E-Filed 3/4/2010

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

MEDIMMUNE, LLC, Plaintiff, v. PDL BIOPHARMA, INC., Defendant.	Case Number C 08-5590 JF (HRL) ORDER DENYING MOTION TO STRIKE INVALIDITY CONTENTIONS Re: Document No. 236

Defendant PDL BioPharma, Inc. ("PDL") moves to strike the invalidity contentions of Plaintiff MedImmune LLC ("MedImmune") to the extent that the contentions are based on 35 U.S.C. § 112(1) and to limit contentions based on §§ 102 and 103 to disclosed references. MedImmune opposes the motion. The Court has considered the moving and responding papers and the oral arguments of counsel presented at the hearing on February 26, 2010. For the reasons discussed below, the motion will be denied. PDL's post-hearing request for an extension of the time period within which the parties must exchange rebuttal expert reports will be granted.

I. BACKGROUND

MedImmune filed the operative Second Amended Complaint ("SAC") on April 16, 2009. The SAC seeks a declaration that the patent-in-suit, United States Patent No. 6,180,370 ("370 Patent"), is invalid under 35 U.S.C. § 112. SAC ¶ 30. MedImmune initiated the instant action in December 2008, claiming without explanation that the '370 patent is invalid under several statutory provisions. Complaint ¶ 16 ("United States Patent No. 6,180,370 is invalid under 35 U.S.C. §§ 101, 102, 103, 112, *et seq.* and/or under the judicially created doctrine of obviousness

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type double patenting."). MedImmune subsequently filed its First Amended Complaint ("FAC"), reasserting the identical allegations. FAC ¶ 29 ("United States Patent No. 6,180,370 is invalid under 35 U.S.C. §§ 101, 102, 103, 112, *et seq.* and/or under the judicially created doctrine of obviousness type double patenting.").

After PDL moved to dismiss the FAC pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim upon which relief may be granted, MedImmune filed the operative SAC, re-alleging invalidity under paragraphs 1 and 2 of § 112. The relevant allegations read as follows:

> The claims of the '370 patent also are invalid under, *inter alia*, 35 U.S.C. Section 112, first paragraph, because the specification does not describe the full scope of the claimed immunoglobulins and methods of producing immunoglobulins, does not enable a person of ordinary skill in the art to make and use the claimed immunoglobulins and practice the claimed methods of producing immunoglobulins without undue experimentation, and does not disclose the applicant's best mode for preparing the claimed immunoglobulins. The claims of the '370 patent also are invalid under, *inter alia*, 35 U.S.C. Section 112, second paragraph, because they do not distinctly claim the purportedly inventive subject matter.

SAC ¶ 30.

MedImmune was required to disclose its invalidity contentions to PDL pursuant to Patent Local Rules 3-3 and 3-4 by May 21, 2009. Dkt. # 100 (Joint Case Management Statement at 6) ("noting that the parties disputed the scope of MedImmune's disclosures); Dkt # 106 (Civil Minutes reflecting adoption of the proposed case management schedule on April 24, 2009). MedImmune timely disclosed its contentions premised upon § 112(1). Declaration of Aaron Y. Huang ("Huang Decl."), Ex. 1 at 10.[1] Five days later, PDL informed MedImmune that it believed the disclosure was inadequate and asked MedImmune to meet and confer, failing which PDL would move to strike the contentions. *See* Declaration of David Berl ("Berl Decl."), Ex. A. On June 4, 2009, MedImmune asked PDL during a meet-and-confer call to identify the alleged inadequacies of the disclosure and to indicate what supplemental information PDL would like

[1] MedImmune also contended that Claim 28 of the patent is indefinite under § 112(2) "because, when read in light of the specification, it does not reasonably apprise a person of skill in the art of the scope of the invention. The use of the term 'humanized immunoglobulin' in Claim 28 renders the claim insolubly ambiguous and not amenable to construction." Huang Decl., Ex. 1 at 11. Because this issue has been resolved in the Court's claim construction order, it will not be addressed here.

MedImmune to provide. *Id.,* Ex. B. MedImmune alleges that counsel for PDL refused to tell MedImmune what additional information PDL was seeking, simply stating that PDL would file a motion to strike unless MedImmune supplemented its contentions. *Id.*

On June 11, 2009, MedImmune served the supplemental invalidity contentions at issue here. Huang Decl., Ex. 2. PDL did not respond to the supplemental contentions or file a motion to strike at that time. The previous day, the parties had submitted a joint case management statement indicating that they had "conferred and confirmed that neither party has any issues it wishes to raise at the scheduled June 19 Case Management Conference." Dkt. 118 at 1. Neither party raised any issue with respect to the supplemental invalidity contentions at the conference itself. A subsequent joint statement filed by the parties in August 2009 advised the Court that "[t]he parties timely exchanged their initial disclosures and infringement and invalidity contentions and have also exchanged document requests" and that "discovery and other issues may arise" but that "[t]he parties do not have any such issues for the Court to resolve at this Case Management Conference." Dkt. 129 at 1.

