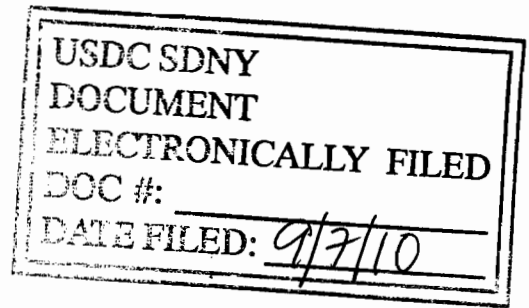


UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK



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TEVA PHARMACEUTICALS USA, INC., :  
TEVA PHARMACEUTICAL INDUSTRIES LTD., :  
TEVA NEUROSCIENCE, INC., and :  
YEDA RESEARCH AND DEVELOPMENT CO. LTD., :  
:  
Plaintiffs, :  
:  
v. :  
:  
SANDOZ, INC., SANDOZ INTERNATIONAL :  
GMBH, NOVARTIS AG, and MOMENTA :  
PHARMACEUTICALS, INC. :  
:  
Defendants. :  
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08 Civ. 7611  
(BSJ) (AJP)

Memorandum and Order

BARBARA S. JONES  
UNITED STATES DISTRICT JUDGE

Defendants Sandoz, Inc., Sandoz International GmbH, Novartis AG, and Momenta Pharmaceuticals, Inc. moved for summary judgment on the basis that the patents at issue are invalid because their claims are indefinite under 35 U.S.C. § 112.<sup>1</sup> As part of their opposition to Defendants' motion for summary judgment, Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc., and Yeda Research and Development Co. Ltd. submitted expert declarations from Dr. Gregory Grant and Dr. Paul Dubin. Defendants subsequently moved to strike both declarations. For

<sup>1</sup> On August 26, 2010, Plaintiffs voluntarily dismissed, without prejudice, their claims against Sandoz International GmbH and Novartis AG. Accordingly, all references to "Defendants" hereinafter are only to Sandoz, Inc. and Momenta Pharmaceuticals, Inc.

the reasons provided below, Defendants' motions for summary judgment and to strike Plaintiffs' expert declarations are DENIED.

**I. Defendants' Motion to Strike the Expert Declarations**

In Daubert v. Merrell Dow Pharmaceuticals, Inc., the Supreme Court explained that expert testimony is admissible where it "rests on a reliable foundation and is relevant to the task at hand." 509 U.S. 579, 597 (1993). Here, the challenged declarations are both reliable and relevant.

**A. Reliability**

Defendants' primary argument regarding reliability is that the declarations should be excluded because neither Dr. Grant nor Dr. Dubin has knowledge regarding "what Teva actually did." First, according to Defendants, Dr. Grant undermined his own opinion by criticizing the approach that Teva used to characterize its own copolymer-1 standards. Second, Defendants claim that Dr. Grant's opinion hinges on "speculative rationalization," as opposed to objective analysis, because he did not verify his measurements against Teva's actual data for copolymer-1. Third, Dr. Dubin's opinion, according to Defendants, contradicts the facts of Teva's molecular weight analysis because Teva did not use "the same mobile phase" for the chromatographic separation and molecular weight analysis of copolymer-1. Defendants contend that Dr. Dubin's opinion also

contradicts Teva's molecular weight analysis because universal calibration would not have been routine for copolymer-1 because copolymer-1 is "highly charged" and universal calibration works for polymers of that nature only occasionally. Lastly, Defendants claim that the opinion of both experts, that "it would have been routine" to analyze copolymer-1 using either self-standards or universal calibration, is unreliable because they contradict Teva's own experiences with copolymer-1. According to Defendants, use of copolymer-1 standards was not routine at the time of filing and size exclusion chromatography ("SEC") analysis of copolymer-1 would not have been routine due to complications caused by electrostatic effects.

