United States Court of Appeals for the Federal Circuit

DEY, L.P., DEY, INC., AND MYLAN, INC.,
Plaintiffs-Appellants,

v.

SUNOVION PHARMACEUTICALS, INC. (formerly known as Sepracor, Inc.),
Defendant-Appellee.

2012-1428

Appeal from the United States District Court for the Southern District of New York in No. 07-CV-2353, Judge John G. Koeltl.

Decided: May 20, 2013

EVAN R. CHESLER, Cravath, Swaine & Moore, LLP, of New York, New York, argued for plaintiffs-appellants. With him on the brief was ROGER G. BROOKS. Of counsel on the brief were EDGAR H. HAUG and ROBERT E. COLLETTI, Frommer, Lawrence & Haug, LLP, of New York, New York.

JOSEPH M. O'MALLEY, JR., Paul Hastings, LLP, of New York, New York, argued for defendant-appellee. With

him on the brief were BRUCE M. WEXLER and DAVID M. CONCA. Of counsel on the brief was STEPHEN B. KINNAIRD of Washington, DC.

Before NEWMAN, BRYSON, and O'MALLEY, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* BRYSON.

Dissenting opinion filed by *Circuit Judge* NEWMAN.

BRYSON, *Circuit Judge.*

During the late 1990s and 2000s, Sunovion Pharmaceuticals, Inc., and the Dey plaintiffs (Dey, L.P.; Dey, Inc.; and Mylan, Inc.) were simultaneously developing pharmaceutical products to treat lung disease. Sunovion filed a patent application, followed by an application to test its products in human subjects. It then received a patent and held clinical trials, all before ultimately releasing a commercial product. Dey likewise filed a series of patent applications, received several patents, ran human subject trials, and released a commercial product. Dey's patent applications were filed after Sunovion's, and its patents were issued after consideration of Sunovion's patent.

When Dey sued Sunovion for patent infringement, Sunovion argued, and the district court agreed, that some of Dey's patents were invalid because a Sunovion clinical trial in which Sunovion tested its own product constituted a prior public use of Dey's inventions within the meaning of 35 U.S.C. § 102(b).[1] In that respect, this case is unusual. To the extent the public use bar is raised in the context of clinical trials, it normally entails a party defending its own clinical trials against the charge that the trials constituted a public use of the same party's invention.

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[1] References to 35 U.S.C. § 102(b) are to the pre-2011 version of the Patent Act.

Here, by contrast, Sunovion asserts that a drug formulation that was tested in its own clinical trial anticipated Dey's inventions and was accessible to the public, thus invalidating the later-issued Dey patents. Although the parties' dispute would seem to present a classic issue of priority, it comes to us as a public use dispute, not a priority contest, and we must apply public use principles to resolve it. Doing so, we conclude that Sunovion has not shown that it is entitled to summary judgment based on its assertion that its use of formulations meeting the limitations of Dey's later-issued patents constituted a public use of Dey's inventions within the meaning of section 102(b). We therefore reverse the grant of summary judgment for Sunovion.

I

Both parties own patents and sell products concerning the treatment of chronic obstructive pulmonary disease ("COPD") by storing the compound formoterol in an aqueous solution and administering it through a nebulizer. Sunovion owns U.S. Patent No. 6,040,344 (the "Gao patent"), which issued in March 2000 from an application filed in 1998. Dey owns two families of patents, the second of which includes U.S. Patent Nos. 7,348,362; 7,462,645; 7,465,756; 7,473,710; and 7,541,385. The patents in the second Dey family all issued in 2008 or 2009 but claim the benefit of an application filed on July 10, 2003.[2] According to Dey, the significant difference between the two companies' patents relates to the stability of the formulations during long-term storage.

Sunovion ultimately produced a commercial product, known as Brovana, in 2007, but the path that led to the marketing of that drug was long. In February 1998, Sunovion filed an Investigational New Drug application

[2] The first family of Dey patents—U.S. Patent Nos. 6,667,344 and 6,814,953—is not at issue in this appeal.

with the FDA, seeking approval to conduct clinical trials with human subjects. Tests began shortly thereafter. One such test was Clinical Study Number 091-050 ("Study 50"), a Phase III trial that began in February 2002. The study, which was double-blind and randomized, tested three different dosages of formoterol known as Batches 3501A, 3501B, and 3501C. The parties have stipulated that the formulation of Batch 3501A is identical to the formulation that Sunovion ultimately marketed as Brovana. During a 12-week period in the middle of the study, the participants received treatments to take home and self-administer twice daily.