On November 16, 2009, PDL advised MedImmune by letter that it objected to MedImmune's supplemental invalidity contentions based upon MedImmune's alleged failure to provide "the grounds" for its contention that the '370 patent is invalid under 35 U.S.C. § 112(1). Berl Decl., Ex. C. In the same letter, PDL requested that MedImmune indicate whether it would supplement its invalidity contentions in the following two days, failing which PDL would move to strike the contentions. On November 18, 2009, MedImmune declined to supplement its contentions. *Id.,* Ex. D. PDL filed the instant motion on December 7, 2009.

II. DISCUSSION

1. Adequacy of Invalidity Contentions

"This district has adopted Patent Local Rules that 'require parties to state early in the litigation and with specificity their contentions with respect to infringement and invalidity." *Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.*, No. C08-04567CW, 2009 WL 3353306, at *2 (N.D. Cal. Oct. 16, 2009), quoting *O2 Micro Int'l, Ltd. v. Monolithic Power Systems, Inc.,* 467 F.3d 1355, 1359 (Fed. Cir. 2006). Rule 3-3(d), which governs invalidity contentions based upon

35 U.S.C. § 112(1), states that a party alleging such invalidity contentions shall provide "[a]ny grounds of invalidity based on...enablement or written description." Patent L.R. 3-3(d).[2]

PDL claims that MedImmune does not state the grounds of its contentions with respect to enablement and written description with a level of specificity sufficient to allow any meaningful discovery. MTS at 6, citing *IXYS Corp. v. Advanced Power Tech. Inc.,* No. C02-03942MHP, 2004 WL 1368860, at *3 (N.D. Cal. June 16, 2004) ("The Local Rules exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases, not to create supposed loopholes through which parties may practice litigation by ambush.") MedImmune argues that it has complied fully with Rule 3-3(d) and that it disclosed the "grounds of invalidity" sufficiently to put PDL on notice.

The parties attempt to frame the instant dispute as a disagreement about the standard of disclosure required pursuant to Rule 3-3(d). However, it appears that the parties agree that the disclosure standard for invalidity contentions based upon enablement and written description is lower than that required for a claim of obviousness, *see e.g.* Patent L.R. 3-3(c) (requiring "a chart identifying where specifically in each alleged item of prior art each limitation of each asserted claim is found..."), but high enough that it must give the other party enough notice that it can engage in full, timely discovery and litigate its case.[3]

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[2] The instant action was filed in December 2008. Accordingly, the Court will apply the Patent Local Rules that became effective on March 1, 2008. Patent L.R. 1-4 (indicating that the Patent Local Rules that took effect on December 1, 2009 "govern patent cases filed on or after that date").

[3] MedImmune argues that a less stringent "notice" standard for invalidity contentions based upon enablement and written description is appropriate given that such contentions are based upon the patent itself. It asserts that because the "patentee wrote the specification; the patentee surely possesses an in-depth understanding of what its specification does and does not disclose and enable," and "[a]t the very least, the patentee has equal access to the facts underlying enablement and written description theories of invalidity." *Id.* PDL argues that Rule 3-3(d) must demand more specificity than Fed. R. Civ. P. 8, because otherwise the local rule itself would be surplusage. The Court need not resolve this theoretical dispute as it concludes that: (1) MedImmune's contentions satisfy the standard asserted by PDL; and (2) discovery has proceeded to the point that PDL has received MedImmune's extensive expert reports with respect to the subject contentions.

The actual dispute between the parties appears to be whether MedImmune's invalidity contentions based upon 35 U.S.C. § 112(1) "crystalize and state with specificity its theories early on in the case so as to allow the opposing party full, timely discovery." PDL Reply at 4. The disputed disclosure concerning MedImmune's invalidity contentions based upon 35 U.S.C. § 112(1), reads in its entirety as follows:

> The specification of the '370 patent neither describes nor enables the full scope of humanized immunoglobulins of claim 28, which is therefore invalid for failure to meet the written description and enablement requirements of 35 U.S.C. § 112, ¶ 1. The specification provides a very limited number of examples of immunoglobulins using the techniques of CDR grafting and framework substitution, few of which fall within the scope of claim 28. The immunoglobulins disclosed in the specification are capable of binding to a very limited set of antigens, and the disclosed binding affinity of those immunoglobulins is limited by the affinity of the donor immunoglobulins that provided the CDRs in the exemplified immunoglobulins. In contrast to the sparse disclosure of the '370 patent, claim 28 covers a virtually innumerable number of immunoglobulins, not limited by, *inter alia*, the antigens to which they bind or the affinity with which they bind them. The specification of the '370 patent does not describe or enable immunoglobulins with the full scope of binding affinities covered by claim 28. *See, e.g.*, '370 Patent Prosecution History, Office Action April 29, 1999. The specification of the '370 patent does not describe or enable the structures and affinities of immunoglobulins within the scope of claim 28 that can be prepared, if at all, only by using methods not described or enabled by the '370 patent. The specification of the '370 patent likewise does not describe or enable the full scope of the humanized immunoglobulin chains, and the antigens to which they bind, that are claimed in claim 28.

