4-3-2019

PAR Pharmaceutical Inc v. QUVA Pharma Inc

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 18-2177

PAR PHARMACEUTICAL, INC.; PAR STERILE PRODUCTS, LLC,

v.

QUVA PHARMA, INC.; STUART HINCHEN; PETER JENKINS; MIKE RUTKOWSKI; DONNA KOHUT; DAVID SHORT; STEPHEN RHOADES; TRAVIS MCGRADY; DAVID HARTLEY

QUVA Pharma, Inc.; Stuart Hinchen; Peter Jenkins; Mike Rutkowski,
Appellants

Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 3-17-cv-06115)
District Judge: Hon. Brian R. Martinotti

Submitted Under Third Circuit L.A.R. 34.1(a)
March 22, 2019

Before: SHWARTZ, KRAUSE, and BIBAS, Circuit Judges.

(Opinion Filed: April 3, 2019)

OPINION*

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* This disposition is not an opinion of the full Court and, pursuant to I.O.P. 5.7, does not constitute binding precedent.

SHWARTZ, Circuit Judge.

QuVa Pharma, Inc., Stuart Hinchen, Peter Jenkins, and Mike Rutkowski (collectively, "QuVa") appeal an order preliminarily enjoining them from marketing and selling vasopressin pharmaceutical products. Because the District Court did not abuse its discretion in granting the preliminary injunction, we will affirm in part and remand for further fact-finding.

I

Par Pharmaceutical, Inc. ("Par") brought suit against QuVa alleging, among other things, that QuVa misappropriated Par's trade secrets "relating to Vasostrict® and other vasopressin products" that it markets. J.A. 117. Vasostrict is a Food and Drug Administration ("FDA") approved intravenous vasopressin injection used to increase blood pressure in adults with vasodilatory shock.

Par alleges that Par former executives Stuart Hinchen and Peter Jenkins left Par and formed a new pharmaceutical company, QuVa, to compete with Par. Hinchen and Jenkins hired several Par employees to join QuVa, allegedly targeting them for their "intimate knowledge of [Par's trade secrets] and other confidential information regarding sterile manufacturing, Vasostrict®, and Par's other vasopressin products." J.A. 106. Based on QuVa's new hires and its development of its own vasopressin product, Par asserted that QuVa misappropriated Par's vasopressin trade secrets, in violation of, among other things, federal and New Jersey law.

Par sought a preliminary injunction to stop QuVa's sale of competing aseptic products. Following expedited discovery, and after considering the parties' voluminous

submissions and arguments, the District Court granted Par's preliminary injunction motion.[1] The Court found that Par demonstrated a reasonable probability of success on the merits concerning at least two of its trade secret misappropriation claims. Par asserted that QuVa misappropriated (1) Par's Aseptic Process Simulation Master Plan ("APS Plan"), which outlines procedures important for regulatory compliance; and (2) certain aspects of Par's vasopressin-product formulation, which QuVa allegedly used to generate the formulation for a competing vasopressin product. As to the APS Plan claim, the Court concluded that it was reasonably likely that the APS Plan constituted a trade secret because Par's expert identified examples of purported non-public information within it, and "while some individual elements of the APS Plan may be known in the industry, Par's combination of the elements . . . constitute[s] a trade secret." J.A. 20. The Court also found that Par would likely be able to demonstrate QuVa misappropriated the APS plan because Par produced evidence that: (1) a Par employee working at QuVa both (a) sent Par's Plan to an outside consultant to help QuVa develop its APS Plan,[2] and (b) admitted that he later deleted Par's APS Plan and other Par documents from his

[1] QuVa claims that the District Court erred by not holding an evidentiary hearing, but QuVa asked "that the motion be decided on the papers or after oral argument." J.A. 229. Thus, QuVa opposed Par's request for an evidentiary hearing and cannot now complain such a hearing was not held. Quva's "alternative" request that if the Court "elects to schedule an evidentiary hearing, . . . it be held as soon as possible . . . ," id., does not save QuVa from having waived its challenge. See Consol. Gold Fields PLC v. Minorco, S.A., 871 F.2d 252, 256 (2d Cir. 1989) ("[Defendant], having been content to rest on affidavits submitted to the District Court [at the preliminary injunction stage], waived its right to an evidentiary hearing.").

[2] The District Court also alluded to the fact that this former Par employee removed the Par logos from the original document before forwarding it to QuVa's consultant.

thumb-drive after receiving a litigation hold, and (2) several parts of Par's and QuVa's plans are identical.

As to the vasopressin-product formulation claim, the District Court concluded that Par had a reasonable probability of demonstrating that its use of a specific diluent and other aspects of its formulation were trade secrets in light of the evidence of the extensive process that went into determining the specific formulation. This was in stark contrast with the sparse evidence QuVa produced of independent development. In addition, the Court rejected QuVa's argument that Par had publicly disclosed its use of a specific diluent in Par's Patent Publication No. US 2017/0290881 ("'881 Application") before QuVa's misappropriation, as "the '881 [Application] was published months after Defendants began preparing to manufacture vasopressin." J.A. 24.

