IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., and ALLERGAN SALES, LLC.,	)
Plaintiffs,	)
v.	)
ALCON INC., ALCON LABORATORIES, INC., and ALCON RESEARCH, LTD.,	)
Defendants.	)

Civil Action No: 04-968-GMS

DEFENDANTS ALCON INC., ALCON LABORATORIES, INC., AND ALCON RESEARCH, LTD.'S MOTIONS *IN LIMINE*

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I. MOTION *IN LIMINE* TO PRECLUDE PLAINTIFFS FROM PRESENTING EVIDENCE OF ALLEGED SUPERIORITY OR COPYING, NEITHER OF WHICH IS RELEVANT TO NON-OBVIOUSNESS IN THIS CASE

Alcon, Inc., Alcon Laboratories, Inc., and Alcon Research, Ltd. ("Alcon") respectfully submit this motion *in limine* to preclude Allergan, Inc. and Allergan Sales, LLC ("Allergan") from presenting evidence at trial in support of:

- Allergan's assertion that its 0.15% brimonidine tartrate product (Alphagan®P) is superior to its 0.2% brimonidine tartrate product (Alphagan®); or
- Allergan's assertion that Alcon "copied" Allergan's formula for Alphagan P when it formulated its own proposed 0.15% brimonidine tartrate product.

Neither of these two assertions has any bearing on the secondary considerations of non-obviousness, or is otherwise relevant to any issue in this case.

FACTS

On September 6, 1996, the Food and Drug Administration ("FDA") approved Allergan's 0.2% brimonidine tartrate product ("Alphagan") for reducing intraocular pressure in patients with open-angle glaucoma or ocular hypertension, and granted Allergan five years of market exclusivity on that product. Allergan began to sell Alphagan shortly thereafter.

REDACTED

REDACTED

Accordingly, on June 29, 2000, Allergan submitted a new drug application ("NDA") for a 0.15% brimonidine tartrate ophthalmic solution, which was to be its reformulation of Alphagan. The FDA approved Allergan's 0.15% brimonidine tartrate product on March 16, 2001, and granted it three years and six months of market exclusivity. Thus, Allergan was able to begin marketing its new 0.15% product – Alphagan P – before the market exclusivity on its 0.2% product, Alphagan, expired. Once Alphagan P was approved, Allergan

simply "waited until it was able to supply adequate amounts of Alphagan P 0.15% to cover Alphagan 0.2%'s prescriptions," and then, in or about August 2002, Allergan simply stopped selling Alphagan. (Ex.1, Letter from FDA to Terry G. Mahn, Esq., dated May 21, 2003, at 10).

Having stopped selling its 0.2% product (Alphagan), Allergan took the next step in its planned product conversion on October 25, 2002. Specifically, Allergan submitted a citizen petition to the FDA requesting that the FDA "refuse to approve or suspend approval of any abbreviated new drug applications (ANDAs) that refer to Alphagan 0.2% (brimonidine tartrate ophthalmic solution) as the reference listed drug." (Id. at 1.) Allergan argued that it had withdrawn Alphagan from the market for reasons of safety and efficacy. The FDA rejected Allergan's petition, and specifically addressed – and rejected – Allergan's argument that the commercial success of Alphagan P 0.15% as a replacement for Alphagan 0.2% was evidence of the comparative effectiveness of the two products. The FDA also rejected Allergan's assertion that the 0.15% formulation exhibited a superior safety profile to that of the 0.2% product.

In April 2004, Alcon submitted an Abbreviated New Drug Application (ANDA) for its own proposed 0.15% brimonidine tartrate ophthalmic solution. Alcon's submission was a so called "paper NDA," because its proposed drug was a modified version of Allergan's brand name drug, rather than a generic copy. REDACTED

REDACTED

[1] Allergan asserts in this lawsuit that these two viscosity enhancers also act to increase the solubility of brimonidine.

Allergan commenced this suit against Alcon in August 2004 under the Hatch-Waxman Act, alleging infringement of U.S. Patent Nos. 6.673,337 ("the '337 patent") and 6,641,834 ("the '834 patent"). The FDA tentatively approved the NDA for Alcon's proposed 0.15% brimonidine product on March 1, 2005, but final approval of the product depends on the outcome of this litigation.

