UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED THERAPEUTICS CORP. Plaintiff, v. WATSON LABORATORIES, INC. Defendant.	Civil Action No. 16-mc-91176

ORDER ON UNITED THERAPEUTICS CORP.'S MOTION TO COMPEL PAREXEL INTERNATIONAL CORP.'S COMPLIANCE WITH SUBPOENA
(Dkt. No. 1)

CABELL, U.S.M.J.

The present motion arises from a patent infringement lawsuit pending in the District of New Jersey. United Therapeutics Corp. (UTC) has sued Watson Laboratories, Inc. (Watson) for allegedly infringing three patents related to one of UTC's products, the Tyvaso Inhalation Solution. (*United Therapeutics Corp. v. Watson Laboratories, Inc.*, No. 15-cv-05723 (D.N.J. filed Jul. 22, 2015)). Paraxel International Corporation (Paraxel) is not a party to the lawsuit but it acquired some Tyvaso Inhalation System Starter Kits from the Glendale Adventist Medical Center (Glendale Adventist) and subsequently conducted some research on the product. UTC initially believed that Parexel used the Starter Kits to assist Watson in developing a generic version of Tyvaso, but apparently now accepts Parexel's representation that it was not Watson for whom it performed its work. Still, UTC seeks documents from Parexel relating to the work it

did do and has served Parexel with a subpoena demanding such information. Parexel objects on the grounds that the subpoena is overbroad and seeks documents that are wholly irrelevant to the lawsuit between UTC and Watson.

Having reviewed the parties' submissions and heard argument on UTC's motion, the Court agrees that UTC has not met its burden of establishing that the documents it seeks are relevant to the claims and defenses in the UTC/Watson litigation. For that reason, UTC's motion to compel is denied.

I. BACKGROUND

The action pending before this court was filed solely to compel compliance with a subpoena served upon Parexel, a life sciences consulting firm located in this district. UTC served the subpoena in a District of New Jersey patent infringement suit, *United Therapeutics Corp. v. Watson Laboratories, Inc.*, No. 15-cv-05723.

A. Hatch-Waxman Act

UTC sued Watson pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585, more commonly known as the Hatch-Waxman Act. The Hatch-Waxman Act creates an expedited process by which the manufacturers of generic drugs can obtain approval of generic drugs. *See* 21 U.S.C. § 355(j).

Where a generic drug contains the same active ingredients and is administered in the same way and with the same dosage as the branded drug, the generic drug manufacturer may file an Abbreviated New Drug Application (ANDA). The ANDA filing process requires that the applicant certify that the name brand drug is not patented, that the patent has or will expire before the generic is put on the market, or that the patent is invalid. A certification that the name

brand drug patent is invalid is known as a "Paragraph IV" certification. 21 U.S.C. § 355(j)(2)(vii)(IV).

Paragraph IV certifications must be served on the patent holder. Under the Hatch-Waxman Act, the patent holder is entitled to file a patent infringement suit immediately upon receiving the notice letter from the generic manufacturer. 35 U.S.C. § 271(e)(2). UTC's patent infringement suit against Watson is one such section 271(e)(2) suit.

B. District of New Jersey Litigation

UTC holds three patents related to Tyvaso, an inhaled drug that treats pulmonary arterial hypertension. Pulmonary arterial hypertension is high blood pressure in the pulmonary arteries, which carry blood from your heart to your lungs. This type of high blood pressure places a strain on the heart, potentially leading to heart failure or death.

On July 22, 2015, UTC filed a six count patent infringement complaint against Watson in the District of New Jersey. The complaint alleges that Watson submitted an ANDA seeking to manufacture, market and sell a generic version of Tyvaso. The ANDA contained a paragraph IV certification claiming that all three of UTC's Tyvaso patents are invalid. UTC alleges that its patents are valid and that Watson's plan to manufacture and sell a generic version of Tyvaso before the patents' expiration constitutes willful patent infringement.

