Keywords: **correction of Inventorship, breach of contract, unjust enrichment, burden of proof, joint inventorship**

General:

Eli Lilly and Co. v. Aradigm Corp.
71 U.S.P.Q.2d 1787 (Fed. Cir. 2004)
Decided July 20, 2004

I. Facts

Lilly invented and marketed an insulin analog called "lispro." When natural insulin is administered by injection, the regular insulin molecules that are in aqueous solution in the syringe self-associate into a stable hexamer. It is believed that the 30-minute delay between an injection of insulin and the onset of its therapeutic affect can be traced the time required for the hexamer to disassociate into unclustered monomers and to diffuse away from the injection site and into the blood stream. Lispro is a modified version of regular insulin that has two amino acids in the chain reversed so that it is less prone to self association. As a result, the therapeutic affects of lispro occur more quickly.

Aradigm's business focuses on drug delivery through the inhalation of aerosols. Aradigm owns a patent having claims directed to methods directed to administering lispro and other monomeric insulin analogs in this manner. When it filed for the patent, Aradigm believed that the inhalation of lispro instead of regular insulin would reduce the tendency for the drug to remain in the lungs because lispro disassociates more quickly than regular insulin. Claims 5 and 6 of Aradigm's patent are reproduced below.

> 5. A method of improving the bioavailability of insulin delivered via the lung, comprising:
>
> aerosolizing a formulation of an insulin analog which analog rapidly disassociates into monomeric form;
>
> inhaling the aerosolized formulation of the insulin analog into the lungs in a manner which allows the particles of the insulin analog to deposit on the lung tissue.
>
> 6. The method of claim 5, wherein the inhaled insulin analog is insulin lispro which rapidly disassociates in a monomeric form producing a relative bioavailability greater than twice that seen after the inhalation of a similar amount of recombinant human insulin.

Prior to the filing of Aradigm's application for patent, Lilly and Aradigm held several meetings to discuss a possible collaboration that would take advantage of Lilly's expertise in insulin compounds and Aradigm's expertise in aerosol drug delivery. Lilly insists that its scientists conveyed to Aradigm the specific advantages to be expected from using lispro instead of regular insulin in an aerosol delivery device, and, thus, certain Lilly employees should have been named as inventors on Aradigm's patent. Accordingly, Lilly brought a claim under 35 U.S.C. § 256 to correct Inventorship. Lilly also sought damages for breach of contract and unjust enrichment.

In the district court, the jury found that one of Lilly's employees, Dr. DiMarchi, was a co-inventor of the subject matter set forth in claim 6 of Aradigm's patent. The jury also found in Lilly's favor under the breach of contract claim, although the jury found against Lilly in the unjust enrichment claim. Lilly appeals the district court's refusal to grant an injunction under the breach of contract claim, as well as the jury's finding under the unjust enrichment claim, and Aradigm cross-appeals the jury verdict finding Dr. DiMarchi to be co-inventor of claim 6.

II. Issues

A. Did the district court correctly determine that Dr. DiMarchi was a co-inventor based on clear and convincing evidence?

B. Should the district court's determinations regarding the breach of contract claim and the unjust enrichment claim stand?

III. Discussion

A. No. Section 256 creates a cause of action in the district courts for correction of non-joinder of an inventor on a patent provided the non-joinder error occurred without deceptive intent. In the Section 256 proceeding, the inventors as named in an issued patent are presumed to be correct. The general rule is that a party alleging misjoinder or non-joinder of inventors must meet the heavy burden of proving its case by clear and convincing evidence and must provide evidence to corraborate the alleged joint inventor's conception. Under 35 USC §116, a person is a joint inventor only if he or she contributes to the conception of the claimed invention. An individual must make a contribution to the conception of the claimed invention that is not insignificant in quality when that contribution is measured against the dimension against the full invention. The alleged joint inventor must demonstrate that his or her labors were conjoined with the efforts of the named inventors, as joint inventorship under Section 116 can only be found when collaboration or concerted effort occurs.

First, Aradigm argued that the jury instructions were erroneous. A party seeking to alter a judgment based on erroneous just instructions must establish (1) they made a proper and timely objection to the jury instructions; (2) the instructions were legally erroneous; (3) the errors has prejudicial effect; and (4) they requested alternative instructions that would have remedied the error. Aradigm initially argued that the district court erred by not construing claim 6 before sending the Inventorship issue to the jury. The Federal Circuit found that while it is true that the legal scope of the claim must be known before the contributions of an alleged co-inventor can be compared to the claim to determine whether the correct inventors were named, Aradigm had never requested that the district court construe any terms in claim 6 and never offered a construction of claim 6. It was only after the presentation of all evidence to the jury that Aradigm even suggested that claim construction might be helpful. Therefore, the Federal Circuit held that Aradigm waived its right to request a construction of claim 6 and that Aradigm had implicitly conceded that the meanings of the terms in claim 6 were clear and not in need of construction. Secondly, Aradigm offered only a vague objection relating to the jury instruction. The Federal Circuit addressed this issue by noting that an objection must state distinctly the matter objected to and the grounds of objection in order to ensure that the objections point out to the district court its alleged error so that the district court has

an opportunity to correct the error. Here, generically alleging that the wording of a jury instruction is confusing, without suggesting the logical error that the jury might make, did not give the district court the information it required to recognize the alleged error and to have a meaningful opportunity to correct it. Furthermore, the Federal Circuit found that the jury instruction had no prejudicial effect in any case.

