

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

07 28 2017
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In the Matter of)
)
)
Impax Laboratories, Inc.,)
a corporation,)
)
Respondent)
_____)

ORIGINAL

DOCKET NO. 9373

COMPLAINT COUNSEL'S MOTION TO COMPEL
PRODUCTION OF PERFORMANCE REVIEW S FOR IMPAX WITNESSES

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Dated: July 28, 2017

UNITED STATES OF AMERICA

Throughout the first half of 2010, Impax prepared to launch its generic version of Opana ER at the expiration of the ~~Harlow~~ ^{Maxman} 30-month stay on June 14, 2010, even if the patent challenge remained unresolved. Such generic entry is commonly referred to as an “~~risk~~ launch.”

Complaint ¶ 41 On February 7, 2017, Impax served its Answer to the Complaint, in which denied that it was preparing to launch ~~risk~~. See Answer ¶ 41.

At the initial Case Scheduling Conference in this case, Impax’s counsel emphatically doubled down on its position that Impax never would have launched its generic version of ER at risk.

What you heard Complaint Counsel say is we would have launched at risk, which a small company like Impax doesn’t do. . . . The idea that we were going to launch at risk is folly. . . . So I look forward to how they are going to prove that we would have launched at risk.

February 16, 2017 Hearing Transcript at 61:16-63:4.

To gather additional evidence that Impax was prepared to launch its generic Opan June 2010, Complaint Counsel issued Request for Production No. 2 from its Third Set of Requests for Production. This request sought relevant performance reviews for Impax do custodians and witnesses

For any current or former Impax employee identified by Impax as a custodian in the FTC Endo Investigation or noticed or subpoenaed for a deposition by the FTC in this proceeding, all documents containing or reflecting personnel reviews or evaluations (whether in draft or final form) that relate to oxymorphone ER, Opana ER, IPX-066, IPX-066a, IPX203, the Opana ER Settlement and License Agreement (including but not limited to the Endo Credit), or the Development and Co-Promotion Agreement.

Declaration of Nicholas Leefer (“Leefer Declaration”) Exhibit A at These performance reviews are likely to be a reliable source of information about the accomplishments of Imp

¹ To be clear, Complaint Counsel does not need to prove that Impax would have launched its generic Opan product in 2010 to demonstrate that Impax’s agreement with Endo was anticompetitive. In *FTC v. the* ~~re~~ ^{avis} Supreme Court explained that “[t]he ~~real~~ ^{relevant} anticompetitive harm” from a reverse payment agreement is the elimination of the “risk of competition.” 133 S.Ct. 2223, 2236 (2016). Here, evidence about Impax’s readiness at capacity to launch its generic product prior to 2013 is relevant to showing potential competition from Impax posed a substantial risk to Endo’s lucrative drug franchise.

employees, including accomplishments relating to generic OpartaUBh preparations.
Nevertheless, Impax refused to produce responsive documents, objecting that the requested documents were not relevant and that finding responsive documents would be unduly burdensome because personnel records predating 2016 are stored “in hard copy only, in offsite facilities.” *Id.*

During the parties’ meet and confer communications, Complaint Counsel o3(e)ffdc

approval in June 2010. In a draft 2010 evaluation, however, the Senior Vice President of Operations touted the completion of launch preparations for oxymorphone (the generic name of the active ingredient of Opana ER) as a significant accomplishment for 2010. ~~See~~ Declaration Exhibit C at 2. Complaint Counsel is entitled to the final version of this review, well as similar documents for this employee and others on Impax's preliminary witness list.