The fact that Dr. Grant and Dr. Dubin do not have knowledge of "what Teva actually did"—either personally or by reviewing Teva's internal documents—does not warrant excluding their declarations. In Daubert, the Supreme Court explained that expert witnesses are permitted "wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation." 509 U.S. at 592 (citations omitted). The "relaxation of the usual requirement of firsthand knowledge . . . is premised," the Court added, "on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline." Id. (citation omitted).

Daubert is particularly apt here because the only information Dr. Grant and Dr. Dubin needed regarding "what Teva actually did," in order to render an opinion on Defendants' indefiniteness claim, is the information disclosed in the patents themselves and in the prosecution history. See, e.g., Kinetic Concepts, Inc. v. Blue Sky Med. Grp., Inc., 554 F.3d 1010, 1022 (Fed. Cir. 2009) ("The definiteness analysis requires a determination of 'whether one skilled in the art would understand the bounds of the claim when read in light of the specification.'" ) (citations omitted). It is beyond dispute that a person of ordinary skill in the art, such as Dr. Grant and Dr. Dubin—a point unchallenged by Defendants—would not have had access to Teva's internal documents. In fact, because neither expert refers back to "what Teva actually did," both opinions carry a greater degree of objectivity than they otherwise would if they did refer to "what Teva actually did."

To the extent that Defendants argue that the opinions of Dr. Grant and Dr. Dubin are unreliable because they are inconsistent with their deposition testimony, previous declarations, or previous writings, these critiques speak, at most, to credibility. As a court in this district recently explained, "[q]uestions of credibility generally do not render an expert's testimony inadmissible." In re Pfizer Inc. Sec. Litig., No. 04 Civ. 9866(LTS)(JLC), 05 md 1688(LTS), 2010 WL

1047618, at \*2 (S.D.N.Y. Mar. 29, 2010) (citing Daubert, 509 U.S. at 596). Issues of credibility, such as those alleged here, are best explored through "[v]igorous cross-examination." See Daubert, 509 U.S. at 596.

In addition to their reliability arguments based on lack of knowledge of "what Teva actually did," Defendants also argue that Dr. Grant's opinion that Figure 1 teaches peak molecular weight is unreliable (1) because he allegedly did not consider the possibility that Figure 1 refers to weight-average molecular weight (Mw) and (2) because the methodology of his analysis has not been tested.

Defendants' first claim is demonstrably false. In Dr. Grant's first declaration, dated October 6, 2009 and expressly incorporated into his declaration in opposition to Defendants' motion for summary judgment, Dr. Grant explicitly explained why a person of ordinary skill in the art would not have interpreted Figure 1 to refer to weight-average molecular weight (Mw). (Grant Decl. ¶¶ 63-64, Oct. 6, 2009.) Any claim that Dr. Grant impeached himself is, again, best explored through "[v]igorous cross-examination." See Daubert, 509 U.S. at 596.

Defendants' other arguments—that Dr. Grant's methodology is flawed because it has not been subjected to peer-review, because his technique has not been generally accepted by the

relevant scientific community, and because he has not articulated a meaningful error rate—are also unpersuasive. After a careful review of Dr. Grant's summary judgment opposition declaration, his first declaration (dated October 6, 2009), his second supplemental declaration (dated November 4, 2009), his third supplemental declaration (dated November 17, 2009), all of which discuss Dr. Grant's interpretation of Figure 1 in great detail, even assuming there is an issue regarding Dr. Grant's methodology, exclusion is not warranted. It also bears worth noting that Defendants did not offer the opinion of a single expert discrediting or casting doubt on Dr. Grant's methodology or his interpretation of Figure 1.

**B. Relevancy**

With respect to Daubert's relevancy requirement, Defendants argue that the declarations are inadmissible because Dr. Grant and Dr. Dubin both address the wrong question. According to Defendants, both experts testify "that skilled artisans would know what standards or conditions to use to accurately determine their own molecular weight," while ducking "the proper question of indefiniteness"—namely, whether a skilled artisan "could meaningfully compare the molecular weight of his or her copolymer-1 to the molecular weight values as determined by Teva and recited in its claims." This requires, Defendants claim, "using the same measurement standards and conditions as Teva."

