FEDERAL CIRCUIT SUMMARY FOR WEEK ENDING SEPTEMBER 22, 2023

***Baxalta Incorporated v. Genentech, Inc.*, No. 2022-1461 (September 20, 2023) (precedential) (3-0); Patent No. 7,033,590**

Key point(s):

- Trial-and-error discovery to enable a functional genus constitutes unreasonable experimentation under *Amgen*.
- *Amgen* leaves prior enablement case law undisturbed, including *Wands* and its factors.

Facts/Background: Baxalta sued Genentech, alleging infringement of the '590 patent. The '590 patent relates to a treatment for Hemophelia A, a blood clotting disorder characterized by the functional absence of an enzyme known as Factor VIII. Although Hemophilia A is traditionally treated by intravenously administering Factor VIII, some patients cannot benefit from this treatment because their bodies develop Factor VIII inhibitors. Therefore, the '590 patent sought to provide an alternative treatment. The claims at issue are directed to antibodies or fragments thereof that bind to an enzyme known as Factor IX/IXa to increase the procoagulant activity of Factor IXa. Only eleven such antibodies, out of potentially millions, are disclosed in the specification. The district court granted summary judgment of invalidity for lack of enablement.

Holding: Affirmed. The Federal Circuit applied the Supreme Court's decision in *Amgen Inc. v. Sanofi*, which held that "the specification must enable the full scope of the invention as defined by its claims," allowing for "a reasonable amount of experimentation." 598 U.S. 594, 610–12 (2023).

Baxalta argued that summary judgment was improper because skilled artisans can make and identify new claimed antibodies using a routine hybridoma-and-screening process disclosed in the '590 patent, and that such routine screening does not amount to undue experimentation. The Federal Circuit rejected Baxalta's argument, finding the facts of the case to be materially indistinguishable from those in *Amgen*. The Federal Circuit asserted that, just like the roadmap rejected by the Supreme Court in *Amgen*, the routine hybridoma-and-screening process disclosed in the '590 patent simply directs skilled artisans to engage in the same iterative, trial-and-error process the inventors followed to discover the eleven antibodies, out of potentially millions, they elected to disclose. The Federal Circuit held that such random trial-and-error discovery, without more, constitutes unreasonable experimentation under *Amgen*. The Federal Circuit further noted that the '590 patent contains no disclosure of a quality common to every functional embodiment and does not explain why the eleven disclosed antibodies perform the claimed functions.

Baxalta further argued that the district court's enablement determination was inconsistent with *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). The Federal Circuit disagreed, stating that it does not interpret *Amgen* to have disturbed prior enablement case law, including *Wands* and its factors, and reiterated that the facts are indistinguishable from those in *Amgen*. The Federal Circuit added that it sees no meaningful difference between *Wands*' "undue experimentation" and *Amgen's* "unreasonable experimentation" standards.

***Target Corporation v. Proxicom Wireless, LLC*, No. 2022-1282 (September 20, 2023) (nonprecedential); Patent Nos. 8,090,359 and 8,374,592**

Key point(s):

- Claim limitations should not be interpreted to include unwritten requirements, particularly where similar limitations in other claims are not so interpreted.
- A claim limitation may be satisfied if the prior art discloses the limitation at least some of the time.

Facts/Background: Target filed IPRs challenging the claims of the '359 patent and the '592 patent. The patents relate to utilizing short-range and long-range wireless capabilities when, for example, two individuals in proximity wish to exchange information or a payment. For each patent, the Board found some claims to be unpatentable and other claims to be patentable. Target appealed the patentability conclusions, while Proxicom appealed the unpatentability conclusions.

Holding: Affirmed-in-part, reversed-in-part, vacated-in-part, and remanded.

With regard to Target's appeal of the patentability conclusions for the '359 patent, the claims at issue require that a "list of goods" be transmitted as part of an electronic commerce transaction. Target argued to the Board that the reference's disclosure of delivering a restaurant menu satisfies the "list of goods" requirement. The Board rejected the argument because, in the Board's view, Target failed to explain how the reference discloses the user interacting with the menu after it has been delivered. The Federal Circuit reversed and held that the reference discloses all limitations of the claims, noting that the claims at issue do not require interaction with the "list of goods," and the Board did not find a similar limitation in a different claim to require such interaction.

