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December 17, 2021

VIA EDIS

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E. Street, S.W., Room 112
Washington, D.C. 20436

Re: *Certain Adalimumab, Processes for Manufacturing or Relating to Same, and Products Containing Same,*
Investigation No. 337-TA-____

Dear Secretary Barton:

Enclosed for filing on behalf of Complainants AbbVie Inc., AbbVie Biotechnology Ltd, and AbbVie Operations Singapore Pte. Ltd. (collectively "AbbVie") are documents in support of Complainants' request that the Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, concerning certain adalimumab, processes for manufacturing or relating to the same, and products containing the same. A request for confidential treatment of Confidential Exhibits A, B, F-J, and M is also being submitted.

In accordance with the Commission's Temporary Change to the Filing Procedures dated March 16, 2020 ("Temporary Procedures"), and the guidance provided on the Commission's "COVID-19-RELATED QUESTIONS" webpage, Complainants submits the following documents for filing via EDIS:

1. A Statement on the Public Interest with respect to remedial orders Complainant seeks in the Complaint, pursuant to Commission Rule 210.8(b).

2. One (1) electronic copy of Complainants' Verified Complaint pursuant to Commission Rule 210.8(a)(1)(i);

3. One (1) electronic copy of the non-confidential exhibits to the Complaint, pursuant to Commission Rule 210.8(a)(1)(i);

4. One (1) electronic copy of the confidential exhibits to the Complaint, pursuant to Commission Rules 201.6(c) and 210.8(a)(1)(ii);

5. A letter and certification requesting confidential treatment for the information contained in Confidential Exhibits A, B, F-J, and M to the Complaint, pursuant to Commission Rule 210.5(d) and 201.6(b).

Thank you for your attention to this matter. Please contact me should you have any questions concerning this submission.

Respectfully submitted,

/s/ Mareesa A. Frederick

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Re: *Certain Adalimumab, Processes for Manufacturing or Relating to Same, and Products Containing Same,*
Investigation No. 337-TA-____

Dear Secretary Barton:

Complainants AbbVie Inc., AbbVie Biotechnology Ltd, and AbbVie Operations Singapore Pte. Ltd. (collectively "AbbVie") through its counsel, hereby requests, pursuant to 19 C.F.R. §§ 210.5 and 201.6, confidential treatment of the confidential business information contained in Confidential Exhibits A, B, F-J, and M to AbbVie's Complaint, which are being filed separately.

Confidential Exhibit A is an email from Rongzan Ho's AbbVie email address to his personal email address sent February 12, 2018.

Confidential Exhibit B is Rongzan Ho's exit declaration dated March 2, 2018.

Confidential Exhibit F is an email on behalf of Rongzan Ho to a current employee of AbbVie.

Confidential Exhibit G is the employment contract between Rongzan Ho and AbbVie Operations Singapore.

Confidential Exhibit H is the employment contract between Zhi Sheng ("Jason") Seah and AbbVie Operations Singapore.

Confidential Exhibit I is the employment contract between Yi Li ("Eunice") Tan and AbbVie Operations Singapore.

Confidential Exhibit J is an email from Rongzan Ho to a current AbbVie employee.

Confidential Exhibit M is a Declaration of Kristin Bartolucci relating to domestic industry.

The information described above qualifies as confidential information pursuant to 19 C.F.R. § 201.6 because:

a. it is not available to the public;

b. unauthorized disclosure of such information could cause substantial harm to AbbVie's competitive position; and

c. its disclosure could impair the Commission's ability to obtain information necessary to perform its statutory function.

Please contact me should you have any questions concerning this submission.

Respectfully submitted,

/s/ Mareesa A. Frederick

Mareesa A. Frederick

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of

CERTAIN ADALIMUMAB, PROCESSES FOR MANUFACTURING OR RELATING TO SAME, AND PRODUCTS CONTAINING SAME

COMPLAINANTS' STATEMENT REGARDING THE PUBLIC INTEREST

Pursuant to 19 C.F.R. § 210.8(b), Complainants AbbVie Inc., AbbVie Biotechnology Ltd, and AbbVie Operations Singapore Pte. Ltd. (collectively, "AbbVie" or "Complainants") respectfully submit this separate statement of public interest regarding the remedial orders AbbVie seeks against proposed Respondents Alvotech hf., Alvotech Germany GmbH, Alvotech Swiss AG, Alvotech USA Inc. (collectively, "Alvotech"), Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA Inc. (collectively, "Teva"), and Ivers-Lee AG (collectively, "Proposed Respondents").

Regarding remedial relief, AbbVie seeks a permanent limited exclusion order excluding from entry into the United States Proposed Respondents' adalimumab biosimilar whose production is based on trade secrets misappropriated from AbbVie ("Accused Products"). AbbVie also seeks permanent cease and desist orders, pursuant to Section 337(f), directing each Proposed Respondent, or subsidiaries or agents thereof, to cease and desist from importing, marketing, advertising, demonstrating, warehousing inventory for distribution, offering for sale, selling, distributing, licensing, or using the Accused Products in the United States.

I. INTRODUCTION

The issuance of the relief requested in the concurrently filed Complaint will not adversely impact the public health, safety, or welfare conditions in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers. Proposed Respondents seek to import and market the Accused Products for indications Complainants already market their products for. AbbVie alone is able to meet the demand for all adalimumab products needed in the United States. Moreover, AbbVie's first licensee is scheduled to enter the adalimumab biologic market beginning January 31, 2023, with additional licensees thereafter, thus creating additional supply in the U.S. market.

The requested Investigation, therefore, does not present an instance where a compelling

public interest might supersede the entry of the requested remedial orders in the event a violation is found. As such, the facts present in this Investigation do not warrant the time and expense of discovery into public interest issues, the presentation of evidence on the public interest before the ALJ, and issuance of a Recommended Determination by the ALJ on the public interest.

II. THE REQUESTED REMEDIAL ORDERS ARE IN ACCORD WITH THE PUBLIC INTEREST

A. How the Articles Potentially Subject to Remedial Orders Are Intended To Be Used in the United States

The Accused Products potentially subject to remedial orders in the proposed Investigation are human monoclonal antibodies that are biosimilars to adalimumab (HUMIRA®), including interchangeable biosimilars, in any form or presentation including all compositions, formulations, or preparations containing the same. Adalimumab products are used for therapeutic purposes, such as treating rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease (adult and pediatric), ulcerative colitis (adult and pediatric), hidradenitis suppurativa (adult and pediatric), uveitis (adult and pediatric), and juvenile idiopathic arthritis. HUMIRA® (adalimumab) and HUMIRA® Citrate-Free (adalimumab) (collectively, "HUMIRA®") are commercial forms of the adalimumab product offered in the United States by AbbVie. HUMIRA® is approved by the FDA for thirteen separate therapeutic indications and has been commercially available in the United States since 2003.

On November 20, 2020, Alvotech announced that the FDA had accepted Alvotech's Biologics License Application ("BLA") for AVT02, seeking approval as a biosimilar to AbbVie's HUMIRA® (adalimumab). Alvotech's launch is dependent on it obtaining FDA approval, pending inspection of its manufacturing facilities,[1] and the issuance of a decision in pending patent

[1] *Alvotech Provides Update on FDA Action Regarding AVT02, Proposed High-Concentration*

litigation between AbbVie and Alvotech hf. in the Northern District of Illinois. In that case, Alvotech hf. has committed not to launch before the Court's issuance of the decision in that matter, which is expected no later than October 2022.[2] Alvotech hf. continues to state publicly that it will manufacture, import and have marketed by Alvotech's marketing partner Teva AVT02 products that will be manufactured in Iceland and foreign jurisdictions and imported to the United States.

B. Public Health, Safety, or Welfare Concerns Relating to the Requested Remedial Orders

The requested remedies would have no adverse impact on the public health, safety, or welfare in the United States. Proposed Respondents' Accused Products, which may be introduced for sale in the United States, have not established a presence in the United States market. There are other adalimumab products available in the United States, namely AbbVie's HUMIRA®, that can meet all the demand in the market. Additionally, the Accused Products, upon FDA approval, will not be approved for all indications for which HUMIRA® is approved, specifically orphan indications. Moreover, the Proposed Respondents' AVT02 is not a "game-changing" product; because it is a biosimilar to HUMIRA®, by its nature it does not possess any unique properties or any health or safety-related features absent from the existing or future adalimumab products on the market. Accordingly, there are no public health, safety, or welfare considerations that caution against excluding Proposed Respondents' Accused Products.

Biosimilar to Humira® (adalimumab), Alvotech Newsroom (Sept. 20, 2021), *available at* https://www.alvotech.com/newsroom/reykjavik-iceland-september-20-2021--alvotech (last visited Oct. 26, 2021); *Alvotech stækkar við sig*, Viðskiptablaðið (November 1, 2021), *available at* https://www.vb.is/frettir/alvotech-staekkar-vid-sig/171183/ (last visited Nov. 2, 2021).

[2] *See AbbVie, Inc. et al v. Alvotech hf.,* No. 1:21-cv-02258, Dkt. No. 63, Scheduling and Discovery Order, at 4 (Sept. 20, 2021) ("In keeping with this schedule, the Court plans to issue its trial decision by the end of October of 2022. In light of that, Defendant agreed not to launch AVT02 in the United States prior to the issuance of the Court's decision.").

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C. Articles that Complainant, Its Licensees, or Third Parties Make Which Could Replace the Subject Articles If They Were To Be Excluded

The Accused Products are not yet approved in the United States, have not been marketed in the United States, and have not established a presence in the United States market. AbbVie has successfully supplied HUMIRA® in the U.S. market since 2003, meeting market demand for all indications. Other pharmaceutical companies (like Amgen, Boehringer Ingelheim, and Pfizer) have also received FDA approval for adalimumab products as biosimilars to HUMIRA® and have negotiated patent licenses with AbbVie to market their products in the U.S. The first of these licensees will enter the U.S. market beginning January 31, 2023, with others following later that year. Thus, given the availability of products and pending availability of alternative supplies available to consumers, the public's health and welfare would not be disserved by precluding the Accused Products from entry into the United States.

D. Ability of Complainant, Its Licensees, and/or Third Parties to Replace the Volume of Articles Subject to the Requested Remedial Orders in a Commercially Reasonable Time in the United States

The requested remedies will not adversely affect the production of like or directly competitive articles in the United States. As mentioned above, AbbVie has successfully supplied adalimumab products since 2003. AbbVie has met all patient demands and needs for adalimumab products and can continue to do so in the future. *See Certain Crystalline Cefradoxil Monohydrate*, Inv. No. 337-TA-293, Comm'n Op. at 46 (Mar. 15, 1990) (finding that, where complainant has "sufficient capacity and resources to satisfy all domestic demand for [the product]" public interest would not bar relief). AbbVie could increase production capacity for HUMIRA® if needed in the event of future increased demand. Additionally, licensed manufacturers will enter the market with their adalimumab biosimilar products beginning in 2023. Thus, AbbVie's HUMIRA® (or, starting in 2023, biosimilar adalimumab from licensed manufacturers) could easily replace the Accused

Products. Moreover, because AVT02 is manufactured abroad, no American manufacturing jobs would be impacted by an exclusion order.

E. How the Requested Remedial Orders Would Impact Consumers

Given that United States consumers will continue to have available to them in the United States marketplace adalimumab products, including HUMIRA® supplied by AbbVie and, beginning in 2023, other licensed adalimumab biosimilar manufacturers, neither an exclusion order nor a cease and desist order would have an adverse impact on consumers. Moreover, the public interest favors the protection of intellectual property rights in the United States. *Certain Two-Handle Centerset Faucets & Escutcheons & Components Thereof*, Inv. No. 337-TA-422, Comm'n Op. at 9 (June 19, 2000); *Certain Hardware Logic Emulation Sys. & Components Thereof*, Inv. No. 337-TA-383, Comm'n Op. at 8-9 (Oct. 15, 1996). The issuance of the requested relief here would serve the public interest by protecting Complainants' intellectual property rights and preventing competitors from entering a market using unfair practices to "cut in line" ahead of other third parties who have independently developed their own manufacturing processes without the use of AbbVie's trade secrets.

III. CONCLUSION

As set forth above, there are no public interest concerns preventing the issuance of an exclusion order and cease and desist orders or that would necessitate discovery, presentation of evidence, and a Recommended Determination by the ALJ.

Date: December 17, 2021

Respectfully submitted,

/s/ Mareesa A. Frederick

Counsel for the Complainants AbbVie Inc., AbbVie Biotechnology Ltd, and AbbVie Operations Singapore Pte. Ltd.

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of

CERTAIN ADALIMUMAB, PROCESSES FOR MANUFACTURING OR RELATING TO SAME, AND PRODUCTS CONTAINING SAME

COMPLAINT OF ABBVIE INC., ABBVIE BIOTECHNOLOGY LTD, AND ABBVIE OPERATIONS SINGAPORE PTE. LTD. UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

Complainants:

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EXHIBIT LIST

Exhibit	Designation	Description
A	Confidential	Email from Rongzan Ho's AbbVie email address to his personal email address
B	Confidential	Rongzan Ho exit declaration
C	Public	Rongzan Ho LinkedIn Profile as posted on February 18, 2021
D	Public	Australian regulatory information for AVT02
E	Public	New Zealand regulatory information for AVT02
F	Confidential	Email on behalf of Rongzan Ho
G	Confidential	Rongzan Ho employment contract
H	Confidential	Jason Seah employment contract
I	Confidential	Eunice Tan employment contract
J	Confidential	Email from Rongzan Ho
K	Public	Alvotech hf. importation records
L	Public	Ivers-Lee AG importation records
M	Confidential	Declaration of Kristin Bartolucci

I. INTRODUCTION

1. This case concerns unfair acts in the importation into the United States of any Accused Product manufactured based on trade secrets misappropriated from Complainants by Alvotech hf., which product will be marketed in the United States under an exclusive strategic partnership with Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA Inc. (collectively, "Teva"). Proposed Respondents have embarked on a scheme to (a) improperly recruit employees with knowledge of Complainants' trade secrets important to the manufacture of adalimumab, (b) misappropriate Complainants' adalimumab-related trade secrets to develop a process to manufacture an adalimumab biosimilar, and (c) import, market and sell their adalimumab biosimilar in the United States.

2. AbbVie manufactures, markets, and sells HUMIRA® (adalimumab) in the United States. Over nearly two decades, AbbVie has invested billions of dollars in the development of the adalimumab market, including the United States domestic market for HUMIRA®, and including the development of the trade secrets misappropriated by Alvotech hf. HUMIRA® belongs to a category of drugs known as biologics. Biologics are complex proteins manufactured in living cells rather than by chemical synthesis. These are critically important drugs that are difficult to develop, manufacture, and formulate.

3. AbbVie's hard work, ingenuity, research, and persistent development of HUMIRA®, including work under the supervision of AbbVie's leadership in North Chicago, Illinois, by AbbVie scientists in a first manufacturing facility in Worcester, Massachusetts and a second facility in Barceloneta, Puerto Rico, ultimately created a domestic market worth billions of dollars.