C. UTC's Subpoena to Parexel

Patients who have been prescribed Tyvaso receive the Tyvaso Inhalation System Starter Kit. The kit contains an inhaler device, accessories, a case, a power supply, the Tyvaso itself and various literature. In December 2015, UTC learned that Parexel obtained several Tyvaso Starter Kits from Glendale Adventist. UTC initially believed that Parexel obtained the kits "to assist

Watson in developing the ANDA Product [*i.e.*, the generic version of Tyvaso]." (Dkt. No. 2 at p. 2).

On February 23, 2016, UTC served a subpoena on Parexel seeking 28 categories of documents. Parexel responding with a letter in which it objected to the subpoena in its entirety, and refused to produce any documents. UTC subsequently agreed to narrow the subpoena to five requests (request nos. 2-6) seeking information about the relationship between Parexel and Glendale Adventist, and Parexel's use of the Tyvaso starter kits it obtained from Glendale Adventist. Parexel still did not produce any documents in response to the subpoena.

D. UTC's Motion and Motion Hearing

On June 1, 2016, UTC moved for an order compelling Parexel to respond to request numbers 2 through 6. UTC argues that Parexel waived any objection to the subpoena because it did not object to each request individually. UTC argues that even if Parexel's objections were preserved, they are not well-taken. UTC contends that the documents sought are relevant to the NJ litigation either because Parexel obtained the Tyvaso Starter Kits to assist Watson in developing its generic version of Tyvaso, or because the documents sought "could tend to prove or disprove objective indicia of nonobviousness . . . [including] commercial success, long felt and unresolved needs, failure of others, industry praise, copying, and unexpected results . . . ." (Dkt. No. 2 at p. 11).

After UTC filed its motion, Parexel clarified that it had not obtained the Tyvaso Starter Kits to assist Watson. Instead, Parexel obtained the starter kits in connection with a study performed under an Investigational New Drug Application comparing Tyvaso to its (unnamed) client's own investigational product, which Parexel's in-house counsel initially represented was a reformulation of Tyvaso. (Dkt. No. 14). Parexel has since clarified that its customer's product

"includes a single active pharmaceutical ingredient that differs structurally from Tyvaso and has its own patents." (Dkt. No. 28).

At the July 12, 2016 oral argument on UTC's motion, the Court found that Parexel had not waived its objections to UTC's subpoena. In light of Parexel's explanation regarding its work with the Tyvaso Starter Kits, the Court directed the parties to file supplemental briefing discussing: 1) whether the scope of UTC's requests had narrowed; and 2) the relevance of the documents sought. In response, UTC narrowed the scope of its motion to compel to request numbers 3 and 4.

Request No. 3 (as narrowed) seeks:

> All documents, communications, agreements, and things concerning any study, research, development or experimentation done on TYV ASO®, any TYV ASO® Starter Kit, or any TYV ASO® Refill Kit provided or attempted to be provided to Parexel by Glendale Adventist, including but not limited to: communications with Glendale Adventist, Accredo Health Group, Inc., or any third party; in relation to any TYV ASO®, TYV ASO® Starter Kit, or TYV ASO® Refill Kit.

Request No. 4 (as narrowed) seeks:

> All documents, communications, and things concerning Parexel's use of any TYV ASO®, TYV ASO® Starter Kit, or TYV ASO® Refill Kit provided to Parexel by Glendale Adventist, including without limitation any study, research, development or experimentation done with the TYV ASO®, TYV ASO® Starter Kit, or TYV ASO® Refill Kit, and any communications with Holopack, Watson, or any third party concerning the TYV ASO®, TYV ASO® Starter Kit, or TYV ASO® Refill Kit.

(Dkt. No. 27). UTC argues that these requests seek documents relevant to Watson's defense, which is that UTC's patents are invalid because the patented invention was obvious in light of the prior art. Specifically, UTC argues that the documents are relevant to the secondary considerations of failure of others, copying, industry praise and commercial success. (*Id*.)

Parexel argues that UTC's relevance argument is too speculative and attenuated to satisfy its burden of proving relevance. Parexel also argues that responding to UTC's subpoena would be unduly burdensome because producing documents would violate its contractual obligation to protect the confidentiality of the not-yet-public research it is conducting for its customer. (Dkt. No. 28).

