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May 13, 2013

VIA ECF (COPY BY FEDERAL EXPRESS)

The Honorable Lois H. Goodman, U.S.M.J.
Clarkson S. Fisher Federal Building
& U.S. Courthouse
402 East State Street
Trenton, NJ 08608

Re: *InSite Vision Corp., et al. v. Sandoz, Inc., et. al.*
Civil Action No. 11-3080 (MLC) (LHG)

Dear Judge Goodman:

Enclosed please find a copy of the Final Pretrial Order. The parties respectfully request that Your Honor execute the same and direct the entry of the Final Pretrial Order in this matter onto the docket.

We thank the Court for its attention and courtesies.

Respectfully submitted,

s/ Sheila McShane

cc: Christina Saveriano, Esq. (via email)
Eric I. Abraham, Esq. (via email)
Elizabeth Crompton, Esq. (via email)
Bruce Gagala, Esq. (via email)
Jeffrey Burgan, Esq. (via email)
James W. Huston (via email)
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Jeff B. Vockrodt, Esq. (via email)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

INSITE VISION INCORPORATED,
INSPIRE PHARMACEUTICALS, INC.
PFIZER INC.,

Plaintiffs,

v.

SANDOZ INC.,
SANDOZ GMBH,
SANDOZ INDUSTRIAL PRODUCTS S.A.,

Defendants.

Civil Action No.:

11-03080-MLC-LHG

FINAL PRETRIAL ORDER

This matter having come before the Court for a pretrial conference pursuant to Fed. R. Civ. P. 16; and Sheila F. McShane of Gibbons P.C., having appeared for Plaintiffs InSite Vision Incorporated, Inspire Pharmaceuticals, Inc., and Pfizer Inc., and Rodger L. Tate, Robert M. Schulman, and Jeff B. Vockrodt of Hunton & Williams LLP, having appeared for Plaintiff InSite Vision Incorporated, and Dominick A. Conde, Lisa B. Pensabene, and Vishal C. Gupta of Fitzpatrick, Cella, Harper & Scinto, having appeared for Plaintiffs Inspire Pharmaceuticals, Inc. and Pfizer Inc.; and Eric I. Abraham and Christina Saveriano of Hill Wallack LLP, and James W. Huston, M. Andrew Woodmansee, and Matthew M. D'Amore of Morrison & Foerster LLP, having appeared for Defendant Sandoz Inc. ("Sandoz"); the following Final Pretrial Order is hereby entered:

1. **JURISDICTION (set forth specifically).**

This is a civil action for patent infringement of U.S. Patent Nos. 6,861,411, 6,569,443, 6,239,113 and 7,056,893 (collectively, "Patents in Suit") under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331, 1367(a), 1338(a), 2201, and 2202.

A) Plaintiffs' Position:

During the course of this litigation, Sandoz agreed to provide discovery from its ex-U.S. entities Sandoz GmbH and Sandoz Industrial Products S.A. Relying on this agreement, Plaintiffs did not serve the complaint upon either Sandoz GmbH or Sandoz Industrial Products S.A. Although Plaintiffs disagree with Sandoz's position that jurisdiction and venue are improper with regard to Sandoz GmbH and Sandoz Industrial Products S.A., the Court need not address this issue during the present litigation.

B) Sandoz's Position:

Sandoz Inc. does not contest personal jurisdiction or venue for the purpose of this case. This Court does not have personal jurisdiction over Sandoz GmbH. This Court does not have personal jurisdiction over Sandoz Industrial Products S.A. Neither Sandoz GmbH nor Sandoz Industrial Products S.A. has been served with the Complaint. Venue is not proper for Sandoz GmbH. Venue is not proper for Sandoz Industrial Products S.A.

2. **PENDING/CONTEMPLATED MOTIONS (Set forth all pending or contemplated motions, whether dispositive or addressed to discovery or to the calendar. Also, set forth the nature of the motion and the return date. If the Court indicated that it would rule on any matter at pretrial, summarize that matter and each party's position).**

Plaintiffs have filed the following motions *in limine*:

1. Plaintiffs' Motion *in Limine* No. 1 to Preclude Defendants From Affirmatively Using Newly Disclosed Technical Publications and References at Trial

2. Plaintiffs' Motion *in Limine* No. 2 to Preclude Defendants from Affirmatively Using Documents Omitted from Contentions and Expert Reports at Trial

3. Plaintiffs' Motion *in Limine* No. 3 to Preclude Sandoz Inc. from Relying on Art After November 1996 In Establishing Its Prima Facie Case of Obviousness

4. Plaintiffs' Motion *in Limine* No. 4 to Preclude Sandoz From Relying on the WHO Reference as Prior Art

5. Plaintiffs' Motion *in Limine* No. 5 to Preclude Sandoz from Relying on the Leiter Declaration and the Secret Leiter Formulations as Prior Art

6. Plaintiffs' Motion *in Limine* No. 6 to Preclude Sandoz from Affirmatively Using Evidence Concerning Commercial Success at Trial

7. Plaintiffs' Motion *in Limine* No. 7 to Preclude Certain Testimony of Dr. Matthew B. Goren

3. **STIPULATION OF FACTS (Set forth in narrative form a comprehensive listing of all uncontested facts, including all answers to interrogatories and admissions, to which there is agreement among the parties).**

See Exhibit 1.

4. **PLAINTIFFS' CONTESTED FACTS (State separately for each plaintiff. Proofs shall be limited at trial to the matters set forth below. Failure to set forth any matter shall be deemed a waiver thereof).**

Plaintiffs intend to prove the following contested facts with regard to liability:

See Exhibit 2.

5. DEFENDANT'S CONTESTED FACTS (State separately for each defendant. See instructions above).

Defendant intends to prove the following contested facts with regard to liability.

See Exhibit 3.

6. PLAINTIFFS' WITNESSES (Aside from those called for impeachment purposes, only those witnesses whose names and addresses are listed below will be permitted to testify at trial).