(2) *Value of the settlement agreement:* Complaint Counsel and Impax disagree about the value of the settlement agreement to Impax at the time it was executed. ~~Complaint Counsel~~ whether Impax employees viewed any provisions as a payment. Impax employees responsible for the negotiation likely would have included statements about their role, and the impact of the agreement on the company, in performance reviews. Such evidence could shed light on the value of the agreement to Impax at the time it was executed. ~~Complaint Counsel~~ (gs) 2 (e) 4 (a) 2 (b) 2 (c) 2 (d) 2 (e) 2 (f) 2 (g) 2 (h) 2 (i) 2 (j) 2 (k) 2 (l) 2 (m) 2 (n) 2 (o) 2 (p) 2 (q) 2 (r) 2 (s) 2 (t) 2 (u) 2 (v) 2 (w) 2 (x) 2 (y) 2 (z)

did not impose an undue burden). *C.f.*, *American Intern. Specialty Lines Ins. Co. v. NMI Inc.*, 240 F.R.D. 401, 412-13 (N.D. Ill. 2007) (notwithstanding the burden of reviewing 19,000 k of documents in storage ordering the parties to work together to create a discovery plan t review those documents). Impax has not explained why searching the employees' personnel files from a limited time period to locate responsive performance reviews is unduly burdens in view of the highly relevant nature of those documents.

Finally, Complaint Counsel's request does not raise undue privacy concerns. Com Counsel is not seeking the employees' personnel files for these thirteen witnesses. *See generally Regan–Touhy v. Walgreen Co.*, 526 F.3d 641, 648 (10th Cir. 2008) (“Personnel files often contain sensitive personal information . . . and it is not unreasonable to be cautious ordering their entire contents disclosed willyilly.”). Instead, this request is narrowly tailored seek only relevant performance reviews, only from those current and former employees t Impax may call to testify at trial, and only from the most relevant time period. Courts have granted similar focused requests for performance reviews. *See Gessling v. Group Long Term Disability Plan*, 639 F. Supp. 2d 947, 948 (S.D. Ind. 2009) (“The Plan has cited a few deci that deny discovery of reviewing employees' personnel files based on undue burden and intrusiveness. The request for evaluations and reviews is more focused, however *emphatically in original*); *Zewdu v. Citigroup Long Term Disability Plan*, 264 F.R.D. 622, 629 (N.D. Cal. 2010) (ordering production of “performance evaluations of medical professionals involvec handling of Plaintiff's claim”). *See also Regan–Touhy* 526 F.3d at 648 (“This is not to say personnel files are categorically off bounds . . . had Ms. Touhy issued a more narrowly targeted request . . . we would face a very different question.”).

² In any case, Impax could designate such documents as confidential under the protective order, which would protect any sensitive information.

CONCLUSION

For the reasons stated above, Complaint Counsel's Motion to Compel should be g

Respectfully submitted,

/s/ Nicholas A. Leeper

STATEMENT REGARDING MEET AND CONFER

The undersigned counsel certifies that Complaint Counsel conferred with Respondent's counsel in a good faith effort to resolve by agreement the issues raised by Respondent's Objections and Responses to Complaint Counsel's Third Set of Requests for Production. On July 7, 2017, Complaint Counsel (Nicholas Leefler) responded to Impax's objections and asked to meet and confer. On July 12, 2017, Complaint Counsel (Nicholas Leefler) and Respondent's Counsel (Anna Fabish) met and conferred, at which point Complaint Counsel proposed a compromise. And on July 21, 2017, Respondent's Counsel (Anna Fabish) communicated via email to Complaint Counsel (Nicholas Leefler) that Complaint Counsel's proposed compromise was rejected.

Dated: July 28, 2017

Respectfully submitted,

/s/ Nicholas A. Leefler

Nicholas A. Leefler
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of)	
)	
)	
Impax Laboratories, Inc.,)	
a corporation,)	DOCKET NO. 9373
)	
Respondent)	

[PROPOSED] ORDER

Having carefully considered Complaint Counsel's Motion to Compel Production of Performance Reviews for Impax Witnesses, Respondent's Opposition thereto, all supporting evidence, and the applicable law, it is hereby ORDERED that Complaint Counsel's Motion to Compel Production of Performance Reviews for Impax Witnesses is GRANTED and it is ORDERED that, no later than August 11, 2017, Respondent shall produce personnel review responsive to Request for Production No. 2 from Complaint Counsel's Third Set of Request for Production for current and former employees on Impax Laboratories, Inc.'s preliminary witness list.