The participants in Study 50 were given some information about the study and were subjected to certain controls. They were told that the study concerned "the effects of (R,R)-formoterol, an experimental medication (not yet approved by the . . . FDA) to treat COPD," and that it would test three particular doses of (R,R)-formoterol (the three batches) as compared to a placebo and another drug.[3] Participants were not provided any more specific information about the formulation of Batch 3501A. A Sunovion witness testified that the specific formulation of Brovana remained "[un]available to the public" and "confidential" even as of the time this action was brought.

The participants in the study signed a consent form stating that the medications "must be taken only by the person for whom it was intended" and that subjects would have to keep usage logs and return unused medications. The form also noted that participants "may wish to discuss this study . . . with [their] regular doctor[s]" and

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[3] The parties agree that formoterol has been in the public domain since at least 1976, when it appeared in U.S. Patent No. 3,994,974, which was directed to compounds "useful as bronchodilating agents."

allowed them to "request that the person who is in charge of this study speak directly with [their] doctor[s]." The participants were not prohibited from speaking with others about the study.

The test administrators were also subject to detailed restrictions. They had to sign a formal "Clinical Investigator Confidentiality Agreement" directing them to hold all proprietary information in confidence for five years. They were forbidden from disclosing the study protocols or dispensing the drug to any person who was not a trial subject, and they were held accountable for securely storing the drug and maintaining records of its disposition and use. Like the trial subjects, the investigators were instructed that unused supplies of the drug were to be returned upon completion or termination of the study.

A total of 587 subjects participated in the study. Of those, 124 received Batch 3501A. At least some of those individuals received Batch 3501A prior to July 10, 2002—one year before Dey filed the patent application that led to its second family of patents. Thousands of vials containing Batch 3501A were distributed during the trial; the study records indicate that a fraction of one percent of those vials were lost and not returned. The subjects who misplaced the vials were given replacements and were allowed to continue with the tests. The study concluded in June 2003.

In March 2007, shortly before Brovana was set to launch, Dey brought suit charging Sunovion with infringement of its first and second families of patents. Sunovion moved for partial summary judgment, and the district court granted the motion. Sunovion conceded for purposes of its motion that "the Batch 3501A composition [fell] within the asserted claims stemming from Dey's second family of patents." That meant that the composition would anticipate Dey's asserted claims if it was in "public use," as that term has been interpreted under 35

U.S.C. § 102(b). The district court concluded that Sunovion's clinical trial of Batch 3501A did constitute a "public use" of Dey's inventions, and, accordingly, held the asserted claims of Dey's second family of patents invalid. Dey appeals.

II

A

An applicant may not receive a patent for an invention that was "in public use . . . in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b) (2006). To decide whether a prior use constitutes an invalidating "public use," we ask "whether the purported use: (1) was accessible to the public; or (2) was commercially exploited." *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1380 (Fed. Cir. 2005).

Our cases have provided considerable guidance as to what it means to be "accessible to the public." We have explained that the policies underlying the public use bar inform its scope and that one such policy is "discouraging the removal, from the public domain, of inventions that the public reasonably has come to believe are freely available." *Tone Bros., Inc. v. Sysco Corp.*, 28 F.3d 1192, 1198 (Fed. Cir. 1994). In addition, we have set forth factors that may be helpful in analyzing the question of public use, including "'the nature of the activity that occurred in public; the public access to and knowledge of the public use; [and] whether there was any confidentiality obligation imposed on persons who observed the use.'" *Bernhardt, L.L.C. v. Collezione Europa USA, Inc.*, 386 F.3d 1371, 1379 (Fed. Cir. 2004). And we have said that a public use may occur when "a completed invention is used in public, without restriction." *Allied Colloids Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1574 (Fed. Cir. 1995). Such formulations are designed to capture the commonsense notion that whether an invention is "accessible to the

public" or "reasonably . . . believe[d] [to be] freely available" depends, at least in part, on the degree of confidentiality surrounding its use: "[A]n agreement of confidentiality, or circumstances creating a similar expectation of secrecy, may negate a 'public use' where there is not commercial exploitation." *Invitrogen*, 424 F.3d at 1382.