4. Over one million patients have benefited from AbbVie's pioneering work, which also has produced a robust portfolio of patents and trade secrets. AbbVie's investment in

HUMIRA® development includes over 100 clinical trials and has resulted in U.S. Food and Drug Administration ("FDA") approval for the treatment of thirteen different disease conditions, including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease (adult and pediatric), ulcerative colitis (adult and pediatric), hidradenitis suppurativa (adult and pediatric), uveitis (adult and pediatric), and juvenile idiopathic arthritis.

5. The Accused Product is any human monoclonal antibody that is a biosimilar of adalimumab (HUMIRA®), including any interchangeable biosimilar,[1] in any form or presentation including all compositions, formulations, or preparations containing the same manufactured by Alvotech hf., Alvotech Germany GmbH, Alvotech Swiss AG, and Ivers-Lee AG based on the misappropriated trade secrets of AbbVie Inc., AbbVie Biotechnology Ltd, and AbbVie Operations Singapore Pte. Ltd. (collectively, "AbbVie") and tortious interference with contract relations. Alvotech currently publicly refers to the Accused Products as AVT02.[2] Alvotech USA Inc., a

[1] The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") established an abbreviated process by which a biosimilar applicant such as Alvotech can pursue FDA approval. A biosimilar drug is one that is highly similar to an already-approved reference product, in this instance AbbVie's HUMIRA®. The BPCIA allows a biosimilar applicant to rely on the extensive and costly clinical trials previously conducted by the original creator of the reference product to show that its biosimilar is safe, pure, and potent. This significantly reduces the cost of obtaining FDA approval for a biosimilar. A biosimilar applicant may also seek an interchangeability designation by meeting additional requirements based on further evaluation and testing of the biosimilar product and outlined by the BPCIA. An interchangeable product may, dependent on the state pharmacy laws and like a typical "generic" drug, be substituted for the reference product without consulting the prescriber. *See* https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#interchange (last visited Dec. 1, 2021).

[2] In Europe, Alvotech's AVT02 has been approved under the product names Libmyris and Hukyndra. *See Alvotech Welcomes Positive CHMP Opinion for AVT02, a Proposed Biosimilar to Humira®,* Alvotech Newsroom (Sept. 17, 20210), *available at* https://www.alvotech.com/newsroom/alvotech-welcomes-positive-chmp-opinion-for-avt02 (last visited Dec. 7, 2021); EMA Medicines Website, Libmyris, *available at* https://www.ema.europa.eu/en/medicines/human/summaries-opinion/libmyris (last visited Dec. 7, 2021); EMA Medicines Website, Hukyndra, *available at* https://www.ema.europa.eu/en/medicines/human/summaries-opinion/hukyndra (last visited Dec.

wholly owned subsidiary and agent of Alvotech hf., filed the regulatory application for AVT02 under Alvotech hf.'s direction. When approved[3] and launched, AVT02 will be commercialized in the United States by Teva Pharmaceutical Industries Ltd. and/or Teva Pharmaceuticals USA Inc. under an exclusive strategic partnership with Alvotech hf. (collectively, Alvotech hf., Alvotech Germany GmbH, Alvotech Swiss AG, Ivers-Lee AG, Alvotech USA Inc., and Teva "Proposed Respondents").

6. Complainants respectfully request that the United States International Trade Commission (the "Commission") institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. Complainants seek a limited exclusion order to remedy the unlawful and unauthorized importation into the United States of the Accused Products. Complainants also request cease and desist orders preventing Proposed Respondents from engaging in and profiting from their unfair trade practices through the importation, sale, or sale for importation of the Accused Products.

7. As discussed at greater length below, AbbVie developed the United States market for adalimumab products through substantial and sustained investment in research and development in the United States, clinical testing in the United States, and sales and marketing in the United States. AbbVie currently maintains substantial operations in Illinois and Puerto Rico related to the development and sale of HUMIRA® in the United States market. Over nearly two decades, AbbVie has invested billions in the development of the adalimumab market, including the United States domestic market for HUMIRA®.

7, 2021). In this complaint, AVT02 is used to refer to any and all forms or presentations of the Accused Products.

[3] On November 15, 2021, the European Commission gave approval issuing decisions granting marketing authorization for Alvotech's Libmyris and Hukyndra AVT02 products. Alvotech's submission to the FDA is currently pending approval.

8. HUMIRA® has been approved for sale in the United States since 2002 and is currently the only adalimumab product on the United States market.

9. AbbVie's two-decade investment in the domestic adalimumab product market will be substantially injured by the unfair acts of Proposed Respondents. Proposed Respondents are each involved in manufacturing, importing, seeking regulatory approval for, and/or preparing to market AVT02 in order to commercialize it in the United States.

10. On information and belief, AVT02 is manufactured using a process developed with trade secrets stolen from AbbVie. AVT02 will directly compete with HUMIRA®. AVT02 will undercut HUMIRA® significantly on price and unfairly compete, leading to lower revenue, lower profits, reduced return on investment and, as a result, significant injury to the industry that AbbVie has invested in significantly to develop in the United States.

11. Alvotech hf. was created in 2013. During its short history, Alvotech hf. has hired directly, or through its wholly-owned subsidiaries Alvotech Swiss AG and Alvotech Germany GmbH, a number of employees who previously worked at AbbVie or its predecessor, Abbott Laboratories ("Abbott"), including employees with access to, training on, and/or know-how of AbbVie's HUMIRA® manufacturing process and related trade secrets for HUMIRA®. Alvotech hf. successfully recruited, unbeknownst to AbbVie, at least Rongzan Ho, Yi Li (Eunice) Tan, and Zhi Sheng (Jason) Seah while they were still employed by AbbVie and directly involved with the manufacture of HUMIRA®. These individuals then resigned from AbbVie while concealing their new employer and the product they would be working on and directly began work at Alvotech hf. On information and belief, Alvotech hf. and its subsidiaries have used these employees' knowledge of AbbVie's trade secrets, *inter alia,* to develop the manufacturing process for Alvotech hf.'s AVT02.

12. On information and belief, Alvotech hf. has directly, or through its wholly-owned subsidiaries Alvotech Swiss AG and Alvotech Germany GmbH, continued to recruit or attempt to recruit current or former AbbVie employees with access to and knowledge of HUMIRA® related trade secrets to work at Alvotech hf., or one of its wholly-owned subsidiaries.

13. Alvotech hf., first through its wholly-owned subsidiary Alvotech Swiss AG and then through its wholly-owned subsidiary Alvotech USA Inc.[4], has been and continues to be engaged in the process of obtaining FDA approval to market AVT02 in the United States, which has involved and continues to involve the importation of AVT02 into the United States. On information and belief, Ivers-Lee AG has been and continues to be engaged in the process for obtaining FDA approval to market AVT02 in the United States through at least performing validation testing on AVT02 manufactured by Alvotech hf., providing samples of AVT02 manufactured by Alvotech hf. for release testing purposes, and importing AVT02 into the United States. On information and belief, Teva is also engaged in the process for obtaining FDA approval to market AVT02 in the United States and preparing to market AVT02 in the United States.[5]

14. Alvotech hf. has announced plans for the commercial launch of AVT02. That launch is dependent on it obtaining FDA approval, pending inspection of its manufacturing facilities,[6] and the issuance of a decision in pending patent litigation between AbbVie and

[4] Alvotech USA Inc. was formed on January 11, 2019.

[5] *See Teva and Alvotech Announce Strategic Partnership to Collaborate in the U.S. Biosimilar Market*, Teva News & Media Post (Aug. 5, 2020), *available at* https://www.tevapharm.com/news-and-media/latest-news/teva-and-alvotech-announce-strategic-partnership-to-collaborate-in-the-u.s.-biosimilar-market/ (last visited Nov. 30, 2021) ("This commercial partnership with Alvotech will enable Teva to lend its technical expertise in working with the FDA to bring products to the U.S. market . . ..").

[6] *Alvotech Provides Update on FDA Action Regarding AVT02, Proposed High-Concentration Biosimilar to Humira® (adalimumab),* Alvotech Newsroom (Sept. 20, 2021), *available at* https://www.alvotech.com/newsroom/reykjavik-iceland-september-20-2021--alvotech (last

Alvotech hf. in the Northern District of Illinois. In that case, Alvotech hf. has committed not to launch before the Court's issuance of the decision in that matter, which is expected no later than October 2022.[7] Alvotech hf. continues to state publicly that it will manufacture, import, and have marketed by Alvotech's marketing partner Teva AVT02 manufactured in Iceland and foreign jurisdictions and imported to the United States.

15. In August 2020, Alvotech hf. entered into a partnership agreement (the "Teva Agreement") with Teva for commercialization of AVT02 in the United States.[8] On information and belief and pursuant to the Teva partnership agreement, Alvotech hf. will manufacture and supply AVT02, and obtain regulatory approval, whereby Alvotech hf., and/or Ivers-Lee AG will import and/or have AVT02 imported into the United States, and Teva will distribute and commercialize AVT02 in the United States.[9] On information and belief, Teva has been and continues to assist Alvotech hf. in working with the FDA to bring Alvotech hf.'s AVT02 to the U.S. market.[10] The Teva Agreement involved an upfront payment by Teva and has been valued at

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visited Oct. 26, 2021); *Alvotech stækkar við sig*, Viðskiptablaðið (November 1, 2021), *available at* https://www.vb.is/frettir/alvotech-staekkar-vid-sig/171183/ (last visited Nov. 2, 2021).

[7] *See AbbVie, Inc. et al v. Alvotech hf.,* No. 1:21-cv-02258, Dkt. No. 63, Scheduling and Discovery Order, at 4 (Sept. 20, 2021) ("In keeping with this schedule, the Court plans to issue its trial decision by the end of October of 2022. In light of that, Defendant agreed not to launch AVT02 in the United States prior to the issuance of the Court's decision.").

[8] *Alvotech and Teva announce strategic partnership to collaborate in the U.S. biosimilar market*, Alvotech Newsroom Post (Aug. 5, 2020), *available at* https://www.alvotech.com/newsroom/alvotech-and-teva-announce-strategic-partnership-to (last visited Oct. 26, 2021).

[9] *Id.*

[10] *See Teva and Alvotech Announce Strategic Partnership to Collaborate in the U.S. Biosimilar Market*, Teva News & Media Post (Aug. 5, 2020), *available at* https://www.tevapharm.com/news-and-media/latest-news/teva-and-alvotech-announce-strategic-partnership-to-collaborate-in-the-u.s.-biosimilar-market/ (last visited Nov. 30, 2021) ("This commercial partnership with Alvotech will enable Teva to lend its technical expertise in working with the FDA to bring products to the U.S. market . . ..").

more than $450 million, exclusive of royalties.[11] Upon information and belief, in the partnership, both Alvotech hf. and Teva will share profits from the commercialization of AVT02 in the United States.

16. On information and belief, the current sole source of AVT02 in the world is Alvotech hf.'s manufacturing facility in Iceland. On information and belief, Ivers-Lee AG is involved with the testing, assembly, sterilization, and/or packaging of AVT02 that was manufactured at Alvotech hf.'s Iceland facility for final presentation and importation into the United States. On information and belief, for at least some presentations, Alvotech hf. manufactures the active biological ingredient, formulates it, and puts it into native pre-filled glass syringes (without an auto-injector), which are then shipped to Ivers-Lee AG in Switzerland. On information and belief, Ivers-Lee AG then finishes the AVT02 native pre-filled glass syringes received from Alvotech hf. by incorporating them into auto-injectors, placing AVT02 in its final presentation for patient use in at least one presentation. On information and belief, Ivers-Lee AG will then package the AVT02 auto-injectors into approved packaging with labeling and the final AVT02 products will then be imported into the United States for sale and use. On information and belief, all AVT02, regardless of presentation, sold worldwide, including any used or sold in the United States, must currently be imported at least indirectly from Alvotech hf.'s facility.

17. To date, Alvotech hf. has directly or indirectly imported AVT02 into the United States under FDA control and release. On information and belief, to date Ivers-Lee AG has directly or indirectly imported AVT02 into the United States under FDA control and release. In addition,

[11] *Form 10-K, Teva Pharmaceutical Industries Ltd.*, U.S. Securities and Exchange Commission (Dec. 31, 2020), *available at* https://www.sec.gov/Archives/edgar/data/818686/000119312521036239/d102112d10k.htm (last visited Oct. 26, 2021).

Alvotech hf. has stated publicly that it expects to begin selling AVT02 in the United States after October 2022.

18. In order to commercialize AVT02 in the United States, each Proposed Respondent must and will import AVT02 into the United States. Each Proposed Respondent's importation of AVT02 threatens substantial injury to the well-established domestic adalimumab product market. *See infra* Section VIII. In particular, AVT02 will be marketed to physicians and others as a direct competitor of HUMIRA® with the objective of undercutting the domestic market in adalimumab products and quickly obtaining substantial market share. For example, Alvotech has stated in public press releases that:

a. Alvotech will be the first company which has "both developed and submitted a filing for a high-concentration biosimilar candidate to Humira,"[12]

b. Alvotech is seeking an interchangeability approval, meaning AVT02 "may be substituted for the reference product without the intervention of a prescriber,"[13] and

c. Alvotech's plan is to substantially undercut the market for HUMIRA® by pricing AVT02 at least 50% lower than the current price of HUMIRA®.[14]

19. Alvotech's clinical studies have indicated that AVT02 has a similar efficacy, safety,

[12] *Alvotech Announces Positive Top-line Results for Switching Study Between Proposed Biosimilar AVT02 and Humira,* Alvotech Newsroom (Sept. 10, 2021), *available at* https://www.alvotech.com/newsroom/alvotech-announces-positive-top-line-results-for-switching (last visited Oct. 26, 2021).

[13] *Id.*

[14] *Alvotech seeks to end AbbVie's wrongful monopoly on Humira and bring affordable arthritis treatment to U.S.,* Alvotech Newsroom (May 11, 2021), *available at* https://www.alvotech.com/newsroom/alvotech-seeks-to-end-abbvies-wrongful-monopoly ("AVT02 could save U.S. taxpayers and the overall healthcare system $8-10 billion annually.") (last visited Oct. 26, 2021).

and immunogenicity profile to HUMIRA®.[15] Its regulatory approval as a biosimilar will lead to direct competition between the two adalimumab products. Moreover, if AVT02 is also approved as interchangeable,[16] that may deepen the competition, including at the pharmacy where pharmacists in some states may be able to substitute Alvotech's AVT02 product for HUMIRA® for physician prescriptions written for HUMIRA®.[17]

20. Importation of AVT02 to seek FDA approval and to compete with HUMIRA® in the United States constitutes unfair acts, the threat or effect of which is to substantially injure an industry in the United States in violation of 19 U.S.C. § 1337(a)(1)(A), because, on information and belief, the commercial-scale manufacturing process for AVT02 was developed on the basis of misappropriated trade secrets stolen from AbbVie by its former employees, including at least Rongzan Ho, Jason Seah, and Eunice Tan, and provided to Alvotech hf. Specifically, Rongzan Ho took from AbbVie confidential documents describing in detail the company's most secret and protected manufacturing processes and went to work for Alvotech hf. Rongzan Ho's theft of AbbVie's trade secrets is well documented by AbbVie's computer security system, as described below. Moreover, the circumstances of each employee's departure from AbbVie and subsequent employment at Alvotech hf., and Alvotech hf.'s purported development of its own adalimumab

[15] *Alvotech Announces Positive Top-line Results for Switching Study Between Proposed Biosimilar AVT02 and Humira,* Alvotech Newsroom (Sept. 10, 2021), *available at* https://www.alvotech.com/newsroom/alvotech-announces-positive-top-line-results-for-switching (last visited Oct. 26, 2021).