The District Court further held that: (1) Par showed irreparable harm by demonstrating that, if QuVa's vasopressin product were allowed to proceed to market, Par would suffer a significant loss in revenue from reduced sales of its current vasopressin products and a resulting reduction in funds for investment in its business; and (2) the balance of the equities and the public's interest in protection of trade secrets favored issuance of an injunction through trial, and not just the few days it would purportedly take for independent development of an APS Plan because the APS Plan was "not the only basis on which Par has demonstrated a likelihood of success on the merits of its misappropriation claims." J.A. 28.

QuVa appeals.

II[3]

To obtain a preliminary injunction, the movants must:

> demonstrate (1) that they are reasonably likely to prevail eventually in the litigation and (2) that they are likely to suffer irreparable injury without relief. If these two threshold showings are made the District Court then considers, to the extent relevant, (3) whether an injunction would harm the [defendants] more than denying relief would harm the plaintiffs and (4) whether granting relief would serve the public interest.

K.A. ex rel. Ayers v. Pocono Mountain Sch. Dist., 710 F.3d 99, 105 (3d Cir. 2013) (alteration in original) (quoting Tenafly Eruv Ass'n v. Borough of Tenafly, 309 F.3d 144, 157 (3d Cir. 2002)); Fed. R. Civ. P. 65.[4] We will examine each element in turn.

A

A plaintiff must establish a likelihood of success on the merits for the court to issue a preliminary injunction. Am. Express Travel Related Servs., Inc. v. Sidamon-

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[3] The District Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1367. We have appellate jurisdiction pursuant to 28 U.S.C. § 1292(a)(1). QuVa decided to omit from its amended answer its patent counterclaims, which would have vested exclusive jurisdiction over this appeal with the Federal Circuit pursuant to 28 U.S.C. § 1295(a). The amended pleadings "supersede[] the original [pleadings] and render[them] of no legal effect." W. Run Student Hous. Assocs., LLC v. Huntington Nat'l Bank, 712 F.3d 165, 171 (3d Cir. 2003) (citation omitted).

[4] The decision to grant or deny a preliminary injunction is within the sound discretion of the district court. Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 24, 33 (2008). "In reviewing a preliminary-injunction order, findings of fact are assessed for clear error, legal conclusions are reviewed de novo, and the ultimate decision to grant relief is reviewed for abuse of discretion." Issa v. Sch. Dist. of Lancaster, 847 F.3d 121, 130 (3d Cir. 2017) (citation and emphasis omitted). To be clearly erroneous, a finding of fact must be "completely devoid of minimum evidentiary support displaying some hue of credibility" or bear "no rational relationship to the supportive evidentiary data." Id. at 130 (quoting Havens v. Mobex Network Servs., LLC, 820 F.3d 80, 92 (3d Cir. 2016)). To constitute an abuse of discretion, a decision must be based on "a clearly erroneous finding of fact, an errant conclusion of law, or an improper application of law to fact." Id. at 131.

Eristoff, 669 F.3d 359, 366 (3d Cir. 2012). On this factor, "a sufficient degree of success for a strong showing exists if there is 'a reasonable chance, or probability, of winning.'" In re Revel AC, Inc., 802 F.3d 558, 568 (3d Cir. 2015) (internal citations omitted). A reasonable chance of winning is one that is "significantly better than negligible but not necessarily more likely than not[.]" Reilly v. City of Harrisburg, 858 F.3d 173, 179 & n.3 (3d Cir. 2017) (internal citations omitted). Thus, at the preliminary injunction phase, the District Court here was not required to find that a preponderance of evidence established the merits of Par's trade secret misappropriation claims to grant relief.

Par alleged, among other things, trade secret claims under the federal Defend Trade Secrets Act ("DTSA"), 18 U.S.C. § 1836, and the New Jersey Trade Secrets Act ("NJTSA"), N.J. Stat. Ann. 56:15-2. Both the DTSA and the NJTSA require claimants to demonstrate (1) the existence of a trade secret, defined broadly as information with independent economic value that the owner has taken reasonable measures to keep secret, and (2) misappropriation of that secret, defined as the knowing improper acquisition and use or disclosure of the secret.[5] 18 U.S.C. §§ 1836(b)(1), 1839(3), (5); N.J. Stat. Ann. § 56:15-2. Par made adequate showings as to both its APS Plan and its vasopressin product formulation trade secrets.

