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E-Filed 8/4/09

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

ASTELLAS PHARMA, INC., et al,

NO. C 08-3466 JW (RS)

Plaintiffs,

**ORDER GRANTING IN PART
AND DENYING IN PART
MOTION TO COMPEL AND
DENYING MOTION FOR
SANCTIONS**

v.

IMPAX LABORATORIES, INC.,

Defendant.

I. INTRODUCTION

Pursuant to Rule 37 of the Federal Rules of Civil Procedure, plaintiffs Astellas Pharma, Inc., and Boehringer Ingelheim Pharmaceuticals, Inc., (collectively “Astellas”) move to compel discovery and, in a separate motion, for the imposition of sanctions against defendant Impax Laboratories, Inc. (“Impax”). Astellas also moves under Rule 36 of the Federal Rules of Civil Procedure to deem certain of Astellas’ first set of requests for admissions (“RFA”) admitted, or in the alternative, to compel further responses to those RFA’s. Lastly, Astellas contends that Impax failed to present an adequately prepared Rule 30(b)(6) witness. Impax opposes the motions.

II. BACKGROUND

In conjunction with an effort by Impax to obtain FDA approval for the sale of a generic version of Astellas’ drug Flomax, Astellas filed this patent infringement suit. The patent at issue¹

¹ U.S. Pat. No. 4,703,063 (hereinafter the “063 patent”).

1 concerns tamsulosin, the active ingredient in Astellas' drug. Impax buys the tamsulosin used in its
2 product from a third party supplier, Divis Laboratories Ltd. ("Divis"), located in India. Impax has
3 moved for summary judgment on the ground that the claims of the '063 patent are invalid for double
4 patenting,² and on the alternative grounds that Astellas' claims are invalid for lack of written
5 description and lack of enablement. Impax's motion for summary judgment was heard by the
6 presiding judge on June 6, 2009, and is currently under submission.

7 During the discovery process, Astellas sought numerous documents relating to Impax's
8 potentially infringing tamsulosin product, including Impax's complete Abbreviated New Drug
9 Application ("ANDA") and the supporting Drug Master File ("DMF"). On March 19, 2009, Impax
10 produced the entire ANDA. On March 20, 2009, Astellas served a Rule 30(b)(6) notice on Impax,
11 and served a second such notice on May 4, 2009 covering various topics.³ The deposition took place
12 on May 12, 2009.

13 In April 2009, Astellas submitted several RFA's seeking full disclosure of the factual basis
14 and any expert evidence on which Impax will rely in support of its invalidity defenses and for
15 information on the processes by which Impax's tamsulosin product is made. On May 8, 2009,
16 Impax produced documents disclosing the processes for making tamsulosin. On May 12, 2009,
17 Impax's third party supplier Divis produced documents in response to a subpoena. Astellas received
18 Impax's supplemental discovery request responses on May 13, 2009.

19 On May 18, 2009, Astellas informed Impax of its view that its discovery responses were
20 deficient. Astellas also notified Impax of its intent to seek sanctions unless Impax was willing to
21 reimburse Astellas for reasonable expenses resulting from Impax's alleged discovery abuses.
22 Astellas sent a follow-up email on May 26, 2009. Impax responded the same day and, according to
23 Astellas, made clear that it was unwilling to compensate Astellas and supplement its responses to

24
25 ² The double patenting claim comes in light of an earlier, now expired, patent, U.S. Pat.
26 No. 4,373,106 (hereinafter the "'106 patent"), also owned by Astellas Pharma, Inc., that covers a
process for making tamsulosin.

27 ³ The topics on which Astellas sought to depose Impax's designee included: the
28 processes used to make and purify tamsulosin, the source and basis for the chemistry section in
Impax's ANDA, correspondence between Impax and its supplier, and Impax's April 20, 2009
responses to Astellas' discovery requests.

1 Astellas' RFA's Nos. 1-5 and 11-12. Astellas replied to Impax via letter and phone on May 27,
2 2009 to confirm Impax's refusal and communicate its intention to seek sanctions.

3 Alleging that Impax has failed to cooperate during the discovery process, Astellas filed this
4 motion to compel and motion to determine the sufficiency of Impax's responses to its first set of
5 RFA's on May 28, 2009. Astellas additionally filed a separate motion for sanctions under Rule 37
6 of the Federal Rules of Civil Procedure.

7 III. DISCUSSION

8 a. Motion to Compel Discovery

9 1. Legal Standard

10 Under the Federal Rules of Civil Procedure, parties may obtain discovery of any
11 nonprivileged matter that is relevant to any party's claims or defenses, or "for good cause,"
12 discovery of any matter relevant to the subject matter involved in the action. Fed. R. Civ. P.
13 26(b)(1). "Relevant information need not be admissible at the trial if the discovery appears
14 reasonably calculated to lead to the discovery of admissible evidence." *Id.* District courts have
15 broad discretion in resolving whether the information sought is relevant for discovery purposes.
16 *Survivor Media, Inc. v. Survivor Prods.*, 406 F.3d 625, 635 (9th Cir. 2005). While the Federal
17 Rules of Civil Procedure allow for liberal discovery, a party is not entitled to take discovery on
18 materials not reasonably calculated to lead to the discovery of admissible evidence. Fed. R. Civ. P.
19 26(b)(1).