[16] An interchangeable biosimilar product may be substituted without the intervention of the health care professional who prescribed the reference product, much like how generic drugs are routinely substituted for brand name drugs. *See Biosimilar and Interchangeable Biologics: More Treatment Choices,* U.S. Food & Drug Administration (October 12, 2021), *available at* https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices (last visited Nov. 17, 2021).

[17] *Id.*

manufacturing process implausibly quickly for a company with zero experience with biologic manufacturing, confirm that the commercial-scale manufacturing process for AVT02 was developed with the benefit of access to AbbVie's stolen trade secrets.

21. Proposed Respondents intend to introduce AVT02 into the United States market at a price that they have touted will be substantially lower than the price of HUMIRA®, and to therefore undercut the market for HUMIRA®, because they were not required to make the massive research and development investments that AbbVie has incurred and continue to incur to develop its product. Importing AVT02 to compete with HUMIRA® in the United States market would accordingly constitute an unfair method of competition and unfair act in violation of 19 U.S.C. § 1337.

22. AbbVie accordingly seeks (a) institution of an investigation pursuant to 19 U.S.C. § 1337 with respect to Proposed Respondents' violation of that section, (b) a hearing on permanent relief pursuant to 19 U.S.C. § 1337(c), (c) a limited exclusion order with respect to forbidding entry into the United States of Proposed Respondents' adalimumab products, including AVT02, (d) cease and desist orders pursuant to 19 U.S.C. § 1337(f) prohibiting Proposed Respondents and their related companies from engaging in the importation, sale for importation, marketing, distribution, offering for sale, the sale after importation of, or otherwise transferring within the United States Proposed Respondents' adalimumab products, including AVT02, that were developed, made, and imported using AbbVie's trade secrets, (e) requirement of a bond during the Presidential review period pursuant to 19 U.S.C. § 1337(j)(3), (f) an order compelling the return of AbbVie's trade secrets, and (g) such other and further relief as the Commission deems just and proper.

II. THE PARTIES

1. Complainants AbbVie Inc., AbbVie Biotechnology Ltd, and AbbVie Operations Singapore Pte. Ltd.

23. Complainant AbbVie Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie Inc., through its subsidiaries, manufactures, markets, and sells HUMIRA®.

24. AbbVie Biotechnology Ltd is a corporation organized and existing under the laws of Bermuda, with a place of business at Harbour Fiduciary Services Limited, Thistle House, 4 Burnaby Street, Hamilton HM1l, Bermuda. AbbVie Biotechnology Ltd owns the trade secrets at issue here and exclusively licenses them to AbbVie Inc. in the United States. Through intermediate organizations, AbbVie Inc. owns AbbVie Biotechnology Ltd.

25. AbbVie Operations Singapore Pte. Lte. ("AbbVie Singapore") is a corporation organized and existing under the laws of Singapore, with a place of business at 23 Tuas South Avenue 6, Singapore 637022. AbbVie Singapore is the signatory on the employment contracts with Rongzan Ho, Jason Seah, and Eunice Tan.

26. AbbVie is a global pharmaceutical company focused on the development, sale, and distribution of a broad range of pharmaceutical and biologic drugs, including HUMIRA®. AbbVie was created in 2013 as a spin-off of its predecessor, Abbott. After the spinoff, AbbVie retained all ownership of HUMIRA®, including the trade secrets at issue here.

27. HUMIRA® is a biologic drug used to treat a range of conditions. It was developed under the leadership of AbbVie's management in the United States. AbbVie was the first company to launch an adalimumab product in the United States, achieving approval from the FDA for HUMIRA® for rheumatoid arthritis in 2002 and the remaining indications over the next 19 years.

28. HUMIRA® is the leading, and currently the only, product in the domestic industry

at issue in this case, that is, the domestic industry in adalimumab products. Importation of AVT02 by Proposed Respondents threatens to cause substantial injury to that domestic industry. After January 31, 2023, AbbVie expects the first adalimumab biosimilar to enter under a royalty-bearing patent license agreement, with others set to enter later that year. At least some of the biosimilar companies will also manufacture their biosimilar adalimumab products in the United States.[18]

2. Proposed Respondents

29. Alvotech hf. is a company organized and existing under the laws of Iceland, with its principal place of business at Sæmundargata 15-19, 101 Reykjavík, Iceland. Alvotech hf. is in the business of developing, manufacturing, marketing, and selling biologic drugs, including the proposed biosimilar version of AbbVie's HUMIRA® (adalimumab) product, AVT02. Alvotech hf. has submitted for regulatory approval of AVT02 through its agent and wholly-owned US subsidiary Alvotech USA Inc. and has partnered with Teva for the distribution and sale in the US of AVT02, among other things. Alvotech hf. conducts manufacturing, quality analysis and quality control, process and drug product development, analytics, finance, business development, human resources, and technical operations for itself and its subsidiaries at its headquarters in Iceland.[19]

30. Alvotech Germany GmbH is a company organized and existing under the laws of Germany, with its principal place of business at Karl-Heinz-Beckurts-Str. 13 52428, Jülich, Nordrhein-Westfalen, Germany. Alvotech Germany GmbH is a wholly-owned subsidiary of Alvotech hf. Alvotech Germany GmbH is responsible for cell line and early process development,

[18] Other manufacturers, including Amgen, Sandoz, Samsung Bioepis, Pfizer, Mylan, and Boehringer Ingelheim, have received FDA approval and entered into patent license and settlement agreements with AbbVie, under which they are licensed at certain dates in 2023, subject to acceleration under certain circumstances.

[19] *See* Alvotech Office Locations *available at* https://www.alvotech.com/about-us/office-locations (last visited Nov. 30, 2021).

bioassay development and analytics, preclinical development, project management, and process technology relating to the development and manufacture of biologic drugs, including, on information and belief, AVT02.[20]

31. Alvotech Swiss AG is a company organized and existing under the laws of Switzerland, with its principal place of business at Thurgauerstrasse 54, Zürich 8050, Switzerland. Alvotech Swiss AG is a wholly-owned subsidiary of Alvotech hf. Alvotech Swiss AG is responsible for clinical development and operations, regulatory affairs, and intellectual property relating to the development and manufacture of biologic drugs, including, on information and belief, AVT02.[21] On information and belief, Alvotech Swiss AG was and is involved in the preparations for and filing of the regulatory application for AVT02 in the United States.

32. Alvotech USA Inc. is a company organized and existing under the laws of the Commonwealth of Virginia, with its principal place of business at 1201 Wilson Blvd, Ste 2130, Arlington, VA, 22209. Alvotech USA is a wholly-owned subsidiary and agent of Alvotech hf. On behalf of Alvotech hf., Alvotech USA filed the regulatory application for AVT02. Alvotech USA Inc. is responsible for regulatory affairs, governmental policy and legal affairs for and at the direction of Alvotech hf.[22]

33. Teva Pharmaceutical Industries Ltd. is a company organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, Petah Tikva, 49131 Israel. Teva Pharmaceuticals USA Inc. is a company organized and existing under the laws of Delaware, with its principal place of business at 1090 Horsham Road North Wales, PA 19454. Teva

[20] *See id.*

[21] *See id.*

[22] *See id.*

Pharmaceuticals USA Inc. is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. (collectively, "Teva"). Teva specializes mainly in generic drugs but also manufactures active pharmaceutical ingredients and proprietary pharmaceuticals. Teva has partnered with Alvotech hf. to commercialize AVT02 in the United States.[23]

34. Ivers-Lee AG is a company organized and existing under the laws of Switzerland, with its principal place of business at Kirchbergstrasse 160, 3400 Burgdorf, Switzerland. Ivers-Lee AG is in the business of providing packaging, filling and sterilization services for the pharmaceutical and cosmetic industries. On information and belief, Ivers-Lee AG is responsible for at least the testing, assembly, and packaging of AVT02.

35. Alvotech hf., including using its wholly-owned subsidiaries Alvotech Germany GmbH, Alvotech Swiss AG, and Alvotech USA to perform related activities on its behalf where appropriate and using its partner Teva's technical expertise in working with the FDA, has and continues to develop, manufacture, and seek regulatory approval for AVT02.

36. Alvotech hf. manufactures the active biological ingredient and formulated drug substance for its AVT02 products at its facilities in Iceland. On information and belief, all AVT02 currently imported and expected to be imported into the United States originates at Alvotech hf.'s manufacturing plant in Iceland.

37. AVT02 is packaged and, when approved, will be sold and administered via an autoinjector delivery device in at least one presentation. On information and belief, Ivers-Lee AG is a contract manufacturer for Alvotech hf., which assembles and packages AVT02 into the

[23] *See Teva: Biosimilars In The US Will Become Like Complex Generics*, Interview, Generics Bulletin Informa Pharma Intelligence (Apr. 13, 2021) (explaining that Teva's alliance with Alvotech is a "very collaborative one") *available at* https://generics.pharmaintelligence.informa.com/GB150826/Teva-Biosimilars-In-The-US-Will-Become-Like-Complex-Generics (last visited Dec. 14, 2021).

autoinjector device and into the drug product's final packaging and has imported AVT02 into the United States.

38. As discussed below, Alvotech hf. plans to commercialize AVT02 into the United States through a partnership with Teva.

39. Alvotech hf. has imported AVT02 into the United States. On information and belief, Alvotech hf. and Ivers-Lee AG will import additional AVT02 into the United States to utilize in preparation for commercial launch. On information and belief, Alvotech hf. and/or Teva will market and sell AVT02 to consumers in the United States upon approval.

III. THE TECHNOLOGY AND PRODUCTS AT ISSUE

40. Pursuant to 19 C.F.R. § 210.12(a)(12), Complainants state that the products at issue are certain adalimumab, processes for manufacturing or relating to same, and products containing same, for example adalimumab (drug substance and drug product), vials, prefilled syringe, autoinjectors or other presentations containing same.[24]

41. AVT02 may be packaged in a native syringe, as depicted below in Figure 1, and thereafter assembled into an autoinjector for final use, as depicted below in Figure 2. AVT02 may also be packaged in other forms including in a vial or a pre-filled syringe.

[24] Adalimumab biosimilar products, including AVT02, can be, for example, imported in the form of vials, native syringes, pre-filled syringes, autoinjectors, or other presentations containing 20 mg, 40 mg, or 80 mg of adalimumab drug substance in a liquid solution; the products may or may not be interchangeable.

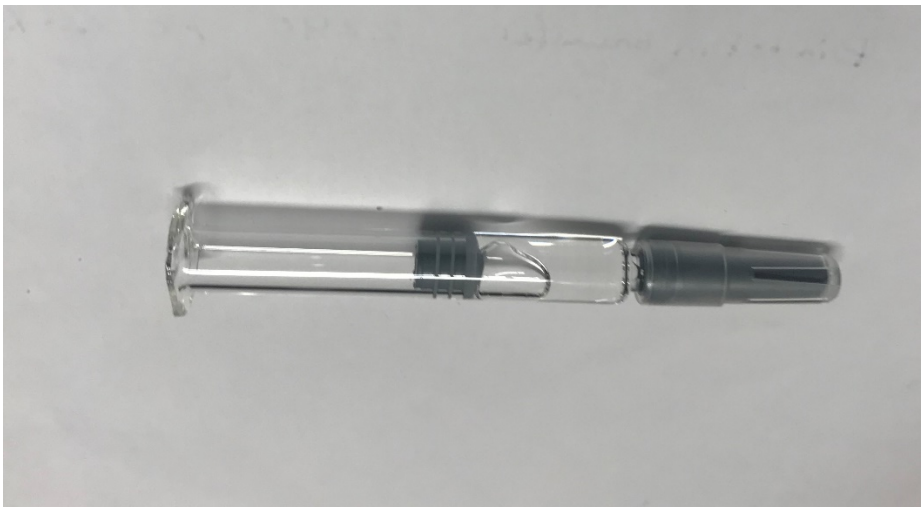

Figure 1. AVT02 in syringe

Figure 2. AVT02 in autoinjector

42. Adalimumab is a monoclonal antibody that works by inactivating tumor necrosis factor-alpha (TNFα). It was the first fully human monoclonal antibody approved by the FDA.

43. Adalimumab is administered by subcutaneous injection and used as a therapeutic for the treatment of thirteen different disease conditions, including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease (adult and pediatric), ulcerative colitis (adult and pediatric), hidradenitis suppurativa (adult and pediatric), uveitis (adult and pediatric),

and juvenile idiopathic arthritis. In the United States, the only adalimumab biologic currently available on the market is AbbVie's HUMIRA®.

44. The technology and intellectual property at issue generally relates to the biologic adalimumab and the processes used to manufacture the same. As will be described in detail below, the trade secrets are directed to manufacturing, testing, and gaining regulatory approval for adalimumab for use in a final biologic product used to treat many different diseases.

45. Biologics are complex proteins manufactured in living cells rather than by chemical synthesis. These are critically important drugs that are difficult to develop, manufacture, formulate, and administer. The manufacturing process for such a complex biologic is a sophisticated, expensive, and highly specialized process. As discussed below, the manufacturing process for adalimumab may be divided into three parts: (1) upstream manufacturing, (2) downstream manufacturing, and (3) formulation.

46. The upstream manufacturing process for an adalimumab biologic begins by establishing a bank of mammalian cells engineered to produce adalimumab. Once the cell bank has been established, an aliquot of cells from the bank are thawed and cultured in an environment that is precisely controlled to encourage the growth of cells (the expansion stage) and ultimately the production of adalimumab, which is secreted into the liquid in which the cells are grown (the production stage). The production is then harvested to remove cells and cell debris, resulting in an adalimumab-containing solution that may enter the downstream manufacturing process.

47. During the downstream manufacturing process, the adalimumab-containing solution is processed to reduce impurities. The purified adalimumab-containing solution may then be formulated into the final drug product and then filled into a presentation for administration, such as a syringe or autoinjector. It must also be labeled for FDA-approved uses by patients. That

results in the final product that is sold – in AbbVie's case, HUMIRA®.

48. In order to gain regulatory approval for adalimumab for use in a final biologic product, the manufacturing processes as well as the manufacturing facility must undergo FDA review and meet GMP requirements.

49. AVT02 is currently pending FDA approval to be sold in the United States. AVT02, if approved, will be a biosimilar to AbbVie's HUMIRA®, meaning that the FDA will have determined AVT02 is very close in structure and function, including in its efficacy and safety profile, to HUMIRA®.

