# **EXHIBIT C**



# ABAXIS, INC., Plaintiff-Counterdefendant, v. CEPHEID, Defendant-Counterclaimant.

Case No. 10-CV-02840-LHK

# UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, SAN JOSE DIVISION

2012 U.S. Dist. LEXIS 100530

July 19, 2012, Decided July 19, 2012, Filed

**PRIOR HISTORY:** Abaxis, Inc. v. Cepheid, 2012 U.S. Dist. LEXIS 49748 (N.D. Cal., Apr. 9, 2012)

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JUDGES: LUCY H. KOH, United States District Judge.

**OPINION BY: LUCY H. KOH** 

#### **OPINION**

ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFF'S MOTION TO EXCLUDE EXPERT TESTIMONY

Plaintiff-Counterclaimant Abaxis, Inc. ("Abaxis") moves to exclude the testimony of Defendant-Counterclaimant Cepheid's ("Cepheid") technical expert, Dr. Philip Williams. Pursuant to *Civil* 

Local Rule 7-1(b), the Court finds the motion appropriate for determination without oral argument. Having considered the submissions of the parties and the relevant law, the Court GRANTS IN PART and DENIES IN PART Abaxis's motion to exclude.

### I. LEGAL STANDARD

Federal Rule of Evidence 702 allows admission of "scientific, technical, or other specialized knowledge" by a qualified expert if it will "help the trier of fact to understand the evidence or to determine a fact in issue." Expert testimony [\*3] is admissible pursuant to Rule 702 if it is both relevant and reliable. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). A district court's decision to admit expert testimony under Daubert in a patent case follows the law of the regional circuit. Micro Chem., Inc. v. Lextron, Inc., 317 F.3d 1387, 1390-91 (Fed. Cir. 2003). When considering expert testimony offered pursuant to Federal Rule of Evidence 702, a district court acts as a "gatekeeper" by "making a preliminary determination that the expert's testimony is reliable." Elsayed Mukhtar v. Cal. State Univ., Hayward, 299 F.3d 1053, 1063 (9th Cir. 2002); see Kumho Tire Co. v. Carmichael, 526 U.S. 137, 147-48, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999); Gen. Elec. Co. v. Joiner, 522 U.S. 136, 142, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997); Daubert, 509 U.S. at 589-90. An expert witness may provide opinion testimony if: (1) the testimony is based upon sufficient facts or data; (2) the testimony is the product of reliable principles and methods; and (3) the expert has reliably applied the principles and methods to the facts of the case. Fed. R. Evid. 702; see also Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1360 (Fed. Cir. 2008). Under Daubert, "a court should consider (1) whether [\*4] a theory or technique 'can be (and has been) tested;' (2) 'whether the theory or technique has been subjected to peer review and publication;' (3) 'the known or potential rate of error;' and (4) whether it is generally accepted in the scientific community." Wagner v. Cnty. of Maricopa, 673 F.3d 977, 989 (9th Cir. 2012) (quoting Daubert, 509 U.S. at 593-94).

The inquiry into admissibility of expert opinion is a "flexible one," where "[s]haky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion." *Primiano v. Cook, 598 F.3d 558, 564 (9th Cir. 2010)* (citing *Daubert, 509 U.S. at 594, 596*). "Under *Daubert*,

the district judge is 'a gatekeeper, not a fact finder.' When an expert meets the threshold established by *Rule 702* as explained in *Daubert*, the expert may testify and the jury decides how much weight to give that testimony." *Id.* (quoting *United States v. Sandoval-Mendoza, 472 F.3d 645, 654 (9th Cir. 2006)).* 

#### II. ANALYSIS

#### A. Dr. Williams's Technical Opinions

Abaxis does not dispute Dr. Williams's qualifications as an expert. Rather, Abaxis contends that Dr. Williams has no personal experience with the designing [\*5] or making of freeze-dried materials and lyophilization, rendering his opinions on these topics inadmissible under *Rule 702* due to lack of proper foundation. Mot. 1, 3. According to Abaxis, Dr. Williams's deposition revealed that he was so inexperienced in these matters that his testimony on such subjects would be unreliable. *Id.* at 3. Thus, Abaxis argues, any opinions of Dr. Williams that require knowledge of the design or manufacture of freeze-dried materials and lyophilization, including his technical evaluation of lyophilization or whether the prior art is enabling, are inadmissible under *Daubert. Id.* 

Similarly, Abaxis argues that Dr. Williams should be precluded from offering any opinion relating to knowledge of precision pumps, including IVEK brand pumps, due to lack of experience with this particular brand of pump. Id. at 3. Abaxis takes particular issue with Dr. Williams's opinions that persons of ordinary skill in the art would have known about IVEK pumps, that the pumps were "well known," and that they were known in pharmaceutical companies. Id. at 3-4. Abaxis argues that Dr. Williams is unqualified to opine on IVEK pumps because Dr. Williams first became familiar with IVEK [\*6] pumps during this litigation. *Id.* at 3. Moreover, Dr. Williams's opinions about the popularity of IVEK pumps is based solely on: (1) IVEK advertisements; (2) the testimony of a former employee of a company that used IVEK pumps (who now works at Cepheid); and (3) the availability of IVEK pumps in a supply ordering catalog. Id. Accordingly, Abaxis argues that Dr. Williams's opinions regarding IVEK pumps, as well as all other precision pumps, should be barred. Id.

