

# **EXHIBIT 35**

2011 WL 691594

Only the Westlaw citation is currently available.  
 United States District Court,  
 D. New Jersey.

NOVARTIS AG and Novartis  
 Pharmaceuticals Corporation, Plaintiffs,  
 v.

APOTEX INC. and Apotex Corp., Defendants.

Civil Action No. 09–5614 (PGS). | Jan. 24, 2011.

#### Attorneys and Law Firms

William J. O'Shaughnessy, Carissa L. Rodrigue, Jonathan M.H. Short, Symone J. Redwine, McCarter & English, LLP, Newark, NJ, for Plaintiffs.

James E. Cecchi, Melissa E. Flax, Carella Byrne Cecchi Olstein Brody & Agnello, P.C., Roseland, NJ, for Defendants.

#### REPORT AND RECOMMENDATION

ESTHER SALAS, United States Magistrate Judge.

\*1 Pending before the Court is Defendants Apotex Inc. and Apotex Corp.'s ("Apotex") motion to disqualify Dr. Alexander Klibanov from serving as an expert witness on behalf of Plaintiffs Novartis AG and Novartis Pharmaceuticals Corp. ("Novartis"). (Docket Entry No. 34, the "Motion"). Apotex also seeks to preclude Novartis from relying on Dr. Klibanov's opinions in their entirety. (*Id.*). The Honorable Peter G. Sheridan, United States District Judge, has referred the Motion to the Undersigned for report and recommendation pursuant to [Local Civil Rule 72.1\(a\)\(2\)](#). Having considered the parties' submissions, the Undersigned respectfully recommends denying Defendant Apotex's Motion.

#### I. FACTUAL AND PROCEDURAL BACKGROUND

This lawsuit stems from Apotex's alleged infringement of several patents owned by Novartis pertaining to Myfortic7 delayed-release tablets. (See Docket Entry No. 1, the "Complaint" at ¶¶ 13, 14). Novartis claims that Apotex submitted an abbreviated new drug application ("ANDA") to the FDA under the provisions of [21 U.S.C. § 355\(j\)](#) seeking approval to engage in the commercial manufacture, use,

offer for sale, sale, and/or importation of generic Myfortic7 delayed-release tablets 180 mg and 360 mg. (See Complaint at ¶ 24). Further, Novartis alleges that Apotex committed an act of infringement under [35 U.S.C. § 271\(e\)\(2\)](#) by filing the ANDA before the expiration of Novartis' patents.<sup>1</sup> On December 15, 2009, Apotex filed an answer and counterclaim alleging declarations of non-infringement and invalidity of the several patents. (Docket Entry No. 10). On May 3, 2010, Apotex moved to disqualify Dr. Klibanov from serving as Novartis' expert, and to preclude Novartis from relying on Dr. Klibanov's opinions. (Docket Entry No. 34).

<sup>1</sup> Novartis AG is the owner of United States Letters Patent Nos. 6,025,391; 6,172,107; and 6,306,900. (See Complaint at Ex. A–C).

#### II. LEGAL STANDARD

A federal court has the inherent power to disqualify experts. *U.S. ex. rel. Cherry Hill Convalescent Ctr., Inc. v. Healthcare Rehab Ctrs., Inc.*, 994 F.Supp. 244, 248 (D.N.J.1997). The court derives this power from its "duty to preserve confidence in the fairness and integrity of judicial proceedings, and to protect privileges which may be breached if an expert is permitted to switch sides in pending litigation." *Id.* at 248–49 (internal citations omitted). This court uses a two-prong test to determine whether an expert who had a prior relationship with a party should be disqualified: (1) whether it was "objectively reasonable for the first party who retained the expert to believe that a confidential relationship existed" and (2) whether "that party disclose [d] any confidential information to the expert." *Id.* at 249; See also *Cordy v. Sherwin-Williams Co.*, 156 F.R.D. 575, 579 (D.N.J.1994).

In addition, the court should balance competing policy objectives in determining whether an expert should be disqualified. *Cordy*, 156 F.R.D. at 580. The policy objectives in favor of disqualification "include the court's interest in preventing conflicts of interest and in maintaining judicial integrity." *Cherry Hill*, 994 F.Supp. at 251. The policy objectives weighing against disqualification "include maintaining accessibility to experts with specialized knowledge and encouraging experts to pursue their professions." *Id.* Apotex, the party seeking disqualification, bears the burden of proof on these issues. *Cordy*, 156 F.R.D. at 580.

