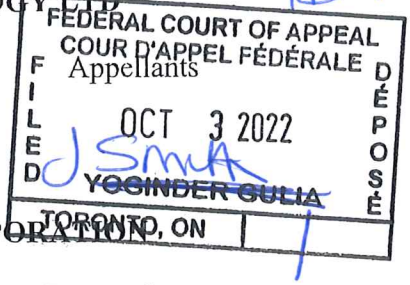
Court File No. A-203 -22
(T-10-22, T-130-22)

FEDERAL COURT OF APPEAL

BETWEEN:

ABBVIE CORPORATION and ABBVIE BIOTECHNOLOGY LTD

Appellants



- and -

THE MINISTER OF HEALTH and JAMP PHARMA CORPORATION

Respondents

NOTICE OF APPEAL

TO THE RESPONDENT:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the appellants. The relief claimed by the appellants appears below.

THIS APPEAL will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court directs otherwise, the place of hearing will be as requested by the appellant. The appellant requests that this appeal be heard at Toronto, Ontario or via video conference.

IF YOU WISH TO OPPOSE THIS APPEAL, to receive notice of any step in the appeal or to be served with any documents in the appeal, you or a solicitor acting for you must prepare a notice of appearance in Form 341A prescribed by the *Federal Courts Rules* and serve it on the appellant's solicitor or, if the appellant is self-represented, on the appellant, WITHIN 10 DAYS after being served with this notice of appeal.

IF YOU INTEND TO SEEK A DIFFERENT DISPOSITION of the order appealed from, you must serve and file a notice of cross-appeal in Form 341B

prescribed by the *Federal Courts Rules* instead of serving and filing a notice of appearance.

Copies of the *Federal Courts Rules*, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPEAL, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

OCT 3 2022
~~September 30,~~ 2022

Issued by: JACQUELINE SMITH
REGISTRY OFFICER
AGENT DU GREFFE

Address of local office:
180 Queen Street West
Suite 200
Toronto, ON M5V 3L6

TO: **ATTORNEY GENERAL OF CANADA**
Department of Justice Canada
Civil Litigation Section
National Litigation Sector
50 O'Connor Street, Suite 500
Ottawa, ON K1A 0H8

J. Sanderson Graham
Kirk Shannon
Elizabeth Koudys

Tel: 613-670-6274
Fax: 613-954-1920

Solicitors for the Respondent,
The Minister of Health

AND TO: **GOODMANS LLP**
Barristers and Solicitors
Bay Adelaide Centre – West Tower
333 Bay Street, Suite 3400
Toronto ON M5H 2S7

Andrew R. Brodkin
Jordan Scopa
Jaclyn Tilak

Tel. (416) 979-2211
Fax (416) 979-1234

Solicitors for the Respondent,
JAMP Pharma Corporation

APPEAL

THE APPELLANTS (collectively, "AbbVie") APPEAL to the Federal Court of Appealfrom the judgment of Justice Fothergill (the "**Applications Judge**"), dated August 17, 2022 ("**Judgment Below**"), by which the applications for judicial review bearing court file nos. T-10-22 and T-130-22 (the "**Applications Below**") were dismissed with costs.

THE APPELLANTS ASK that:

1. This appeal be allowed;

2. The Applications Below be allowed;

3. This Court issue judgment:

   (a) Quashing a decision of the Minister of Health, issued through the Office of Submissions and Intellectual Property ("**OSIP**") and/or Office of Patented Medicines and Liaison ("**OPML**", and collectively the "**Minister**"), communicated to the applicants on December 23, 2021, in which the Minister purported to determine that: (i) the respondent, JAMP Pharma Corporation ("**JAMP**"), is not a second person under subsection 5(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (the "***PM(NOC) Regulations***"), in respect of its proposed SIMLANDI (adalimumab) 40 mg/0.4 ml pre-filled syringe, 40 mg/0.4 ml autoinjector, and 80 mg/0.8 ml pre-filled syringe presentations (the "**Proposed SIMLANDI Products**"), new drug submission No. 244990 for SIMLANDI (the "**JAMP NDS**"), with respect to Canadian Patent Nos. 2,385,745, 2,504,868, 2,801,917, 2,815,689, 2,847,142, 2,898,009, and 2,904,458 that are listed on the Patent Register in respect of HUMIRA® (the "**HUMIRA® Patents**"); and (ii) subsection 7(1) of the *PM(NOC) Regulations* does not apply to JAMP in relation to the JAMP NDS and HUMIRA® Patents so as to prevent the