The Court is not persuaded by Abaxis's arguments, all of which argue, in some form or another, that Dr. Williams's lack of personal knowledge renders his testimony inadmissible. While Abaxis is correct that Dr.

Williams never personally executed a freeze-drying or lyophilization procedure, the record indicates that Dr. Williams was, indeed, familiar with such procedures. In fact, the record makes clear that Dr. Williams's research group had experience with freeze-drying and lyophilization procedures and that Dr. Williams has directed students in his laboratory who have conducted these procedures. *See* Carlson Decl. Ex. H, at ¶ 12; Williams Dep. 18:9-12, 19:5-6. This experience, combined with Dr. Williams's extensive training in [\*7] the field of pharmacy, is sufficient to render his opinions on freeze-drying and lyophilization admissible under *Rule 702. See* Carlson Decl. Ex. H, at ¶¶ 3-7.

Dr. Williams's opinions regarding precision pumps, including IVEK pumps, are similarly admissible. It is true that Dr. Williams admitted that he was unfamiliar with IVEK pumps prior to his involvement in the instant case. Williams Dep. 57:7-15. However, Dr. Williams also testified that he is familiar with a number of highly-precise pumps including syringe-driven, peristaltic, and impeller-driven pumps. Id. at 56:7-10. Moreover, since becoming involved with this case, Dr. Williams has been exposed to evidence in the record that he has used, in combination with his prior experience with other similar pumps, to form his current opinion on IVEK pumps. See Rodriguez Decl. Ex. 3, at ¶¶ 107, 122-23, 125-27. While Abaxis may dispute the credibility, reliability, or sufficiency of the evidence that Dr. Williams used to form his opinions, there is a sufficient factual basis in the record for Dr. William's opinion. Sundance, Inc., 550 F.3d at 1360. Thus, Dr. Williams' testimony regarding IVEK pumps is admissible as well.

Contrary to Abaxis's [\*8] arguments, *Rule 702* imposes no requirement that experts have personal experience in an area to offer admissible testimony relating to that area. *See Daubert, 509 U.S. at 592* ("Unlike an ordinary witness, . . . an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation.") (citing *Fed. R. Evid. 702, 703*). Dr. Williams's knowledge of freeze-drying procedures and IVEK pumps, although indirect, is sufficient to satisfy *Daubert*'s minimum threshold of relevance and accuracy. *See Mformation Techs., Inc. v. Research in Motion Ltd., 08-CV-04990 JW, 2012 U.S. Dist. LEXIS 56784, 2012 WL 1142537, at \*3 (N.D. Cal. Mar. 29, 2012)* ("When the methodology is sound, and the evidence relied upon sufficiently related to

the case at hand, disputes about the degree or relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility."). Thus, Cepheid's objections to the credibility of Dr. Williams's testimony must be resolved on cross-examination, not by wholesale exclusion of his testimony. See DSU Med. Corp. v. JMS Co., Ltd., 296 F. Supp. 2d 1140, 1156 (N.D. Cal. 2003).

Accordingly, Abaxis's motion to exclude the technical [\*9] opinions of Dr. Williams is DENIED.

# B. Dr. Williams's Non-Technical Opinions

# 1. Dr. Williams's Legal Opinions

Abaxis objects to what it alleges are Dr. Williams's legal opinions in paragraphs 157-60 and 182-87 of his expert report. Mot. 4. In particular, Abaxis argues that Dr. Williams improperly opines that an agreement between Pfizer and R.P. Scherer, as well as various agreements between Abaxis and Teramecs, constituted "offer[s] for sale." *Id.* Such opinions, according to Abaxis, are inadmissible under *Rule 702* as they are relevant only to conclusions of law rather than questions of fact. *Id.* 

Cepheid, however, maintains that Dr. Williams explicitly and repeatedly disavowed that he was offering a legal opinion. Opp'n 9-10. Instead, Cepheid contends that Dr. Williams was only offering his opinion as to whether the products that were the subjects of the various agreements actually embodied the asserted patent claims. *Id.* at 10. Because this is a proper subject of expert testimony, Cepheid argues, Dr. Williams's opinions on such matters are admissible. *Id.* 