#### III. ANALYSIS

### A. Confidential Relationship

\*2 The Court must first determine whether Apotex acted reasonably in assuming that a confidential relationship existed between Apotex and Dr. Klibanov. The Court finds that it was objectively reasonable for Apotex to believe that a confidential relationship existed.

Apotex maintains that a confidential relationship existed by virtue of Dr. Klibanov's work as an expert for Apotex during the years 2002 through 2009. (See Docket Entry No. 34–1, “Apotex Brief” at 5). During this time, Apotex claims that Dr. Klibanov served as an expert for Apotex nine times.<sup>2</sup> (*Id.* at 1). Apotex asserts that it provided Dr. Klibanov with confidential documents relating to Apotex's research and development of generic pharmaceuticals, regulatory practices, and litigation strategy—documents Apotex would not disclose without the belief that a confidential relationship existed. (*Id.* at 5). Finally, Apotex states that Dr. Klibanov was privy to Apotex's litigation strategies including the mental impressions, opinions, and legal theories of counsel. (*Id.* at 6).

<sup>2</sup> Three cases in the United States and six cases in Canada.

Novartis, supported by Dr. Klibanov's Affidavit, argues that Dr. Klibanov worked as an expert for Apotex in only one of the three cases in the United States. (See Docket Entry No. 42–1, “Dr. Klibanov Declaration” at ¶ 11). In the other two cases, Dr. Klibanov served as an expert witness for Novartis and PAR Pharmaceuticals *against* Apotex. (*Id.* at n. 1). In addition to working with Novartis and Apotex during this period, Dr. Klibanov was retained to testify against Apotex by the following pharmaceutical companies: Sanofi, Bristol–Myers Squibb, Sanofi–Synthelabo Canada, AstraZeneca, Daiichi, and Janssen Ortho Inc. (See Docket Entry No. 42, “Novartis Brief” at 2).

The objectively reasonable belief of a confidential relationship is not a “high hurdle” for the moving party to clear. *AstraZeneca Pharmaceuticals, LP v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 05–5333, 2007 U.S. Dist. LEXIS 88996 at \*5 (D.N.J. Dec. 4, 2007). In *AstraZeneca*, Teva argued that the proposed experts should not be disqualified “based upon their peripheral relationships” with AstraZeneca. *Id.* at 6. Teva claimed that the imposition of a broad standard would effectively disqualify all other expert clinicians in the field. *Id.* The *AstraZeneca* court noted, however, that the existence of a confidential relationship is merely the first step of the disqualification analysis. *Id.* at 7.

At this point, the court was concerned about AstraZeneca's belief of the existence of a confidential relationship, and not the effects of that belief. *Id.* (finding that “[t]he first prong requires a factual finding, and does not ring in equity”). Factual circumstances supporting the existence of a confidential relationship include: (1) express confidentiality agreements, (see *Id.* at 6); (2) employment contracts, (see *Orion Corp. v. Sun Pharm. Ind.*, Civil Action No. 07–5436, 2009 U.S. Dist. LEXIS 125700 at \*7 (D.N.J. June 12, 2009)); and (3) professional duties of confidentiality, (see *Cherry Hill*, 994 F.Supp. at 249–50).

\*3 Here, Dr. Klibanov admits that he was retained by Apotex to serve as its expert in both a U.S. case and in a number patent infringement cases in Canada. (See Dr. Klibanov Declaration at ¶¶ 12 and 13). Although it is not clear whether these agreements contain confidentiality provisions, Dr. Klibanov certified in his declaration that Apotex did not require him to refrain from working with adverse parties. (See *Id.* at ¶ 17). Although Apotex failed to provide a supporting affidavit, it maintains its position that it did provide Dr. Klibanov with confidential documents during his engagement with the expectation that such disclosures would remain confidential. (See Apotex Br. at 5). Based on Dr. Klibanov's admission that he served as an expert for Apotex in prior litigation, and recognizing the inherent confidential relationship between a party and its expert, the Court is persuaded that Apotex held a reasonable belief that a confidential relationship existed with Dr. Klibanov.

### B. Confidential Information

Next, the Court must consider whether Apotex disclosed confidential information to Dr. Klibanov relating to this specific litigation. In *Cherry Hill*, the court noted that “[c]onfidential information, in the context of expert disqualification, includes: discussion of the [retaining party's] strategies in the litigation, the kinds of expert [the party] expected to retain, [the party's] views of the strengths and weaknesses of each side, the role of each of the [party's] witnesses to be hired, and anticipated defenses.” 994 F.Supp. at 250 (citing *Koch Refining Co. v. Boudreaux MV*, 85 F.3d 1178, 1182 (5th Cir.1996)) (internal quotations omitted). Further, in *Orion Corp.*, the court found that the alleged confidential information must be related to the technology in issue to satisfy the second prong. 2009 U.S. Dist. LEXIS 125700 at \* 10.