With regard to Target's appeal of the patentability conclusions for the '592 patent, the claims at issue require a server "to determine a name of an entity or object located in proximity to the second wireless device." Target argued to the Board that this limitation is met by the reference's disclosure that, for certain types of electronic coupons, such as product offerings with price discounts, the coupons are provided to mobile users through tags or beacons at the store. The Board found the argument to be speculative, since the limitation would only be met when advertised products are in the store. The Federal Circuit vacated the Board's decision and held that, because there is no dispute that the reference would perform the claim limitation at least some of the time, the reference teaches the claim limitation.

With regard to Proxicom's appeal of the unpatentability conclusions, Proxicom argued: (i) that the Board erred by implicitly adopting and applying a claim construction that permits the "entity" or "object" of the claims at issue to be intangible; and (ii) that Target shifted its claim mappings from petition to reply, such that the Board's adoption of Target's new mappings deprived Proxicom of due process. The Federal Circuit rejected the first argument as inconsistent with the specification and other positions taken by Proxicom. Regarding Proxicom's second argument, the Federal Circuit stated that the allegedly new mappings were consistent with the institution decision and that Proxicom had notice and opportunity to respond, as it in fact did in its sur-replies.

***Well Cell Global LLC v. Calvit*, No. 2023-1229 (September 21, 2023) (nonprecedential); Patent No. 10,533,990**

Key point(s):

For a preliminary injunction:

- Irreparable harm generally requires more than speculation about future events.
- Likelihood of success in proving patent infringement or trade secret misappropriation generally requires identification of a patent claim or trade secret, respectively.

Facts/Background: Well Cell and Appellants entered into a license agreement regarding Well Cell's intellectual property. Well Cell later sent Appellants a notice of default alleging Appellants' billing practices breached the license agreement. Well Cell eventually filed a complaint against Appellants and other parties alleging, *inter alia*, patent infringement and misappropriation of trade secrets. The day after filing the complaint, Well Cell filed motions for a temporary restraining order (TRO)—which was granted—and a preliminary injunction. The district court issued the preliminary injunction with an order broadly outlining the enjoined activities. Appellants filed an emergency motion to stay the preliminary injunction pending this appeal, which was granted.

Holding: Reversed and remanded. A district court may grant an injunction only after the moving party demonstrates a reasonable likelihood of success on the merits, irreparable harm in the absence of a preliminary injunction, and the injunction's favorable impact on the public interest. The Federal Circuit held that the district court abused its discretion in granting the preliminary injunction because Well Cell's motion failed to show a likelihood of either success on the merits or irreparable harm.

With regard to irreparable harm, the Federal Circuit stated that Well Cell's evidence rested on multiple levels of speculation – that Appellants may perform the claimed methods illegally or improperly and that Well Cell would be blamed for Appellants' misconduct. The Federal Circuit held that, because Well Cell's irreparable harm allegations rested on unsubstantiated assertions, the district court erred by finding that Well Cell sufficiently established a likelihood of irreparable harm.

With regard to likelihood of proving patent infringement or trade secret misappropriation, the Federal Circuit observed that neither Well Cell nor the district court identified any particular patent claim or any particular trade secret. As such, the Federal Circuit held that the district court erred by finding that Well Cell sufficiently established a likelihood of success on the merits.

***Elekta Limited v. ZAP Surgical Systems, Inc.*, No. 2021-1985 (September 21, 2023) (precedential) (3-0); Patent No. 7,295,648**

Key point(s):

- Silence during prosecution regarding the technological relevance of cited art may support a later finding of a motivation to combine other art from the same field.
- Reasonable expectation of success may be addressed by the Board implicitly with motivation for combine, particularly where the evidence and arguments are intertwined.

Facts/Background: ZAP petitioned for IPR of the '648 patent. The '648 patent is directed to a device for treating a patient with ionizing radiation for certain types of radiosurgery and radiation therapy. The device uses a radiation source, *e.g.*, a linear accelerator (referred to as a "linac"), mounted on a pair of concentric rings, to deliver a beam of ionizing radiation to a target area on the patient.