II. DISCUSSION

A. Legal Standard

Federal Rule of Civil Procedure 45 governs the use of subpoenas to obtain discovery from non-parties. *See* FED. R. CIV. P. 45. A non-party witness is subject to the same scope of discovery as a party is under Rule 34. *See id.* (Advisory Committee's note to the 1970 amendments). Under Rule 34, the rule governing the production of documents between parties, the proper scope of discovery is as specified in Rule 26(b). FED. R. CIV. P. 34. Rule 26(b), in turn, permits the discovery of any non-privileged material:

> relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

FED. R. CIV. P. 26(b)(1). This definition of relevance reflects amendments made in December 2015 that were intended to "[r]estor[e] proportionality as an express component of the scope of discovery," thereby preventing over-discovery and the use of discovery "for delay or oppression." FED. R. CIV. P. 26 (Advisory Committee's note to the 2015 amendments).

As the recent amendments to Rule 26 make clear, the importance of the information sought to the requesting party's case and the burden on the producing party must be assessed as part of the Court's relevance determination. When it comes to assessing burden, courts are

generally more solicitous of non-parties. As the First Circuit has explained, "parties to a law suit must accept [the invasiveness of discovery] as natural and concomitant of modern civil litigation," but "[n]on-parties have a different set of expectations. Accordingly, concern for the unwanted burden thrust upon non-parties is a factor entitled to special weight . . . ." *Cusumano v. Microsoft Corp.*, 162 F.3d 708, 717 (1st Cir. 1998) (finding that district court "balanced the right array of factors" and acted within its discretion when it determined "that the scales tipped in favor of preserving confidentiality" and denied Microsoft's motion to compel a third party to produce documents).

B. Analysis

35 U.S.C. § 103(a) provides that a patent is invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matters as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). Obviousness is a "question of law based on underlying findings of fact." *Leo Pharmaceutical Products, Ltd.*, 726 F.3d 1346, 1353 (Fed. Cir. 2013). The obviousness determination must be based upon the characteristics of the prior art, the differences between prior art and the patented invention, the level of ordinary skill at the time of invention, and "objective evidence of non-obviousness, if any." *Id*. It is this last inquiry to which UTC argues that its discovery requests are targeted.

In *Graham v. John Deere Co.*, 383 U.S. 1 (1966), the Supreme Court first approved of the use of "secondary considerations" that could indicate non-obviousness, including long-felt need, commercial success and failure of others, as part of a Court's obviousness inquiry. *Graham*, 383 U.S. at 17-18 (citing Richard L. Robbins, *Subtests of 'Nonobviousness': a Nontechnical Approach to Patent Validity*, 112 U. PA. L. REV. 1169 (1964)). The purpose of

using these factors is to promote consistency in obviousness determinations by providing the court with "nontechnical facts" upon which it may rely instead of tasking the parties with teaching the court "enough physics or other science in the limited time available to provide it with a sufficient working knowledge to cope with the more technical facts." Robbins, *supra*, at 1170-71. More recently, the Federal Circuit has held that where one party has chosen to introduce evidence "arising out of the so-called 'secondary considerations,'" the court *must* consider that evidence in reaching its obviousness determination. *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012) (citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983)).

UTC argues, in effect, that because a Court must consider "secondary consideration" evidence where available, UTC is entitled to discovery from any entity that has analyzed or studied its patented products, regardless of the nature of that research or analysis.[1] (Dkt. No. 27). However, the secondary consideration evidence that courts consider generally includes the patent holder's own documents, the alleged infringer's documents, expert testimony, and trade publications. *See, e.g. Transocean Offshore Deepwater Drilling, Inc.*, 699 F.3d at 1349-53; *see also Pfizer, Inc. v. Mylan Pharmaceuticals, Inc.*, 71 F. Supp. 3d 458, 475-476 (D. Del. 2014). UTC has not cited, and the Court has been unable to locate, any cases compelling discovery from third parties uninvolved in the alleged patent infringement in order to "prove" objective indicia of non-obviousness. This, coupled with the principle that third parties should not be burdened with discovery requests where the same information is available from other sources, suggests