A. On liability, plaintiffs intend to call the following witnesses who will testify in accordance with the following summaries:

Sandoz has stipulated to infringement of the asserted claims of the '411, '113, '443, and '893 Patents and therefore Plaintiffs need not prove infringement at trial. Moreover, as the patents-in-suit are presumed valid (35 U.S.C. § 282), Plaintiffs have no burden of proof regarding Sandoz's affirmative defenses and counterclaims that the asserted claims of the patents-in-suit are invalid. Sandoz alone must prove these affirmative defenses and counterclaims by clear and convincing evidence. Without assuming any burden of proof, Plaintiffs expect that they may call the following witnesses in person or by deposition in response to Sandoz's affirmative defenses and counterclaims of invalidity.

1. Julie Cossette is a manager of analytical services at Sandoz and manages the development of Sandoz's ANDA product. Plaintiffs may use the deposition testimony of Ms. Cossette regarding Sandoz's ANDA, the development of Sandoz's ANDA product, and the validity of the '411, '113, '443, and '893 Patents at trial.

2. Karine Laliberte is a pharmaceutical development specialist at Sandoz that coordinated development of Sandoz's ANDA product. Plaintiffs may use the deposition testimony of Ms. Laliberte regarding Sandoz's ANDA, the development of Sandoz's ANDA product, and the validity of the '411, '113, '443, and '893 Patents at trial.

3. Roselaine Rocheleau is a formulation chemist and process specialist at Sandoz that assisted with developing Sandoz's ANDA product. Plaintiffs may use the deposition testimony of Ms. Rocheleau regarding Sandoz's ANDA, the development of Sandoz's ANDA product, and the validity of the '411, '113, '443, and '893 Patents at trial.

4. Indranil Nandi, Ph.D. is the Director of Project Management at Sandoz Inc. Plaintiffs may use the deposition testimony of Dr. Nandi, in his capacity as a 30(b)(6) witness, as a representative of Sandoz Inc., regarding Sandoz's ANDA, the development of Sandoz's ANDA product, and the validity of the '411, '113, '443, and '893 Patents.

5. Penny A. Asbell, M.D. is a tenured Professor of Ophthalmology at the Mount Sinai School of Medicine and an Associate Adjunct at the New York Eye and Ear Infirmary. Plaintiffs plan to call Dr. Asbell to testify as to the validity of the '411, '113, '443, and '893 Patents.

6. Vincent H.L. Lee, Ph.D., D.Sc. is a Professor, Director and Graduate Division Head at the School of Pharmacy at The Chinese Universality of Hong Kong. Plaintiffs plan to call Dr. Lee to testify as to the validity of the '411, '113, '443, and '893 Patents.

7. Mark B. Abelson, M.D. is a Clinical Professor of Ophthalmology at Harvard Medical School and a medical doctor holding the position of Senior Surgeon at Lawrence General Hospital in Lawrence and Family Holy Hospital in Massachusetts. Plaintiffs plan to call Dr. Abelson to testify as to the validity of the '411, '113, '443, and '893 Patents.

Plaintiffs' Deposition Designations, Sandoz's Objections and Counter Designations to Plaintiffs' Deposition Designations, and Plaintiffs' Objections to Sandoz's Counter Designations are attached hereto as Exhibit 4.

B. Defendant objects to the following witnesses for the reasons stated:

The parties have agreed not to call live fact witnesses and will use deposition designations only.

Sandoz has set forth specific objections to various specific deposition testimony by the potential witnesses identified by Plaintiffs. See Sandoz's Objections and Counter Designations to Plaintiffs' Deposition Designations, attached hereto as Exhibit 4.

7. DEFENDANT'S WITNESSES (See instructions above).

A. On liability, defendant intends to call the following witnesses who will testify in accordance with the following summaries:

1. Imran Ahmed, Ph.D., (formerly) Pfizer, Inc. (by deposition)
   - Invalidity of U.S. Patent No. 6,239,113
   - Invalidity of U.S. Patent No. 6,569,443
   - Invalidity of U.S. Patent No. 6,861,411
   - Invalidity of U.S. Patent No. 7,056,893
   - Lack of objective evidence of non-obviousness concerning the Patents in Suit
2. Lyle Bowman, Ph.D., InSite Vision, Inc. (by deposition)
   - Invalidity of U.S. Patent No. 6,239,113
   - Invalidity of U.S. Patent No. 6,569,443
   - Invalidity of U.S. Patent No. 7,056,893
3. Samir Roy, Ph.D., (formerly) InSite Vision, Inc. (by deposition)
   - Invalidity of U.S. Patent No. 6,239,113
   - Invalidity of U.S. Patent No. 6,569,443
   - Invalidity of U.S. Patent No. 7,056,893

Defendant may elicit testimony from Samir Roy, Ph.D., in conformity with his deposition testimony in this case.

4. Peng Shen, (formerly) InSite Vision, Inc. (by deposition)

- Invalidity of U.S. Patent No. 6,239,113
- Invalidity of U.S. Patent No. 6,569,443
- Invalidity of U.S. Patent No. 7,056,893

5. Anthony Berlocco, Merck & Co., Inc. (by deposition)

- Lack of objective evidence of non-obviousness concerning the Patents in Suit

6. Allison Sherwood, Sandoz Inc. (by deposition)

- Sandoz Inc.'s ANDA No. 202308 for 1% azithromycin ophthalmic, including Sandoz Inc.'s patent certification, notice letter, and detailed statement
- Lack of objective evidence of non-obviousness concerning the Patents in Suit

7. Sandoz Inc. via 30(b)(6) deposition by Indranil Nandi, Sandoz Inc. (by deposition)

- Lack of objective evidence of non-obviousness concerning the Patents in Suit

8. Kenneth W. Reed, Ph.D., Assistant Professor of Pharmaceutics, Belmont University School of Pharmacy, Department of Pharmaceutical Sciences, Nashville, TN

- Invalidity of U.S. Patent No. 6,239,113
- Invalidity of U.S. Patent No. 6,569,443
- Invalidity of U.S. Patent No. 6,861,411
- Invalidity of U.S. Patent No. 7,056,893
- Lack of objective evidence of non-obviousness concerning the Patents in Suit

Dr. Reed's testimony will be in conformity with his deposition testimony and the opinions, and bases therefor, expressed in his expert report.

