

United States District Court  
For the Northern District of California

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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE DIVISION

ABAXIS, INC.,	)	Case No.: 10-CV-2840-LHK
	)	
Plaintiff,	)	
	)	ORDER DENYING DEFENDANT’S
v.	)	MOTION FOR SUMMARY JUDGMENT
	)	
CEPHEID,	)	
	)	
Defendant.	)	

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On July 28, 2010, Abaxis served Cepheid with a complaint alleging infringement of four patents: United States Patent Nos. 5,413,732 (“the ’732 Patent”), 5,624,597 (“the ’597 Patent”), 5,776,563 (“the ’563 Patent”) and 6,251,684 B1 (“the ’684 Patent”). Dkt. No. 1. Cepheid now moves for summary judgment that claims 1 and 3 of the ’563 Patent and claims 12 and 13 of the ’684 Patent (“the asserted claims”) are invalid under 35 U.S.C. § 102(b). Dkt. No. 170. The Court DENIES Cepheid’s motion for summary judgment because there are genuine issues of material fact as to whether the patented invention was offered for sale or in public use in the United States more than one year before the priority date of the asserted claims. *See* 35 U.S.C. § 102(b).

**I. Background**

Abaxis and Cepheid compete in the medical testing market. Both parties manufacture freeze-dried chemical reagent particles that are useful in automated medical testing. These reagent beads or spheres are typically formed by preparing an aqueous solution of the reagent, dispensing

1 uniform, precisely measured drops of the solution into a cryogenic liquid, and lyophilizing the  
2 frozen drops to form dried beads or spheres. These reagent particles are loaded into small wells in  
3 a rotor. Medical samples are then added into the wells, enabling chemical reactions between the  
4 reagents and the samples that can be measured by an analyzer component to obtain medically  
5 relevant information. This automated testing lowers costs and increases accuracy, benefiting  
6 patients, doctors, and society. Abaxis developed freeze drying technology beginning in the late  
7 1980s, and was awarded patents covering the technology. On July 28, 2010, Abaxis filed this  
8 action accusing Cepheid of infringing Abaxis patents on freeze-dried reagent particles. Dkt. No. 1.  
9 Cepheid now moves for summary judgment that the asserted claims (1 and 3 of the '563 Patent and  
10 12 and 13 of the '684 Patent) are invalid under 35 U.S.C. § 102(b). Dkt. No. 170.

11 Asserted claim 1 of the '563 Patent claims a container holding dried chemical beads, and  
12 recites:

13 A container holding a dried chemical composition which dissolves in less than about 10  
14 seconds in water, wherein said dried chemical composition comprises a pre-selected  
15 precisely measured aliquot of said dried chemical composition which chemical composition  
is in bead form have in a diameter between 1.5 mm and 10.0 mm.

16 '563 Patent 14:42-47. Asserted claim 3 of the '563 Patent recites: "The container of claim 1,  
17 wherein the dried chemical composition has a diameter of between about 1.5 and 3.5 mm." *Id.* at  
18 14:50-52.

19 Claim 1 of the '684 Patent, which is not asserted, claims dried chemical beads, and recites:  
20 "A dried chemical reagent composition comprising a plurality of dried beads having a coefficient  
21 of weight variation of less than about 3%, and a diameter of between about 1.5 mm and about 10  
22 mm or the equivalents thereof." '684 Patent 14:56-59. Asserted claim 12 of the '684 Patent  
23 recites: "The composition of claim 1, wherein the beads have a diameter of less than about 5 mm."  
24 *Id.* at 15:15-16. Asserted claim 13 of the '684 Patent recites: "The composition of claim 12,  
25 wherein the beads have a diameter of less than about 3.5 mm." *Id.* at 15:17-18.

26 Cepheid moves for summary judgment that the asserted claims are invalid under the 35  
27 U.S.C. § 102(b) statutory bar. *See* Mot. at 1; 35 U.S.C. § 102(b). Under 35 U.S.C. § 102(b), "[a]  
28 person shall be entitled to a patent unless . . . (b) the invention was . . . in public use or on sale in

1 this country, more than one year prior to the date of application for patent in the United States.” *Id.*  
2 The ’563 Patent and the ’684 Patent share their specification with application No. 08/134,574, filed  
3 on October 8, 1993. Accordingly, Cepheid argues that the asserted claims are invalid if any  
4 embodiment of the asserted claims was in public use or on sale in the United States before October  
5 8, 1992. *See Mot.* at 1.

