

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., :  
FOREST LABORATORIES HOLDING, :  
LTD. AND H. LUNDBECK A/S :  
 :  
Plaintiffs :  
 : Civil Action No. 03-891-JJF  
v. :  
 :  
 :  
IVEX PHARMACEUTICALS, INC. and :  
CIPLA LTD., :  
 :  
 :  
Defendants. :

---

Melanie K. Sharp, Esquire, and Andrew A. Lundgren, Esquire, of  
YOUNG CONAWAY STARGATT & TAYLOR, LLP, Wilmington, Delaware.  
Of Counsel: John M. Desmarais, Esquire, Peter J. Armenio,  
Esquire, Gerald J. Flattmann, Jr., Esquire, and Maxine Y. Graham,  
Esquire, of KIRKLAND & ELLIS LLP, New York, New York.  
Attorneys for Plaintiff.

Richard D. Kirk, Esquire, of THE BAYARD FIRM, Wilmington,  
Delaware.  
Lead Counsel: Jeffrey S. Ward, Esquire, Thomas P. Heneghan,  
Esquire, Steven P. Means, Esquire, Shane A. Brunner, Esquire,  
Edward J. Pardon, Esquire, Charlene L. Yager, Esquire, of MICHAEL  
BEST & FRIEDRICH LLP, Madison, Wisconsin.  
Attorneys for Defendants.

---

**MEMORANDUM OPINION**  
**CONCERNING**  
**EVIDENTIARY ISSUES**

July 25, 2006  
Wilmington, Delaware

  
Farnan, District Judge.

During the course of the bench trial in the above-captioned action, the Court reserved judgment on several evidentiary objections raised by the parties. The parties have briefed their respective positions, and this Memorandum Opinion constitutes the Court's rulings with regard to the pending evidentiary matters.

## I. PLAINTIFFS' POST-TRIAL EVIDENTIARY OBJECTIONS

### A. Defendants' Demonstrative Exhibits

Plaintiffs object to the admission of Defendants' demonstrative exhibits into evidence. They point to an Order of the Court dated March 9, 2006, stating that "[u]nless otherwise agreed to by the parties, demonstrative exhibits are marked for identification but not admitted into evidence." (D.I. 570 at 2-3.) Plaintiffs state that the parties have not agreed to admit the exhibits into evidence and contend that the exhibits should thus be excluded.

Defendants have not filed a response to this objection. Accordingly, the Court will sustain Plaintiffs' objection pursuant to the Court's March 9 Order.

### B. Dr. Burke's Testimony Regarding Salts in Example 2 of the '590 Patent.

Plaintiffs challenge Dr. Burke's testimony regarding the salts in Example 2 of the '590 patent as inadmissible because Dr.

Burke's opinions in this regard were not disclosed to Plaintiffs in his expert report, in his sworn declaration or during his deposition. Federal Rule of Civil Procedure 26(a)(2)(B) requires that all expert testimony be accompanied by a written report containing "all the opinions to be expressed and the basis and reasons therefor," as well as all data and information to be considered by the expert witness and any exhibits to be used in support of his testimony.

The exclusion of critical evidence under Rule 37(c)(1) is an extreme sanction, not imposed absent a showing of willful deception and flagrant disregard of a court order by the proponent of the evidence. Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 905 (3d Cir. 1977). Here, there is no allegation that Defendants acted in bad faith or with the intent to "mislead or confuse" Plaintiffs. Id. Furthermore, the Court is persuaded that Paragraph 24 of Dr. Burke's expert report sufficiently disclosed the opinions Dr. Burke testified about at trial, and that any deviations were not such as to unduly prejudice Plaintiffs. Accordingly, the Court will overrule Plaintiffs' objection.

C. Dr. Gelenberg's Testimony Regarding Medical Literature and Accompanying Exhibits

Plaintiffs object to the inclusion of a number of exhibits related to Dr. Gelenberg's testimony on the grounds that they are a) inadmissible hearsay under Federal Rule of Evidence ("FRE") 802, b) irrelevant under FRE 402, and c) lacking foundation under FRE 901.

