

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC., BOEHRINGER
INGELHEIM INTERNATIONAL GMBH, and
BOEHRINGER INGELHEIM PHARMA
GMBH & CO. KG,

Plaintiffs,

v.

LUPIN ATLANTIS HOLDINGS SA and
LUPIN LIMITED,

Defendants.

Civil Action No. 18-cv-12663-BRM-TJB
(consolidated)

Filed Electronically

CONFIDENTIAL

**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 MINISTRY OF JUSTICE OF RHINELAND PALATINATE AND THE
PRESIDENT OF THE HIGHER REGIONAL COURT DÜSSELDORF FOR THE
REQUEST FOR JUDICIAL ASSISTANCE IN CIVIL AND COMMERCIAL MATTERS
WITH COPY TO THE GERMAN FEDERAL OFFICE OF JUSTICE 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. Fisher Building & U.S. Courthouse, 402 East State Street, Trenton, NJ 08608, presents its compliments to the German Central Authority 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. Herbert Wachtel, [REDACTED]

[REDACTED], is a named inventor of U.S. Patent No. 7,694,676 (“the ‘676 patent”) at issue in this action and Mr. Horst Wergen, [REDACTED]

██████████, is an alleged inventor of the '676 patent at issue in this action, and therefore, Dr. Wachtel and Mr. Wergen are material witnesses who have 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. Wachtel and Mr. Wergen be examined (remotely) at ██████████

██████████, under oath or affirmation, if permitted by applicable law. Given that the witnesses reside in ██████████, respectively, the competent authorities for the granting of this request are the Ministry of Justice of Rhineland Palatinate (Landesministerium der Justiz) for Dr. Wachtel and the President of the Higher Regional Court Düsseldorf (Präsident des Oberlandesgerichts Düsseldorf) for Mr. Wergen. Although the parties understand that the local competent authorities may require Dr. Wachtel and Mr. Wergen to attend their remote examination via videoconference at the local courthouse, the parties respectfully request that Dr. Wachtel and Mr. Wergen be allowed to attend their remote examination from their homes, respectively, due to the current circumstances and complications related to the COVID-19 pandemic. As is customary, a copy of the present Letter of Request is sent to the German Federal Office of Justice (Bundesamt für Justiz).

This Court, therefore, respectfully requests your assistance pursuant to Article 17 of the Hague Convention in obtaining the oral testimony of Dr. Wachtel and Mr. Wergen 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. Fisher Building & U.S. Courthouse, 402 East State Street, Trenton, NJ 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 issue a commission for the direct taking of evidence abroad under Article 17 of the Hague Convention.

2. The proceedings involve two related patent infringement cases, Civil Action No. 3:18-cv-12663-BRM-TJB and Civil Action No. 3:18-cv-16708-BRM-TJB, regarding alleged infringement of the ‘676 patent, pending in the United States District Court for the District of New Jersey and consolidated for all purposes for the purpose of judicial efficiency. Plaintiffs and Counterclaim-Defendants Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharma GmbH & Co. KG (collectively, “Plaintiffs”) have sued Defendant Lupin Limited and Defendant/Counterclaimant Lupin Atlantis Holdings SA (collectively, “Lupin” or “Defendants”) for patent infringement. Lupin has alleged that the asserted patent is invalid, pursuant to United States patent laws.

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

Party	Representatives
Boehringer Ingelheim Pharmaceuticals, Inc. 900 Ridgebury Road Ridgefield, Connecticut 06877 United States of America	Charles M. Lizza William C. Baton Sarah A. Sullivan SAUL EWING ARNSTEIN & LEHR LLP One Riverfront Plaza, Suite 1520 Newark, New Jersey 07102-5426 (973) 286-6700 clizza@saul.com wbaton@saul.com sarah.sullivan@saul.com
Boehringer Ingelheim International GmbH Binger Str. 173 55216 Ingelheim Germany	
Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Christopher N. Sipes R. Jason Fowler Jeremy D. Cobb COVINGTON & BURLING LLP One City Center Washington, DC 20001 (202) 662-6000 csipes@cov.com

	<p>jfowler@cov.com jcobb@cov.com</p>
<p>Lupin Atlantis Holdings SA Landis & Gyr-Strasse 1 Zug 6300 Switzerland</p> <p>Lupin Limited B/4 Laxmi Towers Bandra Kurla Complex Bandra (E), Mumbai, 400 051 India</p>	<p>Arnold B. Calmann Jeffrey Soos Katherine A. Escanlar SAIBER LLC One Gateway Center 10th Floor, Suite 1000 Newark, New Jersey 07102 (973) 622-3333 abc@saiber.com js@saiber.com kae@saiber.com</p> <p>William A. Rakoczy Paul J. Molino Deanne M. Mazzochi Tara M. Raghavan Matthew V. Anderson Katie A. Boda RAKOCZY MOLINO MAZZOCHI SIWIK LLP 6 West Hubbard Street, Suite 500 Chicago, Illinois 60654 wrakoczy@rmmslegal.com pmolino@rmmslegal.com dmazzochi@rmmslegal.com traghavan@rmmslegal.com manderson@rmmslegal.com kboda@rmmslegal.com</p>

4. According to the electronic records of the U.S. Patent and Trademark Office (“USPTO”), the ‘676 patent was issued on or around April 13, 2010, and is entitled “DRY POWDER INHALER.” The electronic records of the USPTO identify “Boehringer Ingelheim International GmbH” as the purported assignee of the ‘676 patent.

5. Plaintiffs sell and distribute SPIRIVA® HandiHaler® (tiotropium bromide, EQ 0.018MG BASE/INH), which U.S. Food and Drug Administration (“FDA”) records indicate is used for the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Defendant/Counterclaimant Lupin Atlantis Holdings SA filed Abbreviated New Drug Application (“ANDA”) No. 211287 with the FDA seeking approval to manufacture, use and sell tiotropium bromide inhalation powder, 18 mcg/capsule, for which the Reference Listed Drug is SPIRIVA® HandiHaler®.

6. On August 10, 2018, Plaintiffs filed a Complaint in the aforementioned District Court against Lupin for infringement of two U.S. Patents (Nos. 7,070,800 and 7,694,676). On October 30, 2018, Lupin filed its Answer and Counterclaims regarding these patents while also including additional counterclaims seeking a declaratory judgment of non-infringement of three additional U.S. Patents (Nos. RE38,912, 8,022,082, and 9,010,323). On November 30, 2018, Plaintiffs filed a second Complaint in the aforementioned District Court against Lupin for infringement of four additional U.S. Patents (Nos. 6,777,423, 6,908,928, 7,309,707, and 7,642,268). These nine patents concern tiotropium bromide formulations for administration by inhalation and devices for administering the same. The District Court consolidated the cases for all purposes.