ARGUMENT

Obviousness under 35 U.S.C. § 103(a) is a legal question based on underlying factual inquiries. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). In addition to such inquiries as the scope and content of the prior art, the level of ordinary skill in the art, and the differences between the claimed invention and the prior art, a court should consider certain "secondary considerations," or objective indicia, of non-obviousness. Id. These secondary considerations may include evidence of commercial success and evidence of copying. Id. The mere presence of a particular secondary consideration does not mean that it is relevant to non-obviousness, however, because the secondary consideration must serve as an objective indicia of the non-obviousness of the claimed invention in order to be relevant. For example, relevancy requires that a nexus exist between the claimed invention and the secondary consideration. In re Huang, 100 F.3d 135, 140 (Fed. Cir. 1996).

A. Allergan Should Be Precluded From Presenting Evidence As To Whether AlphaganP Is Superior To Alphagan Because There Is No Nexus Between Any Commercial Success And The Claimed Invention

Commercial success may be relevant to non-obviousness "only if there is proof that the sales were a direct result of unique characteristics of the claimed invention -- as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter." Id. Thus, when a party has the right to exclude others from selling a drug, either

because of patent protection or marketing exclusivity granted by the FDA, commercial success of the product is not evidence of non-obviousness. See Merck & Co., Inc. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1376 (Fed. Cir. 2005) (In a case brought under the Hatch-Waxman Act, the Federal Circuit found that because market entry was precluded by others due to patent protection and FDA marketing exclusivity, the rationale of commercial success as a secondary consideration of non-obviousness "has no force.").

Similarly, where, as here, one product is substituted for another product in the market, the commercial success of the substituted product is not evidence of non-obviousness. As the FDA stated in responding to Allergan's petition to withdraw Alphagan 0.2% as a reference listed drug:

> The fact that physicians have begun prescribing Alphagan P 0.15% now that Alphagan 0.2% has been withdrawn from the market does not support a conclusion that Alphagan P 0.15% is more effective than its predecessor. It probably reflects only a lack of alternatives. You acknowledge that when physicians did have a choice, Alphagan 0.2% was overwhelmingly preferred to Alphagan P 0.15%. . . . [W]hen Allergan withdrew Alphagan 0.2%, its sales were four times higher than those for Alphagan P 0.15%.

(Ex. 1 at 10.)

In this case, the "other economic and commercial factors unrelated to the quality of the patented subject matter" determined any commercial success of Alphagan P, not the actual patented matter. See In re Huang, 100 F.3d at 140; see also Syntex (U.S.A.) LLC and Allergan, Inc. v. Apotex, Inc., 407 F.3d 1371, 1383 (Fed. Cir. 2005) (remanding a Hatch-Waxman case for the trial court to "carefully consider whether the nexus requirement of our law is satisfied."). Evidence of any commercial success is not relevant to non-obviousness or any other issue in the case, and should be precluded.

B. Copying Cannot Be A Secondary Consideration of Non-obviousness In A Hatch-Waxman Case

The first goal of the Hatch-Waxman Act is to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." 1984 U.S.C.C.A.N. 2647, 2647. This goal was achieved by allowing generic drug manufacturers to bypass many of the testing requirements imposed on the branded drug manufacturer in support of its NDA and to allow the generic manufacturer to rely on the safety and efficacy studies provided by the NDA. 21 U.S.C. § 355(j). Congress also provided periods of market exclusivity for newly approved un-patentable drugs or improvements on those drugs in order to encourage manufacturers to make the investment necessary to prove the safety and efficacy of useful drugs for which patent protection was unavailable. Id. § 355(c)(3)(E).[2]

Because the Hatch-Waxman Act is designed to encourage the production of generic drug products that are equivalent to patented drug products, any "copying" of the patented drug product is encouraged by congressional policy and irrelevant to non-obviousness[3].

CONCLUSION

For the foregoing reasons, this Court should preclude Allergan from offering testimony on the alleged superiority of Alphagan P over Alphagan or on Alcon's alleged "copying" of Allergan's product.

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[2] Allergan's market exclusivity for Alphagan P under the Hatch Waxman Act expired on September 16, 2004. By filing this suit, Allergan has extended its market exclusivity sixteen months beyond its entitlement under the Act.

