NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ABRAXIS BIOSCIENCE, LLC, *et al*., **Plaintiffs,** **v.** **ACTAVIS, LLC,** **Defendant.**	**Civil Action No. 16-1925 (JMV)** **MEMORANDUM OPINION**

FALK, U.S.M.J.

Before the Court is the motion of Plaintiffs, Abraxis BioScience LLC and Celgene Corporation (together "Celgene"), for the issuance of a letter rogatory to a third-party company in Canada, BioVectra, Inc. Defendant Actavis opposes the motion. No oral argument is necessary. For the reasons stated below, the motion is **GRANTED**.

RELEVANT BACKGROUND

This Hatch-Waxman patent infringement case arises out of Actavis's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Celgene's Abraxane® product, which is used to treat breast, lung, and pancreatic cancer. Abraxane® is comprised of two ingredients: (1) the anti-cancer drug paclitaxel, which

was approved by the FDA more than 20 years ago and sold under a different name; and (2) human serum albumin, a naturally occurring protein made by the liver in the human body.[1] In Abraxane®, the paclitaxel is bound to the albumin in what are referred to as albumin-bound paclitaxel particles.

The Complaint was filed on April 6, 2016. Celgene contends that Actavis's accused ANDA product would infringe four patents: U.S. Patent Nos. 8,853,260 ("'260 patent"); 7,820,788 ("'788 patent"); 7,923,536 ("'536 patent"); and 8,138,229 ("'229 patent"). The initial scheduling conference was held on August 3, 2016, and an initial scheduling order was entered on August 18, 2016. Discovery technically closes on June 29, 2017. However, as the Court recently explained in a separate Opinion granting a recent motion by Actavis to amend its invalidity contentions, *Abraxis BioScience, LLC v. Actavis, LLC*, 2017 WL 2079647 (D.N.J. May 15, 2017), discovery is really still in the early stages.

The current motion[2] is Celgene's request for the issuance of a letter rogatory seeking discovery in Canada from a third-party, BioVectra Inc. BioVectra is a pharmaceutical company that performs part of the manufacturing of Actavis's ANDA product, and Celgene claims that it is the only source of certain relevant materials, including samples of the starting materials comprising the ANDA product. Celgene's

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[1] The two ingredients are, at times, referred to as the "starting materials."

[2] The "motion" is comprised of four letters dated March 10, 2017; March 16, 2017; March 27, 2017; and April 7, 2017.

request is comprised of seven document requests and three categories of deposition testimony that closely track the requests. Celgene contends that Actavis lacks standing to object to its letter rogatory to a third-party, and that Actavis itself has conceded that the raw materials used to produce its ANDA product are not in its possession, custody or control, but rather reside with BioVectra.

Actavis counters that Celgene's proposed discovery is expensive, time-consuming, overbroad, irrelevant, and duplicative. It claims that Celgene could obtain any relevant discovery more effectively through party-discovery in the case. Actavis also claims that Celgene delayed in seeking to issue letters rogatory and that allowing foreign discovery would jeopardize the schedule and timing of the case.

LEGAL STANDARD

Federal Rule of Civil Procedure 28(b)(2)(A) provides that a discovery may be had in a foreign country pursuant to a letter rogatory "on appropriate terms after an application and notice of it." Fed. R. Civ. P. 28(b)(2)(A); *see also* 28 U.S.C. § 1781. In effect, the party seeking to issue a letter rogatory is asking the United States, through this Court, to request the assistance of a foreign country in obtaining discovery:

> A letter rogatory is defined as the medium, in effect, whereby one country, speaking through one of its courts, requests another country, acting through its own courts and by methods of court procedure peculiar thereto and entirely within the latter's control, to assist the administration of justice in the former country; such request being made, and being usually granted, by reason of the comity existing between nations in ordinary peaceful times.

DBMS Consultants Ltd. v. Computer Assoc., Int'l, 131 F.RD. 367, 369 (D. Mass. 1990) (internal quotes omitted).

"On an application for the issuance of a letter rogatory seeking a deposition in a foreign country, the Court will not ordinarily weigh the evidence to be elicited by deposition and will not determine whether the witness will be able to give the anticipated testimony." *Id.* "[S]ome good reason must be shown by the opposing party for a court to deny an application for a letter rogatory." *Jovanovic v. Northrop Grumman Corp.*, 2008 WL 4950064, at *1 (D.N.J. Nov. 18, 2008). Ultimately, the decision to issue letters rogatory is a discretionary one. *Id*.; *see also Leasco Data Processing Equip. Co. v. Maxwell*, 63 F.R.D. 94 (S.D.N.Y. 1973).

ANALYSIS

Celgene claims that the letter rogatory process is necessary in this case because, during discovery, it has become apparent that important materials, including samples of the starting materials, are in the possession of BioVectra. Celgene claims that it requested samples of each ingredient used to manufacture the ANDA product from Actavis, but that Actavis ultimately advised, in March 2017, that it did not have the materials and that BioVectra is the only source. According to Celgene, "[f]or that reason," it "promptly prepared the attached Letter Rogatory seeking discovery from BioVectra." (Pl.'s Letter dated March 10, 2017 at 2.). While the proposed letter seeks more than samples of the core ingredients, it is certainly the driving force behind the application. For the reasons that are detailed below, the Court is satisfied that Celgene

has made a sufficient showing to proceed with the letter rogatory proposed.

