STATE OF VERMONT

SUPERIOR COURT
Chittenden Unit

CIVIL DIVISION
Docket No.: S0041-09 CnC

MYLAN TECHNOLOGIES, INC.
and MYLAN INC.

v.

ZYDUS NOVELTECH, INC., SHARAD K. GOVIL,
CADILA HEALTHCARE, LTD., PANKAJ PATEL and
SUNIL ROY

DECISION ON MYLAN'S MOTION TO PRECLUDE DAVID J. ENSCORE FROM SERVING AS AN ADVERSE EXPERT WITNESS

This case involves a trade secrets claim between competitors in the generic pharmaceutical industry, and specifically the sub-part of that industry dealing with transdermal drug delivery systems. Plaintiffs Mylan Technologies, Inc. and Mylan, Inc. (collectively, "Mylan") allege that defendant Dr. Sharad Govil took important trade secrets when he left his position as a senior Mylan executive and scientist and joined defendant Zydus Noveltech, Inc. Mylan also alleges that Zydus Noveltech, its parent company Cadila Healthcare, Ltd. (Cadila), and two of Cadila's executives are liable under various theories for their alleged role in Dr. Govil's departure.

Mylan has filed a Rule 26 motion seeking an order precluding Dr. David J. Enscore from serving as an adverse witness against Mylan. Mylan hired Dr. Enscore as a non-testifying expert in early 2010 to assist with Mylan's defense of *Grange v. Mylan Laboratories, Inc.*, a products liability suit that has since settled. Mylan maintains that in the course of his work on the *Grange* case, Dr. Enscore obtained in-depth, privileged information on a question that overlaps one of the issues in this trade secrets case: whether Mylan's design choices for Fentanyl resulted in a valuable, superior product. Defendants Zydus Noveltech, Inc. and Dr. Govil (collectively, "Zydus") oppose Mylan's motion, arguing that Dr. Enscore's service as a non-testifying expert in a now-settled products liability case is not connected to the prosecution of this case in a way that would support his disqualification.

BACKGROUND

In or around early 2010, Mylan contacted Dr. Enscore as a potential expert for Mylan in the *Grange* litigation. The plaintiffs in that case had sued Mylan, alleging that due to a design and manufacturing defect, some of Mylan's transdermal patches contain and deliver fentanyl—a powerful pain medicine—in excessive amounts, and that such a defective fentanyl patch caused Ronald Grange, Sr. to die of a fentanyl overdose. *Grange v. Mylan Labs., Inc.*, No. 1:07-CV-107, 2008 WL 4813311, at *1 (D. Utah Oct. 31, 2008) (reciting allegations of complaint); see also Hoar Aff., Ex. D at ¶ 11 (*Grange* first amended complaint, filed June 24, 2009). In or

around early February 2010, Mylan formally retained Dr. Enscore, and he and Mylan entered into a confidentiality agreement on February 5, 2010. Under the agreement, Mylan agreed to provide Dr. Enscore with certain confidential information necessary to permit him to evaluate the issues, and Dr. Enscore agreed not to disclose that information, with certain sensible exceptions (e.g., sharing the information with Dr. Enscore's consultants or employees, or disclosing the information under legal compulsion or with Mylan's prior written consent). See Cuthbertson Decl. Ex. B (Confidentiality Agreement). The confidentiality agreement defined "confidential information" as including "all notes, books, papers, diagrams, documents, reports, e-mail, memoranda, visual observations, oral communications and all other data or information in whatever form, disclosed by one Party and/or its affiliates to the other Party and/or its affiliates, including those made prior to the execution of this Agreement." *Id*. The confidentiality agreement did not include any non-compete language.

After Dr. Enscore entered into the confidentiality agreement, he had telephonic and in-person contact with Mylan scientists and attorneys. Cuthbertson Decl. ¶ 5. He attended an all-day meeting at Mylan's Pennsylvania headquarters with Mylan in-house counsel, outside counsel, scientists, and others. In the words of Clem Trischler—who assisted Mylan in defending the *Grange* case as outside counsel—Dr. Enscore received

> a host of detailed, non-public information about Mylan's development process for its Fentanyl transdermal drug product. He received internal, non-public Mylan documents, and he was present when Mylan scientists described non-public information about how and why they made design choices for the Fentanyl product. The discussion was very detailed and in-depth.

