IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GENENTECH, INC., 1 DNA Way Building 25 South San Francisco, CA 94080, Petitioner, v. NOVARTIS PHARMA AG, Lichtstrasse 35 CH-4056 Basel Switzerland, Respondent.	C.A. No. 1:25-cv-1783

PETITION TO RECOGNIZE AND ENFORCE FOREIGN ARBITRAL AWARD

Petitioner Genentech, Inc. ("Genentech"), by and through its attorneys, Orrick, Herrington & Sutcliffe LLP, for its Petition to Recognize and Enforce Foreign Arbitral Award against Respondent Novartis Pharma AG ("Novartis"), alleges as follows:

INTRODUCTION

1. Genentech is commencing this proceeding to recognize and enforce an arbitration award rendered in Washington, D.C. (the "Final Award") and to have judgment entered thereon, pursuant to Section 207 of the Federal Arbitration Act, 9 U.S.C. § 207. The Final Award, dated April 14, 2025, is attached with redactions[1] as Exhibit 1 to the Declaration of Hagit Muriel Elul

[1] Novartis has requested redactions to the Final Award on the basis of purported confidentiality. Genentech does not agree that the Final Award is confidential. The License and Collaboration Agreements and the parties' stipulated confidentiality order from the arbitration provide a carve-out for use of the Final Award in judicial proceedings to enforce the arbitral award. Nonetheless, as a courtesy to Novartis, Genentech is filing a redacted version of the Final Award with Novartis's proposed redactions as Exhibit 1. Genentech understands that Novartis intends to file a motion to seal explaining why the material should remain redacted. If Novartis fails to do so by June 13, 2025, Genentech will file an unredacted version of the Final Award.

("Elul Declaration"), filed concurrently herewith. The Final Award comprises a decision of the majority of the Tribunal and a dissenting opinion filed by one co-arbitrator.

2. In the arbitration, Novartis claimed that Genentech breached the parties' License and Collaboration Agreement dated June 20, 2003 ("2003 LCA"), as amended and restated by the License and Collaboration Agreement dated May 26, 2019 ("2019 LCA," and together with the 2003 LCA, the "LCAs"), which concerned the commercialization of ranibizumab (marketed under the name Lucentis®), a drug approved for treatment of certain eye diseases. Under the LCAs, Genentech had exclusive commercialization rights to ranibizumab in the United States, while Novartis had exclusive commercialization rights to ranibizumab in the rest of the world. The gravamen of Novartis's claim was that faricimab (marketed under the name Vabysmo®)—a new, novel molecule invented, patented, and controlled by Genentech's parent company, Roche Holding Ltd.—is a Licensed Product under the LCAs. Novartis thus claimed the exclusive rights to commercialize Roche's faricimab, in addition to ranibizumab, outside of the United States.

3. On April 14, 2025, a majority of the Tribunal issued the Final Award in Genentech's favor finding, *inter alia*, that faricimab is not a Licensed Product under the LCAs and that Genentech was not in breach of the LCAs. The Final Award awarded Genentech its legal fees and costs associated with the arbitration in the amount of $17,840,178.62 plus interest.

PARTIES

4. Genentech is a leading biotechnology company dedicated to pursuing groundbreaking science to discover and develop medicines for people with serious and life-threatening diseases. Genentech is incorporated in Delaware, U.S.A and has its principal place of business in South San Francisco, California.

5. Novartis is a multinational pharmaceutical company that is incorporated in Switzerland and has its principal place of business in Basel, Switzerland.

JURISDICTION AND VENUE

6. This Court has original jurisdiction over this action pursuant to 9 U.S.C. § 203, in that this is a civil action seeking recognition and enforcement of an award rendered in an arbitration falling under the Convention on the Enforcement and Recognition of Foreign Arbitral Awards (the "New York Convention").

7. Venue is proper in this judicial district pursuant to 9 U.S.C. § 204 because the parties' arbitration agreement and the enforcement of the Final Award fall under the terms of the New York Convention, and Washington, D.C. is designated in the arbitration agreement as the place of arbitration.