The same is true when an unaffiliated third party is responsible for the allegedly public use. Although prior uses are often carried out by or at the direction of the inventor-patentee, we have held that "third party prior use accessible to the public is a section 102(b) bar." *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1334 (Fed. Cir. 2005). But even in the case of third-party uses, being "accessible to the public" still requires public availability; secret or confidential third-party uses do not invalidate later-filed patents. *See, e.g.*, *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1371 (Fed. Cir. 1998) ("when an asserted prior use is not that of the applicant, § 102(b) is not a bar when that prior use or knowledge is not available to the public"); *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1549-50 (Fed. Cir. 1983); *see also Baxter Int'l, Inc. v. COBE Labs., Inc.*, 88 F.3d 1054, 1061 (Fed. Cir. 1996) (Newman, J., dissenting) (section 102(b) does not cover "unknown and unknowable information in the possession of third persons"). For that reason, we have applied section 102(b) to invalidate a patent based on third-party use when the third party "made no attempt to maintain confidentiality or to deliberately evade disclosure," *Eolas*, 399 F.3d at 1335; made no "discernible effort to maintain the [invention] as confidential," *Baxter*, 88 F.3d at 1058; or "made no efforts to conceal the device or keep anything about it secret," *Beachcombers v. WildeWood Creative Prods., Inc.*, 31 F.3d 1154, 1160 (Fed. Cir. 1994).

The degree of confidentiality necessary to avoid a finding of public use naturally depends on the circum-

stances. For example, if there is no confidentiality agreement in place, the skill and knowledge of those observing an invention can shed light on the degree to which it was kept confidential. Even limited disclosure to those who are skilled enough to know, understand, and "easily demonstrate the invention to others," may mean that there was no reasonable expectation of secrecy and that the invention was therefore in public use. *Netscape Commc'ns Corp. v. Konrad*, 295 F.3d 1315, 1321 (Fed. Cir. 2002); *see also Eolas*, 399 F.3d at 1334; *Baxter*, 88 F.3d at 1058 (invention was in public use when observers included "co-workers, who were under no duty to maintain . . . confidential[ity]"). By contrast, when disclosure is limited to a small number of uninformed observers there may be no reason to believe "that a viewer . . . could thereby learn anything of [the later-patented invention]" and disclose the invention to others. *W.L. Gore*, 721 F.2d at 1549. In such cases, a finder of fact might reasonably conclude that the third party's use remained confidential and that the invention was not "accessible to the public." *Id.* With these principles in mind, we turn to the facts of this case.

B

The district court held that Sunovion was entitled to summary judgment of invalidity because Sunovion's own clinical trial constituted clear and convincing evidence of a third-party public use of Dey's inventions. We disagree. Important issues of fact remain in dispute, principally whether sufficient precautions were taken to exclude members of the public from obtaining information about the potentially invalidating prior art (i.e., Batch 3501A). On the record of this case, we do not agree with the district court that no reasonable jury could return a verdict for Dey.

The district court focused its analysis on two fact-bound issues. On both, we view the record differently than did the district court. First, we do not share the

court's belief that the use of Batch 3501A by Study 50 participants was indisputably open and free. The district court observed that participants were given the drugs, took them home, and, "whether or not they would have been able to reverse engineer batch 3501A, . . . used the invention as intended." The court also highlighted the fact that a few participants failed to return unused medication, as they were required to do, but nonetheless were given more of the medication. Based on those facts, the court concluded that the participants "were not prevented from using their personal supply of that substance however they saw fit" and that "the participants' unfettered use of the composition for weeks at a time itself constituted a public use."

Dey vigorously disputes the district court's view of the facts. Dey argues that the study subjects' use of Batch 3501A was anything but "unfettered" and points to documents showing that neither the study subjects nor the clinical investigators were permitted to use the drugs "however they saw fit." For example, test subjects agreed that only they would take the medications, and they promised to keep accurate usage logs and return all unused medication. Similarly, test administrators could dispense drugs only to trial subjects, were held accountable for secure storage and records of drug use, and knew that unused supplies had to be returned. Viewing this evidence in Dey's favor, as we must, we cannot say that the allegedly anticipating prior art was clearly used "without restriction" during Study 50. *Allied Colloids*, 64 F.3d at 1574. The fact that a tiny fraction of the thousands of vials were lost without penalizing the responsible test subject(s), or that the practicalities of the study required self-administration at home rather than physician administration in a closed facility, does not preclude a reasonable jury from concluding that the use of Batch 3501A was sufficiently controlled and restricted, rather than unfettered and public.