9. Matthew B. Goren, M.D., F.A.C.S., Goren Eye Associates, Assistant Professor of Clinical Ophthalmology, Northwestern University Medical School, Chicago, IL

- Invalidity of U.S. Patent No. 6,239,113
- Invalidity of U.S. Patent No. 6,569,443
- Invalidity of U.S. Patent No. 6,861,411
- Invalidity of U.S. Patent No. 7,056,893
- Lack of objective evidence of non-obviousness concerning the Patents in Suit

Dr. Goren's testimony will be in conformity with his deposition testimony and the opinions, and bases therefor, expressed in his expert report.

10. Sheila K. West, Ph.D., El Maghraby Professor of Preventive Ophthalmology, Department of Ophthalmology, Vice Chair for Research, Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore, MD

- Lack of objective evidence of non-obviousness concerning the Patents in Suit
- First Meeting of the WHO Alliance for the Global Elimination of Trachoma, June 30-July 1, 1997, Geneva, Switzerland

Dr. West's testimony will be in conformity with her deposition testimony and the opinions, and bases therefor, expressed in her expert report.

11. Defendant reserves the right to call any witness identified by Plaintiffs.

Sandoz's Deposition Designations, Plaintiffs' Objections and Counter Designations to Sandoz's Deposition Designations, and Sandoz's Objections to Plaintiffs' Counter Designations are attached hereto as Exhibit 5.

B. Plaintiffs object to the following witnesses for the reasons stated:

The parties have agreed not to call live fact witnesses and will use deposition designations only.

1. Imran Ahmed, Ph.D.

See Plaintiffs' Objections and Counter Designations to Defendant Sandoz Inc.'s Draft Deposition Designations, attached hereto as Exhibit 5.

2. Lyle Bowman, Ph.D.

See Plaintiffs' Objections and Counter Designations to Defendant Sandoz Inc.'s Draft Deposition Designations, attached hereto as Exhibit 5.

3. Samir Roy, Ph.D.

See Plaintiffs' Objections and Counter Designations to Defendant Sandoz Inc.'s Draft Deposition Designations, attached hereto as Exhibit 5.

4. Peng Shen

See Plaintiffs' Objections and Counter Designations to Defendant Sandoz Inc.'s Draft Deposition Designations, attached hereto as Exhibit 5.

5. Anthony Berloco

Plaintiffs object to Sandoz calling Anthony Berloco to testify at trial under Fed. R. Evid. 401, 402 and 403. Sandoz has not explained how Mr. Berloco's testimony would be relevant to any of its defenses. Mr. Berloco's testimony relates only to commercial success of the AzaSite® topical ophthalmic drops. Because Plaintiffs are not relying on commercial success to rebut Sandoz's obviousness defense, Mr. Berloco's testimony is irrelevant.

See also Plaintiffs' Objections and Counter Designations to Defendant Sandoz Inc.'s Draft Deposition Designations, attached hereto as Exhibit 5.

C. The Parties Propose The Following Additions To This Order Regarding Witnesses:

Each party will provide to the other's counsel of record by electronic mail a written list of the names and order of witnesses who will testify live or by deposition, and the identification by exhibit number of the trial exhibits they expect to use on direct examination of the live witness by 7:00PM EDT two calendar days before the day the witness will testify. The other party shall identify any objections to such exhibits by 9:00AM EDT the next day, and the parties shall meet and confer as soon as possible thereafter to resolve the objections. Thereafter, each party shall update its list of expected witnesses at the end of each trial day.

For witnesses who will not be called to testify at trial, each party has designated the specific pages and lines of the transcript that it intends to submit in paper, read, or play during its case-in-chief.

For the depositions that have been videotaped, a party may introduce the deposition excerpt by videotape in addition to by transcript that is submitted in paper or read into the trial transcript. If a party opts to introduce designations by videotape, any counter-designations of the same witness's testimony must also be submitted by videotape. When deposition designations are introduced, all admissible counter-designations, whether by transcript or videotape, will be introduced simultaneously in the sequence in which the testimony was originally given. Nothing in this paragraph precludes a party from playing portions of designated testimony by video and submitting other portions by paper. If selected portions are played by video, the opposing party may choose to play some or all of their counter-designations. The parties agree that any

deposition testimony to be used at trial may be used whether or not the transcripts of such deposition have been signed and filed pursuant to Fed. R. Civ. P. 30(b).

Rebuttal Witnesses:

Sandoz's Position:

Any witness not listed in this Order will be precluded from testifying absent manifest injustice shown, except that each party reserves the right to call such rebuttal witnesses as may be necessary. Because Sandoz bears the burden of proof on invalidity, Sandoz will put on its case-in-chief first. Sandoz will present experts to testify about the invalidity of the asserted patent claims. Then Plaintiffs' experts will follow to testify about why they disagree, including any alleged objective evidence of non-obviousness. Sandoz will then have the opportunity to present expert testimony to rebut Plaintiffs' experts' testimony. Allowing rebuttal witnesses is more efficient than requiring Defendant to attempt to anticipate and address in advance whatever arguments Plaintiffs might make, especially regarding objective evidence of non-obviousness. Prohibiting rebuttal witnesses would require Defendant to present a hypothetical. Defendant would be required to anticipate in its case-in-chief alleged objective evidence of non-obviousness not yet before the Court, and which Plaintiffs might decide not to present at trial.

Defendant shall identify any rebuttal witnesses that they intend to call no later than 8:00PM EDT on the day of the close of plaintiffs' case-in-chief. Plaintiffs shall identify any rebuttal witnesses that they intend to call no later than 8:00PM EDT on the day of the close of Defendant's case-in-chief. No party waives its right to oppose another party's request for rebuttal or any objection it may have to any witnesses called during rebuttal, including without limitation objections based on failure to disclose or identify the rebuttal witness during fact or expert discovery.

