Court File No.:

FEDERAL COURT

PROPOSED CLASS ACTION

BETWEEN

KEVIN HUGHES

Plaintiff

- and -

ABBVIE CORPORATION, ABBVIE INC., ABBVIE BIOTECHNOLOGY INC., AMGEN CANADA INC., AMGEN INC., SAMSUNG BIOEPIS CO., LTD., VIATRIS INC., MYLAN INC., MYLAN PHARMACEUTICALS, INC., SANDOZ CANADA INCORPORATED, SANDOZ, INC., FRESENIUS KABI CANADA LTD., FRESENIUS KABI USA, LLC, and PFIZER CANADA ULC, and PFIZER INC.

Defendants

STATEMENT OF CLAIM

TO THE DEFENDANT:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the Plaintiff. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or a solicitor acting for you are required to prepare a statement of defence in Form 171B prescribed by the Federal Courts Rules serve it on the plaintiff's solicitor or, where the plaintiff does not have a solicitor, serve it on the plaintiff, and file it, with proof of service, at a local office of this Court, WITHIN 30 DAYS after this statement of claim is served on you, if you are served within Canada.

If you are served in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period for serving and filing your statement of defence is sixty days.

Copies of the Federal Court 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 DEFEND THIS PROCEEDING, judgment may be given against

you in your absence and without further notice to you.

Date: 30 March 2023

Issued by: _____
Registry Officer

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

TO:

AbbVie Corporation

8401 Trans-Canada Highway
Saint-Laurent, Quebec, Canada H4S 1Z1
P.O. Box 120, Pointe-Claire/Dorval
Pointe-Claire, QC
H9R 4N5

AbbVie Inc.

1 North Waukegan Road
North Chicago, IL 60064
United States

AbbVie Biotechnology Ltd.

Clarendon House
2 Church Street
Hamilton HM11
Bermuda

Amgen Canada Inc.

6775 Financial Drive
Suite 100
Mississauga, ON
L5N 0A4

Amgen Inc.

One Amgen Center Drive
Thousand Oaks, CA 91320
United States

Samsung Bioepis Co., Ltd.

76, Songdogyoyuk-roYeonsu-gu
Incheon
South Korea

Mylan Inc.

1000 Mylan Blvd.
Canonsburg, PA 15317
United States

Mylan Pharmaceuticals, Inc.

781 Chestnut Ridge Rd.
Morgantown, WV 26505
United States

Viatris Inc (formerly Mylan Canada, ULC)

85 Advance Road
Etobicoke, ON
M8Z 2S6

Sandoz Canada Inc

110 de Lauzon
Boucherville, QC
J4B 1E6

Sandoz, Inc.

100 College Rd. West
Princeton, NJ 08540
United States

Friesenius Kabi Canada Ltd.

165 Galaxy Blvd, Suite 100
Toronto, ONM9W 0C8

Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, IL 60047
United States

Pfizer Canada Inc.

17300 Trans-Canada Highway
Kirkland, QC
H9J 2M5

Pfizer Inc.

235 East 42nd Street
New York, NY 10017
United States

CLAIM

1. The Plaintiff on behalf of himself and the Class described herein, claims:

   (a) an order certifying this action as a class proceeding and appointing the Plaintiff as Representative Plaintiff for the class;

   (b) a declaration that the Defendants are competitors who conspired, agreed or arranged with each other to fix, maintain, increase or control the price for the supply of Adalimumab, the antibody comprising the biologic, Humira, by agreeing to delay the entry of a biosimilar antibody to Adalimumab, the antibody comprising the biologic, Humira ("Biosimilar" or "Biosimilars" in the plural), into the Canadian market in breach of section 45 of the *Competition Act*, R.S.C., 1985, C. c-34 ("*Competition Act*");

   (c) a declaration that the Defendants are competitors who conspired, agreed or arranged with each other to allocate the sales, territories, customers or markets for the production or supply of a Biosimilar, in breach of section 45 of the *Competition Act*;

   (d) a declaration that the Defendants are competitors who conspired, agreed or arranged with each other to fix, maintain, control, prevent, lessen or eliminate the production or supply of a Biosimilar, in breach of section 45 of the *Competition Act*;

   (e) In the alternative, each of Amgen Canada Inc. ("Amgen Canada"), Amgen Inc. ("Amgen US"), Samsung Bioepis Co., Ltd. ("Samsung Bioepis"), Mylan Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan"), Viatris Inc.("Viatris Canada"), Sandoz Canada Inc., ("Sandoz Canada") , Sandoz, Inc. ("Sandoz US"), Fresenius Kabi Canada Ltd.,

("Fresenius Canada"), Fresenius Kabi USA, LLC ("Fresenius US"), Pfizer Canada Inc. ("Pfizer Canada"), and Pfizer Inc. ("Pfizer US"),conspired individually with the defendant AbbVie entities, being AbbVie Corporation, Inc. ("AbbVie Canada"), AbbVie Inc. ("AbbVie US"), and AbbVie Biotechnology Ltd. (hereinafter Abbvie Canada, Abbvie US and Abbvie Biotechnology Ltd. are collectively referred to as "Abbvie", and Abbvie US and Abbvie Biotechnology Ltd. are together referred to as "Abbvie International"), and all of whom agreed or arranged with each other to engage in anti-competitive acts in contravention of sections 45(1)(a)(b) and (c) of the *Competition Act*:

(i) to fix, maintain, increase or control the price for Humira in Canada by agreeing to delay the entry of Biosimilars into the Canadian market;

(ii) to allocate sales, territories, customers, and markets for the production and supply of a Biosimilar by making arrangements to provide the manufacturers of Biosimilars early access to European markets for the sale of Biosimilars and restricting access for the sale of Biosimilars in Canada until 2021, instead of an earlier date including as early as 2017; and

(iii) to fix, maintain, control, prevent, lessen or eliminate the production or supply of a Biosimilar by agreeing to delay the entry of Biosimilars in Canada to 2021, instead of an earlier date including as early as 2017;

