Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC
30 F.4th 1109 (Fed. Cir. 2022)

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BACKGROUND

Defendant Meso Scale Diagnostics, LLC ("Meso") was formed in 1995 from a joint research program venture agreement with IGEN International, Inc. ("IGEN"). The agreement required Meso to develop electrochemiluminescence ("ECL") immunoassays and included a licensing agreement to retain the rights to the technology produced during the research period.

Plaintiff Roche Diagnostics Corporation ("Roche") entered into a joint venture with IGEN in 1998, inheriting ECL licensing rights after purchasing Boehringer Mannheim GmbH ("Boehringer"), who was licensed by IGEN in 1992 to "develop, use, manufacture, and sell ECL assays in a particular field."[1]

IGEN terminated the 1992 Boehringer agreement in 2003 and created a new agreement with Roche that granted a non-exclusive license to their ECL technology in the human patient diagnostics field. The agreement allowed Roche to make sales out of the specified field and required Roche to label its packaging with the field restriction. After the agreement, IGEN transferred their ECL patents to the newly formed BioVeris Corporation ("BioVeris").

Roche acquired BioVeris in 2007 and publicized its complete ownership of the patented ECL technology, thereby granting its clients unrestricted access to the technology. Roche sent their customers a letter specifying that the field restriction labels were to be ignored and would soon be removed from their ECL products. Roche then began selling their products beyond the human patient diagnostics field restriction.

PROCEDURAL HISTORY

Meso filed an initial suit in the Delaware Court of Chancery in 2010, alleging Roche breached the 2003 agreement with IGEN, as the sales without the field restriction labels violated their rights to the ECL patent claims. The Delaware court found Meso could not enforce the field restriction because BioVeris was the intended party to the 2003 agreement with IGEN.

Subsequently, Roche initiated a suit in 2017 in the United States District Court for the District of Delaware, seeking a declaratory judgment that it did

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1. Roche Diagnostics Corp. v. Meso Scale Diagnostics, LLC, 30 F.4th 1109, 1113 (Fed. Cir. 2022).

not infringe on Meso's 1995 agreement with IGEN, challenging the scope of Meso's exclusive license.

Meso filed a counterclaim for patent infringement. A jury found Meso held exclusive rights to the patent claims, and Roche directly infringed the No. 6,808,939 U.S. patent ("'939 patent") and willfully induced infringement of the No. 5,935,779 and No. 6,165,729 U.S. patents ("'779 patent" and "'729 patent" respectively). The jury awarded Meso $137,250,000 in damages.

The district court denied Roche's post-trial challenges for infringement and damages but granted a motion for judgment as a matter of law ("JMOL") on willfulness. It further denied Meso's motion to enhance damages and denied their claims for infringement on three additional patents. The district court found Meso compulsorily waived their claims for the additional patents for failing to claim them. Roche appealed the district court judgment and Meso cross-appealed.

ISSUE

Did Roche directly infringe and willfully induce infringement of Meso's rights to ECL technology patents by selling their products without field restriction labels after purchasing BioVeris and IGEN's original ECL patents?

DECISION

The Court of Appeals for the Federal Circuit affirmed the district court's ruling that Roche directly infringed Meso's ECL '939 patent and reversed the induced infringement ruling of the '779 patent and '729 patent. The Federal Circuit vacated the damages award and remanded for a new trial on damages. The court vacated the judgment of noninfringement for three additional patents and remanded Meso's cross-appeal.

REASONING

To determine whether Roche directly infringed the ECL technology patents, the court first defined the scope of Meso's rights under their 1995 agreement with IGEN. The agreement granted Meso an exclusive license to make or sell technology that was, first, "developed in the course of the research program," and second, "utilized or related to the research technologies."[2]

Under the first prong, Roche claimed a natural reading of the provisional language of the agreement, arguing Meso owned the rights only to the specific products, processes and new improvements created during the research program but not the '939 patent claims. Roche argued that Meso's course of conduct demonstrated that neither Meso nor IGEN interpreted the agreement to grant Meso exclusive rights to the claims. Additionally, IGEN and BioVeris had continuously sold the products alongside them without Meso objecting.

2. *Id.* at 1115.

Although the Federal Circuit found Roche's interpretation of Meso's rights to be more convincing, clear testimony from the research program manager between Meso and IGEN demonstrated that Meso's work directly involved developing the ECL technology for the '939 patent. As such, the Federal Circuit held that Meso did not produce the '939 patent during the research program and reasoned that Roche's sole comment into Meso's exclusive ownership was raised in a footnote and overall insufficient "to preserve an argument for review."[3] The Federal Circuit agreed with Roche's reasoning of the plain-language interpretation of the agreement but affirmed the trial court's denial of a JMOL motion, finding that Roche directly infringed the '939 patent claims.

Under the second prong, Roche argued that co-reactant tripropylamine ("TPA")—which was part of the infringed claims for the '779 patent and '729 patent—did not fall within the research technologies" category. The district court found sufficient evidence that TPA was reasonably within the definition and affirmed that Meso held the rights to both patents.