Plaintiffs' Position:

Any witness not listed in this Order will be precluded from testifying at trial. Sandoz bears the burden of proof on all issues in this case and that burden never shifts. The order of witnesses will follow that burden—Sandoz will put on its case-in-chief first. All of Sandoz's experts will have the opportunity to go first to explain why they think the asserted patent claims are invalid. Then Plaintiffs' experts will follow to explain why they disagree. Neither party will have an opportunity for additional rebuttal absent some showing of manifest injustice.

This approach is fair. The witnesses testifying live are all experts for whom reports have been provided and depositions taken. Under this approach, each side has an equal opportunity to put on its case. Additionally, this approach is straightforward and will save time, avoiding repeat appearances by any witness. Indeed, in similar Hatch-Waxman patent cases, this Court has ordered the same procedure with respect to the order of witnesses and prohibition on repeat appearance of witnesses for "rebuttal." *See Daiichi Sankyo Co., et al. v. Mylan Pharms, Inc., et al.*, Civ. No. 2.06-CV-03462 (WJM)(MF), Mar. 20, 2009 Order (D.I. 99) at 3.

8. EXPERT WITNESSES (No opposing counsel shall be permitted to question the expert's qualifications unless the basis of an objection is set forth herein).

A. Plaintiffs' expert witnesses are:

Sandoz has stipulated to infringement of the asserted claims from the '411, '113, '443, and '893 patents and therefore Plaintiffs need not prove infringement at trial. Moreover, as the patents-in-suit are presumed valid, Plaintiffs have no burden of proof regarding Sandoz's affirmative defenses and counterclaims that the asserted claims of the '411, '113, '443, and '893 patents are invalid. Sandoz alone must prove these affirmative defenses and counterclaims by clear and convincing evidence. Without assuming any burden of proof, Plaintiffs expect that it

may call the following expert witnesses in person in response to Sandoz's affirmative defenses and counterclaims of invalidity.

1. Dr. Mark B. Abelson

Dr. Mark B. Abelson is a Clinical Professor of Ophthalmology at Harvard Medical School in Boston, MA, where he began teaching in 1982.

He is a medical doctor specializing in ophthalmology, and holds the positions of Senior Surgeon at Lawrence General Hospital in Lawrence, MA, and Family Holy Hospital in Methuen, MA. He was Chief of Ophthalmology at both of these hospitals from 1988-1990. He has been an Assistant Surgeon at Massachusetts Eye and Ear Infirmary since 1998. Dr. Abelson is also the Senior Clinical Scientist at Schepens Eye Research Institute in Boston, MA, where he was a Clinical Scientist since 1978. He has been a Director of the Multi-Specialty Group at Andover Eye Associates since 1977 and was a Director of Ophthalmology at Spaulding Rehabilitation Hospital from 1976-1998 . After completing his residency in ophthalmology, Dr. Abelson was a Clinical Fellow in the Department of Ophthalmology at Harvard Medical School, a Clinical Fellow in the Department of Cornea Service at Massachusetts Eye and Ear Infirmiry, and a Research Fellow in the Department of Cornea Research at Schepens Eye Research Institute.

Dr. Abelson has published 106 peer-reviewed publications in medical journals and is the author of at least 380 reviews, book-chapters and editorials on topics related to dry eye disease, ocular wound flora, ocular inflammation, ocular surface diseases, ocular treatments, and numerous specific compounds. He has edited over 38 books and book chapters and is a reviewer and on the editorial board of various ophthalmology publications. During his career, Dr. Abelson has taught over 10 different medical school courses and has given presentations at over 90 seminars, courses, and invited lectures all over the world.

He has been honored with numerous awards by professional societies and institutions including an Honor Award from the American Academy of Ophthalmology, Hall of Fame at Alcon Laboratories Ophthalmology, Distinguished Alumnus Award at Harvard Medical School, and Silver Fellow at ARVO Fellows Class of 2011.

Dr. Abelson's research has focused on the identification, screening, and development of novel therapies for treating external ocular diseases, and he has worked in collaboration with other leading investigators in the field and many pharmaceutical and biotech companies in the development of numerous new ophthalmic drugs.

2. Dr. Vincent Lee

Dr. Lee has been a Professor of Pharmaceutical Sciences at the University of Southern California since 1979. His positions at the University of California include Associate Dean for Research and Graduate Affairs and Professor of Ophthalmology at the Keck School of Medicine from 1998 to 2003. Since 2006, Dr. Lee has been a professor and director of the School of Pharmacy at the Chinese University of Hong Kong and since 2011 he has served as the Graduate Division Head.

Dr. Lee holds a Ph.D. in Pharmaceutics with a minor in Physical Chemistry. He has extensive experience in ophthalmic pharmaceutical formulation design, development and drug delivery; and his research includes innovative drug delivery and epithelial drug transport, including corneal drug transport. He has served as a consultant for many pharmaceutical companies and has received more than 70 grants in support of his drug delivery research.

Dr. Lee has authored over 207 peer-reviewed publications in technical journals, authored or co-authored more than 34 books and book chapters and given over 256 invited lectures and presentations on drug delivery and drug formulation, primarily in the area of ocular drug

delivery. He was the former editor-in-chief of *Advanced Drug Delivery Reviews*, *Pharmaceutical Research*, and *Journal of Drug Targeting* and has served on the editorial board of numerous publications. Dr. Lee has also been a reviewer for over 29 peer-reviewed journals and over 13 grant-making organizations.

Dr. Lee has been honored with many awards by professional societies and institutions as a result of his scientific endeavors, including being named a Fellow by the Inaugural CRS College of Fellows, a silver Fellow by The Association for Research in Vision and Ophthalmology, a Fellow by the American Institute for Medical and Biological Engineering, an International Fellow of the Academy of Pharmaceutical Science and Technology in Japan, along with many other accolades.