(f) in the alternative, a declaration that AbbVie US, a U.S. company which carries on business in Canada through its affiliate and/or a corporation it

controls, AbbVie Canada, implemented in whole or in part an agreement, directive, instruction, intimation of policy or other communication in Canada to give effect to a conspiracy, combination, agreement, or arrangement as made in the United States, which would have been in contravention of section 45 of the *Competition Act* if originally made in Canada, for which any director or officer in Canada or otherwise conducting business in Canada, knew or ought to have known of, or in the alternative willfully and/or blindly and/or recklessly followed, any such conspiracy, combination, agreement or arrangement, in breach of section 46 of the *Competition Act*;

(g) in the further alternative, a declaration that Amgen US, a U.S. company which carries on business in Canada through its affiliate and/or a corporation it controls, Amgen Canada, implemented in whole or in part an agreement, directive, instruction, intimation of policy or other communication in Canada to give effect to a conspiracy, combination, agreement, or arrangement as made initially in the United States which would have been in contravention of section 45 of the *Competition Act* if originally made in Canada, for which any director or officer in Canada or otherwise conducting business in Canada, knew or ought to have known of, or in the alternative willfully and/or blindly and/or recklessly followed, any such conspiracy, combination, agreement or arrangement, in breach of section 46 of the *Competition Act*;

(h) in the further alternative, a declaration that Samsung Bioepis, a South Korean company, which carries on business in Canada and the United States, implemented in whole or in part an agreement, directive, instruction, intimation of policy or other communication in Canada to give effect to a

conspiracy, combination, agreement, or arrangement as made initially in the United States, which would have been in contravention of section 45 of the *Competition Act* if originally made in Canada, for which any director or officer in Canada or otherwise conducting business in Canada, knew or ought to have known of, or in the alternative willfully and/or blindly and/or recklessly followed, any such conspiracy, combination, agreement or arrangement, in breach of section 46 of the *Competition Act*;

(i) in the further alternative, a declaration that Mylan, which are U.S. companies which carry on business in Canada and the United States, implemented in whole or in part an agreement, directive, instruction, intimation of policy or other communication in Canada to give effect to a conspiracy, combination, agreement, or arrangement as made initially in the United States, which would have been in contravention of section 45 of the *Competition Act* if originally made in Canada, for which any director or officer in Canada or otherwise conducting business in Canada, knew or ought to have known of, or in the alternative willfully and/or blindly and/or recklessly followed, any such conspiracy, combination, agreement or arrangement, in breach of section 46 of the *Competition Act*;

(j) in the further alternative, a declaration that Sandoz US., a U.S. company, which carries on business in Canada through its affiliate and/or a corporation it controls, Sandoz Canada, implemented in whole or in part an agreement, directive, instruction, intimation of policy or other communication in Canada to give effect to a conspiracy, combination, agreement, or arrangement as made initially in the United States, which would have been in contravention of section 45 of the *Competition Act* if originally made in

Canada, for which any director or officer in Canada or otherwise conducting business in Canada, knew or ought to have known of, or in the alternative willfully and/or blindly and/or recklessly followed, any such conspiracy, combination, agreement or arrangement, in breach of section 46 of the *Competition Act*;

(k) in the further alternative, a declaration that Fresenius US, a U.S. company, which carries on business in Canada through its affiliate and/or a corporation it controls, Fresenius Canada, implemented in whole or in part an agreement, directive, instruction, intimation of policy or other communication in Canada to give effect to a conspiracy, combination, agreement, or arrangement as made initially in the United States, which would have been in contravention of section 45 of the *Competition Act* if originally made in Canada, for which any director or officer in Canada or otherwise conducting business in Canada, knew or ought to have known of, or in the alternative willfully and/or blindly and/or recklessly followed, any such conspiracy, combination, agreement or arrangement, in breach of section 46 of the *Competition Act*;

(l) in the further alternative, a declaration that Pfizer US, a U.S. company, which carries on business in Canada through its affiliate and/or a corporation it controls, Pfizer Canada, implemented in whole or in part an agreement, directive, instruction, intimation of policy or other communication in Canada to give effect to a conspiracy, combination, agreement, or arrangement as made initially in the United States, which would have been in contravention of section 45 of the *Competition Act* if originally made in Canada, for which any director or officer in Canada or otherwise conducting

business in Canada, knew or ought to have known of, or in the alternative willfully and/or blindly and/or recklessly followed, any such conspiracy, combination, agreement or arrangement, in breach of section 46 of the *Competition Act*;

(m) a declaration that the referenced agreement, directive, instruction, intimation of policy or other communication to give effect in Canada to the conspiracy, combination, agreement, or arrangement caused damage to the Plaintiff and Class Members;

(n) damages or compensation, calculated on an aggregate basis or otherwise, in the amount of $2.2 Billion, or such additional or other sum as is determined at trial, for breach of Part VI, sections 45(1)(a)(b) and (c) of the *Competition Act* pursuant to Part IV, section 36 of the *Competition Act* and 334.28 of the *Federal Courts Rules*;

(o) in the alternative, damages or compensation, calculated on an aggregate basis or otherwise, in the amount of $2.2 Billion, as against each of the Defendants carrying on business in Canada, or such additional or other sum as is determined at trial, for breach of Part VI, section 46 of the *Competition Act* pursuant to Part IV, section 36 of the *Competition Act* and 334.28 of the *Federal Courts Rules*;

(p) pre-judgment and post-judgment interest in accordance with sections 36 and 37 of the *Federal Courts Act*;

(q) costs of both the investigation and prosecution of the action, including applicable taxes, on a full or complete indemnity basis pursuant to section 36 of the *Competition Act* and the *Federal Courts Rules*;

(r) the costs of notice and administering the plan of distribution of the recovery in this action, plus applicable taxes, pursuant to Rules 334.16(1) and 334.28 of the *Federal Courts Rules*;

(s) pre-judgment and post-judgment interest; and

(t) such further and other relief as this Honourable Court may deem just.