Since ownership of the patents predated the research program agreement, the Federal Circuit focused on reversing the induced infringement decision for the '779 patent and '729 patent which rested on two independent grounds: an "absence of intent"[4] and an "absence of an inducing act that could support liability" during the six-year patent-damages limitation on collecting back damages.[5]

First, in addressing absence of intent, a defendant is liable for 'induced infringement' if the defendant took certain affirmative acts to bring about the commission—by others—of infringing acts and if the alleged inducer 'had knowledge that the induced acts constituted patent infringement.'[6] Here, the Federal Circuit held that willful blindness can satisfy the intent element if "(1) the defendant subjectively believes that there is a high probability that a fact exists, and (2) the defendant takes deliberate actions to avoid learning of that fact."[7]

The Federal Circuit also found that the district court incorrectly denied Roche's JMOL for no willful infringement by incorrectly applying a negligence standard rather than requiring specific intent. The standard of "knew or should have known"[8] is inconsistent and no longer applicable.

Here, the Federal Circuit found that the lower court's finding that Roche never subjectively intended to infringe due to its good faith belief in its reasonable contract interpretation directly contradicted the jury's verdict. As such, Roche's willfulness failed to exhibit inducement.

Second, in addressing an absence of an inducing act, the Federal Circuit held that acts that support the inducement of infringement must have occurred

3. *Id.* at 1116.
4. *Id.* at 1117-18.
5. *Id.*
6. *Id.*
7. *Id.*
8. *Id.*

during the six-year damages period, which here, began in April 2011. Meso could not prove Roche committed acts within the limitation period since the cited acts occurred in 2007.

Additionally, the district court held Roche's customer letter, press release, decision to end the use of field-restricting labels, and failure to withdraw guidelines satisfied the standard for Meso to collect damages, because they were continuously damaging.

However, the Federal Circuit rejected the application of a continuing-impact standard, arguing that Roche's acts did not support the induced infringement verdict since none of the acts occurred within the six-year damages period. Further, although Roche sold products during the damages period without labels restricting their use, these were not acts of inducement because "the products [had] both in-field (non-infringing) and out-of-field (infringing) applications."[9]

The appeals court found Meso failed to provide evidence of causation between the alleged inducing acts and direct infringement nor demonstrate that customers purchasing Roche's products during the damages period received the 2007 communication and relied on it to engage in out-of-field uses. The Federal Circuit reversed the induced infringement for the '779 patent and '729 patent, vacated the damages award and remanded for a new trial.

Roche argued that the district court allowed Meso's damages expert to testify a reasonable royalty base rather than a royalty rate which caused the jury to find an unreasonable ruling for damages. Roche further challenged the $137,250,000 damages award, claiming it originated from 100% of the profits from their out-of-field sales based on the infringement of the three cited patents. According to the 2003 license, Roche claimed they received only 65% of the profits as a royalty rate from over one hundred ECL technology licenses granted to them.

In response, the Federal Circuit held that damages must be attributable only to the infringing features, and expert damage opinions must isolate the value of the infringing features to be admissible. Here, the expert was conservative regarding Roche's royalties from the infringed patents since their business often outperformed their estimates. Additionally, the jury reasonably determined the apportionment of the damages as the three infringed patents primarily drove their profits. The appellate court did not decide whether the district court erred in their ruling but found that Meso failed to demonstrate the comparability of the infringed patents and the jury's royalty award and, with both parties stipulating, agreed that a reversal required a new trial for damages.

Meso cross-appealed, challenging the district court's ruling on compulsory counterclaims for three other patents and arguing that they inappropriately found non-infringement of those patents solely for not being counterclaimed. The Federal Circuit agreed with Meso that the compulsory-

9. *Id.* at 1120.

counterclaim rule did not authorize adverse judgments for claims listed in the declaratory-judgment complaint in the same action.[10] Roche argued the issue arose as Meso failed to counterclaim with respect to the patents at trials. However, while neglecting to render an opinion on the matter, the court vacated the district court's ruling of non-infringement for those three patents and remanded the case to the district court to determine whether Roche adequately pled its declaratory judgment claims to prevent Meso from bringing a future infringement action.

DISSENT

In her dissent, Circuit Judge Pauline Newman agreed that the induced infringement judgment should be reversed, but that Roche could not infringe patents it already owned and therefore should not be liable for either direct or induced infringement as Meso did not have an exclusive license to the claims. She reasoned that the majority should not have disregarded Meso's acceptance of Roche's rights due to the placement of the evidence in a footnote and that Meso never claimed they held the exclusive rights to the patents when IGEN sold the estate to Roche in 2007, nor throughout the years while IGEN, BioVeris, and Roche utilized the claimed patents. He argued that the holding defeated an "orderly administration of justice" by not "seek[ing] truth and justice, even from footnotes."[11]

10. FED. R. CIV. P. 13(a).

11. *Id.*