Huang Decl., Ex. 2 at 10-11.

PDL contends that this disclosure consists of bare legal conclusions that would not satisfy even Rule 8 pleading standards. *See Ashcroft v. Iqbal,* 556 U.S. ----, ----, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009). (citation omitted) ("A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.' Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'").

However, after stating what admittedly is a legal conclusion in the opening sentence, the disclosure at issue here identifies the specific grounds for that conclusion. It goes on to state that the '370 patent provides very few examples of humanized immunoglobulins, and that only a subset of those fall within the scope of Claim 28. In addition, it alleges that Claim 28 captures humanized antibodies that do not have framework substitutions, but that the only example of such an antibody in the '370 patent falls outside Claim 28 and "is characterized as a resounding

failure." Opp. Mot. at 6.

While PDL claims that the disclosure leaves many important questions unanswered,[4] the Court concludes that the disclosure nonetheless meets the requirements of the local rules. PDL obviously has an in-depth understanding of its own patent specification. Based upon that knowledge of the specification, it can, for instance, determine which examples within the specification fall within the scope of claim 28.

Following the hearing on the instant motion, PDL submitted a letter to the Court requesting that the deadline for exchange of rebuttal expert reports be extended from March 9, 2010 to March 16, 2010.[5] Its request for additional time was based primarily upon the voluminousness of MedImmune's expert reports. Dkt. 414 at 1 (explaining that "MedImmune's expert invalidity reports...served on February 16, 2010, from two experts, comprised more than 66 pages of § 112(1) arguments – and nearly 300 pages of invalidity arguments in total.")

The Court's primary concern in considering an extension of the deadline for exchange of expert rebuttal reports is the potential prejudice to MedImmune if such an extension is granted. MedImmune contends that it will suffer prejudice even from a one-week extension for two reasons: (1) its experts on invalidity "have extremely busy schedules" and "any extension granted to PDL would narrow the already brief window of time MedImmune's experts will have prior to their depositions to read and analyze PDL's experts' reports", and (2) an extension would shorten the time period before trial during which the Court could consider case-dispositive motions. MedImmune Response at 7. While the Court is sympathetic to MedImmune's concern regarding its experts' busy schedules, an extension of one additional week would not appear to be unduly

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[4] "Which subset of examples is MedImmune referring to? And why are those not in the subset not 'within the scope'? More importantly, what immunoglobulins are 'within the scope' but not in the enabled and described 'subset,' why, and what is the evidence to support that?'" PDL Reply at 3.

[5] PDL's letter submission did not comply with Civil L.R. 7-3(d). The Court has addressed PDL's repeated noncompliance with the Civil Local Rules in its order on MedImmune's motion for a preliminary injunction, which was heard concurrently with the instant motion. *See* Order on Preliminary Injunction at 1, n. 1. The Court expects that this pattern will not continue.

prejudicial under the circumstances. MedImmune's concern regarding the impending trial date is more substantial, but in light of the status of the Court's criminal calendar and in view of the Court's intended disposition of other motions argued by the parties on February 26, 2010, it appears quite doubtful that the current trial date will hold. Accordingly, the deadline for exchange of rebuttal expert reports will be extended to Tuesday, March 16, 2010.

3. MedImmune's References to Prior Art

PDL moves to limit MedImmune's §§ 102 and 103 contentions to the specific prior art pincites MedImmune already has disclosed and to limit MedImmune's use of those pincites to the particular explanations and limitations for which they have been disclosed. MedImmune contends that no authority supports depriving it of the right to seek leave to amend its prior art references in the future if circumstances arise that would justify that action.

Patent Local Rule 3-6 contemplates this exact situation. Rule 3-6 states:

> Amendment of the Infringement Contentions or the Invalidity Contentions may be made only by order of the Court upon a timely showing of good cause. Nonexhaustive examples of circumstances that may, absent undue prejudice to the non-moving party, support a finding of good cause include...(b) recent discovery of material, prior art despite earlier diligent search.

Patent L.R. 3-6(b). While Rule 3-6 clearly predicts a party's discovery of prior art and subsequent desire to seek amendment of its contentions, it also cautions that leave to amend shall be granted only "absent undue prejudice." *Id.* PDL alleges that if leave to amend were granted allowing MedImmune to assert additional prior art it would suffer undue prejudice because fact discovery has ended and PDL no longer could prepare properly with respect to previously undisclosed references. MedImmune argues persuasively that a blanket prohibition would be premature at this stage of litigation. The Court always has the ability to permit additional discovery if necessary.

IV. ORDER

PDL's motion to strike MedImmune's invalidity contentions is DENIED. PDL's request to extend the deadline for the exchange of rebuttal expert reports from Tuesday, March 9, 2010 to Tuesday, March 16, 2010 is GRANTED.

IT IS SO ORDERED.

DATED: 3/4/2010

JEREMY FOGEL
United States District Judge