OVERVIEW

2. Humira is a biologic injectable solution containing the antibody Adalimumab which is indicated to treat a variety of chronic inflammatory conditions, including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn's disease, and ulcerative colitis, which was manufactured originally by AbbVie US and AbbVie Biotechnology Ltd., and is now manufactured solely by AbbVie US pursuant to registered patents in the US, Canada and elsewhere globally, and marketed, promoted, and sold by AbbVie under the brand name Humira ("Humira").

3. Humira is presently one of the best-selling prescription drugs in the world, with over $130 billion in total sales since its global launch in or around 2003.

4. Humira is the single largest revenue source for AbbVie, with sales of nearly $20 billion in 2018 alone, which account for approximately 61% of the company's global revenues.

5. Humira was first approved by Health Canada in or around 2004. In 2020, Humira sales in Canada were nearly $974 Million.

6. Humira's list price can now reach $50,000 per year per patient.

7. In 2017, AbbVie was subject to a Voluntary Compliance Undertaking in Canada with respect to pricing requirements for Humira with the Patented Medicines Price Review

Board ("PMPRB") to ensure compliance with pricing requirements and to repay any excess revenues collected between 2017 and 2019.

8. Despite the expiry of the primary patent for Humira and eight other manufacturers developing Biosimilars in the United States, AbbVie has successfully prevented all Biosimilars from launching in the U.S. market through its conduct that has allowed it to maintain its monopoly and supra-competitive prices. AbbVie has made agreements with drug manufacturers, who are competitors or reasonably likely to compete with AbbVie in the absence of an agreement, in the United States to allocate sales, territories, customers or markets for the production or supply of Biosimilars which had a consequential effect of preventing the production or supply of the Biosimilar in the United States and thereby ensuring that patients pay a non-competitive price for the patented product, Humira, in the United States. In implementing and carrying out these agreements made in the United States, the parties to said agreements likewise agreed to and in fact prevented any Biosimilar from launching in the Canadian market, which ensured that patients in Canada paid a non-competitive price for Humira.

9. The eight U.S. or Korean-based manufacturers that were parties to the anti-competitive agreements are listed as follows, along with the date of a confidential agreement with AbbVie in the United States, not to compete in the United States until at least 2023 with a right for early entry in the European Union:

a) Amgen US, with a settlement dated 28 September 2017 including an agreed entry date in the United States of 31 January 2023;

b) Samsung Bioepis, with a settlement date of 5 April 2018 including an agreed entry date in the United States of 30 June 2023;

c) Mylan Inc., with a settlement date of 17 July 2018 including an agreed

entry date in the US of 31 July 2023;

d) Sandoz US, with a settlement date of 11 October 2018 including an agreed entry date in the United States of 30 September 2023;

e) Fresenius US, with a settlement date of 17 October 2018 including an agreed entry date in the United States of 30 September 2023;

f) Momenta Pharmaceuticals Inc., who is not a defendant to this action, with a settlement date of 6 November 2018 including an agreed entry date in the United States of 20 November 2023;

g) Pfizer US, with a settlement date of 30 November 2018 including an agreed entry date in the United States of 20 November 2023; and

h) Coherus BioSciences, Inc., who is not a defendant to this action, with a settlement date of 25 January 2018 including an agreed entry date in the United States of 15 December 2023.

10. Amgen US had its biosimilar approved by the FDA on 23 September 2016, however, it has not been marketed to date in the United States but is on the Ontario Formulary at least as early as 29 March 2021 in Canada. Similarly, Sandoz US had its biosimilar approved by the FDA on 31 October 2018, however, it has not been marketed to date in the United States but is on the Ontario Formulary at least as early as 29 March 2021 in Canada.

11. Through the aforementioned agreements, AbbVie has erected significant barriers to entry to block competition from Biosimilars. These agreements were entered as part of a concerted effort to delay the entry of a Biosimilar in the United States until at least 2023, as well as delaying their entry into Canada as well. Meanwhile, as part of the trade-off in the

agreements, patients in Europe do not have to wait for the benefits of Biosimilar competition, as AbbVie agreed to earlier entry dates of entry thereby permitting Biosimilar competitors. This trade-off meant that the lower price for Humira in Europe was subsidized by the much higher price in the United States and Canada, where AbbVie unlawfully maintained its monopoly.

12. The different drug pricing landscape in Europe means that, when Biosimilars enter in that jurisdiction, the economic effect to AbbVie is less than it would be in the United States. Accordingly, AbbVie has strategically agreed with the other Defendants to permit entry of their Biosimilars in Europe years earlier than the 2023 date for entry into the U.S. market and the 2021 entry date in Canada.

13. Absent the agreements in the United States and Canada,, Biosimilars would have launched in Canada, as well as the United States, years earlier. The primary patent for Humira in Canada, No. 2,243,459 (the "Primary Patent"), expired on 10 February 2017 in Canada. However, AbbVie has applied for nearly 250 patents in the United States since its biologic was first developed, 89% of which were filed after the FDA's approval of its initial new drug application. Humira is now blanketed by over 100 issued patents in the United States. Many of these additional patents expire in 2034, over three decades since the drug's launch.

14. In Canada, a series of patents have also been filed and registered subsequent to the Primary Patent expiring in 2017, which are properly characterized as constituting add-ons or "ever-greening" for additional inflammatory conditions already disclosed by the prior art or involve methods of treatment. Notwithstanding, Notices of Compliance were issued to the Defendants who were competitors to AbbVie, yet these competitors did not enter the Canadian market for three years after these Notices of Compliance were issued to them.

15. The aforementioned competitors have opted to settle and AbbVie has entered into

unlawful market division agreements in Canada with these manufacturers.

16. Through the agreements, the Defendants, who were the parties to said agreements, illegally allocated the market for Adalimumab. AbbVie has consequently maintained its Adalimumab monopoly in the U.S. market and continues to charge inflated prices, capturing nearly $20 billion in revenues, while allowing Biosimilars to sell in the European market, notwithstanding registered patents for Humira, where drug prices, and hence profits, are generally much lower.