REDACTED

II. MOTION *IN LIMINE* TO PRECLUDE DR. WILSON FROM OFFERING OPINION TESTIMONY REGARDING THE STATISTICAL ANALYSIS OF HIS STUDENT'S SOLUBILITY MEASUREMENTS

This motion *in limine* seeks to preclude Allergan's expert witness, Dr. Clive Wilson, from offering opinion testimony about the validity, reliability, or appropriateness of the statistical analysis of certain solubility measurements made by his student, Hardik Shah. By his own admission, Dr. Wilson has no expertise in statistics, biostatistics, or the statistical analysis of experimental data, and therefore is not qualified to offer opinions about the proper way to analyze Mr. Shah's experimental data. Such testimony should also be precluded for the second, independent reason that despite requests made at the deposition of Dr. Wilson, Allergan has declined to produce documents germane to Dr. Wilson's opinions on this topic.

FACTS

In order to meet its burden of proving that Alcon's proposed brimonidine product infringes the asserted claims of Allergan's '337 patent, Allergan must show, among other things, that the type of povidone used in Alcon's product "increases the solubility" of the brimonidine tartrate in Alcon's product as compared to the solubility of the brimonidine tartrate in a "similar composition" without the povidone. Allergan retained Dr. Clive Wilson, a professor in Scotland with ongoing consultancy contracts with Allergan, and a long-time colleague of one of the named inventors, Dr. Olejnik, to offer opinions on this subject. (Ex. 2, Wilson Dep. 59:15-22, 65:24 – 68:4, Nov. 29, 2005.)

Dr. Wilson in turn asked his student, Hardik Shah, to conduct experiments for him.

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Mr. Shah then analyzed his experimental results using a statistical method called "two-way analysis of variance" or "two-way ANOVA." (Ex. 2, Wilson Dep. 194:10-19.) This statistical method is dramatically different from the "regression" method that Allergan's scientists used when they analyzed their solubility studies on the compound "CMC," which they reported in the '337 patent. ('337 patent, col. 15, ll. 38-43.)

REDACTED

REDACTED

Dr. Wilson selected some of Mr. Shah's measurements, and some of the "two-way ANOVA" analysis, to draw different conclusions.[4]

Alcon's expert witness, Dr. Gordon Amidon, has taught statistical methods for approximately ten years, and has written numerous articles and textbook chapters on solubility.

(Id. at 16; Ex. 5, Curriculum Vitae of Gordon L. Amidon.) REDACTED

REDACTED

Dr. Wilson testified during his deposition that after reviewing Dr. Amidon's critique, he did further investigation about statistical methodology, and further analysis. (Ex. 2, Wilson Dep. 197:10 – 201:23). Documents relating to that investigation and analysis were requested but not produced.

ARGUMENT

As will be shown at trial, there are a number of deficiencies in the experiments that Mr. Shah conducted. In addition, the parties do not agree as to the appropriate statistical method for analyzing Mr. Shah's experimental results, including the decision to ignore many of the measurements, and the decision to use "two-way ANOVA." Dr. Wilson should not be permitted to offer opinions about the statistical analysis of Mr. Shah's experimental results.

Fed. R. Evid. 702 provides, in pertinent part, that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise." Fed. R. Evid. 702. The proponent of an

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[4] Allergan's other expert witness, Dr. Stella, relies on Dr. Wilson's findings of "increased" solubility.

expert witness must establish the witness's qualification as an expert by a preponderance of evidence. Daubert v. Merrell Dow Pharms., 509 U.S. 579, 592 n.10 (1993).

Here, by his own admission, Dr. Wilson does not have expertise in statistics or the application of statistics to Mr. Shah's experimental measurements:

> Q. Are you an expert in statistics?
> A. No, certainly not.
> Q. Biostatistics?
> A. No.
> Q. Statistical analysis of experiments?
> A. I have a working knowledge, but I wouldn't claim to be an expert.

(Ex. 2, Wilson Dep. 48:19-25.) Indeed, Dr. Wilson thoroughly disavowed any expertise whatsoever in statistics, testifying that he had never taught or published in the area of statistics, biostatistics, or the statistical analysis of experiments (id. at 48:19-50:6), that when he needs to analyze experimental results he is typically assisted by a statistician (id. at 49:16-17), and that the closest he had come to teaching statistics was to tell his students "who to talk to and the resources available in the university." (Id. at 50:8-9).