Secondly, Aradigm argued that the district court's paraphrase of claim 6 permitted the jury to find that Dr. DiMarchi had contributed only information about the chemical properties of lispro that were in the public domain and that a contribution of information in the prior art cannot give rise to joint inventorship. Specifically, Aradigm argued that "producing a relative bioavailability greater than twice that seen after the inhalation of a similar amount of recombinant human insulin" in claim 6 merely recites a fact of nature. Unfortunately, Aradigm only proffered this argument during appeal, and the Federal Circuit refused to accept these presumptions, regardless of their veracity, at this point in the proceedings.

Third, Aradigm argued that there is insufficient evidence in the record to support the jury verdict to satisfy the burden of proof by clear and convincing evidence. The Federal Circuit noted that inventorship is a mixed question of law and fact in that the overall inventorship determination is a question of law, but is premised on underlying questions of fact. Therefore, the Federal Circuit noted that it must sustain the jury's conclusion unless the jury was not presented with substantial evidence to support any set of finding sufficient under the law to arrive at its conclusion. In this case, the Federal Circuit noted that Lilly cannot demonstrate by clear and convincing evidence that Dr. DiMarchi communicated to Aradigm's scientists that aerosolized lispro might be used to produce "a relative bioavailability greater than twice that seen after the inhalation of a similar amount of human insulin." Dr. DiMarchi only testified that he remembered talking about insulin at one of the meetings, and none of the witnesses testified to the specific subject matter set forth in claim 6. In fact, one of the witnesses specifically testified that he did not mention the subject matter set forth in claim 6. Therefore, Lilly's evidence of conception relied largely on circumstantial evidence. However, the Federal Circuit found that the circumstantial evidence in this case was not sufficient to meet the burden of clear and convincing evidence.

Finally, Lilly argued that it need only demonstrate that Dr. DiMarchi contributed to the conception of claim 6 by a preponderance of the evidence. Under this less demanding burden of proof, Lilly argued that the circumstantial evidence of record was sufficient to support a jury verdict in its favor and that the Federal Circuit must remand for a new trial. Lilly asserted that the general rule requiring clear and convincing evidence under Section 256 does not apply when there are two co-pending patent applications claiming the same subject matter in front of the PTO, one of which issues as a patent allegedly omitting the inventor, and the other of which was filed by the allegedly omitted inventor. Instead, Lilly argued that the burden of proof used in interference proceedings, either before the PTO or before the district court under 35 U.S.C. § 291, should apply relying upon the *Environ Products* case. The Federal Circuit disagreed. The Federal Circuit noted that the *Environ Products* case did not involve a Section 256 claim for non-joinder of inventorship. Instead, it involved a priority determination between two issued patents and a patent application, all of which were pending before the PTO at the same time. In drawing distinctions, the Federal Circuit noted that the existence of co-pending applications throws into question the presumption of validity for the first-filed patent in so far as the presumption involves an issue of timing or priority, but the existence of co-pending applications does not undermine to the same degree that each of the groups of inventors listed on the patent applications acted independently. Furthermore, the Federal

Circuit noted that in an interference proceeding, the parties place their own patent claims on the line and may lose their rights if not successful, while in a Section 256 proceeding the allegedly aggrieved party does not have to put its patent assets at risk. Finally, the Federal Circuit noted that Lilly could have provoked an interference if it wished to avail itself of this lower burden of proof, but it chose not to. Therefore, the Federal Circuit reversed the district court.

B. Yes. Lilly and Aradigm had entered into an insulin supply agreement under which Lilly supplied regular insulin for Aradigm's use and, in return, Aradigm agreed that all information provided to Aradigm by Lilly would be kept in confidence for at least 10 years. At trial, Lilly argued that Aradigm breached the agreement by filing patent applications containing information encompassed within the supply agreement without obtaining Lilly's permission. The jury agreed and awarded Lilly nominal damages – the only damages sought by Lilly. During post-judgment briefing, Lilly requested an injunction prohibiting Aradigm from continuing to breach the supply agreements and, in particular, from filing further patent applications containing the information encompassed by the supply agreements. The district court denied Lilly's request for injunctive relief by emphasizing that Lilly has not requested this remedy at any point prior to entry of the judgment. The Federal Circuit concluded that the district court did not abuse its discretion in denying Lilly's belated request.

In regard to the unjust enrichment claim, the jury found that Lilly provided valuable services or benefits to Aradigm and that the services or benefits provided were at the express or implied request of Aradigm. However, the jury also found that the services or benefits were not provided under circumstances such that Lilly was entitled to compensation. In post judgment briefing, Lilly argued that the district court's judgment following the jury's verdict was erroneous because the jury's factual findings in Lilly's favor should have led to a verdict in Lilly's favor. The Federal Circuit found that the district court did not abuse its discretion in denying Lilly's motion, because the district court properly followed the appropriate law in determining that a claim of unjust enrichment can be made out only "under circumstances under which equity demands compensation to prevent unjust enrichment."

IV. Conclusion