IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WISCONSIN

ILLUMINA, INC.,

OPINION and ORDER

Plaintiff,

09-cv-277-bbc 09-cv-665-bbc

v.

AFFYMETRIX, INC.,

Defendant.

Plaintiff Illumina, Inc. is suing defendant Affymetrix, Inc. for infringement of two patents related to genetic testing, U.S. Patent Nos. 7,510,841 and 7,612,020. The question before the court is whether the case must be dismissed because neither of the patents credited Gregory Kirk as an inventor. Because I conclude that defendant has made a prima facie showing that Kirk is a joint inventor of the patents, I will hold a hearing to determine whether the patent should be corrected under 35 U.S.C. § 256. The resolution of that hearing will determine whether plaintiff lacks standing to sue for failing to join Kirk as a plaintiff.

OPINION

A. <u>Do the Patents Need to be Corrected before Defendant Can Challenge Plaintiff's</u> Standing to Sue?

The '020 and '841 patents identify John Stuelpnagel, Mark Chee and Steven Auguer as the patents' inventors, but defendant argues that Dr. Gregory Kirk was omitted incorrectly from that list. If the court agrees with that initial premise, defendant argues that one of two consequences must follow: (1) the court must dismiss the case for lack of standing because plaintiff did not join all the owners of the patent; or (2) the court must declare the '020 and '841 patents invalid under 35 U.S.C. § 102(f) because they do not name the correct inventors.

In an order dated October 29, 2010, dkt. #192, I questioned whether defendant's first argument was properly before the court. There is no dispute that an individual owner of a patent must join all other owners to have standing to sue. Israel Bio-Engineering Project
V. Amgen, Inc., 475 F.3d 1256, 1264-65 (Fed. Cir. 2007)("Absent the voluntary joinder of all co-owners of a patent, a co-owner acting alone will lack standing."). Ordinarily, however, a plaintiff's standing to sue is challenged for its failure to join a named inventor or that inventor's assignee. E.g., Lucent Technologies, Inc. v. Gateway, Inc., 543 F.3d 710, 720 (Fed. Cir. 2008); Propat Intern. Corp. v. Rpost, Inc., 473 F.3d 1187 (Fed. Cir. 2007); Sicom Systems, Ltd. v. Agilent Technologies, Inc., 427 F.3d 971, 973 (Fed. Cir. 2005). In the October 29 order, I noted that defendant had not cited any cases in which the court of

appeals considered a defendant's challenge to the plaintiff's standing for its failure to join a party whose rights were not recognized in the patent or by assignment. Rather, in the cases involving an inventor wrongfully omitted from the patent, the defendant raised an invalidity defense under § 102(f). E.g., Checkpoint Systems, Inc. v. All-Tag Sec. S.A., 412 F.3d 1331, 1338 (Fed. Cir. 2005); Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998).

Plaintiff relied primarily on Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456 (Fed. Cir. 1998), to argue that plaintiff lacked standing to sue. However, in that case, the alleged infringer first obtained a correction of the patent from the district court under 35 U.S.C. § 256 and then had the case dismissed because the newly named inventor had not agreed to an infringement suit. In addition, defendant cited one district court case in which the court dismissed the complaint for the plaintiff's failure to join an unnamed inventor, but that court did not cite any authority for its approach or even consider the question whether the patent needed to be corrected first. Bushberger v. Protecto Wrap Co., 2008 WL 725189, at *5 (E.D. Wis. Mar. 17, 2008). Because the parties failed to address this question, I asked them to submit supplemental briefs.

One might ask why it matters whether the question is decided as one of standing or invalidity. In its original briefs on the subject, defendant treated the questions as interchangeable and plaintiff simply ignored the standing question. In the October 29 order, I stated that standing is an issue of subject matter jurisdiction, which always must be decided