ORDERED:

D. Michael Chappell
Chief Administrative Law Judge

CERTIFICATE OF SERVICE

I hereby certify that on July 28, 2017, I filed the foregoing documents electronically using the FTC's eFiling System, which will send notification of such filing to:

Donald S. Clark
Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580 Fed2

CERTIFICATE FOR ELECTRONIC FILING

I certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

July 28, 2017

By: /s/ Nicholas A. Leefler
Attorney

UNITED STATES OF AMERICA

5. Exhibit C is a true and correct copy of a document used at the deposition of Mr. Chuck Hildenbrand, marked as exhibit number CX2899, and bearing bates numbers Impax_Opana_PartIII_0024286-88.

I declare under the penalty of perjury that the foregoing is true and correct. Executed this 28th day of July, 2017 in Washington, DC.

/s/ Nicholas A. Leefer

Exhibit A

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

In the Matter of:

IMPAX LABORATORIES, INC.,
a corporation.

Docket No. 9373

**RESPONDENT IMPAX LABORATORIES, INC.'S OBJECTIONS AND RESPONSES
TO COMPLAINT COUNSEL'S THIRD SET OF REQUESTS FOR PRODUCTION OF
DOCUMENTS**

Pursuant to the Federal Trade Commission's Rules of Practice, 16 C.F.R. §3.37, Respondent Impax Laboratories, Inc. ("Impax") hereby objects and responds to Complaint Counsel's Requests for Production of Documents ("Requests") dated May 30, 2017. Impax's objections and responses are based upon information presently known to Impax. Impax reserves the right to amend, modify, or supplement these objections and responses, and therefore the absence of an objection to any Request does not constitute a waiver of any general or specific objection or privilege.

GENERAL OBJECTIONS

These objections apply to all document Requests as though set out as specific objections immediately following each document Request:

1. Impax objects to each Request to the extent it is vague, ambiguous, overbroad, unduly burdensome, and/or fails to describe the information sought with reasonable particularity.
- 2.

Requests constitutes an admission that any responsive documents are within the possession, custody, or control of Impax.

5. Impax's agreement to search for and make available any particular document or documents shall not be construed as or deemed to be a representation either that responsive information exists or that such information is in Impax's possession, custody, or control.
6. Impax objects to each Request to the extent it does not contain reasonable time limits.
7. Impax objects to the Requests to the extent they call for information that is protected by the attorney-client privilege, the joint prosecution privilege, the joint defense privilege, the work-product doctrine, or any other privileges, protections, or doctrines of similar effect. To the extent Impax inadvertently produces any information protected by the attorney-client privilege, the joint prosecution privilege, the joint defense privilege, the work-product doctrine, or any other privilege or protection, such production is not intended to and shall not operate as a waiver of any applicable privilege or protection with respect to that document and/or information, or any other document and/or information. Impax reserves the right to demand that Complaint Counsel return any such information and/or documents or copies thereof. If Impax notifies Complaint Counsel that an inadvertent disclosure has occurred, Complaint Counsel must immediately return the inadvertently produced privileged material to Impax, including any copies, must not use or disclose the information, and must take reasonable steps to retrieve the information if Complaint Counsel disclosed such information before being notified. If the production or identification of a document is deemed by this Court to be a waiver of any privilege or immunity, the waiver shall be a limited waiver pertaining to that document only.

8. Impax objects to each Request to the extent that it requires or purports to require Impax to locate and produce “all” documents. Subject to its objections, Impax will respond to the Requests by conducting a reasonable search of those files at Impax that are reasonably believed to possess potentially responsive documents.

9. Impax objects to the Requests to the extent that the burden or expense of the proposed discovery outweighs its likely benefit.