Nor do we agree with the district court's conclusion that the confidentiality obligations imposed in Study 50 were so loose that summary judgment of invalidity was justified. The district court emphasized that "participants were under no obligation of confidentiality to Sunovion (let alone Dey), and indeed, they were explicitly told that they 'may wish to discuss this study and your participation in it with your regular doctor.'" The court also repeated several times that there was "no evidence to suggest that anyone involved in the study was 'under [any] limitation, restriction or obligation of secrecy to the [putative] inventor' or the putative inventor's assignee, Dey" and that such restrictions were necessary to render the use non-public. In sum, the court concluded that "all of the indicia of lack of confidentiality for the clinical trial in this case, coupled with the plain lack of any control or obligations to the patent holder, demonstrate that the patented invention was in public use when Sunovion used it in its clinical trial."

Dey responds that a reasonable jury could find that the particulars of its invention—embodied in the formulation and stability characteristics of Batch 3501A—were kept sufficiently confidential to avoid a finding of "public use." Investigators were the most knowledgeable persons involved in the study, and they were required to sign a pledge of confidentiality. The district court focused on the study subjects, but as Dey points out, they were given incomplete descriptions of the treatment formulation: While they were informed about the active chemical compound and the range of possible dosages being investigated, they were not even told the identity of the particular drug or formulation they were receiving. In other words, according to Dey, while it is true that participants were permitted to discuss the study with their doctors, they were not in a position to reveal the composition of the allegedly invalidating prior art, because they were unaware of the specifics of the inventive formulations.

Dey's view of the record is a reasonable one. This case does not involve undisputed evidence of a complete lack of confidentiality protections, as there was in prior cases basing invalidity on third-party public use. *See Eolas*, 399 F.3d at 1335; *Baxter*, 88 F.3d at 1058-59; *Beachcombers*, 31 F.3d at 1160. And the fact that no formal obligation of secrecy was imposed on the study subjects does not automatically transform Sunovion's clinical trial into a public use. We have never required a formal confidentiality agreement to show non-public use, *e.g.*, *Bernhardt*, 386 F.3d at 1379-81; in the absence of such an agreement, we simply ask whether there were "circumstances creating a similar expectation of secrecy," *Invitrogen*, 424 F.3d at 1382. The "public use" inquiry is replete with factual considerations, such as the (disputed) extent to which study participants were informed of and able to disclose the pertinent details of the claimed prior art. *See, e.g.*, *W.L. Gore*, 721 F.2d at 1549. Because a finder of fact could conclude that the study was conducted with a reasonable expectation of confidentiality as to the nature of the formulations being tested, summary judgment on the public use issue was inappropriate.

Our conclusion is bolstered by the fact that the confidentiality controls in Study 50 were far from unique. In fact, Sunovion appears to have conducted its clinical trial like many others, at least with respect to formal confidentiality obligations and restrictions on information regarding the drugs being studied. Most notably, clinical trial subjects "typically do[] not sign a confidentiality agreement," as "patients must be free at least to provide information to their other healthcare providers and family members." Allan Horwich, *The Clinical Trial Research Participant as an Inside Trader: A Legal and Policy Analysis*, 39 J. Health L. 77, 100 (2006); *see also* Norman M. Goldfarb, *Confidentiality Challenges in Clinical Trials*, J. of Clinical Res. Best Practices, May 2008, at 1, 2 ("Study subjects do not sign confidentiality agreements.").