Trischler Decl. ¶ 8. Mylan says that Dr. Enscore was also made privy to attorney work product and attorney-client privileged communications, whose subject matter included "Mylan's legal strategy for highlighting certain of the design choices Mylan scientists made when developing Fentanyl and Mylan's legal strategy for explaining why the product reflects superior design choices and thus is a valuable, well-developed product." *Id*. ¶ 9; see also Cuthbertson Decl. ¶ 10.

Dr. Enscore has supplied an affidavit describing his role in the *Grange* litigation as follows:

> The focus of my work was to review and comment on a report that had been prepared by an expert for the plaintiff, which stated in part that the Mylan patch was defective and caused an overdose of fentanyl that resulted in the death of the plaintiff's relative.
>
> As part of my work to respond to the plaintiff's expert report, I reviewed certain Mylan documents that described the composition and manufacture of its fentanyl patch. The main documents I reviewed were "development reports," which describe a manufacturer's design choices for its product and provide the rationale for the final design. Additional materials included product development and bioequivalence testing sections of the Abbreviated New Drug Application (ANDA) that a generic manufacturer like Mylan submits to the FDA to obtain

> approval of its generic product. I also reviewed at least some parts of the "Chemistry, Manufacturing, and Controls" (CMC) section of the ANDA, which is the part of the ANDA that describes the product formulation, its stability and how it will be manufactured. Additionally, I reviewed some exemplar batch records for manufacture of the product.
>
> My discussions with the attorneys for Mylan centered on my explanation of what I thought was inaccurate in the report from the plaintiffs' expert as to technical and pharmaceutical issues, specifically, if the Mylan fentanyl patch was defective and if the patch delivered an overdose of fentanyl. There were a number of points in the report of the plaintiff's expert that I thought were incorrect, and I explained my opinion to the attorneys for Mylan.
>
> I did not recognize any of these discussions as the attorneys telling me their litigation strategy, except I knew of course that Mylan, as the manufacturer of a generic pharmaceutical in a product liability case, would take the position that its product was not defective, did not cause the patient's death, and had been approved by the FDA as bioequivalent to the already-approved innovator product.

Enscore Aff. ¶¶ 2–5 (filed Oct. 30, 2012).

Dr. Enscore was not a testifying expert in the *Grange* case—he did not file any affidavit, and he did not testify in any deposition or court hearing. He did prepare work that he submitted to Mylan's attorneys, but Mylan did not release a report from Dr. Enscore to any opposing party. The *Grange* case settled before trial, and Dr. Enscore's work on behalf of Mylan in that case concluded in 2010.

As part of Mylan's trade-secrets claim in this case, Mylan will have to show that Zydus took a trade secret—i.e., information that "derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use." 9 V.S.A. § 4601(3). On September 7, 2012, Zydus disclosed Dr. Enscore as a proposed expert witness adverse to Mylan. Zydus says that it is asking Dr. Enscore to evaluate questions like: "(i) if Mylan's claimed trade secrets really are such, or to the contrary if they are reasonably available in the public domain, and (ii) the extent (if any) to which Zydus Noveltech's proposed products are based on anything confidential to Mylan." Zydus's Mem. in Opp'n at 2 (filed Oct. 26, 2012); see also *id*. at 16 (asserting that Dr. Enscore's work for Zydus would "focus on whether manufacturing processes for transdermal products contain trade secrets and whether those trade secrets were misappropriated by Zydus Noveltech."). In his affidavit, Dr. Enscore states that he understands that he should not discuss with Zydus's lawyers in this case the discussions he had with the Mylan attorneys in the *Grange* case. Enscore Aff. ¶ 6. He says that:

> It will be easy for me to refrain from doing that because I do not remember details of those discussions, except for certain things I remember telling them about the report of the plaintiff's expert in the product liability case. I also promise that I

> will not in the future disclose to the defendants' lawyers here anything about those discussions if I remember more about them in the future.