7. To date and pursuant to agreement of the parties, all patents, except the ‘676 patent, have been dismissed from the case.

8. The parties are currently in the midst of the fact discovery process, with the close of fact discovery currently set for March 12, 2021.

9. The ‘676 patent lists Dr. Wachtel as the only inventor. On July 26, 2019, a Request to Correct Inventorship was filed with the USPTO, seeking to add Mr. Wergen as a named inventor of the ‘676 patent. The Request was granted on February 8, 2021.

10. Dr. Wachtel is an employee of Plaintiffs, and was purportedly involved in the research and development of the invention claimed in the ‘676 patent. As such, Dr. Wachtel is

expected to testify regarding, *inter alia*:

- Dr. Wachtel's scientific background;
- Dr. Wachtel's experience while working for Plaintiffs;
- Dr. Wachtel's role in the research and development related to the invention claimed in the '676 patent;
- The alleged invention disclosed in the '676 patent;
- The correction of inventorship for the '676 patent;
- The research and development of the SPIRIVA® HandiHaler® and/or the invention that is claimed in the '676 patent; and
- Any Rule 30(b)(6) Topics Plaintiffs have or will designate Dr. Wachtel as corporate representative.

11. Mr. Wergen was purportedly involved in the research and development related to the invention claimed in the '676 patent. As such, Mr. Wergen is expected to testify regarding, *inter alia*:

- Mr. Wergen's scientific background;
- Mr. Wergen's experience while working for Plaintiffs;
- Mr. Wergen's role in the research and development related to the invention claimed in the '676 patent;
- The alleged invention disclosed in the '676 patent;
- The correction of inventorship for the '676 patent;
- The research and development of the SPIRIVA® HandiHaler® and/or the invention that is claimed in the '676 patent; and
- Any Rule 30(b)(6) Topics Plaintiffs have or will designate Mr. Wergen as corporate representative.

12. Accordingly, Defendants believe that evidence from Dr. Wachtel and Mr. Wergen, which Dr. Wachtel and Mr. Wergen have separately in principle 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 and validity. Under United States law, the testimony of the purported inventors of a patent, generally speaking, has been found to be relevant to patent infringement and validity issues, and Lupin believes that the same will be true here as to the evidence obtained from Dr. Wachtel and Mr. Wergen.

II. EVIDENCE REQUESTED

13. Defendants contend that Dr. Wachtel and Mr. Wergen have material information related to this pending action for use in the litigation and at trial, and that justice cannot be completely done between the parties without their testimony.

14. Defendants request that this Court issue the present Letter of Request seeking your assistance in obtaining testimony from Dr. Wachtel and Mr. Wergen under Article 17 of the Hague Convention. The evidence to be obtained is oral testimony to be taken in Germany, the country of residence of Dr. Wachtel and Mr. Wergen, and is intended to be used as evidence in the litigation and at trial for this matter. Dr. Wachtel has been informed about his rights under German law and has consented to testify in Germany. *See Exhibit A.* Mr. Wergen has also been informed about his rights under German law and has consented to testify in Germany. *See Exhibit B.*

15. The Court requests assistance in permitting the commissioners appointed by this Court to take the following testimony from voluntary witnesses Dr. Wachtel and Mr. Wergen:

- a. Testimony regarding their scientific background;
- b. Testimony regarding their experience while working for Plaintiffs;
- c. Testimony regarding their role in the research and development related to the invention claimed in the '676 patent;
- d. Testimony regarding the alleged invention disclosed in the '676 patent;
- e. Testimony regarding the correction of inventorship for the '676 patent;

- f. Testimony regarding the research and development of the SPIRIVA® HandiHaler® and/or the invention that is claimed in the '676 patent; and
- g. Any 30(b)(6) Topics Plaintiffs have designated Dr. Wachtel and/or Mr. Wergen as corporate representatives.

16. Defendants contend 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, Defendants and this Court therefore seek permission to have commissioners take this testimonial evidence for the purpose of using such evidence at trial. Plaintiffs have satisfied this Court that Plaintiffs will pay Dr. Wachtel's and Mr. Wergen's reasonable witness attendance costs to the extent required.

17. It is requested that the testimonial evidence be given in the English language, or with an English language translator, and on oath or affirmation. It is also hereby requested that the testimony be in the form of a recorded (via stenography) remote examination via a secure session using the videoconferencing technology, Zoom (or other equivalent platform), upon questions communicated to the witness by a German attorney acting as commissioner, and/or U.S. counsel of the Plaintiffs and Defendants, also acting as commissioners. It is requested that the testimonial evidence be given at some time agreeable to all involved, whereby the pre-trial depositions are intended to be conducted between February 1, 2021 and March 12, 2021, but the parties are amenable to scheduling these examinations after that time period.

18. The Court hereby appoints Dr. Andrea Heister (or as an alternate in her absence, Dr. Günter Pickrahn) to serve as a non-party, neutral German commissioner, and Dr. Anna Wolters-Hoehne and Dr. Barbara Maucher to serve as additional German commissioners (the "German commissioners"). Dr. Andrea Heister is a Richterin am Landgericht [Judge at the Regional Court] at the Oberlandesgericht München [Higher Regional Court Munich],

Prielmayerstraße 5, D-80335 München, Germany. Dr. Günter Pickrahn (guenter.pickrahn@bakermckenzie.com) is a lawyer with the law firm Baker McKenzie, Bethmannstrasse 50-54, 60311 Frankfurt/Main, Germany, and admitted to practice as an attorney in Germany. Dr. Anna Wolters-Hoehne (anna.wolters@twobirds.com; Telephone: +49 (0) 40 46063 6000) is a lawyer with the law firm Bird & Bird LLP, Am Sandtorkai 50, 20457 Hamburg, Germany, and admitted to practice as an attorney in Germany.¹ Dr. Barbara Maucher (barbara.maucher@noerr.com; Telephone: +49 211 499860) is a lawyer with the law firm Noerr PartG mbB, Speditionstraße 1, 40221 Düsseldorf, Germany, and admitted to practice as an attorney in Germany. In their capacity as German commissioners, Dr. Anna Wolters-Hoehne and Dr. Barbara Maucher will complete and oversee the following tasks: liaise with the German authorities, including dispatch/submission of the present Letter of Request to the Ministry of Justice of Rhineland Palatinate for Dr. Wachtel and the President of the Higher Regional Court Düsseldorf for Mr. Wergen, and a copy of the same to the German Federal Office of Justice; act as an agent of service for any communication of the Ministry of Justice of Rhineland Palatinate, President of the Higher Regional Court Düsseldorf, and/or the German Federal Office of Justice to this Court and the parties; invite Dr. Wachtel and Mr. Wergen to the examinations once authorization is granted; verify and confirm the identity of Dr. Wachtel and Mr. Wergen each time before testimonial evidence is taken; supervise the testimony of Dr. Wachtel and Mr. Wergen by remote videoconferencing software from their respective locations in Germany; instruct the witnesses on their privileges and duties as per Article 21 of the Hague Convention (*i.e.*, privileges and duties