20 A party may make a motion for an order to compel a disclosure pursuant to Fed. R. Civ. P.
21 37(a)(1). The Federal Rules provide that an evasive or incomplete disclosure, answer, or response is
22 to be treated as a failure to disclose, answer, or respond. Fed. R. Civ. P. 37(a)(3). Furthermore,
23 parties are under a duty to provide discovery regarding those facts that they know about as well as
24 those of which they reasonably ought to have been aware. *Arthur v. Atkinson Freight Lines Corp.*,
25 164 F.R.D. 19, 20-21 (S.D.N.Y. 1995).

26 2. Discussion

27 Astellas contends that it has adequately demonstrated the relevance of the requested
28 materials, and that Impax's responses to its discovery requests are deficient. While there is a dispute

1 regarding the history of document production, with Astellas contending that Impax has unduly
2 delayed its production of responsive materials such as the ANDA, Impax insists it has now produced
3 all relevant documents. Astellas responds that the paucity of produced documents in areas such as
4 agreements between Impax and Divis indicate that an inadequate search has been undertaken. While
5 disputing such an inference, at the hearing on the motion counsel for Impax offered to conduct a
6 further review. Accordingly, within twenty days of the date of this order, Impax will conduct a
7 further review and will produce all documents responsive to Astellas' requests for production.

8 b. Sufficiency of Impax's Responses to Astellas' RFA's

9 Astellas claims that Impax's responses to its first set of RFA's constitute incomplete and
10 evasive denials that should be deemed insufficient and therefore admitted pursuant to Rule 36(a)(6)
11 of the Federal Rules of Civil Procedure. Impax denies Astellas' characterization of its responses and
12 requests that the motion either be denied outright or, in the alternative, that Impax be accorded the
13 opportunity to supplement those responses.

14 1. Legal Standard

15 Under Rule 36 of the Federal Rules of Civil Procedure, a party may serve on another party a
16 written request to admit the truth of the matters within the scope of Rule 26(b)(1), relating to the
17 facts, the application of law to fact, opinions, and the genuineness of any described documents. The
18 party receiving the request for admissions has thirty days to provide a written answer or objection
19 addressed to the matter, otherwise it will be deemed admitted. Fed. R. Civ. P. 36. If a matter is not
20 admitted, however, the answer provided must specifically deny or state in detail why the answering
21 party cannot truthfully admit or deny. *Id.* The answering party may assert lack of knowledge or
22 information as a reason for failing to admit or deny only if the party states that it has made a
23 reasonable inquiry. *Id.*

24 2. Discussion

25 i. RFA's 1-5 and 11-12

26 Astellas' RFA's Nos. 1-5 ask Impax to admit as of February 4, 1981, the compounds of
27 claim [1, 4, 8, 10 & 14] of the '063 patent could be manufactured using processes other than the
28 process set forth in claim 3 of the '106 patent. Astellas' RFA's Nos. 11 & 12 ask Impax to admit

1 that the tamsulosin in Impax's ANDA will not be manufactured using the process of [claims 3 and 4]
2 of the '106 patent. According to Impax, it responded to both requests informing Astellas that
3 although it had made reasonable inquiries, it had insufficient information to admit or deny the
4 RFA's. Impax additionally contends that Astellas' RFA's require an infringement analysis that is a
5 mixed question of law and fact requiring expert testimony.

6 While Impax's supplier, Divis, may be the entity with the most direct knowledge on the
7 questions underlying the requests, that does not relieve Impax from providing a more thorough
8 response to requests about which it too presumably has knowledge or contentions. Accordingly,
9 within sixty days of the date of this order, Impax will supplement its responses to RFA numbers 1-5
10 and 11-12.

11 ii. RFA's 29 and 30

12 Astellas' RFA numbers 29 and 30 seek information concerning when Impax knew about
13 defenses that were asserted in the prior *Ranbaxy* case.⁴ Astellas claims that this information is
14 relevant to Impax's delay in asserting its written description and enablement defenses. As Impax
15 observes, however, these questions are no longer relevant in light of the decision of the presiding
16 judge to grant Impax leave to amend its pleadings to include such defenses. Accordingly, no further
17 response to RFA's 29 and 30 will be required and Impax's responses are deemed sufficient.