Id.

ANALYSIS

There is no question that the court has the power to disqualify an expert. See *Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2011 WL 3843956, at *2 (D. Vt. Aug. 30, 2011); *In re Ambassador Grp., Inc., Litig.*, 879 F. Supp. 237, 241 (E.D.N.Y. 1994) ("It is inherently within a court's power to disqualify an expert."). Compared to cases raising questions about attorney disqualification, cases involving expert disqualification are relatively rare. See *Ambassador*, 879 F. Supp. at 241–42. Of that already rare category of cases, the subset in which courts grant the disqualification of experts is even smaller. See *Lyman* at *2 ("[C]ases that grant disqualification [of experts] are rare." (quoting *Koch Ref. Co. v. Jennifer L. Boudreaux M/V*, 85 F.3d 1178, 1181 (5th Cir. 1996))); see also *Hewlett-Packard Co. v. EMC Corp.*, 330 F. Supp. 2d 1087, 1092 (N.D. Cal. 2004) ("[D]isqualification [of experts] is a drastic measure that courts should impose only hesitantly, reluctantly, and rarely.").

In the absence of a Vermont Supreme Court case setting forth a standard for expert disqualification based on a conflict of interest, the court looks to the analytical framework employed in other jurisdictions. See *Haner v. State*, No. 290-7-07 Bncv (Vt. Super. Ct. May 12, 2010) (Wesley, J.), available at http://www.vermontjudiciary.org/20062010%20TCdecisioncvl/2010-5-19-2.pdf (looking to Colorado and Texas cases for a standard for evaluating a claim of expert disqualification on the basis of a conflict of interest). The federal courts have generally coalesced around a two-part inquiry, asking: "1) was it objectively reasonable for the moving party to conclude that a confidential relationship existed; and 2) did the moving party disclose confidential information to the expert?" *Lyman* at *2; see also *Ambassador*, 879 F. Supp. at 242; accord *Haner* (citing state court cases). "Some courts have considered a third factor: whether the public interest would be served by allowing or not allowing the expert to testify." *Lyman* at *2.[1]

Mylan argues that there is a fourth factor in the analysis: the confidential information it shared with Dr. Enscore in *Grange* must be relevant to the present case. See Mem. of Law in Supp. of Pls.' Mot at 6 (filed Oct. 11, 2012). The court concludes that this is not a separate factor in the test, but that it is part of the analysis of the second prong. See *Return Mail, Inc. v.*

[1] Some cases also suggest that, in addition to the multi-factor inquiry—or perhaps as an extreme instance of that inquiry—there might also be a bright-line test under which disqualification results every time an expert switches sides in the same case. See *Rhodes v. E.I. Du Pont de Nemours & Co.*, 558 F. Supp. 2d 660, 664 (S.D.W.Va. 2008) (noting lack of clarity as to whether there is a bright-line rule); compare *Return Mail, Inc. v. United States*, No. 11-130 C, 2012 WL 5866140, at *2 (Fed. Cl. Nov. 16, 2012) (stating that expert side-switching is a "clear-cut case for disqualification"); with *Life Technologies Corp. v. Biosearch Technologies, Inc.*, No. C-12-00852 WHA, 2012 WL 1604710, at * (N.D. Cal. May 7, 2012) ("There is no bright-line rule for expert disqualification."). Here, as in *Lyman*, this case does not involve side-switching within the same litigation. *Lyman* at *4 ("This is not a case of an expert who has 'switched sides' in the same litigation after having received confidential information."). In any case Mylan does not argue for the application of a bright-line test, so the court does not comment on or apply any such test.

