IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AMGEN INC., AMGEN MANUFACTURING, LIMITED, and AMGEN USA INC.,	)	
Plaintiff,	)	
v.	)	Civ. No. 14-1317-SLR (Consolidated)
SANOFI; SANOFI-AVENTIS U.S. LLC; AVENTISUB LLC; and REGENERON PHARMACEUTICALS, INC.,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 2nd day of March, 2016, having heard oral argument on, and having reviewed papers submitted in connection with, the various evidentiary disputes identified in the parties proposed pretrial order (D.I. 215, exs. 15, 16);

IT IS ORDERED that, in connection with the issues raised by plaintiffs:

1. **Plaintiffs' evidentiary issues 1 and 2.** Plaintiffs argue that defendants should be precluded from relying on the Schering and Novartis references as prior art because they failed to meet their burden to prove that these references are entitled to priority to their provisional applications. Plaintiffs rely on the Federal Circuit's decision in *Dynamic Drinkware v. National Graphics*, 800 F.3d 1375 (Fed. Cir. 2015), for this proposition. The issue addressed by the Federal Circuit in *Dynamic Drinkware* was whether the alleged anticipatory patent was prior art based on its provisional

application. The Federal Circuit explained that, "[f]or a patent to claim priority from the filing date of its provisional application," "the specification of the **provisional** must 'contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms' . . . to enable an ordinarily skilled artisan to practice the invention **claimed** in the **non-provisional** application." *Id.* at 1378 (emphasis in original) (citing *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002)).[1] The Federal Circuit concluded that defendant "failed to compare **the claims** of the . . . patent . . . to the disclosure in the . . . provisional application. A reference patent is only entitled to claim the benefit of the filing date of its provisional application if the disclosure of the provisional applicaiton provides support for the claims in the reference patent in compliance with § 112, ¶ 1." *Id.* at 1381.

2. Defendants concede that their experts did not satisfy the legal requirements as set forth above, but argue that the Federal Circuit's reasoning in *Dynamic Drinkware* is not applicable to the facts of this case, where the alleged prior art references are published applications, not patents. As explained by defendants, "[c]laims in a published application are fluid and have not been examined. They could be altered or

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[1]The Court in the *New Railhead* case addressed the issue of whether a utility application (that issued as the patent-in-suit) was entitled to the priority date of a provisional application because the disclosure in the provisional specification failed to adequately describe the invention claimed in the patent-in-suit as required by 35 U.S.C. § 119(e)(1). The Court concluded that, while the patent disclosed "verbatim" certain language from the provisional's specification, "the disclosure of the provisional application [did] not adequately support the invention claimed in the [5,899,283] patent as to the angle limitation. As a result, the '283 patent is not entitled to the filing date of the provisional application" pursuant to § 119(e)(1). 298 F.3d at 1297.

deleted entirely. If *Drinkware* applied, the identical disclosure in a published application could qualify as prior art one day and not the next day, merely because a claim has been changed." (D.I. 241 at 2) Defendants assert that the better explanation for the legal issue at hand is that provided in *Apple Inc. v. Int'l Trade Com'n*, 725 F.3d 1356 (Fed. Cir. 2013), an appeal from the International Trade Commission ("ITC") in which the alleged prior art was a patent claiming priority to an earlier filed provisional application. Without reference to any authority, the Federal Circuit simply agreed with the ITC that "substantial evidence" supported the ITC's determination that the provisional application "provide[d] adequate written support for" the allegedly anticipatory patent. *Id.* at 1362. The Court framed its discussion in terms of "both references disclos[ing]" the same sensor matrix and multitouch detection algorithms, without specifically referring to the **claimed** invention or that the provisional must adequately support **the claims** of the patents.

3. Because I asked the parties to identify the case that best supports their respective positions, I assume that there is no case on point, that is, a case where defendants are relying for their obviousness defense on a published application (as opposed to a patent) which is only prior art by claiming priority to an earlier filed unpublished application, neither of which have claims that have been examined. I recognize that the references at issue may change; nevertheless, I believe the law is more accurately described in *Dynamic Drinkware*. However, because plaintiffs did not object to the two prior art references at issue until the conclusion of expert discovery through the *Daubert* motion exercise, I decline to grant plaintiffs' motion to preclude

defendants from presenting their obviousness defense and will, instead, give defendants the opportunity to supplement their expert reports to appropriately address the question of whether the Schering and Novartis references constitute prior art by comparing their claims to the prior disclosures. (D.I. 247 at 62) If the parties need a short postponement of the trial date to accommodate this order, I will make it so.