[1] UTC argues that third party secondary consideration discovery becomes an overbroad "fishing expedition" only when a party approaches "all entities in the industry to determine whether they have analyzed or studied" the patented product. That UTC has constructed such an extreme scenario to support the reasonableness of its own requests hurts its position more than it helps it.

that UTC is already treading in an area on the outskirts of permissible discovery. Nonetheless, the Court considers each of UTC's four relevance arguments.

1. Failure of Others

UTC argues that Parexel's research using Tyvaso may be relevant to demonstrate that others have tried, but failed to develop an inhaled pulmonary arterial hypertension treatment. "[T]hat others failed to develop a claimed invention may carry significant weight in an obviousness inquiry." *In re Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litig.*, 676 F.3d 1063, 1081 (Fed. Cir. 2012). However, "[i]n receiving evidence of unsuccessful research, courts must take care that such research was conducted under the same state of the art as that which confronted the patentee." Robins, supra, at 1173 n. 30 (citing *Reiner v. I. Leon Co.*, 285 F.2d 501, 504 (2nd Cir. 1960)). For example, in *In re Cyclobenzaprine*, which UTC cites, the Federal Circuit held that evidence of a third party's unsuccessful attempt to develop an extended release muscle relaxant ten years before the patent holder's success supported a finding of non-obviousness. *In re Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litig.*, 676 F.3d at 1081; *see also Pfizer, Inc. v. Mylan Pharmaceuticals, Inc.*, 71 F. Supp. 3d 458, 475 (D. Del. 2014) (fact that many others had tried to develop treatment for kidney and pancreatic cancer before patent-holder developed successful angiogenesis blocking treatment that could be used on these cancers was relevant to non-obviousness inquiry).

In contrast to the evidence considered in *In re Cyclobenzaprine*, UTC seeks information about research conducted *using* Tyvaso, the patented invention. Research conducted using a patented invention necessarily occurs after the invention has been developed and made available to the public. The development and release of that invention changes the state of the art because every artisan working in the field now has the benefit of the patented invention. As such,

evidence of research, successful or otherwise, conducted after Tyvaso's invention is not relevant to the question of whether Tyvaso was obvious at the time it was developed. *See, e.g., Computrol, Inc. v. Lowrance Electronics, Inc.*, 893 F. Supp. 1440, 1460 (D. Idaho 1994) (noting that it is the "prior failure of others" to develop a similar invention that is relevant to obviousness); *AstraZeneca LP v. Breth Ltd.*, 88 F. Supp. 3d 326, 390 (D.N.J. 2015) (describing secondary consideration as "prior failures of others" and rejecting argument that failures of patent holder should be taken into account).

2. Copying

UTC argues that documents related to Parexel's research might demonstrate that Parexel has copied at least some of the claims in UTC's patents. The copying of a patented invention may be evidence that an invention is not obvious where circumstances suggest that the copying is motivated by the merits of the patented invention. *See Crocs, Inc. v. International Trade Commission*, 598 F.3d 1294, 1311 (Fed. Cir. 2010); *Apple, Inc. v. Samsung Electronics Co., Ltd.*, 816 F.3d 788, 809-810 (Fed. Cir. 2016). *Compare Cable Elec. Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1028 (Fed. Cir. 1985) (noting that copying may also indicate obviousness such as, for example, copying motivated by the belief that a particular patent is invalid); *Bayer Healthcare Pharm., Inc. v. Watson Pharm., Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013) ("copying in the ANDA context is not probative of nonobviousness because a showing of bioequivalence is required for FDA approval"). In this case, Parexel has represented that its research involves a reformulation that is a "new compound that is not a generic equivalent of TYVASO," (Dkt. No. 14), and "includes a single active pharmaceutical ingredient that differs structurally from Tyvaso." (Dkt. No. 28). In other words, Parexel has represented that the documents that UTC seeks will not provide evidence of copying because Parexel's client did not actually copy

Tyvaso. Parexel has also represented that it was hired to test the client's product many years after its development, which would make it highly unlikely that any document in Parexel's possession would describe the thought process that initially went into developing the product. In this context, UTC's argument that the documents sought are relevant to copying is simply too speculative to justify granting its motion to compel.

