

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

AMGEN INC.,

Plaintiff,

v.

SANDOZ INC., ET AL.,

Defendants.

Civil Action No. 18-11026 (MAS)(DEA)
(consolidated)

Hon. Michael A. Shipp, U.S.D.J.

Hon. Douglas E. Arpert, U.S.M.J

**APPOINTMENT OF COMMISSIONERS UNDER THE HAGUE CONVENTION AND
REQUEST FOR JUDICIAL ASSISTANCE – PERMISSION OF TAKING EVIDENCE
BY A COMMISSIONER UNDER ARTICLE 17 HAGUE EVIDENCE CONVENTION
1970 TO THE HIGH COURT OF THE CANTON OF ZURICH, COURT
ADMINISTRATION, INTERNATIONAL JUDICIAL ASSISTANCE, FOR THE
REQUEST FOR JUDICIAL ASSISTANCE IN CIVIL MATTERS WITH COPY TO THE
FEDERAL OFFICE OF JUSTICE (FOJ), CENTRAL AUTHORITY FOR THE
REQUEST FOR JUDICIAL ASSISTANCE IN CIVIL AND COMMERCIAL MATTERS**

The United States District Court for the District of New Jersey, located at the Clarkson S. Fischer Federal Building & U.S. Courthouse at 402 East State Street, Trenton, New Jersey 08608, presents its compliments to the Federal Office of Justice and has the honor of requesting its assistance in obtaining evidence to be used in a civil proceeding now pending before this Court in the above-captioned matter, specifically by permitting commissioners appointed by this Court to take evidence under Article 17 of the Hague Convention of 18 March 1970 on the Taking of Evidence Abroad in Civil or Commercial Matters (“Hague Convention”).

It appears to this Court that Dr. Fabia Gozzo, whose home address is Avenue du Léman 33, 1005 Lausanne, Switzerland, is a material expert witness, for reasons discussed herein, who has submitted an expert report on behalf of Plaintiff in this action and therefore has evidence relevant to this action. It is necessary for the purposes of justice and for the due determination of the matters in question between the parties that Dr. Gozzo be examined (remotely) at the office of

the law firm of VISCHER AG (“VISCHER”) at Schuetzengasse 1, P.O. Box, CH-8021 Zurich (“VISCHER Zurich Office”), under oath or affirmation. Given that trial testimony¹ would take place (remotely) at the VISCHER Zurich Office, the competent authority for the granting of this request is the High Court of the Canton of Zurich, International Judicial Assistance, Hirschengraben 13/15, 8021 Zurich 1, Switzerland. As is customary, a copy of the present Letter of Request is sent to the Federal Office of Justice, Central Authority for the Request for Judicial Assistance in Civil and Commercial Matters, Bundesrain 20, 3003 Bern, Switzerland.

This Court, therefore, respectfully requests your assistance pursuant to the Hague Convention in obtaining the oral testimony of Dr. Gozzo under the terms set forth in this Letter of Request:

I. SUMMARY OF ACTION

1. This action is properly under the jurisdiction of and is now pending before the United States District Court for the District of New Jersey, Clarkson S. Fischer Federal Building & U.S. Courthouse at 402 East State Street, Trenton, New Jersey 08608, United States of America. The United States District Court for the District of New Jersey is fully sanctioned as a court of law and equity and is authorized by Rule 28(b) of the Federal Rules of Civil Procedure to direct the taking of evidence abroad by Letters of Request.

2. The parties to the civil action pending in the United States District Court for the District of New Jersey are as follows:

- a. Plaintiff Amgen Inc. (“Plaintiff”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One

¹ Trial is scheduled for June 14, 2021. In the event that trial will be conducted remotely, or that Dr. Gozzo cannot travel to the United States due to COVID related restrictions, the current Letter of Request seeks the remote trial testimony of Dr. Gozzo pursuant to the Hague Convention.