DTX 1197, 1156, 1238, 1213 and 1221 are internal e-mails sent among employees of Plaintiffs, used by Dr. Gelenberg to support his testimony that published articles overstated the benefits of (+)-citalopram because data was selectively chosen to obtain the desired result. Defendants contend that the exhibits are not hearsay because they are party admissions within the meaning of FRE 801 and that even if they meet the definition of "hearsay" they fall under the "then-existing state of mind" and "records of regularly conducted activities" exceptions under FRE 803. According to Defendants, the exhibits are evidence that may properly be considered by an expert under FRE 703 even if they are not otherwise admissible. Furthermore, Defendants argue that the exhibits do not lack foundation under the Amended Pre-Trial Order which stipulates that "[a]ny document that on its face appears to have been authored by an employee, officer or agent of a party shall be deemed prima facie to be authentic, subject to

the right of the party against whom such a document is offered to adduce evidence to the contrary." (D.I. 526.) Defendants also contend that the exhibits are directly related to the issues in the case and serve to impeach Plaintiffs' testimony, and are thus relevant. Finally, Defendants point out that Plaintiffs did not object to the documents at trial based on relevance grounds, and therefore, their objection is waived.

The Court concludes that the exhibits are not hearsay under FRE 801(d)(2)(D), which provides that "[a] statement is not hearsay if . . . [t]he statement is offered against a party and is a statement by the party's agent or servant concerning a matter within the scope of the agency or employment, made during the existence of the relationship." The correspondence constituting the exhibits is between employees of one or more of the Plaintiffs and is within the scope of their employment. The Court further concludes that the exhibits do not lack foundation under the Amended Pre-Trial Order, because they fall within its bounds, and Plaintiffs have not offered any evidence to indicate that the correspondence is not genuine. In light of the prima facie authentication contained in the Amended Joint Pretrial Order, the Court concludes that Plaintiffs' objection that the documents are irrelevant because "the comments alleged to be made by others and put forth in the document cannot be verified" (D.I.

598 at A-2, #3) is without merit. Accordingly, the Court will overrule Plaintiffs' objections to these documents.

D. Dr. Gelenberg's Testimony Regarding the Effects of Marketing on Physicians' Prescribing Habits

Plaintiffs object to Dr. Gelenberg's testimony opining that drug marketing has an effect on physicians' prescribing habits (Tr. 557:23 - 561:21) on the grounds that Dr. Gelenberg is not qualified as an expert on this subject and does not possess any marketing or business degrees, and therefore, his testimony on this issue will not be of use to the Court in understanding the issues in this case. Defendants reply that Dr. Gelenberg has extensive experience as a clinical psychiatrist, supervisor of numerous clinical practices, and editor of well-respected peer-reviewed journals, which qualifies him to testify on the subject of the prescribing habits of psychiatrists.

FRE 702 provides that an expert witness must be qualified by "knowledge, skill, experience, training or education." The "fundamental requirement for qualifying an expert" is the helpfulness of the expert's testimony to the finder of fact. Stephen A. Saltzburg et al., Federal Rule of Evidence 702 Commentary, available at LEXIS USCS Fed Rules Evid R 702. To the extent that certain portions of testimony given by an expert may be less credible, the Supreme Court has held that the appropriate

method of challenging such testimony is through cross-examination rather than exclusion. Daubert v. Merrell Dow Pharms., 509 U.S. 579, 596 (1993).

Here, the Court cannot conclude that Dr. Gelenberg, a respected clinical psychiatrist with experience in writing prescriptions himself, as well as supervising others who write prescriptions, is not qualified to testify on physicians' prescribing habits. He possesses sufficient experience to shed light on the relevant issues, and Defendants had the opportunity to cross-examine Dr. Gelenberg on the matter. Thus, the Court concludes that Plaintiffs' objection goes to the weight to be afforded to Dr. Gelenberg's testimony and not to its admissibility, and therefore, the Court will overrule Plaintiffs' objection.

E. Exhibits Accompanying Dr. Gelenberg's Testimony Regarding the Effects of Marketing on Physicians' Prescribing Habits

DTX 589, 960, 1003, 1049 and 1388 are published studies purporting to quantify the effect of marketing by pharmaceutical companies on the behavior of physicians. Plaintiffs challenge these exhibits as not being a proper basis for Dr. Gelenberg's expert testimony, as inadmissible hearsay, and as irrelevant to any of the disputed issues in the case. In Defendants' view, the

trial testimony shows that the exhibits are the type reasonably relied upon by experts in Dr. Gelenberg's field, and the exhibits are admissible either on that basis, or under the "market reports and commercial publications" exception to the hearsay rule. Fed. R. Evid. 803(17). Further, Defendants argue that the exhibits are directly relevant to the issue of obviousness.