4. **Plaintiffs' evidentiary issue 5.** Plaintiffs assert that defendants should be precluded from using post-priority date evidence to show a motivation existing before the priority date. *See Daiichi Sankyo Co. v. Matrix Labs., Ltd.*, 619 F.3d 1346, 1354 (Fed. Cir. 2010) (court "must look at the state of the art at the time the invention was made to find a motivation" to select and then modify a lead compound). Defendants respond by citing to two Federal Circuit decisions, neither of which stand for contrary propositions. In *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371 (Fed. Cir. 2005), the Court concluded that a report that was published five days after the priority date but that reflected the state of the art at the relevant time was appropriate evidence of motivation. *Id.* at 1379-80. As far as I can tell, the issue in *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293 (2005), was whether the problem solved by the patent had to be disclosed in the prior art or in the patent itself. In reversing a district court's grant of summary judgment of nonobviousness, the Federal Circuit determined that "a reasonable juror could conclude that at the time of the invention, one of ordinary skill in the art could have been motivated to modify the [patented device] in light of the problem to be solved." *Id.* at 1322. More specifically,

> the clinical investigators recognized the bottom-tightening problem with the [patented device] and proposed changes. The problem was within the

> general knowledge of those of ordinary skill in the art, and thus provided sufficient motivation to navigate the prior art in the spinal implant field in search of a teaching on how one might modify the [patented device] away from a bottom-tightening assembly.
>
> The district court erred in discounting the clinical investigators' recognition of the problem. . . . If the problem is within the knowledge of one of ordinary skill in the art, then it is irrelevant that the prior art does not disclose the problem.

Id. at 1322-23.

5. The bottom line is that, whether defendants are proffering "statements in the prior art, the knowledge of one of ordinary skill in the art, or . . . the nature of the problem of the solved"[2] as evidence of motivation, the evidence must relate to the state of the art at the time of the invention. Therefore, while defendants' work to make J16 and alirocumab may be relevant to demonstrate knowledge of one of skill in the art or recognition of the nature of the problem solved by the patents-in-suit (evidence of a motivation to develop antibodies that block PCSK9's interaction with the LDLR and, therefore, admissible evidence), I conclude that the antibodies themselves, not completed until after the priority date, are not evidence of motivation to make the claimed invention (and, therefore, are inadmissible evidence).

6. **Plaintiffs' evidentiary issue 15.** Defendants shall not be permitted to introduce argument or elicit testimony that alirocumab is patented, as they have not proffered any issue (other than "telling their story") to which their patent would be relevant. As noted above, however, defendants will be able to share their development story, but will not be able to use any of that story as **evidence** of obviousness if it is

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[2]*Cross Medical*, 424 F.3d at 1321 (citation omitted).

post-priority date evidence.

7. **Plaintiffs' evidentiary issues 10 and 14.** These issues relate to the damages phase of the trial and will not be addressed in this memorandum order. Plaintiffs shall file one-page submissions on each on or before **March 4, 2016,** with defendants responding in kind on **March 7, 2016.**

8. **Plaintiffs' evidentiary issues 4 and 13.** These issues were not addressed during the pretrial conference. To the extent they need resolution, plaintiffs may submit one-page letter submissions by **March 4, 2016**, with defendants responding in kind by **March 7, 2016.**

IT IS FURTHER ORDERED that, in connection with the issues raised by defendants:

9. **Defendants' evidentiary issues 1 and 15.** Defendants seek to preclude plaintiffs from eliciting testimony about arguments made to the PTO in prosecuting different patents where defendants have made allegedly inconsistent statements regarding adequate written description. I acknowledge the general principle that defendants "should not be permitted to make statements in this case that are inconsistent with [their] statements to the . . . PTO," based on "judicial estoppel, [which] is an equitable doctrine that precludes a party from gaining an advantage by asserting one position, and then later taking to their benefit a clearly inconsistent position." *MasterObjects, Inc. v. Google, Inc.*, 2013 WL 2606626, *1 (N.D. Cal. June 11, 2013). The devil is in the detail, however, and whether the matters asserted by defendants before the PTO are so similar to the patents-in-suit that the alleged inconsistencies are

relevant cannot be discerned without a concentrated review of the records from the various other cases. Given the complexity of the technology at issue and the prospect of jury confusion, I decline to give blanket permission to admit such evidence on the record presented, especially in light of plaintiffs' vigorous opposition to the admission of patent expert testimony. If plaintiffs want to use their trial time to convince me that some identified particular testimony offered at trial can be impeached by some identified prior inconsistent testimony given to the PTO, I will entertain such a focused request (more likely to be granted in terms of Dr. Siegel than of defendants generally) .