6 Cepheid argues that it is entitled to summary judgment of invalidity on two independent §  
7 102(b) grounds: (1) the on sale bar; and (2) prior public use. *See Mot.* at 1. Cepheid first argues  
8 that embodiments of the asserted claims were on sale in the United States pursuant to a contract  
9 between Abaxis and a Japanese entity, Teramecs, (“the Teramecs agreement”). *See Mot* at 1. It is  
10 undisputed that this contract was executed on September 21, 1991, before October 8, 1992. *See id.*  
11 Second, Cepheid argues that embodiments of the asserted claims were used publicly in the United  
12 States when Abaxis demonstrated the embodiments for potential investors during pre-initial public  
13 offering (“pre-IPO”) roadshows. *See id.* It is undisputed that these roadshows occurred in January  
14 1992, before October 8, 1992. *See id.*

15 Abaxis disputes whether embodiments of the asserted claims were on sale pursuant to the  
16 Teramecs agreement or in public use during the pre-IPO roadshows. *See Op.* at 10-14. Abaxis  
17 also disputes whether the October 8, 1993 application, No. 08/134,574, is the relevant patent  
18 application for determining the priority date under § 102(b). *See Op.* at 3-10. The October 8, 1993  
19 application, No. 08/134,574, is a continuation-in-part (CIP) of an earlier application, No.  
20 07/747,179, filed on August 18, 1991, which issued as the ’732 Patent on May 9, 1995. Abaxis  
21 argues that the asserted claims of the ’564 and ’684 Patents are entitled to the August 18, 1991  
22 priority date of the ’732 Patent application because the ’732 specification provides adequate  
23 written description and enables the asserted claims. *See Op.* at 3-10. Accordingly, Abaxis argues  
24 that the Teramecs agreement and the pre-IPO roadshows are not § 102(b) prior art because they did  
25 not occur more than one year before August 18, 1991. *See id.*

26 The Court finds that there is a genuine dispute of material fact as to whether the Teramecs  
27 agreement offered to sell a product embodying the asserted claims in the United States. The Court  
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1 also finds a genuine dispute of material fact as to whether Abaxis publicly used embodiments of  
2 the asserted claims when Abaxis demonstrated its technology at pre-IPO roadshows. Finally, the  
3 Court finds a genuine dispute of material fact as to whether the asserted claims are entitled to the  
4 August 18, 1991 priority date of the '732 Patent application. Accordingly, there is a genuine  
5 dispute of material fact as to whether the asserted claims are invalid under § 102(b), and the Court  
6 DENIES Cepheid's motion for summary judgment of invalidity.<sup>1</sup>

## 7 **II. Legal Standard**

8 Summary judgment is appropriate if, viewing the evidence and drawing all reasonable  
9 inferences in the light most favorable to the nonmoving party, there are no genuine issues of  
10 material fact, and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a);  
11 *Celotex Corp. v. Catrett*, 477 U.S. 317, 321 (1986). At the summary judgment stage, the Court  
12 "does not assess credibility or weigh the evidence, but simply determines whether there is a  
13 genuine factual issue for trial." *House v. Bell*, 547 U.S. 518, 559-60 (2006). A fact is "material" if  
14 it "might affect the outcome of the suit under the governing law," *Anderson v. Liberty Lobby, Inc.*,  
15 477 U.S. 242, 248 (1986), and a dispute as to a material fact is "genuine" if there is sufficient  
16 evidence for a reasonable trier of fact to decide in favor of the nonmoving party, *id.* "If the  
17 evidence is merely colorable, or is not significantly probative, summary judgment may be granted."  
18 *Id.*

19 The moving party bears the initial burden of identifying those portions of the pleadings,  
20 discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. *Celotex*  
21 *Corp.*, 477 U.S. at 323. Where the moving party will have the burden of proof on an issue at trial,  
22 it must affirmatively demonstrate that no reasonable trier of fact could find other than for the  
23 moving party, but on an issue for which the opposing party will have the burden of proof at trial,  
24 the party moving for summary judgment need only point out "that there is an absence of evidence  
25 to support the nonmoving party's case." *Id.* at 325; *accord Soremekun v. Thrifty Payless, Inc.*, 509

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26  
27 <sup>1</sup> Abaxis has filed a motion objecting to allegedly new legal arguments and evidence presented in  
28 Cepheid's reply brief. Dkt. No. 188. The Court DENIES Abaxis's motion as moot because the  
Court DENIES Cepheid's motion for summary judgment.

1 F.3d 978, 984 (9th Cir. 2007). Once the moving party meets its initial burden, the nonmoving  
2 party must set forth, by affidavit or as otherwise provided in Rule 56, “specific facts showing that  
3 there is a genuine issue for trial.” *Anderson*, 477 U.S. at 250.

### 4 **III. Discussion**

#### 5 **A. Invalidity pursuant to the § 102(b) on sale bar based on the Teramecs agreement**

6 Cepheid moves for summary judgment on the grounds that the September 21, 1991  
7 agreement between Abaxis and Teramecs invalidates the asserted claims under the § 102(b) on sale  
8 bar. *See* Mot. at 6-13. At trial, Cepheid would have the burden of proving invalidity by clear and  
9 convincing evidence. *SIBIA Neuroscis., Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355 (Fed.  
10 Cir. 2000). A patent is invalid under the on sale bar when two conditions are satisfied more than  
11 one year before the invention’s priority date. First, the product embodying the claimed invention  
12 “must be the subject of a commercial offer for sale” in the United States. *Pfaff v. Wells*  
13 *Electronics, Inc.*, 525 U.S. 55, 67 (1998); 35 U.S.C. § 102(b). “Second, the invention must be  
14 ready for patenting.” *Pfaff*, 525 U.S. at 67.