Apotex argues that Dr. Klibanov was exposed to documents relating to Apotex's regulatory strategies and the research and

development of its generic drug products. (*See* Apotex Brief at 6). Apotex contends that Dr. Klibanov's general knowledge is relevant in light of Novartis' Requests for Production seeking information regarding Apotex's regulatory filings. (*Id.*). Further, Apotex claims that Dr. Klibanov was privy to the mental impressions, opinions, and legal theories of Apotex's legal counsel. (*Id.*).

In response, Novartis posits that Apotex fails to demonstrate that any confidential information was disclosed to Dr. Klibanov which encompassed facts and ideas directly relating to or impacting the present litigation. (*See* Novartis Brief at 7). Novartis claims that Apotex's allegedly confidential information relates to different pharmaceutical products, different patents, and different theories of patent infringement and/or invalidity. (*Id.*). Lastly, Dr. Klibanov certified that he has never performed work with Apotex concerning Novartis' Myfortic product or Apotex's proposed generic copy. (*See* Dr. Klibanov Declaration at ¶ 16).

\*4 The Court agrees with Novartis and finds that Apotex failed to identify any confidential information specific to the subject matter underlying this litigation shared with Dr. Klibanov. Similarly, in *Syngenta Seeds, Inc. v. Monsanto Co.*, the court denied a motion to disqualify an expert because the moving party failed to point to any specific confidential communications that were shared with the proposed expert. Civil Action No. 02-1331, 2004 U.S. Dist. LEXIS 19817 at \*11 (D.Del. Sept. 27, 2004). The moving party claimed that the proposed expert received confidential proprietary materials and was provided with confidential information in the course of deposition preparation. *Id.* The court declined to disqualify the expert since neither allegation identified specific confidential information nor explained how the information related to the present matter. *Id.*

Here, Apotex has failed to carry its burden of showing that Apotex disclosed confidential information related to this litigation. The Court is not persuaded that Dr. Klibanov's alleged knowledge of Apotex's regulatory strategies rises to the level of confidential information sufficient to disqualify. Moreover, Apotex has not demonstrated how Dr. Klibanov's general knowledge of Apotex's regulatory practices relates to the technology at issue in this case. If the Court were

to base Dr. Klibanov's disqualification on his knowledge of Apotex's general regulatory strategies, then the Court would effectively bar Dr. Klibanov from ever appearing as an expert adverse to Apotex. Accordingly, the Court finds that any confidential information disclosed to Dr. Klibanov does not relate to Novartis' Myfortic product.

Further, the Court declines to disqualify Dr. Klibanov on the basis that he was previously exposed to Apotex's legal strategies and the opinions of its legal counsel. In *Atlantic City Assocs.*, the court found that a generalized and vague allegation that the expert knew "mental impressions and trial strategies" did not support disqualification of the expert. 2007 U.S. Dist. LEXIS 1185 at \*7. Therefore, the Court concludes that Apotex did not disclose any confidential information to Dr. Klibanov sufficient to disqualify him from serving as an expert witness or to prevent Novartis from relying on his opinions.

### C. Policy Considerations

In addition to the two-prong test, *Cherry Hill* instructs the court to balance potential conflicts of interests against maintaining accessibility to experts. 994 F.Supp. at 251. The Court does not perceive a conflict of interest between Apotex and Dr. Klibanov because the Court is satisfied that there was no exchange of confidential information pertaining to this case. Therefore, the balance weighs in favor of maintaining Novartis' accessibility to an expert with specialized knowledge and encouraging Dr. Klibanov's pursuit of his profession. In light of the Court's determination, the Court need not consider whether Novartis would be prejudiced by having to retain a substitute expert.

### III. CONCLUSION

\*5 For the reasons set forth above, the Undersigned respectfully recommends that the District Court **DENY** Apotex's motion to disqualify Dr. Alexander Klibanov from serving as Novartis' expert witness and to preclude Novartis from relying on Dr. Klibanov's opinions. Pursuant to Local Civil Rule 72. 1, the parties have fourteen days from receipt of this Report and Recommendation to file and serve any objections.