United States, No. 11-130 C, 2012 WL 5866140, at *4 (Fed. Cl. Nov. 16, 2012) (describing second inquiry as whether the moving party disclosed any confidential information relevant to the issues in the present case);[2] *Ascom Hasler Mailing Sys., Inc. v. U.S. Postal Serv.*, 267 F.R.D. 9, 12 (D.D.C. 2010) (concluding that the first prong was met, but not the second prong because it was "inconceivable that any thing [the consultant] did in the Pitney Bowes case could have influenced his work in this case"); *Lacroix v. BIC Corp.*, 339 F. Supp. 2d 196, 199–200 (D. Mass 2004) (articulating second prong as "whether the moving party disclosed confidential information to the expert *that is relevant to the current litigation*" (emphasis added)); *Ambassador*, 879 F. Supp. at 243 (noting that, in order to warrant disqualification, the confidential information transmitted by the moving party must have been "disqualifying information").

"Although most expert disqualification cases involve a testifying expert, courts employ the same test in determining whether to disqualify a consulting expert." *Lacroix*, 339 F. Supp. 2d at 199. The court will therefore apply the test described above to this case. As the party seeking Dr. Enscore's disqualification, Mylan has the burden of proof. *Lyman* at *3.

1. Was it objectively reasonable for Mylan to conclude that a confidential relationship existed with Dr. Enscore?

There are a variety of factors that courts consider when determining whether it was reasonable for the moving party to believe that there was a confidential relationship. See *Hewlett-Packard Co. v. EMC Corp.*, 330 F. Supp. 2d 1087, 1093 (N.D. Cal. 2004) (listing factors). Here, the most relevant factors are that Mylan and Dr. Enscore entered into a formal confidentiality agreement that explicitly defined "confidential information" very broadly. After Dr. Enscore executed the agreement, Mylan gave Dr. Enscore access to its scientists and documents, including development reports and batch records. Cf. *Lyman* at *3 (brief consultation with a neuropharmacologist on textbook questions, where the consultant was not provided with any confidential documents and did not enter into a formal confidentiality agreement, was insufficient to meet the first prong). The court concludes that Mylan has shown that it was objectively reasonable for it to conclude that its communications with Dr. Enscore would be maintained in confidence. This does not end the inquiry, however. *Lyman* at *2 ("Only if the answers to *both* questions are 'yes,' should the expert be disqualified." (emphasis added)).

2. Did Mylan disclose disqualifying confidential information to Dr. Enscore?

Mylan argues that, in the course of his work on the *Grange* case, Dr. Enscore received "privileged information from attorneys and insights from Mylan scientists on an issue directly relevant to trade secret law—whether a product at issue has independent economic value . . . ." Mem. of Law in Supp. of Pls.' Mot at 5. Mylan maintains that:

[2] Zydus cites *Return Mail* in a letter to the court dated November 28, 2012. In a letter dated December 3, 2012, Mylan asserts that Zydus's November 28 letter is unauthorized, and contends that *Return Mail* does not add anything to the parties' existing briefs. The court appreciates that the *Return Mail* opinion was not public until after briefing on the pending motion was complete, which explains why neither party cited it in their original briefs. Since Mylan took the opportunity to provide its analysis of *Return Mail*, the court sees no harm in considering it.

> It makes no difference that product liability law and trade secret law differ in some respects, because they share a common denominator: a party must show that the choices that went into its product design resulted in a valuable product—one that is "safe" in product liability parlance, and one that has "economic value" in trade secret parlance.

Id. at 7. Zydus argues that: (1) Dr. Enscore reviewed only purely "technical" documents, which are not privileged and must be produced by Mylan in discovery in this case; (2) to the extent Mylan shared its legal strategy for defending the *Grange* case with Dr. Enscore, that is not grounds for disqualification; and (3) any exposure to confidential information in the *Grange* case is irrelevant to this litigation. Zydus's Mem. in Opp'n at 9–16. According to Zydus, the only common thread between the *Grange* case and this case is that they both involve transdermal products. *Id*. at 14. Mylan replies that Dr. Enscore gained knowledge about Mylan's legal strategy for how best to emphasize the value of its design choices for the fentanyl product, and that the same legal strategy would overlap with Mylan's strategy in this case about how best to satisfy the "independent economic value" requirement in this trade secrets case. Reply at 3 (filed Nov. 9, 2012).