¹ In the event of Dr. Anna Wolters-Hoehne's unforeseen unavailability, Dr. Christopher Maierhoefer will serve as an alternate in her absence. Dr. Christopher Maierhoefer (christopher.maierhoefer@twobirds.com; Telephone: +49 (0) 89 3581 6000) is a lawyer with the law firm Bird & Bird LLP, Maximiliansplatz 22, 80333 Munich, Germany, and admitted to practice as an attorney in Germany.

stemming from both the law of the State of execution and the law of the State of origin); and ensure that the testimony is conducted in accordance with those privileges and duties. In her capacity as the neutral German commissioner, Dr. Andrea Heister (or in her absence, Dr. Günter Pickrahn) will: examine Dr. Wachtel and Mr. Wergen, respectively, with the set of questions related to the subject matter areas noted above (attached as **Exhibit C**) before any subsequent examination by the additional commissioners listed herein²; supervise the testimony of Dr. Wachtel and Mr. Wergen by remote videoconferencing software from their respective locations in Germany; and ensure that the testimony is conducted in accordance with those privileges and duties noted above.

19. The U.S. counsel of the parties, which the Court upon request of Defendants hereby also appoints as commissioners, and who will be present for the deposition testimony of Dr. Wachtel and Mr. Wergen to further examine Dr. Wachtel and Mr. Wergen following examination by the neutral German commissioner noted above, are the following:

a. For Defendants:

- i. Deanne Mazzochi
Tara Raghavan
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Ste. 500
Chicago, IL 60654

b. For Plaintiffs:

- i. Christopher N. Sipes
R. Jason Fowler

² As contemplated by Art. 21 lit.d of the Hague Convention, the evidence may be taken in the manner provided by the law applicable to the court in which the action is pending provided that such manner is not forbidden by the law of the State where the evidence is taken (*e.g.*, here, the U.S. Federal Rules of Civil Procedure), and may be supplemented in a particular case by instructions set out in the commission. Although Defendants provide with this application a set of questions for the neutral German commissioner (attached as **Exhibit C**), Plaintiffs reserve all rights to object to the questions asked on any applicable U.S. and German law grounds. These rights will also apply during any subsequent examination by the additional commissioners listed herein.

COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001

20. In addition to the U.S. counsel and commissioners listed above and the German commissioners, it is also requested that client representatives for each party be allowed to be present, and, as agreed upon by the parties and Dr. Wachtel and Mr. Wergen, that a stenographer be present to take and record a verbatim transcript of all testimony and proceedings in the English language (or with an English language translator), 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 and the German commissioners may enter the rooms where U.S. counsel and German commissioners are remotely attending the deposition, respectively. U.S. counsel, the party representatives, and the stenographer will attend the deposition remotely from their respective offices in the U.S.A. The German commissioners, Dr. Wachtel, and Mr. Wergen will attend the depositions by videoconference from their respective locations in Germany.

21. As mentioned, it is requested that the neutral German commissioner and U.S. counsel for Plaintiffs and Defendants take Dr. Wachtel's and Mr. Wergen's testimony in the English language or with an English language translator (to which Dr. Wachtel and Mr. Wergen have agreed; *see Exhibit A and Exhibit B*), under oath or affirmation, and that the German commissioners accordingly be allowed to administer such oath or request for affirmation on Dr. Wachtel and Mr. Wergen 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. Wachtel and Mr. Wergen be allowed after completion of the transcript to review, submit any errata, and sign the transcript of

their testimony, and that the signed and transcribed 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 German and U.S. commissioners appointed above to question Dr. Wachtel and Mr. Wergen under oath or affirmation at the remote depositions between February 1, 2021 and March 12, 2021, or at another time after that time period agreeable to all involved, and that a verbatim transcript be prepared and be transmitted to the parties' U.S. counsel for submission and use before this Court.


24. It is also requested that you inform the German commissioners, 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 testimonial evidence of Dr. Wachtel and Mr. Wergen. This Court and U.S. counsel hereby appoint Dr. Anna Wolters-Hoehne to file the Letter of Request with you and act as the agent of service in Germany for any and all communication from you in this respect. As mentioned above, Dr. Anna Wolters-Hoehne's professional address in Germany for purpose of your communications is: Bird & Bird LLP, Am Sandtorkai 50, 20457 Hamburg, Germany; anna.wolters@twobirds.com; Telephone: +49 (0) 40 46063 6000.

25. This Court expresses its appreciation to the German Central Authority for its courtesy and assistance in this matter and states that this Court shall be ready and willing to assist the courts of Germany in a similar manner when required. This Court is also willing to reimburse (through the Defendants) the competent judicial authorities of Germany for any costs incurred in executing this request for judicial assistance. This Court extends to the competent judicial authorities of Germany 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:

March 15, 2021
Date


Honorable Tonianna J. Bongiovanni, U.S.M.J.
United States District Court
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, NJ 08608

Boehringer Ingelheim Pharmaceuticals, Inc. et al. v. Lupin Atlantis Holdings SA et al.,
Consolidated Civil Action No. 18-cv-12663-BRM-TJB (D.N.J.)

Exhibit A
to the Article 17 Request
[FILED UNDER SEAL]

English Original

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

**BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC., BOEHRINGER
INGELHEIM INTERNATIONAL GMBH, and
BOEHRINGER INGELHEIM PHARMA
GMBH & CO. KG,**

Plaintiffs,

v.

LUPIN ATLANTIS HOLDINGS SA and LUPIN
LIMITED,

Defendants.