50. In November 2020, the FDA accepted Alvotech hf.'s Biologics License Application ("BLA") for AVT02 for review.[25] All AVT02 sold in the United States will be manufactured abroad and ultimately imported into the United States.

51. Alvotech announced the it expected an FDA decision on its BLA in September 2021.[26] On September 17, 2021, Alvotech received a positive opinion recommending approval of AVT02, under the product names Libmyris and Hukyndra, from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP).[27] On September 20, 2021, Alvotech announced that the FDA is deferring action on Alvotech hf.'s application for

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[25] *U.S. FDA and EMA have accepted regulatory submissions for AVT02,* Alvotech Newsroom (Nov. 19, 2020), *available at* https://www.alvotech.com/newsroom/alvotech-announces-that-the-u.s.-fda-and-ema-have-accepted (last visited Oct. 26, 2021).

[26] *Id.*

[27] *Alvotech Welcomes Positive CHMP Opinion for AVT02, a Proposed Biosimilar to Humira®,* Alvotech Newsroom (Sept. 17, 20210), *available at* https://www.alvotech.com/newsroom/alvotech-welcomes-positive-chmp-opinion-for-avt02 (last visited Dec. 7, 2021); EMA Medicines Website, Libmyris, *available at* https://www.ema.europa.eu/en/medicines/human/summaries-opinion/libmyris (last visited Dec. 7, 2021); EMA Medicines Website, Hukyndra, *available at* https://www.ema.europa.eu/en/medicines/human/summaries-opinion/hukyndra (last visited Dec. 7, 2021).

AVT02 until facility assessments can be completed.[28] According to Alvotech hf., this indicates that "no deficiencies have been identified and the application otherwise satisfies the requirements for approval," meaning that, as soon as the FDA completes its facility inspections related to the AVT02 product, it may approve AVT02 for marketing in the United States.[29] On November 15, 2021, the European Commission gave approval issuing decisions granting marketing authorization for Libmyris and Hukyndra.[30]

52. If approved and launched prior to January 31, 2023, AVT02 will be the first adalimumab product other than HUMIRA® sold in the United States. AVT02 will therefore be a direct competitor of HUMIRA® and will disrupt the market for HUMIRA®.

IV. INTELLECTUAL PROPERTY AT ISSUE

A. The Misappropriated Trade Secrets

53. The trade secrets in this case relate to the development of AbbVie's high-concentration HUMIRA® product and manufacturing process. On information and belief, Alvotech hf. misappropriated AbbVie's trade secrets and used them in developing and seeking FDA approval of its the commercial-scale manufacturing process for AVT02 including a 100

[28] *Alvotech Provides Update on FDA Action Regarding AVT02, Proposed High-Concentration Biosimilar to Humira® (adalimumab),* Alvotech Newsroom (Sept. 20, 2021), *available at* https://www.alvotech.com/newsroom/reykjavik-iceland-september-20-2021--alvotech (last visited Oct. 26, 2021); *Alvotech stækkar við sig*, Viðskiptablaðið (November 1, 2021), *available at* https://www.vb.is/frettir/alvotech-staekkar-vid-sig/171183/ (last visited Nov. 2, 2021).

[29] *See Alvotech Provides Update on FDA Action Regarding AVT02, Proposed High-Concentration Biosimilar to Humira® (adalimumab),* Alvotech Newsroom (Sept. 20, 2021), *available at* https://www.alvotech.com/newsroom/reykjavik-iceland-september-20-2021--alvotech (last visited Oct. 26, 2021).

[30] European Commission Marketing Authorizations Nos. EU/1/21/1590 and EU/1/21/1589, *available at* https://ec.europa.eu/health/documents/community-register/html/h1589.htm#mod_download (last visited Dec. 7, 2021); https://ec.europa.eu/health/documents/community-register/html/h1590.htm (last visited Dec. 7, 2021).

mg/ml formulation. For the reasons set out below, these comprise economically valuable, protectable trade secrets that are not generally available and which AbbVie has benefited from.

54. AbbVie maintains considerable details of its large-scale manufacturing process as secrets. These details include, for example, AbbVie's day-to-day procedures for monitoring, adjusting, and controlling numerous process parameters, including plant equipment set-up and operation. They also include AbbVie's day-to-day procedures for monitoring cell count, viable cell density, and indicators of contamination, as well as AbbVie's day-to-day procedures for measuring, preparing, monitoring, and controlling process components and parameters. AbbVie's processes and strategy for bringing a new plant online to commercial-scale manufacturing are also included. The detailed aspects of AbbVie's manufacturing process, including these parameters and others, ensure a high quality, consistent, and efficient manufacturing process. These processes also reflect years of trial-and-error and set out what to do when manufacturing adalimumab.

55. These process details are also invaluable in seeking regulatory approval of a biologic and its associated manufacturing process. The process parameters, operation, and validations encompassed in these trade secrets are required by the FDA to show that the biologic drug is safe, consistent, and effective.

B. AbbVie's Development of Trade Secrets

56. HUMIRA® is an adalimumab biologic manufactured by AbbVie at various locations worldwide, including in the United States and Singapore. It has been marketed and sold in the United States since 2003 and is currently sold worldwide.

57. HUMIRA® has been the subject of research and development since the 1990s. In 2013, AbbVie was created as a spin-off of its predecessor, Abbott, and was charged with the development and sale of HUMIRA®. Adalimumab is manufactured using living cells. AbbVie has continuously expended significant time and resources on research and development of

HUMIRA®, including working to optimize the commercial-scale manufacturing process for adalimumab. This required a substantial investment by AbbVie. Specifically, AbbVie spent billions and significant human capital to perfect a manufacturing process designed to produce adalimumab and the final product, HUMIRA®.

58. AbbVie's first manufacturing facility for HUMIRA® was in Worcester, Massachusetts. Under the leadership of AbbVie management in North Chicago, Illinois, AbbVie's scientists there developed AbbVie's first commercial-scale manufacturing process. AbbVie later built an additional manufacturing facility in Barceloneta, Puerto Rico. Based on AbbVie's experience and continued investment in research and development, both facilities continued to improve upon the manufacturing process, focusing on quality, consistency, and efficiency. The sum of this know-how was embodied in AbbVie's Puerto Rico facility, which was the first AbbVie facility to manufacture AbbVie's 100 mg/ml high concentration formulation of HUMIRA®.

59. AbbVie's manufacturing process for HUMIRA® is the product of meticulous, time-consuming, and expensive research and refinement, both in laboratories and in the factories. AbbVie's more than two decades of experience and investment in its processes have generated substantial know-how for AbbVie in the form of confidential and proprietary trade secrets. The manufacturing process for HUMIRA® becomes increasingly complex when it is run at large scale, and AbbVie's confidential and proprietary trade secrets include the technical know-how required to run a high quality, efficient, and consistent commercial-scale manufacturing process for adalimumab, as well as protocols to avoid many pitfalls that would otherwise be encountered. AbbVie was the first company in the world to successfully manufacture an adalimumab product and its manufacturing processes were not publicly known. Even now, AbbVie zealously guards the secrecy of its product manufacturing processes.

60. AbbVie's manufacturing process was refined over years of improving the process in factories, all of which generated substantial know-how for AbbVie in the form of confidential and proprietary intellectual property – *i.e.,* trade secrets – relating to the manufacturing of its adalimumab product, HUMIRA®. Over its decades of experience manufacturing HUMIRA®, AbbVie has developed sophisticated protocols, procedures, timelines, and checklists to ensure achievement of an efficient and consistent manufacturing process. Such information is documented, for example, in voluminous multi-sheet Excel spreadsheets amassing hundreds of rows and columns and hundreds of pages of information. AbbVie even has documents providing day-by-day manufacturing instructions for adalimumab spanning multiple months. These documents are sensitive and kept confidential by AbbVie.

61. These documents explain in detail the entire step-by-step manufacturing process for the HUMIRA® drug substance. They are AbbVie's ultimate blueprint for making adalimumab. For each step of the manufacturing process, these documents explain: (1) the raw materials required and in what quantities; (2) the equipment needed, including the proper calibration and use in the process; (3) step-by-step instructions on what to do with the raw materials and equipment, including the timing of those steps; and (4) other special instructions and safety and regulatory precautions. These items are not found in the publicly accessible literature. Moreover, these documents demonstrate an integrated sequential process, whereby the output of one step is the input for the next step. The details of this process are highly unique to each manufacturer and highly valuable.

62. While this information is important for efficiently maintaining existing commercial-scale operations, it is also instrumental for launching commercial-scale operations in a new facility. Even with AbbVie's well-established protocols for producing adalimumab, and its

substantial know-how in commercial-scale adalimumab manufacturing, it takes years to bring a new facility online. Indeed, even with an FDA-approved manufacturing process, AbbVie must manufacture various engineering and process batches to register a new facility with the FDA as an adalimumab manufacturing site. AbbVie also must ensure that the general operations of the facility, including room classifications, HVAC, gowning procedures, and material and personnel flows, are acceptable to the FDA.

63. The information contained in these documents is not and never has been publicly available. To the contrary, AbbVie guards this type of information as important and confidential trade secret information.

64. In addition, AbbVie employees receive extensive training on AbbVie's trade secrets, including its HUMIRA® manufacturing process. For example, Rongzan Ho and Jason Seah were trained on AbbVie's upstream manufacturing process for HUMIRA® and thereby learned how AbbVie prepares adalimumab. They also learned how AbbVie sets up components and process equipment; operates, monitors, and adjusts the operation of equipment including bioreactors, scales, and analytical tools; and performs process sampling for adalimumab.

65. Eunice Tan was trained on AbbVie's central services and downstream manufacturing process for HUMIRA® and thereby learned how AbbVie prepares adalimumab, including purification and fill and finish. As part of central services, she provided operations in support of the full manufacturing process, including preparation and transfer of media and buffer, autoclaving, raw material sampling, sterilization, and other activities.

66. Rongzan Ho, Jason Seah, and Eunice Tan were involved in setting up AbbVie's HUMIRA® manufacturing plant in Singapore from the ground up and so also learned what approaches did not work when manufacturing adalimumab. AbbVie optimized its processes over

time, constantly improving to increase efficiencies through trial-and-error and based on AbbVie's prior experiences. As a Team Leader for upstream manufacturing, Rongzan Ho was qualified to execute, and was certified to train other biotechnologists (such as Jason Seah) to execute, many AbbVie upstream manufacturing tasks.

67. Further, Rongzan Ho was one of a handful of employees who spent months at AbbVie's manufacturing facility in Barceloneta, Puerto Rico to study the HUMIRA® manufacturing processes developed there such that they could be implemented at AbbVie Singapore. Beginning in May 2016, he trained on the specific processes, automations, principles of manufacture, and quality systems used to manufacture HUMIRA®. At the end of his training in Puerto Rico, Rongzan Ho was expected to demonstrate hands-on competency with the HUMIRA® upstream manufacturing process and use that knowledge to startup AbbVie Singapore.

68. Rongzan Ho, Jason Seah, and Eunice Tan were exposed to and learned AbbVie's most highly sensitive information regarding the manufacturing of HUMIRA®, including AbbVie's trade secrets. Each not only learned and/or had access to documents describing AbbVie's manufacturing process for HUMIRA®, but also learned and/or had access to documents describing how AbbVie operates and runs its manufacturing facilities in order to achieve an efficient and consistent manufacturing process for HUMIRA®. This involves, for example: critical information about the timing of various process parameters; information about materials for laboratory operations, such as logbook monitoring, equipment maintenance, and requisition of material; and information about AbbVie's inventory of non-bill of materials laboratory consumables, including about how much is consumed per process run. Such information is instrumental to running a commercial-scale adalimumab manufacturing process.

69. These employees not only learned and had access to documents describing AbbVie's know-how for running a high-quality manufacturing process for commercial-scale production of adalimumab, but also learned and had access to documents describing AbbVie's know-how for bringing a new adalimumab facility online and obtaining GMP certification of a new adalimumab facility.

70. This information contains nearly all the information needed to implement a process to manufacture adalimumab on a commercial scale. As discussed below, Rongzan Ho, after accepting a position at Alvotech and before leaving AbbVie, and without disclosing his position at Alvotech, emailed himself copies of multiple voluminous Excel files containing AbbVie's trade secrets, such as its adalimumab master production schedule ("MPS"), shift instructions and notes, weekly checklists for the manufacturing process, lists of the materials needed to run the process, and the training status of AbbVie Singapore employees. On information and belief, Rongzan Ho, stole AbbVie's trade secrets and transferred them to Alvotech hf., which then misappropriated them by using them to develop a commercial-scale manufacturing process for AVT02. And the evidence indicates that Alvotech hf. directly, or indirectly through its wholly-owned subsidiaries, targeted and recruited AbbVie employees, including at least Rongzan Ho, Jason Seah, and Eunice Tan, who, on information and belief, subsequently provided this information and other trade secret know-how to Alvotech hf.

C. AbbVie Took Extensive Steps to Maintain the Secrecy of Its Trade Secrets

71. As a leader in the biologics industry, AbbVie has expended considerable resources in R&D, which has resulted in significant confidential and proprietary trade secrets, including the trade secrets at issue here. While developing HUMIRA®, AbbVie obtained and created an enormous amount of valuable confidential and proprietary information. AbbVie engaged in years of research and development to develop the optimal manufacturing process for the drug substance.

As discussed, the results of these efforts were recorded in various highly confidential documents and are taught to AbbVie employees who need to know the process. AbbVie keeps significant aspects of these processes as trade secrets to protect their value and the significant investments AbbVie has made in their development. This confidential information derives considerable independent economic value from being not generally known outside of AbbVie. AbbVie's years of research reflected in its manufacturing process contributed to AbbVie's commercial advantage over its competitors or its would-be competitors, and these items are of exceptional value to AbbVie.

72. With access to AbbVie's trade secrets, described above, a competitor would have a significant advantage in developing a manufacturing process for its own adalimumab product that competes with AbbVie's HUMIRA®. Not only would the competitor be able to enter the market with a competing product, but it would be able to do so without having invested the resources or time in research and development that AbbVie had to invest to get to the same point.

73. Given the importance of these items to AbbVie's commercial advantage and success, AbbVie guards them carefully.

74. First, AbbVie has in place physical and technological safeguards to ensure the security of its computer systems, which contain its trade secrets. All of AbbVie's computers, tablets, and smart phones are password protected, have security firewalls, and employ encryption technology. Much of the information regarding manufacturing processes—while known to specialized professionals responsible for manufacturing—is stored on non-networked servers, is subject to encryption policies, may only be accessed by those who need to know, and requires the use of two-factor authentication. Additionally, all such information is restricted from communication outside of AbbVie personnel and devices and must be returned prior to an

employee leaving AbbVie.

75. All incoming employees are also given training on AbbVie's confidentiality and information security policies. Employees are instructed, for example, that sending data or information through a personal email account is prohibited. Employees are also instructed that no printouts of AbbVie documents should be left unsecured, let alone taken outside of the company offices. AbbVie additionally provides its trade secret policy statement in employee handbooks and legal education programs and conducts periodic reviews of confidentiality policies.