In the specific context of section 102(b) cases, we find strong parallels to the protocols of Study 50. Many cases concern studies in which investigators sign strict confidentiality agreements but patients do not, and courts have routinely rejected the argument that such an arrangement necessarily strips the trial of confidentiality protection or renders it accessible to the public. *See, e.g.*, *Bayer Schering Pharma AG v. Barr Labs., Inc.*, No. 05-CV-2308 (PGS), 2008 WL 628592, at *11-12, *38-42 (D.N.J. Mar. 3, 2008); *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 364 F. Supp. 2d 820, 873-75, 912-13 (S.D. Ind. 2005), *aff'd*, 471 F.3d 1369, 1380-81 (Fed. Cir. 2006); *Janssen Pharmaceutica N.V. v. Eon Labs Mfg., Inc.*, 374 F. Supp. 2d 263, 276 (E.D.N.Y. 2004), *aff'd*, 134 F. App'x 425, 430-31 (Fed. Cir. 2005); *see also In re Omeprazole Patent Litig.*, 490 F. Supp. 2d 381, 508 (S.D.N.Y. 2007) (dismissing as "meritless" the contention that "inventions were not kept sufficiently confidential" because "patients were not required to sign confidentiality agreements"), *aff'd on other grounds*, 536 F.3d 1361 (Fed. Cir. 2008). It is not uncommon for patients in these studies to know the active ingredient of the drug being studied. *E.g.*, *Bayer*, 2008 WL 628592, at *12, *41 (such a disclosure did not divulge "the alleged innovation" and was "necessary" because "obviously . . . a participant taking a regimen of drugs requires the liberty of discussing same with a spouse, medical personnel in case of emergency, etc."); *Janssen*, 374 F. Supp. 2d at 276, *aff'd*, 134 F. App'x at 431. And, in at least one of those cases, patients also self-administered the drug at home and did not return all unused test products—an occurrence that the testimony established is "'very common'" in comparable trials. *Bayer*, 2008 WL 628592, at *11-12, *38-42, *47.

C

The district court's decision was also premised on several misconceptions about the reach of section 102(b). First, the court found it significant that the patent holder, Dey, did not control Sunovion's clinical studies and that study participants did not owe any obligation of confidentiality to Dey. Those findings were based on language from our cases stating that "[p]ublic use includes 'any use of [the claimed] invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy *to the inventor*.'" *E.g.*, *Konrad*, 295 F.3d at 1320 (emphasis added). As is clear from the context, however, those statements are not meant to apply to third-party use cases. If they did, any unaffiliated third-party use, no matter how secret, would necessarily invalidate a patent because such uses are, by definition, made by persons not owing a duty of secrecy "to the inventor." Our third-party use precedent is not so limited. *E.g.*, *W.L. Gore*, 721 F.2d at 1549-50.

Instead, we measure the adequacy of the confidentiality guarantees by looking to the party in control of the allegedly invalidating prior use. In third-party use cases, that is the third party. In *Eolas*, therefore, we observed that those who saw a demonstration by the third party, Wei, "were under no limitation, restriction or obligation of secrecy to Wei." 399 F.3d at 1334; *see also, e.g.*, *Baxter*, 88 F.3d at 1058-59; *Konrad*, 295 F.3d at 1320 (asking only "whether there was any confidentiality obligation imposed on persons who observed the use," with no limitation on its source). Because a secret third-party use is not invalidating, our task is to assess whether the third party's use was sufficiently "public" to impose the section 102 bar. That Sunovion's trial subjects owed no duty of confidentiality to Dey is, of course, true, but it does not bear on that question.

Second, the district court seized on language in cases dealing with the nature of the prior use, and based on that language held that Study 50 is invalidating. In particular, the district court cited *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1299 (Fed. Cir. 2002), for the proposition that "the core issue is not public knowledge of the invention, but the public *use* of it." Sunovion likewise points to cases such as *Egbert v. Lippmann*, 104 U.S. 333 (1881), to contend that a "public use need not be enabling in the sense of disclosing each later-claimed feature to the interested public." According to the district court and Sunovion, it was not especially important whether test subjects knew or understood the contours of the prior art alleged to anticipate Dey's inventions, because their at-home use of the formulation of Batch 3501A without an affirmative confidentiality obligation doomed Dey's patents.