17. The Defendants had made and implemented anti-competitive agreements in Canada, giving effect to a conspiracy, agreement, combination or arrangement, as entered into by the US-based defendants, to prohibit the introduction into the Canadian market of Biosimilars until at least as early as 2021, three-years after the first NOC was issued. Pursuant to these agreements, all of the Canadian based defendant manufacturers delayed introduction of their respective Biosimilars for one to three years until 2021 after obtaining their own respective NOC's at earlier time frames.

18. Absent anti-competitive agreements, there would have been competition between AbbVie and the other defendant manufacturers based in Canada, leading to a decrease in pricing. This competition would have led to at least a 40% reduction in the price with the presence of at least one competitor and considerably more if there were a number of competitors. Instead, due to the anti-competitive agreements, the Plaintiff and Class Members incurred significant additional costs to purchase Humira absent the availability of Biosimilars for a period up to three years.

19. Absent the Defendants' conduct in the United States and by anti-competitive agreements and their impact in Canada, the Plaintiff and Class Members would have been able to purchase, at significantly lower prices than what AbbVie has charged for Humira, Biosimilars as early as 8 May 2018 in Canada, the date on which a Notice of Compliance

("NOC") was issued to Samsung Bioepis for its Biosimilar.

20. A market division agreement by rivals, such as the ones at issue in this litigation, is anticompetitive regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other.

21. Accordingly, the Plaintiff brings this action on behalf of himself and the Class Members in order to redress the economic injury the Defendants have already caused, and continue to cause, including by seeking remedial relief pursuant to section 36 of the *Competition Act* for a breach of sections 45 and 46 thereof.

THE PARTIES

Plaintiff

22. Kevin Hughes ("Kevin") is an individual residing in Ottawa, Ontario. Kevin was diagnosed with Crohn's Disease in or around 2007 and was prescribed and has been taking Humira as a subcutaneous injection on a bi-weekly basis as a treatment since late 2008. Kevin has paid for Humira directly during periods while uninsured, at which time he incurred as an out-of-pocket expense the full purchase price. During the periods when Kevin had private insurance through an employer-based plan, his insurance would cover either part of the full purchase price or the full purchase price of Humira, with Kevin paying as an out-of-pocket expense any difference not covered by his insurance.

The Canadian Defendants and International Defendants

23. Defendant AbbVie Canada is a Canadian company with its principal place of business at 8401 Trans-Canada Highway, Saint-Laurent, Quebec, Canada, H4S 1Z1, which has sold Humira throughout Canada. AbbVie Inc. is a Delaware corporation with its principal place of business at 1 North Waukegan Road, North Chicago, IL, 60064.

24. Defendant AbbVie US is a Delaware corporation with its principal place of

business at 1 North Waukegan Road, North Chicago, IL 60064.

25. Defendant AbbVie Biotechnology Ltd. is a Bermuda corporation with its principal place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda.

26. As stated above, AbbVie US and AbbVie Biotechnology Ltd. are together referred to herein as "AbbVie International, and Abbvie US, Abbvie Biotechnology Ltd. and Abbvie Canada are collectively referred to as "Abbvie".

27. Defendant Amgen Canada is a Canadian company with its principal place of business at 6775 Financial Drive, Suite 100., Mississauga, Ontario, L5N 0A4. Amgen Inc., is a Delaware corporation with its principal business at One Amgen Center Drive, Thousand Oaks, CA, 91320.

28. Defendant Samsung Bioepis is a company organized and existing under the laws of the Republic of Korea with its principal place of business at 107, Cheomdan-daero, Yeonsu-gu, Incheon, Republic of Korea.

29. Defendant Sandoz Canada is a Canadian company with its principal place of business at 110 de Lauzon, Boucherville, Quebec, J4B 1E6.

30. Defendant Sandoz US is a Colorado corporation with its principal place of business at 100 College Rd. West, Princeton, NJ 08540. Sandoz is a subsidiary of Novartis AG, a global pharmaceutical company based in Basel, Switzerland.

31. Defendant Fresenius Canada is a Canadian company whose principal place of business is at 165 Galaxy Blvd., Suite 100, Toronto, Ontario, M9W 0C8.

32. Defendant Fresenius US is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, IL 60047.

33. Defendant Pfizer Canada is a Canadian company whose principal place of business

is at 17300 Trans-Canada Highway, Kirkland, Quebec, H9J 2M5. Pfizer Inc., is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, NY 10017.

34. Defendant Amgen US is a Delaware corporation with its principal place of business at One Amgen Center Drive, Thousand Oaks, CA 91320.

35. Defendant Viatris Inc., formerly Mylan Canada, ULC ("Viatris Canada"), is a Canadian company with its principal place of business at 85 Advance Road, Etobicoke, Ontario, M8Z 2S6.

36. Defendant Mylan Inc. isa Pennsylvania corporation with its principal place of business at 1000 Mylan Blvd., Canonsburg, PA 15317.

37. Defendant Mylan Pharmaceuticals, Inc., is a West Virginia corporation with its principal place of business at 781 Chestnut Ridge Rd., Morgantown, WV 26505, and a subsidiary of Mylan Inc.

38. Defendant Mylan Inc. is a Pennsylvania corporation with its principal place of business at 1000 Mylan Blvd., Canonsburg, PA 15317. Mylan Inc. is a wholly-owned subsidiaries of Mylan N.V., a Dutch pharmaceutical company.

39. As stated above, Mylan Inc. and Mylan Pharmaceuticals, Inc. are collectively referred to herein as "Mylan".

40. Defendants AbbVie Canada, AbbVie International, Amgen Canada, Amgen US, Samsung Bioepis, Mylan, Viatris Canada, Sandoz Canada, Sandoz US, Fresenius Canada, Fresenius US, Pfizer Canada, and Pfizer US, are collectively referred to as the "Defendants."