Dr. Lee was a past Associate Director of the Office of Pharmaceutical Science in the Center for Drug Evaluation and Research for the Food and Drug Administration.

3. Dr. Penny A. Asbell

Dr. Asbell is a tenured Professor of Ophthalmology at the Mount Sinai School of Medicine and an Associate Adjunct at the New York Eye and Ear Infirmary. She has been a Professor at Mount Sinai School of Medicine since 1995 and was the Acting Chair of the Department of Ophthalmology from 2005 to 2007. Dr. Asbell is a medical doctor with over 35 years of experience in the field of ophthalmology and holds an MBA from the Zicklin School of Business.

Dr. Asbell is an author of over 196 peer-reviewed publications in medical journals on topics relating to refractive surgery, ocular surface disease, immunology, dry eye disease, and antibiotic resistance in ocular infections. Dr. Asbell has also authored or co-authored over 38 books and book chapters. She has been the director or instructor of over 260 courses and

symposia and has given well over 500 invited academic lectures. Dr. Asbell is Editor-in-Chief of the Mount Sinai Journal of Medicine: a Journal of Translational and Personalized Medicine and has served on editorial boards for numerous publications as well as serving as a reviewer for over 23 peer-reviewed publications.

Dr. Asbell is currently a member of the Board of Directors of the Cornea Society, member of the Board of Governors of the Tear Film and Ocular Surface Society and on the Fight for Sight Review Board. She is the Director of Cornea Service and Cornea Fellowship Program at Mount Sinai School of Medicine and Vice-Chair of the Appointment and Promotion Committee of Mount Sinai School of Medicine. Dr. Asbell has been honored with numerous awards by professional societies and institutions including the American Academy of Ophthalmology Life Achievement Honor Award, Fellow of the Association for Research in Vision and Ophthalmology, Honor Recipient from the American Academy of Ophthalmology, Women in Ophthalmology Suzanne Veronneau-Troutman Award, and the Research to Prevent Blindness RPB Physician-Scientist Award.

B. Defendant's objections to the qualifications of plaintiff's expert are:

Defendant does not object to the qualifications of Plaintiffs' experts Dr. Lee, Dr. Abelson, and Dr. Asbell.

C. Defendant's expert witnesses are:

1. Kenneth W. Reed, Ph.D., Assistant Professor of Pharmaceutics, Belmont University School of Pharmacy, Department of Pharmaceutical Sciences, Nashville, TN. Dr. Reed received a Bachelor of Science degree in Chemistry from Nebraska Wesleyan University, a Master of Science degree in Biomedicinal Chemistry from the University of Nebraska Medical Center, and a Ph.D. in Pharmaceutical Sciences from the University of Nebraska Medical Center. Dr. Reed

is an Assistant Professor in Pharmaceutics at Belmont University School of Pharmacy and has held this position since 2010. His current research interests include ocular drug delivery, drug binding to contact lenses, and the use of microspheres to achieve sustained release. From 2006-2009, Dr. Reed worked at Hospira, Inc., in the Generics Technical Development Group as an Associate Director of Research & Development. At Hospira, he was involved with the development of new manufacturing processes for dosage forms that were new to Hospira and the development of injectable dosage forms. Dr. Reed's responsibilities included, among other things, analytical methods development and validation, definition of finished product, qualification of excipients, and generation of stability data.

From 1992 to 2005, Dr. Reed worked in various capacities at Ciba Vision Ophthalmics / Novartis Ophthalmics. At Ciba, Dr. Reed led teams responsible for formulation development, analytical chemistry, stability analysis, and the development of manufacturing processes. He was also involved in the development of marketed ophthalmic products including Voltaren Opthalmic®, Zaditor®, Rescula®, and Vexol®. In addition to Dr. Reed's work in academia and industry, he has consulted for the pharmaceutical industry on the development of various ophthalmic dosage forms. Dr. Reed's CV is found at DTX176, previously produced to Plaintiffs.

2. Matthew B. Goren, M.D., F.A.C.S., Goren Eye Associates, Assistant Professor of Clinical Ophthalmology, Northwestern University Medical School, Chicago, IL. Dr. Goren was selected as a member of Northwestern University's Honors Program in Medical Education in 1982, gaining simultaneous admissions to the College of Arts and Sciences as well as the Medical School. Dr. Goren was awarded a Bachelors of Science in Medical Sciences in 1987 and was awarded an MD in 1989. Dr. Goren, as President of his medical school class at Northwestern, founded the medical school's program in medical ethics – one of the first of its

kind in the world. Dr. Goren was appointed Instructor of Clinical Ophthalmology at Northwestern in 1994 upon joining the faculty after completing his training and he was given a professorial rank in 1997. Dr. Goren has served as adjunct faculty for Northwestern's Medical Ethics and Human Values Program, the program that he helped found in 1985.

Dr. Goren maintained the position of Chief of Ophthalmology at the Veterans Administration Chicago Healthcare System for 7 years. In that role, he was primarily responsible for the teaching and training of the ophthalmology residents at Northwestern as well as the medical students rotating through the service. This is the busiest clinical service in the training program at Northwestern and cared for the entire gamut of the most serious eye conditions encountered in clinical practice – both medical and surgical. Dr. Goren was certified by the American Board of Ophthalmology in 1995 and then again in 2005.

Dr. Goren completed his residency in ophthalmology at the New England Eye Center of Tufts University in 1993. While at Tufts, he was awarded the Charles Preefer Award for research excellence. He also earned a Fisons grant for his research in ocular immunology by the Contact Lens Association of Ophthalmologists. Dr. Goren also served as a Fellow in the Department of Cornea and External Diseases at the Wills Eye Hospital in Philadelphia – at the time the oldest and most established dedicated eye hospital in the world.