10. **Defendants' evidentiary issue 14.** Defendants argue that, although "the jury should be permitted to hear evidence of the invention and development of both sides' products, that evidence can and should be done without focusing on dates and on whether Amgen was 'first.'" (D.I. 239 at 2) Although I have precluded evidence relating to defendants' post-filing development story as evidence relevant to the issue of "motivation," I agree with plaintiffs that their status as "first" to develop the claimed invention is relevant, at least as to "the backdrop against which the" invalidity analyses are performed. (D.I. 242, ex. 2)

11. **Defendants' evidentiary issue 3.** Having reviewed the proffer (D.I. 239, ex. 2) of Robert Bradway, I conclude that only paragraphs 1-4 are appropriate fodder for his testimony in part one of the trial addressing liability.

12. **Defendants' evidentiary issue 5.** I will allow plaintiffs to offer evidence from both experts, each on their respective areas of expertise, but will preclude any allusion by plaintiffs to the fact that only one of defendants' experts offered an ultimate

opinion. (D.I. 247 at 70-79)

13. **Defendants' evidentiary issues 10-13.** These issues were not addressed during the pretrial conference. To the extent they need resolution, defendants may submit one-page letter submissions on each issue by **March 4, 2016,** with plaintiffs responding in kind by **March 7, 2016.**

IT IS FURTHER ORDERED that, in connection with the various other issues raised by the parties:

14. **Sequencing.** Consistent with my past practice, plaintiffs shall proceed first with their opening, and proceed first with their two trial witnesses to present plaintiffs' story.

15. **The well-characterized antigen doctrine.** Defendants have argued that plaintiffs' experts should be precluded from sharing their written description opinions based on a "novel, well characterized antigen" theory. More specifically, defendants "dispute that the *dicta* in *Centocor [Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1352 (Fed. Cir. 2011)] establishes a 'theory' for determining written description support for antibody claims." (D.I. 186 at 13) However, defendants go on to state that "that issue need not be decided here," for "[e]ven if it were an appropriate test, the Amgen patents and claims do not meet the requirements set forth by the discussion in *Centocor.*" (*Id.*) I decline to preclude plaintiffs' evidence on the well-characterized antigen doctrine.

16. **Defendants' representative species analysis under 35 U.S.C. § 112.** Plaintiffs have argued that defendants' experts have incorrectly applied the

representative species test for written description. (D.I. 185; D.I. 247 at 44) As I understand the dispute, plaintiffs' experts have provided testimony and evidence relating to the diversity of structural features among the antibodies disclosed in the Amgen patents (including features that are shared by antibodies that do not fall within the scope of the claim), to prove that such disclosed antibodies "'are representative of the full variety or scope of the genus.'" (D.I. 192 at 14, citing from *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.,* 759 F.3d 1285,1300 (Fed. Cir. 2014)). Defendants' expert, Dr. Siegel, has opined at bar that the representative species test is limited to comparing those structural features that are unique to the claimed antibodies. By contrast, Dr. Siegel in *AbbVie* based his written description testimony on comparing five structural distinctions between the structural features shared by the antibodies described in the patents and the structure of the accused antibody, without reference to whether such structural features were shared or not by antibodies falling outside the scope of the claim. The Court in *AbbVie* also did not limit the representative species test to assessment of features that distinguish claimed from unclaimed antibodies. I conclude from the above that plaintiffs' experts have not used an improper legal standard and approach for demonstrating the diversity of the representative species. It is not clear to me, however, whether the Federal Circuit has squarely addressed this issue, as it has been my experience that courts generally do not address issues that are not raised by the parties. Since I am not sure whether there is a right or a wrong approach, plaintiffs' motion to exclude defendants' expert testimony in this regard is denied. At this point, however, the parties and their experts will be precluded from

characterizing their opponents' approach and opinions as legally wrong, and plaintiffs certainly can use Dr. Siegel's *AbbVie* testimony as impeachment in terms of his opinion as to the better approach.

17. **Bifurcation.** Just to be sure that the parties are all on the same page, the trial hours allocated for this case include both phases of the trial - liability and damages. It is up to the parties to set aside the appropriate number of hours for each phase; the parties need not reach agreement on the number of hours they intend to use. There is to be **no mention** during the liability phase of the trial of such issues as damages, injunctive relief, or willfulness. The sanction for such conduct will be a reduction in the number of trial hours that the offending party has been allocated.

18 If the parties need to follow up with me prior to the first day of trial, I will be available for a conference on Friday, March 4, 2016 anytime before 2:00.

United States District Judge