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United States Court of Appeals for the Federal Circuit

03-1272

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA
and BIAGRO WESTERN SALES, INC.,

Plaintiffs-Appellees,

v.

ACTAGRO, LLC,

Defendant-Appellant.

DECIDED: June 9, 2004

Before RADER, Circuit Judge, ARCHER, Senior Circuit Judge, and GAJARSA, Circuit Judge.

ARCHER, Senior Circuit Judge.

Actagro, LLC (“Actagro”) appeals the United States District Court for the Eastern District of California’s grant of a motion preliminarily enjoining the sale of Actagro’s Resist® (0-21-18) fertilizer product. The district court found that Actagro failed to show that there was a substantial question as to the validity of claims in U.S. Patent No. 5,514,200 (“the ‘200 patent”), owned by the Regents of the University of California and licensed to Biagro Western Sales, Inc. (collectively “The Regents”). The Regents of the Univ. of Cal. v. Actagro, LLC, CV F 02-6530 AWI DLB (E.D. Calif. Jan. 13, 2003) (“Preliminary Injunction Order”). The district court further found that The Regents were entitled to a presumption of irreparable harm and that this presumption was not overcome. Id. at 3. Because Actagro

did in fact raise a substantial question as to the validity of the '200 patent, we vacate the preliminary injunction and remand the case to the district court for further proceedings.

I

The '200 patent is drawn to a concentrated phosphorus fertilizer. Several months after the patent issued, a reexamination was initiated by The Regents for the purpose of establishing patentability in view of product literature for an Australian product called Supa Stand Phos ("the SSP reference"). A reexamination certificate issued without amending the patent. Claims 1 and 13 are at issue and recite as follows:

1. A concentrated phosphorus fertilizer comprising a buffered composition comprising an organic acid and salts thereof and a phosphorous-containing acid selected from the group consisting of phosphorous acid, hypophosphorous acid, polyphosphorous acid, polyhypophosphorous acid and salts thereof, such that when said composition is diluted with water, there is formed a substantially fully solubilized use-dilution fertilizer having a foliage-acceptable pH for phosphorus uptake.

13. A method of providing phosphorus to a plant comprising diluting a concentrated phosphorus fertilizer comprising a buffered composition comprising an organic acid and salts thereof and a phosphorous-containing acid selected from the group consisting of phosphorous acid, hypophosphorous acid, polyphosphorous acid, polyhypophosphorous acid and salts thereof with water to form a substantially fully solubilized use-dilution fertilizer having a foliage-acceptable pH for phosphorus uptake, and applying said use-dilution fertilizer to the foliage of said plant.

'200 Patent, col. 8, line 48 – col. 10, line 3.

The Regents filed a complaint for patent infringement against Actagro, claiming Actagro's Resist® (0-21-18) fertilizer infringed claims 1 and 13 of the '200 patent. The Regents also filed a motion for preliminary injunction with the complaint. The district court granted The Regents' motion in an order dated January 13, 2003. At the preliminary injunction hearing, the district court stated that its oral statements at the hearing would constitute the court's findings. (Tr. Jan. 13, 2003 at 56).

The district court found that Actagro had failed to meet its burden with regard to the element of likelihood of success on the merits. In reaching this conclusion, the court did not perform a claim construction and did not analyze in any significant way the primary references offered by Actagro to

support its invalidity arguments. The court stated, with respect to the SSP reference, that it “agree[ed] with defense [i.e., Actagro] that there are a number of indications on here that appear to be similar or at least contained within one or more claims within the patent.” Id. at 52-53. However, apparently because the SSP reference taught the use of phosphorous acid as a fungicide rather than as a fertilizer, the district court found that the SSP reference did not teach the limitations of the ‘200 patent. Id.; Preliminary Injunction Order at 3. With respect to the Robertson and Boyer article, the court stated in the written order that there were “compositional distinctions between the ‘200 Patent and the solutions of the Robert [sic] and Boyer Article.” Preliminary Injunction Order at 3. Based upon these determinations the court found that Actagro had not shown a likelihood that the patent was invalid, that The Regents were entitled to a presumption of irreparable harm, and that Actagro had not overcome the presumption. Id. The court also found that the hardship and public interest factors fell in favor of granting the preliminary injunction. For these reasons the district court granted The Regents’ motion for a preliminary injunction.