1

[5] Par also brought a trade secret claim under New Jersey common law, but we need not analyze that claim because the DTSA and NJTSA violations are a sufficient basis for the injunction. In addition, because we need not rely on New Jersey common law, we need not address QuVa's argument that the trade secret statutes of Texas and Michigan "abrogate common law trade secret claims," Appellants' Br. at 25-26 n.6.

Par demonstrated a reasonable likelihood that the APS Plan was a trade secret.[6] The Plan discloses aspects of Par's economically valuable FDA-mandated sterile manufacturing procedures. Par took reasonable steps to protect the secrecy of its plan through the use of non-disclosure agreements and appropriate facility security measures. Moreover, the District Court's conclusion that the APS plan was not publicly known is supported by several examples of non-public information from Par's APS Plan that Par's expert identified. As the Court observed, "while some individual elements of the APS Plan may be known in the industry, Par's combination of the elements" in its own process likely constitutes a trade secret itself. J.A. 20.

Par also demonstrated a reasonable likelihood of showing that the APS Plan was misappropriated. First, portions of QuVa's APS Plan are a verbatim copy of Par's APS Plan, up to and including at least one typographical error. Second, a former Par employee who joined QuVa instructed a QuVa consultant to use Par's APS Plan as a "template" while drafting QuVa's, apparently stripping the Par logo from the APS Plan before sending it to the consultant. Third, that same former employee deleted an electronic copy of the Plan that he had kept from his time at Par despite being subject to a

[6] QuVa also argues that it was prejudiced by Par's late identification of the APS Plan as a trade secret, and that the District Court abused its discretion in denying QuVa's motion to strike it. We disagree. QuVa had the opportunity and in fact sought to refute Par's assertion that the APS Plan is a trade secret through its own expert declaration. Moreover, Par had identified methods to meet FDA requirements among its trade secrets, which include the APS Plan. Given the notice provided about the APS Plan, the opportunity to address it, and the lack of prejudice to QuVa, as well as the absence of bad faith on Par's part, the Court correctly denied QuVa's motion to strike reference to the APS Plan. See In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 791-92 (3d Cir. 1994).

litigation hold. This action provides a basis to infer that this QuVa employee understood he wrongly possessed and used information Par would deem confidential.

2

Par also showed a reasonable likelihood of demonstrating that its vasopressin product formulations are a trade secret. The formulations have independent economic value, as they are the blueprints for Par's premix vasopressin products, and were chosen after years of testing. As with the APS Plan, Par took reasonable steps to protect its product formulations.

Moreover, QuVa's arguments that Par formulations are publicly known are unavailing. QuVa argues that hospitals were requesting a formulation with the specific diluent shared by Par and QuVa's premix formulations because it was one of the two diluents hospitals commonly used to dilute existing concentrated vasopressin products, and further asserts that the use of each ingredient is public knowledge, as disclosed in industry literature and Par's patents. Common usage of the specific diluent in question to dilute concentrated vasopressin products, however, does not explain why customers would demand that a premix product (which, by its nature, does not require user dilution) use the same diluent. In addition, as with the APS Plan, though "each and every element of plaintiff's [ingredients in a product formulation may be] known to the industry, the combination of those elements may be a trade secret if it produces a product superior to that of competitors." Rohm and Haas Co. v. Adco Chem. Co., 689 F.2d 424, 433 (3d Cir. 1982) (internal quotation marks and citations omitted). Furthermore, according to Par's expert, the literature and patents publicly available at the time QuVa began

experimenting with its ready-to-use formula did not disclose the qualities that make the ingredients, when combined, the most effective. Thus, the District Court had sufficient evidence to conclude that, at least before the publication of the '881 Application, it was reasonably probable that QuVa would have needed Par's trade secrets to arrive at its formulation.

The District Court also did not clearly err in holding that Par demonstrated a reasonable probability of showing that QuVa misappropriated this trade secret. As the Court emphasized, QuVa's direct evidence of independent production of its formulation, which was comprised of limited testing of a small number of formulas over a matter of days, is sparse compared to the relatively extensive evidence of testing over the course of years that Par submitted. This circumstantial evidence is sufficient to support the Court's finding that it is reasonably probable QuVa misappropriated Par's trade secrets. See SI Handling Sys., Inc. v. Heisley, 753 F.2d 1244, 1261 (3d Cir. 1985); see also Bimbo Bakeries USA, Inc. v. Botticella, 613 F.3d 102, 117-18 (3d Cir. 2010).[7]

While additional discovery may reveal other evidence of QuVa's independent development of its formulation, or other literature may reveal that Par's formulations did not constitute trade secrets, we cannot conclude today that the District Court clearly erred in holding that Par met its burden of demonstrating a "significantly better than

[7] Though both of these cases arise under Pennsylvania law, New Jersey and Pennsylvania trade secret laws are substantially similar. See Rohm & Haas Co., 689 F.2d at 429.

negligible" likelihood of success on the merits of its trade secret claims. Reilly, 858 F.3d at 179.