76. In addition, employee access to AbbVie trade secrets is on a need-to-know basis. Not all employees have access to all of AbbVie's data and manufacturing process information. Employees are only given access to trade secrets and other proprietary information if they needed to access it in order to perform their job. Employee obligations to protect trade secrets include, but are not limited to: prohibitions against disclosing the trade secret information externally; implementing procedures for visitors, such as signing in and out, wearing a visitor's badge, and requiring an escort; prohibitions against disclosing confidential information during new employee interviews; limiting tours of the facility; having applicants sign a confidentiality and non-disclosure agreement; prohibiting photography on AbbVie premises; prohibiting the use of non-AbbVie devices, and non-AbbVie servers and drives; designating and classifying data, documents and emails according to classification policies; and reminding departing employees of their obligation to keep AbbVie trade secrets confidential, especially with respect to a new employer. All of these measures apply to all non-public information regarding AbbVie's manufacturing process for HUMIRA®.

77. AbbVie also employs a data loss prevention program to monitor company email and personal email sent from company servers and auto-encrypt all files.

78. These safeguards are intended to prevent the improper misuse, theft, or disclosure of electronically-stored AbbVie proprietary information or trade secrets.

79. Second, all of AbbVie's employees are required to sign confidentiality and non-compete agreements governing, among other things, the use and disclosure of AbbVie's proprietary information and trade secrets. The agreements Rongzan Ho, Jason Seah, and Eunice Tan signed expressly stated that the confidentiality obligations described remain in effect after termination of employment and that the employees should not seek employment in similar positions with competitors.

80. Upon departure from AbbVie, Rongzan Ho, Jason Seah, and Eunice Tan reaffirmed his or her employment agreement obligations as outlined above.

V. UNLAWFUL AND UNFAIR ACTS COMMITTED BY THE PROPOSED RESPONDENTS

81. Pursuant to 19 C.F.R. § 210.12(a)(2), Complainants state that AVT02 is the product of unfair methods of competition and unfair acts, specifically the misappropriation of trade secrets belonging to AbbVie and tortious interference with AbbVie employee contracts. Alvotech hf. directly, or through its wholly-owned subsidiaries Alvotech Swiss and Alvotech Germany, targeted and recruited AbbVie's employees on the other side of the globe for their specialized and particularized knowledge of AbbVie's trade secrets related to HUMIRA®.

82. On information and belief, a former employee of AbbVie, Rongzan Ho, stole AbbVie's trade secrets and transferred them to Alvotech hf., which then misappropriated them by using them to develop a commercial-scale manufacturing process for AVT02. Alvotech hf. then used Rongzan Ho to engage in a campaign to hire additional AbbVie employees with specialized and particularized knowledge of AbbVie's trade secrets related to HUMIRA® manufacturing. Several other employees, including at least Jason Seah and Eunice Tan were also recruited from

AbbVie by Alvotech hf. based on their knowledge of AbbVie's confidential and trade secret information related to the manufacture of HUMIRA®. Alvotech hf. engaged in the unlawful practice of encouraging AbbVie employees to breach their contractual obligations. In exchange for providing Alvotech hf. with AbbVie's trade secrets, which were necessary to the rapid development of the AVT02 product including the commercial-scale manufacturing process for AVT02, Alvotech hf. directly, or through its wholly-owned subsidiaries, provided Rongzan Ho, and others with monetary compensation.

A. Alvotech Misappropriated AbbVie's Trade Secrets

1. Rongzan Ho had access to and stole documents reflecting AbbVie's most closely guarded trade secrets regarding its manufacturing process.

83. Rongzan Ho joined AbbVie in April 2016 as part of AbbVie's bringing its Singapore plant online to manufacture HUMIRA®. From May through August 2016, Rongzan Ho trained in Puerto Rico at AbbVie's HUMIRA® manufacturing plant. On January 12, 2018, Rongzan Ho resigned from AbbVie.

84. Rongzan Ho was a Team Leader for adalimumab upstream manufacturing at AbbVie. His responsibilities included overseeing the upstream manufacturing process, training team members on the relevant processes and procedures, and ensuring the process ran smoothly.

85. Rongzan Ho learned and had access to highly sensitive documents describing how to coordinate commissioning and qualification activities needed to bring the manufacturing facility at AbbVie Singapore online. Such documents included, for example: documentation describing the commissioning and qualification of new equipment and new areas; AbbVie's standard operating procedures; AbbVie's training programs; documentation describing how AbbVie conducts trial, development, and engineering process runs; and documentation describing AbbVie's process validation. These highly sensitive AbbVie documents ensure that department

and site metric goals are achieved through schedule adherence and quality execution. As part of his work at AbbVie, Rongzan Ho helped devise training plans and coordinate the preparation of training materials for Upstream and Downstream personnel.

86. Like all AbbVie employees, Rongzan Ho was required to protect AbbVie's trade secrets. He signed a confidentiality agreement when he first joined AbbVie in 2016 and again in 2018. These confidentiality obligations required Rongzan Ho to, among other things, only use AbbVie's proprietary information in connection with his employment, protect that information as trade secrets, and not disclose any of AbbVie's confidential information to unauthorized third parties. These obligations continue even after Rongzan Ho left AbbVie's employ. Rongzan Ho violated his confidentiality obligations and stole AbbVie's trade secrets by emailing himself key documents that, on information and belief, he would later pass on to Alvotech hf.

87. AbbVie maintained information technology security records which tracked how its employees engaged with its systems. These included systems that allow for the tracking and review of employee emails.

88. Rongzan Ho was targeted by Alvotech hf. for a similar position in Alvotech hf.'s adalimumab upstream manufacturing at its Iceland facility with responsibilities including overseeing the upstream manufacturing process, training team members on the relevant processes and procedures, and ensuring the process ran smoothly. On information and belief, in late 2017, Rongzan Ho traveled to Iceland for an interview with Alvotech hf. On January 12, 2018, Rongzan Ho resigned from AbbVie and did not inform AbbVie about his new position at Alvotech hf.

89. On February 12, 2018, three days before his last day at AbbVie, Rongzan Ho made three attempts to send to his personal email address five large Excel spreadsheets containing AbbVie's confidential and trade secret information. First, he twice attempted to send them under

the subject line "Useful info." AbbVie's security systems blocked these attempts. In response, and to subvert the security systems, he changed the subject line to the deceptively innocuous "Keep in touch (AbbVie)" and overrode the security alert to send the email.

90. The attached Excel spreadsheets included extensive details of AbbVie's adalimumab manufacturing process, such as (a) an overview for manufacturing adalimumab, (b) the schedule for manufacturing adalimumab on multiple manufacturing lines, (c) the validation schedules for bringing a new adalimumab manufacturing plant online, (d) critical manufacturing parameters, (e) key consumables and other materials for the process, and (e) training requirements and status for AbbVie employees. Confidential Exhibit A, email from Rongzan Ho's AbbVie email address to his personal email address.

91. With these documents, a competitor would have the necessary know-how to manufacture an adalimumab drug substance.

92. Rongzan Ho had no legitimate reason or business justification for emailing to himself AbbVie's confidential and highly sensitive documents, particularly three days before submitting his resignation. Though he had access to such documents as part of his job responsibilities as an upstream Team Lead, he had no business purpose for sending the documents to his personal email account. Rather, doing so was contrary to his confidentiality agreement, company policy, and the professional obligations that he owed to AbbVie as his employer.

93. Upon discovery of this theft via the DLP system, AbbVie contacted Rongzan Ho, who confirmed via a declaration that he had deleted the stolen documents. Confidential Exhibit B, Rongzan Ho exit declaration. With this assurance, and without knowledge of Rongzan Ho's recruitment by Alvotech hf. to work on its adalimumab product, AbbVie had no reason to suspect any misappropriation of its manufacturing trade secrets.

94. Rongzan Ho's theft of AbbVie's trade secrets was intertwined with his plan to commence his employment with Alvotech hf. promptly after his departure from AbbVie. Exhibit C, Rongzan Ho LinkedIn Profile as posted on February 18, 2021 (showing Alvotech employment starting in March 2018). The only possible inference is that Rongzan Ho took the documents with the intent to use AbbVie's sensitive trade secret manufacturing information in his role at Alvotech hf.

2. After leaving AbbVie, Rongzan Ho provided AbbVie's manufacturing know-how to Alvotech.

95. Alvotech hf. was founded in 2013 and has repeatedly delayed the planned launch date for an unidentified drug: what was first announced as a launch date of 2018 was pushed to 2019, and then to 2020.[31] Significant turnover in leadership also indicates problems within the company.[32] As time marched on with continued delays and little progress towards a product launch, Alvotech hf. increasingly felt pressure, including from its investors, to finalize and launch a product as soon as possible. Alvotech hf.'s adalimumab product fell behind that of other

[31] *Alvotech invests $250 million in Biopharmaceuticals,* Alvotech Newsroom (Mar. 5, 2013), *available at* https://www.alvotech.com/newsroom/alvotech-invests-250-million-in-biopharmaceuticals (last visited Oct. 26, 2021); *Alvotech opens 50 new positions,* Alvotech Newsroom (Nov. 6, 2014), *available at* https://www.alvotech.com/newsroom/alvotech-opens-50-new-positions (last visited Oct. 26, 2021); *Generics Bulletin casts spotlight on Alvotech,* Alvotech Newsroom (July 12, 2016), *available at* https://www.alvotech.com/newsroom/generics-bulletin-casts-spotlight-on-alvotech (last visited Oct. 26, 2021); *The story of Alvogen and the founding of a pharma empire,* World Finance (Jan. 22, 2018), *available at* https://www.worldfinance.com/markets/the-story-of-alvogen-and-the-founding-of-a-pharma-empire (last visited Oct. 26, 2021).

[32] *Eef Schimmelpennink Joins Alvotech as CEO,* Alvotech Newsroom (Nov. 27, 2015), *available at* https://web.archive.org/web/20151217230521/http://www.alvotech.com/newsroom/read/eef-schimmelpennink-joins-alvotech-as-ceo (last visited Oct. 26, 2021); *Rasmus Rojkjaer appointed CEO of Alvotech,* Alvotech Newsroom (Aug. 4, 2017), *available at* https://www.alvotech.com/newsroom/rasmus-rojkjaer-appointed-ceo-of-alvotech (last visited Oct. 26, 2021); *Mark Levick appointed CEO of Alvotech,* Alvotech Newsroom (May 9, 2019), *available at* https://www.alvotech.com/newsroom/mark-levick-appointed-ceo-of-alvotech (last visited Oct. 26, 2021).

competitors, including Amgen, Sandoz, Mylan and Samsung Bioepis / Biogen, all of whom launched adalimumab biosimilars in the European market in 2018. At that time, Alvotech had not even filed for regulatory approval in Europe.

96. Alvotech hf. is owned and funded privately and depends on bonds and other private financing to fund its operations.[33] AVT02 is Alvotech hf.'s first product, and, until 2021, it did not even have another product in clinical trials.

97. On his LinkedIn page, Rongzan Ho indicated that he went to work as a Scientist/DSM-USP Specialist at Alvotech hf. in March 2018. Exhibit C.

98. The timing of Rongzan Ho's departure from AbbVie, armed with AbbVie's trade secrets, coincided almost exactly with Alvotech hf.'s need to develop a commercial-scale adalimumab manufacturing process with pending clinical studies and repeated statements and promises of a 2020 launch date for AVT02.[34]

99. In its first clinical study beginning in May 2018, Alvotech hf. used AVT02 manufactured at a contract manufacturer, Patheon Italia S.p.A., rather than its own facility in Iceland. Exhibit D, Australian regulatory information for AVT02 (showing Patheon Italia S.P.A. as the "Manufacturer" of AVT02 for Alvotech). On information and belief, this was because

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[33] *Alvotech completes U.S. $300M financing deal,* Alvotech Newsroom (Jan. 22, 2019), *available at* https://www.alvotech.com/newsroom/alvotech-completes-u.s.-300m-financing-deal (last visited Oct. 26, 2021).

[34] *Alvotech invests $250 million in Biopharmaceuticals,* Alvotech Newsroom (Mar. 5, 2013), *available at* https://www.alvotech.com/newsroom/alvotech-invests-250-million-in-biopharmaceuticals (last visited Oct. 26, 2021); *Alvotech opens 50 new positions,* Alvotech Newsroom (Nov. 6, 2014), *available at* https://www.alvotech.com/newsroom/alvotech-opens-50-new-positions (last visited Oct. 26, 2021); *Generics Bulletin casts spotlight on Alvotech,* Alvotech Newsroom (July 12, 2016), *available at* https://www.alvotech.com/newsroom/generics-bulletin-casts-spotlight-on-alvotech (last visited Oct. 26, 2021); *The story of Alvogen and the founding of a pharma empire,* World Finance (Jan. 22, 2018), *available at* https://www.worldfinance.com/markets/the-story-of-alvogen-and-the-founding-of-a-pharma-empire (last visited Oct. 26, 2021).

Alvotech hf. did not yet have an adalimumab manufacturing process in place.

100. It was not until September 2018, six months after Rongzan Ho arrived at Alvotech hf., that Alvotech hf. obtained its first manufacturing license for its Iceland facility.[35]

101. The first batch of AVT02 manufactured at Alvotech hf.'s Iceland facility that was usable for clinical trials – that is, produced by a validated manufacturing process – was not complete until December 2018, 9 months after Rongzan Ho arrived at Alvotech hf. Exhibit E, New Zealand regulatory information for AVT02 (showing Alvotech's Iceland facility as the "Manufacturing and release testing site" for adalimumab manufactured on December 6, 2018).

102. Obtaining AbbVie's trade secrets from Rongzan Ho helped solve an existential problem for Alvotech hf., permitting it to refine its manufacturing process and begin to secure necessary regulatory approvals to bring to market AVT02 when it desperately needed a product to launch after years of delays.

103. In January 2019, only 10 months after his arrival at Alvotech hf. and one month after the first successful batch of AVT02, Rongzan Ho was promoted to Manager, DSM-USP Manufacturing. *See* Exhibit C. On information and belief, this promotion was compensation provided to him by Alvotech hf. for AbbVie's trade secrets.

3. Alvotech targeted AbbVie employees who had knowledge of AbbVie's HUMIRA® trade secrets.

104. Alvotech hf. began targeting and hiring multiple, highly experienced employees of AbbVie with knowledge of AbbVie's trade secrets that could be used by Alvotech to further improve its commercial scale adalimumab manufacturing process.

[35] *Alvotech receives manufacturing license for its Biopharmaceutical facility,* Alvotech Newsroom (Sept. 25, 2018), *available at* https://www.alvotech.com/newsroom/alvotech-receives-manufacturing-license-for-its-biopharmaceutical (last visited Oct. 26, 2021).