We have jurisdiction under 28 U.S.C. § 1292(c)(1).

II

A

The grant or denial of a preliminary injunction under 35 U.S.C. § 283 is within the sound discretion of the district court. Novo Nordisk of N. Am., Inc. v. Genentech, Inc., 77 F.3d 1364, 1367 (Fed. Cir. 1996). “An abuse of discretion may be established by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings.” Id.

As the moving party, The Regents are entitled to a preliminary injunction if they succeeded in showing: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest. Reebok Int'l Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1555 (Fed. Cir. 1994).

In order to demonstrate a likelihood of success on the merits, The Regents have to show that, in light of the presumptions and burdens that will inhere at trial on the merits, (1) The Regents will likely prove that Actagro infringes the '200 patent, and (2) The Regents' infringement claim will likely withstand Actagro's challenges to validity. Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001). If Actagro raised a substantial question concerning validity, *i.e.*, asserted an invalidity defense that the patentee did not prove "lacks substantial merit," the preliminary injunction should not issue.^[1] *Id.* at 1350-51. Accordingly, at the preliminary injunction stage vulnerability is the issue, while validity is the issue at trial. *See Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1335 (Fed. Cir. 2004) (citing Amazon.com, 239 F.3d at 1359). "The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself" at trial. Amazon.com, 239 F.3d at 1359.

B

The first step in determining whether Actagro raised a substantial question concerning validity is to determine the meaning and the scope of the claims to the best of our ability on the preliminary record before us. *See Nat'l Steel Car*, 357 F.3d at 1334 (citing Lemelson v. Gen. Mills, Inc., 968 F.2d 1202, 1206 (Fed. Cir. 1992)); Amazon.com, 239 F.3d at 1351. The '200 patent has two essential features, both of which are at issue here. First, the invention of the '200 patent is a concentrated phosphorus fertilizer; and second, it must buffer at a foliage-acceptable pH when diluted with water.

Actagro contends that the limitation "a concentrated phosphorus fertilizer" essentially means a "concentrated fertilizer that contains phosphorus." The Regents, on the other hand, argue that the limitation means "a fertilizer where phosphorus is concentrated." The meaning of the phrase may not be perfectly clear from the claim language itself. However, the specification indicates that the limitation is properly read as "a concentrated fertilizer that contains phosphorus." For example, when discussing the possible dilution ratios of the concentrated phosphorus fertilizer to water, the specification explains the ratios in terms of concentrate to water, not in terms of concentrated phosphorus. '200 Patent at col. 3, lines 15-19 ("The concentrated phosphorus fertilizer can be diluted with water . . . at ratios of

concentrate to water at about 1:40 to about 1:1600 to result in a fully solubilized fertilizer having a pH in a range acceptable for foliar uptake of phosphorus.”). Similarly, the specification states that “[i]t is also an object that the phosphorus fertilizer formulations be conveniently formulated in concentrated solutions that are stable during storage and shipping,” *Id.* at col. 2, ll. 65-67 (emphases added), and “the highly concentrated fertilizers of the present invention, which can be diluted with water” *Id.* at col. 4, line 67- col. 5, line 1 (emphasis added). These excerpts indicate that it is the fertilizer that is concentrated, not the phosphorus. Finally, nowhere in the specification can we find reference to “concentrated phosphorus” as opposed to a “concentrated phosphorus fertilizer.”