Minister from issuing a notice of compliance ("**NOC**") to JAMP in respect of the JAMP NDS (the "**First Decision**");

(b) Quashing a decision of the Minister, communicated to the applicants on January 5, 2022, to grant JAMP an NOC in respect of its Proposed SIMLANDI Products and the JAMP NDS (the "**Second Decision**");

(c) Declaring that JAMP was and is a second person under subsection 5(1) of the *PM(NOC) Regulations* in respect of the JAMP NDS and the HUMIRA® Patents;

(d) Declaring that subsection 7(1) of the *PM(NOC) Regulations* applies to JAMP in relation to the JAMP NDS and the HUMIRA® Patents;

(e) Granting AbbVie its costs of this appeal and of the Applications Below;

(f) Requiring the return of any costs paid by AbbVie to the respondents in respect of the Applications Below; and

(g) Such further and other relief as counsel may request and/or this Honourable Court may permit.

THE GROUNDS OF APPEAL are as follows:

A. The Judgment Below

4. By the Judgment Below, the Applications Judge dismissed the Applications Below, holding that the applicable standard of review was reasonableness and that the First and Second Decisions were reasonable. In so holding, the Applications Judge:

(a) Selected the incorrect standard of review; and

(b) Irrespective of the correct standard of review, applied that standard improperly.

5. The correct standard of review is correctness.

6. Irrespective of which standard of review is applied, the Applications Below should have been allowed. Both the First Decision and Second Decision should have been quashed. The First Decision and Second Decision are both incorrect and unreasonable.

7. In addition, the Applications Judge failed to consider and address several arguments made by AbbVie in support of the Applications Below, including AbbVie's arguments that:

(a) The process of listing patents on the Patent Register is submission-specific, rather than and contrary to the Minister's determination that it is DIN-specific;

(b) According to the Federal Court of Appeal's decision in *Merck & Co. v. Canada (Attorney General)*, 2000 CarswellNat 566 (Fed. C.A.) ("***NuPharm***"), "another drug" within the meaning of subsection 5(1) of the *PM(NOC) Regulations* is not restricted to the Canadian reference product ("**CRP**") in the context of generic drugs, so it should not be so limited to the reference biologic drug ("**RBD**") in the context of biosimilars, contrary to the Minister's determinations;

(c) JAMP compared SIMLANDI to AbbVie's original 40 mg/0.8 mL HUMIRA® presentations and utilized AbbVie's data related to those presentations, which are marketed in Canada pursuant to NOCs in respect of which patent lists were filed; and

(d) *Teva Canada Limited v. Pfizer Canada Inc.*, 2016 FCA 248 ("***Teva***"), is not applicable and does not displace the exception set out in *Rogers Communications Inc. v. Society of Composers, Authors and Music Publishers of Canada*, 2012 SCC 35 (the "***Rogers* exception**"), because that case was decided under a prior and different version of the *PM(NOC) Regulations*. The *PM(NOC) Regulations* have since

been amended to provide the Federal Court with concurrent first-instance jurisdiction to determine whether a party is or is not a second person, and the Federal Court has already done so in *Genentech, Inc. v. Celltrion Healthcare Co., Ltd.*, 2019 FC 293.

B. Regulatory Context: The *PM(NOC) Regulations*

8. In order to market a drug in Canada, a sponsor requires an NOC. Pursuant to subsection 5(1) of the *PM(NOC) Regulations*:

> If a second person files a submission for a notice of compliance in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, another drug 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 include in the submission the required statements or allegations set out in subsection (2.1).

9. If a drug sponsor files a drug submission that makes a comparison or reference contemplated by subsection 5(1), the Minister will review the submission and determine that no NOC may be issued to the sponsor in respect of the drug submission until, among other things, the requirements of the *PM(NOC) Regulations* have been complied with.