In order to properly consider the relevancy of the declarations, it is imperative to take into account Defendants' indefiniteness arguments. In their motion for summary judgment, Defendants argue, first, that the patents at issue are indefinite because Teva did not expressly define average molecular weight. Defendants argue, second, that the patents are indefinite because Teva failed to disclose the SEC standards and calibration conditions necessary to determine if an accused product's molecular weight matches Teva's claimed molecular weights.

With respect to Defendants' first argument, in his declaration, Dr. Grant explains why a person of ordinary skill in the art would have understood that the average molecular weight reported in the patents' specifications refers to peak average molecular weight. Dr. Grant also provides a detailed description of why a person of ordinary skill in the art would not have understood average molecular weight to refer to number average molecular weight ( $M_n$ ), weight average molecular weight ( $M_w$ ), z average molecular weight ( $M_z$ ), or viscosity average molecular weight ( $M_v$ )—the other possible meanings identified by Defendants. Thus, Dr. Grant's declaration is clearly relevant to Defendants' first indefiniteness argument.

With respect to Defendants' second argument, Dr. Grant and Dr. Dubin both opine that, since 1994, a person of ordinary

skill would not have needed to know or use the same measurement standards and conditions as Teva in order to understand what Teva claimed. Since 1994, according to Dr. Grant and Dr. Dubin, a person of ordinary skill would be independently capable of selecting appropriate calibration standards and SEC conditions to determine if an accused product's molecular weight matches Teva's claimed molecular weight values. Because both declarations address the proper definiteness analysis—namely, whether the meaning of the claim is “discernible,” see, e.g., Exxon Research and Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001) (citations omitted)—they are relevant to Defendants' second indefiniteness argument.

To the extent Defendants made arguments not explicitly addressed in this Memorandum and Order, the Court has considered these arguments, and finds they do not warrant excluding Plaintiffs' experts' declarations.

## **II. Defendants' Motion for Summary Judgment**

As the moving party, Defendants bear the burden of demonstrating “the absence of a genuine issue of material fact” that the patents at issue are indefinite (1) because Teva did not expressly define average molecular weight and (2) because Teva failed to disclose the SEC standards and calibration conditions necessary to determine if an accused product's



molecular weight matches Teva's claimed molecular weights. See, e.g., Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

With respect to Defendants' first argument, in his declaration, Dr. Grant explained that a person of ordinary skill in the art would have understood that the average molecular weight reported in the patents' specifications refers to peak average. In addition to Dr. Grant's declaration, in its opposition, Teva explained that the term "average molecular weight" first appeared in the '539 patent. When the patent examiner rejected claims directed to that term, on the precise indefiniteness grounds that Defendants assert here, Teva explained that a person of ordinary skill in the art would understand, upon reviewing the specification, that "'average molecular weight' refers to the molecular weight at the peak of the molecular weight distribution curve shown in Figure 1." (Doyle Decl. Ex. 11 ('539 Patent, Dec. 1, 2004 Amendment at 10).) The examiner accepted that explanation and issued a Notice of Allowability. See, e.g., Mas-Hamilton Grp. v. LaGard, Inc., 21 F. Supp. 2d 700, 717 (E.D. Ky. 1997) ("There is a 'heavy presumption against [Defendants] in arguing that the patents and claims do not comply with 35 U.S.C. § 112 where the Examiner reviewed the adequacy of the descriptions and found the patent descriptions to be definite and allowed the patents thereafter.'" ) (citations omitted).

Defendants claim that statements Teva made while prosecuting the other patents are inconsistent with the reference to peak average. Even assuming Defendants are correct, which does not appear to be the case in light of Teva's explanation regarding why none of the other statements identified by Defendants conflict or undermine the reference to peak average, Teva has provided more than ample evidence to demonstrate that there is a genuine issue of material fact regarding whether the patents adequately defined average molecular weight. See, e.g., Santos v. Murdock, 243 F.3d 681, 683 (2d Cir. 2001) ("Once a party moving for summary judgment has made the requisite showing that there is no factual dispute, the nonmoving party bears the burden of presenting evidence to show that there is, indeed, a genuine issue for trial.") (citing Celotex Corp., 477 U.S. at 323-24).