Reviewing the identified exhibits and the related trial testimony, the Court notes first that Dr. Gelenberg clearly testified that the exhibits are of the type reasonably relied upon by experts in his field. Tr. 557:3-5. Defendants have not disputed this testimony. As to whether the exhibits themselves should be excluded even though Dr. Gelenberg's testimony is admitted, FRE 703 provides that evidence that is otherwise hearsay may be admitted "if the court determines that their probative value in assisting the [trier of fact] to evaluate the expert's opinion substantially outweighs their prejudicial effect." In this case, the Court concludes that the published studies have some probative value in supporting Dr. Gelenberg's contention that marketing has an effect on physicians' prescribing habits, and that this value is not outweighed by any prejudice to Plaintiffs. Specifically, the evidence does not directly relate to Plaintiffs so as to result in a significant prejudicial effect. Furthermore, the Court concludes that the

data presented in the exhibits is sufficiently related to the issue of obviousness to meet the threshold of the relevance standard set forth in FRE 402. Accordingly, the Court will overrule Plaintiffs' objections to these exhibits.

F. Exhibits Related to Dr. Trombetta's Testimony

Plaintiffs challenge a number of exhibits related to Dr. Trombetta's testimony that Plaintiffs contend lack foundation and were neither used nor identified during Dr. Trombetta's examination. According to Defendants, the exhibits were all identified in the demonstrative exhibits used by Dr. Trombetta which, though not admitted into evidence, are stipulated to be part of the trial record. Defendants also point out that the exhibits are stipulated to be authenticated pursuant to the Amended Pre-Trial Order, and therefore, do not lack foundation.

As an initial matter, the Court concludes that all of the challenged exhibits are sufficiently identified within Dr. Trombetta's testimony because the demonstrative exhibits identifying those exhibits are by stipulation part of the trial record. To the extent that Plaintiffs contend that Defendants are using the demonstrative exhibits as a "backdoor for inadmissible evidence," the Court disagrees with Plaintiffs' assertion. Defendants are simply claiming that the exhibits in question were identified by the demonstratives, and are not using

the demonstratives as a means to admit otherwise inadmissible evidence.

In addition, DTX 380, 382, 383, 384, 386, 387, 401 and 1068 were authored by Plaintiffs and produced in discovery, and therefore, the Court concludes that these exhibits do not lack foundation under the Amended Pre-Trial Order. (D.I. 526.) DTX 370 and 1425 were also authored by third parties and produced by Plaintiffs during discovery, and therefore, the Court concludes that these exhibits do not lack foundation under the Amended Pre-Trial Order. DTX 713, 786, 822, 904, 950, 958, 989, 995, 997, 1036 and 1037 are journal articles or other publications that were not "produced" during discovery, but were listed in a disclosure made during discovery. (D.I. 608, Ex. 4.) Given the readily verifiable nature of the exhibits, the Court concludes that the disclosure is within the bounds of the Amended Pre-Trial Order, and therefore, the exhibits do not lack foundation. Accordingly, the Court will overrule Plaintiffs' objection to these exhibits.

G. Dr. Gibbons' Testimony

Plaintiffs challenge several excerpts of Dr. Gibbons' testimony as beyond the scope of his expert reports. First, Plaintiffs object to his testimony regarding the Auquier study, and his comparison of it to the French study. (Tr. 778:23-779:2;

780:24-782:7; 782:19-784:13; 787:18-24.) Dr. Gibbons testified that "meta-analysis" was "hypothesis-generating" rather than "hypothesis testing," that the subsequent French study changed the parameters to address only a certain sub-group of patients, and that when the original parameters were used no statistically significant difference was reported. According to Plaintiffs, this was beyond the scope of his expert report, which made no comparison between the two studies and did not state that the Auquier study was "hypothesis-generating."

Dr. Gibbon's expert report contained his opinion that the Auquier study was a "meta-analysis," which, as Defendants note, is functionally equivalent to a "hypothesis-generating study." Furthermore, the expert report contains analysis of both the Auquier study (D.I. 540, Ex. 1 at 10) and the French study (D.I. 540, Ex. 5 at 14), and thus, the Court finds that Dr. Gibbons' trial testimony was a synthesis of those analyses. Because the Court finds that such a synthesis is permissible and was within the scope of Dr. Gibbons' expert report, the Court will overrule Plaintiffs' objection.

Plaintiffs also object to Dr. Gibbons' testimony regarding violations of the French study protocol (Tr. 795:1-796:12) and his predictions regarding how the FDA would have treated such violations. (Tr. 796:13-15.) While the expert report mentions

the problem with the study (D.I. 540, Ex. 5 at 6), it does not expressly characterize it as a violation of protocol, and says nothing at all about the FDA. In the Court's view, Dr. Gibbons' testimony regarding the protocol violation is a permissible elaboration on the opinions set out in the expert report. See e.g., Mineba Co. v. Papst, 231 F.R.D. 3, 8 (D.D.C. 2005) (recognizing that experts should be "permitted a certain degree of latitude," may "explain the opinions and conclusions" in their reports and may provide "reasonable explanations"). However, the Court concludes that Dr. Gibbons should not have offered his opinions regarding how the FDA would have treated the violation because this was not included in his expert report. Although Dr. Gibbons did address the FDA issue during his deposition, that does not serve to place his trial testimony within the scope of his expert report. Accordingly, the Court will overrule Plaintiffs' objection with respect to Dr. Gibbons' testimony regarding violations of the French study protocol, and sustain it with respect to his testimony regarding how the FDA would have treated such violations.