These arguments take the cited precedent out of context and stretch it too far. The language quoted from *New Railhead* derives from the seminal "experimental use" case, *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126, 136 (1877), and it makes good sense in that setting: During experimentation, the public might have knowledge of an invention (because they see it), but may not be using the invention within the meaning of the statute (because the inventor is experimenting).[4] As for *Egbert*, although the invalidating use in that case was not

[4] In *New Railhead*, the invalidating public use took place at a public commercial job site, with the knowledge of the patentee inventor. 298 F.3d at 1293, 1298. "Commercial exploitation is a clear indication of public use," even absent separate consideration of public accessibility, *Invitrogen*, 424 F.3d at 1380, and "secret commercialization" by a third party is not public use, even if it might have resulted in forfeiture were the third party the one filing the patent application, *W.L. Gore*, 721 F.2d at 1550.

visible to the general public, the case turned on the lack of control the inventor maintained over his invention. The Court held that an inventor could not give or sell the invented article "to another, to be used . . . without limitation or restriction, or injunction of secrecy" and still avoid the public use bar. 104 U.S. at 336-37. Neither of those cases, nor their progeny, permitted the district court to discount the relevance of the study participants' limited knowledge of Batch 3501A's formulation or to sidestep disputed factual questions about the nature of the allegedly public use. Put another way, although Sunovion is correct that we do not ask for an "'enablement-type inquiry'" under section 102(b), a court still must decide whether the "claimed features of the patents [were placed] in the public's possession." *Konrad*, 295 F.3d at 1323. And here, a reasonable jury could conclude that if members of the public are not informed of, and cannot readily discern, the claimed features of the invention in the allegedly invalidating prior art, the public has not been put in possession of those features.

Finally, the district court attempted to distinguish *W.L. Gore* and *Eolas* by holding that this case was not one in which the third party, Sunovion, was using the invention confidentially or hiding a trade secret because Sunovion was "operating within the patent and regulatory system," not outside of it. That conclusion was based on the fact that Sunovion was working to receive FDA approval and had received its own patent claiming "pharmaceutical compositions containing formoterol." Sunovion repeats the same argument throughout its brief on appeal, pointing to its Gao patent as evidence that it did not use Dey's inventions confidentially.

These contentions may have resonated in a priority contest, but they ring hollow here. The issue for purposes of this appeal is not whether Sunovion pursued the proper administrative channels in order to patent and develop *its* invention, as reflected in the Gao patent; the issue is

whether Sunovion kept its use of *Dey's* inventions confidential. And the only allegedly public use of Dey's inventions occurred in the context of a closely monitored clinical trial, not in filing the Gao patent.

* * *

By allowing publicly accessible prior uses to block a later-filed patent, the public use bar seeks to prevent assigning a monopoly to "inventions that the public reasonably has come to believe are freely available." *Tone Bros.,* 28 F.3d at 1198. Study 50, with all of its restrictions on the use of the drugs and information concerning the formulations, does not indisputably fall within that description. Accordingly, we decline to hold, on summary judgment, that Sunovion's clinical trials of its own product represent clear and convincing evidence that Dey's inventions were accessible to the public more than a year before Dey sought to patent them. [5]

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[5] The dissent agrees that the district court erred in granting summary judgment to Sunovion but would go farther and direct the entry of judgment for Dey. Our decision is not intended to foreclose the district court from entering summary judgment for Dey if the district court determines to do so on remand. We think it appropriate, however, to leave that decision to the district court. While a reviewing court has the authority, on appeal from a summary judgment in favor of the appellee, to direct the entry of judgment in favor of the appellant, that course is ordinarily followed only when the appeal involves issues of law or when such a ruling would clearly entail no unfairness to the appellee. *See Fountain v. Filson,* 336 U.S. 681, 683 (1949); *Conoco, Inc. v. Dep't of Energy*, 99 F.3d 387, 394-95 (Fed. Cir. 1996); *Turner v. J.V.D.B. & Assocs., Inc.*, 330 F.3d 991, 998 (7th Cir. 2003) ("In most instances, . . . such a decision is best made by the district court; we would rarely find it appropriate to direct the

REVERSED and REMANDED

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entry of summary judgment."). That is particularly true in a case such as this one, in which the appellant has not moved for summary judgment in the district court. *See Ramsey v. Coughlin*, 94 F.3d 71, 74 (2d Cir. 1996) (in such a setting, "great care must be exercised to assure that the original movant has had an adequate opportunity to show that there is a genuine issue and that his [or her] opponent is not entitled to judgment as a matter of law"). Finally, Dey has not sought that relief from us and thus has not put its opponent on notice that it is at risk of having judgment directed against it. Dey asked that the district court's judgment be "vacated or reversed" but did not ask us to direct the district court to enter judgment in its favor. Although Sunovion may ultimately have nothing of significance to add to the record in response to a summary judgment motion from Dey, it should be given the opportunity to do so, and the district court should be given the opportunity to review its submission in the first instance in light of our opinion. *See* 10A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice & Procedure*, § 2720, at 354-55 & n.35 (1998) ("Although it occasionally is proper for an appellate court to enter summary judgment for the nonmoving party, this occurs only in rare cases in which it is very clear that all the material facts are before the reviewing court . . . .").