10. Impax objects to the Requests to the extent they seek to impose obligations different from, or in excess of, those required or authorized by the Federal Trade Commission’s Rules of Practice or any applicable order or rule of this Court.

11. Impax’s discovery and investigation into the matters specified are continuing.

Accordingly, Impax reserves its right to supplement, alter, or change its responses and objections to the Requests and to provide additional responsive documents that Impax has in its possession, custody, or control at the time the Requests were propounded, in the manner and to the extent required by the Federal Trade Commission’s Rules of Practice. Furthermore, Impax reserves the right, during any proceedings in this action, to rely on documents, evidence, and other matters in addition to the information provided in response to the Requests, whether or not such documents, evidence, or other matters are newly discovered or are now in existence but have not been located despite diligent and good faith efforts.

12. Impax’s production of any documents is not a waiver of any of the objections set forth herein or an admission or acknowledgment that such information is relevant to the subject matter of this action. Further, these responses are without prejudice to and not a waiver of (a) Impax’s right to contend at any proceeding in this action that such

information is inadmissible, irrelevant, immaterial, or not a proper basis for discovery;
and (b) any objection by Impax to any future use of such information that Complaint
Counsel may attempt to make. Impax construes the Requests as requiring it to engage in,
and it has engaged in, reasonable inquiry about the specific matters referenced therein.

13.

broad, or unduly burdensome; (ii) are inconsistent with the ordinary and customary meaning of the words or phrases they purport to define; and (iii) seek to impose obligations different from, or in excess of, those created by the Federal Trade Commission's Rules of Practice. Without limiting the generality of this objection, Impax specifically objects to the following:

- A. Impax objects to the definition of the terms "Impax" and "the Company" in Definition 1 to the extent they purport to include third-party "agents," "consultants," "representatives," or "affiliates" on the grounds that the definition is vague, ambiguous, overly broad, and/or unduly burdensome.
- B. Impax objects to the definition of the term "agreement" in Definition 3 to the extent it purports to include any "oral or written . . . understanding," even if informal, on the grounds that the definition is vague, ambiguous, overly broad, and/or unduly burdensome.
- C. Impax objects to the definition of "At Risk" in Definition 5 to the extent the definition is vague and ambiguous.
- D. Impax objects to the definition of the term "Endo" in Definition 14 to the extent it purports to include third-party "agents," "consultants," "representatives," or "affiliates" on the grounds that the definition is vague, ambiguous, overly broad, and/or unduly burdensome.
- E. Impax objects to the definition of the term "Generic Opana ER" in Definition 16 to the extent it purports to include any ANDA product that references Reformulated Opana ER (NDA No. 201655) and thus does not discriminate between different formulations of Opana ER.

- F. Impax objects to the definition of the term “Opana ER” in Definition 18 to the extent it purports to include both Reformulated Opana ER (NDA No. 201655) and Opana ER and thus does not discriminate between different formulations of Opana ER.
 - G. Impax objects to the definition of the term “Penwest” in Definition 22 to the extent it purports to include third-party “agents,” “consultants,” “representatives,” or “affiliates” on the grounds that the definition is vague, ambiguous, overly broad, and/or unduly burdensome.
 - H. Impax objects to the definition of the term “Opioid Products” to the extent that the definition is vague, ambiguous, and potentially under-inclusive, and to the extent it purports to define any market, sub-market, or market segment.
16. To the extent that Impax adopts any term defined by Complaint Counsel, it is adopted solely for convenience in responding to Complaint Counsel’s Requests for Production of Documents, and Impax does not accept or concede that any of the terms or definitions contained therein are appropriate, descriptive, or accurate.
17. Impax objects to Complaint Counsel’s Instructions to the extent that they purport to impose burdens and requirements upon Impax that exceed or differ from the requirements of the Federal Trade Commission’s Rules of Practice. Without limiting the generality of this objection, Impax specifically objects to the following:
- A. Impax objects to Complaint Counsel’s Instruction 1 to the extent that it does not contain reasonable time limits.