15 Abaxis disputes whether a product embodying the asserted claims was offered for sale in  
16 the United States.<sup>2</sup> Specifically, Abaxis disputes: (1) whether the Teramecs agreement offered the  
17 claimed beads rather than simply “reagent” in any form, beads or otherwise (Op. at 10-12); and (2)  
18 whether any offer for sale in the Teramecs agreement occurred in the United States (Op. at 12-13).  
19 Therefore, the Court finds that genuine issues of material fact remain as to whether the Teramecs  
20 agreement offered an embodiment of the asserted claims for sale in the United States.  
21 Accordingly, the Court DENIES summary judgment due to invalidity based on the Teramecs  
22 agreement.

#### 23 **1. Did the Teramecs agreement offer beads embodying the claimed invention?**

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<sup>2</sup> Abaxis does not dispute that the claimed beads were ready for patenting on September 21, 1991.  
27 Indeed, Abaxis argues that the claimed beads were disclosed in the August 18, 1991 application for  
28 the ’732 Patent. *See* Op. at 10-13.

1           The Court finds that a genuine issue of material fact exists as to whether the September 21,  
2 1991 Teramecs agreement offered for sale an embodiment of the claimed beads. The Teramecs  
3 agreement was not clearly offering the claimed beads. Instead, the agreement only mentioned  
4 “reagent” without specifying that the reagent should take the form of small beads having uniform  
5 size. *See* Rodriguez Decl., Ex. B (Teramecs agreement). In addition to this plain language of the  
6 contract, Abaxis’ witness Dr. Ostoich testified in deposition that the agreement did not require use  
7 of the beads. *See* Rodriguez Decl., Ex. 14 at 443:6-9 (Ostoich Depo) (“Q: Was it your  
8 understanding that those [Teramecs] agreements required Abaxis to use reagent beads in the  
9 products that were covered by those agreements? A: Not at all.”). Dr. Ostoich further explained:  
10 “The agreement did not specify the technologies. Remember at the time the agreements were  
11 signed, the product was not completely developed.” *See id.* at 443:15-19. Indeed, although Abaxis  
12 does not dispute that the claimed bead technology existed at the time of the Teramecs agreement,  
13 there is evidence that several aspects of the testing apparatus were not fully developed, potentially  
14 requiring reformulation of the reagent beads. These undeveloped areas included the actual  
15 chemical tests, the rotor design for mixing and processing the reagent and the medical sample  
16 together, and the analyzer for measuring the test results. *See* Rodriguez Decl. Ex. 13 at 143:5-  
17 144:19 (Stroy Depo). Indeed, disagreement over analyzer design led to the 1992 resignation of  
18 Abaxis’s CEO, Leute. *Id.* 73:15-74:17.

19           Cepheid argues that the continuing development of Abaxis’s testing system does not  
20 preclude applying the on sale bar because the claimed beads were ready for patenting in September  
21 1991. In support, Cepheid cites *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, in which a joint  
22 development agreement was found to include an offer for sale because one of the contract clauses  
23 was a requirements contract. *Id.*, 424 F.3d 1276, 1281-82 (Fed. Cir. 2005). The *Enzo Biochem*  
24 agreement referred only to “Active Ingredients.” *Id.* However, although the *Enzo Biochem* court  
25 found that the agreement included an offer for sale, the court did not find that the vague “Active  
26 Ingredients” language sufficiently specified the product being offered. *Id.* at 1283. Indeed, the  
27 Court explicitly stated that the contract did not specifically offer the patented product for sale. *Id.*

1 Instead, the court looked to Enzo Biochem’s delivery of the patented product pursuant to the  
2 agreement two years later, more than one year before the critical date of the Enzo Biochem patent.  
3 *Id.* This later delivery clarified that the original agreement had “relate[d] to” the patented product.  
4 *Id.*

5 It is undisputed that Abaxis did not actually sell any beads to Teramecs until six years after  
6 the agreement, four years later than the October 1993 filing of the CIP application. *See* Reply at 2  
7 n. 3. Cepheid correctly notes that if a patented product was offered for sale more than a year before  
8 the patent filing, the patent is invalid, regardless of when or whether the actual sale occurred. *Id.*  
9 (citing *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1370 (Fed. Cir. 2007)). However, the  
10 six year gap between the Teramecs agreement’s offer to sell “reagent” and the actual bead sale to  
11 Teramecs raises a genuine dispute of material fact as to whether the Teramecs agreement offered  
12 reagent beads embodying the asserted claims for sale in 1991. A reasonable jury might find that  
13 Cepheid has not met its burden of proving by clear and convincing evidence that beads embodying  
14 the asserted claims were offered to Teramecs before the alleged 1993 priority date for the asserted  
15 claims. Accordingly, the Court DENIES Cepheid’s motion for summary judgment on the grounds  
16 of invalidity based on the Teramecs agreement.