before the merits. Steel Co. v. Citizens for Better Environment, 523 U.S. 83, 93-102 (1998). Although that statement is correct as a general matter, I overlooked the fact that a failure to join a patent owner raises a question of prudential standing, not standing under Article III, Amgen, 475 F.3d at 1264-65, which means that a court has discretion to consider the merits first under some circumstances. United Transporation Union-Illinois Legislative Bd. v. Surface Transp. Bd., 183 F.3d 606, 611 (7th Cir. 1999) ("In some circumstances, moreover, we may 'elide the jurisdictional issue' in order to reach the merits even prior to resolving a question of statutory or prudential standing."); McNamara v. City of Chicago, 138 F.3d 1219 (7th Cir. 1998)("'prudential standing' . . . may be bypassed in favor of deciding the merits"). See also In re Grand Jury Proceedings, 616 F.3d 1186, 1199 (10th Cir. 2010) ("Unlike Article III standing, prudential standing is discretionary; thus, if we deny judicial relief on the merits, we can decline to address prudential standing in favor of proceeding to the merits of the issues presented."); American Iron and Steel Institute v. Occupational Safety and Health Administration, 182 F.3d 1261, 1274 (11th Cir. 1999) ("[C]ourts cannot pretermit Article III standing issues, but can pretermit prudential standing issues, in order to resolve cases where the merits are relatively easy.")

Even so, courts generally resolve questions of prudential standing before the merits.

E.g., Lozano v. City of Hazleton, 620 F.3d 170, 183 (3d Cir. 2010) ("'[E]ven in cases concededly within our jurisdiction under Article III,' we will decline to decide the merits of

unified School District v. Newdow, 542 U.S. 1, 11 (2004)). In particular, the Court of Appeals for the Federal Circuit seems to treat prudential standing as a threshold question, even framing it as a matter of "jurisdiction" in some cases. Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc., 583 F.3d 832, 848-49 (Fed. Cir. 2009); Morrow v. Microsoft Corp., 499 F.3d 1332, 1344 (Fed. Cir. 2007); Amgen, 475 F.3d at1263. Regardless whether "jurisdiction" is the proper term, the court's treatment of this issue suggests that district courts are not free to set it aside once a party has raised it.

The way defendant's argument is framed has other important consequences. For one thing, factual disputes regarding the merits are resolved by the fact finder, but factual disputes about standing generally are resolved by the court. Pavey v. Conley, 544 F.3d 739, 741 (7th Cir. 2008) (generally, judges resolve fact disputes unrelated to merits). In addition, a dismissal on invalidity grounds is on the merits while a dismissal for lack of standing is not.

In their supplemental briefs, neither side uncovered any cases in which the court addressed the question whether an alleged infringer may challenge the plaintiff's standing on the ground that it failed to join an inventor not listed on the patent. However, I believe that the better argument is that an unnamed inventor is not relevant to the standing analysis until the patent has been corrected. A party's standing to sue for patent infringement derives from the Patent Act, which provides that "[a] patentee shall have remedy by civil

action for infringement of his patent." 35 U.S.C. § 281; Enovsys LLC v. Nextel Communications, Inc., 614 F.3d 1333, 1341 (Fed. Cir. 2010). Under 35 U.S.C. § 100, a "patentee" is the party "to whom the patent was issued" or "the successors in title" to that party. This suggests that the named owners and their assignees have standing to sue until the patent is corrected to reflect any omitted inventors.

Defendant cites <u>Teets v. Chromalloy Gas Turbine Corp.</u>, 83 F.3d 403, 407 (Fed. Cir. 1996), for its statement that "[o]wnership springs from invention." However, <u>Teets</u> was not a case about standing; the plaintiff was seeking "a declaration of ownership." Saying that ownership "springs from" invention is not the same thing as saying that all inventors are owners for the purpose of standing regardless whether their status as an inventor is reflected in the patent. As plaintiff points out, this distinction was recognized in <u>Arachnid, Inc. v. Merit Industries</u>, Inc., 939 F.2d 1574, 1578 -1579 (Fed. Cir. 1991):

[A]lthough the act of invention itself vests an inventor with a common law or "natural" right to make, use and sell his or her invention absent conflicting patent rights in others. . . , a patent on that invention is something more. A patent in effect enlarges the natural right, adding to it the right to exclude others from making, using or selling the patented invention. A patent is a creature of statute, as is the right of a patentee to have a remedy for infringement of his patent. Suit must be brought on the patent, as ownership only of the invention gives no right to exclude, which is obtained only from the patent grant. In order to exercise that right, a plaintiff must necessarily have standing as comprehended by the patent statute.