THE CLASS

41. The Plaintiff proposes the Class to include:

> All persons who are residents of Canada except Excluded Persons, as defined below, who were prescribed and/or advised by a medical practitioner to use Humira for the treatment of a medical condition since as early as 8 May 2018 and up to and including the date of certification.

FACTS SUPPORTING THE CLAIMS AGAINST THE DEFENDANTS

The Market for Biologics and Biosimilars

42. Biologics encompass a wide range of products, including "vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins." They can be composed of sugars, proteins, or nucleic acids, or combinations of these substances, or may even be living cells and tissues. They are derived from a variety of natural sources, including human, animal, or micro-organism. Biologics are used to treat a range of diseases including cancer, rheumatoid arthritis, diabetes, and anemia.

43. Biologics are more complex than small-molecule drugs. Due to a biologic's complexity, biosimilars, the generic equivalent of biologics, are generally more challenging and expensive to produce than small-molecule generic drugs.

44. As healthcare costs continue to rise, biosimilars offer significant cost savings opportunities for drug purchasers, insurers, and patients.

45. In the U.S., a Federal Trade Commission ("FTC") study found that biosimilars can be as much as 30% cheaper than the innovator biologics. In Canada, the price of biosimilars can be 40% or more cheaper than the corresponding biologics. In addition to the reduction in the price of the biosimilars, studies on the effects of biosimilar competition

in Europe found that pioneer biologic manufacturers also reduce prices on their innovator biologics in the face of biosimilar competition. One biosimilar manufacturer projected that biosimilars could generate $250 billion in savings to consumers over ten years in the U.S. In Canada, savings may range from $400 Million to $800 Million per year from the introduction of a Biosimilar to Humira alone, leading to a savings of $1.2 Billion to $2.4 Billion over three years.

AbbVie's Acquisition and Development of Adalimumab

46. Adalimumab, the antibody underlying AbbVie's blockbuster biologic Humira, was originally developed through a partnership between BASF AG and Cambridge Antibody Technology.

47. On February 9, 1996, BASF AG filed a U.S. patent application disclosing Adalimumab, which later was issued as U.S. Patent No. 6,090,382 ("the '382 Patent"). The '382 Patent is the primary patent in the United States underlying Humira and created exclusivity in Adalimumab, formulations containing Adalimumab, and methods of making and using Adalimumab.

48. Just five years later, on March 2, 2001, Abbott Laboratories ("Abbott"), the predecessor to AbbVie through a spin-off in 2013, purchased BASF AG's pharmaceutical business for $6.9 billion, which included the rights to Adalimumab.

49. At the time of purchase, Abbott was aware that the '382 Patent was set to expire in December 2016.

50. On December 31, 2002, the FDA approved AbbVie's Biologics License Application ("BLA") No.125057, Humira (Adalimumab), 40 mg/0.8 mL single-use syringes, for use in treating humans. Adalimumab was the first fully human antibody approved by the FDA.

51. Humira, which is administered to a patient by injection, was originally indicated for

moderate to severe rheumatoid arthritis in adults, but over time was approved for a number of additional indications. Health Canada has approved Humira for the following indications to date:

a. rheumatoid arthritis;

b. polyarticular juvenile idiopathic arthritis;

c. psoriatic arthritis;

d. ankylosing spondylitis;

e. adult and pediatric (13 to 17 years of age weighing ≥ 40 kg) Crohn's disease;

f. adult and pediatric (5 to 17 years of age) ulcerative colitis;

g. adult and adolescent (12 to 17 years of age weighing ≥ 30 kg) hidradenitis suppurativa;

h. psoriasis; and

i. adult and pediatric uveitis.

The FDA Has Approved Adalimumab Biosimilars in the U.S. Market

52. Given the massive size of the market for Humira (with global annual sales reaching nearly $20 billion in 2018 alone), many other pharmaceutical manufacturers have developed Adalimumab Biosimilars in an effort to compete.

53. On September 23, 2016, in response to BLA No. 761024, Defendant Amgen US received FDA approval for its Biosimilar, Amgevita Injection, 20 mg/0.4 mL and 40 mg/0.8 mL. Amgevita is indicated for rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, and plaque psoriasis.

54. On August 25, 2017, in response to BLA No. 761058, Boehringer Ingelheim

International GmbH along with its affiliated companies Boehringer Ingelheim Pharmaceutical, Inc. and Boehringer Ingelheim Fremont, Inc. (collectively, "Boehringer"), received FDA approval for Cyltezo (adalimumab-adbm), 40 mg/0.8 mL. Cyltezo is indicated for rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, and plaque psoriasis.

55. On October 30, 2018, in response to BLA No. 761071, Defendant Sandoz US received FDA approval for Hyrimoz (adalimumab-adaz), 40 mg/0.8 mL. Hyrimoz is indicated for rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, and plaque psoriasis.

56. Meanwhile, Defendant Samsung Bioepis filed its BLA in September 2018 seeking approval of its Biosimilar, Imraldi, and received FDA approval on 24 July 2019.

57. AbbVie US spent considerable effort seeking U.S. approval for hundreds of patents related to Humira, which is not the case in Canada..

58. To date, nearly every Biosimilar manufacturer has settled with AbbVie (either after litigation or threat of litigation). Those competitors have agreed to delay launching their Biosimilars in the U.S. until 2023.

The Defendants entered into Market Division Agreements to Eliminate and Delay Biosimilar Competition

59. Between September 2017 and November 2018, the Defendants entered into a series of confidential agreements that eliminate and delay sales of Biosimilars from the U.S. market until at least January 2023. The agreements, while announced as settlements or licensing agreements, operate as market division between the U.S. and European markets. As in the U.S., AbbVie had Humira patent protection in Europe. However, AbbVie ceded the European market to biosimilar competition, despite its extensive patent

protection, in exchange for maintaining its monopoly in the U.S., as well as Canada as set out below.