Without this necessary expertise[5], Dr. Wilson is not qualified to opine on the appropriate way to analyze Mr. Shah's experimental results, or the applicability of methods such as two-way ANOVA in comparison to other statistical methods, such as regression, which Allergan's own scientists had used to analyze their "solubility-enhancing component," CMC.

Additionally, Dr. Wilson should be precluded from offering an opinion regarding the statistical analysis of Mr. Shah's results because Allergan declined to produce the materials that were requested during the deposition of Dr. Wilson that related to his analysis of Mr. Shah's

[5] Notably, Dr. Wilson also denies expertise in the very subject of Mr. Shah's experiments and his own opinions, namely, solubility: "Q. Do you consider yourself an expert in solubility studies? A. No." (Wilson Dep. 50:23-25.)

experiments, and the opinions he formed on that subject. Fed. R. Civ. P. 26(a)(2)(B) requires, with respect to expert witness opinions, disclosure of "the data or other information considered by the witness in forming the opinions." Rule 37, in turn, provides that a party that without substantial justification fails to disclose information required to be disclosed under Rule 26(a) may not use that information at trial, unless the failure to disclose is harmless. See Fed. R. Civ. P. 37(c)(1). Without justification, Allergan has failed to disclose the following documents that Dr. Wilson considered:

- The articles that Dr. Wilson had gathered for his analysis, which "described the different approaches used pharmaceutically with regard to solubility of materials." (Wilson Dep. 11-12)
- The data plot prepared by Dr. Wilson of some of Mr. Shah's results (Id. at 198; also at 88-89).
- The manual and book that Dr. Wilson consulted and relied on to guide him on his use and understanding of the "two-way ANOVA" statistical method (Id. at 201-02)

The failure to produce these materials is certainly not harmless, and, indeed, is particularly significant, given Dr. Wilson's own acknowledged lack of expertise in solubility studies and statistical analysis – making the materials that he reviewed and considered even more germane to the bases of his opinions. Having failed to produce these materials, which were requested at deposition and which come within the scope of expert materials to be produced according to Fed. R. Civ. P. 26, Dr. Wilson should not be permitted to offer opinions concerning the applicability or appropriateness or reliability of the statistical analysis of Mr. Shah's data.

CONCLUSION

For the foregoing reasons, Dr. Clive Wilson should be precluded from offering opinion testimony about the validity, reliability, or appropriateness of the statistical analysis of the solubility measurements made by his student, Hardik Shah.

III. MOTION *IN LIMINE* TO EXCLUDE OPINIONS OF DR. VALENTINO STELLA PERTAINING TO THE ALLEGED INFRINGEMENT OF CLAIM 6 OF THE '337 PATENT

In this motion *in limine*, Alcon seeks, pursuant to Fed. R. Evid. 403 and 702, to exclude Dr. Valentino Stella's opinions regarding the alleged infringement of claim 6 of the '337 patent. Dr. Stella's anticipated testimony concerning claim 6 of the '337 patent would seek impermissibly to alter the plain meaning of claim 6 by construing the claim term "biological environment" to mean a certain range of pH values. Such testimony should be excluded because it would not assist the Court in determining any fact at issue, and would simply confuse the issues in this case.

The issue in this case pertaining to the alleged infringement of claim 6 of the '337 patent is whether Alcon's proposed brimonidine product meets the limitations of that claim. The claim describes an ophthalmic composition with a "solubility enhancing component" ("SEC") effective to increase the solubility of the active ingredient in a biological environment. Dr. Stella opines that the povidone in Alcon's proposed product enhances the solubility of brimonidine at a pH range representative of the pH range in the biological environment of the eye, and, on that basis, concludes that Alcon's proposed product meets the limitations of claim 6. The plain language of claim 6, however, contains no mention of "pH," much less a narrowing of the term "biological environment" to a pH range. Nor could any valid conclusion conceivably be drawn as to the solubility of brimonidine in the complex environment of the human eye from lab tests of its solubility at varying pH values but nothing else.