Civil Action No. 18-cv-12663-BRM-TJB

(consolidated)

Filed Electronically

I, Herbert Wachtel, as an employee of,
and fact witness for, Plaintiffs in the
above-captioned patent litigation in the
United States District Court for the Dis-
trict of New Jersey, have been informed
of and understand that:

1. By virtue of Plaintiffs identifying me as an individual likely to have discoverable information that Plaintiffs may use to support their claims or defenses in the above-captioned litigation pursuant to Federal Rule of Civil Procedure 26(a)(1), Defendants may take my deposition pursuant to Federal

Unverbindliche einfache Übersetzung

VOR DEM US-BEZIRKSGERICHT FÜR DEN
BEZIRK NEW JERSEY

**BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC., BOEHRINGER
INGELHEIM INTERNATIONAL GMBH, und
BOEHRINGER INGELHEIM PHARMA
GMBH & CO. KG,**

Klägerinnen

gegen

LUPIN ATLANTIS HOLDINGS SA und LUPIN
LIMITED,

Beklagte.

Zivilklage Nr. 18-cv-12663-BRM-TJB

(konsolidiert)

Elektronisch eingereicht

Ich, Herbert Wachtel, als Angestellter der
und Tatsachenzeuge für die Klägerinnen
in dem oben bezeichneten Patentrechts-
streit vor dem US-Bezirksgericht für den
Bezirk New Jersey, bin darüber informiert
worden und verstehe, dass:

1. In Hinblick darauf, dass mich die Kläger als eine Person einstufen, die wahrscheinlich über auffindbare Informationen verfügt, die sie zur Untermauerung ihrer Ansprüche oder Verteidigungen in dem oben genannten Rechtsstreit gemäß Federal Rule of Civil Procedure 26(a)(1) verwenden können, sind

Rule of Civil Procedure 30(b)(1) (and Federal Rule of Civil Procedure 30(b)(6) if Plaintiffs so designate me to testify on their behalf under Rule 30(b)(6)) if permission for the examination is granted by the relevant German authority following application under Article 17 of the Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters ("**the Convention**") and subject to any conditions that the German Central Authority may impose.

2. If permission is granted, the taking of evidence will be done in compliance with the conditions imposed by the German Central Authority.
3. I understand that I am not obligated to appear for and participate in the trial or the taking of evidence and cannot be subjected to any coercive measures.
4. During the taking of evidence, I may be assisted by my own counsel.
5. During the taking of evidence, I may be assisted by an interpreter.
6. At any time during examination, I may invoke any right or duty to refuse testimony under German or American Law. Concerning German Law, I understand that my rights to refuse testimony can, for example, be found in Sections 383 and 384 of the German Code of Civil Procedure.

die Beklagten berechtigt, mich gemäß Federal Rule of Civil Procedure 30(b)(1) (und Federal Rule of Civil Procedure 30(b)(6)) zu vernehmen, falls die Kläger mich in ihrem Namen gemäß Rule 30(b)(6) als Zeuge benennen und wenn die zuständige deutsche Behörde auf Antrag gemäß Artikel 17 des Haager Übereinkommens über die Beweisaufnahme im Ausland in Zivil- oder Handelssachen ("**das Haager Beweisübereinkommen**") vorbehaltlich aller Bedingungen, die die deutsche Zentrale Behörde auferlegen kann, die Erlaubnis zur Vernehmung erteilt.

2. Wird die Erlaubnis erteilt, so erfolgt die Beweisaufnahme unter Einhaltung der Bedingungen der deutschen Zentralen Behörde.
3. Mir ist bekannt, dass ich zum Erscheinen sowie zur Teilnahme an der Hauptverhandlung und der Beweisaufnahme nicht verpflichtet bin und keinerlei Zwangsmaßnahmen unterworfen werden kann.
4. Bei der Beweisaufnahme kann ich mich von meinem eigenen Rechtsbeistand unterstützen lassen.
5. Während der Beweisaufnahme kann ich mich von einem Dolmetscher unterstützen lassen.
6. Während der Vernehmung kann ich mich jederzeit auf ein Zeugnisverweigerungsrecht oder eine Zeugnisverweigerungspflicht nach deutschem oder amerikanischem Recht berufen. Für das deutsche Recht ist mir bekannt, dass sich meine Zeugnisverweigerungsrechte z.B. aus den §§ 383, 384 der deutschen Zi-

dure (Zivilprozessordnung).

In view of the above, I hereby confirm to have understood my rights related to having my testimony taken in the above-captioned matter by oral examination using remote videoconferencing technology and recorded by stenography if so allowed by the German Central Authority, at a date to be determined.

I confirm that I am cooperating of my own accord.

[Ort/Wort], [Datum/monat]

Ingenheim, Feb. 23, 2021

Herbert Wachtel

Herbert Wachtel

vilprozessordnung ergeben.

In Anbetracht des Vorstehenden bestätige ich hiermit, dass ich meine Rechte verstanden habe, die damit verbunden sind, dass meine Aussage zu einem noch festzulegenden Termin in der oben genannten Angelegenheit durch eine mündliche Vernehmung unter Verwendung von Videokonferenztechnologie aus der Ferne aufgenommen und stenografisch auf-gezeichnet wird, sofern dies von der deutschen Zentralen Behörde erlaubt wird.

Ich bestätige, dass ich aus eigenem Antrieb kooperiere.

Boehringer Ingelheim Pharmaceuticals, Inc. et al. v. Lupin Atlantis Holdings SA et al.,
Consolidated Civil Action No. 18-cv-12663-BRM-TJB (D.N.J.)

Exhibit B
to the Article 17 Request
[FILED UNDER SEAL]

English Original

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BOEHRINGER **INGELHEIM**
PHARMACEUTICALS, INC., BOEHRINGER
INGELHEIM INTERNATIONAL GMBH, and
BOEHRINGER **INGELHEIM** **PHARMA**
GMBH & CO. KG,

Plaintiffs,

v.

LUPIN ATLANTIS HOLDINGS SA and LUPIN
LIMITED,

Defendants.

Civil Action No. 18-cv-12663-BRM-TJB

(consolidated)

Filed Electronically

I, Horst Wergen, as a fact witness for, Plaintiffs 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 Plaintiffs identifying me as an individual likely to have discoverable information that Plaintiffs may use to support their claims or defenses in the above-captioned litigation pursuant to Federal Rule of Civil Procedure 26(a)(1), Defendants may take my deposition pursuant to Federal

Unverbindliche einfache Übersetzung

VOR DEM US-BEZIRKSGERICHT FÜR DEN
BEZIRK NEW JERSEY

BOEHRINGER **INGELHEIM**
PHARMACEUTICALS, INC., BOEHRINGER
INGELHEIM INTERNATIONAL GMBH, und
BOEHRINGER **INGELHEIM** **PHARMA**
GMBH & CO. KG,

Klägerinnen

gegen

LUPIN ATLANTIS HOLDINGS SA und LUPIN
LIMITED,

Beklagte.