<u>Id.</u> at 1578-79 (citations and footnotes omitted). In other words, until the patent reflects the inventor's status, he has no enforceable rights under the Patent Act, which means that

his presence in the lawsuit is not necessary to establish standing to sue. <u>Amgen</u>, 475 F.3d at 1263 ("When . . . multiple inventors *are listed on the face of the patent*, each co-owner presumptively owns a pro rata undivided interest in the entire patent.") (emphasis added).

If I adopted defendant's position, it would mean that an invalidity defense under § 102(f) would serve no purpose because all such defenses could be reframed as a challenge to the plaintiff's standing. This is demonstrated in defendant's own opening brief. Dkt. #123. The first 21 pages of the 22-page brief are devoted to defendant's argument on standing. Defendant's argument under § 102(f) consists of two paragraphs and is little more than a repetition of its standing argument.

Defendant cites two new cases in its supplemental briefs, but neither is directly on point. In <u>Hydril Co. v. Baker Hughes Inc.</u>, 1997 WL 469722, *1 (Fed. Cir. 1997) (nonprecedential), the alleged infringer was the assignee of one of the inventors named in the patent, but the plaintiff claimed that the defendant could be held liable for infringement because the inventor at issue had been named improperly. Plaintiff argues that <u>Hydril</u> stands for the proposition that a correction is not necessary to establish inventorship because the court of appeals concluded that the district court should not have entered judgment in favor of the defendant and a remand was required to determine inventorship, even though the plaintiff had not filed a motion under § 256. However, even setting aside the fact that Hydril is a nonprecedential decision, the holding of the case is not so clear. One of the

reasons for the remand was that the plaintiff "did explicitly bring § 256 [the statute regarding judicial correction of a patent] to the attention of the district court in its opposition to Baker Hughes' motion for a stay of proceedings" and the court "was aware of § 256 and, presumably, that it had the power to correct inventorship." <u>Id.</u> at *4. Thus, under at least one reading of <u>Hydril</u>, the court affirmed the view that a party must establish inventorship through correction of the patent.

In <u>Roche</u>, 583 F.3d at 838, the question was whether the plaintiff lacked standing to sue because one of the inventors of the patent at issue had assigned his ownership interest to the defendant. The court concluded that the plaintiff's "inability to establish that it possessed [one inventor's] interest in the patents-in-suit defeats its right to assert its cause of action against" the defendant. The court did not need to consider the circumstances under which a correction of the patent is required because the dispute was over the validity of the *assignment*; no one was challenging the accuracy of the *patent*. Thus, <u>Roche</u> does not support a conclusion that an unnamed inventor may be treated as an owner before a patent correction.

B. Should the Patents be Corrected?

The remaining question is whether defendant should be permitted to seek a correction of the patent in the context of this case. Plaintiff raises a number of objections to this

possibility, but none are persuasive. First, plaintiff says that defendant does not have standing to request a correction under 35 U.S.C. § 256 and suggests that only the inventor himself may do so. That view cannot be squared with Ethicon, 135 F.3d at 1459. In that case, a defendant being sued for patent infringement filed a motion under § 256. The court of appeals affirmed the district court's decision to grant the motion, even though the defendant was not the alleged inventor, but only the alleged inventor's licensee. (Plaintiff says in its brief that the inventor filed the § 256 motion, but the decision states clearly that it was "U.S. Surgical's [the defendant's] motion to correct inventorship." Id. at 1458.) Because defendant is Kirk's licensee as well, Chin Decl., dkt. #130, exh. W, Ethicon is controlling. Although the court of appeals did not discuss the issue of the defendant's standing to file a motion under § 256, its result makes sense because an inventor's licensee has an economic interest in correcting the patent.

Alternatively, plaintiff says that a court cannot consider a motion under §256 unless the alleged inventor is a *party* to the lawsuit, but plaintiff cites no authority for this proposition. The statute says only that "all parties concerned" must be given "notice and hearing" before the court orders correction. It does not require a particular line-up of litigants in the case.