105. Alvotech hf. has unfairly and improperly obtained AbbVie's trade secrets through a strategic campaign to raid AbbVie for employees who could provide and apply AbbVie's trade secrets in Alvotech hf.'s manufacturing facilities in Iceland.

106. Alvotech hf. has directly, or through its wholly-owned subsidiaries Alvotech Swiss AG and Alvotech Germany GmbH, recruited or attempted to recruit at least half a dozen former AbbVie employees to work at Alvotech hf., or one of its wholly-owned subsidiaries, since at least 2016.

107. Rongzan Ho was specifically targeted and recruited by Alvotech hf. Confidential Exhibit F, email on behalf of Rongzan Ho. On information and belief, Alvotech hf. then used Rongzan Ho to solicit more AbbVie employees, going so far as to have Rongzan to contact, recruit, and interview at least Jason Seah.

108. Alvotech hf. also used external recruiters to target AbbVie employees. Rongzan Ho even appeared in an Alvotech recruitment video posted on Alvotech's website and on LinkedIn.[36] And Alvotech hf. continued to target and attempt to recruit other AbbVie employees who were not ultimately hired and remain employed at AbbVie.

109. The targeted AbbVie employees are highly experienced in core aspects of AbbVie's technology, and had access to, and knowledge of, AbbVie's trade secrets based on their employment with AbbVie.

110. On information and belief, Alvotech hf. intentionally solicited from AbbVie employees what they had learned about AbbVie's trade secrets and could provide to Alvotech hf.

111. Each of the former AbbVie or Abbott employees is now working at Alvotech hf.,

[36] *Previously available at* https://web.archive.org/web/20201025001251/https:/storf.alvotech.is/ (last viewed Feb. 25, 2021) (the video has since been taken down by Alvotech).

or one of its wholly-owned subsidiaries, or has worked at Alvotech hf., or one of its wholly-owned subsidiaries, since leaving AbbVie. These employees are or were working at Alvotech hf., or one of its wholly-owned subsidiaries, in similar job positions to those they formerly occupied at AbbVie. Indeed, on information and belief, Rongzan Ho, Jason Seah, and Eunice Tan all worked or work on AVT02, Alvotech hf.'s biosimilar to HUMIRA®.

112. After recruiting Rongzan Ho, Alvotech hf. was looking to further access AbbVie's trade secret know-how by recruiting additional AbbVie employees with similar knowledge of AbbVie's trade secrets. Jason Seah and Eunice Tan, who started at Alvotech hf. in May 2020, fit the bill.

113. Jason Seah and Eunice Tan joined AbbVie in November 2015 as part of AbbVie's bringing its Singapore plant online to manufacture HUMIRA®.

114. Both Jason Seah and Eunice Tan were Biotechnologists for adalimumab manufacturing at AbbVie. Their knowledge and access spanned the AbbVie adalimumab manufacturing process, with Jason Seah working in upstream manufacturing and Eunice Tan working in both central services and downstream manufacturing. Their responsibilities included executing manufacturing process and ensuring the process ran smoothly.

115. Both Jason Seah and Eunice Tan learned and had access to highly sensitive documents describing how to coordinate commissioning and qualification activities needed to bring the manufacturing facility at AbbVie Singapore online. Such documents included, for example: documentation describing the commissioning and qualification of new equipment and new areas; AbbVie's standard operating procedures; AbbVie's training programs; documentation describing how AbbVie conducts trial, development, and engineering process runs; and documentation describing AbbVie's process validation. These highly sensitive AbbVie documents

ensure that department and site metric goals are achieved through schedule adherence and quality execution.

116. Like all AbbVie employees, Jason Seah and Eunice Tan were required to protect AbbVie's trade secrets. Each signed a confidentiality agreement when they first joined AbbVie in 2015. These confidentiality obligations required Jason Seah and Eunice Tan to, among other things, only use AbbVie's proprietary information in connection with their employment, protect that information as trade secrets, and not disclose any of AbbVie's confidential information to unauthorized third parties. These obligations continued even after each left AbbVie's employ. On April 3 and April 1, 2020, respectively, Jason Seah and Eunice Tan resigned from AbbVie. Jason Seah and Eunice Tan violated their confidentiality obligations and misappropriated AbbVie's trade secrets by taking nearly identical positions with Alvotech hf. to work on a directly competing product and passing on AbbVie's trade secrets to Alvotech hf.

117. Rongzan Ho, Jason Seah and Eunice Tan had each signed non-compete agreements, and at the time of their resignation each of them did not disclose that their departure was for a biosimilar manufacturer, specifically Alvotech hf., or that they would be working for a competitor to develop and manufacture an adalimumab biosimilar to compete with HUMIRA®.

118. Given the timing and nature of the departure of these employees from AbbVie, the similarity of the positions they then occupied at Alvotech hf., and having disclosed to Alvotech hf. the misappropriated trade secrets, on information and belief, Jason Seah and Eunice Tan will continue to disclose the misappropriated trade secrets.

119. By hiring highly experienced former AbbVie employees, with knowledge of AbbVie's trade secrets, Alvotech hf. gained access to AbbVie's trade secrets. On information and belief, Alvotech hf. was aware of the agreements between AbbVie and its employees protecting

AbbVie's trade secrets.

120. On information and belief, it was understood by the former AbbVie employees that they would be expected to use and/or disclose at Alvotech hf. the proprietary know-how and trade secrets learned at AbbVie.

121. Alvotech hf.'s concerted recruiting effort, targeted towards AbbVie employees with knowledge of AbbVie's adalimumab manufacturing trade secrets, is more evidence of Alvotech hf.'s blatant and willful trade secret misappropriation.

4. Alvotech has failed to appropriately investigate and respond to AbbVie's inquiries regarding its suspicions.

122. Given Alvotech hf.'s short time in existence, lack of other products, and late start, AbbVie was surprised to learn of the FDA's acceptance of Alvotech's BLA for AVT02 in late 2020. Upon further investigation, AbbVie discovered that Rongzan Ho had gone to Alvotech hf. to work on AVT02, in a nearly identical role, directly after departing AbbVie.

123. On February 24, 2021, AbbVie wrote to Alvotech's CEO, Mark Levick, regarding its belief that Alvotech had embarked on an unlawful plot to surreptitiously take AbbVie's confidential and proprietary trade secrets related to the manufacturing process for HUMIRA® to develop and manufacture its competing biosimilar product. AbbVie asked Alvotech to address this belief, particularly given the timing of Alvotech's hiring of Rongzan Ho, the timing of his tenure with Alvotech, and the timing of Alvotech's announcements regarding its biosimilar to AbbVie's HUMIRA®. In its March 3, 2021 response, Alvotech did not deny that Mr. Ho worked on a biosimilar to HUMIRA® while employed at Alvotech. Alvotech also did not deny that it deployed Mr. Ho in the exact same role he performed at AbbVie and tasked him with developing and overseeing manufacturing for a biosimilar of the exact same drug that he was responsible for at AbbVie, AVT02, a high-concentration HUMIRA® biosimilar, again in violation of his obligations

to AbbVie. And while Alvotech stated it would investigate AbbVie's claims, it never presented the results of any investigation, let alone any exculpatory evidence. Nor has Alvotech taken any steps to remediate its willful misconduct.

124. On July 30, 2021, AbbVie again wrote Alvotech to confirm that Alvotech was complying with its obligation to preserve potentially relevant information regarding the district court trade secret litigation. *See* Section X.A. The letter also raised AbbVie's concern that Alvotech was continuing to recruit AbbVie employees to place them in similar roles at Alvotech and use additional AbbVie trade secrets. AbbVie asked that Alvotech address this concern by providing written confirmation that no AbbVie former employees, including but not limited to Rongzan Ho, Jason Seah, and Eunice Tan, were responsible for, participating in, or otherwise working in any fashion on Alvotech's efforts to develop, replicate, optimize, or operate a manufacturing process for adalimumab. Similarly, AbbVie sought identification of any former AbbVie employees connected to Alvotech's regulatory filings for adalimumab. AbbVie also sought assurances that Alvotech is not engaging and will not engage in any efforts to recruit additional current or former AbbVie employees into the same roles they held at AbbVie concerning any adalimumab biosimilar manufactured or being developed at Alvotech. Alvotech responded on August 6, 2021, indicating that only some of the named individuals no longer work at Alvotech and the only assurance provided with regard to the work of those individuals is that none of the listed individuals is involved with setting up Alvotech's new manufacturing facility in China.

5. The manufacturing process for AVT02 was developed through the misappropriation of AbbVie's Trade Secrets.

125. The evidence supports the conclusion that the commercial-scale manufacturing process for AVT02 was developed through the misappropriation of AbbVie's trade secrets stolen

from AbbVie by at least Rongzan Ho, Eunice Tan, and Jason Seah. Specifically, and as discussed at further length below:

a. The timeline of Alvotech hf.'s development of AVT02 was implausibly short: Alvotech hf. has experienced continuous turnover of high level management and missed deadlines, and in 2017, Alvotech hf.'s facilities were not ready to begin manufacturing, forcing Alvotech hf. to use a contract manufacturing facility instead. Surprisingly, given Alvotech hf.'s slow progression and inability to execute, in late 2018, Alvotech hf. was able to manufacture a batch of AVT02 at its Iceland facility which could be used in clinical trials.

b. AbbVie's electronic records demonstrate that Rongzan Ho stole its confidential manufacturing information.

c. After leaving AbbVie in February 2018, Rongzan Ho began working for Alvotech hf. in a nearly identical role on its adalimumab manufacturing process. He worked in that role at Alvotech hf. from at least March 2018 to July 2020, the same time Alvotech hf. was developing its commercial-scale manufacturing process for AVT02.

d. After leaving AbbVie in April 2020, Eunice Tan began working for Alvotech hf. in a nearly identical role on its adalimumab manufacturing process.

e. After leaving AbbVie in May 2020, Jason Seah began working for Alvotech hf. in a nearly identical role on its adalimumab manufacturing process.

126. This evidence, and the evidence that AbbVie expects to elicit from Alvotech hf., Alvotech Swiss AG, Alvotech Germany GmbH, Teva, and others if an Investigation is instituted, will conclusively establish that the manufacturing process for AVT02 is the product of

misappropriation of AbbVie's trade secrets in contravention of 19 U.S.C. § 1337(a)(1)(A).

6. The timing of Alvotech hf.'s purported development of AVT02 is implausible.

127. The speed with which Alvotech hf. was able to develop an adalimumab product and manufacturing process for regulatory submission is so implausible as to leave no inference other than that Alvotech hf. had the benefit of receiving AbbVie's trade secrets.

128. Alvotech hf. was created in 2013. As is clear from an outside perspective, Alvotech hf. struggled to develop and launch a product. For example, Alvotech hf. has repeatedly delayed the planned launch date for its unspecified first drug: what was first announced as a launch date of 2018 was pushed to 2019, and then to 2020.[37] Regular turnover in leadership also indicated problems within the company.[38] As time marched on with continued delays and little progress towards any product launch, Alvotech hf. increasingly felt pressure, including from its investors, to finalize and launch a product – any product – as soon as possible.

129. AVT02 is Alvotech hf.'s first ever product; until 2021, Alvotech did not have

[37] *Alvotech invests $250 million in Biopharmaceuticals,* Alvotech Newsroom (Mar. 5, 2013), *available at* https://www.alvotech.com/newsroom/alvotech-invests-250-million-in-biopharmaceuticals (last visited Oct. 26, 2021); *Alvotech opens 50 new positions,* Alvotech Newsroom (Nov. 6, 2014), *available at* https://www.alvotech.com/newsroom/alvotech-opens-50-new-positions (last visited Oct. 26, 2021); *Generics Bulletin casts spotlight on Alvotech,* Alvotech Newsroom (July 12, 2016), *available at* https://www.alvotech.com/newsroom/generics-bulletin-casts-spotlight-on-alvotech (last visited Oct. 26, 2021); *The story of Alvogen and the founding of a pharma empire,* World Finance (Jan. 22, 2018), *available at* https://www.worldfinance.com/markets/the-story-of-alvogen-and-the-founding-of-a-pharma-empire (last visited Oct. 26, 2021).

[38] *Eef Schimmelpennink Joins Alvotech as CEO,* Alvotech Newsroom (Nov. 27, 2015), *available at* https://web.archive.org/web/20151217230521/http://www.alvotech.com/newsroom/read/eef-schimmelpennink-joins-alvotech-as-ceo (last visited Oct. 26, 2021); *Rasmus Rojkjaer appointed CEO of Alvotech,* Alvotech Newsroom (Aug. 4, 2017), *available at* https://www.alvotech.com/newsroom/rasmus-rojkjaer-appointed-ceo-of-alvotech (last visited Oct. 26, 2021); *Mark Levick appointed CEO of Alvotech,* Alvotech Newsroom (May 9, 2019), *available at* https://www.alvotech.com/newsroom/mark-levick-appointed-ceo-of-alvotech (last visited Oct. 26, 2021).

another product in clinical trials.

130. Outside observers noted the challenges and delays faced by Alvotech hf..[39] In May of 2017, Alvotech hf.'s highly touted Iceland manufacturing facility was still not fully operational.[40]

131. In its first clinical study beginning in May 2018, Alvotech Swiss used AVT02 manufactured at a contract manufacturer, Patheon Italia S.p.A., rather than at Alvotech hf.'s own facility in Iceland. Exhibit D. This indicates that Alvotech hf. did not yet have the ability to manufacture at its Iceland facility. On information and belief, this was because Alvotech hf. did not yet have an adalimumab manufacturing process in place.

132. It was not until September 2018 that Alvotech hf. obtained its first manufacturing license for its Iceland facility.[41]

133. On information and belief, the first batch of AVT02 manufactured at Alvotech hf.'s Iceland facility that was usable for clinical trials – that is, produced by a validated manufacturing process – was not complete until December 2018, only 19 months *at most* after the facility was complete. Exhibit E.

134. This is an implausibly short amount of time. The speed of this adalimumab

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[39] *Biosimilars Producer, Alvotech, Finds Opportunities in Iceland,* Pharmaceutical Online (May 11, 2017), *available at* https://www.pharmaceuticalonline.com/doc/biosimilars-producer-alvotech-finds-opportunities-in-iceland-0001 (last visited Nov. 17, 2021) (reporting that Alvotech's CEO at the time recalled that, in October 2015, the facility seemed to be "just a set of walls and floors, with nothing else built in.").

[40] *Alvotech 2017* at 6, *available at* http://businessdocbox.com/Biotech_and_Biomedical/73190478-1-1-0-0-10-4-3-0-0-0-2-0.html (last visited Nov. 18, 2021).

[41] *Alvotech receives manufacturing license for its Biopharmaceutical facility,* Alvotech Newsroom (Sept. 25, 2018), *available at* https://www.alvotech.com/newsroom/alvotech-receives-manufacturing-license-for-its-biopharmaceutical (last visited Oct. 26, 2021).

manufacturing process development can only be explained if, after a rapid change in strategy – targeting high-concentration HUMIRA® – Alvotech hf. leveraged AbbVie's trade secrets (developed over more than a decade) about how to produce and gain approval for a high-concentration adalimumab product on a commercial scale.