Dr. Goren has taught dozens of classes at the Feinberg School of Medicine at Northwestern University and has also taught at the Weinberg College of Arts and Sciences at Northwestern University. Dr. Goren has been recognized often for his research accomplishments, teaching successes, and professional achievements. These awards include recognition from the American Academy of Ophthalmology for his contributions to ophthalmic education. Dr. Goren has been chosen by the ophthalmology residents at Northwestern

University as the outstanding teacher of the department on four separate occasions—more than any other faculty member in the history of the department. Dr. Goren has given over one hundred lectures on a variety of topics (although concentrating on cornea and external disease) at Northwestern, locally, and at internationally attended meetings.

Dr. Goren is the author of sixty-five articles appearing in peer-reviewed journals. Most of his research has focused on topics of cornea and external diseases ranging from infectious diseases and immunology to corneal transplantation to dry eye disease. Dr. Goren was a founding editor of Comprehensive Ophthalmology Update and edited a section devoted to reviewing Internet content of interest to the ophthalmologic community. He has also served as a scientific referee for some of the world's most prestigious journals including the AMA Archives of Ophthalmology, Ophthalmology, Cornea, The British Journal of Ophthalmology, the European Journal of Ophthalmology, and the American Ophthalmological Theses. Dr. Goren is also a member of many ophthalmologic associations including the American Academy of Ophthalmology, the Cornea Society (formerly the Castroviejo Cornea Society), and the Wills Eye Hospital Society. He is a Fellow of the American College of Surgeons and has been an associate of Research to Prevent Blindness, the Chicago Ophthalmological Society, and the Association for Research in Vision and Ophthalmology.

Dr. Goren also is a practicing physician. He maintains one of the strongest traditional cornea and external disease practices in the Chicago area. Dr. Goren performed the first permanent keratoprosthesis surgery in Chicago and was the first surgeon at Northwestern and among the first in Chicago to perform endothelial keratoplasty surgery. The majority of new patients seen by Dr. Goren on a daily basis are referred to him by fellow ophthalmologists for cornea and external disease problems. Infectious disease is one of the most common reasons for

referrals of patients to his practice. Dr. Goren's CV is found at DTX251, previously produced to Plaintiffs.

3. Sheila K. West, Ph.D., El Maghraby Professor of Preventive Ophthalmology, Department of Ophthalmology, Vice Chair for Research, Wilmer Eye Institute, Johns Hopkins University School of Medicine, Baltimore, MD. Dr. West received the Pharm.D. degree at the University of California San Francisco school of Pharmacy in 1971, where she received the Bowl of Hygeia in recognition of my academic and professional achievements. Dr. West has been licensed to practice in California, Nevada and Maryland. Dr. West was recruited to Johns Hopkins Health Services Research and Development Center in 1971, to work with a team investigating novel ways of using allied health professionals. At the same time, Dr. West taught Pharmacology in the Johns Hopkins School of Health Services. In 1980 Dr. West completed her Ph.D. in the Department of Epidemiology of the Johns Hopkins School of Public Health and Hygiene, and formally graduated in 1981. In 1984 Dr. West joined the Wilmer Eye Institute as an Instructor, became an Assistant Professor one year later, then Associate professor and in 1998 a full professor, accepting a chair from the department in 1999.

Dr. West received the Chibret Gold Medal for research in Trachoma, awarded to outstanding researchers and program leaders in the field of trachoma. She have served as the vice chair and chair of the World Health Organization Alliance for the Global Elimination of Trachoma by 2020, and chaired several of the World Health Organization Global Scientific Meetings, which provide guidelines for trachoma control. Dr. West is or has been a member of several professional societies, including the American Pharmacists Association and American Society of Hospital Pharmacists, Society for Epidemiologic Research, and was elected to the American Epidemiological Society on the basis of her work in Trachoma. Dr. West has also

been a member of The American Society of Tropical Medicine and Hygiene; The Association of University Professors of Ophthalmology; Association of Research in Vision and Ophthalmology, where she served in numerous capacities including on the Board of Trustees and was elected President (the first female president)and she is a Gold Fellow of ARVO, so honored for years of service. Dr. West serves on the Research to Prevent Blindness Scientific Advisory Panel, the Alcon Research Institute Scientific Selection Committee, the Technical Expert Committee of the International Trachoma Initiative, the National Advisory Eye Council for The National Eye Institute, and chairs and has chaired numerous Data and Safety Monitoring Committees and NIH Review committees.

Dr. West has authored or co-authored 286 publications, many in the leading medical and ophthalmology journals, written several chapters and was an Editor for the textbook on Epidemiology of Eye Disease (where she also co-wrote the chapter on Trachoma). Dr. West has served on the Editorial Boards of Investigative Ophthalmology and Visual Science and Ophthalmic Epidemiology, where she also became the Editor in Chief for five years. Dr. West reviews for numerous journals including Journal of the American Medical Association, New England Journal of Medicine, Ophthalmology, American Journal of Ophthalmology, Investigative Ophthalmology and Visual Science, PloS Medicine and NTD, and many others. She has also given invited presentations and lectures world-wide and currently teaches a course on Epidemiology of Eye Disease. Dr. West has also mentored numerous medical students and graduate students. Dr. West's CV is found at DTX227, previously produced to Plaintiffs.

D. Plaintiffs' objections to the qualifications of defendant's experts are:

Plaintiffs do not object to the qualifications of Sandoz's experts Dr. Reed, Dr. Goren, and Dr. West.

9. **PLAINTIFFS' EXHIBITS (Except for exhibits the need for which could not reasonably have been foreseen or which are used solely for impeachment purposes, only the exhibits set forth on the exhibit list attached hereto may be introduced at trial. Any objection to an exhibit, and the reason for said objection, must be set forth below or it shall be deemed waived. All parties hereby agree that it will not be necessary to bring in the custodian of any exhibit as to which no such objection is made).**

The parties jointly intend to introduce into evidence the exhibits listed on the attached Joint Exhibit List. *See* Exhibit 6.

A. **Plaintiffs intend to introduce into evidence the exhibits listed on the attached exhibit list (list by number with a description of each):**

See Exhibit 7.

B. **Defendant objects to the introduction of plaintiffs' exhibits (set forth number of an exhibit and grounds for objection):**

See Exhibit 7.