Plaintiffs also object to Dr. Gibbons' testimony regarding how the French study results changed when a single treatment center was removed from the analysis. (Tr. 797:2-798:24.) Notably, Defendants concede that this testimony was not in Dr.

Gibbons' expert report, but contend that the deviation is justified because the testimony was in direct rebuttal to Dr. Thisted's expert report, which was "late-produced" on January 26 2006. (D.I. 607 at 25.) However, Defendants had more than six weeks from the filing of the Thisted report to the trial date to file a response to Dr. Thisted's report, and Dr. Gibbons filed an unsworn "declaration" two weeks after the filing of Dr. Thisted's report, which contained no mention of his additional analyses. Thus, the Court concludes that Dr. Gibbons should not have testified on this issue for the first time at trial. Accordingly, the Court will sustain Plaintiffs' objection as it relates to this portion of Dr. Gibbons' trial testimony.

Finally, Plaintiffs object to Dr. Gibbons' testimony comparing the assumptions in his analysis of the French study to those of Plaintiffs' expert Dr. Thisted. Dr. Gibbons testified that he considered his assumptions to be more reasonable than Dr. Thisted's. (Tr. 801:9-11.) The Court concludes that this testimony was not outside the scope of Dr. Gibbons' expert reports. Dr. Gibbons' reports were predominantly dedicated to his analyses of various studies and his employment of a "mixed-effects regression model." (D.I. 540, Ex. 1 at 2; Ex. 3 at 3; Ex. 5 at 2.) His Second Supplemental Expert Report specifically applied this model to the French study, and set out in detail the

various assumptions employed. (D.I. 540, Ex. 5 at 3-6.) The Court concludes that these disclosures were sufficient to enable Dr. Gibbons to defend these assumptions at trial by comparing them to assumptions employed by other researchers. Accordingly, the Court will overrule Plaintiffs' objection to Dr. Gibbons' testimony comparing the assumptions in his analysis of the French study to those of Plaintiffs' expert Dr. Thisted.

#### H. Dr. Bøgesø's Testimony and Related Exhibits

Plaintiffs object to DTX 9, DTX 366, and Dr. Bøgesø's testimony regarding DTX 366 and DTX 160 on the grounds that they lack foundation. As Defendants point out, however, all of these exhibits are authenticated under the provisions of the Amended Joint Pretrial Order, and thus, do not lack foundation. Furthermore, Plaintiffs' objection to DTX 366 and the related testimony was already overruled by the Court at trial. (Tr. 1047:6-15.) Accordingly, the Court will overrule the objection with respect to the challenged exhibits and testimony.

#### I. DTX 800 [DX 91] and Accompanying Deposition Testimony

Plaintiffs object to this exhibit, a newspaper article, and the accompanying testimony in the deposition of Dr. Olanoff on the grounds that the exhibit is hearsay and lacks foundation. This exhibit was only used to elicit the witness' agreement with one statement in the article. Because the witness is an

executive vice president of Forest Laboratories, against whom the exhibit was being offered, and because he evidenced his agreement with the statement (Olanoff Dep. 261:12-17), the Court concludes that it qualifies as an adopted admission under FRE 801(d)(2). Therefore, the Court will overrule Plaintiffs' objection to DTX 800.

## II. DEFENDANTS' POST-TRIAL EVIDENTIARY OBJECTIONS

### A. Dr. Bøgesø's Testimony Regarding Research About the Pharmacological Effects of the (R)-Enantiomer of Citalopram.

Defendants object to Dr. Bøgesø's testimony about a review article (PTX 264) he authored that discusses research about the pharmacological effects of the (R)-enantiomer of citalopram. Defendants contend that because Dr. Bøgesø was not offered as an expert witness, and because he admits to not being an expert in pharmacology, the testimony should be excluded as improper expert testimony.

