UNITED STATES DISTRICT COURT
For the Northern District of California

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Northern District of California

SHIRE LLC, and SUPERNUS PHARMACEUTICALS, INC.,

Plaintiffs,

v.

IMPAX LABORATORIES, INC., WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC.–FLORIDA, WATSON PHARMA, INC., and ANDA, INC.,

Defendants.

No. C 10-5467 RS (MEJ)

DISCOVERY ORDER

Re: Dkt. No. 236

INTRODUCTION

This is a patent infringement action under the Hatch-Waxman Act, 35 U.S.C. 271(e). Plaintiff Shire LLC ("Shire") is an exclusive licensee of United States Patent Numbers 6,287,599 and 6,811,794. Both patents pertain to the manufacture and sale of guanfacine hydrochloride extended release tablets called Intuniv. Defendant Impax Labratories ("Impax") submitted Abbreviated New Drug Application number 202238 ("Impax ANDA"), seeking approval to engage in the commercial manufacture and sale of generic guanfacine hydrochloride extended release tablets. Shire claims that Impax infringed on their patents when Impax submitted the Impax ANDA.

DISCOVERY MOTION

Before the Court is Impax Laboratories, Inc.'s motion to compel responses to patent infringement contention interrogatories served upon Shire LLC, which seek Shire's infringement theories and evidence.

On February 26, 2013, the parties filed a joint letter regarding a discovery dispute over the adequacy of Shire's responses to Impax's infringement contention interrogatories ("ICs"). Jt. Ltr.,

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Dkt. No. 236. Impax asserts that these interrogatories are necessary to test the bases of Shire's allegations that Impax's products contain a "pH dependent agent, because Shire has yet to provide any evidence that Impax's products satisfy this claim limitation." *Id*. Under the Court's claim construction, determining whether a composition contains a "pH dependent agent" requires comparing "the rate of release of the drug "when the composition is in an environment having a pH above 5.5," to the rate of release of the drug "when the composition is in an environment of pH 5.5 or below." *Id*. (quoting Dkt. No. 180 at 11; 16-17). Impax contends that Shire's January 17, 2013 meet and confer letter is also inadequate because it does not apply any of its measurements to Impax's products or explain how they allegedly show infringement. *Id*.

Shire counters that the ICs comply with Patent Local Rule 3-1 and remain valid after the *Markman* Order, without need for amendment. *Id*. at 3-4. The ICs specifically set forth Shire's infringement theories on a claim by claim basis, and rely on and cite to Impax's ANDA dissolution data, which contains the only information about Impax's proposed products, and are thus fully responsive to the interrogatories. *Id*. Impax's ANDA dissolution data shows that the proposed products meet the claim limitation literally, or alternatively, under the doctrine of equivalents by (i) percent dissolved, (ii) incremental percent increase, or (iii) percent of previous increase. *Id*. at 4. Shire's responses to the interrogatories explained how each of these measurements were calculated. *Id*. Shire also objected to the interrogatories on the grounds that they call for expert discovery, which is not due until June 7, 2013.

As set forth below, the Court finds that Shire's responses to the infringement contention interrogatories are sufficient.

A. Legal Standard.

The Patent Local Rules of this District provide for a "streamlined mechanism to replace the series of interrogatories that accused infringers would likely have propounded in its absence." *FusionArc, Inc. v. Solidus Networks, Inc.*, No. C-06-06770 RMW (RS), 2007 WL 1052900, at *2 (N.D. Cal. Apr. 5, 2007) (quoting *Network Caching Tech., LLC v. Novell Inc*., No. C-01-2079-VRW, 2002 WL 32126128 (N.D. Cal. Aug. 13, 2002). As such, a plaintiff is required to include in its

infringement contentions all facts known to it, including those discovered in its Federal Rule of Civil Procedure 11 pre-filing investigation. *Network Caching Tech., LLC*, 2002 WL 32126128, at *4. The rules "require parties to crystallize their theories of the case early in litigation and to adhere to those theories once they have been disclosed." *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc*., 467 F.3d 1355, 1366 n. 12 (Fed. Cir. 2006); *see also Atmel Corp. v. Info. Storage Devices, Inc.*, C 95–1987 FMS, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998).

Patent Local Rule 3-1 requires a plaintiff in a patent infringement action to serve infringement contentions setting forth "[e]ach claim of each patent in suit that is allegedly infringed by each opposing party" and identifying for each asserted claim "each accused apparatus, product, device, process, method, act, or other instrumentality ("Accused Instrumentality") of each opposing party of which the party is aware." Patent L.R. 3-1(a), (b). A plaintiff must also provide a "chart identifying specifically where each limitation of each asserted claim is found within each Accused Instrumentality, including for each limitation that such party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in the Accused Instrumentality that performs the claimed function." *Id.* at 3–1(c). "The degree of specificity under Local Rule 3-1 must be sufficient to provide reasonable notice to the defendant why the plaintiff believes it has a 'reasonable chance of proving infringement.'" *Shared Memory Graphics LLC v. Apple, Inc.*, 812 F.Supp.2d 1022, 1025 (N.D. Cal. 2010) (quoting *View Eng'g, Inc. v. Robotic Vision Systems, Inc*., 208 F.3d 981, 986 (Fed. Cir. 2000)).