10. The allegations that a second person is permitted to make are set out in paragraph 5(2.1)(c) of the *PM(NOC) Regulations*. Pursuant to subsection 5(3) of the *PM(NOC) Regulations*, a second person who makes an allegation referred to in paragraph 5(2.1)(c) is required to serve on the first person listed in respect of the patent or certificate of supplementary protection listed on the Patent Register a notice of allegation.

11. Pursuant to subsection 6(1) of the *PM(NOC) Regulations*, the first person who receives a notice of allegation may, within 45 days, bring an action against the second person for a declaration that the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsections 5(1) or (2)

would infringe any patent or certificate of supplementary protection that is the subject of an allegation set out in that notice.

12. Pursuant to subsection 7(1) of the *PM(NOC) Regulations*, if the first person brings an action, the Minister shall not issue a notice of compliance to a second person unless the action is dismissed or the 24-month statutory stay has expired. AbbVie, indeed, commenced actions pursuant to subsection 6(1), which are ongoing before the Federal Court.

C. AbbVie's Patented HUMIRA® (adalimumab) Drug

13. HUMIRA® is an injectable biologic containing the drug adalimumab, a monoclonal antibody. HUMIRA® was first approved in Canada in 2004 in a subcutaneous 40 mg/0.8 ml solution presentation (Drug Identification Number ("**DIN**"), 02258595). Since then, over nearly two decades, AbbVie has invested hundreds of millions of dollars in continuing research and innovation. Over time, supplement submissions to the original HUMIRA® NDS were submitted and approved by the Minister through the issuance of additional NOCs, all to the benefit of patients and their healthcare providers. These supplements included:

(a) New and extended indications; and

(b) New presentations.

14. Throughout, HUMIRA® was required to have, and only had, one DIN, 02258595.

15. AbbVie's continued research and development resulted in a high-concentration (100 mg/mL) HUMIRA® formulation. AbbVie filed submissions to obtain marketing approval for its high-concentration HUMIRA® as a supplement submission that relied on the original HUMIRA® NDS and supplements approving new and extended indications, and new presentations. The Minister approved high-concentration HUMIRA® in its two new presentations, and required each to have a new, and unique, DIN.

16. Since 2016, AbbVie has filed supplement submissions for high-concentration HUMIRA® that were approved by the Minister through the issuance of additional NOCs for the benefit of patients and their healthcare providers. These supplements included:

(a) New and extended indications; and

(b) New high-concentration presentations.

17. The Minister required each of the new high-concentration presentations to have a new, and unique, DIN. The original HUMIRA® presentations (DIN 02258595) are marketed in Canada. AbbVie also markets high-concentration HUMIRA® in Canada in its 0.2 mg/0.2 ml pre-filled syringe presentation (DIN 02474263). All of the supplement submissions for high-concentration HUMIRA® relied on data establishing the safety and efficacy of AbbVie's original HUMIRA®. In the end, AbbVie now has seven DINs for presentations of HUMIRA®. At no time did the Minister advise AbbVie that their new requirement to issue a new DIN for each new HUMIRA® presentation would later be met with the consequence that the failure to market any one of those presentations would disentitle AbbVie from the protections to which it is entitled under the *PM(NOC) Regulations*.

18. AbbVie's innovative work has been recognized by the medical and scientific community. For example, in 2007, HUMIRA® was awarded the Prix Galien, one of the most prestigious honours in the pharmaceutical and biotechnology world. More importantly, AbbVie's work has benefited patients immensely. Children have gone from wheelchairs to playgrounds, and adults have gone from bed to work. AbbVie is very proud of the fact that HUMIRA® has improved the lives of more than one million patients to date. The HUMIRA® Patents claim and embody AbbVie's innovative work.

D. The JAMP NDS

19. On or about December 24, 2020, JAMP filed the JAMP NDS with Health Canada seeking a NOC in respect of its proposed high-concentration adalimumab

biosimilar, marketed under the name SIMLANDI. JAMP sought approval to do so in three presentations: a 40 mg/0.4 ml pre-filled syringe, 40 mg/0.4 ml autoinjector, and 80 mg/0.8 ml pre-filled syringe. These are all high-concentration (100 mg/ml) formulations.

20. As stated in the First Decision, "[t]he [Biologic and Radiopharmaceutical Drugs Directorate of Health Canada] has informed the OSIP that the NDS for SIMLANDI relies on studies/information pertaining to the drug HUMIRA® containing 100 mg/ml adalimumab from the European Union and the United States."