Zivilklage Nr. 18-cv-12663-BRM-TJB

(konsolidiert)

Elektronisch eingereicht

Ich, Horst Wergen, als Tatsachenzeuge für die Klägerinnen in dem oben bezeichneten Patentrechtsstreit vor dem US-Bezirksgericht für den Bezirk New Jersey, bin darüber informiert worden und verstehe, dass:

1. In Hinblick darauf, dass mich die Kläger als eine Person einstufen, die wahrscheinlich über auffindbare Informationen verfügt, die sie zur Untermauerung ihrer Ansprüche oder Verteidigungen in dem oben genannten Rechtsstreit gemäß Federal Rule of Civil Procedure 26(a)(1) verwenden können, sind

Rule of Civil Procedure 30(b)(1) (and Federal Rule of Civil Procedure 30(b)(6) if Plaintiffs so designate me to testify on their behalf under Rule 30(b)(6)) if permission for the examination is granted by the relevant German authority following application under Article 17 of the Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters ("**the Convention**") and subject to any conditions that the German Central Authority may impose.

2. If permission is granted, the taking of evidence will be done in compliance with the conditions imposed by the German Central Authority.
3. I understand that I am not obligated to appear for and participate in the trial or the taking of evidence and cannot be subjected to any coercive measures.
4. During the taking of evidence, I may be assisted by my own counsel.
5. During the taking of evidence, I may be assisted by an interpreter.
6. At any time during examination, I may invoke any right or duty to refuse testimony under German or American Law. Concerning German Law, I understand that my rights to refuse testimony can, for example, be found in Sections 383 and 384 of the German Code of Civil Proce-

die Beklagten berechtigt, mich gemäß Federal Rule of Civil Procedure 30(b)(1) (und Federal Rule of Civil Procedure 30(b)(6)) zu vernehmen, falls die Kläger mich in ihrem Namen gemäß Rule 30(b)(6) als Zeuge benennen und wenn die zuständige deutsche Behörde auf Antrag gemäß Artikel 17 des Haager Übereinkommens über die Beweisaufnahme im Ausland in Zivil- oder Handelssachen ("**das Haager Beweisübereinkommen**") vorbehaltlich aller Bedingungen, die die deutsche Zentrale Behörde auferlegen kann, die Erlaubnis zur Vernehmung erteilt.

2. Wird die Erlaubnis erteilt, so erfolgt die Beweisaufnahme unter Einhaltung der Bedingungen der deutschen Zentralen Behörde.
3. Mir ist bekannt, dass ich zum Erscheinen sowie zur Teilnahme an der Hauptverhandlung und der Beweisaufnahme nicht verpflichtet bin und keinerlei Zwangsmaßnahmen unterworfen werden kann.
4. Bei der Beweisaufnahme kann ich mich von meinem eigenen Rechtsbeistand unterstützen lassen.
5. Während der Beweisaufnahme kann ich mich von einem Dolmetscher unterstützen lassen.
6. Während der Vernehmung kann ich mich jederzeit auf ein Zeugnisverweigerungsrecht oder eine Zeugnisverweigerungspflicht nach deutschem oder amerikanischem Recht berufen. Für das deutsche Recht ist mir bekannt, dass sich meine Zeugnisverweigerungsrechte z.B. aus den §§ 383, 384 der deutschen Zi-

dure (Zivilprozessordnung).

In view of the above, I hereby confirm to have understood my rights related to having my testimony taken in the above-captioned matter by oral examination using remote videoconferencing technology and recorded by stenography if so allowed by the German Central Authority, at a date to be determined.

I confirm that I am cooperating of my own accord.

KÖLN, 19. FEBRUARY 2021

[Ort/place], [Datum]/[date]



Horst Wergen

vilprozessordnung ergeben.

In Anbetracht des Vorstehenden bestätige ich hiermit, dass ich meine Rechte verstanden habe, die damit verbunden sind, dass meine Aussage zu einem noch festzulegenden Termin in der oben genannten Angelegenheit durch eine mündliche Vernehmung unter Verwendung von Videokonferenztechnologie aus der Ferne aufgenommen und stenografisch auf-gezeichnet wird, sofern dies von der deutschen Zentralen Behörde erlaubt wird.

Ich bestätige, dass ich aus eigenem Antrieb kooperiere.

Boehringer Ingelheim Pharmaceuticals, Inc. et al. v. Lupin Atlantis Holdings SA et al.,
Consolidated Civil Action No. 18-cv-12663-BRM-TJB (D.N.J.)

Exhibit C
to the Article 17 Request
[FILED UNDER SEAL]

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC., BOEHRINGER
INGELHEIM INTERNATIONAL GMBH, and
BOEHRINGER INGELHEIM PHARMA GMBH
& CO. KG,

Plaintiffs,

v.

LUPIN ATLANTIS HOLDINGS SA and
LUPIN LIMITED,

Defendants.

Consolidated Civil Action
No. 18-cv-12663-BRM-TJB

CONFIDENTIAL

**STATEMENT OF THE SUBJECT MATTER
ABOUT WHICH THE IDENTIFIED PERSONS ARE TO BE EXAMINED**

I. Witness Background.

Introductory questions relating to witness background, qualifications, experience, and circumstances under which the witness learned of the request for his testimony and the preparation for testimony.

1. When did you first learn that your examination in connection with this matter was being sought?
2. From whom did you learn your examination was being sought?
3. Did you speak with anyone about this litigation? Who? When?
4. What did you do to prepare for today's examination?
5. Did you speak with anyone from Boehringer Ingelheim to prepare for today's examination?
6. Do you understand Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharma GmbH KG & Co. to be the Plaintiffs in a U.S. litigation involving a tiotropium bromide product?
 - i. Do you understand when we use the term "Plaintiffs," we are referring to Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharma GmbH KG & Co.?
7. Do you understand you are to give testimony today on various topics in connection with U.S. Patent No. 7,694,676?
 - i. Do you understand if we reference "the '676 patent," we are referring to U.S. Patent No. 7,694,676?
8. Do you understand that you will be giving testimony on the research and development that led to the '676 patent?
9. Do you understand you will be giving testimony on the research and development of the HandiHaler device?
 - i. Do you understand that if we reference "HandiHaler I", we are referencing the first generation HandiHaler that was marketed by Plaintiffs in the U.S. before the current version of the HandiHaler was launched and marketed?
 - ii. Do you understand that if we reference "HandiHaler II", we are referencing the inhalation device claimed in the '676 patent and currently marketed by Plaintiffs in the U.S. as part of its SPIRIVA® HandiHaler® product?
10. What is your educational background?