7. Alvotech hf. rewarded Rongzan Ho for his theft.

135. On his LinkedIn page, Rongzan Ho indicated that he went to work as a Scientist/DSM-USP Specialist at Alvotech hf. in March 2018. Exhibit C.

136. The timing of Rongzan Ho's departure from AbbVie, armed with AbbVie's critical trade secrets, coincided almost exactly with Alvotech hf.'s need to develop a commercial-scale adalimumab manufacturing process with pending clinical studies and repeated statements and promises of a 2020 launch date for AVT02.[42]

137. On information and belief, the first batch of AVT02 manufactured at Alvotech hf.'s Iceland facility that was usable for clinical trials – that is, produced by a validated manufacturing process – was not complete until December 2018, 9 months after Rongzan Ho arrived at Alvotech. Exhibit E.

138. In January 2019, only 10 months after his arrival at Alvotech hf. and one month after the first successful batch of AVT02 from Alvotech hf.'s Iceland facility, Rongzan Ho was

[42] *Alvotech invests $250 million in Biopharmaceuticals,* Alvotech Newsroom (Mar. 5, 2013), *available at* https://www.alvotech.com/newsroom/alvotech-invests-250-million-in-biopharmaceuticals (last visited Oct. 26, 2021); *Alvotech opens 50 new positions,* Alvotech Newsroom (Nov. 6, 2014), *available at* https://www.alvotech.com/newsroom/alvotech-opens-50-new-positions (last visited Oct. 26, 2021); *Generics Bulletin casts spotlight on Alvotech,* Alvotech Newsroom (July 12, 2016), *available at* https://www.alvotech.com/newsroom/generics-bulletin-casts-spotlight-on-alvotech (last visited Oct. 26, 2021); *The story of Alvogen and the founding of a pharma empire,* World Finance (Jan. 22, 2018), *available at* https://www.worldfinance.com/markets/the-story-of-alvogen-and-the-founding-of-a-pharma-empire (last visited Oct. 26, 2021).

promoted to Manager, DSM-USP Manufacturing. Exhibit C. On information and belief, this promotion was compensation provided to him by Alvotech hf. for AbbVie's trade secrets.

B. Alvotech hf. Tortiously Interfered With Contractual Relations

139. Alvotech hf. has violated Section 337 by intentionally interfering with AbbVie's contractual relationships with its employees. See Rest 2d. Torts §§ 766, 766A, and 766B.

140. Alvotech hf. induced AbbVie's employees, including at least Rongzan Ho, Jason Seah, and Eunice Tan, to each breach his or her agreement with AbbVie to protect and keep confidential AbbVie's trade secrets. Confidential Exhibit G, Rongzan Ho employment contract; Confidential Exhibit H, Jason Seah employment contract; and Confidential Exhibit I, Eunice Tan employment contract. On information and belief, Alvotech hf. was aware of the agreements between AbbVie and its employees that prohibit use of AbbVie's confidential and trade secret information outside of AbbVie. In fact, Alvotech hf. itself requires its employees to sign a similar agreement. Confidential Exhibit J, email from Rongzan Ho. But Alvotech hf. sought out and recruited AbbVie's employees – from the other side of the globe – who had knowledge of AbbVie's trade secret manufacturing process for HUMIRA® to use AbbVie's trade secrets to develop a commercial-scale manufacturing process for AVT02, which resulted in those employees' breach of agreements with AbbVie without any justification.

141. Alvotech hf. has induced and continues to induce AbbVie's current and former employees to breach their noncompetition and confidentiality agreements with AbbVie by joining Alvotech hf. Alvotech hf.'s acts have interfered and continue to interfere with AbbVie's contractual relationships with its employees.

142. Complainants have suffered and continue to suffer injury on account of Alvotech hf.'s interference with AbbVie's contractual relationships with its employees. AbbVie has been injured by the disclosure and misappropriation of its trade secrets that has resulted from Alvotech

hf.'s interference with AbbVie's contractual relationships with its employees. The disclosure and misappropriation of AbbVie's trade secrets enabled Alvotech hf. to quickly develop a manufacturing process for an adalimumab product that will unfairly compete directly with AbbVie's HUMIRA®.

VI. IMPORTATION INTO, SALE FOR IMPORTATION INTO, AND SALE AFTER IMPORTATION INTO THE UNITED STATES

143. Pursuant to 19 C.F.R. § 210.12(a)(3), Complainants state that Proposed Respondents have imported, will import, and will sell within the United States after importation, AVT02, an adalimumab product. The specific instances of importation of AVT02 set forth below are illustrative and non-exhaustive.

144. AVT02 is manufactured as a drug substance by Alvotech hf. in a single facility in Iceland.[43] On information and belief, AVT02 is then transferred to Switzerland, where Ivers-Lee AG assembles and packages AVT02 into the autoinjector device and conducts final packaging and sterilization. On information and belief, AVT02 is then imported into the United States either directly or indirectly by Alvotech hf., Ivers-Lee AG, and/or Teva.

145. Teva has stated in securities filings that, as part of its exclusive partnership with Alvotech hf., Alvotech hf. is responsible for the development, registration and supply of AVT02.[44] Alvotech hf.'s only manufacturing facility to date is in Iceland.

146. Products labeled as "adalimumab" and manufactured by Alvotech hf. in Iceland

[43] *Alvotech completes U.S. $300M financing deal,* Alvotech Newsroom (Jan. 22, 2019), *available at* https://www.alvotech.com/newsroom/alvotech-completes-u.s.-300m-financing-deal (last visited Oct. 26, 2021).

[44] *Form 10-K, Teva Pharmaceutical Industries Ltd.*, U.S. Securities and Exchange Commission (Dec. 31, 2020), *available at* https://www.sec.gov/Archives/edgar/data/818686/000119312521036239/d102112d10k.htm (last visited Oct. 26, 2021).

have been imported into the United States since at least July 2020. *See* Exhibit K, Alvotech hf. importation records. Alvotech's Iceland facility has an FDA-assigned FEI number of 3013702557 and this FEI number is associated with each shipment described below. On information and belief, each shipment described below contains adalimumab manufactured by Alvotech hf. based on the importation information provided to the FDA.

a. On July 7, 2020, a shipment of "ADALIMUMAB" totaling "1.0 Carton, 120 Milligrams" arrived in the United States.

b. On October 8, 2020, a shipment of "PURIFIED MONOCLONAL ANTIBODY – ADALIMUMAB USTEKINUMAB" totaling "1.0 Box, 11.0 Pieces" arrived in the United States.

c. On November 18, 2020, a shipment of "AVT02 ADALIMUMAB SAMPLES" totaling "1.0 Box, 1.0 Pieces" arrived in the United States.

d. On November 18, 2020, a shipment of "AVT02 ADALIMUMAB SAMPLES" totaling "1.0 Box, 2.0 Pieces" arrived in the United States.

e. On February 11, 2021, a shipment of "AVT02 ADALIMUMAB SAMPLES" totaling "4.0 Vial, 1.5 Milliliters" arrived in the United States.

f. On February 11, 2021, a shipment of "HUMIRA (ADALIMUMAB) SAMPLES" totaling "1.0 Carton, 16.0 Pieces" arrived in the United States.

g. On April 13, 2021, a shipment of "AVT02 ADALIMUMAB SAMPLES" totaling "8.0 Vial, 30.0 Milliliters" arrived in the United States.

h. On July 24, 2021, a shipment of "AVT02 ADALIMUMAB FOR R&D" totaling "1.0 Carton, 85.0 Pieces" arrived in the United States.

i. On October 23, 2021, a shipment of "AVT02 ADALIMUMAB SAMPLES"

totaling "1.0 Box, 10.0 Pieces" arrived in the United States.

j. On October 28, 2021, a shipment of "AVT02 ADALIMUMAB SAMPLES" totaling "1.0 Box, 12.0 Pieces" arrived in the United States.

147. Products labeled as "adalimumab" with a listed manufacturer of Ivers-Lee AG in Switzerland have been imported into the United States since at least January 23, 2020. *See* Exhibit L, Ivers-Lee AG importation records. One of Ivers-Lee's Swiss facilities has an FEI number of 3002420194 and is associated with the shipment described below. On information and belief, the shipment of adalimumab described below is AVT02 based on Ivers-Lee AG's role in assembling auto-injectors containing AVT02 manufactured by Alvotech hf.

a. On January 23, 2020, a shipment of "ADALIMUMAB" totaling "9.0 Pieces, 9.0 Pieces" arrived in the United States.

148. Under the terms of the Teva Agreement, Alvotech hf. will manufacture AVT02 for commercial sale and will supply Teva with AVT02.[45] AVT02 is then imported into the United States either directly or indirectly by Alvotech hf., Ivers-Lee AG, and/or Teva. Teva made an upfront payment to Alvotech hf. in the third quarter of 2020 and additional upfront and milestone payments in the second quarter of 2021 that were recorded as R&D expenses, and agreed to make milestone payments upon the completion of certain development and commercial milestones of up to an aggregate of $450 million exclusive of royalties.[46] Alvotech hf. and Teva will share the

[45] *Alvotech and Teva announce strategic partnership to collaborate in the U.S. biosimilar market*, Alvotech Newsroom Post (Aug. 5, 2020), *available at* https://www.alvotech.com/newsroom/alvotech-and-teva-announce-strategic-partnership-to (last visited Oct. 26, 2021).

[46] *Form 10-Q, Teva Pharmaceuticals Industries Ltd.*, U.S. Securities and Exchange Commission (Dec. 31, 2020), *available at* https://www.sec.gov/Archives/edgar/data/0000818686/000119312521308672/d223700d10q.htm (last visited Dec. 14, 2021); *Form 10-K, Teva Pharmaceutical Industries Ltd*., U.S. Securities and

profits from its commercialization.

149. On September 25, 2018, Alvotech hf. announced that it had received a manufacturing license from the Icelandic Medicines Agency for its facility in Iceland. As Alvotech hf. has reported, "The granting of the manufacturing license by the Icelandic Medicines Agency, in consultation with the Irish Health Products Regulatory Authority, is a significant milestone for Alvotech and confirms compliance with the principles and guidelines of Good Manufacturing Practices (GMP) laid out in directive 2003/94/EC."[47] Alvotech hf. has repeatedly stated that all of its products, including AVT02, "will be produced at the company's new state of the art manufacturing facility in Reykjavik, Iceland."[48]

150. In addition to the AVT02 that has already been imported, upon approval and marketing, Alvotech hf., Ivers-Lee AG, and/or Teva must import AVT02 product for commercial sale in the United States, and that product will also be imported directly or indirectly from Iceland.

151. Alvotech hf. has taken and continues to take actions to ensure that it is ready and able to launch its AVT02 product in the United States as soon as possible. In May 2021, Alvotech hf. gave notice of commercial marketing of AVT02 to AbbVie, which under the BPCIA allows Alvotech to launch its product, assuming it is approved, in the United States any time after 180

Exchange Commission (Dec. 31, 2020), *available at* https://www.sec.gov/Archives/edgar/data/818686/000119312521036239/d102112d10k.htm (last visited Oct. 26, 2021).

[47] *Alvotech receives manufacturing license for its Biopharmaceutical facility,* Alvotech Newsroom (Sept. 25, 2018), *available at* https://www.alvotech.com/newsroom/alvotech-receives-manufacturing-license-for-its-biopharmaceutical (last visited Oct. 26, 2021).

[48] *Alvotech completes U.S. $300M financing deal,* Alvotech Newsroom (Jan. 22, 2019), *available at* https://www.alvotech.com/newsroom/alvotech-completes-u.s.-300m-financing-deal (last visited Oct. 26, 2021).

days has passed.[49] Thus, now that 180 days has passed, nothing in the BPCIA prevents Alvotech from launching its product as soon as it receives FDA approval.

152. As soon as the FDA can complete its inspection of Alvotech hf.'s facility, it may approve AVT02 for marketing in the United States.[50] While on September 20, 2021, Alvotech hf. announced that the FDA is deferring action on Alvotech hf.'s application for AVT02 until facility assessments can be completed,[51] Alvotech hf. remains confident that approval is imminent and explained that this deferral indicates that no deficiencies have been identified and the application otherwise satisfies the requirements for approval.[52]

153. With regard to when it will launch in the United States, Alvotech hf. has indicated that it "is looking for some measure of patent certainty before it makes its decision to launch"[53] and has "agreed not to launch AVT02 in the United States prior to the issuance of the Court's decision [in the patent case C.A. No. 1:21-cv-02258 (N.D. Ill.)]."[54] That decision is expected no later than October 2022, and could occur earlier.[55] Alvotech continues to import AVT02 into the

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[49] *See AbbVie Inc., et al. v. Alvotech hf.*, C.A. No. 1:21-cv-02899 (N.D. Ill. May 28, 2021), Complaint at ¶ 53.

[50] *Id.*

[51] *Alvotech Provides Update on FDA Action Regarding AVT02, Proposed High-Concentration Biosimilar to Humira® (adalimumab),* Alvotech Newsroom (Sept. 20, 2021), *available at* https://www.alvotech.com/newsroom/reykjavik-iceland-september-20-2021--alvotech (last visited Oct. 26, 2021); *Alvotech stækkar við sig*, Viðskiptablaðið (November 1, 2021), *available at* https://www.vb.is/frettir/alvotech-staekkar-vid-sig/171183/ (last visited Nov. 2, 2021).

[52] *Id.*

[53] *See AbbVie, Inc. et al v. Alvotech hf.,* No. 1:21-cv-02258, Dkt. No. 49, August 12, 2021 Hearing Transcript at 45:15-17.

[54] *See AbbVie, Inc. et al v. Alvotech hf.,* No. 1:21-cv-02258, Dkt. No. 63, Scheduling and Discovery Order, at 4 (Sept. 20, 2021). ("In keeping with this schedule, the Court plans to issue its trial decision by the end of October of 2022. In light of that, Defendant agreed not to launch AVT02 in the United States prior to the issuance of the Court's decision.")

[55] *See id.*

United States in preparation of selling it with its commercialization partner, Teva.

VII. DOMESTIC INDUSTRY

154. Pursuant to 19 C.F.R. § 210.12(a)(7), Complainants state that the relevant domestic industry under 19 U.S.C. § 1337(a)(1) is the domestic United States market for sale of adalimumab products, a mature, well-developed market in which the only product currently available is AbbVie's HUMIRA®.

155. Before AbbVie introduced HUMIRA® in 2003, there was no market for HUMIRA® or adalimumab products in the United States. Over the course of 18 years, AbbVie has invested billions researching, developing, and expanding the adalimumab product domestic market in which HUMIRA® is sold.

156. AbbVie has created a domestic industry that includes significant investments in research and development facilities, plants and equipment, and employment of significant labor forces, and substantial investment in the exploitation of HUMIRA® in the United States.

157. AbbVie has engaged in, and is continuing to engage in, a wide range of qualifying domestic industry activities in the United States that center around HUMIRA®.