- B. Impax objects to Complaint Counsel's Instruction 2 to the extent Complaint Counsel's instruction to produce "all other responsive documents" demands that Impax produce documents protected by the attorney-client privilege, work product doctrine, or any other privilege or immunity. Impax interprets all requests contained herein that are duplicative of requests reflected in the Civil Investigative Demand Impax received in the prior investigation, FTC No. 141-0004, to be modified per agreements reached during that investigation between Impax Counsel and FTC Staff regarding the respective duplicative CID request or the respective duplicative portion or portions of the CID requests.
- C. Impax objects to Complaint Counsel's assertion in Instruction 3 that their Discovery Requests are "continuing in nature," thereby obligating Impax to produce subsequently discovered documents. Impax will supplement its responses pursuant to the requirements set forth in Rule §3.31(e) of the Federal Trade Commission's Rules of Practice.
- D. Impax objects to Complaint Counsel's Instruction 4 because Impax is under no obligation pursuant to the Federal Trade Commission's Rules of Practice to produce documents in the fashion specified by Complaint Counsel. Except where indicated otherwise, Impax will produce non-objectionable responsive documents as they are kept or maintained in the usual course of business. Impax will seek to meet and confer with Complaint Counsel regarding its objections to Instructions 4 and 7(a) and possible redactions or excerpting of certain types of documents based on relevance.

- E. Impax objects to Instruction 5 to the extent it requires Impax to search or otherwise gather documents from all personal devices or files of its employees, former employees, directors, or officers, as such materials are not reasonably accessible.
- F. Impax objects to Complaint Counsel's Instructions 6 and 7 on the grounds that they are overbroad and burdensome, and purport to impose duties or obligations on Impax that are greater than or inconsistent with the applicable requirements of the Federal Trade Commission's Rules of Practice. When both reasonable and possible, Impax will produce metadata coextensive and consistent with the metadata produced in prior productions to the Federal Trade Commission.
- G. Impax further objects to Instructions 6 and 7 to the extent they require Impax to adjust in any way to form of documents previously produced to the Commission in the prior investigation, FTC No. 141-0004.
- H. Impax objects to Complaint Counsel's Instructions 6(c) and 11 on the grounds that they purport to impose duties or obligations on Impax that are greater than, inconsistent with, and/or not required by the Federal Trade Commission's Rules of Practice governing discovery.
- I. Impax objects to Instruction 8 to the extent it requires Impax to adjust in any way privilege logs previously produced to the Commission in the prior investigation, FTC No. 141-0004, or to provide additional privilege or redaction logs for documents listed in the privilege logs previously produced.
- J. Impax objects to Plaintiffs' Instruction 10 to the extent it requests information about documents that are lost, destroyed, or otherwise missing. Impax is under no obligation to produce documents that are not in its possession, custody, or control, or

it from IMS. Because Complaint Counsel can purchase this data, Request No. 1 seeks discovery that Complaint Counsel may seek from another source that is less burdensome.

Document Request No. 2:

For any current or former Impax employee identified by Impax as a custodian in the FTC

employees covered by Request No. 2 would be to manually review those 33 individuals' hard copy personnel files, dating back as many as seven years in many instances, which is unduly burdensome as compared to any potential relevant information that may be contained in these files.

Response to Request No. 5:

Impax objects to Request No. 5 on the grounds that it cannot be reasonably expected to

Impax Laboratories, Inc., Civil Action No. 2:16-2526 (D.N.J.), and any anticipated or potential appeal thereof.

Response to Request No. 7

Impax objects to Request No. 7 as seeking documents that cannot be reasonably expected

CERTIFICATE OF SERVICE

I, the undersigned, declare:

I am and was, at all times mentioned herein, a resident of the United States, over the age of 18 years, and neither a party nor interested in the above-captioned action. My business address is O'Melveny & Myers LLP, 1625 Eye St. NW, Washington, DC 20006. On June 29, 2017, I

Exhibit B

We are still considering the issue of your non-privilege related clawback. During our call last week, you indicated that you would be providing us with a list of the final forecasts supporting board presentations – in other words those forecasts that you believe were properly produced. We would like to review that list before making a decision on these other forecasts.