II. Employment at Boehringer.

Employment, consulting or other similar agreements with Plaintiffs including job titles, duties, and responsibilities as well as dates of employment and history of employment with Plaintiffs.

11. Where are you employed?
12. Have you ever been or are you currently employed by Plaintiffs?
 - i. When did your employment or consulting engagement with Plaintiffs begin?
 - ii. What was your title in around the 2002-04 time frame?
 - iii. Which Boehringer corporate entity employed you or retained you?
 - iv. Who was your boss or supervisor?
 - v. Did you have any direct reports?
 - vi. Who was on the team for the development of:
 1. HandiHaler I?
 2. HandiHaler II?
 3. Any efforts to improve handling of the HandiHaler I device?
 4. Any efforts to develop a double functioning actuator button?
 5. Any efforts to develop a “pocket watch” type opening system?
13. What were the terms of your contract with Plaintiffs?
 - i. Did the employment contract have terms involving assignment rights?
14. Were you involved in the development of the inhalation device in the late 1990s/early 2000s now branded as SPIRIVA® HandiHaler®?
 - i. When?
 - ii. What duties did you have on this project?
 - iii. What was your involvement?
15. Were you involved in the SPIRIVA® HandiHaler® Product Development Team?
 - i. When?
 - ii. What duties did you have?
 - iii. What was your involvement?
16. How did you interact with other members of the SPIRIVA® HandiHaler® Product Development Team?
 - i. Who had decision-making authority?
 - ii. Who was the project manager?
 - iii. What did you understand were the goals for the team?
 - iv. What were the goals specific to:
 1. Improvements to the HandiHaler I device?
 2. Double functioning actuator?
 3. “Pocket watch” type opening system?
 4. Handling?
 - v. Who generated those goals?

1. Marketing?
 2. Users?
 3. Other inputs for improvement?
-
17. Were you involved in regulatory issues relating to SPIRIVA® HandiHaler®, e.g., the preparation and submission of New Drug Application (“NDA”) No. 021395 to the FDA?
 - i. When? What duties did you have? What was your involvement?
 18. Were you involved in the prosecution of the ‘676 patent? Nature of involvement?
 - i. When? What duties did you have?
 19. Have you left and when did you leave employment with Plaintiffs?
 20. Did you or have you had any ongoing relationship with Plaintiffs since your departure, e.g., consulting relationship?
 - i. Nature of that relationship? How many hours? Are you compensated?

III. Involvement in Development of HandiHaler.

Involvement and role in the development of SPIRIVA® HandiHaler® in the late 1990s and early 2000s, including work with tiotropium bromide, knowledge regarding the time to development of the inhalation device claimed by Plaintiffs in the ‘676 patent, and contribution to the invention claimed in the ‘676 patent.

21. When was your first involvement with any tiotropium product at Boehringer?
22. When did the development of the inhalation device claimed in the ‘676 patent begin?
 - i. What was the rationale for including:
 1. A double functioning actuator?
 2. A “pocket watch” type opening system?
 3. Aids for gripping/opening?
 4. Opening aids placed in a particular location?
 - ii. Who proposed these ideas? Who decided who was responsible for implementing them?
23. Who did you work with in developing the inhalation device claimed in the ‘676 patent?
24. When was development of the inhalation device claimed in the ‘676 patent completed?
25. Who decided to seek patent protection for the double-functioning actuator button?
 - i. Wasn’t this double-functioning actuator button disclosed in a prior art patent for a different device, U.S. Pat. No. 7,252,087 B2 to Herbert Wachtel (DX 18)?
26. Who decided to seek patent protection for the inhalation device claimed in the ‘676 patent?

The ‘676 Patent

27. Turn to DX 1, the ‘676 patent.
 - i. Paragraph 1 in column 1 of the ‘676 patent states “the invention relates to an inhaler for inhaling powdered pharmaceutical compositions from capsules which are inserted in a capsule holder provided in the inhaler before use” correct?
 1. Are the capsules pierced with a pin to release the pharmaceutical composition within the inhalers?
 - ii. In the second paragraph of column 1 of the ‘676 patent, it states “an inhaler of this kind is described for example in EP 07 03 800 B1 or EP 091 10 47 A1” correct?
 1. Are you familiar with these patents or patent applications?
 2. Were the devices described in these two EP patents disclosed before the HandiHaler I was developed?

- iii. At around line 25 of column 1, does it state in the '676 patent that the capsule could be "pierced by means of a spring loaded actuating member"?
 - iv. Does the third full paragraph in column 1 of the '676 patent state that "the intention of the invention is to improve the known inhalers still further in terms of their handling"?
 - v. Does the section in the '676 patent from column 1 line 61, to column 2 line 7 discuss the mouthpiece?
 - vi. Was BI's target market for this device people who were suffering from arthritis or those who had some other restriction to the mobility of their fingers? If yes, how/why did you decide that this patient population required these changes? Were the changes driven by marketing studies?
 - vii. Were you working with any drug besides tiotropium in connection with development of HandiHaler II?
 - viii. Were the Handihaler devices designed for inhalation of the drug powder formulation contained in the SPIRIVA capsule?
 - ix. Are there any discussions in the '676 patent relating to the flow rates for tiotropium or any other drug?
 - x. Does the device in the '676 patent require any particular dimensions of the air duct?
 - xi. Does the device in the '676 patent require any particular particle size dimensions of the drug?
28. Turn to DX 4, the EP 070 3800 B1, and DX 5, EP 091 1047 A1.
- i. Do the inhalers described in these documents have a mouthpiece?
 - ii. Were these known inhalers also known as of their publication to have a capsule holder provided underneath, and also attached to the joint?
 - iii. Do the devices described in DX4 and DX5 relate to the HandiHaler I device or some other device?

Contribution to '676 Patent

29. When someone has contributed to an invention, for purposes of this deposition, what definition of "contribution" are you using?
30. Did you contribute to the conception of the improvement to include the double functioning actuator (first function to detach the closure element for pivoting the lid, second function to pierce the capsule) as described in column 1 of the '676 patent, lines 34-41?
31. Did you contribute to the conception of the improvement to include a gripping aid on the mouthpiece?
32. Did you contribute to the conception of the preferred embodiments described in the '676 patent?
33. Did you contribute to the structural drawings referenced in the '676 patent as Figure 1, and described in detail in column 3, line 29 through column 4, line 48?

IV. Involvement in Regulatory Issues Regarding SPIRIVA® HandiHaler®.

Involvement and role in regulatory issues, including the preparation and submission of the components of NDA No. 021395 relating to SPIRIVA® HandiHaler®, including efforts to secure FDA approval for NDA No. 021395.