Next, plaintiff says that defendant waived its right to request a correction under § 256 because it did not include such a claim in its counterclaim and answer. However, plaintiff

cites no language from the statute or any case law that supports the proposition that a request for correction is a "claim" that must be pleaded. Rather, in <u>Ethicon</u>, the defendant simply filed a motion for correction. In <u>Pannu</u>, 155 F.3d at 1350, the court stated that district courts *must* consider whether a patent may be corrected under § 256 before invalidating the patent under § 102(f).

Finally, plaintiff argues that it would be unfairly prejudicial to allow defendant to seek correction of the patent because plaintiff needs to do discovery on the questions whether Kirk may be barred by the doctrine of laches from asserting his status as an inventor, whether Kirk's employer may own any rights he has to the patents and whether any of Kirk's colleagues may be inventors. I disagree that discovery is necessary. Plaintiff's only basis for asserting a laches defense is that Kirk traces his claim of inventorship back to a 1998 email. This argument is misguided because, as defendant points out, "the laches period does not accrue until each patent issues, even if the patents are interrelated." Stark v. Advanced Magnetics, Inc., 29 F.3d 1570, 1576 (Fed. Cir. 1994). The patents in this case were issued in 2009. Because a presumption of laches does not apply unless the inventor waited more than six years to make a claim, Serdarevic v. Advanced Medical Optics, Inc., 532 F.3d 1352, 1358 (Fed Cir. 2008), it is difficult to conceive of any basis for a laches defense.

Plaintiff fails to explain why it needs discovery related to Kirk's employer and colleagues. Even if it is true that plaintiff's employer has an interest in Kirk's inventions or

that others may have contributed to the invention, neither of these facts is relevant to the question whether the patent should be corrected to identify Kirk as inventor. "[I]ssues of patent ownership are distinct from questions of inventorship." Amgen, 475 F.3d at 1263. Thus, it is not necessary for an inventor to show that he still owns all the rights to his invention to obtain a correction. Chou v. University of Chicago, 254 F.3d 1347, 1358 (7th Cir. 2001) ("[Section 256] statute imposes no requirement of potential ownership in the patent on those seeking to invoke it."). Further, § 256 does not say that all potential corrections to a patent must be sought at the same time and plaintiff points to no other authority requiring that. Thus, even if there may be other contributing inventors, this would not prevent a correction as to Kirk.

Section 256 does not require courts to hold a hearing in every case in which a party requests one. It would be pointless to hold a hearing if defendant had not made a prima facie showing that Kirk is an inventor of the '020 and '841 patents. I conclude that defendant has made that showing.

"A person must contribute to the conception of the claimed invention to qualify as a joint inventor. . . The interplay between conception and collaboration requires that each co-inventor engage with the other co-inventors to contribute to a joint conception." Vanderbilt University v. ICOS Corp., 601 F.3d 1297, 1303 (Fed. Cir. 2010). The court has stated somewhat awkwardly that the contribution must be one that is "not insignificant in

quality, when that contribution is measured against the dimension of the full invention." Nartron Corp. v. Schukra U.S.A. Inc., 558 F.3d 1352, 1356-57 (Fed. Cir. 2009) (quoting Pannu, 155 F.3d at 1351). Making such a contribution "as to even one claim" is sufficient to qualify as a joint inventor. Amgen, 475 F.3d at 1263.

In support of its argument that Kirk is a joint inventor, defendant points to a lengthy email that Kirk sent to one of the named inventors, John Stuelpnagel, shortly after they met at the laboratory of David Walt, who had developed "bead-based fiber-optic array technology" related to genetic testing. Dft.'s PFOF ¶ 12, dkt. #124, Plt.'s Resp. to Dft.'s PFOF ¶ 12, dkt. #170. The email included the following statements:

The detection methods can be massively parallel. For instance: 1536 fiber bundles (with up to 6000 tests) can be fixtured to perform simultaneous testing of ALL wells in our new 1536 μ l well plates! However, the readout is performed by ONE high resolution CCD chip.

* * *

Test samples can be prepared in separate wells until test fibers are ready to be dipped.

* * *

Coupling to the fiber bundle method seems like a big winner. For instance, a low cost fixture can be fabricated that would arrange 1536 fiber bundles to line up with the wells of one of the new Costar plates.