3. Industry Praise

"Evidence of . . . acceptance and praise [of an invention] after patenting are probative factors for evaluating non-obviousness." *Pfizer, Inc.*, 71 Supp. 3d at 476. For example, evidence that a drug was "widely praised by researchers and doctors," *id.*, and positive articles in industry publications have been admitted to demonstrate that particular inventions were break-throughs in their industries. *Transocean Offshore Deepwater Drilling, Inc.*, 699 F.3d at 1351. UTC argues that Parexel may have documents that discuss its client's positive view of Tyvaso and that such documents would constitute "industry praise." Like UTC's copying argument, UTC's industry praise argument is simply too speculative in light of Parexel's representations to justify the relief sought. Further, UTC's requests are extremely overbroad given the argued relevance of the documents sought. It is difficult to justify ordering Parexel to turn over every single document it has regarding its experimentation with Tyvaso because UTC believes a few of them might contain positive statements about Tyvaso.

4. Commercial Success

Evidence that a patented product enjoys commercial success can demonstrate non-obviousness where there is a nexus between the product's commercial success and the patented features of the invention. *Transocean Offshore Deepwater Drilling, Inc.*, 699 F.3d at 1349-50. Despite the fact that commercial success is generally proven by introducing the patent-holders

own sales figures, UTC argues that it needs Parexel's documents to rebut any argument by Watson that Tyvaso's success derived from something other than the patented features. The reasoning of the court in *Eli Lilly and Co. v. Sicor Pharmaceuticals, Inc.*, 705 F. Supp. 2d 971 (S.D. Ind. 2010), which UTC cites, disposes of this argument. In that case, a district court rejected a generic drug manufacturer's argument that a patent on a cancer drug was invalid for obviousness. Discussing the blockbuster success of the patented drug, the court explained that in cases where the infringing product "embodies the claimed features, and is coextensive with them," a nexus between commercial success and the merits of the patented invention is presumed. *Eli Lilly and Co.*, 705 F. Supp. 2d at 1008-09 (citing *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F. 3d 1120, 1130 (Fed. Cir. 2000)). That is because "[i]f the patented drug were not a commercial success, generic manufacturers would have little interest in offering their own versions of the drug." *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 2001 WL 1397304, at *12 (S.D. Ind. Oct. 29, 2001). Watson, the alleged infringer in the NJ litigation, is seeking to market a generic version of Tyvaso and will not be heard to argue that there is not a nexus between Tyvaso's success and its patented features. As such, UTC does not need documents to rebut an argument that will not be raised.

III. CONCLUSION

Based upon the foregoing analysis, the Court concludes that UTC at best has established that the information it seeks from Parexel has minimal relevance to the question of obviousness. Weighing the burden that production of its client's confidential documents would impose upon Parexel against the limited value the documents have to UTC's case, the Court concludes that it would be inappropriate to compel Parexel to produce documents in response to the subpoena, even as narrowed by UTC.

That is not to say that a third party should never have to produce documents that might support a non-obviousness argument. If, for example, Parexel's client actually was Watson as UTC initially suspected, the Court would have no problem concluding that Parexel should be ordered to produce at least some documents. But, under the facts presented here, granting UTC's motion would be tantamount to holding that anyone who conducts research on a patented product can be ordered to produce *all* documents pertaining to that research in *any* subsequently filed patent litigation. To impose such an obligation on non-parties to patent litigation would have the effect of chilling invention, which is contrary to the intent of our patent system. *See Graham*, 383 U.S. at 9 ("The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge.").

Accordingly, UTC's motion to compel is denied.

/s/ Donald L. Cabell
DONALD L. CABELL, U.S.M.J.

DATED: September 22, 2016