FRE 701 provides that "if the witness is not testifying as an expert, the witness' testimony in the form of opinions and inferences is limited to those opinions and inferences which are (a) rationally based on the perception of the witness, and (b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue." The Third Circuit has interpreted these requirements to mean that "the witness'

perception [must] provide a truly rational basis for his or her opinion," and that "in order to be 'helpful,' an opinion must be reasonably reliable." Asplundh Mfg. Div. v. Benton Harbor Eng'g, 57 F.3d 1190, 1201 (3d Cir. 1995). In other words, a lay witness' opinion on technical matters may be admissible if it "derive[s] from a sufficiently qualified source as to be reliable and hence helpful to the [finder of fact]." Id.

The Court concludes that Dr. Bøgesø, though not an expert in pharmacology, possesses sufficient knowledge and expertise to testify as to the results of research work that he himself performed. Dr. Bøgesø was not asked to give general expert opinions on topics of pharmacology; rather, he was asked about research in which he participated and about his surprise at its results. Thus, the Court concludes that Dr. Bøgesø's testimony is sufficiently grounded in the witness' first-hand knowledge and sufficiently reliable to be admissible under FRE 701. Accordingly, the Court will overrule Defendants' objection.

B. Dr. Lader's Testimony Regarding (S)-Citalopram Being a Major Breakthrough Drug

Defendants contend that "Dr. Lader improperly offered expert testimony that (S)-citalopram was a major breakthrough drug based on Forest's sales information." (D.I. 597 at 2.) Because Dr. Lader admits to not having expert knowledge about sales,

Defendants contend that he is unqualified to offer such testimony. Defendants also contend that Dr. Lader's testimony is inadmissible because it is beyond the scope of his expert reports.

After reviewing the record, the Court concludes that Dr. Lader's testimony was not "based on Forest's sales information," but rather on Dr. Lader's experience as a clinician. In addition, the Court concludes that Dr. Lader's expert report addressed his opinion that (S)-citalopram was a breakthrough drug based on his clinical expertise, and the Court is persuaded that his testimony, which was primarily based on his clinical experience, was not unrelated to his expert report. To the extent Dr. Lader interjected his "amateurish knowledge of sales" into his opinion, the Court will consider his lack of expertise in that area in the weight to be afforded to his testimony. Accordingly, the Court will overrule Defendants' objection to Dr. Lader's testimony on this issue.

C. Mr. Gundertofte's Testimony Regarding His Attempts to Separate the Enantiomers of Citalopram Using Chiral HDLC.

Defendants object to Mr. Gundertofte's testimony regarding his attempts to separate the enantiomers of citalopram using chiral HDLC on the grounds that it goes beyond the lay witness' personal experience and thus violates FRE 701. In the Court's

view, most of the testimony objected to is fact testimony describing Mr. Gundertofte's personal experience performing research at Lundbeck. As for the few portions of his testimony that may be considered opinion (Tr. 1070:8-71:7; 1090:15-17), the Court finds that his testimony falls well within the Asplundh standard articulated above for the admission of lay opinion testimony. All of Mr. Gundertofte's opinions were sufficiently grounded in his experience working for Lundbeck, and therefore, the Court concludes that they are sufficiently reliable to be helpful to the Court. Accordingly, the Court will overrule Defendants' objection.

D. Dr. Lader's Testimony that the Moore Study Statistical Analysis Did Not Contain any Subgroup Analyses.

Defendants contend that Dr. Lader's opinion that the Moore study did not include a subgroup analysis of those with an MADRS score of over 35 is outside the scope of Dr. Lader's expert report. Dr. Lader's report includes a detailed analysis of the Moore study, including the results as they relate to subjects' MADRS scores. (D.I. 610 Ex. I at 4-5.) The testimony objected to was in response to Dr. Gelenberg's opinion that the Moore study showed that the drug did not have advantages for patients with MADRS scores over 35, and the Court finds the testimony was an assertion that the Moore study did not include that particular

subgroup analysis. In the Court's view, Dr. Lader's expert report sufficiently addressed his opinions regarding the study's treatment of the MADRS variable to encompass the testimony in question here. Accordingly, the Court will overrule Defendants' objection.

E. Dr. Pochapsky's Testimony About the Predictability of Chiral Acids

Defendants object to Dr. Pochapsky's testimony that chiral acids are not predictable in performing separations as beyond the scope of his expert report. Dr. Pochapsky's expert report discloses that he expected to testify regarding the "theory and use of chiral acids" and contained his opinion that "other separation techniques were better known and better understood and would have been preferred [to chiral HDLC], including the classical resolution technique of crystallization using chiral acids." (D.I. 610 Ex. M at 4.) In the Court's view, Dr. Pochapsky's opinion that chiral acids were more unpredictable than chiral HDLC, but still relatively unpredictable, is an acceptable elaboration on the opinions contained in his expert report. See e.g., Mineba Co. v. Papst, 231 F.R.D. at 8 (D.D.C. 2005). Accordingly, the Court will overrule Defendants' objection.

