

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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HOFFMANN-LA ROCHE INC.,	:	
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Plaintiff,	:	Civil Action No. 07-4582 (SRC) (MAS)
	:	Civil Action No. 08-4051 (SRC) (MAS)
v.	:	Civil Action No. 10-4050 (SRC) (MAS)
	:	(consolidated with 07-4582 for all purposes)
ORCHID CHEMICALS &	:	
PHARMACEUTICALS LTD., ORCHID	:	
HEALTHCARE, ORCHID	:	
PHARMACEUTICALS INC., and	:	OPINION & ORDER
ORGENUS PHARMA INC.,	:	
	:	
Defendants.	:	
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CHESLER, U.S.D.J.

This matter comes before the Court on the motion by Plaintiff Hoffman-La Roche Inc. (“Roche”) to dismiss the third counterclaim and fifth affirmative defense asserted by Defendants Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare, Orchid Pharmaceuticals Inc., and Orgenus Pharma Inc. (collectively, “Defendants”). For the reasons stated below, the motion will be granted.

This matter involves several Hatch-Waxman actions for patent infringement. The cases have been consolidated for pretrial purposes and arise from the following facts. Briefly, Roche owns a number of patents directed to compounds and treatment methods associated with Roche’s osteoporosis drug Boniva®. Defendants are generic pharmaceutical manufacturers who have filed Abbreviated New Drug Applications seeking FDA approval to engage in the manufacture and sale of generic versions of Boniva® prior to the expiration of the Roche patents.

Plaintiff now moves to dismiss Defendants' third counterclaim. Defendants' third counterclaim seeks an order compelling Roche to change certain use codes published by the FDA for two patents at issue. The motion to dismiss the third counterclaim may be decided easily. Defendants' sole argument in opposition is that a case is pending before the Supreme Court which might change existing law, and so this Court should abstain from deciding this motion now. This Court construes this position as a concession that the third counterclaim is not valid under existing law. As to Defendants' third counterclaim, the motion to dismiss will be granted.

Plaintiff also moves to strike Defendants' fifth affirmative defense, which asserts that Plaintiff lacks standing to bring this suit for failure to own all rights to the patent at issue. Plaintiff contends that the Answer to the First Amended Complaint fails to plead sufficient facts to support the affirmative defense. Much of the briefing focuses on the issue of whether the Iqbal pleading standard should be applied to affirmative defenses. Viewing the situation in terms of Iqbal, however, raises some thorny legal issues. As Defendants note, it is not at all clear that the pleading standard for Rule 8(a) should apply to Rule 8(b), and this Court hesitates to resolve that legal problem at this time because of its thorniness. There is, instead, a more straightforward approach to take to deal with the problems raised by Defendants' having asserted a new defense but not disclosed supporting factual allegations, and that is provided by this district's Local Patent Rules.

L. Pat. R. 3.3 sets forth the disclosure requirements applicable to contentions of patent invalidity, including invalidity pursuant to 35 U.S.C. § 102(f). 35 U.S.C. § 102 states, in relevant part: "A person shall be entitled to a patent unless— . . . (f) he did not himself invent the subject matter sought to be patented."

Defendants argue that the fifth affirmative defense raises issues of standing and patent ownership, not of patent invalidity, and cites Isr. Bio-Engineering Project v. Amgen Inc., 475 F.3d 1256, 1263 (Fed. Cir. 2007): “issues of patent ownership are distinct from questions of inventorship.” This, of course, is true, in the abstract.

This Court will not examine this matter, however, purely in the abstract. Undercutting the niceties of analysis in the abstract are the realities of what Defendants actually argue in their opposition brief – arguments that entirely undermine the contention that the fifth affirmative defense is a pure issue of standing, untouched by inventorship. Defendants state openly that the issues of standing and ownership rest on fundamental issues of inventorship. In their opposition brief, Defendants state: “The issue is whether it is possible that Roche does not own all the rights of all the co-inventors of the ’634 patent.” (Defs.’ Opp. Br. 2.) And then: “The starting point for an analysis of patent ownership is determination of patent inventorship.” (Id.) This is a naked admission that Defendants’ affirmative defense rests on the foundation of a determination of patent inventorship.