These rules do not, as is sometimes misunderstood, "require the disclosure of specific evidence nor do they require a plaintiff to prove its infringement case." *See DCG Sys. v. Checkpoint Tech., LLC*, No. C-11-3729-PSG, 2012 WL 1309161, at *2 (N.D. Cal. Apr. 16, 2012) (quoting *Whipstock Serv., Inc. v. Schlumberger Oilfied Sers*., No. C-09-113, 2010 WL 143720, at *1 (E.D. Tex. Jan. 8, 2010). "But to the extent appropriate information is reasonably available to it, a patentee must nevertheless disclose the elements in each accused instrumentality that it contends practices each and every limitation of each asserted claim." *Droplets, Inc. v. Amazon.com, Inc.*, 2013 WL 1563256, at *2 (N.D. Cal. Apr. 12, 2013).

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B. Discussion.

Impax served two interrogatories to test the bases of Shire's infringement theories. Interrogatory No. 1 asked Shire to describe in detail all factual and legal bases for their contention that Impax's products meet the claim limitations, and to identify all documents, tests or other evidence supporting Shire's contention. Jt. Ltr., Exh. 1 at 3:19-4:6. Interrogatory No. 2 asked Shire to identify all factual and legal bases for their claims that Impax's dissolution data ***do not*** satisfy, either literally or under the doctrine of equivalents, the claims limitations that require "at least one pH dependent agent that increases the rate of release the drug from the composition in an environment having a pH above 5.5 as compared to when the composition is in an environment of pH 5.5 or below." *Id.* at 5:6-16, emphasis in original.

Shire responded to both interrogatories by referring Impax to Shire's Infringement Contentions and stating that: "if the Impax formulations on the cited pages were to have all of the components of claim 1 of the '599 patent and claims 3 and 8 of the '794 patent and if the Court's construction of these claims were correct, those Impax formulations appear to meet the cited limitation literally or, alternatively, under the doctrine of equivalents, by one or more of the following measurements as reported: (i) percent dissolved over time, (ii) incremental percent increase over time, and (iii) percent of previous increase over time." *Id.* at 5:26-6-3. Shire's subsequent letter reiterated this language, but defined the various methods it used to determine infringement under the doctrine of equivalents. Jt. Ltr., Exh. 3 at 1. Shire's letter also disputed the accuracy of the Court's claim interpretation, but stated it stood by its infringement contentions as drafted. *Id*.

Under Rule 3-1(e), a party asserting infringement must disclose " [w]hether each limitation of each asserted claim is alleged to be literally present or present under the doctrine of equivalents in the Accused Instrumentality." A party asserting infringement under the doctrine of equivalents must provide specific analysis, on an element-by-element basis, as to its theory of why there is infringement under the doctrine. *GN Resound A/S v. Callpod, Inc.*, 2013 WL 1190651, at *6 (N.D. Cal. Mar. 21, 2013).

Shire's responses rely on the ICs, which state, on a claim-by-claim basis, which elements of Impax's ANDA products Shire alleges infringe literally or under the doctrine of equivalents. Shire also set forth, on an element-by-element basis, the specific theories of infringement by stating that Impax's own ANDA dissolution studies show that the proposed products meet the claim limitation under the doctrine of equivalents by (i) percent dissolved, (ii) incremental percent increase, or (iii) percent of previous increase. Dkt. 236 at 4. Shire's ICs also cite to Impax's ANDA dissolution studies. *Id*. Accordingly, Shire's infringement contentions are "sufficient to provide reasonable notice to the defendant why the plaintiff believes it has a reasonable chance of proving infringement" and "to raise a reasonable inference that all accused products infringe." *Infineon Technologies v. Volterra Semiconductor,* No. C-11-06239 MMC, 2013 WL 322570, at *3 (N.D.Cal., Jan. 28, 2013) (quoting *Shared Memory Graphics, LLC,* 2011 WL 3878388, at *4 (citations and quotation marks omitted)). Shire's infringement contention interrogatory responses, read in conjunction with the claim-by-claim analysis in the ICs, have identified all theories and evidence in Shire's possession that the patentee contends can be used to evaluate its claims of infringement. The interrogatory responses are thus fully responsive.

Accordingly, the Court DENIES Impax's motion to compel.

IT IS SO ORDERED.

Dated: April 25, 2013

Maria-Elena James
United States Magistrate Judge

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