Chin. Decl., dkt. #130, exh. Q. (The full email is too long to include in the text, so I am attaching it to the opinion.) Kirk sent the email in March 1998, several months before the

first patent application was filed for what later became the '841 and '020 patents. (The two patents share the same specification.) At that time, plaintiff and Stuelpnagel were recruiting Kirk to work for plaintiff. Stuelpnagel Dep., dkt. #95, at 108. Although Stuelpnagel says that he does not remember reading the email, Stuelpnagel Dep., dkt. #95, at 115, he told plaintiff on March 19, 1998, that Walt was "impressed" with what Kirk had written. Chin Decl., dkt. #130, exh. S.

In his report, defendant's expert, Andre Sharon, creates a chart that he says demonstrates that Kirk's email includes a discussion of all the elements of certain claims in both the '020 and '841 patents. Dkt. #129. The chart identifies those matters that were disclosed in Walt's patent, U.S. Patent No. 6,023,540, and those that Kirk included in his email:

Claims in '841 Patent	
1. A method of detecting the presence or absence of a plurality of different target analytes, comprising	The Walt patent disclosed that fiber bundles can be used such that "the presence or not of the analyte targeted by the functionality may be determined" (e.g., 3:50-51)

(a) providing a first substrate with a surface comprising a plurality of assay wells, wherein said assay wells contain sample solutions each having a plurality of different target analytes;

The patents acknowledge that a microtiter plate qualifies as a first substrate. (5:19) Dr. Kirk disclosed a 1536 well microtiter plate when he suggested "simultaneous testing of ALL wells in our new 1536 μ l well plates!"

Dr. Kirk disclosed that the wells contain sample solutions: "Test samples can be prepared in separate wells until test fibers are ready to be dipped."

The Walt patent disclosed that each sample solution has a plurality of different target analytes (e.g., 3:36-37)

(b) providing a second substrate comprising a plurality of array locations, each array location comprising a plurality of discrete sites on a projection, wherein said sites comprise different bioactive agents; Dr. Kirk disclosed that "a low cost fixture can be fabricated that would arrange 1536 fiber bundles to line up with the wells of one of the new Costar plates." The low cost fixture including the fiber bundles (which are projections) corresponds to the second substrate comprising a plurality of array locations.

The Walt patent disclosed fiber optic bundles with arrays of discrete sites on a projection (e.g., Fig 5B)

The Walt patent disclosed that the discrete sites can contain different chemical functionalities (bioactive agents) (e.g., 3:61-4:3, 8:8-11)

(c) dipping the projections of said second substrate into said assay wells such that each array location of said second substrate contacts sample solution in a different well of said first substrate under conditions suitable for binding of said different target analytes to said different bioactive agents, thereby processing said sample solutions in parallel; and	Dr. Kirk disclosed that "tests can be performed by a simple dipping step" in order "to perform simultaneous testing of ALL wells" in a 1536 well plate. Dr. Kirk disclosed that "the detection methods can be massively parallel" using "1536 fiber bundles (with up to 6000 tests)"
(d) detecting the presence or absence of said target analytes.	The Walt patent disclosed that fiber bundles can be used such that "the presence or not of the analyte targeted by the functionality may be determined" (e.g., 3:50-51)
20. The method of claim 1, wherein said assay wells comprise wells of a microtiter plate.	Dr. Kirk disclosed a Costar 1536 well microtiter plate
23. The method of claim 1, wherein said plurality of assay wells comprises 1536 wells.	Dr. Kirk disclosed that the microtiter plate may include "our new $1536 \mu l$ well plates"

Claims in '020 patent	
1. An array of arrays comprising:	Dr. Kirk disclosed an arrangement of 1536 fiber bundles lined up in an array format, and each of the fiber bundles has an array of discrete sites (e.g. Walt patent, Fig. 5B), which is an array of arrays

