A" of the Plaintiffs' Notice of Motion, to consider and determine if the Plaintiffs have established a *prima facie* case that contempt has been committed by the Defendant.

[58] A preliminary issue is that Schedule “A” of the Plaintiffs’ Notice of Motion contains a summary of parts of the Plaintiffs’ argument followed by what more properly may be described as allegations of contempt. Paragraphs 1 to 6 of Schedule “A” of the Plaintiffs’ Notice of Motion are not capable of being, in and of themselves, acts of contempt. Therefore I will review the remaining allegations set out in paragraphs 7 to 11 of the said Schedule “A”.

[59] In summary, for the reasons that follow, I am satisfied that *prima facie* cases have been made that contempt has been committed as outlined in paragraphs 7 to 11 of Schedule “A” of the Plaintiffs’ Notice of Motion.

A. *7. Within days after the Injunction was pronounced, Janssen Inc. disobeyed the Injunction by implementing a campaign of directly communicating to hundreds of physicians to influence their decisions about whether to initiate or continue using Stelara for treating psoriasis.*

1. Analysis

[60] The Injunction *prima facie* prohibits the Defendant from communicating with physicians to promote, or influence their decisions about whether to initiate or continue using STELARA for treating psoriasis, and prohibits the Defendant from detailing, promoting or making any representations or claims respecting the use of STELARA for the treatment of psoriasis.

[61] Specifically, and *prima facie*, the Injunction does so in four ways:

- a) paragraph 1 prohibits the Defendant from “promoting the use of” STELARA “in Canada, for the treatment of psoriasis”. It does so in broader language that prohibits the Defendant from “making, using, selling, offering for sale, or

promoting the use of a product [STELARA], in Canada, for the treatment of psoriasis”;

- b) subparagraph 2A exempts the Defendant from paragraph 1 in respect of physicians treating their existing patients with STELARA. However regarding new patients, the Injunction re-imposes limits on the Defendant stating the Defendant is exempted-only when “doing any act solely intended to provide STELARA for the treatment of psoriasis to a person who has not previously received STELARA for that purpose, provided that such person’s own physician has determined that such treatment is necessary for that purpose”;
- c) paragraph 2 concludes with an important proviso that directly enjoins the Defendant. The Defendant “shall not communicate directly or indirectly with any such physician for the purpose of influencing the decision to initiate or continue such treatment”, i.e. treatment with STELARA; and
- d) subparagraph 3A again directly enjoins the Defendant. It states, “for greater certainty”, that the Defendant “shall not, directly or indirectly, detail, ... promote or make any representations or claims, in Canada, respecting the use of STELARA for the treatment of psoriasis”.

[62] While paragraph 2 of the Injunction exempts the Defendant from conduct described in subparagraphs A and B, those exceptions are specific and narrow, and apply “solely” to the conduct described.

[63] Script 1 was designed and described by the Defendant as proactive. Its rollout by the Defendant's detailers was immediate. The Defendant instructed its STELARA sales staff to meet prescribing dermatologists and deliver the message in Script 1. The Defendant's detailers (sales staff) carried through and delivered the message in Script 1 to all or virtually all dermatologists in Canada within a month or a month and a half, i.e., before Script 2 was proffered.

[64] To the extent Script 1 was adhered to by the Defendant's detailers, they would have told dermatologists/physicians that:

It is important to note that this court order does not impact your ability to prescribe STELARA[®] to your patients. The product itself has not changed and there are no changes from a safety and efficacy standpoint. The court order does not impact the BioAdvance[®] program.