34. Were you involved in the review or preparation of components of Plaintiffs' NDA No. 021395? How?
35. Did you receive information regarding the filing of Plaintiffs' NDA No. 021395? From whom? Why?
36. Were you in communication with members of the Plaintiffs' regulatory affairs department during 2001 when the NDA was being prepared and submitted? Nature of the communications?
37. Did you review the material you received regarding NDA No. 021395?

V. Involvement in Prosecution of U.S. Patent No. 7,694,676.

Introductory questions regarding involvement in the prosecution of the application that issued as U.S. Patent No. 7,694,676 (“the ‘676 patent”).

38. Were you involved in the prosecution of the application that issued as the ‘676 patent?
 - i. What was the nature of your involvement?
 - ii. What did you do to ensure you had complied with your duty of good faith and fair dealing with the Patent and Trademark Office?
 1. Did you review your files to disclose relevant prior art you were aware of?
 2. Did you independently conduct a search of the literature?
 3. Why did you believe you deserved to be an inventor?
 - a. What was it about your contribution that you believe makes you an inventor, and not others who were part of the HandiHaler development group working on improvements to HandiHaler I?
39. Why were you involved in communications with Plaintiffs’ patent department regarding the ‘676 patent?
 - i. Did you ever check them for accuracy?
40. Were you informed about the prosecution of the ‘676 patent?
 - i. By whom?
41. Were you asked to participate in the prosecution of the ‘676 patent?
 - i. By whom?
42. Are you aware of certain terms of art in patent prosecution such as conception and reduction to practice? What is your understanding of those terms?

VI. Origin of the HandiHaler.

Introductory questions regarding the development of the HandiHaler.

- 43. Boehringer brought to market the HandiHaler I device with tiotropium before the '676 patent was filed, correct?
- 44. Can you look at a document marked DX 6, BI-SPIRIVA_00163052-221?
 - i. Do you recognize this document?
 - ii. What is this document?
- 45. Can you look at a document marked DX 7, BI-SPIRIVA 00011292-302?
 - i. [REDACTED]
 - 1. Who are these people listed? What were each of their roles?
 - ii. [REDACTED]
 - 1. Was that true?
 - 2. What role did [REDACTED] play in developing the HandiHaler?
 - iii. Please turn to BI-SPIRIVA 00011300, [REDACTED]
 - 1. Why would there be [REDACTED] [REDACTED]?
- 46. Can you look at a document marked DX 8, BI-SPIRIVA 00011331-336?
 - i. [REDACTED]
 - ii. [REDACTED]
 - iii. When did [REDACTED] as noted in this document?
 - iv. Take a look at next page in DX 8, BI-SPIRIVA 00011332. [REDACTED]
 - Do you know who determined that?
 - v. Please look to BI-SPIRIVA 00011335.
 - 1. [REDACTED]
 - 2. What was [REDACTED] role in this study?
 - vi. Please look at DX 8, page BI SPIRIVA 11336. [REDACTED]
 - [REDACTED]

1. [REDACTED]
 - a. What was the role of each of these individuals in the development of the 2nd generation HandiHaler?
 - b. Why were you not involved with this?
2. [REDACTED]
 - a. What does [REDACTED] capsule refer to?
3. [REDACTED]
 - a. Who was tasked with implementing these changes to the Handihaler I for the second generation product?
 - b. What did you understand to be your roles/responsibilities for HandiHaler I/second generation product at this time?

47. Can you look at a document marked DX 9, BI-SPIRIVA 01749956?
- i. [REDACTED]
 1. [REDACTED]
 - ii. [REDACTED]
 1. Who asked for [REDACTED]? Who was responsible? What ideas came from [REDACTED]? Were any ideas specifically yours?
 - iii. [REDACTED]
 1. It was given [REDACTED], correct?
 2. Why?
 3. What was driving the need for [REDACTED]?

48. Can you look at a document marked DX 10, BI-SPIRIVA 00009379?
- i. [REDACTED]
 - ii. [REDACTED]
 1. [REDACTED] Marketing? Clinicians? Patients? Engineers?
 - iii. [REDACTED]

- iv. [REDACTED]
1. Who was [REDACTED]? What were his roles/responsibilities?

49. Can you look at a document marked DX 11, BI-SPIRIVA 00011054?

- i. [REDACTED]
- ii. [REDACTED]
- iii. Did [REDACTED] continue to work on the HandiHaler projects for very long after the date in this letter? Who took over [REDACTED] work?

50. Can you look at a document marked DX 12, BI-SPIRIVA 1749881-882?

- i. [REDACTED]
- ii. [REDACTED] Who are these people?
What were their roles at Boehringer?
- iii. What role did these individuals play in the development of the second generation HandiHaler?
- iv. [REDACTED] Who was [REDACTED] at Boehringer? What was his role?
- v. [REDACTED] Is this accurate?
1. Did you work with or for [REDACTED]? How did his roles/responsibilities differ from yours when it came to the HandiHaler projects?

51. Can you look at a document marked DX 13, BI-SPIRIVA_01749822, [REDACTED]

- i. Were you a member of this R&D subteam? How many people were on this team?
- ii. [REDACTED]
- iii. Turn to page BI-SPIRIVA 01749826, [REDACTED]
- iv. Take a look at the next page, BI-SPIRIVA 01749827, [REDACTED]

1. [REDACTED]
2. [REDACTED]

52. Can you look at a document marked DX 14, BI-SPIRIVA 01749802, [REDACTED]

i. Please take a look at page BI-SPIRIVA 01749807, [REDACTED]

1. [REDACTED]
2. Did you have a role in deciding [REDACTED]? If so, what? Where is that documented?