Because Dr. Stella offers no opinion as to whether Alcon's proposed product contains an SEC effective to enhance the solubility of brimonidine under the sum of surrounding

conditions that actually constitute the "biological environment" of the human eye, his opinions with respect to the alleged infringement of claim 6 of the '337 patent are unhelpful and inadmissible.

FACTS

Claim 6 of the '337 patent is to an ophthalmic composition with a solubility enhancing component "effective to increase the solubility [of the active ingredient] in a biological environment." This claim depends from independent claim 1, and therefore includes all of that claim's limitations, as well as the additional limitation mandating the efficacy of the SEC in a "biological environment." Portions of the patent specification place the term "biological environment" in further context. For example, the section entitled "Summary of the Invention" states that the claimed composition contains materials that assist in solubilization in "biological environments, such as the human eye." ('337 patent, col. 1, ll. 57-64.) Similarly, the "Detailed Description of the Invention" specifies one embodiment of the invention in which "a composition comprising a SEC and an alpha-2-adrenergic agonist component may be administered to the cornea of the eye, which has a pH of about 7, wherein the alpha-2-adrenergic agonist component is substantially solubilized at the administered area." (Id. at col. 4, ll. 47-51.) The "Background of the Invention" specifies a need for solubility of the active ingredient in biological environments, and describes, "for example," advantages of solubility at "biological pH's." (Id. at col. 1, ll. 33-51.)

Dr. Stella proposes to testify that the povidone in Alcon's brimonidine product increases the solubility of brimonidine in a "biological environment," simply because it allegedly increases brimonidine's solubility in compositions with pH values of approximately 7.1-7.3 and higher -- a pH range he asserts to be representative of the pH range in the biological environment

of the cornea. None of Allergan's proffered expert witnesses claims that pH is the only property that could affect a putative SEC's ability to solubilize brimonidine.

ARGUMENT

Courts have complete discretion to adopt, consider or exclude an expert opinion concerning the construction of a patent claim, because claim construction is a matter of law, requiring an analysis of a patent's intrinsic evidence. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). While a court may certainly allow expert testimony bearing on claim construction to the extent that the testimony assists the court -- for example, in determining the meaning of patent claims to persons of ordinary skill in the art -- expert testimony cannot be used to alter the plain meaning of patent claims. See Markman, 52 F.3d at 983. A court's discretion to exclude expert testimony that is contrary to a claim's plain meaning is consistent with both Fed. R. Evid. 403, which permits exclusion of evidence that would confuse the issues or waste time, and Fed. R. Evid. 703, which provides that expert testimony, to be admissible, must assist the trier of fact.

Here, Dr. Stella's anticipated testimony with regard to claim 6 of the '337 patent is that (i) the term "biological environment" should be construed to mean a pH range of about 7.0-7.3; (ii) he believes that the povidone in Alcon's product acts as an SEC at that pH range; and (iii) therefore the povidone in Alcon's product acts as an SEC in a "biological environment." The keystone of this opinion is thus essentially an opinion on claim construction – i.e., that "biological environment" should be construed to mean a pH range of about 7.0-7.3. The Court should exercise its discretion to exclude Dr. Stella's anticipated testimony because that claim interpretation distorts the plain language of the claim and is inconsistent with the '337 patent's intrinsic evidence.

"It is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitrionics Corp. v. Conceptronic, Inc. 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citation omitted). "As a starting point, the court gives claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art." Hockerson-Halberstadt, Inc. v. Avia Group Int'l., Inc., 222 F.3d 951, 955 (Fed. Cir. 2000) (citations omitted). The court may consult dictionaries, encyclopedias, and treatises in determining the ordinary and customary meaning of claim terms. See Genzyme Corp. v. Transkaryotic Therapies, Inc., 346 F.3d 1094, 1098 (Fed. Cir. 2003). The words of a claim are presumed to carry their ordinary meaning, and that presumption may be rebutted only where the patentee acts as his own lexicographer by explicitly providing in the intrinsic record a definition different from the ordinary meaning, or by disavowing the ordinary meaning "using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Texas Digital Systems, Inc v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed. Cir. 2002).