158. HUMIRA® is currently approved by the FDA and is commercially available in the United States for thirteen therapeutic indications. AbbVie continues to conduct research and development on additional uses and indications, all of which are designed to expand the domestic industry that AbbVie created.

159. AbbVie has made and continues to make significant investments in plants and equipment with respect to HUMIRA®, the Domestic Industry Product. In North Chicago, Illinois, AbbVie owns or leases and maintains a large number of separate buildings and with millions of square feet of commercial space for, among other things, the research, development, testing, manufacturing, and clinical operations of the Domestic Industry Product. In Barceloneta, Puerto

Rico, AbbVie owns multiple buildings totaling several hundred thousand square feet for the commercial manufacturing, testing, quality control, and storage of the Domestic Industry Product. In each location, AbbVie owns and maintains specialized equipment purchased and designed for the research, development, testing, manufacturing, and clinical operations of the Domestic Industry Product. AbbVie has made a capital investment of hundreds of millions in acquiring and building these facilities, and AbbVie spends millions on average annually to maintain and operate them based on an allocation of the Domestic Industry Product.

160. AbbVie has significant employment of labor and capital with respect to the Domestic Industry Product. AbbVie has hundreds of employees in the United States engaged in the research, development, formulation, manufacturing, clinical and non-clinical testing, delivery and patient support of and for the Domestic Industry Product. In 2020, AbbVie spent over $100 million for the labor force responsible for the Domestic Industry Product.

161. In 2020, AbbVie's global net revenue from all products was approximately $45.8 billion of which HUMIRA® was the largest product segment accounting for approximately $19.8 billion, or 43% of net product revenues. In the United States, HUMIRA® has earned $12.8 billion through the third quarter of 2021. This is the result of billions of sustained and significant investments made by AbbVie in HUMIRA® projects and activities.

162. AbbVie's investment activities are important to the Domestic Industry Product and represent significant added value, particularly given that HUMIRA® has been and continues to be substantially designed and developed in the United States. Moreover, AbbVie's investments and activities are significant and substantial in the context of comparable products, the company's overall investments, and the relevant marketplace.

163. The activities and investments described above are explained in detail in the

Declaration of Kristin Bartolucci, a true and accurate copy of which is attached as Confidential Exhibit M, Declaration of Kristin Bartolucci.

VIII. SUBSTANTIAL INJURY, THREAT OF SUBSTANTIAL INJURY AND TENDENCY TO SUBSTANTIALLY INJURE A DOMESTIC INDUSTRY

164. Pursuant to 19 C.F.R. § 210.12(a)(8), Complainants state that Proposed Respondents' acts of unfair competition have given Proposed Respondents an unfair and significant competitive advantage that will substantially and irreparably injure Complainants' domestic industry pursuant to 19 U.S.C. § 1337(a)(1)(A)(i) in at least the following ways:

a. Creating a new competitor (Teva) in the market for the Domestic Industry Product that did not exist beforehand. But for AVT02, Teva has no product that will compete with the Domestic Industry Product, HUMIRA®. In 2020, Teva partnered with Alvotech hf. for AVT02, which was developed from the trade secrets stolen from AbbVie. Alvotech hf. could not have developed an adalimumab product, supplied such product for clinical trials and filed for FDA approval to launch such product in the United States market in the timeframe alleged herein but for Alvotech hf.'s theft and misuse of AbbVie's trade secrets. The loss of valuable and confidential technical information to a new competitor, including the necessary design and development information to make and have approved a substantially similar adalimumab product without dedicating the time and resources otherwise required will substantially and irreparably injure Complainants' domestic industry;

b. Allowing Proposed Respondents to unlawfully and unfairly compete with AbbVie and the Domestic Industry Product, HUMIRA®, in a way and manner that would not have existed without the theft of AbbVie's trade secrets. Through the misuse of AbbVie's trade secrets, Alvotech hf. has produced and is seeking FDA approval to

launch adalimumab products (AVT02) that contain the same active ingredient as the Domestic Industry Product – adalimumab. By launching products with the same active ingredient as a biosimilar, Proposed Respondents intend to make an attack on the Domestic Industry Product; Alvotech's founder and chairman, Robert Wessman, has stated that AVT02 is intended to "rapidly convert[] the existing market."[56]

c. Destroying the secrecy and confidentiality of AbbVie's trade secrets has diminished and substantially impaired the value of such trade secrets directly to AbbVie;

d. Causing ongoing and systematic damage to the competitive position that AbbVie has established; and

e. Reducing the goodwill that AbbVie has built with physicians, distributors and the public by being a market leader and innovator in the adalimumab product marketplace.

165. Proposed Respondents are specifically targeting the domestic industry that AbbVie has spent substantial funds and time to develop as described above.

166. In November 2020, the FDA accepted Alvotech hf.'s Biologics License Application ("BLA") seeking approval of AVT02 as a biosimilar to HUMIRA®.[57] Alvotech hf. seeks approval for the same indications that AbbVie has obtained for HUMIRA® beginning in

[56] *Alvotech reaches primary completion date in its switching study for AVT02, a proposed interchangeable biosimilar to AbbVie's Humira®,* Alvotech Newsroom (June 15, 2021), *available at* https://www.alvotech.com/newsroom/alvotech-reaches-primary-completion-date-in-its-switching (last visited Oct. 26, 2021).

[57] *U.S. FDA and EMA have accepted regulatory submissions for AVT02,* Alvotech Newsroom (Nov. 19, 2020), *available at* https://www.alvotech.com/newsroom/alvotech-announces-that-the-u.s.-fda-and-ema-have-accepted (last visited Oct. 26, 2021).

2002, when HUMIRA® became the first fully human monoclonal antibody and the first adalimumab product approved by the FDA.

167. On September 20, 2021, Alvotech hf. reported that that the FDA is deferring action on Alvotech hf.'s application for AVT02 until facility assessments can be completed.[58] This indicates that no deficiencies have been identified and the application otherwise satisfies the requirements for approval. As soon as the FDA can complete its necessary inspections, it may approve AVT02 for marketing in the United States. Alvotech hf. has repeatedly stated that it expects to bring AVT02 to market as soon as possible.

168. Alvotech hf. projects that its Iceland facility will be able to manufacture 3 million units of product each year.[59]

169. Alvotech hf. has hired and attempted to hire multiple employees directly from AbbVie, including manufacturing employees, called biotechnologists. *See* Section V, *supra.* Each of these employees had access to confidential and trade secret information belonging to AbbVie during their employment. Each of these employees worked directly on Alvotech hf.'s adalimumab product, AVT02.

170. Alvotech hf. has stated clearly and unapologetically that AVT02 has been designed, developed, and will be sold with the intention of targeting AbbVie and the domestic industry that AbbVie created. For instance, Alvotech hf.'s founder and chairman, Robert Wessman, stated that

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[58] *Alvotech Provides Update on FDA Action Regarding AVT02, Proposed High-Concentration Biosimilar to Humira® (adalimumab),* Alvotech Newsroom (Sept. 20, 2021), *available at* https://www.alvotech.com/newsroom/reykjavik-iceland-september-20-2021--alvotech (last visited Oct. 26, 2021); *Alvotech stækkar við sig*, Viðskiptablaðið (November 1, 2021), *available at* https://www.vb.is/frettir/alvotech-staekkar-vid-sig/171183/ (last visited Nov. 2, 2021).

[59] *Alvotech 2017* at 14, *available at* http://businessdocbox.com/Biotech_and_Biomedical/73190478-1-1-0-0-10-4-3-0-0-0-2-0.html (last visited Nov. 18, 2021).

AVT02 is intended to "rapidly convert[] the existing [Humira] market."[60]

171. Alvotech hf. has conducted interchangeability studies in support of its application for an interchangeable designation for AVT02, meaning it may be fully interchangeable with HUMIRA® at pharmacies.[61]

172. Given that AVT02 may be the first (and only) adalimumab product marketed in the United States since HUMIRA® was first approved, and given that Alvotech hf. is seeking an interchangeability designation[62] for its biosimilar product and claims to have the first high concentration biosimilar product for which an interchangeability designation will be sought,[63] there can be no question that Proposed Respondents intend to substantially injure or threatens to injure AbbVie's position in the domestic industry.

173. With former AbbVie employees to guide the development and approval of its commercial manufacturing process using AbbVie's trade secrets, Alvotech hf. has developed its adalimumab product to directly target HUMIRA®.

174. The damage caused by Proposed Respondents' actions is expected to cause an immediate loss of market share along with price suppression and erosion if FDA approval of AVT02 is received and Proposed Respondents market and sell AVT02 in the United States.

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[60] *Alvotech reaches primary completion date in its switching study for AVT02, a proposed interchangeable biosimilar to AbbVie's Humira®,* Alvotech Newsroom (June 15, 2021), *available at* https://www.alvotech.com/newsroom/alvotech-reaches-primary-completion-date-in-its-switching (last visited Oct. 26, 2021).

[61] *Alvotech Announces Positive Top-line Results for Switching Study Between Proposed Biosimilar AVT02 and Humira,* Alvotech Newsroom (Sept. 10, 2021), *available at* https://www.alvotech.com/newsroom/alvotech-announces-positive-top-line-results-for-switching (last visited Oct. 26, 2021).

[62] *Supra* n.1..

[63] Q3 2021 Earnings Call, Teva Pharmaceutical Industries Ltd. (TEVA) (Oct. 27, 2021), *available at* https://www.fool.com/earnings/call-transcripts/2021/10/28/teva-pharmaceutical-industries-teva-q3-2021-earnin/ (last visited Nov. 2, 2021).

Further, Proposed Respondents' actions will cause damage to AbbVie's reputation. And there is likely to be other damage that will become clear when AVT02 is approved and launched based on the confidential and valuable trade secret information unlawfully obtained.

175. Alvotech has announced that it intends to and will price its AVT02 product lower than those of the Domestic Industry Product, specifically more than 50% lower than the price of HUMIRA®, so as to capture significant portions of the adalimumab product market.

176. On information and belief, Complainants allege that Proposed Respondents' costs of producing AVT02 are significantly lower than the costs of producing HUMIRA®, because, among other reasons, Proposed Respondents have not invested in the research and development and infrastructure necessary to bring an adalimumab product to market without the unlawful misappropriation of AbbVie's trade secrets.

IX. HARMONIZED TARIFF SCHEDULE NUMBERS

177. The adalimumab products at issue are believed to fall within the following classification of the Harmonized Tariff Schedules of the United States: 3002.15.0090. This classification is intended for illustrative purposes only and is not intended to restrict the scope or type of subject products.

X. RELATED LITIGATION

178. Pursuant to 19 C.F.R. § 210.12(a)(5), Complainants state that the following litigation is related to the issues described herein.

A. Illinois Litigation

179. Litigation involving AbbVie's Trade Secrets against Alvotech hf. in the U.S. District Court for the Northern District of Illinois was filed on March 19, 2021 as *AbbVie Inc. et al v. Alvotech hf.,* Case No. 21-cv-1530 (N.D. Ill. 2021), alleging that Alvotech hf. misappropriated trade secrets stolen from AbbVie by Rongzan Ho and others to develop and market AVT02.

180. On May 13, 2021, Alvotech hf. moved to dismiss the case on the basis of lack of jurisdiction and failure to state a claim. Dkt. No. 21. On October 6, 2021, the Illinois court dismissed the action for lack of personal jurisdiction. Dkt. No. 38. On November 4, 2021, AbbVie filed a notice of appeal. Dkt. No. 42.

B. Singapore Litigation

181. On April 1, 2021, AbbVie, through its wholly-owned subsidiary AbbVie Operations Singapore Pte. Ltd., filed a Writ of Summons against Rongzan Ho for breach of the non-competition clause in his employment agreement and misuse of confidential information in breach of his duty of confidence to AbbVie.

182. Since that time, AbbVie has been unable to serve Rongzan Ho with the Writ due to difficulty locating him. The High Court of the Republic of Singapore has repeatedly extended the deadline to serve the Writ upon a showing of AbbVie's diligence in searching for Rongzan Ho.

183. Other than as described above, the alleged unfair acts, or subject matter thereof, are not and have not been the subject of any court or agency litigation.

XI. REQUEST FOR RELIEF

WHEREFORE, by reason of the foregoing, Complainants respectfully request that the United States International Trade Commission:

a. institute an immediate investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to Proposed Respondents' violations of that section based on the importation into the United States, sale for importation, and/or the sale within the United States after importation of Proposed Respondents' adalimumab products, including AVT02, that were developed, made, and imported using AbbVie's trade secrets;

b. schedule and conduct a hearing on permanent relief pursuant to 19 U.S.C. § 1337(c) for

the purposes of receiving evidence and hearing argument concerning whether there has been a violation of Section 337;

c. issue a limited exclusion order, pursuant to 19 U.S.C. § 1337(d) forbidding entry into the United States of Proposed Respondents' adalimumab products, including AVT02, that were developed, made, and imported using AbbVie's trade secrets;

d. issue cease and desist orders, pursuant to 19 U.S.C. § 1337(f), prohibiting Proposed Respondents and their related companies from engaging in the importation, sale for importation, marketing, distribution, offering for sale, the sale after importation of, or otherwise transferring within the United States Proposed Respondents' adalimumab products, including AVT02, that were developed, made, and imported using AbbVie's trade secrets;

e. require a bond during the Presidential review period pursuant to 19 U.S.C. § 1337(j)(3);

f. order the return of AbbVie's trade secrets and other confidential information whether maintained electronically or by hard copy, and the destruction of all copies of such trade secrets and other confidential information in Proposed Respondents' possession; and

g. issue such other and further relief as the Commission deems just and proper under the law, based upon facts determined by the investigation and the authority of the Commission.

Date: December 17, 2021

Respectfully submitted,

/s/ Mareesa A. Frederick

Counsel for the Complainants AbbVie Inc., AbbVie Biotechnology Ltd, and AbbVie Operations Singapore Pte. Ltd.

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of

CERTAIN ADALIMUMAB, PROCESSES FOR MANUFACTURING OR RELATING TO SAME, AND PRODUCTS CONTAINING SAME

VERIFICATION OF COMPLAINT

I, Mareesa A. Frederick, am counsel for Complainants AbbVie Inc., AbbVie Biotechnology Ltd, and AbbVie Operations Singapore Pte. Ltd. (collectively "AbbVie") and am duly authorized by AbbVie to execute this verification of the accompanying Complaint under Section 337 of the Tariff Act of 1930, as Amended, on behalf of AbbVie. I have read the Complaint and am aware of its contents. To the best of my knowledge, information and belief, and based upon a reasonable inquiry under the circumstances, I hereby certify that:

1. The allegations contained in the Complaint are well grounded in fact and have evidentiary support, or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery;

2. The claims and other legal contentions set forth in the Complaint are warranted by existing laws and by a good faith, non-frivolous argument for extension, modification, or reversal of existing law, or by the establishment of new law; and

3. The Complaint is not being filed for any improper purpose, such as to harass or cause unnecessary delay or needless increase in the cost of litigation.

Dated: December 17, 2021

Mareesa Frederick

Mareesa A. Frederick