[65] The first sentence of Script 1 (*"It is important to note that this court order does not impact your ability to prescribe STELARA[®] to your patients."*) appears to be inaccurate. The Injunction was apparently intended to effect a change in physician practices – otherwise *prima facie* there would be no need for the Court to have spoken of reliance on the medical profession and in particular, for its direction concerning reliance on the "integrity" of physicians. That would come about through the combination of physicians making professional decisions as to what is necessary for a patient uninfluenced by the Defendant's marketing campaign carried out by its detailers. In my *prima facie* view, the Injunction was intended to achieve a balance. It is true that the usual absolute prohibition made against the infringing product in paragraph 1 of the Injunction was tempered by the narrow exemptions in paragraph 2. But the *quid pro quo* was that the Defendant would cease promoting, marketing, and trying to influence physicians to prescribe STELARA to new patients as manifest by the proviso with which paragraph 2 concludes. The

Injunction-ordered change in the Defendant's marketing campaign would therefore result in a change in physician prescribing practices – an intended result of the Injunction. It appears to me that to argue otherwise is to argue that detailers, pharmaceutical salespersons, have little or no effect on the prescribing practices of physicians.

[66] In addition, and in any event, the first sentence of Script 1 is *prima facie* promotional in nature. It is *prima facie* designed to influence physicians to initiate or continue treating with STELARA. It is *prima facie* a representation and claim respecting the use of STELARA for the treatment of psoriasis. Therefore I conclude that *prima facie* contempt has been committed in that the first sentence appears to violate all four aspects of the Injunction noted in paragraph 61 above.

[67] For the same reasons, the second sentence in Script 1 (“*The product itself has not changed and there are no changes from a safety and efficacy standpoint.*”) is also *prima facie* contempt, and is committed against all four aspects of the Injunction noted in paragraph 61 of these reasons. This sentence is *prima facie* purely promotional and calculated and designed to influence physician decisions, in addition to it being both a claim and a representation, all of which are prohibited by the Injunction. In this connection, I accept *prima facie* that representations regarding safety and efficacy are central to the successful marketing of STELARA.

[68] The third sentence of Script 1 (“*The court order does not impact the BioAdvance® program.*”) is also a *prima facie* contempt in that, even if it is also true, it is promotional and

marketing in nature and therefore *prima facie* seeks to influence the initiation and continuation of treatment with STELARA for psoriasis contrary to the proviso with which paragraph 2 concludes. It also *prima facie* is contrary to the first and third aspects of the Injunction noted in paragraph 61 above.

[69] I am further reinforced in these *prima facie* findings by paragraph 4 of the Injunction, which sets out further particulars of what the Defendant may do and was *prima facie* expected to do by way of exemptions from the general terms of the Injunction in paragraph 1.

[70] I am unable to conclude that any of subparagraphs 4A to 4D authorize the Defendant's sales staff (detailers) to promote or market STELARA for psoriasis to physicians/dermatologists. *Prima facie*, the Injunction allows only the reverse:

- A. 4A allows written communication of "information required by law," which was not the case with the campaign and Script 1.
- B. 4D authorizes the Defendant's Medical Information Group, not the Defendant's detailers, to "respond to inquiries about STELARA".
- C. And while Injunction subparagraph 4F allows the Defendant's detailers to discuss "the use of STELARA for use in treatment of psoriatic arthritis to rheumatologists", it does not authorize what occurred here, namely detailers discussing the use of STELARA with dermatologists for the treatment of psoriasis.

[71] These differences appear telling.

[72] I note that the Defendant, upon receipt of a complaint by the Plaintiffs, revised Script 1 and indicated it intended that its detailers would use a different script, namely Script 2. Script 2 states in part:

It is important to note that this court order permits your existing Stelara patients (those that have already received at least one injection of Stelara) to continue to receive Stelara. Patients who have not previously received Stelara for the treatment of psoriasis may receive Stelara if you determine that Stelara is necessary for the treatment of their psoriasis.

The product itself has not changed and there are no changes from a safety and efficacy standpoint. The court order does not impact the BioAdvance[®] program.

[73] With respect, in my view Script 2 *prima facie* offends the four prohibitions outlined in paragraph 61 above, and does not change the results of this analysis. Indeed the fact the Defendant proposed to change Script 2 *prima facie* reinforces the foregoing conclusions regarding Script 1.

[74] The Defendant argues everything it did was informational and therefore permitted. That of course depends on how one characterizes the Defendant's conduct. However to be clear, my *prima facie* finding is that the Defendant's actions were contrary to the Injunction even if they were merely informational (which I *prima facie* do not accept) because *prima facie* they offends the Injunction's prohibition against promotion, marketing, making claims and representations, influencing physician decisions to treat patients with STELARA and otherwise as outlined at paragraph 61.