17 **2. Was the Teramecs agreement an offer for sale “in the United States?”**

18 A reasonable jury could find that Cepheid has not carried its burden of proving by clear and  
19 convincing evidence that the Teramecs agreement constitutes an offer for sale “in the United  
20 States.” 35 U.S.C. § 102(b). This genuine dispute of material fact provides a second, independent  
21 basis for denying summary judgment of invalidity under the on sale bar. *Id.* Teramecs is a  
22 Japanese company, and it is undisputed that under the agreement Teramecs had no right to sell  
23 Abaxis products in the United States. Cepheid notes that at the time the Teramecs agreement was  
24 signed, Abaxis had its principle place of business in Mountain View, CA and manufactured its  
25 products in Mountain View, CA. Reply at 4. However, a United States company can sometimes  
26 export its product for sale overseas without triggering the on sale bar. *Robbins Co. v. Lawrence*  
27 *Mfg. Co.* held that to determine whether an offer for sale occurs in the United States, the Court  
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1 must determine whether sufficient prefatory activity occurred in the United States. *Id.*, 482 F.2d  
2 426, 434 (9th Cir. 1973); *see also Monolithic Power Systems, Inc. v. O2 Micro Intern. Ltd.*, Nos. C  
3 04-2000 CW, C 06-2929 CW, 2007 WL 3231709, at \*3 (N.D. Cal., Oct. 30, 2007). However, this  
4 prefatory activity must be related to the offer for sale. *See B.F. Goodrich Co. v. Aircraft Braking*  
5 *Systems Corp.*, 825 F. Supp. 65, 71–72 (D. Del. 1993).

6 Cepheid notes that the Teramecs agreement specified Mountain View as the venue for any  
7 arbitration and chose to be governed under United States and California law. Reply at 4.  
8 However, parties have freedom to contract for any arbitration venue or choice of law, independent  
9 of the jurisdiction in which the agreement was reached. It is also undisputed that Abaxis developed  
10 and manufactured its various products, including beads, in the United States. However, if the  
11 specific activity prefatory to the offer for sale occurred outside the United States, mere  
12 development and manufacture within the United States would not render the offer for sale  
13 domestic. *See B.F. Goodrich*, 825 F. Supp. at 71–72. Cepheid relies on witness testimony as to  
14 where the Teramecs agreement was signed, and what prefatory negotiations may have occurred in  
15 the United States. Cepheid points to the testimony of Dr. Ostoich, Abaxis’s 30(b)(6) witness:

16 Q. Okay. Were you present when this agreement was actually signed?

17 A. I don’t remember that.

18 Q. Do you remember if it was actually signed in the U.S. or in Japan?

19 A. My recollection is that it was in the United States.

20 Q. What’s that recollection based on?

21 A. On the fact that Mr. Kondo was with us, and this is typically the kind of document that  
22 need [sic] to be reviewed several times by our lawyers and that sort of thing. So it require  
23 [sic] fair amount of interaction –

24 Q. Okay.

25 A. – in the fact that Mr. Kondo, which was the president of Teramecs, was at Abaxis, I  
26 wouldn’t say all the time, but very, very often. But I don’t recall the actual physical event  
27 of signing the document.

28 Rodriguez Decl., Ex. 14 at 323:12-324:7 (Ostoich Depo); *see also* Reply at 4.

Viewing this evidence in the light most favorable to the non-moving party, Abaxis, the  
Court finds that a reasonable jury could find that Dr. Ostoich’s testimony is equivocal (“my  
recollection is”). Furthermore, a reasonable jury might question whether the purported basis for  
Dr. Ostoich’s recollection renders Dr. Ostoich’s testimony clear and convincing evidence that the  
contract was negotiated and signed in the United States. Specifically, Dr. Ostoich does not recall



1 witnessing the signing or being told that it occurred in the United States. Instead, Dr. Ostoich’s  
2 recollection is based on two facts: that the president of Teramecs, Mr. Kondo, often visited Abaxis  
3 and that Abaxis’s lawyers would have had to review the agreement. Yet there is no evidence as to  
4 the nature of Mr. Kondo’s visits, and whether they involved substantial negotiations prefatory to  
5 the offer for sale contained in the Teramecs agreement. There is also no evidence as to the  
6 frequency with which Abaxis’s signatory to the agreement, Mr. Leute, traveled to Japan. Indeed,  
7 Mr. Leute could not recall where he signed the Teramecs agreement. Furthermore, there is no  
8 evidence as to why Abaxis would need proximity to its U.S. lawyers while Teramecs would not  
9 need proximity to its Japanese lawyers. Accordingly, a reasonable jury might find that Cepheid  
10 has not met its burden of proving by clear and convincing evidence that any offer for sale under the  
11 Teramecs agreement occurred in the United States. Therefore, the Court DENIES summary  
12 judgment as to invalidity under the § 102(b) on sale bar based on the Teramecs agreement.

13 **B. Invalidity due to § 102(b) public use during Abaxis’s 1992 pre-IPO roadshows**

14 The Court finds a genuine dispute of material fact as to whether the patented invention was  
15 publicly used during Abaxis’s pre-IPO roadshows. In January 1992, Abaxis held a series of  
16 roadshows intended to generate investor interest in its impending IPO. Cepheid argues that the  
17 claimed invention was publicly used when Abaxis demonstrated its product during these  
18 roadshows, rendering the invention invalid under 35 U.S.C. § 102(b). Mot. at 13-17.