First, samples of the starting materials are sufficiently relevant, *see, e.g.*, *SmithKline Beecham Grp. v. Apotex Corp.*, 1999 WL 311697, at *6 (N.D. Ill, May 13, 1999); *see also Medtronic Ave, Inc., v. Advanced Cardiovascular Sys.*, 2004 WL 115594, at *3 (D. Del. Jan. 13, 2004), especially since there are disputes over the adequacy of the sample ANDA product defendant has provided.[3] And there is no dispute that, if anyone, BioVectra would be the company that has the materials.[4] That alone is a compelling reason to grant Celgene's request.

Second, the Court is satisfied that the request is timely. The record shows that the discussion relating to samples of the underlying starting materials started around September 20, 2016, and that meet-and-confer conversation about the issue lasted until March 1, 2017. (*See* Pl.'s Letter dated March 27, 2017, at 3.) Celgene's opening

[3] The parties have a separate discovery dispute, currently being briefed, in which Celgene claims that Actavis provided effectively-expired samples of its ANDA product and should be compelled to create new, unexpired product or incur a spoliation reference. This dispute was discussed on-the-record with the Court at a recent case management conference. *See* Transcript of Case Management Conference dated April 25, 2017, at 9-11. And, in the course of that discussion, it seemed possible, whether through the letter rogatory process or otherwise, communication with, and the involvement of, BioVectra could be necessary. While that dispute will be decided separately, it does provide some context for the letter rogatory request in this case.

[4] In its April 7, 2017 letter, Actavis states that ingredients are "unavailable" from BioVectra, and that the letter request should be denied on that basis. (*Id*. at 3.) However, during the subsequent case management conference on April 25, Actavis's counsel conceded he was not sure what ingredients BioVectra has, *see* Transcript of Case Management Conference dated April 25, 2017, at 9:9-17.

application was filed less than 10 days later.

Third, the standard for the issuance of letters rogatory is relatively lenient and discretionary, and the Court is satisfied that allowing Celgene to serve its letter will not unduly delay the case, as there remains other discovery to complete before the case is ready for motion practice and trial. Indeed, the fact that the case is still in the early stages was an important factor in granting Actavis's request for leave to amend its invalidity contentions, which was filed *after* Celgene's current request for foreign discovery, *see Abraxis BioScience, LLC v. Actavis, LLC*, 2017 WL 2079647, at *3 (D.N.J. May 15, 2017).

Fourth, even assuming that Actavis has standing to object to the letter rogatory, which the parties dispute,[5] the Court finds both the samples and documents requested to be sufficiently relevant within the scope of Rule 26. In the context of an application for a letter rogatory, the request may be granted even if "the admissibility is not immediately apparent, as long as the inquiry is reasonably calculated to lead to the discovery of admissible evidence." *See, e.g.*, *Brake Parts, Inc. v. Lewis*, 2009 WL 1939039, at *4 (E.D. Ky. July 6, 2009)[6]; *see also DBMS Consultants*, 131 F.RD. at 369-70. Schedule A

[5] Celgene claims that Actavis lacks standing to object to a letter rogatory directed to a third-party; Actavis contends otherwise. No binding authority is cited and non-binding cases have been cited for both views. For purposes of completeness, the Court assumes that Actavis has standing.

[6] The quoted *Brake Parts* language traces a prior version of Rule 26's well-known relevance standard that governed the scope of discovery prior to amendments to the Federal Rules of Civil Procedure effective December 1, 2015. However, the current language of

to the letter request contains 7 demands that seek documents and communications relating to, *inter alia*, manufacture of albumin-bound paclitaxel nanoparticles; stability studies regarding same; comparative studies relating to the active ingredients; and testing regarding any albumin-bound paclitaxel nanoparticles. (Pl.'s Letter dated March 27, 2017, at Ex. 3.) The deposition topics cover the same ground. (*Id*.) While the parties engage in argument regarding the true benefit of the information and whether it would be ultimately be admissible, there is nothing facially improper or overbroad about the requests, which seem targeted to the subject matter involved and proportionate to the needs of this large patent case.

Fifth, to the extent there is any burden involved with complying with the request it would be on BioVectra, not Actavis. The Court has not received any papers from BioVectra stating that compliance with the letter rogatory would be unduly burdensome or expensive. There are limited document demands and deposition topics. And the parties are seemingly speculating about what kind of burden this will impose on BioVectra. More fundamentally, much of Actavis's claim of burden is based on its argument that *it* can provide some of the discovery requested, and therefore, there is no need for BioVectra to be involved. Plaintiff is not, however, required to accept information only from Defendant, and is within its rights to seek relevant discovery from

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Rule 26 would also support the request, especially considering "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, [and] the parties' resources." Fed. R. Civ. P. 26(b)(1). This is a patent case involving substantial sums, in monetary terms.

non-parties, including BioVectra. *See, e.g.*, *Brake Parts*, 2009 WL 1939039, at *4 ("The Magistrate Judge is also unpersuaded . . . that [applicant] should first make efforts to obtain the discovery from [defendant] before it would be entitled to [letters rogatory]. The fact that the same information may be available from two different sources does not excuse one of those sources from producing the information.").

CONCLUSION

Based on the above, Celgene's motion for the issuance of a letter rogatory is **GRANTED**. An appropriate order will be entered.

Counsel should arrange issuance of the executed Letter Rogatory. Any delay may cause the Court to reconsider its decision.

s/Mark Falk
MARK FALK
United States Magistrate Judge

DATED: May 25, 2017