60. On 28 September 2017, AbbVie announced an agreement with Amgen US to globally resolve intellectual property-related litigation over Amgen's Biosimilar, Amgevita. AbbVie granted Amgen US a licence to launch in Europe on 16 October 2018. Amgen US' licence blocks a U.S. launch until 31 January 2023, more than four years later. Amgen US agreed to pay licensing royalties to AbbVie as part of the resolution.

61. On 5 April 2018, AbbVie announced an agreement with Samsung Bioepis to globally resolve intellectual property-related litigation over Samsung Bioepis's Biosimilar, Imraldi (Hadlima in Canada). AbbVie granted Samsung Bioepis a licence to launch in Europe on 16 October 2018. Samsung Bioepis's licence blocks a U.S. launch until 30 June 2023, again more than four years later. Samsung Bioepis US agreed to pay licensing royalties to AbbVie as part of the resolution.

62. On 17July 2018, AbbVie announced an agreement with Mylan US to licence Mylan's Biosimilar, Hulio. AbbVie granted Mylan US, through its global partner Fujifilm Kyowa Kirin Biologics Co., Ltd., a sublicence to launch its Biosimilar in Europe on 16 October 2018. Mylan's licence blocks a U.S. launch until 31 July 2023, more than four years later. Mylan US agreed to pay licensing royalties to AbbVie as part of the resolution.

63. On 11 October 2018, AbbVie announced an agreement with Sandoz US to globally resolve intellectual property-related litigation over its Biosimilar, Hyrimoz. AbbVie granted Sandoz US a licence to launch in Europe on 16 October 2018. Sandoz's licence for the U.S. blocks a U.S. launch until 30 September 2023, nearly five years later. Sandoz US agreed to pay licensing royalties to AbbVie as part of the resolution.

64. On 18 October 2018, AbbVie announced an agreement with Fresenius US to

globally resolve intellectual property-related litigation over its Biosimilar, MSB11022. AbbVie granted Fresenius US a licence to launch in Europe upon approval from the European Medicines Agency. Fresenius's licence blocks a U.S. launch until 20 September 2023. Fresenius US agreed to pay licensing royalties to AbbVie as part of the resolution.

65. On 6 November 2018, AbbVie announced an agreement with Momenta to licence Momenta's Biosimilar, M923. AbbVie granted Momenta a licence to launch in Europe upon approval from the European Medicines Agency. Momenta's licence in the U.S. blocks a U.S. launch until November 20, 2023. Momenta agreed to pay licensing royalties to AbbVie as part of the resolution.

66. On 30 November 2018, AbbVie announced an agreement with Pfizer US to licence its Biosimilar, PF-06410293. AbbVie granted Pfizer US a non-exclusive licence to launch in Europe upon approval from the European Medicines Agency. Pfizer US's licence blocks a U.S. launch until November 20, 2023. Pfizer US agreed to pay licensing royalties to AbbVie as part of the resolution.

67. The timeline below demonstrates that no biosimilar could launch in the U.S. until at least 31 January 2023:

Competitor	Biosimilar	U.S. Launch Date
Amgen US	Amgevita	31 January 2023
Samsung Bioepis	Imraldi	30 June 2023
Mylan US	Hulio	31 July 2023
Sandoz US	Hyrimoz	30 September 2023
Fresenius Kabi US	MSB11022	30 September 2023

Pfizer US	PF-06410293	20 November 2023

68. As a result of this market division arrangement, AbbVie has blocked Biosimilars from the U.S. market until 2023. Meanwhile, the remaining Defendants, who settled patent disputes with AbbVie, are today selling Biosimilars in Europe.

69. Through these agreements, AbbVie and the other Defendants have divided the markets for Humira and its Biosimilars. In exchange for allowing unimpeded European market entry, AbbVie secured an obligation by the remaining Defendants to delay entry into the U.S. market until 2023, and likewise delayed entry into Canada as set out below.

70. Biosimilar competition necessarily has a significant impact on pricing. Upon entry of Biosimilars, from its already lower price in Europe, Humira's price has dropped between 10% and 80% depending on jurisdiction.

71. With no competition in Canada prior to introduction of Biosimilars in 2021, AbbVie's price for Humira skyrocketed since the drug's launch in 2003, and can now cost each patient $50,000 per year.

Monopoly Power and Market Definition

72. Only biologics that are Biosimilars can be substituted for Humira.

73. AbbVie needed to control only Humira and its Biosimilars, and no other products, in order to maintain a non-competitive price of Humira. Only the market entry of a competing Biosimilar would render AbbVie unable to profitably maintain its prices of Humira without losing substantial sales.

74. AbbVie, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product and geographic markets due to

patent and other regulatory protections and high costs of entry and expansion.

75. AbbVie has maintained and exercised the power to exclude and restrict competition to Humira and Biosimilars.

76. Before the introduction of Biosimilars, AbbVie's market share in the relevant market in Canada was at or near 100%.

The anti-competitive conduct in Canada

77. Each of the U.S. company Defendants that made an agreement with AbbVie in the U.S. to carve out markets in Europe in exchange for agreeing to enter in the U.S. at a later date in 2023, regardless of registered patents relating to Humira still being in force in the U.S., also made and implemented a Canadian version of that agreement in Canada in or around April of 2018 (the "Canadian Agreement"), either through the Defendant affiliates and subsidiaries of these U.S. companies in Canada or through the Defendant company itself if it had no affiliate or subsidiary in Canada. The Canadian Agreement set out and had the purpose and effect of ensuring no Biosimilar would enter the Canadian market place until at least 2021, despite the Primary Patent expiring approximately three years earlier.

Litigation in Canada and Notices of Compliance

78. Samsung Biopepis served Notices of Allegation for each of the following Canadian patents that AbbVie Canada had listed on the Patent Register as it's Notice of Compliance ("NOC") submissions for its Biosimilar, Hadlima, were making a direct comparison to Humira:

(i) Patent No. 2,385,745;

(ii) Patent No. 2,494,756;

(iii) Patent No. 2,847,142; and

(iv) Patent No. 2,504,868.