19 A claimed invention was in public use if a product embodying every claim limitation was  
20 “shown to or used by an individual other than [the] inventor under no limitation, restriction, or duty  
21 of confidentiality.” *Clock Spring, L.P. v. Wrapmaster, Inc.*, 560 F.3d 1317, 1325 (Fed. Cir. 2009).  
22 At trial, Cepheid would have the burden of proving invalidity by clear and convincing evidence.  
23 *SIBIA Neuroscis., Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355 (Fed. Cir. 2000).

24 Abaxis raises four possible reasons why the claimed beads may not have been in public use.  
25 *See Op.* at 13-15. First, Abaxis raises a genuine dispute of fact as to whether the roadshow  
26 demonstrations used real blood. *See Op.* at 14 (citing Rodriguez Decl., Ex. 13 at 139:12-140:17  
27 (Stroy Depo.) (“Q. But do you now recall that the instrument used at the January 1992 roadshows  
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1 did in fact include dried beads? A. Yes. Q. And that those dried beads were used to analyze blood  
2 samples? . . . [A.] I don't think we used blood in the roadshow. I think we used a simulated fluid  
3 to look like blood."'). However, the asserted claims are addressed only to bead properties such as  
4 size, uniformity, and dissolution time, and do not limit the use of the beads to blood testing. *See*,  
5 *e.g.*, '563 Patent 14:42-47. Accordingly, whether the beads were used to test real blood or fake  
6 blood is not material to the question of whether the claimed beads were used.

7 Second, Abaxis raises a genuine dispute of fact as to whether the beads and their claimed  
8 properties were ever apparent or explained to roadshow attendees. Abaxis presents evidence that:  
9 (1) the demonstration beads were placed inside the rotor wells before the demonstrations began,  
10 and consequently the beads (and bead size) would not have been easily visible to attendees; (2)  
11 during the roadshow demonstrations, attendees could not have determined whether the beads  
12 dissolved in under 10 seconds; and (3) the technical properties of the beads were likely never  
13 explained to the attendees. *See* Mot. at 14-15 (citing *Stroy Depo*). However, it is a basic principle  
14 of patent law that public use need not reveal the underlying details of the invention to the public.  
15 *See Egbert v. Lippmann*, 104 U.S. 333, 336-37 (1881) (finding that an improved corset stay was in  
16 public use when a woman wore the stay under her dress); *see also Zenith Electronics Corp. v. PDI*  
17 *Comm'n Systems*, 522 F.3d 1348, 1356-58 (Fed. Cir. 2008). Accordingly, whether the beads and  
18 their properties were apparent to roadshow attendees is immaterial to the question of whether the  
19 beads were publicly used.

20 Third, Abaxis suggests that the use was not public for two reasons: (1) the roadshows may  
21 have had only small audiences; and (2) the audiences were largely investors who did not care about  
22 the technical properties of the beads. *See* Mot. at 14 (citing *Stroy Depo* 104:21-105:5; *id.* at  
23 100:13-18). However, neither of these factors is relevant to the question of whether the use was  
24 public. The relevant question is whether those viewing the use were bound by any duty of  
25 confidentiality. *See Clock Spring*, 560 F.3d at 1325 ("An invention is in public use if it is shown to  
26 or used by an individual other than the inventor *under no limitation, restriction, or obligation of*  
27 *confidentiality*") (emphasis added); *see also Invitrogen Corp. v. Biocrest Mfg.*, 424 F.3d 1374, 1380  
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1 (Fed. Cir. 2005). There is no suggestion that any such duty existed for roadshow attendees.  
2 Indeed, the purpose of the roadshows was to foment public interest in Abaxis’s impending IPO and  
3 confidentiality restrictions would have been directly contrary to this purpose. *See* Carlson Decl,  
4 Ex. D at 69:18-70:14 (Leute Depo). Accordingly, the nature and number of roadshow attendees is  
5 not material to whether the demonstrations were public.

6 Finally, Abaxis suggests that there is a genuine dispute as to whether the beads used in the  
7 demonstrations embodied all the limitations of the claimed invention, citing to the Stroy  
8 deposition. *Op.* at 14-15 (citing Stroy Depo); *see also* *Clock Spring*, 560 F.3d at 1325. All Abaxis  
9 witnesses to which the parties cite, including Mr. Story, have testified that the demonstrated rotor  
10 included beads. *See* Carlson Decl., Ex. E at 145:25-146:2 (Stroy Depo); *id.* at 137:8-14 (“Q: And  
11 did you show the device to investors on the roadshow? A: Yes... Q: And the rotor did include  
12 beads? A: Yes.”) There is undisputed evidence that Abaxis validated that the specific bead lots  
13 which were intended for use at the roadshows met all the claim limitations. *See* Carlson Decl., Ex.  
14 F at ABAX 000931 (describing test runs with the relevant bead lots, “The following steps were  
15 done to ensure the best performance possible for the roadshow (January 1992)”); *id.*, Ex. O at  
16 ABAX 000922 (documenting measurements of the size and consistency (CV, or coefficient of  
17 weight variation) of the relevant bead lots); *see also* Carlson Decl, Ex. V at 17:16-22, 67:7-69:13,  
18 81:14-83:11, 100:2-8 (Schembri Depo) (discussing dissolution times).