FACTS

8. The arbitration agreement between the parties provides as follows:[2]

> 14.2 Arbitration
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> (a) ICC Rules. Subject to Section 14.3, in the event that the Parties are unable to resolve any Dispute through the procedures described in Section 14.1(b), the Dispute shall, at the request of either Party, be finally settled by arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce in force from time to time (ICC Rules).
>
> (b) Arbitration Panel. The arbitration panel shall consist of three (3) arbitrators, each of whom must have legal or business experience in pharmaceutical licensing, development or marketing matters, as appropriate, and who shall each be nominated, appointed and confirmed by the International Court of Arbitration of the International Chamber of Commerce in Paris, France (ICC Court) in accordance with the ICC Rules (other than Article 8 of the ICC Rules). The ICC Court shall appoint one of

[2] Attached to the Elul Declaration as Exhibit 2 is a true and correct copy of the arbitration agreement between the parties contained in section 14.2 of the 2019 LCA. Attached to the Elul Declaration as Exhibit 3 is a true and correct copy of the arbitration agreement between the parties contained in section 15.2 of the 2003 LCA which uses substantially the same language as section 14.2 of the 2019 LCA.

the arbitrators as the presiding arbitrator. The place of arbitration shall be Washington D.C., and the language of the arbitration shall be English.

(c) Exclusive Means of Resolution. Except as otherwise provided in this Agreement, the arbitration procedure set forth in this Section 14.2 shall be the exclusive means of settling or resolving any Dispute.

(d) Procedures. Within sixty (60) days after the arbitrators have been confirmed by the ICC Court, the Parties shall exchange all documents in their respective possession that are relevant to the issues in the Dispute and not protected from disclosure by attorney client privilege or other immunity. Each Party shall also be permitted to take sworn oral deposition of a reasonable number of individuals, such depositions to be scheduled by mutual agreement and concluded within forty-five (45) days after the exchange of documents described above. At least twenty (20) days prior to the first scheduled hearing date, the Parties shall identify the witnesses that they intend to present at the arbitration hearing and the documentation on which they intend to rely. The Parties shall use their commercially reasonable efforts to conclude the arbitration hearings within ten (10) months following the confirmation of the third and presiding arbitrator. The arbitrators shall issue their decision (including grounds and reasoning) in writing no later than sixty (60) days following the conclusion of the last arbitration hearing.

(e) Awards. Subject to the limitations set forth in Section 13.3 above, the arbitrators may award such remedies as are provided in the U.S. Federal Arbitration Act, as amended from time to time, and notwithstanding the foregoing, the Parties specifically agree that the arbitrators shall also be empowered to award injunctive relief should they see fit. The award of the arbitrators shall be final and binding on the Parties and may be presented by either of the Parties for enforcement in any court of competent jurisdiction, and the Parties hereby consent to the jurisdiction of such court solely for purposes of enforcement of this arbitration agreement and any order or award entered therein.

(f) Fees. The fees of the arbitrators and the other costs of such arbitration (including, without limitation, reasonable attorneys' fees), shall be borne and paid as the arbitrators determine.

(g) Continued Performance. Provided the Agreement has not terminated, the Parties covenant to continue the performance under the Agreement in accordance with the terms thereof, pending the final resolution of the Dispute.

9. On September 16, 2022, Novartis commenced an arbitration against Genentech with the ICC Court of International Arbitration.

10. Pursuant to an agreed procedure, Novartis designated Robert S. Smith as co-arbitrator and Genentech designated John Fellas as co-arbitrator. Fabien Gélinas was jointly appointed as president of the Tribunal.

11. The parties agreed to the bifurcation of the proceedings with liability to be addressed in a first phase and, depending on the result of the first phase, remedies to be addressed in a second phase.

12. Between May 11, 2023 and June 15, 2023, the parties conducted an accelerated document exchange process for the liability phase of the arbitration.

13. Between June 20, 2023 and February 8, 2024, the parties exchanged evidence, expert witness reports, and legal briefing on liability.

14. A hearing was held in New York City from March 11 to March 14, 2024, during which the parties presented opening arguments and fact and expert witnesses were heard.