With respect to its second indefiniteness argument, Defendants concede that the '161 patent specification expressly identifies SEC as a method for determining the molecular weight distribution of copolymer-1. Despite identifying this particular method, Defendants argue that the patent claims are invalid because Teva omitted "essential" information regarding how to set the testing standards and conditions to achieve Teva's claimed molecular weights.

Teva's experts, Dr. Grant and Dr. Dubin, rebut Defendants' argument by explaining that, since 1994, a person skilled in the art would not need to know the exact SEC standards and conditions Teva used. Since 1994, according to Dr. Grant and Dr. Dubin, a person of ordinary skill in the art would be capable of independently selecting appropriate SEC standards and conditions to determine if an accused product's molecular weight matches Teva's claimed molecular weights.

Defendants present no expert testimony directly challenging the opinions of Plaintiffs' experts. Instead, Defendants point to excerpts from Dr. Grant's deposition testimony and to other internal Teva documents in an effort to show that it is "impossible" to know whether an accused product's molecular weight matches Teva's claimed molecular weights without using the same SEC standards and conditions as Teva. Defendants essentially offer nothing more than attorney argument. In light of Plaintiffs' experts' declarations, Defendants fail to demonstrate they are entitled to summary judgment on their second indefiniteness argument. See Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1068 (Fed. Cir. 2005) ("Unsubstantiated attorney argument regarding the meaning of technical evidence is no substitute for competent, substantiated expert testimony."); see also Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc., 45 F.3d 1550, 1562 (Fed. Cir.

1995) ("There must be sufficient substance, other than attorney argument, to show that the issue requires trial.") (citations omitted).

Although Defendants' theories of indefiniteness do not warrant summary judgment, in light of the emphasis Defendants place on it, it is important to explain why Defendants' reliance on Honeywell International, Inc. v. International Trade Commission, 341 F.3d 1332 (Fed. Cir. 2003), is misplaced. In Honeywell, the patent holder taught one example for measuring the "melting point elevation" ("MPE") of polymer yarn for automobile tires. Id. at 1335-36. It failed, however, to disclose any method for preparing the yarn for measurement. Id. at 1336. As of the earliest priority date of the Honeywell patent, only "[t]hree sample preparation methods were published in the art." Id. A fourth method existed, but was unpublished and documented only in the patent holder's proprietary files. Id. The Federal Circuit found that "knowing the proper sample preparation method is necessary to practice the invention" because the calculated MPE could "vary greatly" based on which method was used. Id. at 1336, 1340. Because "the claims, the written description, and the prosecution history" gave no "guidance as to what one of ordinary skill in the art would interpret the claim to require," the Federal Circuit found the claims "insolubly ambiguous." Id. at 1340.


Here, by contrast, Teva specifically identified SEC as a method for determining the molecular weight distribution of copolymer-1. In response to the patent examiner's initial rejection of the term "average molecular weight" during the prosecution of the '539 patent—specifically on the basis of Honeywell—Teva also explained that upon reviewing the specification, a person of ordinary skill in the art would understand that "'average molecular weight' refers to" peak average molecular weight. (Doyle Decl. Ex. 11 ('539 Patent, Dec. 1, 2004 Amendment at 10).) Because intrinsic evidence directly instructs how a person of ordinary skill in the art should interpret the term "average molecular weight," Honeywell is not controlling.

To the extent Defendants made arguments not explicitly addressed in this Memorandum and Order, the Court has considered these arguments, and finds they do not warrant summary judgment.

#### CONCLUSION

For the reasons provided above, Defendants' motions for summary judgment (Dkt. 121) and to strike the expert declarations of Dr. Grant and Dr. Dubin (Dkt. 144) are DENIED.

SO ORDERED:

  
BARBARA S. JONES  
UNITED STATES DISTRICT JUDGE

Dated: New York, New York  
September 7, 2010