79. It is duly noted that by the time of filing of the applications by Samsung Bioepis, the main patent for Humira in Canada, Patent No. 2,243,459 (the Primary Patent as defined above), effectively for a monoclonal antibody (Humira) used in the treatment of inflammatory diseases, had already expired on or about 10 February 2017. Samsung Bioepis sought to impeach patents underlying Humira in Canada; it alleged material misrepresentation as well as patent invalidity on the grounds of anticipation, obviousness, double-patenting, lack of utility, over breadth, insufficiency, ambiguity and unpatentable subject matter with respect to medical treatment.

80. On 25 April 2017, AbbVie Canada initiated eight applications pursuant to the Regulations in response to the Notice of Allegations for orders prohibiting the Minister of Health from issuing NOC's to Samsung Bioepis for its Biosimilar.

81. However, on or about 10 April 2018, AbbVie Canada settled with Samsung Bioepis during the cross-examination phase of the litigation, as part of a global settlement between AbbVie and Samsung Bioepis. Canadian terms of settlement have never been disclosed nor is there a statutory or regulatory requirement to disclose such settlement terms in Canada. In the US, terms of settlement between AbbVie and the US Defendants included a right to enter the market in the European Union through a licence as early as 16 October 2018 and to enter the US market in 2023; royalty payments based on licencing of specific patents will be applicable, although the specific patents subject to licence have not been clarified publicly.

82. The Biosimilar manufactured by Samsung Bioepis, Hadlima, was approved by Health Canada and a NOC was issued on 8 May 2018. However, due to the agreement

with AbbVie, Samsung Bioepis did not market Hadlima until 2021, when it was first listed on the *Ontario Drug Benefit Formulary/Comparative Drug Index* (the "Formulary").

83. Five other Biosimilars were approved by Health Canada within a 6-month period and each were promptly listed on the Ontario Formulary, effective on 29 March 2021, the same day as Hadlima, as set out below:

Competitor	Biosimilar	Canadian NOC Granted
Amgen	Amgevita	4 November 2021
Samsung Bioepis	Hadlima	8 May 2018
Viatris (Mylan US) through a licence with BGP Pharma ULC	Hulio	24 November 2020
Sandoz	Hyrimoz	4 November 2020
Fresenius Kabi	Idacio	30 October 2020
Pfizer	Abrilada	14 January 2021

84. None of the other biosimilar manufacturers, namely the Amgen Canada, Viatris Canada, Sandoz Canada, Fresenius Canada, and Pfizer Canada Defendants, ever challenged the patents underlying Humira in Canada, yet all applied for and received NOC's for a Biosimilar during the same time frame in Canada and were listed on the Ontario Formulary on the same day on and other provincial formularies shortly thereafter.

Switching Rates and Price Decreases with Increased Competition

85. Switching rates, which are the percentages of new prescriptions and renewals or refills of existing prescriptions change from the biologic to an available biosimilar, have steadily increases for other biologics introduced in Canada. The average switching rate in Ontario for biologics is currently estimated to be approximately 40%. Uptake of biosimilars in European Union member states has traditionally been significantly higher. With the aim of increasing switching rates in Canada given the significant cost savings that come with the prescribing of a biosimilar as compared to the corresponding biologic, provinces led by British Columbia and Alberta have instituted new policies and mandates for biosimilar switching which has and will continue to necessarily result in increasing switching rates; in British Columbia alone, approximately 75% of all patients being treated with a biologic have switched to biosimilars under their new policy. In Alberta, a Biosimilars Initiative policy was launched in 2019 and has succeeded in switching 16% of patients from using certain reference biologics to biosimilars by 2021, including 30% of Infliximab (Remicade) users, a biologic which is also a monoclonal antibody.

86. The increase in switching rates following introduction of a biosimilar, however, is gradual rather than sudden and occurs over the course of years after the introduction of a biosimilar.

87. The cost incentives to switch from a biologic to a biosimilar in Canada are very significant. For example, on the provincial formularies which set out the reimbursement price for drugs and biologics/biosimilars which are covered at least in part by a provincial drug plan, the price for the biosimilar is significantly lower than the reference biologic. On the Ontario Formulary, biosimilars are priced at a discount based on the number of approved biosimilars, with an average discount of approximately 40% of the reference biologic. In addition to the discounted price of the biosimilar, the introduction of a biosimilar

also leads to a decrease in price of the reference biologic. As with switching rates, the drop in price of the biologic is not immediate but rather is gradual over a number of years.

88. Economic analyses of generic small molecule drug entry into the market place within the first month after a patent expires have indicated that the generic manufacturer can expect to receive 50% of the generic market share in the following years. The introduction of multiple competitors will have an increased effect on price as well as on the share of the market place. Since the recent introduction of biologics and biosimilars into the drug marketplace, this effect has similarly been demonstrated in different jurisdictions and will likely approach parity with the effect seen in the small molecule drug market.

89. Although all the terms of the settlement agreement in Canada between AbbVie and Samsung Bioepis are not known, the Plaintiff and other Class Members would have necessarily paid an anti-competitive premium for the purchase of Humira in Canada, as would the provincial governments as they began to pay for medical use of the biologic for its residents covered under a provincial drug plan. The Defendants manufacturing Biosimilars to Humira had the benefit of entering into the European market place earlier than would have been otherwise feasible had AbbVie launched challenges to their introduction under the respective intellectual property regimes in each jurisdiction, due to the unlawful conspiracy between competitors or would-be competitors, and as the trade-off in the agreement the markets in North America were unduly protected from any form of competition until at least as early as 2021 in Canada and 2023 in the U.S.

Discoverability and Fraudulent Concealment

90. The Plaintiff pleads and relies on the doctrine of Fraudulent Concealment.

91. The Plaintiff and other Class Members reasonably considered and/or would reasonably consider pricing for Humira to be in accordance with the law and that any

litigation between AbbVie and Samsung Bioepis in Canada or between AbbVie US and any other party in the US. or elsewhere, if applicable, to also be in accordance with the law.