21. On or before December 30, 2020, the Minister reviewed the JAMP NDS and determined it was incomplete because JAMP had failed to include any statements or allegations contemplated by subsection 5(2.1) of the *PM(NOC) Regulations*, as required by subsection 5(1) of the *PM(NOC) Regulations*. On December 30, 2020, the Minister advised JAMP that, as a second person, it was required to comply with the requirements of section 5 of the *PM(NOC) Regulations*, by filing a *Form V: Declaration re. Patent List* with respect to the HUMIRA® Patents within 10 calendar days and that the JAMP NDS was being placed on hold until the required Form Vs were submitted.

22. On February 17, 2021, JAMP purported to comply with its obligations under the *PM(NOC) Regulations* by serving four notices of allegation on AbbVie Corporation, in order to comply with subsection 5(3) of the *PM(NOC) Regulations* in respect of the HUMIRA® Patents.

23. In response, on March 31, 2021, AbbVie brought four actions in the Federal Court under subsection 6(1) of the *PM(NOC) Regulations*, one action per alleged notice of allegation,[1] seeking declarations that the making, constructing, using or selling by JAMP of SIMLANDI (adalimumab) 40 mg/0.4 ml pre-filled syringe, 40

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[1] Court File Nos. T-557-21 (Canadian Patent Nos. 2,504,868, 2,847,142, and 2,801,917), T-559-21 (Canadian Patent No. 2,385,745), T-560-21 (Canadian Patent No. 2,898,009), T-561-21 (Canadian Patent No. 2,904,458).

mg/0.4 ml autoinjector, and 80 mg/0.8 ml pre-filled syringe presentations in accordance with the JAMP NDS would directly or indirectly infringe the HUMIRA® Patents. As a result of AbbVie bringing these actions, subsection 7(1) of the *PM(NOC) Regulations* ought to have prevented the Minister from issuing an NOC to JAMP in respect of the JAMP NDS until permitted by the terms of section 7 of the *PM(NOC) Regulations*. This litigation remains ongoing.

E. The First Decision

24. Even though the Minister had already decided that JAMP was a "second person" within the meaning of subsection 5(1) of the *PM(NOC) Regulations*, at JAMP's request, the Minister permitted JAMP to make additional submissions regarding whether JAMP was indeed a second person.

25. On March 15, 2021, after numerous *ex parte* communications with JAMP, the Minister advised AbbVie for the first time that it was the Minister's preliminary view that some of AbbVie's high-concentration (100 mg/ml) HUMIRA® presentations were not actively marketed in Canada, specifically, the 80 mg/0.8 ml pre-filled syringe (DIN 02466872), 40 mg/0.4 ml pre-filled syringe (DIN 02458349), and 40 mg/0.4 ml auto-injector (pen) (DIN 02458357). As a result the Minister advised AbbVie for the first time that it did not benefit from the protections of the *PM(NOC) Regulations*. The Minister requested additional information relating to the marketing status of these presentations, in order for the Minister to make a final decision.

26. On March 29, 2021, the Minister advised both AbbVie and JAMP that it was purporting to begin the process of determining JAMP's second person status anew, purportedly to increase transparency.

27. On May 7, 2021, both AbbVie and JAMP made submissions on whether JAMP was a second person within the meaning of subsection 5(1) of the *PM(NOC) Regulations*.

28. On September 22, 2021, the Minister issued its "preliminary decision" that JAMP was not a second person within the meaning of subsection 5(1) of the

PM(NOC) Regulations because the "another drug" that JAMP had used for comparison were AbbVie's 40 mg/0.4 ml pre-filled syringe (DIN 02458349), 40 mg/0.4 ml auto-injector (pen) (DIN 02458357), and 80 mg/0.8 ml pre-filled syringe (DIN 02466872) presentations, and that they were not actively marketed in Canada.

29. The preliminary decision invited the parties to make additional submissions on two issues:

(a) Whether JAMP was a second person in respect of the JAMP NDS and the HUMIRA® Patents; and

(b) The effect of a decision that JAMP was not a second person on the extant 24-month statutory stay under subsection 7(1) of the *PM(NOC) Regulations* after AbbVie brought its four actions under subsection 6(1) of the *PM(NOC) Regulations*.

