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UNITED STATES DISTRICT COURT
Northern District of California

SHIRE LLC, and SUPERNUS
PHARMACEUTICALS, INC.,

No. C 10-5467 RS (MEJ)

Plaintiffs,

DISCOVERY ORDER

v.

Re: Dkt. No. 236

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

Defendants.

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 Laboratories (“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.,

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

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

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

22 **A. Legal Standard.**

23 The Patent Local Rules of this District provide for a “streamlined mechanism to replace the
24 series of interrogatories that accused infringers would likely have propounded in its absence.”
25 *FusionArc, Inc. v. Solidus Networks, Inc.*, No. C-06-06770 RMW (RS), 2007 WL 1052900, at *2
26 (N.D. Cal. Apr. 5, 2007) (quoting *Network Caching Tech., LLC v. Novell Inc.*, No. C-01-2079-VRW,
27 2002 WL 32126128 (N.D. Cal. Aug. 13, 2002). As such, a plaintiff is required to include in its
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1 infringement contentions all facts known to it, including those discovered in its Federal Rule of Civil
2 Procedure 11 pre-filing investigation. *Network Caching Tech., LLC*, 2002 WL 32126128, at *4. The
3 rules “require parties to crystallize their theories of the case early in litigation and to adhere to those
4 theories once they have been disclosed.” *O2 Micro Int’l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d
5 1355, 1366 n. 12 (Fed. Cir. 2006); *see also Atmel Corp. v. Info. Storage Devices, Inc.*, C 95–1987
6 FMS, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998).

7 Patent Local Rule 3-1 requires a plaintiff in a patent infringement action to serve infringement
8 contentions setting forth “[e]ach claim of each patent in suit that is allegedly infringed by each
9 opposing party” and identifying for each asserted claim “each accused apparatus, product, device,
10 process, method, act, or other instrumentality (“Accused Instrumentality”) of each opposing party of
11 which the party is aware.” Patent L.R. 3-1(a), (b). A plaintiff must also provide a “chart identifying
12 specifically where each limitation of each asserted claim is found within each Accused
13 Instrumentality, including for each limitation that such party contends is governed by 35 U.S.C. §
14 112(6), the identity of the structure(s), act(s), or material(s) in the Accused Instrumentality that
15 performs the claimed function.” *Id.* at 3–1(c). “The degree of specificity under Local Rule 3-1 must
16 be sufficient to provide reasonable notice to the defendant why the plaintiff believes it has a
17 ‘reasonable chance of proving infringement.’” *Shared Memory Graphics LLC v. Apple, Inc.*, 812
18 F.Supp.2d 1022, 1025 (N.D. Cal. 2010) (quoting *View Eng’g, Inc. v. Robotic Vision Systems, Inc.*,
19 208 F.3d 981, 986 (Fed. Cir. 2000)).

20 These rules do not, as is sometimes misunderstood, “require the disclosure of specific
21 evidence nor do they require a plaintiff to prove its infringement case.” *See DCG Sys. v. Checkpoint*
22 *Tech., LLC*, No. C-11-3729-PSG, 2012 WL 1309161, at *2 (N.D. Cal. Apr. 16, 2012) (quoting
23 *Whipstock Serv., Inc. v. Schlumberger Oilfield Sers.*, No. C-09-113, 2010 WL 143720, at *1 (E.D.
24 Tex. Jan. 8, 2010). “But to the extent appropriate information is reasonably available to it, a patentee
25 must nevertheless disclose the elements in each accused instrumentality that it contends practices
26 each and every limitation of each asserted claim.” *Droplets, Inc. v. Amazon.com, Inc.*, 2013 WL
27 1563256, at *2 (N.D. Cal. Apr. 12, 2013).

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1 **B. Discussion.**

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

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

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

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

16 Accordingly, the Court DENIES Impax’s motion to compel.

17 **IT IS SO ORDERED.**

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20 Dated: April 25, 2013

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23 Maria-Elena James
24 United States Magistrate Judge
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