IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Andrulis Pharmaceuticals Corp., Plaintiff, v. **Celgene Corporation,** Defendant.	Civil Action No. 13-1644-RGA

MEMORANDUM ORDER

Before the Court is Defendant Celgene Corporation's Motion to Dismiss Plaintiff's First Amended Complaint For Failure to State a Claim (D.I. 17) and related briefing. (D.I. 18, 19, 20). The Court heard oral argument on this motion on April 4, 2014.

Plaintiff alleges direct, induced, and contributory infringement. Defendant contends that Plaintiff has failed to state a claim. At oral argument, Plaintiff agreed to dismiss the contributory infringement claim without prejudice. Therefore, the contributory infringement claim is dismissed without prejudice.

As for the direct infringement claim, Plaintiff alleges two factually distinct direct infringement claims. The first is that Celgene itself directly infringes the claims because it administers the patented method, which Andrulis refers to as the undivided direct infringement claim. The second is that Celgene is a joint infringer because physicians administer the patented method under Celgene's direction and control, which Andrulis refers to as the joint direct infringement claim.

I find that Plaintiff's undivided direct infringement theory fails to state a claim. Andrulis alleges that Celgene itself administers the patented method because authorization is required from Celgene before a prescription will be filled. Andrulis contends that dismissal is inappropriate because the pleading complies with Form 18 and that any such dismissal would require construing the claims, which is inappropriate at the pleadings phase. While Andrulis is correct inasmuch as complying with Form 18 is the appropriate inquiry, the analysis is not limited to whether the form was simply parroted. "The touchstones of an appropriate analysis under Form 18 are notice and facial plausibility. While these requirements serve as a bar against frivolous pleading, it is not an extraordinarily high one. The adequacy of the facts pled depends on the breadth and complexity of both the asserted patent and the accused product or system and on the nature of the defendant's business activities." *K-Tech Telecommunications, Inc. v. Time Warner Cable, Inc.*, 714 F.3d 1277, 1286 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 1026 (U.S. 2014) (citations omitted).

Here, Andrulis' undivided direct infringement claim failed to provide notice or facial plausibility. At oral argument, Celgene stated it was not even aware that Andrulis accused it of practicing the patented method itself until receipt of Andrulis' answering brief. (*compare* D.I. 18 at 8, D.I. 20 at 1). This claim also fails because it is not facially plausible. Andrulis argues that claim construction is inappropriate at the pleading stage, and the claims should be afforded their broadest possible construction.[1] The Court need not engage in claim construction to dismiss this infringement theory. Andrulis does set forth factual allegations that Celgene administers

[1] I am always hesitant to engage in claim construction without a *Markman* hearing. On the other hand, the claim at issue is a method claim that cannot possibly be read to make direct infringers out of anyone other than the medical personnel who treat patients. Celgene is a drug manufacturer and distributor. There is no hint that it employs medical personnel who treat patients.

alkylating agents.[2] Even assuming that Celgene administers thalidomide via authorizing prescriptions, there is no plausible basis to infer that Celgene administers thalidomide in combination with an alkylating agent, as required by the claim. I therefore dismiss the undivided direct infringement claim.

I find that Plaintiff's joint direct infringement claim survives the motion to dismiss. Celgene argues that the complaint does not allege facts to support a plausible inference that Celgene "directs or controls" doctors' performance of the claimed method. Essentially, Celgene asserts that the allegations do not support a finding that prescribing doctors are agents of Celgene. I disagree. Andrulis has pled more than enough factual allegations describing the relationship between prescribing doctors and Celgene. Andrulis has alleged that Celgene exerts a high degree of control over the prescribing of thalidomide. Andrulis has also alleged that Celgene directs doctors to prescribe thalidomide in concert with alkylating agents by promoting off label uses of thalidomide. Given the number of factual allegations, I find that there is a plausible inference that Celgene "directs or controls" doctors' performance of the claimed method.

I also find that Plaintiff's induced infringement claim survives the motion to dismiss. The factual allegations for this claim are largely the same as the "direction" prong of the joint infringement claim. Celgene argues that disseminating publications about an unapproved use of a

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[2] The complaint states the conclusory claim that Celgene itself administers thalidomide with an alkylating agent. (D.I. 12 ¶ 107). However, the factual allegations do not support this conclusion. The only basis for asserting that Celgene administers alkylating agents is that Celgene authorizes the distribution of thalidomide, which may have been prescribed with an alkylating agent. Celgene sold an alkylating agent up until 2009. (D.I. 12 at ¶ 44). Even assuming that Celgene's veto power constituted administration of thalidomide, there is no allegation that Celgene had the power to veto the administration of an alkylating agent, if it were prescribed concurrently. The claim requires the administration of "thalidomide in combination with...[an] alkylating agent." ('346 patent claim 2). Alleging that Celgene administers just thalidomide is not enough. There must be an allegation that Celgene administers an alkylating agent as well. Merely selling an alkylating agent is not sufficient.

product does not serve as evidence of intent that the product be used for that unapproved use because the FDA guidelines allow for dissemination of these materials. What the FDA allows, while probably relevant, is not controlling on whether the conduct is probative of an intent to induce infringement. Celgene argues that the Court must consider the industry context, yet the cited case states, "a court must assess the facts in the context in which they occurred and from the standpoint of the speakers and listeners within that context." *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1340 (Fed. Cir. 2012). Just because the FDA labels materials as "non-promotional" does not mean that doctors do not view these materials as promoting off-label uses. Additionally, Andrulis has plausibly alleged that Celgene was aware of the patent. This allegation must also be taken into account in the overall "context." The fact that Celgene was aware of the patent and disseminated materials which it knew might be viewed as promoting that use is sufficient at this stage.

Defendant's motion (D.I. 17) is hereby **GRANTED IN PART** and **DENIED IN PART**. The claims of "undivided direct infringement" and "contributory infringement" are **DISMISSED WITHOUT PREJUDICE**. Leave to amend is not granted at this time.

Entered this 10th day of April, 2014.

Richard G. Andrews
United States District Judge