18 c. Impax's Rule 30(b)(6) Witness

19 1. Legal Standard

20 Pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, a party may name as the
21 deponent a public or private corporation. The deposition notice must name the party and describe
22 with reasonable particularity the matters for examination. Fed. R. Civ. P. 30(b)(6). A deposition
23 notice is sufficiently particular when it is relevant to the case's underlying claims, covers a
24 reasonable period of time, and is narrowly tailored. *LG Display Co., LTD v. Chi Mei*
25 *Optoelectronics Co.*, No. 08-2408-L(POR), 2009 WL 223585, at *2 (S.D. Cal. Jan. 28, 2009). The
26 named organization must then designate one or more officers, directors, or managing agents to

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28 ⁴ *Astellas Pharma, Inc. v. Ranbaxy, Inc.*, 255 F. App'x 512 (D.N.J. 2007) (involving
the same patent at issue in the current litigation).

1 testify on its behalf. *Id.* The persons designated must testify about information known or reasonably
2 available to the organization. *Id.*

3 2. Discussion

4 Astellas argues that Impax failed to produce an adequately prepared Rule 30(b)(6) witness.
5 In response to Astellas’ second deposition notice, Impax produced Mr. Richard Ting, Impax’s senior
6 vice president for generic product development, who has been with the company since 1995 as an
7 analytical chemist. Astellas, however, argues that Mr. Ting was not knowledgeable or prepared on
8 the noticed topics and that Impax terminated the deposition after only three hours, contrary to the
9 presumptive seven hour time allotted under the Federal Rules.

10 In response, Impax contends that its witness provided responsive testimony even though the
11 deposition questioning focused on how third party Divis manufactures tamsulosin. In his deposition,
12 Mr. Ting explained that Impax’s expertise is in the formulation and not the production of underlying
13 compounds or chemical synthesis of such compounds, which is why Impax obtains its compounds
14 from a third party supplier. Impax additionally claims that it gave Astellas advance notice the
15 witness would only be available for three hours and points out that Astellas never asked to continue
16 the deposition or to meet and confer before bringing this motion, to which Astellas responds that it
17 would have been futile to continue a deposition with a wholly unprepared witness.

18 While it appears that Mr. Ting may not have been adequately prepared for some of the
19 noticed deposition topics, Impax has produced an acceptable Rule 30(b)(6) witness. The parties are
20 ordered to meet and confer and then resume the Rule 30(b)(6) deposition of Mr. Ting within thirty
21 days of the date of this order.

22 d. Sanctions

23 1. Legal Standard

24 A court may impose sanctions as part of its inherent power to manage its docket. *Chambers*
25 *v. NASCO, Inc.*, 501 U.S. 32, 43 (1991). A court may also impose sanctions pursuant to Rule 37
26 against a party who “fails to obey an order to provide or permit discovery.” Fed. R. Civ. P.
27 37(b)(2)(A). The purpose of Rule 37 sanctions is to ensure compliance with discovery orders.
28 *Grimes v. City and County of San Francisco*, 951 F.2d 236, 241 (9th Cir. 1991). It is within the

1 broad discretion of the district court to decide whether or not sanctions are appropriate. *See Yeti by*
2 *Molly, Ltd. v. Deckers Outdoor Corp.*, 259 F.3d 1101, 1006 (9th Cir. 2001). The court's inherent
3 power to impose sanctions must be exercised with restraint and discretion. *See Chambers*, 501 U.S.
4 at 44-45.

5 2. Discussion

6 Astellas claims it has unsuccessfully attempted to resolve its discovery disputes with Impax
7 without judicial intervention. Accordingly, Astellas contends that Impax should reimburse it for
8 reasonable expenses it incurred as a result of Impax's alleged discovery abuses, such as those
9 incurred in filing the motion to compel and those resulting from Impax's failure to produce the
10 requested discovery and timely supplement its discovery responses. Impax contends, however, that
11 it has cooperated throughout the discovery process and has provided Astellas with all the documents
12 responsive to its numerous requests. Impax also argues that Astellas has not made a showing of bad
13 faith or prejudice to warrant the imposition of sanctions.

14 The record on these motions does not support a finding that Impax has failed to abide by its
15 discovery obligations, let alone any showing of bad faith or wilful refusal to comply with such
16 obligations. No sanctions award, therefore, is warranted.

17 IV. CONCLUSION

18 For the reasons set forth above, Astellas' motion for sanctions is denied and its motion to
19 compel is granted in part and denied in part as follows:

20 (1) Astellas' motion to compel discovery is granted to the extent that Impax is ordered to
21 renew its search for responsive documents, including any supply on technical agreements with Divis
22 regarding tamsulosin, and produce within twenty days of the date of this order any such materials
23 discovered.

24 (2) Astellas' motion to determine the sufficiency of RFA's 1-5 and 11-12 is granted to the
25 extent that Impax must supplement its responses within sixty days of the date of this order.

26 (3) Astellas' motion to deem RFA numbers 29 and 30 as admitted or to require further
27 response is denied.

28 (4) Astellas' motion for sanctions is denied.

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(5) The parties are ordered to meet and confer regarding the Rule 30(b)(6) deposition of Mr. Ting, which is to be completed within thirty days of the date of this order.

IT IS SO ORDERED.

Dated: 8/4/09



RICHARD SEEBORG
United States Magistrate Judge