10. **DEFENDANT'S EXHIBITS (See instructions above).**

A. **Defendant intends to introduce into evidence the exhibits listed on the attached exhibit list (list by number with a description of each):**

See Exhibit 8.

B. **Plaintiffs object to the introduction of defendant's exhibits (set forth number of exhibit and grounds for objection):**

See Exhibit 8.

C. **The Parties Propose The Following Additions to This Order Regarding Exhibits:**

Plaintiffs and Defendant, respectively, reserve the right to offer exhibits set forth in the opposing party's exhibit list, even if not set forth in its own exhibit list. All objections to such exhibits are preserved, regardless of whether such exhibits also appear on the objecting party's exhibit list.

Objections:

Sandoz's Position:

The lodging of specific objections to an exhibit within this Order does not preclude a party from subsequently making further objections to that exhibit.

Plaintiffs' Position:

Plaintiffs' position is the same as paragraph 9 (above) of Judge Cooper's Form of Final Pretrial Order.

Demonstratives and Physical Exhibits to Be Used With Witnesses:

Each party shall serve on opposing counsel by electronic mail and/or electronic media (for large exhibits and any videos or animations to be offered), full color copies of the demonstrative exhibits or make available for inspection physical exhibits each intends to use during direct examination of a witness by 7:00PM EDT two days before such direct examination is expected to take place. The receiving party shall inform the opposing party of any objections to such demonstrative exhibits or physical exhibits by 9:00AM the next day, and the parties shall meet and confer as soon as possible thereafter to resolve the objections. The notice provisions of this paragraph shall not apply to demonstrative exhibits created in the courtroom during testimony at trial or the enlargement, highlighting, ballooning, etc. of trial exhibits or of testimony.

If good faith efforts fail to resolve objections to the demonstrative or physical exhibits (including videos or animations), the objecting party shall raise its objections with the Court prior to their anticipated use.

The demonstrative exhibits the parties intend to use at trial do not need to be specifically described on their respective lists of trial exhibits.

For each demonstrative exhibit that is based on a document or documents produced or exchanged in discovery in this litigation, each party will disclose to the other parties, either: (a) on the face of the exhibit; or (b) in a table or other writing provided at the time the exhibit is exchanged with the other parties, all documents data or information that form the basis of the exhibit, to the extent that there are such documents, data or information. Such information shall include the respective Bates numbers for the source documents where such source documents were produced with Bates numbers.

Complete legible copies of documents may be offered and received in evidence to the same extent as an original unless a genuine question is raised as to the authenticity of the original, or under the circumstances it would be unfair to admit the copy in lieu of the original.

The parties will serve by overnight mail to the opposing party electronic copies of their respective pre-marked non-demonstrative exhibits in pdf format on or before 5 days before the final pre-trial conference, with supplemental exhibits to be provided in the same format on the day they are identified.

The parties agree that exhibits to be used or offered into evidence solely for cross examination and/or impeachment need not be included on the lists of trial exhibits or disclosed in advance of being used or offered at trial. Such exhibits used for cross-examination and/or impeachment may be admitted into evidence subject to the Federal Rules of Evidence or other applicable principles of law.

11. PLAINTIFFS' LEGAL ISSUES

Defendants have stipulated to infringement of asserted claims 3 and 5 of the '411 Patent, claims 6 – 9 of the '113 Patent, claims 16 and 44 of the '443 Patent, and claims 4, 6, 7, 9 – 12, 30, 36, and 40 of the '893 Patent and therefore Plaintiffs need not prove infringement at trial. In

addition, the parties have stipulated to dismiss all claims, defenses, and counterclaims related to the '458 Patent. Moreover, as the patents-in-suit are presumed valid, Plaintiffs have no burden of proof regarding Defendants' affirmative defenses and counterclaims that the asserted claims of the patents-in-suit are invalid. Defendants alone must prove these affirmative defenses and counterclaims by clear and convincing evidence.

VALIDITY

1. Whether Defendants can prove by clear and convincing evidence that claims 3 and 5 of the '411 Patent, claims 6-9 of the '113 Patent, claims 16 and 44 of the '443 Patent, or claims 4, 6, 7, 9 – 12, 30, 36, and 40 of the '893 Patents are invalid under 35 U.S.C. § 103. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1996).

2. Whether Defendants can prove by clear and convincing evidence that claims 3 and 5 of the '411 Patent are invalid under 35 U.S.C. § 112 for failure to comply with the requirement of enablement of the invention.

3. Whether Defendants can prove by clear and convincing evidence that claim 3 of the '411 Patent and claim 44 of the '443 Patent are invalid under 35 U.S.C. § 112 for indefiniteness.

REMEDIES

5. Whether Plaintiffs are entitled to an order that the effective date of any approval of Defendants' ANDA be a date which is not earlier than the expiration dates of the '411, '113, '443, and '893 Patents or any other exclusivity to which Plaintiffs are or become entitled. 35 U.S.C. § 271(e)(4)(A). *See also Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 2007 WL 869545 (D.N.J. 2007), *aff'd* 520 F.3d 1358 (Fed. Cir. 2008).

6. Whether Plaintiffs are entitled to a permanent injunction against Defendants and their officers, agents, attorneys, and employees and those acting in privity or concert with them, enjoining them from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendants' generic topical ophthalmic 1% azithromycin product described in Defendants' ANDA until after the expiration of the '411, '113, '443, and '893 Patents, or any other exclusivity to which Plaintiffs are or become entitled. 35 U.S.C. § 271(e)(4)(B). *See also eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 390 (2006).

7. Whether Plaintiffs are entitled to monetary damages and prejudgment interest if Sandoz Inc., Sandoz GmbH, or Sandoz Industrial Products S.A. commercially makes, uses, sells, or offers to sell the Sandoz ANDA product within the United States, or imports the Sandoz ANDA product into the United States, prior to the expiration of any one of the '411, '113, '443, and '893 Patents, including any extensions.