The plain meaning of "biological environment," in the context of claim 6 of the '337 patent, is the surrounding conditions in the eye, and specifically the cornea of the eye, of a living human being. As a matter of common sense, the biological environment for an eye-drop drug approved for the reduction of intraocular pressure is the eye. In addition, claim 6 explicitly requires an "ophthalmic" composition, and the patent specification refers to "biological environment" in the particular context of "the human eye" and the "cornea of the eye" See supra, pp. 2-3 Merriam Webster's Collegiate Dictionary 115 (10th ed. 1996). "Environment" necessarily refers to a totality of surroundings in view of its plain meaning, but it is not necessary

to consult a dictionary in that regard.[6] See, e.g., C.R. Bard, Inc. v. United States Surgical Corp., 388 F.3d 858, 863 (Fed. Cir. 2004) ("Courts regularly forego detailed dictionary analyses [of a patent term] if the term is . . . commonplace").

It is beyond dispute that the environment of the cornea comprises numerous elements that could affect an ophthalmic composition, including tear dynamics such as drainage rates; tear components such as mucins, lipids, proteins and acid- and base-neutralizing buffers; and physical properties such as tonicity, or osmotic pressure, as well as pH. See Ex. 7, 11 Encyclopedia of Pharmaceutical Technology 58-59 (1995); Ex. 8, 58 Ophthalmic Drug Delivery Systems 38, 62 (1993). Dr. Stella's testimony would limit the scope of the term "biological environment" to a mere pH range only, improperly disregarding the full scope of the limitation. As such the testimony is irrelevant, confusing, and would not assist the Court in determining any issue of fact, and should be excluded.

CONCLUSIONS

For all of the foregoing reasons, the Court should enter an order excluding Dr. Valentino Stella's anticipated testimony regarding the alleged infringement of claim 6 of the '337 patent.

[6] Nonetheless, a representative dictionary definition of "environment" would confirm its plain meaning -- e.g., "the circumstances, objects or conditions by which one is surrounded." Merriam Webster's Collegiate Dictionary 388 (10th ed. 1996).

IV. MOTION *IN LIMINE* TO EXCLUDE OPINIONS OF DR. VALENTINO STELLA PERTAINING TO THE EXPERIMENTAL DATA OF DR. CLIVE WILSON

This motion *in limine* seeks, pursuant to Fed. R. Civ. P. 37(c)(1), to exclude Dr. Valentino Stella's opinions based Dr. Clive Wilson's experimental data.

On one hand, Dr. Wilson's report discloses results of solubility studies and purported statistical analysis, but offers the Court no opinion at all as to their import on any ultimate issue (e.g., infringement) in this case. See Section II, supra. On the other hand, Dr. Stella conducted no studies or statistical analysis of his own, but relies upon Dr. Wilson's experimental data for his opinion that Alcon's proposed brimonidine product infringes the asserted claims of the '337 patent. The method by which Dr. Stella analyzed Wilson's data in order to reach his proffered opinion is therefore a key issue for examination at trial. Yet Allergan has failed to disclose material directly relevant to that issue.

Dr. Stella, in his review of Dr. Wilson's data, generated and visually inspected a hand-drawn graph (hereinafter referred to as the "solubility graph") plotting certain data points that he selected from Dr. Wilson's report. Although such a document is clearly relevant, significant and discoverable, and despite Alcon's repeated requests for its production, Allergan has failed to produce the document. Given that this failure is unjustified and involves key evidence regarding Dr. Stella's analysis of Dr. Wilson's solubility data, an order of sanction under Fed. R. Civ. P. 37(c)(1) precluding Dr. Stella from offering opinions based on Dr. Wilson's data is appropriate. In the alternative, and at a minimum, the Court should enter an order pursuant to Rule 37 compelling Allergan to disclose Dr. Stella's solubility graph. This motion is necessary, as Alcon has requested orally and in writing that Allergan comply with the disclosure obligation at issue, to no avail.

FACTS

Dr. Stella opines in his opening expert report that "Dr. Wilson's Solubility Tests Demonstrate that Povidone Acts as an SEC in Alcon's Proposed Brimonidine Product." Dr. Stella was examined at his deposition with regard to how he drew this conclusion from Dr. Wilson's data, which is set out in certain numbered tables in Dr. Wilson's report. In that regard, Dr. Stella testified, in relevant part, as follows:

Q: Did you give any weight whatsoever in your analysis to Tables 1 and Tables 2?. . .