[75] The Defendant also argues that the Injunction is unclear. I disagree, and find that the actions complained of are *prima facie* contempt of the words and intent of the Injunction.

[76] For these reasons, I am satisfied that a *prima facie* case has been made that contempt was committed as set out in paragraph 7 of Schedule “A” of the Plaintiffs’ Notice of Motion in relation to paragraph 1, the limitation in subparagraph 2B and the concluding proviso in paragraph 2, and subparagraph 3A of the Injunction.

B. *8. Within days after the Injunction was pronounced Janssen Inc. also disobeyed the Injunction by implementing a campaign in which its detailers were instructed to detail, promote, and make representations and claims about Stelara for use in the treatment of psoriasis.*

1. Analysis

[77] For the same reasons as with paragraph 7 of Schedule “A” of the Plaintiffs’ Notice of Motion analyzed above, I am satisfied that a *prima facie* case that contempt has been committed is established in respect of paragraph 1, the limitation in subparagraph 2B and concluding proviso in paragraph 2, and subparagraph 3A of the Injunction as outlined in paragraph 8 of Schedule “A” of the Plaintiffs’ Notice of Motion.

- C. *9. Within days after the Injunction was pronounced, Janssen Inc. acted in such a way as to interfere with the administration of justice and impair the authority and dignity of the Court by establishing the campaign that included actively telling physicians any one, or more, or all of the following: (a) that “the injunction does not affect your ability to prescribe Stelara to your patients”; and (b) that physicians were not required to make any change in their prescribing practices after the injunction; and (c) that they could continue to prescribe Stelara as they did before the Injunction; and, (d) that they should continue to prescribe Stelara as they did before the Injunction; and, (e) that in respect of physicians prescribing Stelara it was “business as usual” despite the pronouncement of the Injunction, and (f) that the product itself has not changed and there are no changes from a safety and efficacy standpoint.*
- D. *10. The said campaign was deployed using the Stelara detailing force and required each detailer to visit and execute the campaign to the very same physicians that each detailer had been detailing for Stelara immediately before the Injunction.*
- E. *11. Janssen Detailers were instructed to execute the campaign and deliver the above statements regardless of whether the physician asked any questions about the Injunction, raised the issue of Stelara use at all, or even knew about the Injunction.*

1. Analysis

[78] These three paragraphs of Schedule “A” of the Plaintiffs’ Notice of Motion should be dealt with together. The Plaintiffs argue them under Rule 466(c).

[79] This Court found that the Defendant infringed the Plaintiffs’ ‘281 patent. The Court issued the Injunction balancing the rights of the Plaintiffs to statutory patent protection with the interests of patients in having access to safe and effective alternative treatment for psoriasis. When the Court decided not to order an outright ban on STELARA, it decided that the decision to prescribe STELARA for psoriasis to existing and new patients should be made by physicians, uninfluenced by the Defendant’s promotional, marketing, claims, representations and other sales efforts designed to influence their decisions.

[80] In other words, in my view, the Defendant was supposed to leave it to the physicians to make prescribing decisions: i.e., no Defendant promotion, no Defendant marketing, no Defendant claims, no representations. The Defendant was ordered to do nothing to influence prescription decisions to be made by physicians. Doctors were exclusively to decide what was necessary for new patients.

[81] In this connection, I refer again to paragraphs 66 and 71 of the Injunction Reasons quoted above.

[82] As of May 22, 2014, the date of the permanent Injunction made by this Court, the Defendant was *prima facie* prohibited by paragraph 1 from most, if not all of its previous sales and marketing activities related to STELARA. While it was given exemptions in paragraph 2, they were narrowed and were also subject to the proviso and limitations with which paragraph 2 concludes. Furthermore, subparagraph 3A “for greater certainty” prohibits the Defendant from promoting and from making “any representations or claims, in Canada, respecting the use of STELARA for the treatment of psoriasis”.

