

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE LLC,

Plaintiff,

v.

BAXALTA INC., BAXALTA US INC., and
NEKTAR THERAPEUTICS,

Defendants.

No. 16-cv-1122-RGA

MEMORANDUM ORDER

Presently before the Court are the issues of (1) whether Plaintiff may seek pre-issuance damages under 35 U.S.C. § 154(d), and (2) Plaintiff's motion for leave to file an amended complaint (D.I. 346). I previously reviewed the parties' briefing on pre-issuance damages in the proposed pretrial order. (D.I. 326 at 11; D.I. 327, Sched. I). Per my instructions at the pretrial conference, the parties submitted additional letters, as well as letters on the motion for leave to file an amended complaint. I have reviewed the parties' letters. (D.I. 345, 347, 349, 351).

A. Section 154(d) Pre-Issuance Damages

Plaintiff seeks damages under 35 U.S.C. § 154(d) based on Defendants' actions prior to issuance of the '520 patent. Defendants argue that such pre-issuance damages are unavailable here as a matter of law. (D.I. 326 at 11).

Section 154(d) is a narrow exception to the general rule that damages are only available for infringement occurring after a patent is issued. *Rosebud LMS Inc. v. Adobe Sys. Inc.*, 812 F.3d 1070, 1073 (Fed. Cir. 2016). The statute provides the right to pre-issuance reasonable

royalties for infringement occurring “during the period beginning on the date of publication of the application of [the asserted] patent under [35 U.S.C.] section 122(b),” provided that the infringer “had actual notice of the published patent application,” and “the invention as claimed in the [asserted] patent is substantially identical to the invention as claimed in the published patent application.” 35 U.S.C. § 154(d)(1)–(2).

The parties dispute the meaning of “the published patent application.” The ’520 patent application (U.S. Patent App. Pub. No. 2010/0081615A1) was first published on April 1, 2010 with claims substantially different from the issued claims. (D.I. 327, Sched. I at 2–4; D.I. 345 at 1, Ex. 2). The applicants later amended the claims to be substantially identical to the issued claims. The amended claims were published in November 2011 to the application’s file wrapper on the Patent Office Public Patent Application Information Retrieval system (“Public PAIR”). (D.I. 327, Sched. I at 1–4). Plaintiff argues that under § 154(d), it may rely on the published application as amended by the November 2011 claims to seek pre-issuance damages. Defendants argues that § 154(d) limits the patentee to damages related to the initial published patent application, that is, the April 2010 application.

This appears to be an issue of first impression. Previous decisions under § 154(d) have focused on the “actual notice” and “substantially identical” requirements as applied to the initial published patent application. *See Rosebud*, 812 F.3d at 1073–75; *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F. Supp. 2d 569, 579–80 (D. Md. 2014); *Baseball Quick, LLC v. MLB Advanced Media L.P.*, 2014 WL 3728623, at *11–12 (S.D.N.Y. July 25, 2014); *Loops, LLC v. Phoenix Trading, Inc.*, 2010 WL 3041866, at *5–6 (W.D. Wash. July 30, 2010). To my knowledge, no court has addressed the question of whether a patentee may rely on amendments to the original published patent application for pre-issuance damages.

Neither the U.S. Code nor the Code of Federal Regulations (“C.F.R.”) explicitly defines “published patent application.” Section 154(d) states that it applies to patent applications published under 35 U.S.C. § 122(b). Likewise, the C.F.R. defines “[a] published application” as “an application for patent which has been published under 35 U.S.C. 122(b).” 37 C.F.R. § 1.9(c). Section 122(b) merely provides that “each application for a patent shall be published . . . promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought under [title 35 of the U.S. Code].” 35 U.S.C. § 122(b). Therefore, it is unclear from the plain language of the statute whether “the published patent application” in § 154(d) is limited to the initial published application or includes later amendments.