Amgen Center Drive, Thousand Oaks, California 91320. Plaintiff is represented by Gibbons P.C., One Gateway Center, Newark, New Jersey 07102; Covington & Burling LLP, One CityCenter, 850 Tenth Street, NW, Washington, DC 20001, Salesforce Tower, 415 Mission Street, San Francisco, CA 94105, and 3000 El Camino Real, Palo Alto, CA 94306; and Sidley Austin LLP, One South Dearborn, Chicago, IL 60603 and 555 California Street Suite 2000, San Francisco, CA 94104. Correspondence to Plaintiff can be emailed at the following email addresses: CChevalier@gibbonslaw.com; GPappas@cov.com; JElisan@cov.com; AHansen@cov.com; MKennedy@cov.com; KCollins@cov.com.

- b. Defendant Zydus Pharmaceuticals (USA) Inc. (“Defendant”) is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Defendant is represented by Epstein Becker & Green, P.C., 150 College Road West, Suite 301, Princeton, New Jersey 08540 and Locke Lord LLP, 111 South Wacker Drive, Chicago, IL 60606. Correspondence to Defendant can be emailed at the following email addresses: DAbramowitz@lockelord.com; ESavas@lockelord.com; Jennifer.Coronel@lockelord.com; CBlessing@lockelord.com; MGAertner@lockelord.com; RLufrano@ebglaw.com; TMcCormick@ebglaw.com; LCooper@ebglaw.com.

3. This is a civil action for infringement of United States Patent Nos. 7,427,638 (the “638 patent”), 8,455,536 (the “536 patent”), 7,893,101 (the “101 patent”), 8,093,283 (the “283 patent”), and 10,092,541 (the “541 patent”) (collectively, the “Patents-in-suit”). Plaintiff has sued Defendant for patent infringement. Defendant has alleged that the asserted patents are invalid, pursuant to United States patent laws.

4. The '638 Patent is entitled, "(+)-2-[1-(3-Ethoxy-4-Methoxyphenyl)-2-Methylsulfonylethyl]-4-Acetylaminoisoindoline-1,3-Dione, and Methods of Synthesis and Compositions Thereof." The '638 Patent issued on September 23, 2008. George W. Muller, Peter H. Schafer, Han-Wah Man, and Chuansheng Ge are the named inventors of the '638 Patent. Amgen owns all right, title, and interest in the '638 Patent.

5. The '536 Patent is entitled, "Methods of Using (+)-2-[1-(3-Ethoxy-4-Methoxyphenyl)-2-Methylsulfonylethyl]-4-Acetylaminoisoindoline-1,3-Dione." The '536 Patent issued on June 4, 2013. George W. Muller, Peter H. Schafer, Han-Wah Man, and Chuansheng Ge are the named inventors of the '536 Patent. Amgen owns all right, title, and interest in the '536 Patent.

6. The '101 Patent is entitled, "Solid Forms Comprising (+)-2-[1-(3-Ethoxy-4-Methoxyphenyl)-2-Methylsulfonylethyl]-4-Acetylaminoisoindoline-1,3-Dione, Compositions Thereof, and Uses Thereof." The '101 Patent issued on February 21, 2011. George W. Muller, Peter H. Schafer, Han-Wah Man, Chuansheng Ge, and Jean Xu are the named inventors of the '101 Patent. Amgen owns all right, title, and interest in the '101 Patent.

7. The '283 Patent is entitled, "Solid Forms Comprising (+)-2-[1-(3-Ethoxy-4-Methoxyphenyl)-2-Methylsulfonylethyl]-4-Acetylaminoisoindoline-1,3-Dione, Compositions Thereof, and Uses Thereof." The USPTO issued the '283 Patent on January 10, 2012. George W. Muller, Peter H. Schafer, Hon-Wan Man, Chuansheng Ge, and Jean Xu are the named inventors of the '283 Patent. Amgen owns all right, title, and interest in the '283 Patent.

8. The '541 Patent is entitled, "Methods for the Treatment of Diseases Ameliorated by PDE4 Inhibition Using Dosage Titration of Apremilast." The USPTO issued the '541 Patent on October 9, 2018. Robert Day is the named inventor of the '541 Patent. Amgen owns all right, title, and interest in the '541 Patent.