A: I gave them little weight except for the data above pH 7.

Q: Which data is that?

A: That's the 7.4 and the 7.6 data; the theoretical 7.4 and 7.6 data.

Q: And what, if anything, did you take from that data in connection with your analysis?

A: Combining that with Tables 5 and 6, I concluded that PVP had a positive effect on solubility.

Q: Did you do a statistical analysis of the values in Table 1 and Table 2 connected with the theoretical pH's of 7.4 and 7.6?

A: I did no analysis. I did plot on a graph in my office the data for 7.4 and 7.6, and the data from Tables 5 and 6.

Q: Did you put all of that data on one plot?

A: Yes.

Q: And did you draw curves?

A: No, I did not.

Q: What did you do with that data?

A: I did a visual inspection . . .

A: . . . I'm very much a data visual person. I did not do an analysis or any regression analysis on the data that I just described previously because I just didn't have time to do it.

(Ex. 6, Stella Dep. 50:18-52:17, Nov. 30, 2005.)

During Dr. Stella's deposition, and later orally and in written correspondence, Alcon requested that Allergan produce the solubility graph that Dr. Stella testified he had

considered in analyzing Dr. Wilson's data. Allergan has failed to produce that graph or to respond to Allergan's written correspondence requesting its production.

ARGUMENT

Fed. R. Civ. P. 26(a)(2)(B) requires the proponent of expert witness testimony to disclose to opponent parties "the data or other information considered by the witness in forming his opinions." Rule 26(a) requires disclosure not only of materials that an expert witness may have obtained from others in preparation for his reports and testimony, but also any materials generated by the expert himself. See B.C.F. Oil Refining, Inc. v. Consolidated Edison Co. of New York, Inc., 171 F.R.D. 57, 62 (S.D.N.Y. 1997). Furthermore, the discoverability of such materials does not depend on whether the expert actually relies upon the materials to support his opinions; the expert need only have "considered" them, per the language of Rule 26. See Haworth v. Herman Miller, Inc., 162 F.R.D. 289, 296 (W.D. Mich. 1995).

Where a party without substantial justification fails to disclose information required to be disclosed under Rule 26(a), then, unless the failure to disclose is harmless, the court may, on motion, impose any appropriate sanctions in addition to the automatic, self-executing, sanction precluding that party from introducing into evidence the information improperly withheld. See Fed. R. Civ. P. 37(c)(1). Appropriate "sanctions may include any of the actions authorized under Rule 37(b)(2)(A), (B), and (C)." Id. Among those sanctions, Rule 37(b)(2)(B) specifically authorizes "an order prohibiting [the delinquent] party from introducing designated matters into evidence." Fed. R. Civ. P. 37(b)(2)(B).

The Court should prohibit Allergan from introducing into evidence Dr. Stella's testimony with regard to the solubility data of Dr. Wilson, because Allergan refuses, with no justification whatsoever, to disclose information that is obviously material to Dr. Stella's analysis of the Wilson data. In reviewing Dr. Wilson's data, Dr. Stella selected particular data points,

plotted those points on a graph, and performed a visual inspection of the graph. See supra. Allergan's failure to disclose this graph deprives Alcon of potentially critical evidence for cross-examination, and is especially prejudicial to Alcon in light of Dr. Stella's testimony that he conducted no statistical analysis of Dr. Wilson's data and is "very much a data visual person." Allergan's withholding of such information under the circumstances is a flagrant violation of its discovery obligations that warrants appropriate sanction.

CONCLUSION

For all of the foregoing reasons, the Court should enter an order excluding Dr. Valentino Stella's anticipated testimony pertaining to Dr. Wilson's solubility data. Alternatively, and at a minimum, the Court should enter an order compelling Allergan to produce Dr. Stella's solubility graph.