[83] Each of the acts alleged here appear to have been committed by the Defendant. Each individually, and taken as a whole, are representations and promotional activities, and were calculated to influence prescribing decisions of dermatologists and physicians. Each of them and all of them are specifically prohibited by paragraph 1, the limitation in subparagraph 2B and the concluding proviso in paragraph 2, and subparagraph 3A of the Injunction.

[84] I am satisfied *prima facie* that these alleged acts were done in such a way as to interfere with the administration of justice and impair the authority and dignity of the Court and that therefore a *prima facie* case of contempt has been committed as alleged in paragraph 9 of Schedule “A” of the Plaintiffs’ Notice of Motion.

[85] It appears that paragraphs 10 and 11 of Schedule “A” of the Plaintiffs’ Notice of Motion are also accurate statements of what occurred in this case. Janssen described the campaign underlying Script 1 as “proactive”, and stressed that it was to be “immediate”. The essence of being proactive is taking the initiative and getting information out, even before it is requested.

[86] Paragraph 11 of Schedule “A” of the Plaintiffs’ Notice of Motion alleges that the Defendant’s detailers were instructed to and did, as discussed above, market, promote, and make representations about STELARA whether the physicians with whom they met asked about STELARA or knew about the Injunction. *Prima facie* such conduct was not contemplated or allowed by the Injunction in addition to being *prima facie* contrary to the words of the Injunction itself.

[87] In addition I am satisfied *prima facie* that the acts alleged in paragraphs 9, 10 and 11 of Schedule “A” of the Plaintiffs’ Notice of Motion were committed in such a way as to interfere with the administration of justice and impair the authority and dignity of the Court and that therefore a *prima facie* case of contempt has been committed.

[88] I am therefore satisfied that a *prima facie* case of contempt was committed contrary to paragraph 1, the limitation in subparagraph 2B and the concluding proviso in paragraph 2, and subparagraph 3A of the Injunction by the acts described in paragraphs 9, 10 and 11 of Schedule “A” of the Plaintiffs’ Notice of Motion, all as contemplated by Rule 466(c).

V. Additional considerations raised by the Defendant

[89] The Defendant made a number of additional submissions, both in its written material and at the hearing. Some arguments went to whether there is a case of *prima facie* contempt and are dealt with above. Other issues dealt with the merits of the contempt allegations and defences and are matters for a contempt trial court.

[90] The Defendant emphasises that part of the task of a show cause court is to determine whether the alleged contempt is deserving of sanction by this Court. The Defendant argues that it does not “deserve to be punished” for its conduct, that the Defendant did not act with “wilful and contumacious conduct” per *Direct Source, supra*, and *Chaudhry, supra*, and that the Defendant was not “flouting” the Injunction. Therefore it argues there is no *prima facie* contempt.

[91] With respect, I disagree. This Court made an order against the Defendant. Injunctions are to be obeyed unless stayed, amended, set aside on appeal, or otherwise altered according to law. None of this happened. *Prima facie* my decision is that an unambiguous Order of this Court was disobeyed. *Prima facie* the Defendant undermined the dignity of this Court through its deliberate and wilful post-Injunction actions outlined above.

[92] With respect, in this circumstance I not able to find that the conduct of the Defendant is undeserving of punishment or sanction, nor am I able to find that the Defendant's conduct was other than *prima facie* wilful and contumacious. A party is presumed to intend the natural consequences of their actions. *Prima facie* the Scripts and related campaign were deliberate, planned and thought out.

VI. Conclusion

[93] For the reasons outlined above, the motion should be granted. An order under Rule 467(1) should issue directing the Defendant to appear before a contempt trial judge in relation to paragraphs 1, 2, 3, 4, and 5 as set out in Schedule "A" of these Order and Reasons. The Order should also give notice to the Defendant outlining the relief the Plaintiffs may request from the contempt trial judge as set out in Schedule "B" of these Order and Reasons.