9. Through procedures set forth by the FDA, Defendant seeks permission from the FDA to market generic versions of Plaintiff's 10 mg, 20 mg, and 30 mg OTEZLA® tablets. Defendant submitted ANDA No. 211859 for 10 mg, 20 mg, and 30 mg apremilast tablet ("Defendant's ANDA Products"). Plaintiff alleges that Defendant's submission of ANDA No. 211859 constitutes infringement of claims 3 and 6 of the '638 patent, claim 6 of the '536 patent, claims 1 and 15 of the '101 patent, claims 2 and 27 of the '283 patent, and claims 2, 19, and 21 of the '541 patent.

10. Dr. Gozzo submitted an expert report on behalf of Plaintiff, written by Dr. Gozzo in the English language and signed and dated November 23, 2020. Dr. Gozzo was hired by Plaintiff to perform synchrotron x-ray powder diffraction ("XRPD") on Defendant's API and ANDA Products. Dr. Gozzo performed such testing and submitted the details of those experiments to Plaintiff's counsel in an expert report setting forth the testimony she plans to present at trial in this matter. Dr. Gozzo is expected to testify regarding:

- Dr. Gozzo's scientific background;
- Dr. Gozzo's synchrotron-XRPD testing conducted as an expert witness in connection with the above-captioned litigation;
- The methods and results of Dr. Gozzo's synchrotron-XRPD testing; and
- Dr. Gozzo's analysis and conclusions set forth in her expert reports.

11. Accordingly, Plaintiff believes that evidence from Dr. Gozzo, which Dr. Gozzo has agreed to give, is likely to help this Court determine the issues at trial because such evidence is of the type and nature that courts in the United States routinely find relevant to resolving issues of patent infringement. Under United States law, the testimony of experts, generally speaking, has been found to be relevant to patent infringement, and Plaintiff believes that the same will be true here as to the evidence obtained from Dr. Gozzo. As Plaintiff has already

offered a report from Dr. Gozzo and as U.S. courts routinely recognize in patent infringement cases such as this one, Plaintiff believes that Dr. Gozzo's testamentary evidence is necessary for the Court's analysis of infringement.

II. EVIDENCE REQUESTED

12. Plaintiff contends that Dr. Fabia Gozzo has material information related to this pending action for use at trial, and that justice cannot be completely done between the parties without their testimony.

13. Plaintiff requests that this Court issue the present Letter of Request seeking your assistance in obtaining testimony from Dr. Gozzo. The evidence to be obtained is oral testimony to be taken in Switzerland, the country of residence of Dr. Gozzo, and is intended to be used as evidence in the trial for this matter. Dr. Gozzo has also been apprised of her rights under Swiss law and has consented to being questioned during trial in Switzerland. *See Exhibit A.*

14. The Court requests assistance in permitting the commissioners appointed by this Court to take the following testimony from Dr. Gozzo, which will be given voluntarily by Dr. Gozzo:

- Testimony regarding and relating to Dr. Gozzo's expert opinions contained within the Expert Report of Dr. Fabia Gozzo, Ph.D. Regarding S-XRPD Testing of Zydus Pharmaceuticals (USA) Inc. Samples signed and dated November 23, 2020.

15. Plaintiff contends the testimonial evidence is relevant to the pending proceeding and is likely to be used at trial to assist this Court in resolving the dispute presented in the civil action before it. With the approval of this Court, Plaintiff and this Court therefore seek permission to have commissioners take this testamentary evidence for the purpose of using such evidence at trial.

16. It is requested that the testamentary evidence be given in the English language, and on oath or affirmation. It is also hereby requested that the testimony be in the form of a recorded remote trial testimony via a secure session using the videoconferencing technology, Zoom, upon questions communicated to the witness by a Swiss attorney acting as commissioner, U.S. counsel of Plaintiff, U.S. counsel of Defendant, and/or the Honorable Judge Michael A. Shipp, U.S.D.J., also acting as commissioners. It is requested that the testamentary evidence be given at some time agreeable to all involved, whereby the trial testimony is intended to be conducted between June 14, 2021 and the conclusion of the trial (which is currently expected at June 25, 2021, but may be at a later date).