30. On October 29, 2021, both AbbVie and JAMP made additional submissions.

31. On December 23, 2021, the Minister issued its final decision, holding that JAMP was not a second person within the meaning of subsection 5(1) of the *PM(NOC) Regulations* because no "another drug" JAMP compared to was actively marketed in Canada, and that subsection 7(1) of the *PM(NOC) Regulations* did not preclude the Minister from issuing a NOC to JAMP in respect of its SIMLANDI.

32. According to the Minister, the obligations under subsection 5(1) only arise, and there will only be a second person, where:

(a) A drug submission is filed and the submission "directly or indirectly compares the drug with, or makes reference" to "another drug";

(b) The "another drug" is either the CRP or RBD, is DIN-specific, and must be marketed in Canada under an NOC issued to a first person; and

(c) The first person must have listed a patent on the Patent Register in respect of its "another drug".

33. According to the Minister:

(a) "Another drug" refers to either the CRP or RBD (as the case may be) in respect of an identical and specific strength, dosage form, and route of administration (*i.e.*, it is DIN-specific);

(b) The direct or indirect comparison or reference must be to the DIN-specific "another drug"; and

(c) The marketing requirement for "another drug" is likewise DIN-specific.

34. Even though the JAMP NDS relies on studies/information pertaining high-concentration (100 mg/ml) HUMIRA® from the European Union, which is marketed in Canada in the 20 mg/0.2 ml prefilled syringe presentation (DIN 02474263), and even though JAMP incorporates data from original HUMIRA® (50 mg/ml) presentations in order to extrapolate to multiple indications for SIMLANDI, the RBDs were only the HUMIRA® 40 mg/0.4 ml pre-filled syringe (DIN 02458349), 40 mg/0.4 ml auto-injector (pen) (DIN 02458357), and 80 mg/0.8 ml pre-filled syringe (DIN 02466872), which are not marketed in Canada. Therefore, the Minister found that JAMP was not a second person in respect of the JAMP NDS and HUMIRA® Patents.

F. The Second Decision

35. According to the Minister, where there is no "second person", subsection 7(1) of the *PM(NOC) Regulations* has no application. As such, the Minister held that subsection 7(1) did not prevent NOC issuance, disregarding the fact that there was and is extant litigation under subsection 6(1) of the *PM(NOC) Regulations*.

36. On January 5, 2022, the Minister granted JAMP's NOC.

37. AbbVie sought judicial review of the Minister's First Decision and Second Decision by the Applications Below. By the Judgment Below, those applications were dismissed.

G. The Correct Standard of Review is Correctness

38. Both the Federal Court and the Minister of Health have concurrent first-instance jurisdiction over the interpretation of "second person" within the meaning of the *PM(NOC) Regulations*. Pursuant to the *Rogers* exception, in these circumstances, the applicable standard of review is correctness. *Teva* does not displace the *Rogers* exception under the current version of the *PM(NOC) Regulations*. The Applications Judge incorrectly held that the applicable standard of review was reasonableness.

H. Irrespective of the Correct Standard of Review, the Applications Judge Applied that Standard Improperly

39. For the reasons that follow, the First Decision and Second Decision are both incorrect and unreasonable. When the standard of review is applied properly, the First Decision and Second Decision should both be quashed.

F. Text, Context, and Purpose Confirm that "Another Drug" Has a Broader Meaning than CRP or RBD, as the Case May Be

40. The Minister's decision that JAMP was not a second person within the meaning of subsection 5(1) of the *PM(NOC) Regulations* was predicated on the holding that "another drug", as used within subsection 5(1) of the *PM(NOC) Regulations*, is limited to a DIN-specific CRP or RBD, as the case may be, having the same strength, dosage form, and route of administration.

41. The text, context, and purpose of subsection 5(1) all indicate that "another drug" as used in this provision is not so limited. The Minister's decision is based on an incoherent and irrational chain of analysis that is not justified based on the facts and law that constrain him, leading to an absurd result that defeats the purpose of the regulatory regime.