With respect to Interrogatory No. 21, I believe we have reached an understanding. We are asking you to reproduce the identified documents with summary sheets included. We do not need the underlying detail sheets that solely concern non-oxymorphone products.

Best Regards,

Nicholas Leefer
Federal Trade Commission
Bureau of Competition, Health Care Division
202-326-3573
nleefer@ftc.gov

We are considering this issue, and will try to get back to you by early next week. We will also keep an eye out for the coming privilege clawback you reference, below.

In addition, we want to follow up on a few other issues from our meet and confer call yesterday.

- Interrogatory No. 20
 - During our call, I asked about the units associated with the quantities of finished goods in Impax's response. You indicated that this information came from the documents cited in the response (Impax_Opana_PartIII_0026746) and that we should look there for that information. You further suggested that if the document did not answer the question, you would be willing to ask someone at Impax for more information.
 - Unfortunately, this document does not appear to indicate units for the quantity information. As such, we ask that you consult with Impax to determine the appropriate units for this quantity information.
AMF: The units referenced in this document are 100 count bottles.


- Interrogatory No. 21
 - As I mentioned, we believe that the spreadsheets referenced in this response (and some similar documents) are missing relevant tabs. In particular, summary or data aggregation/processing tabs appear to have been removed before production. You indicated that, if we sent a list of spreadsheets where we had identified with missing tabs, you would review them and get back to us. The list of these documents is as follows:

- IMPAX-OPANA-CID000009339 + 9340 (referenced in ROG response)
- IMPAX-OPANA-CID00011906
- IMPAX-OPANA-CID00007096
- IMPAX-OPANA-CID00007117
- IMPAX-OPANA-CID00007077
- IMPAX-OPANA-CID00006511
- IMPAX-OPANA-CID00008011

AMF: As you are conducting the investigation, C star and company
Impax would produce certain forecasts (excerpted for, removing sensitive and

detailed

Impax's production, even though some such documents were referenced in the communications from the DEA that Impax did produce. During our call, you said that you had searched for these documents—including by searching hard copies—and had been unable to find them. However, we just found a document in Impax's production suggesting that hard copies of the quota requests sent to the DEA were preserved by Impax in Philadelphia. Please see the attached document (Impax_Opana_PartIII_0021533). We hope that this document may provide some additional insight and help Impax to locate these records. (Impax's Opana Part III HQ 255



warranted. Our hope is to avoid unnecessary effort and time spent on documents the parties have already agreed need not be produced.

Note that this list is of “master” documents; there are one or more exact duplicates of several of these that would be the subject of the proposed responsiveness clawback as well.

Please let me know whether Complaint Counsel will agree to our proposed approach. Of course, as part of our previously agreed upon approach to forecasts, we will still produce (if we have not already) the forecasts supporting all board presentations after Impax’s launch of oxymorphone ER in 2013 (until the date of collection), as well as forecast documents supporting sales or other projections regarding oxymorphone contained in any board presentations between 2009 and 2012. We will identify these for you by bates number as well.

Finally, please note that we will be sending separate correspondence today or tomorrow regarding a separate clawback *based on privilege*. That separate clawback is *not* based on responsiveness (though, some of these privileged documents are non-responsive as well). I just wanted to clarify that these are two separate issues and avoid any confusion that might otherwise arise when you receive our privilege clawback correspondence today or tomorrow.

Best,

Anna







O'Melveny

Anna M. Fabish

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Exhibit C

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Notice of Electronic Service

Complaint

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I hereby certify that on July 28, 2017, I served via other means, as provided in 4.4(b) ob4/Tradyoregonga Public), upon:

Nicholas Leefer
Attorney