17. The Court hereby appoints Mr. Jonas D. Gassmann, LL.M., CIPP/E, to serve as commissioner (“the Swiss commissioner”). Mr. Gassmann is a lawyer with VISCHER at the VISCHER Zurich Office and admitted to practice as an attorney in Switzerland. In his capacity as commissioner, Mr. Gassmann will complete and oversee the following tasks: liaise with the Swiss authorities, including dispatch/submission of the present Letter of Request to the High Court of the Canton of Zurich, International Judicial Assistance, Hirschengraben 13/15, 8021 Zurich 1, Switzerland and of a copy of the same to the Federal Office of Justice, Central Authority for the Request for Judicial Assistance in Civil and Commercial Matters, Bundesrain 20, 3003 Bern, Switzerland; act as an agent of service for any communication of the High Court of the Canton of Zurich and/or the Federal Office of Justice to this Court and the parties; invite Dr. Gozzo to the trial once authorization is granted; verify and confirm the identity of Dr. Gozzo each time before testamentary evidence is taken; supervise the testimony of Dr. Gozzo by remote videoconferencing software from his firm’s offices in Zürich; instruct Dr. Gozzo on her rights and obligations as per Article 21 of the Hague Convention; and ensure that the testimony is conducted in accordance with those rights and obligations.

18. Plaintiff also request that for trial testimony, the Honorable Judge Shipp may instruct the witnesses on their rights and obligations as per Article 21 of the Hague Convention; ensure that the testimony is conducted in accordance with those rights and obligations; and ask questions to witnesses during trial.

19. The U.S. counsel of Plaintiff and Defendant, which the Court upon request of Plaintiff hereby also appoints as commissioners, and who will be present for the trial testimony of Dr. Gozzo, are the following:

a. For Plaintiff:

- Charles H. Chevalier, J. Brugh Lower, Rachel Johnston of Gibbons P.C. at One Gateway Center, Newark, NJ 07102-5310, USA;
- George F. Pappas, Jeffrey B. Elikan, Kevin B. Collins, Michael N. Kennedy, Jay Alexander, Priscilla Dodson, Alexander Trzeciak, Philip S. May, Antonio J. Carvalho, Joseph Hykan, Priscilla N.A. Nyankson, Daniel H. Lee from Covington & Burling LLP at One CityCenter, 850 Tenth St. NW, Washington, DC 20001, USA;
- Alexa Hansen, David S. Denuyl from Covington & Burling LLP at Salesforce Tower, 415 Mission St., Ste. 5400, San Francisco, CA 94105, USA;
- Robert Zhou from Covington & Burling LLP at 3000 El Camino Real, Palo Alto, CA 94306, USA;
- Steven J. Horowitz from Sidley Austin LLP at One South Dearborn, Chicago, IL 60603, USA;
- Sue Wang from Sidley Austin LLP at 555 California Street Suite 2000, San Francisco, CA 94104, USA.

b. For Defendant:

- Theodora McCormick, Lauren B. Cooper, Robert Lufrano from Epstein Becker & Green, P.C. at 150 College Road West, Suite 301 Princeton, New Jersey 08540, USA;
- Michael J. Gaertner, David B. Abramowitz, Carolyn A. Blessing, Emily L. Savas, Jennifer M. Coronel, August Melcher from Locke Lord LLP at 111 South Wacker Drive Chicago, IL 60606, USA.

20. In addition to the U.S. counsel and commissioners listed above and of the Swiss commissioner, it is also requested that client representatives for each party be allowed to be

present, and that a videographer and a stenographer be present to take and record a verbatim transcript of all testimony and proceedings in the English language and that the transcript of the testimony be authenticated. When necessary, persons belonging to the information technology departments of the law firms of U.S. counsel may enter the rooms where U.S. counsel are remotely attending the trial. U.S. counsel, the party representatives, the videographer, and the stenographer will attend the deposition remotely from their offices in the U.S.A. The Swiss commissioner and Dr. Gozzo will attend the remote trial by videoconference from the VISCHER Zurich Office. When necessary, persons belonging to the IT department of the VISCHER law firm may enter the room where Dr. Gozzo is remotely attending the trial.