42. The ***text*** of subsection 5(1) does not support the Minister's interpretation:

(a) The Federal Court of Appeal has already held in *NuPharm* that "another drug" is not limited to the CRP in the case of a generic drug submission. There is no basis in the *PM(NOC) Regulations* for interpreting "another drug" as being limited to either the CRP or RBD, as the case may be.

43. The ***context*** does not support the Minister's interpretation:

(a) Sections 3, 4, and 5 of the *PM(NOC) Regulations* create a regime for the listing and enforcement of patents that is submission-specific, not DIN-specific.

(b) The *Food and Drugs Act* and *Food and Drug Regulations*, which are linked to the *Patent Act*, R.S.C. 1985, c. P-4, by the *PM(NOC) Regulations*, form part of the essential regulatory context of subsection 5(1). The *Food and Drugs Act* defines "drug" expansively as meaning an active ingredient or mixture of active ingredients, no matter how formulated, no matter the dosage form of the drug product, and no matter how (or whether) a DIN is assigned. This is also how "drug" is used in the *Food and Drug Regulations*.

(c) Health Canada's Guidance Document, "Information and Submission Requirements for Biosimilar Biologic Drugs" ("**Biosimilar Guidance**"), indicates that the comparison or reference required by subsection 5(1) does not require the RBD to have the same strength, dosage form, or route of administration. The Minister did not explain why it interpreted "another drug" more narrowly by requiring identicality when that is not required by the Biosimilar Guidance itself, which in any event has no legal force or effect.

44. The ***purpose*** of subsection 5(1) of the *PM(NOC) Regulations* and the *Patent Act* are frustrated by the Minister's interpretation:

(a) The specific purpose of the marketing requirement in subsection 5(1) is to address the practice of withdrawing products, and DINs, to forestall generic competition. This purpose is not engaged when the patented drug is still approved and/or marketed in Canada (even if in a different strength than a proposed second-entry drug).

(b) The purpose of the *PM(NOC) Regulations* – in part, preventing abuse of the early-working exception provided in subsection 55.2(1) of the *Patent Act* – is defeated by the Minister's interpretation of "another drug" in that it is disconnected from whether listed patents will be early-worked. Permitting patents to be early-worked without requiring second-entry drug manufacturers to address those patents under the *PM(NOC) Regulations* sanctions abuse of the early-working exception.

(c) The purpose of the *PM(NOC) Regulations* – in part, to implement Canada's international treaty obligations, including Article 20.50 of the Canada-United States-Mexico Agreement ("**CUSMA**") – is defeated by the Minister's interpretation of "another drug" because it fails to fully implement Canada's international obligations.

(d) The purpose of the *Patent Act* – advancing research and development, and encouraging economic activity by coaxing inventive solutions to practical problems into the public domain through the promise of a time-limited monopoly – is frustrated by the Minister's interpretation of "another drug" because it requires a drug company to continue to actively market all presentations in order to preserve its rights under the *PM(NOC) Regulations*. This disincentivizes drug companies from developing and seeking approval for new presentations in Canada, to the great detriment of Canadian patients.

45. Correctly and reasonably interpreted, "another drug" within the meaning of subsection 5(1) is broader than the CRP or RBD. With respect to biologic drugs, the

"another drug" need not be pharmaceutically equivalent; it need not have the same strength, dosage form, or route of administration.

G. The JAMP NDS Indirectly Compared SIMLANDI to Original HUMIRA®

46. All of AbbVie's high-concentration presentations and nearly all of the approved indications were submitted to the Minister for approval by way of supplement to the original HUMIRA® NDS. These supplements invoked and relied on the original HUMIRA® data package demonstrating the safety and efficacy of adalimumab.

47. JAMP extensively referred to and relied upon those data in JAMP's SIMLANDI product monograph. Indeed, JAMP conducted only two limited clinical trials to support the approval of SIMLANDI:

(a) One comparative bioavailability comparing SIMLANDI and 40 mg/0.4 mL high-concentration HUMIRA®; and

(b) One controlled efficacy and safety study in patients with Psoriasis.

48. JAMP conducted no clinical trials to obtain approval for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, polyarticular juvenile idiopathic arthritis, or adult ulcerative colitis. Yet, SIMLANDI was approved for use in each indication because it relied on AbbVie's original HUMIRA® data package.