8. Whether this case is exceptional pursuant to 35 U.S.C. § 285. *See Takeda Chemical Industries, Ltd. v. Mylan Labs., Inc.*, 549 F.3d 1381 (Fed. Cir. 2008).

9. Whether Plaintiffs are entitled to an award of attorney's fees, costs, and expenses. *See id.*

12. DEFENDANT'S LEGAL ISSUES

The '411 Patent

1. Whether claims 3 and 5 of the '411 patent are invalid as obvious under 35 U.S.C. § 103.

a. Whether there is any objective evidence of non-obviousness probative of the obviousness of claims 3 and 5 of the '411 patent.

b. Whether objective evidence of non-obviousness, if any, lacks the required nexus with claims 3 and 5 of the '411 patent, such that the objective evidence is not probative of the obviousness of claims 3 and 5.

2. Whether claims 3 and 5 of the '411 patent are not enabled, and thus are invalid under 35 U.S.C. § 112, first paragraph.

3. Whether claim 3 of the '411 patent is indefinite, and thus invalid under 35 U.S.C. § 112, second paragraph.

The '113 Patent

4. Whether claims 6-9 of the '113 patent are invalid as obvious under 35 U.S.C. § 103.

a. Whether there is any objective evidence of non-obviousness probative of the obviousness of claims 6-9 of the '113 patent.

b. Whether objective evidence of non-obviousness, if any, lacks the required nexus with claims 6-9 of the '113 patent, such that the objective evidence is not probative of the obviousness of claims 6-9.

The '443 Patent

5. Whether claims 16 and 44 of the '443 patent are invalid as obvious under 35 U.S.C. § 103.

a. Whether there is any objective evidence of non-obviousness probative of the obviousness of claims 16 and 44 of the '443 patent.

b. Whether objective evidence of non-obviousness, if any, lacks the required nexus with claims 16 and 44 of the '443 patent, such that

the objective evidence is not probative of the obviousness of claims 16 and 44.

6. Whether claim 44 of the '443 patent is indefinite, and thus invalid under 35 U.S.C. § 112, second paragraph.

The '893 Patent

7. Whether claims 4, 6, 7, 9-12, 30, 36, and 40 of the '893 patent are invalid as obvious under 35 U.S.C. § 103.

a. Whether there is any objective evidence of non-obviousness probative of the obviousness of claims 4, 6, 7, 9-12, 30, 36, and 40 of the '893 patent.

b. Whether objective evidence of non-obviousness, if any, lacks the required nexus with claims 4, 6, 7, 9-12, 30, 36, and 40 of the '893 patent, such that the objective evidence is not probative of the obviousness of claims 4, 6, 7, 9-12, 30, 36, and 40.

Attorney Fees and Costs:

Remedies

8. Whether this case is exceptional pursuant to 35 U.S.C. § 285. *See Takeda Chemical Industries, Ltd. v. Mylan Labs., Inc.*, 549 F.3d 1381 (Fed. Cir. 2008).

9. Whether Defendant is entitled to an award of attorney's fees, costs, and expenses. *See id.*

13. CHOICE OF LAW:

(If there is any issue as to what state's law is applicable to any count of the complaint, set forth the choice of law question. This issue shall be separately briefed in accordance with an order to be entered herewith).

The Parties respectfully submit that there are no choice of law questions.

14. **MISCELLANEOUS (Set forth any other matters which require action by, or should be brought to the attention of the Court).**

15. **JURY TRIALS - Not applicable.**

16. **NON-JURY TRIALS - Not later than April 23, 2013.**

A. **Each side shall submit to the Judge and opposing counsel a trial brief or memorandum in accordance with Local Civil Rule 7.2B with citation to authorities and arguments in support of its position on all disputed issues of law. In the event a brief shall not be filed, the delinquent party's complaint or defense may be stricken.**

B. **The Parties agree that the following section will not apply: Each side shall submit to the Judge and other counsel proposed written findings of fact and conclusions of law. There is reserved to counsel the right to submit additional proposed findings of fact and conclusions of law during the course of the trial on those matters that cannot reasonably be anticipated.**

17. **TRIAL COUNSEL (List the names of trial counsel for all parties).**

The following attorneys will try the case for InSite Vision Incorporated: Sheila F. McShane of Gibbons P.C., and Rodger L. Tate, Robert M. Schulman, and Jeff B. Vockrodt of Hunton & Williams LLP.

The following attorneys will try the case for Inspire Pharmaceuticals, Inc. and Pfizer Inc.: Sheila F. McShane of Gibbons P.C., and Dominick A. Conde, Lisa B. Pensabene, and Vishal C. Gupta of Fitzpatrick, Cella, Harper & Scinto.

The following attorneys will try the case for Sandoz: Eric I. Abraham and Christina Saveriano of Hill Wallack LLP, and James W. Huston, M. Andrew Woodmansee, and Matthew M. D'Amore of Morrison & Foerster LLP.

18. **BIFURCATION (Where appropriate, the issues relating to liability shall be severed and tried to verdict. Thereafter, all issues relating to damages will be tried).**

Not applicable

19. **ESTIMATED LENGTH OF TRIAL**

Sandoz's Position:

____6____ DAYS FOR LIABILITY

and

____0____ DAYS FOR DAMAGES.

Plaintiffs' Position:

While the Parties previously discussed a 5 day trial length estimate with the Court, should the Court have sufficient time in its schedule, Plaintiffs have no objection to a 6 day trial length (with time to be allocated evenly between the Parties).

AMENDMENTS TO THIS PRETRIAL ORDER WILL NOT BE PERMITTED UNLESS THE COURT DETERMINES THAT MANIFEST INJUSTICE WOULD RESULT IF THE AMENDMENT IS DISALLOWED.

s/ Sheila F. McShane
(ATTORNEY FOR PLAINTIFF)

s/ Eric I. Abraham
(ATTORNEY FOR DEFENDANT)

UNITED STATES MAGISTRATE JUDGE

DATED: May 23, 2013

(EXHIBIT LIST TO FOLLOW)