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2012-1428

Appeal from the United States District Court for the Southern District of New York in No. 07-CV-2353, Judge John G. Koeltl.

NEWMAN, *Circuit Judge*, dissenting.

I would reverse the district court's judgment and hold that Sunovion's clinical trial does not constitute an invalidating "public use" of Dey's invention. There are no facts to be found, no debate as to how the trials were conducted. No sound reason appears for remanding for findings or trial, when the matter is readily resolved on undisputed facts. Nor is there any reason for casting judicial doubt on the standard confidentiality procedures of clinical trials, at this late date of decades of established practice.

It is not disputed that the patients who participated in the trial were strictly limited by Sunovion's policies that prevented dissemination of drug samples and en-

forced confidentiality on the administrators of the trial. Although the patients were necessarily told the identity of the active ingredient, the specific formulation and related details were not disclosed to the patients. Nor was the information published to the public, nor used outside of the rigorous controls of FDA regulations of clinical trials. There are no disputed facts, and no facts requiring finding or that could be found to show that these trials were a public use. The issue requires resolution, not perpetuation. From the court's decision to remand, I respectfully dissent.

The patent statute, 35 U.S.C. § 102(b) (2006), bars a patent on an invention in "public use" more than one year before the date of the patent application:

> § 102 A person shall be entitled to a patent unless–
>
> * * *
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . .

"A bar under § 102(b) arises where, before the critical date, the invention is in public use and ready for patenting." *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005). "The proper test for the public use prong of the § 102(b) statutory bar is whether the purported use: (1) was accessible to the public; or (2) was commercially exploited." *Id.* at 1380. To determine whether the invention was "accessible to the public," courts consider such factors as "the nature of the activity that occurred in public; the public access to and knowledge of the public use; whether there was any confidentiality obligation imposed on persons who observed the use; whether progress records or other indicia

of experimental activity were kept; whether persons other than the inventor or acting for the inventor conducted the experiments; how many tests were conducted; the scale of the tests compared with commercial conditions; the length of the test period in comparison with tests of similar products; and whether payment was made for the product of the tests." *Allied Colloids Inc. v. Am. Cyanamid Co.,* 64 F.3d 1570, 1574 (Fed. Cir. 1995). In short, a use "without limitation or restriction, or injunction of secrecy . . . is public." *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881).

Sunovion's Batch 3501A was in clinical trial before the critical date of Dey's patents. Sunovion states that its clinical trials were a "public" use because the patients did not sign confidentiality agreements and knew that the active ingredient was the known drug formoterol. Sunovion stresses that a few drug doses were lost during the trial.

However, it was not disputed that the formulation of Sunovion's Batch 3501A was "confidential," was "not available to the public," and was not known to the patients in the trial. The clinical investigators were subject to strict written confidentiality agreements that prohibited the investigators from disclosing information designated by Sunovion as secret and any information the investigators reasonably believed was "secret, confidential, or proprietary." Clinical Investigator Confidentiality Agreement, at 1, Sept. 21, 1999.

The trial subjects were only told the identity of the active ingredient and the dosage being tested, which were not novel aspects of Dey's patents. The details of the formulation and stability of Batch 3501A—the subject of Dey's patents—was not disclosed to the trial subjects. Having not received this information, the clinical patients were unable to disseminate Dey's invention, even though they were not subject to written confidentiality restrictions.

Dey points out that Sunovion exercised great care to avoid dissemination of the test material itself. During the trial, Sunovion had a protocol expressly prohibiting dispensing trial medication to any person who was not a trial subject. The trial subjects were informed prior to their participation that all unused medication was to be returned to the investigator. Moreover, trial subjects were carefully selected, in part based on their ability to fill out logs accurately and create a precise record of their use of the medication during the study.