Nothing The Regents offer compels us to find otherwise. For example, claim 9 simply states the percentage of the phosphorus fertilizer that must be phosphorous-containing acid. This sheds no light on whether the fertilizer is concentrated or the source of the phosphorus is concentrated – or even what “concentrated” might mean in the context of referring solely to the phosphorus source. The Regents’ reference to the prosecution history’s treatment of the Offenlegungsschrift 3,417,133 (“Offen. ‘133”) reference also does not help its position. The ‘200 patent applicant’s statement that “Offen. ‘133 does not teach or suggest a concentrated phosphorus fertilizer as required by the claims” (emphasis in original) suggests nothing other than that the fertilizer must be concentrated. The rest of the discussion simply refers to the weight percent of phosphorous-containing acid present in the fertilizer. This discussion, as explained above, says nothing that suggests it is not the fertilizer itself that is concentrated. During the reexamination, The Regents explained that the SSP reference taught a 13 weight percent of phosphorous acid and that this was “even less concentrated than the other phosphorous acid-containing formulations that were mentioned in col. 4 lines 60-65 of the captioned patent which contain approximately 16% phosphite.” The relevance of this text is doubtful, as the referenced section of the specification was deleted in a Certificate of Correction because “Applicant’s attorney, believe[d] that [it was] inaccurate and was perhaps originally made based on misinformation or a misunderstanding of information.” The statement in the reexamination could arguably be said to mean that “concentrate” as used in that sentence refers to the amount of a compound contained in a composition. However, this does not illustrate that “concentrated” in the phrase “a concentrated

phosphorus fertilizer” used throughout the specification is intended to refer both to the fertilizer and to the phosphorus.

Turning to the limitation that the composition be “buffered,” both parties appear to agree on the general meaning of this term: “a material is said to be buffered if it resists changes in pH when either an acid or a base is mixed with it.” (Grech Supp. Decl. ¶4). Therefore, in the context of the claims, the composition should be buffered “such that when said composition is diluted with water, there is formed a substantially fully solubilized use-dilution fertilizer having a foliage-acceptable pH for phosphorus uptake.” ‘200 Patent, col. 8, lines 53-56. The specification defines “foliage-acceptable pH for phosphorus uptake” to mean: “a pH that allows phosphorus to be absorbed by the plant without causing damage to the foliage[; a] foliage-acceptable pH for phosphorus uptake usually ranges between about 5.0 to 7.0, and preferably between about 5.5 to about 6.5.” ‘200 Patent at col. 4, lines 19-24. In other words, the claimed composition, when diluted, should buffer in the range of about 5.0 to 7.0, and preferably between about 5.5 to about 6.5.^[2]

Therefore, based on the preliminary record before us, “a concentrated phosphorus fertilizer” as used in the ‘200 patent is best described as a “concentrated fertilizer that contains phosphorus.” When diluted, this fertilizer should buffer in the range of about 5.0 to 7.0, and preferably between about 5.5 to about 6.5.

C

Actagro contends that it has raised a substantial question as to the validity of the ‘200 patent. Specifically, Actagro offers the SSP reference and an article by Robertson and Boyer, entitled “Orthophosphite as a Buffer for Biological Studies,” to support this contention. Actagro asserts that the SSP reference anticipates the claims of the ‘200 patent at issue here and that the Robertson & Boyer article offers additional support for the position that phosphorous acid salt solutions are inherently buffered solutions. Additionally, Actagro conducted tests on a series of fertilizer solutions and contends that the results suggest the product of the SSP reference was inherently a buffered composition. The Regents respond with the argument that the SSP reference is neither inherently a concentrated

phosphorus fertilizer (not only because there is not sufficient phosphorus, but because the phosphorus is not intended to be used as a fertilizer) nor inherently buffered. To support this position, The Regents offer “expert evaluation of the SSP [reference] which duly considered the entire composition instead of evaluating the separate behavior of selected components or evaluating a ‘test composition.’” Additionally, The Regents obtained a 2002 version of the SSP product and tested that sample for buffering. According to The Regents, the results of this test showed that the newer SSP did “not provide any significant buffering in the relevant range.” Naturally, each party asserts that its tests are more accurate and relevant than the other’s.

The SSP reference describes a “New Generation Starter fertiliser [sic]” that contains 13% weight per volume phosphorous acid as well as 10% Kelpak and 10% organic extract which is applied to soil in a 1:50 solution. Given our interpretation of “a concentrated phosphorus fertilizer” above, this reference clearly discloses a concentrated fertilizer that contains phosphorus: it is concentrated and contains phosphorus. That phosphorus is not listed as the ingredient doing the fertilizing does not change the fact that the product is a fertilizer. Additionally, the specification of the ‘200 patent itself points out that phosphorus is a well-known fertilizer. (‘200 Patent Col. 1, ll. 30-40).