Based on other provisions of the C.F.R., however, it appears that the most natural reading of “the published patent application” is as the initial published document, not the entire file wrapper on Public PAIR. For example, section 1.215 states:

- (a) The publication of an application under 35 U.S.C. 122(b) shall include a patent application publication. . . . The patent application publication will be based upon the specification and drawings deposited on the filing date of the application, as well as the application data sheet and/or the inventor’s oath or declaration. The patent application publication may also be based upon . . . amendments to the claims that are reflected in a complete claim listing under § 1.121(c) [general procedure for amending claims], . . . provided that such substitute [] amendment is submitted in sufficient time to be entered into the Office file wrapper of the application before technical preparations for publication of the application have begun. Technical preparations for publication of an application generally begin four months prior to the projected date of publication.
. . . .
- (c) At applicant’s option, the patent application publication will be based upon the copy of the application (specification, drawings, and the application data sheet and/or the inventor’s oath or declaration) as amended, provided that applicant supplies such a copy . . . within one month of the mailing date of the first Office communication that includes a confirmation number for the application, or fourteen months of the earliest filing date for which a benefit is sought under title 35, United States Code, whichever is later.

37 C.F.R. § 1.215(a), (c). Under the C.F.R., the application published pursuant to section 122(b) includes a “patent application publication,” which is based on the initial filing materials and any amendments made within certain time periods in the early stages of prosecution. *See id.* Amendments are not included in the “patent application publication” unless they are supplied within those time periods. Therefore, later amendments, such as those in the November 2011 claims, would not be considered part of the “patent application publication.”

Therefore, I find “the published patent application” in § 154(d) is limited to the initial published application. As such, Plaintiff cannot seek § 154(d) pre-issuance damages based on the later amended November 2011 claims published to the application file wrapper.

B. Leave to File Amended Complaint

Plaintiff moves for leave to file an amended complaint to add (1) pre-suit infringement claims, and (2) infringement claims under 35 U.S.C. § 271(f).

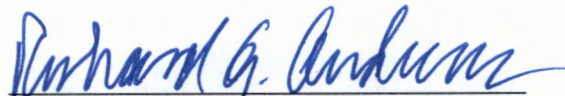
Although Federal Rule of Civil Procedure 15(a) governs amendments to the pleadings generally, Rule 16(b) also applies when a party moves to amend past the date set by the scheduling order. *E. Minerals & Chemicals Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000); *Media Pharm. Inc. v. Teva Pharm. USA, Inc.*, 2016 WL 6693113, at *1 & n.2 (D. Del. Nov. 14, 2016). Rule 16(b)(4) provides that “[a] schedule may be modified only for good cause and with the judge’s consent.” Fed. R. Civ. P. 16(b)(4). “Good cause is present when the schedule cannot be met despite the moving party’s diligence.” *Media Pharm.*, 2016 WL 6693113, at *1. “In contrast to Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party.” *S. Track & Pump, Inc. v. Terex Corp.*, 722 F. Supp. 2d 509, 521 (D. Del. 2010).

Plaintiff asserts that it did not acquire evidence supporting pre-suit infringement until the last month of fact discovery, June 2018. Plaintiff provides no explanation for why it did not move to add the pre-suit claims between June 2018 and now. Therefore, Plaintiff fails to show diligence under Rule 16(b).

Plaintiff also appears to have known since June 2018 that it was likely to assert claims under § 271(f). (D.I. 351 at 2). Plaintiff has been aware since at least June 7, 2018 that the claims were not in the complaint. (D.I. 176 at 1 (“Bayer did not assert a § 271(f) claim in its Complaint, and the time to amend has passed.”)). Again, Plaintiff provides no explanation for why it waited until now to move to add the § 271(f) claims, and thus fails to show diligence under Rule 16(b).

Therefore, Plaintiff’s motion for leave to file an amended complaint (D.I. 346) is **DENIED.**

IT IS SO ORDERED this 22 day of January 2019.


United States District Judge