19 The portions of Mr. Stroy’s deposition cited by Abaxis do not refute this evidence that  
20 beads were used in the roadshow demonstrations and that specific bead lots intended for roadshow  
21 use were pre-validated and met all the limitations of the asserted claims. *See* *Op.* at 14-15.  
22 However, Abaxis also notes that Cepheid has not shown that the pre-validated beads were actually  
23 used in the roadshows. *Mot.* at 14. Furthermore, Abaxis argues that even if the pre-tested beads  
24 were used, as was clearly Abaxis’s intent when the beads were pre-tested, there is no evidence that  
25 the fragile beads were undamaged after transport to the roadshow sites. *Id.* These arguments  
26 present a slender thread on which to hang validity. However, in light of the “clear and convincing  
27 evidence” standard for proving invalidity, a reasonable jury could find that Cepheid has not met its  
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1 burden of showing that beads embodying all limitations of the asserted claims were actually used  
2 during the roadshows. Accordingly, the Court DENIES summary judgment of invalidity under the  
3 public use prong of § 102(b).

4 **C. Abaxis’s entitlement to an August 18, 1991 priority date**

5 Even if the Court did not deny summary judgment because of genuine disputes of material  
6 fact as to the nature of the Teramecs agreement and the roadshow demonstrations, the Court would  
7 still DENY summary judgment because there is a genuine issue of material fact as to whether the  
8 asserted claims of the ’563 and ’684 Patents are entitled to a priority date of August 18, 1991.  
9 August 18, 1991 is the filing date of the parent application, No. 07/747,179, which issued as the  
10 ’732 Patent with an unaltered specification (“the August 1991 specification”). The August 1991  
11 specification is similar, but not identical, to the specification shared by the October 8, 1993  
12 continuation-in-part application, No. 08/134,574; the ’684 Patent; and the ’563 Patent (“the  
13 October 1993 specification”). To invalidate the asserted claims under § 102(b), the Teramecs  
14 agreement and the pre-IPO roadshows must have occurred more than one year before the priority  
15 date of the asserted claims. *See* 35 U.S.C. 102(b). There is a genuine issue of material fact as to  
16 whether the August 1991 specification supports an August 1991 priority date for the asserted  
17 claims. The potential August 1991 priority date precedes both the September 1991 Teramecs  
18 agreement and the January 1992 pre-IPO roadshows. Accordingly, the potential August 1991  
19 priority date is an independent basis for denying summary judgment of invalidity under § 102(b).

20 Abaxis has the burden of producing evidence that raises a genuine issue of material fact as  
21 to whether the asserted claims are entitled to the August 1991 priority date. *See PowerOasis v. T-*  
22 *Mobile USA*, 522 F.3d 1299, 1305-06 (Fed. Cir. 2008). To show entitlement to the August 1991  
23 priority date, Abaxis must show that the August 1991 specification: (1) provides adequate written  
24 description for the asserted claims; and (2) enables the asserted claims. *See Bradford Co. v.*  
25 *Conteyor North Am.*, 603 F.3d 1262, 1269 (Fed. Cir. 2010) (holding that claims are entitled to the  
26 priority date of an earlier application only if the earlier application provides adequate written  
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1 description); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253-54 (Fed. Cir. 2004) (holding  
2 that an earlier application must enable later claims that claim priority to the earlier filing date).

3 **1. Adequacy of written description**

4 Cepheid argues that Abaxis cannot meet its burden of showing that the August 1991  
5 specification provides adequate written description for: (1) the later-claimed “beads;” or (2) for  
6 bead sizes larger than 2.3 mm in diameter. Mot. at 18-21; Reply at 10-14. “[T]he test for  
7 sufficiency [of written description] is whether the disclosure of the application relied upon  
8 reasonably conveys to those skilled in the art that the inventor had possession of the claimed  
9 subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F. 3d 1336, 1351  
10 (Fed. Cir. 2010) (en banc). However, “it is unnecessary to spell out every detail of the invention in  
11 the specification; only enough must be included to convince a person of skill in the art that the  
12 inventor possessed the invention.” *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F. 3d 1336,  
13 1345 (Fed. Cir. 2005).

14 “*Beads.*” The asserted claims cover “beads,” and Cepheid points out that the August  
15 1991 specification mentions only “reagent spheres.” See Mot. at 19-20. Although the parties have  
16 not sought claim construction of “spheres,” Cepheid argues that “spheres” are not “beads” and that  
17 possession of “spheres” would not indicate to a person of ordinary skill in the art that Abaxis was  
18 in possession of a broader category, “beads.” *Id.*

19 Abaxis points to its own internal documents referring to the “beads” of its invention. See  
20 Op. at 9 (citing Rodriguez Decl, Ex. 12). These documents predate the August 1991 specification,  
21 and suggest that Abaxis was actually in possession of beads in August 1991. See *id.* However, the  
22 relevant question is whether the August 1991 specification alone would have indicated to a person  
23 of ordinary skill in the art that Abaxis was in possession of beads. See *Ariad*, 598 F. 3d 1336 at  
24 1351. That said, viewed in the light most favorable to the non-moving party, Abaxis, the fact that  
25 Abaxis scientists referred to their reagent spheres as beads suggests that a person of ordinary skill  
26 in the art might view spheres and beads as highly similar. Accordingly, a reasonable jury might  
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1 find that a person of ordinary skill in the art would understand possession of reagent spheres to  
2 imply possession of reagent beads.