V. MOTION *IN LIMINE* TO REQUIRE ALLERGAN TO BRING THE INVENTORS ON THE PATENTS-IN-SUIT TO TESTIFY AT TRIAL

Alcon seeks an order requiring Allergan to bring Drs. Orest Olejnik and Edward D. S. Kerslake, the inventors named on the '337 and '834 patents, to testify at trial. Drs. Olejnik and Kerslake are or were employees of Allergan and have assigned their claimed invention to Allergan. Specifically, they executed assignment agreements with Allergan containing the following language:

> ASSIGNOR further covenants that ASSIGNEE will, upon its request, be provided promptly with all pertinent facts and documents relating to said application, said invention and said Letters Patent and legal equivalents in foreign countries as may be known and accessible to ASSIGNOR and will testify to the same in any interference or litigation related thereto...

(Exhibit 9) (emphasis added). Where, as here, an inventor expressly covenants in an assignment to testify in any legal proceeding or litigation involving their invention, the inventors must be produced to testify at trial. See, e.g., Minebea Co., Ltd. v. Papst, 370 F. Supp. 2d 302 (D.D.C. 2005); In re Nifedipine Capsule Patent Litigation, No. 88 Civ. 1374 (JFK), 1989 U.S. Dist. LEXIS 11061 (S.D.N.Y. Sept. 20, 1989)[7].

In Minebea Co., Ltd., Minebea sought an order requiring the defendants to produce inventors living outside the United States for live testimony at trial, including inventors who were also former employees of defendants. Minebea, 370 F. Supp. 2d at 306-07. These inventors had all signed assignment agreements containing express language whereby they agreed to "testify in any legal proceeding" or "testify...in any interference or other litigation when requested" regarding their invention. Id. at 308-309.

Defendants argued that because these "ordinary employees" were not their officers, directors, or managing agents they had no obligation to produce them under the Federal

Rules of Civil Procedure. Id. The court found that this express agreement to provide testimony at the request of defendants was enough to demonstrate that defendants have the ability to compel the inventors to appear at trial and thus required them to be produced. Moreover, the court held that if the defendants did not produce the witnesses, it would have allowed the jury to be instructed with an adverse inference. Id. at 309. Referencing the Nifedipine case, the court explained that where the agreement provides that the inventor will testify in "any legal proceeding," it literally means, "any legal proceeding and not just those in which [the patent holder] would like them to testify." Id. at 309 (citing Nifedipine, 1989 U.S. Dist. LEXIS 11061, at *2-*3 (emphasis added)).

The assignment agreements executed by Drs. Olejnik and Kerslake are indistinguishable from the agreements in Minebea and Nifedipine. Both of the Allergan named inventors have promised to testify in *any* litigation related to their invention. Moreover, Allergan's named inventors are located in the United States, making Allergan's obligation to bring them to trial even more compelling.

Even without the assignment agreements, Allergan would be obligated to produce its employees. First, parties are required as a general matter to procure the attendance of their own employees for trial. See, e.g., Affymetrix, Inc. v. Synteni, Inc., 28 F. Supp. 2d 192, 203 (D. Del. 1998) (affording no weight in a motion to transfer context to the convenience of party witnesses or witnesses who are employed by a party since each party is "able, indeed, obligated to procure the attendance of its own employees for trial"); see also Adams v. Crowley, C.A. No. 04-1565-SLR, slip op. at p. 6 n.5 (D. Del. May 25, 2005) ("Employees of parties must make

[7] All unreported decisions cited in Alcon's motions *in limine* are appended hereto as Exhibit 10.

themselves available for purposes of deposition and trial."). As a current employee of Allergan, Dr. Olejnik must therefore make himself available to testify at trial.

Second, when a plaintiff chooses to file an action in this District, it must produce its witnesses for deposition in this district. See Bayer AG v. Sony Electronics, Inc., C.A. 95-8-JJF, Memo Op. (D. Del. Sept. 30, 1998). It therefore follows that if a plaintiff avails itself of this District's jurisdiction, it must not only produce its witnesses for deposition in this district, but must also produce its witnesses for trial in this district. Therefore, Allergan, who chose to file its patent infringement action in this Court, should be ordered to produce its employee witnesses for trial in this Court.

CONCLUSION

Because of the covenant to testify found in the assignments of the invention at issue to Allergan and the fact that plaintiff has availed itself of this jurisdiction and the accompanying benefits of this Court, Drs. Olejnik and Kerslake, the inventors named on the '337 and '834 patents should be ordered to appear to testify at trial.

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Dated: January 9, 2006

CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire hereby certify that on January 9, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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