F. Dr. Thisted's Testimony Regarding Dr. Gibbons' Calculation of Effect Sizes in the Moore Study.

Defendants object to Dr. Thisted's testimony that Dr. Gibbons' calculation of effect sizes in his analysis of the Moore study was incorrect, claiming that it was beyond the scope of Dr. Thisted's expert report. Dr. Thisted not only addressed the effect sizes in his expert report, but specifically performed the calculation. (D.I. 610 Ex. K at 30-31.) Given that the testimony responded to Dr. Gibbons' opinions presented for the first time at trial, and the fact that the subject is directly addressed in the expert report, the Court concludes that the testimony objected to was not beyond the scope of Dr. Thisted's expert report, and therefore, the Court will overrule Defendants' objection.

G. Dr. Danishefsky's Testimony Discussing What He Would Have Done Had He Devised a Way to Obtain Substantially Pure (+)-Citalopram in 1988.

Defendants contend that Dr. Danishefsky's testimony that had he discovered a way to obtain substantially pure (+)-citalopram in 1988 he would have patented it is irrelevant and speculative. As Plaintiffs note, much of Defendants' cross-examination of Dr. Danishefsky was devoted to eliciting testimony that the separation of the enantiomers of citalopram would have been obvious to a person of ordinary skill in the art. In that

context, the Court concludes that the testimony objected to by Defendants is relevant to the issue of obviousness under the liberal standard of FRE 401. Accordingly, the Court will overrule Defendants' objection.

H. Dr. Danishefsky's Testimony That Dr. Bøgesø, Mr. Perregaard and Mr. Gundertofte Were Persons of Ordinary Skill in the Art

Defendants contend that Dr. Danishefsky's testimony that Dr. Bøgesø, Mr. Perregaard and Mr. Gundertofte were persons of ordinary skill in the art is irrelevant because no one can personify the hypothetical standard of a person of ordinary skill in the art. Plaintiffs reply that the testimony is relevant to the issue of obviousness as it pertains to the factual claim that Lundbeck workers of ordinary skill or above tried and failed to do what Defendants now claim was obvious.

Under the standard set out in Graham v. John Deere Co., 383 U.S. 1 (1966), a court weighing the issue of obviousness must ascertain "the scope and content of the prior art," "differences between the prior art and the claims at issue," and "the level of ordinary skill in the pertinent art." Id. at 17. The court may also consider a number of secondary factors, among them the "failure of others" to come up with the invention at issue. Id. at 18. In that context, the question of whether researchers who had tried and failed to do what is claimed to be obvious could be

considered "persons of ordinary skill in the art" is, while not conclusive, relevant to the issue of obviousness within the meaning of FRE 401. While Defendants are correct that the "person of ordinary skill in the art" is a hypothetical person, they do not point to any precedent that would preclude comparisons of real people to that standard. In fact, courts have described or compared real people in terms of the hypothetical standard of one skilled in the art. See e.g., Markman v. Westview Instruments, Inc., 52 F.3d 967, 983 (Fed. Cir. 1995); Biacore v. Thermo Biaanalysis Corp., 79 F. Supp. 2d 422, 441 n. 22 (D. Del. 1999). Accordingly, the Court will overrule Defendants' objection.

I. PTX 746A

Defendants object to PTX 746A, the certified translation of the finalized statistical analysis plan for the Moore study, on the grounds that it lacks foundation, that Defendants were denied discovery on the exhibit, and that the exhibit was outside the scope of Dr. Lader's expert report.

As an initial matter, the Court notes that Defendants proffered this same exhibit for admission into evidence as DTX 1335, thus mooting the foundation and denial of discovery objections. As for Defendants' objection based on the scope of Dr. Lader's expert report, the Court concludes that Dr. Lader

should not be precluded from testifying on an updated version of the statistical analysis plan already discussed in his expert report, where as here, the only available analysis at the time was the "prefinal" analysis. In addition, the Court concludes that the admissibility of this analysis is justified to prevent prejudice stemming from the admissibility of the two earlier versions of the Moore study (DTX 1269, 1333) and to rebut the testimony of Dr. Gibbons. Accordingly, the Court will overrule Defendants' objection.

J. PTX 819

Defendants object to this exhibit on the grounds that Plaintiffs have not provided a certified translation. However, Defendants' counsel asked for the opportunity to submit a certified translation at trial. (Tr. 1057:16-23.) To the Court's knowledge, Defendants have not done so, and therefore the Court concludes that the lack of a certified translation does not prejudice Defendant. Furthermore, the exhibit was introduced for the sole purpose of demonstrating the existence of a Danish patent, and therefore, the Court concludes that a certified translation is not required. Accordingly, the Court will overrule Defendants' objection.