ORDER

THIS COURT ORDERS that:

- 1) Pursuant to Rule 467, the Defendant Janssen Inc. shall appear before this Court in Toronto, at a time and place to fixed by the Judicial Administrator, to hear proof of the alleged acts of contempt described in Schedule “A” of this Order and Reasons, and at which time the Defendant shall be prepared to present any defence that it may have in respect of such acts;
- 2) The Defendant Janssen Inc. is hereby advised that at the hearing referred to in paragraph 1. above, the Plaintiffs may seek, *inter alia*, the relief described in Schedule “B” of this Order and Reasons;
- 3) The Plaintiffs shall have their costs of this motion in the cause.

"Henry S. Brown"

Judge

FEDERAL COURT
SOLICITORS OF RECORD

DOCKET: T-1310-09

STYLE OF CAUSE: ABBVIE CORPORATION, ABBVIE DEUTSCHLAND GMBH & CO., KG AND ABBVIE BIOTECHNOLOGY LTD v JANSSEN INC.

PLACE OF HEARING: TORONTO, ONTARIO

DATE OF HEARING: AUGUST 12, 2014

JUDGMENT AND REASONS: BROWN J.

DATED: SEPTEMBER 10, 2014

APPEARANCES:

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Brian Gover FOR THE DEFENDANT

SOLICITORS OF RECORD:

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Schedule “A”

1. Within days after the Injunction was pronounced, Janssen Inc. disobeyed the Injunction by implementing a campaign of directly communicating to hundreds of physicians to influence their decisions about whether to initiate or continue using STELARA for treating psoriasis.
2. Within days after the Injunction was pronounced Janssen Inc. also disobeyed the Injunction by implementing a campaign in which its detailers were instructed to detail, promote, and make representations and claims about STELARA for use in the treatment of psoriasis.
3. Within days after the Injunction was pronounced, Janssen Inc. acted in such a way as to interfere with the administration of justice and impair the authority and dignity of the Court by establishing the campaign that included actively telling physicians any one, or more, or all of the following:
 - a) that “the injunction does not affect your ability to prescribe STELARA® to your patients”; and
 - b) that physicians were not required to make any change in their prescribing practices after the injunction; and
 - c) that they could continue to prescribe STELARA as they did before the Injunction; and,
 - d) that they should continue to prescribe STELARA as they did before the Injunction; and,

- e) that in respect of physicians prescribing STELARA it was “business as usual” despite the pronouncement of the Injunction, and
- f) that the product itself has not changed and there are no changes from a safety and efficacy standpoint.

4. The said campaign was deployed using the STELARA detailing force and required each detailer to visit and execute the campaign to the very same physicians that each detailer had been detailing for STELARA immediately before the Injunction.

5. Janssen Detailers were instructed to execute the campaign and deliver the above statements regardless of whether the physician asked any questions about the Injunction, raise the issue of STELARA use at all, or even knew about the Injunction.

Schedule “B”

1. An Order that Janssen Inc. has committed a civil contempt of the Judgment of Justice Hughes of the Federal Court of Canada dated May 22, 2014.

2. An Order forbidding any Janssen Inc. sales representative from any contact with dermatologists in Canada for the duration of the life of Canadian Letters Patent Number 2,365,281.

3. In the alternative to paragraph 2, an Order requiring Janssen Inc. to obtain monthly at its expense a report from IMS (or another third party supplier approved by the Court) which sets out the results of a survey of no less than 50 dermatologists from across Canada, which is designed to summarize the substance of all Janssen Inc. detailing efforts for STELARA which have been directed at such dermatologists in the previous month.

4. An Order that Janssen Inc. may purge its contempt by sending a letter to all Canadian dermatologists in the following words:

Dear Dr. ●,

On or after May 26, 2014, you may have been visited by your Janssen sales representative who may have delivered a message to you about the effect of an injunction issued by the Federal Court of Canada against Janssen in relation to STELARA.

That message may have included a suggestion that the Court injunction does not impact your ability to prescribe STELARA to your patients or that prescribing STELARA is “business as usual”.

Janssen is writing to you to correct that message.

The Federal Court of Canada has found that STELARA infringes a valid Canadian patent and, unlike before, STELARA can be prescribed to new patients only in cases of necessity.

6. An Order that Janssen Inc. shall amend its BioAdvance form to provide a space for dermatologists to certify the existence of a medical need to prescribe STELARA that cannot be met by HUMIRA.