Lastly, Defendants aptly summarize the standard for determination of inventorship by quoting from Pannu v. Iolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998). The Federal Circuit stated this standard in Pannu in the context of resolving a dispute over inventorship under § 102(f). Conspicuously absent from Defendants’ brief is a citation to any case which supports the proposition that there is a standard for determination of inventorship that exists independently of § 102(f).

This Court rejects Defendants’ attempt to squeeze the fifth affirmative defense through a loophole, safely outside the reach of the Local Patent Rules, by saying that this determination of

patent inventorship would not be related to an issue of patent invalidity. This Court finds that the fifth affirmative defense sufficiently implicates issues of inventorship, which sufficiently coincide with issues of inventorship raised by an invalidity defense under § 102(f), to trigger the requirements of L. Pat. R. 3.3(a). In regard to the fifth affirmative defense, Defendants have failed to make the disclosures required by L. Pat. R. 3.3(a).

As a remedy, this Court will grant Plaintiff's motion to strike the fifth affirmative defense. At the same time, however, this Court will grant Defendants leave to apply for permission to amend their invalidity contentions, pursuant to L. Pat. R. 3.7, contingent on their demonstrating good cause, as that provision requires, for their failure to timely comply with the disclosure requirements of L. Pat. R. 3.3(a).¹

This decision finds support in the Federal Circuit's approving discussion of very similar local patent rules in the Northern District of California:

Second, discovery is designed to allow the defendant to pin down the plaintiff's theories of liability and to allow the plaintiff to pin down the defendant's theories of defense, thus confining discovery and trial preparation to information that is pertinent to the theories of the case.

In practice the latter objective--allowing the parties to discover their opponent's theories of liability--has been difficult to achieve through traditional discovery mechanisms such as contention interrogatories. Answers to such interrogatories are often postponed until the close of discovery, or are amended as a matter of course during the discovery period. The local patent rules in the Northern District of California are designed to address this problem by requiring both the plaintiff and the defendant in patent cases to provide early notice of their infringement and invalidity contentions, and to proceed with diligence in amending those contentions when new information comes to light in the course of discovery. The rules thus seek to balance the right to develop new information in discovery with the need for certainty as to the legal theories.

¹ Should Defendants make the required demonstration of good cause, they will be granted leave to amend the Answer to assert appropriate counterclaims.

O2 Micro Int'l, Ltd. v. Monolithic Power Sys., 467 F.3d 1355, 1365-1366 (Fed. Cir. 2006)

(citations omitted). The same policy rationales motivate this district's Local Patent Rules, and Defendants have failed to distinguish their fifth affirmative defense from that class of contentions subject to these principles. Plaintiff has been entitled to early notice which pins down Defendants' theory of defense involving inventorship, and which Defendants have thus far failed to provide.

For these reasons,

IT IS on this 7th day of November, 2011

ORDERED that Roche's motion to dismiss the third counterclaim and fifth affirmative defense asserted by Defendants (Docket Entry No. 156) is **GRANTED**; and it is further

ORDERED that, as to Defendants' third counterclaim, Roche's motion to dismiss is **GRANTED**, and Defendants' third counterclaim is hereby **DISMISSED** with prejudice; and it is further

ORDERED that, as to Defendants' fifth affirmative defense, Roche's motion to strike is **GRANTED**, and the fifth affirmative defense is hereby **STRICKEN**; and it is further

ORDERED that, in regard to the fifth affirmative defense, Defendants are given leave to apply for permission to amend their disclosures under L. Pat. R. 3.3(a), as provided by L. Pat. R. 3.7.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.