K. PTX 1082

Defendants object to PTX 1082 on the grounds that its title - "The Branded SRI Market" - is misleading and confusing, since the exhibit itself purports to show revenue for all of the products sold by companies who have a branded drug in the SRI market. However, the witness was not confused or misled by the title of the document during questioning. Specifically, he was asked whether the chart "accurately characterizes the relative sizes of the branded companies in the SRI market," and he answered in the affirmative. (Tr. 702:23-703:19.) Defendants' objection to the question inquiring whether it was "about right for the relative sizes of the SRI markets" was overruled. (Tr. 703:12-17.) Furthermore, because this was a bench trial, the Court concludes that there is no risk of confusion. Accordingly, the Court will overrule Defendants' objection.

L. PTX 21

Defendants object to PTX 21 as inadmissible hearsay, on the grounds that Dr. Smith was not entitled to rely on a hearsay document, because he was not qualified as an expert witness. Defendants waived this objection, because it was not raised at the time stipulated to in the Amended Pre-Trial Order. (D.I. 526 at 14; D.I. 609 Ex. E.). Accordingly, the Court will overrule Defendants' objection.

M. PTX 778

Defendants object to Dr. Gundertofte's curriculum vitae being entered into evidence, on the grounds that he is not an expert witness. Plaintiffs have agreed to redesignate this exhibit as a demonstrative. (D.I. 610 at A-10.) Accordingly, the Court concludes that Defendants' objection is moot.

N. DTX 190, 191, 192, and 193 as Used in the Testimony of Dr. Bøgesø.

Defendants object to DTX 190, 191, 192 and 193 as inadmissible hearsay for which Dr. Bøgesø did not establish foundation. However, as with PTX 21 (see section J, supra), Defendants did not timely object to the exhibits in accordance with the stipulation in the Amended Pre-Trial Order (D.I. 526 at 14; D.I. 610 Ex. E.) Accordingly, the Court will overrule Defendants' objection to these exhibits.

O. DTX 690 and Related Testimony

Defendants object to DTX 690 and Dr. Gundertofte's accompanying testimony as hearsay and inappropriate expert testimony on the part of a lay witness. The exhibit is a paper Dr. Gundertofte authored and published in the Journal of Computational Chemistry. The Court concludes that the exhibit and testimony are appropriate lay opinion testimony under the Asplundh. The witness did not offer general expert opinion, but

rather, he limited his testimony to his personal experience writing the journal article. Accordingly, the Court will overrule Defendants' objection.

P. Plaintiffs' Corrections to Translations of DTX 134, 188, 189, 190, 191, 193, 194, 196, 197 and 199.

Defendants object to Plaintiffs' corrections to Defendants' translations of DTX 134, 188, 189, 190, 191, 193, 194, 196, 197 and 199 on the grounds that the corrections were untimely. Defendants do not cite the trial transcript where they preserved this objection. The Court concludes that Defendants may not make this objection for the first time post-trial. Accordingly, the Court will overrule Defendants' objection.

Q. Plaintiffs' Demonstrative Exhibits

Defendants object to Plaintiffs' demonstrative exhibits being considered as evidence. According to the Amended Joint Pretrial Order, "[u]nless otherwise agreed by the parties, demonstrative exhibits are marked for identification but not admitted into evidence." (D.I. 570 at 2-3.) Plaintiffs agree that demonstratives should not be considered evidence. Accordingly, the Court concludes that this objection is mooted by Plaintiffs' acquiescence in the inadmissibility of these documents, or in the alternative, sustained in accordance with the Amended Joint Pretrial Order.

R. PTX 1151

Defendants object to PTX 1151 as irrelevant, misleading and confusing. Because PTX 1151 is, by Defendants' admission, a demonstrative exhibit, and because the Court has mooted, or in the alternative, sustained Defendants' objection to demonstrative exhibits being admitted into evidence, supra, the Court concludes that this objection is moot.

**III. CONCLUSION**

For the reasons discuss the Court will overrule and/or sustain the various objections lodged by Plaintiffs and Defendants.

An appropriate Order detailing the Court's rulings on these evidentiary matters will be entered.