(a) a first substrate with a surface comprising a plurality of assay wells comprising samples; and	The patents acknowledge that a microtiter plate qualifies as a first substrate. (5:19) Dr. Kirk disclosed a 1536 well microtiter plate when he suggested "simultaneous testing of ALL wells in our new 1536 μ l well plates!" Dr. Kirk disclosed that the wells contain sample solutions: "Test samples can be prepared in separate wells until test fibers are ready to be dipped."
(b) a second substrate comprising a plurality of projections, each projection comprising an array location, each array location comprising a plurality of discrete sites, wherein said sites comprise different bioactive agents, and	Dr. Kirk disclosed that "a low cost fixture can be fabricated that would arrange 1536 fiber bundles to line up with the wells of one of the new Costar plates." The low cost fixture including the fiber bundles corresponds to the second substrate comprising a plurality of projections. The Walt patent disclosed fiber optic bundles with arrays of discrete sites (e.g., Fig 5B) The Walt patent disclosed that the discrete sites can contain different chemical functionalities (bioactive agents) (e.g., 3:61-4:3, 8:8-11)
wherein said first substrate and said second substrate are arranged such that projections of said second substrate are fitted into assay wells of the first substrate.	Dr. Kirk disclosed a low cost fixture which arranges the 1536 fiber bundles to line up with the wells of the Costar plate
3. The array of arrays according to claim 1, wherein said assay wells comprise wells of a microtiter plate.	Dr. Kirk disclosed a Costar 1536 well microtiter plate

, ,	Dr. Kirk disclosed that the microtiter plate may include "our new 1536 ul well
2 0	plates"

Sharon provides a similar comparison with respect to other claims in the patents.

Plaintiff does not develop any argument in opposition to Sharon's analysis. In particular, plaintiff does not deny that Kirk's email discloses parallel processing for multiple arrays, which is a key feature of the inventions. E.g., '841 patent, Abstract ("The invention relates to sensor compositions comprising a composite array of individual arrays, to allow for simultaneous processing of a number of samples."); Response to Office Action, attached to Chin Decl., dkt. #130, at 10 (applicants distinguished prior art by arguing that the invention "teaches that an advantage of using a substrate having a plurality of array locations is the ability to do parallel analysis rather than sequential analysis of arrays"). Instead, plaintiff argues that certain parts of the email should be viewed as a summary of ideas Kirk learned at the meeting rather than his own ideas. Although I agree that the email is ambiguous, I do not agree that it forecloses Kirk's claim as a joint inventor. Kirk testified that the ideas in the email regarding parallel processing were his own. Kirk Depo., dkt. #149, at 291-92. Kirk's testimony is supported by Stuelpnagel's, who admits that he did not have the idea for his invention as of March 1998. Stuelpnagel Dep., dkt. #95 at 77-80. (Stuelpnagel's testimony is that he and the other two named inventors developed the idea for the '841 and '020 in the summer of 1998.) Plaintiff does not identify anyone else who asserts that he or she gave Kirk the ideas in the email. Accordingly, I conclude that the email and the testimony suffice to require a hearing under § 256.

As noted above, § 256 requires that "all parties concerned" be given "notice and hearing" before the court orders correction. The parties do not cite any cases in which a court has defined what a "concerned party" is and I have not uncovered a discussion of the term in my own research. However, in the cases involving § 256, the court of appeals has not suggested that notice is required to anyone other than the alleged inventor and the named inventors and their assignees. <u>E.g.</u>, <u>Ethicon</u>, 135 F.3d at 1459; <u>Pannu</u>, 155 F.3d at 1347. However, the parties are free to call other witnesses at the hearing if they have relevant testimony.

ORDER

IT IS ORDERED that

- 1. All pending motions filed by the parties, dkt. ##118, 122, 125 and 133 and 150 are STAYED.
- 2. The court will hold a hearing during the week of December 13, 2010, to determine whether the '841 and '020 patents should be corrected under 35 U.S.C. § 256 to add Gregory Kirk as an inventor. The parties should confer with each other and contact the clerk of court with a date during that week, other than December 17, that they are available. If

the parties are not available any of those days, they should contact the court promptly.

3. Defendant Affymetrix, Inc. may have until November 30, 2010, to give written notice to Kirk, each of the named inventors on the '841 and '020 patents and any assignees of the named inventors other than plaintiff Illumina, Inc. The notice should give the date of the hearing, explain its purpose and state that each inventor may have an opportunity to testify if he chooses.

Entered this 23d day of November, 2010.

BY THE COURT: /s/ BARBARA B. CRABB District Judge