15. At the end of the hearing, the parties put on the record that they had agreed to waive the contractual time limit for rendering the award.

16. Following the hearing, the parties exchanged post-hearing briefing and cost submissions. A further hearing was held in New York City on September 3, 2024, during which the parties presented their closing arguments.

17. On April 14, 2025, a majority of the Tribunal issued the Final Award. In the Final Award, a majority of the Tribunal reached the following conclusions:

> We accordingly find in favour of Genentech: the fragment that is licensed under the LCA is the stand-alone ranibizumab: Vabysmo®, faricimab, or the VEGF-binding arm thereof, are not covered by the LCA. Claimant has failed to establish a breach of the LCAs. The remedy it seeks, "that the Tribunal declare Vabysmo® (faricimab) to be a Licensed Product under the LCA and that Genentech has breached and will continue to breach the LCA by encroaching on Novartis' exclusive Territory, including by seeking regulatory approval of, using, selling, importing, and/or promoting

> Vabysmo® in countries outside the United States" is therefore denied. Respondent seeks a declaration "that Vabysmo® (faricimab) is not a Licensed Product under the LCA", which is granted. Respondent also initially sought a broad declaration "that Genentech did not breach the terms of the LCA". To the extent this prayer for relief was not abandoned, it exceeds the scope of the dispute before us and must accordingly be denied.

18. Accordingly, in the Final Award, a majority of the Tribunal:

a. DECIDED AND DECLARED that Vabysmo® (faricimab) is not a Licensed Product under the LCAs;

b. DENIED Novartis's claim for breach of contract;

c. ORDERED Novartis to pay to Genentech the costs it incurred for the arbitration, including attorneys' fees, as follows:

i. US$ 584,250 for the advance on the fees and expenses of the arbitrators and the ICC administrative expenses fixed by the Court;

ii. US$ 17,255,928.62 for the reasonable legal and other costs incurred for the arbitration;

d. ORDERED Novartis to pay to Genentech interest on these amounts at the rate of 9% annually from the date of the Award until full and final payment, subject to any order by an enforcement court applying its own rules to post-judgment interest.

19. The Final Award has not been set aside or suspended by a competent authority of the country in which, or under the law of which, the Final Award was made.

20. Pursuant to 9 U.S.C. § 207, Genentech has brought this action within three years after the Final Award was made on April 14, 2025.

21. No grounds exist for this Court to refuse recognition and enforcement and recognition of the Final Award. Novartis has paid Genentech the costs that it incurred for the arbitration, including attorneys' fees, as ordered by the Tribunal.

COUNT ONE
(Recognize and Enforce Foreign Arbitral Award Under the Federal Arbitration Act)

22. Petitioner repeats and realleges paragraphs 1 through 21 hereof, as if fully set forth herein.

23. The Federal Arbitration Act provides that the "court shall confirm the award unless it finds one of the grounds for refusal or deferral of recognition or enforcement of the award specified in the said Convention." 9 U.S.C. § 207.

24. None of the grounds available for refusal or deferral of recognition or enforcement of an award specified in the New York Convention is applicable to the Final Award.

25. Therefore, pursuant to 9 U.S.C. § 207, Petitioner requests that this Court recognize and enforce the Final Award and enter judgment in favor of Petitioner Genentech and against Respondent Novartis.

26. By reason of the foregoing, the court should issue an order recognizing and enforcing the Final Award and direct that judgment be entered thereon.

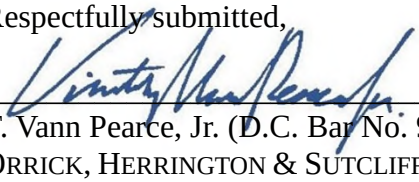
WHEREFORE, Genentech respectfully requests that this Court:

A. Issue an order pursuant to 9 U.S.C. § 207 recognizing and enforcing the Final Award in its entirety and entering a judgment in favor of Genentech and against Novartis in accordance with the Final Award in its entirety.

B. Awarding Genentech such other and further relief as this Court deems just and proper.

Dated: June 5, 2025

Respectfully submitted,



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