3           3.5 - 10.0 mm beads. The asserted claims cover beads up to 3.5, 5, or 10.0 mm in diameter.  
4 '563 Patent 14:42-47; Id. at 14:50-52; '684 Patent 15:15-16. Cepheid argues that the August 1991  
5 specification only describes spheres up to 2.3 mm or 4.0 microliter volume (less than 2.3 mm in  
6 diameter). See Mot. at 20. However, Abaxis points to the August 1991 specification's statement  
7 that "the exact volume of the drops will depend on the particular application." '732 Patent 6:3-4.  
8 This statement supports several '732 Patent claims without any diameter limitation (e.g. claim 1 at  
9 14:16-30). Indeed, Abaxis's expert, Dr. Carpenter stated in his rebuttal report that the large  
10 diameter beads "are fully supported" by the 1991 specification's statement that "the exact volume  
11 of the drops will depend on the particular application." See Rodriguez Decl, Ex. 16 at 33-34  
12 (Carpenter Rebuttal Report) (quoting '732 Patent 6:3-4). Accordingly, Abaxis has raised a genuine  
13 issue of material fact as to whether a person of ordinary skill in the art would have understood the  
14 August 1991 specification to convey that the inventors possessed larger bead sizes in August 1991.

15           In sum, Abaxis has produced evidence raising a genuine dispute of material fact as to  
16 whether the August 1991 specification provides adequate written description for the asserted  
17 claims.

## 18           **2. Enablement**

19           Cepheid argues that Abaxis cannot meet its burden to show that the 1991 specification  
20 enables bead sizes larger than 2.3 mm in diameter. Mot. at 21-23; Reply at 14-15. Enablement  
21 requires that "one skilled in the art, after reading the specification, could practice the claimed  
22 invention without undue experimentation." *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501  
23 F.3d 1274, 1282 (Fed. Cir. 2007). Among the factors a court may consider in determining the need  
24 for undue experimentation are, "(1) the quantity of experimentation necessary, (2) the amount of  
25 direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of  
26 the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the  
27 predictability or unpredictability of the art, and (8) the breadth of the claims." *In re Wands*, 858  
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1 *F.2d 731, 737 (Fed. Cir. 1988)*. In contrast to written description, the adequacy of enablement is a  
2 question of law, although like claim constructions, enablement findings may have factual  
3 underpinnings such as the *Wands* factors. *Martek Bioscis. Corp. v. Nutrinova, Inc.*, 579 F.3d 1363,  
4 1378 (Fed. Cir. 2009).

5 Abaxis presents a variety of evidence that the 1991 specification enables the large diameter  
6 beads (3.5, 5, and 10 mm) covered by the asserted claims. *See Op.* at 4-7. Abaxis's expert, Dr.  
7 Carpenter, states that the large diameter beads "are fully supported" by the 1991 specification's  
8 statement that "the exact volume of the drops will depend on the particular application." *See*  
9 *Rodriguez Decl*, Ex. 16 at 33-34 (Carpenter Rebuttal Report) (quoting '732 Patent 6:3-4). In  
10 further support of enablement, Abaxis points to two instances in which large diameter beads were  
11 made after August 1991, but without any apparent post-August 1991 technology or undue  
12 experimentation. The Court may consider these two post-filing events as evidence that the August  
13 1991 specification's disclosures would enable practice of the invention without undue  
14 experimentation. *See Gould v. Quigg*, 822 F.2d 1074, 1078 (Fed. Cir. 1987); *Amgen Inc. v.*  
15 *Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 162 (D. Mass. 2001), *aff'd in part, vacated in*  
16 *part, remanded sub nom*, 314 F.3d 1313, 1336 (Fed. Cir. 2003).

17 First, Abaxis argues that in February 1992, an Abaxis researcher, Chi-Sou Yu, made 333  
18 microliter beads (roughly 8.6 mm in diameter), with a coefficient of weight variation ("CV") less  
19 than 1%. *See Rodriguez Decl.*, Ex. 10 (Yu Notebook). The only special technique that appears to  
20 have been used was indicated by Yu's note in the lab notebook margin that the droplet had to be  
21 caught immediately beneath the tip of the liquid-dispensing pump, which the Court does not find to  
22 suggest "undue experimentation." *Id.* at ABAX 9807. Indeed, in deposition, Abaxis's then-CEO,  
23 Leute, testified that although he believes 10.0 mm beads would have been achievable, they were  
24 unnecessary. *Rodriguez Decl.*, Ex. 11 at 108:6-15 (Leute Depo). Accordingly, Leute testified that  
25 he would never have devoted resources to creating such large beads. *Id.* This testimony strongly  
26 suggests that Yu would not have had the resources of time or funding to engage in undue  
27 experimentation. Furthermore, Cepheid does not dispute that Yu made freeze-dried beads. *See*  
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1 Reply at 15. Accordingly, a genuine issue of underlying material fact exists as to whether Abaxis  
2 created 8.6 mm beads in February 1992, and whether undue experimentation beyond the teachings  
3 of the August 1991 specification was required.