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., :  
FOREST LABORATORIES HOLDING, :  
LTD. AND H. LUNDBECK A/S :  
 :  
Plaintiffs :  
 : Civil Action No. 03-891-JJF  
v. :  
 :  
IVEX PHARMACEUTICALS, INC. and :  
CIPLA LTD., :  
 :  
Defendants. :

O R D E R

At Wilmington, this 25 day of July 2006 for the reasons  
discussed in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that:

1. Plaintiffs' objection to the admissibility of Defendants' demonstrative exhibits is **SUSTAINED**.
2. Plaintiffs' objection to the admissibility of Dr. Burke's testimony regarding salts in example 2 of the '590 patent is **OVERRULED**.
3. Plaintiffs' objection to the admissibility of Dr. Gelenberg's testimony regarding medical literature and accompanying exhibits is **OVERRULED**.
4. Plaintiffs' objection to the admissibility of Dr. Gelenberg's testimony regarding the effects of marketing on

physicians' prescribing habits is OVERRULED.

5. Plaintiffs' objection to the admissibility of exhibits accompanying Dr. Gelenberg's testimony regarding the effects of marketing on physicians' prescribing habits is OVERRULED.

6. Plaintiffs' objection to the admissibility of exhibits related to Dr. Trombetta's testimony is OVERRULED.

7. Plaintiffs' objection to the admissibility of Dr. Gibbons' testimony regarding the Auquier study is OVERRULED.

8. Plaintiffs' objection to the admissibility of Dr. Gibbons' testimony regarding the violations of the French study protocol and the probable response of the FDA is SUSTAINED IN PART and OVERRULED IN PART.

9. Plaintiffs' objection to the admissibility of Dr. Gibbons' testimony regarding the removal of a single treatment center from the Moore study analysis is SUSTAINED.

10. Plaintiffs' objection to the admissibility of Dr. Gibbons' testimony comparing the assumptions in his analysis of the French study to Dr. Thisted's is OVERRULED.

11. Plaintiffs' objection to the admissibility of Dr. Bøgesø's testimony and related exhibits is OVERRULED.

12. Plaintiffs' objection to the admissibility of exhibit DTX 800 and the related testimony in Dr. Olanoff's deposition is OVERRULED.

13. Defendants' objection to the admissibility of Dr. Bøgesø's testimony regarding research about the pharmacological effects of the (R)-enantiomer of citalopram is OVERRULED.

14. Defendants' objection to the admissibility of Dr. Lader's testimony regarding (S)-citalopram being a major breakthrough drug is OVERRULED.

15. Defendants' objection to the admissibility of Mr. Gundertofte's testimony regarding his attempts to separate the enantiomers of citalopram using chiral HPLC is OVERRULED.

16. Defendants' objection to the admissibility of Dr. Lader's testimony that the Moore study statistical analysis did not contain any subgroup analyses is OVERRULED.

17. Defendants' objection to the admissibility of Dr. Pochapsky's testimony regarding the predictability of chiral acids is OVERRULED.

18. Defendants' objection to the admissibility of Dr. Thisted's testimony regarding Dr. Gibbons' calculation of effect sizes in the Moore study is OVERRULED.

19. Defendants' objection to the admissibility of Dr. Danishefsky's testimony discussing what he would have done had he devised a way to obtain substantially pure (+)-citalopram in 1988 is OVERRULED.

20. Defendants' objection to the admissibility of Dr. Danishefsky's testimony that Dr. Bøgesø, Mr. Perregaard and Mr.

Gundertofte were persons of ordinary skill in the art is

**OVERRULED.**

21. Defendants' objection to the admissibility of exhibit PTX 746A is **OVERRULED.**

22. Defendants' objection to the admissibility of exhibit PTX 819 is **OVERRULED.**

23. Defendants' objection to the admissibility of exhibit PTX 1082 is **OVERRULED.**

24. Defendants' objection to the admissibility of exhibit PTX 21 is **OVERRULED,**

25. Defendants' objection to the admissibility of exhibit PTX 778 is **OVERRULED AS MOOT.**

26. Defendants' objection to the admissibility of exhibits DTX 190, 191, 192 and 193 as used in the testimony of Dr. Bøgesø is **OVERRULED.**

27. Defendants' objection to the admissibility of exhibit DTX 690 and related testimony is **OVERRULED.**

28. Defendants' objection to the admissibility of Plaintiffs' corrections to translations of DTX 134, 188, 189, 190, 191, 193, 194, 196, 197, 199 is **OVERRULED.**

29. Defendants' objection to the admissibility of Plaintiffs' demonstrative exhibits is **MOOTED** by the acquiescence of Plaintiffs, or in the alternative, **SUSTAINED.**

30. Defendants' objection to the admissibility of exhibit  
PTX 1151 is OVERRULED AS MOOT.

  
UNITED STATES DISTRICT JUDGE