92. The Plaintiff and Class Members did not discover and could not discover through their exercise of due diligence, the existence of an illegal conspiracy with respect to the anti-competitive agreements between the Defendants, nor specifically the Canadian Agreement through which the Defendants would not permit a Biosimilar into the Canadian market place until 2021.

93. The Defendants conducted themselves through confidential settlement agreements as part of a litigation process in such a manner so as to preclude detection of the anti-competitive agreements, including the Canadian Agreement.

94. AbbVie along with the other Defendants, actively, intentionally, and fraudulently concealed the existence of the illegal anti-competitive conspiracy, being the Canadian Agreement in Canada, from the public including the Plaintiff and other Class Members and represented that its litigation settlement agreements, in Canada and internationally, were in accordance with the law, thereby misleading the Plaintiff and other Class Members and concealing their illegal conduct that is the subject matter of this litigation. The Plaintiff and Class Members were consequently unaware of the unlawful nature of the Canadian Agreement and the effect it had on the pricing of Humira in Canada.

BREACH OF THE *COMPETITION ACT*

95. The Defendants are legally independent of one another and are competitors in the respective market, for the purposes of section 45 of the *Competition Act*.

96. As particularized above in the Claims section, the Defendants conspired, agreed or arranged with each other to engage in anti-competitive acts in contravention of sections

45(1)(a)(b) and (c) of the *Competition Act*:

(i) to fix, maintain, increase or control the price for Humira in Canada by agreeing to delay the entry of Biosimilars into the Canadian market;

(ii) to allocate sales, territories, customers, and markets for the production and supply of a Biosimilar by making arrangements to provide the manufacturers of Biosimilars early access to European markets for the sale of Biosimilars and restricting access for the sale of Biosimilars in Canada until 2021, instead of an earlier date in 2017; and

(iii) to fix, maintain, control, prevent, lessen or eliminate the production or supply of a Biosimilar by agreeing to delay the entry of Biosimilars in Canada to 2021 instead of in 2017.

97. As particularized above, and in the alternative, each of Amgen Canada, Amgen US, Samsung Bioepis, Mylan US, Viatris Canada, Sandoz Canada, Sandoz US, Fresenius Canada, Fresenius US, Pfizer Canada, and Pfizer US conspired individually with AbbVie and agreed or arranged with each other to engage in anti-competitive acts in contravention of sections 45(1)(a)(b) and (c) of the *Competition Act*:

(i) to fix, maintain, increase or control the price for Humira in Canada by agreeing to delay the entry of Biosimilars into the Canadian market;

(i) to allocate sales, territories, customers, and markets for the production and supply of a Biosimilar by making arrangements to provide the manufacturers of Biosimilars early access to European markets for the sale of Biosimilars and restricting access for the sale of Biosimilars in Canada until 2021, instead of an earlier date in 2017; and

(ii) to fix, maintain, control, prevent, lessen or eliminate the production or

supply of a Biosimilar by agreeing to delay the entry of Biosimilars in Canada to 2021 instead of in 2017. All of which constitute a contravention of section 46(1) of the *Competition Act.*

98. As particularized above, and in the alternative, the Defendants carrying on business in Canada implemented in whole or in part an agreement, directive, instruction, intimation of policy or other communication in Canada to give effect to a conspiracy, combination, agreement or arrangement as made initially in the U.S. by the Defendant companies based in the United States, for which officers and directors in Canada knew or ought to have known of any such conspiracy, combination, agreement or arrangement or in the alternative willfully and/or blindly and/or recklessly followed any such conspiracy, combination, agreement or arrangement such that the Defendants carrying on business in Canada conspired, agreed and arranged with each other to engage in anti-competitive acts in contravention of sections 45(1)(a)(b) and (c) of the *Competition Act*:

(i) to fix, maintain, increase or control the price for Humira in Canada by agreeing to delay the entry of Biosimilars into the Canadian market;

(ii) to allocate sales, territories, customers, and markets for the production and supply of a Biosimilar by making arrangements to provide the manufacturers of Biosimilars early access to European markets for the sale of Biosimilars and restricting access for the sale of Biosimilars in Canada until 2021, instead of an earlier date in 2017; and

(iii) to fix, maintain, control, prevent, lessen or eliminate the production or supply of a Biosimilar by agreeing to delay the entry of Biosimilars in Canada to 2021 instead of in 2017. All of which constitute a contravention of section 46(1) of the *Competition Act.*

114. The Defendants' conduct caused loss and damage to the Plaintiff and other Class Members within the meaning of section 36(1) of the *Competition Act*. The Defendants are jointly and severally liable to pay damages to the Plaintiff and other Class Members, as well as the full cost of the investigation, pursuant to section 36 of the *Competition Act*.

DAMAGES

115. During the Class Period, the Plaintiff and other Class Members were impeded from the opportunity to purchase Biosimilars from at least 5 competitors as a result of the anti-competitive conduct as set out above as implemented in Canada with respect to these Biosimilars and, therefore, paid a higher price for Humira than they would have otherwise had Biosimilars been available.

116. The damages to the Plaintiff and other Class Members include the difference between the price actually paid as a result of the anti-competitive agreements and the price that would have been paid in the absence of the agreements.

117. The damages are capable of being quantified on an aggregate basis and the amounts payable to the classes in respect to damages may be calculated on an aggregate basis pursuant to Rule 334.28 of the *Federal Courts Rules.*

118. The Plaintiff and other Class Members plead and rely upon the *Federal Courts Act* and the *Competition Act*, and, all as amended.

CLASS PERIOD AND PLACE OF TRIAL

119. The Class Period is from 1 January 2018 until and including the date that the within proceeding is certified as a class proceeding.

120. The Plaintiff on behalf of the Class Members propose that this action be tried in Toronto, Ontario.

Date: 30 March 2023

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