4 Second, Abaxis argues that the 1993 specification shared by the '563 and '684 Patents  
5 provides evidence that Abaxis made beads larger than 2.3 mm without using any bead-making  
6 techniques beyond those disclosed in the August 1991 specification. *See Op.* at 3-4. Specifically,  
7 “example 6” in the 1993 specification describes making 3.37 mm beads. *See '563 Patent* at 14:12-  
8 34 (example 6). Despite making these larger beads, “example 6” did not describe any new bead-  
9 making technology that had not been disclosed in the original specification. *See id.*; Rodriguez  
10 Decl., Ex. 6 at 41:14-19 (Williams Decl.).

11 Cepheid’s argument for non-enablement is based upon statements that Abaxis made to the  
12 European Patent Office (EPO). On November 11, 1999, the EPO issued to Abaxis the European  
13 Patent No. EP 0,641,389 B1 (“the EP '389 Patent”). *See Carlson Decl., Ex. Z* (the EP '389  
14 Patent). It is undisputed that the EP '389 Patent has a priority date of August 18, 1991 because the  
15 EP '389 Patent specification is materially the same as the August 1991 specification. *See id.*; *Op.*  
16 at 3-10. Accordingly, Cepheid argues that Abaxis’s statements before the EPO regarding the bead  
17 sizes that the EP '389 Patent covers indicate that the August 1991 specification enables only the  
18 same size beads.

19 In 2003, Abaxis told the EPO that the EP '389 Patent’s invention encompassed only beads  
20 less than 2.3 mm in diameter because larger beads would shatter and break. *See Mot.* at 22  
21 (quoting *Carlson Decl., Ex. AA*). This shattering would create a variety of bead sizes such that the  
22 CV would be greater than 3%. *Id.* Abaxis’s 30(b)(6) witness affirmed that Abaxis’s invention was  
23 directed at beads with diameters less than 2.3 mm and CV less than 3%, stating “to the best of my  
24 knowledge, this is what we do.” *See Carlson Decl., Ex. C* at 401:9-402:8 (Ostoich Depo.).

25 Abaxis also distinguished the EP '389 Patent invention from a prior art patent which  
26 claimed larger “drops” having diameters 3.6 to 5.1 mm. *See Mot.* at 22 (quoting *Carlson Decl., Ex.*  
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1 AA). Again, Abaxis explained to the EPO that the prior art patent's larger drops would have CVs  
2 greater than 3% due to splitting. *Id.*

3 As an initial matter, the Court notes that the '563 Patent does not include the limitation  
4 requiring CV of less than 3%. *See, e.g.,* '563 Patent 14:42-47. Accordingly, Abaxis's statements  
5 before the EPO do not apply to the '563 Patent, and the August 1991 specification enables the  
6 asserted claims of the '563 Patent as a matter of law.

7 Furthermore, although the Court may consider Abaxis's representations before the EPO as  
8 relevant to enablement, there is no doctrine of prosecution history estoppel based upon foreign  
9 filings that would bar Abaxis from arguing that the August 1991 specification enables larger bead  
10 sizes. *See Tanabe Seiyaku Co. v. United States Int'l Trade Comm'n*, 109 F.3d 726, 733 (Fed. Cir.  
11 1997). Abaxis's EPO statements are mere statements that the August 1991 specification would not  
12 enable larger bead sizes.

13 Abaxis supported its EPO statements with data showing that when creating beads of  
14 reagents for the "total bilirubin" test, CV rose to roughly 5% as the bead size increased to 20  
15 microliters (roughly 3.37 mm in diameter) and 25 microliters (roughly 3.6 mm in diameter). *See*  
16 Carlson Decl., Ex. DD at 11. However, as discussed above, there is evidence that the technology  
17 disclosed in the August 1991 specification did, in fact, enable larger bead sizes of 3.37 mm  
18 diameter as disclosed in "example 6" of October 1993 specification. Further, there is evidence that  
19 the methods disclosed in the August 1991 specification enabled Yu to create 8.6 mm beads with  
20 CV less than 3% without undue experimentation.

21 Accordingly, viewing the facts in the light most favorable to Abaxis, a reasonable jury  
22 could find facts necessary to support a conclusion that the August 1991 specification enabled  
23 production of the large beads in the asserted claims without undue experimentation.

24 In sum, Abaxis has met its burden of raising a genuine dispute of material fact as to whether  
25 the asserted claims are entitled to the August 18, 1991 priority date of the parent application, No.  
26 07/747,179. August 18, 1991 predates the Teramecs agreement and Abaxis's pre-IPO roadshows.  
27 Accordingly, the potential entitlement of the asserted claims to the August 1991 priority date  
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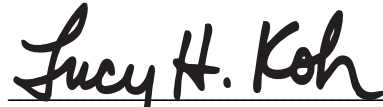
presents an independent genuine issue of material fact as to whether the asserted claims are invalid under 35 U.S.C. § 102(b). Therefore, the Court DENIES Cepheid's motion for summary judgment.

**IV. CONCLUSION**

For the foregoing reasons, the Court DENIES Cepheid's motion for summary judgment of invalidity.

**IT IS SO ORDERED.**

Dated: August 8, 2012



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LUCY H. KOH  
United States District Judge