On these undisputed facts, it cannot be held that the trial was a "public use" pursuant to 35 U.S.C. §102(b). As the panel majority observes, "courts have routinely rejected the argument that such an arrangement necessarily strips the trial of confidentiality protection or renders it accessible to the public," maj. op. at 12. For instance, in *Janssen Pharmaceutica v. Eon Labs Manufacturing, Inc.,* 134 Fed. App'x 425, 431 (Fed. Cir. 2005), this court similarly held that there was not public use where the clinical trial "was confidential and controlled by Janssen" even though "none of the subjects of the trials were bound by confidentiality restrictions." *See also Bayer Schering Pharma AG v. Barr Labs., Inc.,* No. 05-CV-2308 (PGS), 2008 WL 628592, *38–42 (D.N.J. Mar. 3, 2008) (finding no public use even though "the human patients did not execute confidentiality agreements"); *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 364 F. Supp. 2d 820, 873–75, 912-13 (S.D. Ind. 2005) (rejecting the contention that failing to execute a confidentiality agreement constituted a controlling factor in the public use inquiry), *aff'd*, 471 F.3d 1369, 1380–81 (Fed. Cir. 2006); *In re Omeprazole Patent Litig.*, 490 F. Supp. 2d 381, 508 (S.D.N.Y. 2007) ("[T]he lack of a confidentiality agreement is not dispositive as a matter of law [under 35 U.S.C. §102(b)], especially where [the movant] has come forth with no evidence to demonstrate what material confidential information the patients were privy to."), *aff'd on other grounds*, 536 F.3d

1361, 1372 (Fed. Cir. 2008). These holdings are consistent with the policy of protecting the public's justifiable reliance by "discourag[ing] the removal of inventions from the public domain which the public justifiably comes to believe are freely available." *Am. Seating Co. v. USSC Grp.*, 514 F.3d 1262, 1267 (Fed. Cir. 2008). Confidential clinical trials subject to the restrictions of this protocol do not engender such public reliance.

My colleagues state that material facts are in dispute, and therefore that trial is necessary. However, the court fails to identify any controverted facts. The facts of the clinical trials are well-established in FDA records and are uncontested by the parties. We know the formulation and quantity of drug distributed; the number of trial participants; the terms of the investigators and participants' participation agreements; the information disclosed to the trial participants; and the restrictions on drug use and distribution imposed by Sunovion. Moreover, both parties agree that Batch 3501A used in Study 50 falls within Dey's patent claims. No pertinent fact remains at issue; the only question is the legal conclusion of whether these facts constitute a "public use" within the meaning of 35 U.S.C. §102(b). "Whether a public use has occurred is a question of law." *Baxter Int'l, Inc. v. COBE Labs., Inc.,* 88 F.3d 1054, 1058 (Fed. Cir. 1996).

My colleagues state we should not decide whether Sunovion's clinical trial constitutes "public use" because Dey "did not ask us to direct the district court to enter judgment in its favor," op. at 17 n.5. Dey's primary argument to the district court was that "as a matter of law, Sunovion's confidential 050 clinical trial does not constitute a public use of Dey's invention." Dey's Mem. of Law in Opp'n to Sunovion's Mot. for Summ. J. at 1. Dey fairly raised its legal argument to the district court, and Sunovion was given an opportunity to respond. The district court was thus free to enter summary judgment for either party. *First Fin. Ins. Co. v. Allstate Interior Demolition*

Corp., 193 F.3d 109, 114 (2d Cir. 1999) ("[I]f a motion for summary judgment has been made, a district court may grant summary judgment to any party—including a non-movant.").

On appeal, Dey requested that this court "vacate or reverse" the district court's judgment:

> Whether the district court erred in holding that Defendant-Appellee's clinical trial, conducted under confidentiality restriction's by an alleged infringer, constituted a "public use" of Plaintiff-Appellants' second patent family within the meaning of 35 U.S.C. § 102(b), and in invalidating the patents on that basis.

Statement of the Issue, Dey Br. at 3. We need go no further than to answer the legal question presented: On the uncontested facts, Sunovion's clinical trial was not a "public use" within the meaning of 35 U.S.C. §102(b).

On the undisputed facts, the legal question is readily answered. The invention claimed in Dey's patent was not in "public use" in Sunovion's clinical trials. I respectfully dissent from the court's refusal to resolve the question, for there is nothing requiring further trial, whether to a jury or to the bench.