49. Without the original HUMIRA® data package, SIMLANDI would not be approvable based on the reduced clinical and non-clinical data package submitted with the SIMLANDI submission. Those data were relied upon by JAMP in order to obtain approval for the JAMP NDS.

50. AbbVie directly compared its 40 mg/0.4 mL and 80 mg/0.8 mL high-concentration presentations to its original 40 mg/0.8 mL presentations to obtain approval for the high-concentration HUMIRA® presentations. JAMP directly

compared SIMLANDI to AbbVie's 40 mg/0.4 mL and 80 mg/0.8 mL high-concentration HUMIRA® presentations to obtain approval for SIMLANDI. Therefore, JAMP has indirectly compared SIMLANDI to AbbVie's original 40 mg/0.8 mL HUMIRA® presentations. There is no dispute, AbbVie markets original HUMIRA® (adalimumab) in Canada in several 40 mg/0.8 mL presentations and patents are listed. Accordingly, JAMP is a second person within the meaning of subsection 5(1) of the *PM(NOC) Regulations* and must address those listed patents before being approved.

51. The Minister's decisions fail to account for and give effect to the fact that his own practice has been and is to treat all biosimilars of HUMIRA® as interchangeable, regardless of which presentation of HUMIRA® the biosimilar made comparisons to, with the direct consequence that AbbVie was deprived of the protections of the *PM(NOC) Regulations* for high-concentration HUMIRA®.

H. The JAMP NDS Directly Compared SIMLANDI to High-Concentration (100 mg/ml) HUMIRA®

52. The JAMP NDS contains direct comparisons to, and makes reference to, high-concentration HUMIRA®. SIMLANDI contains adalimumab in the same 100 mg/ml concentration. All of AbbVie's high-concentration HUMIRA® presentations contain the exact same liquid in differing volumes.

53. By directly comparing the liquid in SIMLANDI to the liquid in AbbVie's high-concentration HUMIRA®, JAMP relied on AbbVie's non-DIN-specific high-concentration HUMIRA® data in order to submit a reduced data package.

54. Regardless of the presentations JAMP seeks to sell to Canadians, the drug being compared to includes at least AbbVie's non-DIN-specific high-concentration adalimumab, and this is marketed in Canada by AbbVie in a 20 mg/0.2 mL presentation. Accordingly, JAMP is a second person within the meaning of subsection 5(1) of the *PM(NOC) Regulations*. The Minister's decision to the contrary is neither justifiable nor intelligible in light of these facts.

55. Indeed, Canadians benefit from the other high-concentration HUMIRA® presentations from several biosimilar versions of HUMIRA® that are marketed under licence from AbbVie for the HUMIRA® Patents, including Celltrion, which markets 40 mg/0.4 mL high-concentration adalimumab presentations in Canada.

56. Accordingly, the First Decision and Second Decision are both incorrect and unreasonable, in light of the factual legal constraints imposed on the Minister.

57. AbbVie pleads and relies on:

(a) The pleadings and proceedings in the Applications Below;

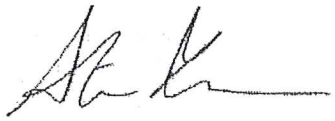
(b) The *Patent Act*, as amended;

(c) The *PM(NOC) Regulations*, as amended; and

(d) The *Federal Courts Act,* R.S.C., 1985, c. F-7, as amended;

(e) The *Federal Courts Rules,* S.O.R./98-106, as amended; and

(f) Such further and other grounds as AbbVie may advise and this Honourable Court may permit.



September 30, 2022

McCarthy Tétrault LLP
Suite 5300, TD Bank Tower
Toronto ON M5K 1E6

Steven Mason (smason@mccarthy.ca)
David Tait (dtait@mccarthy.ca)
James S.S. Holtom
(jholtom@mccarthy.ca)
Adam H. Kanji (akanji@mccarthy.ca)

Tel: (416) 601-8452
Fax: (416) 868-0673

Solicitors for the Appellants

I HEREBY CERTIFY that the above document is a true copy of the original issued out of / filed in the Court on the _____

day of OCT 3 2022 A.D. 20 ____

Dated this _____ day of OCT 3 2022 20____

JACQUELINE SMITH
REGISTRY OFFICER
AGENT DU GREFFE