The Court agrees with Abaxis that Dr. Williams cannot offer his opinion on purely legal matters. *Cf. McHugh v. United Serv. Auto. Ass'n, 164 F.3d 451, 454 (9th Cir. 1999)* [\*10] ("[Expert] testimony cannot be used to provide legal meaning . . . ."). Accordingly, Abaxis's motion to exclude Dr. Williams's opinions on legal matters is GRANTED. This grant is narrow, however, and only bars Dr. Williams from offering his opinion on legal conclusions, such as the legal rights or obligations of various parties or the legal effects of particular agreements. It does not preclude Dr. Williams from testifying about technical matters related to the various agreements mentioned above. As Cepheid rightly points out, Dr. Williams's opinion as to whether the products in the above agreements embodied the asserted

claims is admissible. See Fed. R. Evid. 704(a) ("An opinion is not objectionable just because it embraces an ultimate issue."). Nevertheless, any legal conclusions Dr. Williams might have, such as whether a particular agreement constitutes an "offer for sale" is hereby excluded.

# 2. Dr. Williams's Opinions on "Commercial Success"

Abaxis also seeks to exclude Dr. Williams's opinions on the commercial success of products containing the patented technologies. Mot. 5. In particular, Abaxis wishes to exclude Dr. Williams's opinion that some of the Abaxis products are not commercially [\*11] successful, arguing that such an opinion is not based on any technical knowledge and is therefore beyond the scope of *Rule 702*. *Id.* Cepheid contends, however, that Dr. Williams is not offering his opinion as to the ultimate question of commercial success, but only to the limited question as to whether Abaxis's commercial success (assuming it exists) is attributable to the patented invention. Opp'n 10-11.

The Court is persuaded by Abaxis's arguments and agrees that Dr. Williams's opinion on whether or why any product enjoys commercial success is inadmissible. Nothing in Dr. Williams's qualifications indicates that he is qualified to testify as an expert on such topics. Dr. Williams is an expert in pharmacy, not in sales, marketing, or consumer preferences and demand. See Rodriguez Decl. Ex. 3, at ¶¶ 8-10. Accordingly, Abaxis's motion to exclude Dr. Williams's opinions on commercial success is GRANTED. Dr. Williams may not speculate as to what he believes is responsible for the commercial success of Abaxis's process and beads. However, Dr. Williams may educate the jury on whether Abaxis's process and beads contain technology in the prior art or other features not claimed in the patents-in-suit. [\*12] The jurors are free to draw their own conclusions as to whether the evidence establishes that the patented features, rather than other features, drive the sale of Abaxis's process and beads. See Ormco Corp. v. Align Tech. Inc., 463 F.3d 1299, 1311-12 (Fed. Cir. 2006) ("Evidence of commercial success . . . is only significant if there is a nexus between the claimed invention and the commercial success.").

# 3. Dr. Williams's Opinions on Copying

Abaxis finally objects to Dr. Williams's opinion that the patented inventions were not copied by Cepheid. Mot. 5. Such a conclusion, Abaxis argues, is only based on deposition testimony and does not draw at all upon Dr. Williams's technical background. Id. Accordingly, Abaxis argues that Dr. Williams is simply acting as a layperson in giving this opinion, thereby rendering it inadmissible under Rule 702. Id. Cepheid argues, however, that Dr. Williams has no intention of offering his opinion on the ultimate question of copying, but instead only intends to offer his analysis regarding a comparison of the two parties' technologies, how Cepheid's process was developed, and which parts of the technologies were well known in the art. Opp'n 11-12. Such [\*13] subjects, Cepheid contends, are proper subjects of expert testimony. Id.

Dr. Williams is not entitled to offer his opinion as to the ultimate question of whether Cepheid copied Abaxis. Accordingly, insofar as Abaxis's motion objects to such an opinion, it is GRANTED. Nevertheless, Dr. Williams will be allowed to give his opinion regarding the comparison of the technologies of the parties, the development of Cepheid's process, and whether the parties' technologies were well-known in the art. Such subjects are beyond the scope of a layperson's experience and within Dr. Williams's expertise. Dr. Williams's testimony on these subjects is therefore proper, and to the extent Abaxis's motion seeks to exclude such testimony, it is DENIED.

### III. CONCLUSION

For all of the foregoing reasons, Plaintiff's motion to exclude Dr. Williams's testimony is GRANTED IN PART and DENIED IN PART as set forth above.

#### IT IS SO ORDERED.

Dated: July 19, 2011

/s/ Lucy H. Koh

LUCY H. KOH

United States District Judge