21. As mentioned, it is requested that the commissioners and U.S. counsel for Plaintiff and Defendant take Dr. Gozzo's testimony in the English language (to which Dr. Gozzo has agreed; *see Exhibit A*), under oath or affirmation, and that the Swiss commissioner or the Honorable Judge Shipp accordingly be allowed to administer such oath or request for affirmation on Dr. Gozzo in accordance with United States law, as follows: "Do you swear or affirm that the testimony you are about to provide is the truth, the whole truth, and nothing but the truth?"

22. It is also requested that after giving testimony, Dr. Gozzo be allowed after completion of the transcript to review, submit any errata, and sign the transcript of her testimony, and that the signed, transcribed, and videotaped testimony together with any documents marked as exhibits be transmitted to the parties' U.S. counsel as soon as possible thereafter.

23. Accordingly, it is hereby requested that you grant assistance and authorize the Swiss and U.S. commissioners appointed above to question Dr. Gozzo under oath or affirmation at the remote trial between June 14, 2021 and the conclusion of the trial (which is currently expected at June 25, 2021, but may be at a later date).

24. It is also requested that you inform the Swiss commissioner, this Court, and the parties through their above-mentioned U.S. counsel of your approval of this Court's request and of all relevant dates and times determined by you for the production of the aforementioned requested testamentary evidence of Dr. Gozzo. This Court and U.S. counsel hereby appoint Mr. Gassmann to file the Letter of Request with you and act as the agent of service in Switzerland for any and all communication from you in this respect. As mentioned above, Mr. Gassmann's professional address in Switzerland for purpose of your communications is: Schuetzengasse 1, P.O. Box, CH-8021 Zurich.

25. This Court expresses its appreciation to the Federal Office of Justice for its courtesy and assistance in this matter and states that this Court shall be ready and willing to assist the courts of Switzerland in a similar manner when required. This Court is also willing to reimburse (through Plaintiff) the competent judicial authorities of Switzerland for any costs incurred in executing this request for judicial assistance. This Court extends to the competent judicial authorities of Switzerland the assurances of its highest consideration.

26. This Letter of Request is signed and sealed by Order of the Court made on the date set forth below:

April 19, 2021

Date



Honorable Douglas A. Arpert, U.S.M.J.
United States District Court
District of New Jersey
Clarkson S. Fisher Fed. Bldg. & U.S.
Courthouse
402 East State Street
Trenton, New Jersey 08608

Exhibit A

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

AMGEN INC.,

Plaintiff,

v.

SANDOZ INC., ET AL.,

Defendants.

Civil Action No. 18-11026 (MAS)(DEA)
(consolidated)

Hon. Michael A. Shipp, U.S.D.J.
Hon. Douglas E. Arpert, U.S.M.J

I, Fabia Gozzo, Ph.D., as an expert witness retained by Plaintiff in the above-captioned patent litigation in the United States District Court for the District of New Jersey, have been informed of and understand that:

1. By virtue of my submission of an expert report on behalf of Plaintiff in the above-captioned litigation, I may provide testimony at trial under Federal Rule of Evidence 702, 703, or 705.

2. I am not obligated to appear for and participate in the trial and cannot be subjected to any coercive measures.

3. At any time during examination, I may invoke any right or duty to refuse testimony under Swiss Law. I understand that my rights to refuse testimony are set out in particular in Articles 165-166 of the Swiss Code of Civil Procedure.

In view of the above, I hereby consent to having my trial testimony taken in the above-captioned matter by oral examination in the English language under oath, using remote videoconferencing technology and recorded by video and stenography, at a date to be determined.

I confirm that I am cooperating of my own accord.

Date: April 16, 2021

Fabia Gozzo

Fabia Gozzo, Ph.D.