B

Par also showed that an injunction was necessary to avoid irreparable harm. The plaintiff bears the burden of demonstrating imminent irreparable injury in the absence of an injunction. Campbell Soup Co. v. ConAgra, Inc., 977 F.2d 86, 91 (3d Cir. 1992). To be imminent, the injury cannot be remote or speculative; it must be poised to occur before the District Court can hold a trial on the merits. See BP Chems. Ltd. v. Formosa Chem. & Fibre Corp., 229 F.3d 254, 263-64 (3d Cir. 2000).

Par presented evidence that if QuVa released a competing vasopressin product, Par would suffer: (1) difficult-to-quantify decreases in future sales of Par products that are currently in development, and (2) harm to Par's reputation and "attractiveness to investors." J.A. 506; BP Chems. Ltd., 229 F.3d at 263 (stating "injuries to reputation" like those identified here "are difficult to calculate, and thus money damages [may be] an inadequate remedy").

In an effort to show that Par has not proven imminent irreparable harm, QuVa relies on Campbell Soup's ruling that the plaintiff there failed to show imminent irreparable harm because there was no evidence that either company planned to use Campbell's trade secret. 977 F.2d at 93. Unlike the plaintiff in Campbell Soup, however, Par has demonstrated that its premix vasopressin product is far from theoretical. In addition to acquiring patents pertinent to various aspects of its product, Par also produced evidence that its premix vasopressin product had been in development through

2017, and that it is developing a particular product similar to QuVa's. There is nothing to suggest that Par's product will not be ready for release before this case reaches trial. Meanwhile, until the injunction was issued, QuVa was imminently preparing to take the irreversible step of releasing its premix vasopressin product allegedly based on Par's trade secrets, thus creating the threat of immediate irreparable harm to Par's sales and reputation. The District Court therefore had sufficient evidence to conclude that Par demonstrated immediate irreparable harm to support a preliminary injunction.

C

The District Court also appropriately balanced both the equities and the public interest when considering whether to impose the injunction. On this record, Par's interest in protecting its trade secrets outweighs any harm QuVa may suffer from the injunction. Moreover, the public has a clear interest in ensuring fair business practices and safeguarding trade secrets. See Nat'l Reprographics, Inc. v. Strom, 621 F. Supp. 2d 204, 229 (D.N.J. 2009) (quoting Ingersoll-Rand Co. v. Ciavatta, 542 A.2d 879, 894 (N.J. 1988)).

D

Having concluded a preliminary injunction is warranted, we next examine whether the District Court acted within its discretion in imposing an injunction through the trial. "Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents." Trump v. Int'l Refugee Assistance Project, 137 S. Ct. 2080, 2087 (2017) (per curiam). In trade secret cases, we have endorsed the use of "lead time" injunctions

"whereby the trade secret injunction lasts only so long as is necessary to negate the advantage the misappropriator would otherwise obtain by foregoing independent development." SI Handling Sys., 753 F.2d at 1266.

Par initially requested an injunction that blocks all of QuVa's aseptic products. The District Court rejected this request and tailored the injunction to enjoin the marketing and sale of only vasopressin products through trial. QuVa argues that the Court should have further limited this narrow injunction to only the "lead time" QuVa allegedly received by using Par's trade secret, which QuVa argues lasted from the time it began work on its actual formulation in September 2017 until Par allegedly publicly disclosed the formulation in its '881 Patent in October 2017.

The District Court did not abuse its discretion in issuing an injunction for the "lead-time" that QuVa may have misappropriated. See SI Handling Sys., 753 F.2d at 1266. The Court, however, did not make any factual findings as to the duration of that lead-time or explain whether this case presented any special circumstances that could possibly warrant imposing an injunction longer than the period QuVa allegedly misappropriated a trade secret. Instead, the District Court seemingly recognized that the misappropriation of the APS Plan would not justify a lengthy injunction by noting that it "was not the only basis on which Par has demonstrated a likelihood of success" and observed that the '881 Application was published only after QuVa began experimenting with a ready-to-use vasopressin formula. J.A. 28. Although the timing of the '881 Application's publication informs Par's likelihood of success, it does not necessarily support an indefinite injunction. It would make little sense to impose a multi-year

injunction if Par voluntarily disclosed its trade secret shortly after the alleged misappropriation began. Accordingly, we will affirm the District Court's issuance of an injunction and remand for it to conduct further fact-finding concerning the duration of the injunction and, if need be, to consider the other alleged trade secrets Par raised in its preliminary injunction motion.

III

For the foregoing reasons, we will affirm in part the District Court's order granting the preliminary injunction and remand for the District Court to conduct further fact-finding on the proper length of the injunction and, if need be, to consider the other alleged trade secrets. This injunction shall remain in effect pending the District Court's decision on remand.