The Board held that all challenged claims were unpatentable as obvious, including some as obvious over the combination of Grady (U.S. Patent No. 4,649,560) and Ruchala (NPL reference). The Board addressed, *inter alia*, Elekta's arguments that a skilled artisan would not have been motivated to combine, and would not have had a reasonable expectation of success in combining, the Grady device with a linac described in Ruchala. The Board also considered whether a skilled artisan would have been dissuaded from combining the devices because one device was an imaging device, rather than a radiation device, and because the linac's weight would render the Grady device inoperable, imprecise, and unsuitable for treatment. The Board concluded that a skilled artisan would have been motivated to combine Grady and Ruchala.

Holding: Affirmed. Elekta argued: (i) that the Board's findings on a motivation to combine were unsupported by substantial evidence; (ii) that the Board failed to make any findings, explicit or implicit, on a reasonable expectation of success; and (iii) that even had the Board made such findings on a reasonable expectation of success, such hypothetical findings were not supported by substantial evidence.

With regard to (i), the Federal Circuit held that that the Board's finding that a skilled artisan would have been motivated to combine the Grady device with Ruchala's linac were supported by substantial evidence, including the prosecution history of the '648 patent, the teachings of the asserted prior art references, and the expert testimony of record. In particular, with regard to prosecution history, the Federal Circuit found it notable that, during prosecution, the patentee did not argue that cited references directed to imaging devices were not relevant art.

With regard to (ii), the Federal Circuit held that the Board implicitly addressed reasonable expectation of success based on the arguments and evidence presented to it on motivation to combine. The Federal Circuit observed, for example, that the Board addressed Elekta's argument that the linac's weight would render the Grady device inoperable, imprecise, and unsuitable for treatment. The Federal Circuit stated that the blended manner in which the Board addressed the two issues was appropriate since the evidence and arguments were intertwined.

With regard to (iii), the Federal Circuit referred to its earlier discussion of reasonable expectation of success and motivation to combine, and held that the Board's finding of a reasonable expectation of success was supported by substantial evidence.

***Caddo Systems, Inc. v. Siemens AG*, No. 2022-1623 (September 22, 2023) (nonprecedential); Patent Nos. 7,191,411, 7,216,301, 7,640,517, 7,725,836, 8,352,880, and 10,037,127**

Key point(s):

- License and covenant-not-to-sue provisions that broadly cover combinations with other products may reach an expansive class of third parties.

Facts/Background: Caddo asserted six related patents against Siemens Industry and Siemens AG. Caddo accused two products: Siemens Industry's Desigo CC software and Siemens AG's website.

Before the action was filed, litigation between Microsoft and Caddo was resolved by a settlement agreement containing license, release, and covenant-not-to-sue provisions that limit Caddo's actions regarding, *inter alia*, the six Caddo patents at issue here and certain non-Microsoft products. The settlement agreement reaches third-party products "to the extent that they are combined with, used with or aggregated with [a Microsoft product], but only the portion of such combination, usage or aggregation that consists of or uses [a Microsoft product]."

Siemens Industry moved for summary judgment on the ground that the settlement agreement protected it from the infringement liability Caddo alleged. In Desigo CC, the accused functionality is provided by "RadBreadcrumb" software supplied to Siemens Industry by third-party software provider Telerik. Siemens Industry pointed to record evidence demonstrating that the entirety of RadBreadcrumb requires and uses Microsoft's .NET framework. The district court granted Siemens Industry's motion. The district court also dismissed Caddo's complaint against Siemens AG, a German company, for lack of personal jurisdiction.

Holding: Affirmed. With respect to summary judgment, Caddo argued that only a "portion," and not the entirety, of RadBreadcrumb "consists of or uses" .NET. The Federal Circuit rejected this argument, noting that Caddo failed to present evidence of a portion of RadBreadcrumb that does not "use" .NET for the accused functionality, even though Caddo, as a party to the settlement agreement, was well-positioned to understand the agreement's terms and to produce the crucial evidence if it existed. Thus, the Federal Circuit held that the settlement agreement with Microsoft bars Caddo from succeeding in the infringement case against Siemens Industry.

The Federal Circuit also affirmed the district court's grant of Siemens AG's motion to dismiss for lack of personal jurisdiction, pointing out, *inter alia*, that Siemens AG's website is maintained and hosted outside the United States and provides no direct means to buy products from or sell products to Siemens AG.