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UNITED STATES DISTRICT COURT
Northern District of California

SHIRE LLC, and SUPERNUS
PHARMACEUTICALS, INC.,

No. C 10-05467 RS (MEJ)

Plaintiffs,

DISCOVERY ORDER

v.

Re: Dkt. No. 223

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 MOTIONS

On November 5, 2012, the parties filed a joint letter regarding certain discovery disputes. Jt. Ltr., Dkt. No. 223. In that letter, Shire contends that Impax’s production has been “only partially responsive or entirely non-responsive to about 95% of Shire’s [Request For Production of Documents]” and that Impax gives no “credible or sustainable reason why it has not or should not produce.” *Id.* at 2. Specifically, Shire has two claims: (1) that Impax has not produced any

1 electronically stored information related to employee-to-employee communication within Impax, or
2 communication between Impax and third parties, and (2) that Impax has not produced physical
3 samples of the raw materials used in Impax’s generic version of Intuniv.

4 Impax contends that Shire is withholding and refuses to produce relevant documents related to
5 other current guanfacine hydrochloride cases in which Shire is involved.

6 **A. Shire’s Motion to Compel**

7 Shire moves for an order compelling additional responses from Impax to the following
8 discovery requests:

- 9 1. Electronically Stored Information Related to Shire’s Second Set of Requests for
10 Production of Documents.¹

11 On October 19, 2012, following a meet and confer between the parties, Impax produced 5,535
12 pages of documents. *Jt. Ltr.* at 2. Shire contends that this production was “virtually devoid of
13 electronically stored information (“ESI”),” – specifically, information related to “why Impax is
14 proposing to market a copy cat product, the market research Impax did, the research and development
15 of its proposed infringing products, and more.” *Id.* Shire alleges that Impax has not fulfilled its
16 promise to produce additional discovery after implementing new software to adequately retrieve the
17 requested information. *Id.* at 3. In response, Impax claims that this is a non-issue and that any delay
18 was due to Shire originally providing overbroad search terms. *Id.* at 4. However, Impax contends
19 that Shire has since narrowed its search terms and that the requested information will be produced in
20 two to three weeks. *Id.*

21 Given that Impax does not object to producing such documents, and that it has stated that it
22 intends to produce the material Shire requests, the Court orders that Impax produce these documents

23 ¹ Shire does not contend that Impax has failed to respond or produce documents and things
24 particular to one request for production; rather, it argues that Impax has failed generally to respond
25 to its second set of RFPs. However, an example of what Shire is requesting from its second set of
26 RFPs is “Request for Production No. 71: ALL DOCUMENTS RELATING TO ANY agreements
27 between DEFENDANT AND third parties concerning the IMPAX ANDA PRODUCTS AND/OR
28 IMPAX ANDA, including those agreements relating to this action, expenses for this action, or the
distribution, marketing, sales, or promotion of the IMPAX ANDA PRODCUTS in the attention
deficit hyperactivity disorder market.” *Ex. B.* at 11, Dkt. No. 223.

1 within 14 days of the date of this Order.

2 2. Request For Production No. 93: Sufficient Quantities of Each Component of Each
3 Strength of IMPAX's Guanfacine Hydrochloride Extended Release Tablets to Make
4 Two Hundred (200) Tablets of Every Dosage Strength of IMPAX'S Guanfacine
5 Hydrochloride Extended Release Tablets.

6 Shire contends that Impax has not produced any samples of the components of Impax's ANDA
7 products and that these products are "necessary for Shire to study in light of the functions that various
8 individual components are alleged to perform or not to perform in Impax's product." Jt. Ltr. at 3. In
9 response, Impax states that it will not produce these samples due to the public availability of each of
10 the raw materials that make up its product. *Id.* at 5.

11 Given that Shire does not dispute that the raw materials of Impax's products are publically
12 available, the Court finds Shire can obtain these products from the open market and there is no need
13 for Impax to produce them for Shire. Therefore, the Court denies Shire's motion to compel Impax to
14 produce such samples.

15 **B. Impax's Motion to Compel**

16 Impax moves for an order compelling additional responses from Shire to Requests for
17 Production Nos. 4–8: Documents and things related to other Guanfacine Hydrochloride cases. Jt. Ltr.
18 at 6. Impax's requests are focused on a case that Shire litigated in Delaware last September. *Id.* at 5.
19 On October 19, 2012, following a meet and confer between the parties, Shire produced 1,318 pages
20 of documents related to other guanfacine hydrochloride cases. *Id.* at 1. Impax contends that Shire
21 has refused to produce necessary documents, and that any documents that were produced were overly
22 redacted. Impax alleges that Shire's claim of third-party confidentiality is overbroad given that
23 public disclosures were made during the Delaware trial and the "Delaware defendants' indication that
24 they would review and approve Shire's proposed redactions." *Id.* at 5. In response, Shire claims that
25 another court's protective order precludes Shire's counsel from seeing much of the information
26 requested. *Id.* at 3.

27 Since the Delaware defendants agreed to review any proposed redactions, the Court finds that
28 Shire can ensure that Shire will not violate any third party confidentiality or the Delaware court's

1 protective order by providing such documents to the Delaware defendants for their review and
2 approval. Accordingly, the Court orders Shire to produce documents to Impax after it has provided
3 the Delaware defendants with the proposed redactions. Shire shall also produce a privilege log
4 detailing its claimed privileges relating to Impax's requests for production.

5 **IT IS SO ORDERED.**

6 Dated: November 26, 2012



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8 Maria-Elena James
Chief United States Magistrate Judge

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