UNITED STATES DISTRICT COURT
For the Northern District of California

UNITED STATES DISTRICT COURT

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 10-05467 RS (MEJ)

DISCOVERY ORDER

Re: Dkt. No. 223

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 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

UNITED STATES DISTRICT COURT
For the Northern District of California

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

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

A. Shire's Motion to Compel

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

1. Electronically Stored Information Related to Shire's Second Set of Requests for Production of Documents.[1]

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

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

[1] Shire does not contend that Impax has failed to respond or produce documents and things particular to one request for production; rather, it argues that Impax has failed generally to respond to its second set of RFPs. However, an example of what Shire is requesting from its second set of RFPs is "Request for Production No. 71: ALL DOCUMENTS RELATING TO ANY agreements between DEFENDANT AND third parties concerning the IMPAX ANDA PRODUCTS AND/OR 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.

within 14 days of the date of this Order.

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

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

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

B. Impax's Motion to Compel

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

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

UNITED STATES DISTRICT COURT
For the Northern District of California

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

IT IS SO ORDERED.

Dated: November 26, 2012

Maria-Elena James
Chief United States Magistrate Judge

UNITED STATES DISTRICT COURT
For the Northern District of California