The SSP reference makes no mention of “buffering.” The Regents’ test results on the 2002 SSP product claim that the product does not buffer in the correct range and The Regents’ expert declaration states that “[t]here is nothing in the label to suggest that SUPA STAND PHOS forms . . . a buffered solution having a foliage-acceptable pH.” On the other hand, the Robertson and Boyer article and a declaration by Actagro’s expert, Dr. Farone, indicate that the phosphorous acid in the product described by the SSP reference inherently acts as a buffer.[3] Farone’s declaration states that the phosphorous acid in the product described by the SSP reference “is present in sufficient amounts that make SSP a ‘buffered composition,’ that is, when diluted with water, has a foliage-acceptable pH for phosphorous uptake.” (Farone Supp. Dec. ¶11). Similarly, the Robertson and Boyer article teaches that a salt of phosphorous acid buffers over the range of pH 5.5 to pH 7.5. See E. E. Robertson et al., *Orthophosphite as a Buffer for Biological Studies*, 62 Archives of Biochemistry and Biophysics 396, 397 (1956) (explaining that phosphite (a salt of phosphorous acid) solutions had a range of appreciable buffering

which “extended from pH 5.5 to 7.5 and buffering capacity was greatest at the vicinity of pH 6.5”).

Of course, the ‘200 patent enjoys a presumption of validity. 35 U.S.C. § 282 (2002). But this is not absolute. During the reexamination, the examiner found that a substantial question of patentability existed based on the SSP reference because the Kelpak and Organic Extract listed in the ingredients both contain amino acids and could buffer the composition. The applicant argued in response that even if some amino acids in the Kelpak and Organic Extract were freely available and thus able to potentially act as a buffer, there would be too few to provide “significant buffering so as to result in a ‘buffered solution’ as defined [in the ‘200 patent].” Based on this representation, the examiner granted the reexamination certificate. True, the examiner issued the reexamination certificate in view of the SSP reference. However, the examiner had neither the Robertson and Boyer article nor Farone’s declaration before him, both of which explain that phosphorous acid is an inherent buffer.

At oral argument counsel for The Regents represented that phosphorous acid buffers at two discrete points: pH 1.3 and pH 6.7. This is not correct. In fact, “all acids are good buffers at pH values near (within one pH unit of) their pK_a .” Carnegie Mellon University Biochemistry I Fall Term, Lecture 3: Acid-Base Equilibria & Buffers (Aug. 29, 2003) at <http://info.bio.cmu.edu/courses/03231/LecF03/Lec03/lec03.html>; cf. Douglas A Skoog et al., Fundamentals of Analytical Chemistry 206 (7th ed., Sanders College Publ. 1996) (“[T]he pK_a of the [acid] chosen for a given application should lie within ± 1 unit of the desired pH in [order] for the buffer to have a reasonable capacity.”). The relevant pK_a value here is pH 6.7 as given by counsel for The Regents at oral argument. Therefore, phosphorous acid buffers at least over the range of pH 5.7 to pH 7.7. Thus, the solution taught by the SSP reference, which contains phosphorous acid, would buffer at least in the range of pH 5.7 to pH 7.7. As such, the SSP reference appears to teach a fertilizer that buffers in the range of about pH 5.0 to pH 7.0, and preferably between about pH 5.5 to about pH 6.5.

Thus, as we read the record before us, the SSP reference illustrates a concentrated phosphorus fertilizer comprising a buffered composition that when diluted has a foliage-acceptable pH for

phosphorus uptake.[4]

III

The district court found that Actagro failed to show that there was a substantial question as to the validity of the '200 patent claims at issue. Given the evidence offered by Actagro, which on its face suggests that the SSP reference is a concentrated phosphorus fertilizer as contemplated by the claims, we find that Actagro has raised a substantial question as to the validity of the '200 patent. For that reason, we must conclude that the first prerequisite for entry of a preliminary injunction is lacking. We therefore vacate the preliminary injunction and remand the case for further proceedings.

COSTS

No Costs.

[1] Infringement is not at issue on appeal, and it appears Actagro has conceded infringement by failing to provide any argument on the issue to the district court.

[2] We make no determination of what “about” and “preferably between” precisely mean.

[3] Farone’s declaration was not even mentioned by the district court.

[4] While not argued by the parties, the SSP reference does include organic extracts which appear to meet the “organic acid” requirement of the claims.