53. Can you look at a document marked DX 15, BI-SPIRIVA 01749856, [REDACTED]

i. On page BI-SPIRIVA 01749874, [REDACTED]

1. Do you know who was in [REDACTED]?

ii. On page BI-SPIRIVA 01749875, [REDACTED]

1. [REDACTED]
2. [REDACTED]

iii. On page BI-SPIRIVA 01749877, [REDACTED]

1. This was [REDACTED], correct?

iv. On page BI-SPIRIVA 01749880, [REDACTED]

1. [REDACTED] What does that refer to?
2. These were observations that came from [REDACTED]?
3. Why did BI care about these types of observations from [REDACTED]?

v. Turn to page BI-SPIRIVA 01749869, [REDACTED]

vi. On page BI-SPIRIVA 01749873, [REDACTED]

vii. On page BI-SPIRIVA 01749864-65, [REDACTED]

- 1. [REDACTED]
- viii. On page BI-SPIRIVA 01749867, [REDACTED]
 - 1. These are from [REDACTED]?
- ix. Please turn to BI-SPIRIVA 01749868 [REDACTED]
- x. Turn to BI-SPIRIVA 01749857. [REDACTED]
 - 1. [REDACTED]
 - 2. The next slides, BI-SPIRIVA 01749858-59, [REDACTED]
 - 3. If we continue on page BI-SPIRIVA 01749860, [REDACTED]
 - a. [REDACTED]
 - b. [REDACTED]
 - c. [REDACTED]
 - 4. Turn to DX 12, BI-SPIRIVA 01749881, [REDACTED]
 - a. [REDACTED]

- 54. Can you look at a document marked DX 16-A, BI-SPIRIVA 01749883?
 - i. [REDACTED]

VII. U.S. Patent No. 7,694,676.

Additional questions regarding U.S. Patent No. 7,694,676 (“the ‘676 patent”).

55. Please look to DX ___, Zierenberg WO 03/084502. Does this publication cover the HandiHaler I device?
- i. Is the HandiHaler I inhaler structure depicted there on the cover of this document?
 - ii. Does the inhaler structure depicted in this document have a gripping aid to assist the user?
 - iii. Aside from a gripping aid, are all of the other elements of the device claimed in the ‘676 patent present in the device described in the Zierenberg reference?

VIII. Wachtel Patent (U.S. Patent No. 7,252,087).

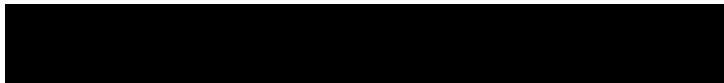
Introductory questions regarding U.S. Patent No. 7,252,087.

56. Look at DX 18, U.S. Patent No. 7,252,087 to Wachtel. This is a patent that covers an inhalation device?

- i. Does this '087 patent involve the pocket watch opening system to apply to the inhalers?
- ii. Does this '087 patent disclose all of the claim elements of the inhalation device in the '676 patent that did not involve the gripping aid?
- iii. Does the '087 patent disclose a dual functioning actuator?
 1. Does the dual-functioning actuator in the '676 patent share the same features as the multi-function actuator set forth in the '087 patent? If yes, how? If no, what do you believe is different?
- iv. Look to column 2, third paragraph under "Detailed Description of the Invention." It states:

"As the forces required for releasing the cover and mouthpiece components are significantly lower, there is no need to provide gripping aids. By gripping aids are meant, for example, depressions or grooves, which may have the disadvantage of attracting dirt. By dispensing with these gripping aids, in addition to improving the optical appearance, the hygiene conditions are also improved. This is particularly important in the area around the mouthpiece, as this component is placed in the oral cavity when the inhaler is used" correct?

If this statement in this patent was true, why was there a need for the gripping aid for the device claimed in the '676 patent?

1. When you say gripping aids involve depressions, what did you mean by that?
2. When you say gripping aids involve grooves, what did you mean by that?
 - a. Would you be able to draw grooves as you are describing here?
 - b. 

Why or why not?

v. Look to DX 1, was there a need for a gripping aid discussed in the '676 patent? Where? Why?

IX. Inventorship of the '676 Patent.

Introductory questions regarding the inventorship of U.S. Patent No. 7,694,676.

57. Please look at DX 2-D, the Petition for Correction of Inventorship. Have you seen this document before?
- i. Do you have an understanding as to why this petition for a change of inventors needed to be filed?
 1. What is the factual basis for that understanding?
 2. Who decided this petition needed to be filed?
 3. What prompted the decision for this petition to be filed?
 - ii. Did Horst Wergen reach out to Plaintiffs stating that he believed he should be named as an inventor on any patent application owned by Plaintiffs?
 - iii. Tell me about the facts underlying the process Plaintiffs went through for this change in inventorship.
 - iv. Was the change in inventorship petition prompted by activities associated with litigation? In the United States?
 - v. Do you believe there are claims in this patent that were invented only by you?
 - vi. What claims in this patent do you believe involved ideas from both Wachtel/Wergen?
 - vii. What claims in this patent do you believe involved ideas or drawings that originated with [REDACTED]? Or others on the BI R&D team?

X. Assignment of the '676 Patent.

Introductory questions regarding assignment of U.S. Patent No. 7,694,676.

58. Please look at DX __, Assignment for Herbert Wachtel. This is an English translation of the original document in German. Have you seen this document before?
 - i. Did you review and sign this document?
59. Please look at DX __, Assignment for Horst Wergen. This is an English translation of the original document in German. Have you seen this document before?
 - i. Did you review and sign this document?
60. Did you authorize attorneys to file this for you?
61. Did you have any employment agreements that required you to transfer ownership of inventions to your employers?
62. What consideration or funds separate from the ordinary work you performed were you paid for this assignment?
63. Who contacted you from BI asking for this assignment? Who did you consult with before issuing the assignment?
64. Have you ever assigned any other rights in this work to any other person or company?
65. Did DesignQuadrat ever have any legal interests to any patents you obtained?
66. How did anyone at DesignQuadrat come to work on this project?

XI. Marketing involving the HandiHaler product.

67. Who assisted BI in marketing the HandiHaler I device?
68. Did [REDACTED] assist BI in marketing the HandiHaler device?
69. Did [REDACTED] ever provide ideas and feedback for improvements to the HandiHaler device?
70. Did DesignQuadrat ever have any legal interests to any patents you obtained?

XII. BI documents-Wachtel

71. Please look at BI-Spiriva_00011747. What is this document? Who are the individuals listed as part of the team? What were their roles/responsibilities? What task (if any) were you assigned? Who was responsible for the handle grooves? Who suggested these changes to the existing design? Who identified the problems with the smoothness of the mouthpiece?
72. Please look at BI-Spiriva_00012447-531. What is this document? Who prepared? When? What type of project were you responsible for?
- i. On page BI-Spiriva_00012496, who did this field work? Who did the work in the USA? Were the individuals subjected to confidentiality agreements? If so, where would those records be?
 - ii. On page BI-Spiriva 00012514, [REDACTED]
[REDACTED] Who were they? What did they do? Were they ever consulted in connection with the HandiHaler II design? Why/why not?
 - iii. Did the HandiHaler II design ever win a similar “best in show” award? If so, where is that documented?
 - iv. On page BI-Spiriva 00012496, [REDACTED]
[REDACTED] Did any of that work lead to design changes found in the ‘676 patent? Other patents?
73. Please look at BI-Spiriva_01749816. What is this document? Who prepared? Who performed the work reflected in this document?