Mylan plainly shared scientific information with Dr. Enscore, but that sort of technical information does not qualify for present purposes as confidential information. See *Lyman* at *3 ("[P]urely technical information is not confidential." (quoting *Koch Ref. Co. v. Jennifer L. Boudreaux M/V*, 85 F.3d 1178, 1181 (5th Cir. 1996))). The technical information necessary to evaluate the existence of a trade secret in this case may not be public, but it is discoverable in this litigation. See Reply at 3 (conceding that the features of Mylan's product are discoverable). If Dr. Enscore did not already obtain that technical information in *Grange*, he will be able to do so in this case, subject to the July 2, 2009 amended Stipulation and Protective Order.

Mylan's argument is focused instead on the alleged communication of litigation strategy with Dr. Enscore. Reply at 2 ("Mylan's distinct point is that when Dr. Enscore worked on [*Grange*], he obtained non-discoverable, attorney-client privileged information about the thinking of Mylan's attorneys regarding the value of its product design choices for Fentanyl and their strategy for emphasizing their value."). It is true that confidential information includes discussion of the retaining party's strategies in the litigation. *Koch*, 85 F.3d at 1182. In this case, however—similar to *Lyman*— Mylan's defense strategy in the *Grange* case "would appear to be self-evident." *Lyman* at *3. Dr. Enscore states as much when he notes that he knew that Mylan "would take the position that its product was not defective, did not cause the patient's death, and had been approved by the FDA as bioequivalent to the already-approved innovator product." Enscore Aff. ¶ 5. Undoubtedly the *Grange* litigation was about whether Mylan's product was safe, and all other things being equal, a safer product is a more valuable product. But aside from those general propositions, Mylan has not explained precisely what it thinks Dr. Enscore knows that might be used against it in this trade secrets case. Ultimately, although this case and *Grange* both involve transdermal drug delivery products, that is where the similarities end. The court concludes that Mylan has not met its burden on the second prong.

3. Public policy considerations

"The policy objectives favoring disqualification include preventing conflicts of interest and maintaining the integrity of the judicial process." *Koch*, 85 F.3d at 1182 (quotation omitted). "The main policy objectives militating against disqualification are ensuring that parties have access to expert witnesses who possess specialized knowledge and allowing experts to pursue their professional calling." *Id.* at 1183. "Courts have also expressed concern that if experts are too easily subjected to disqualification, unscrupulous attorneys and clients may attempt to create an inexpensive relationship with potentially harmful experts solely to keep them from the opposing party." *Id.* Therefore, "courts have considered whether another expert is available and whether the opposing party had time to hire him or her before trial." *Id.*

Here, Dr. Enscore has valuable specialized knowledge that might assist the court to understand the evidence. For the reasons above, the court does not believe that he has a conflict in this case that would undermine the integrity of the judicial process in this case. As to whether another expert might be available, Mylan argues that Zydus has already disclosed one other expert, and should be able to select an expert to replace Dr. Enscore if necessary. For its part, Zydus contends that disqualifying Dr. Enscore would impose a severe hardship because of the difficulty of finding experts in transdermal drug development who are not conflicted because they work for or are affiliated with Mylan's competitors. Mylan replies that Zydus's contention is empty rhetoric without any factual support. Although the record is sparse concerning what Zydus's alternatives might be, the court is unconvinced that disqualification is required just because it might be possible for Zydus to obtain a different expert. If that were so, disqualification would be the rule rather than the exception. The court does not believe that this consideration outweighs the analysis above.

ORDER

Because plaintiffs have not met their burden of proving disqualification, their motion to preclude Dr. Enscore from serving as an adverse expert witness (filed Oct. 11, 2012) is denied.

Dated at Burlington this ___ day of December 2012.

_____
Geoffrey W. Crawford
Superior Court Judge