

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

**WELL CELL GLOBAL LLC, WELL CELL SUPPORT
LLC,**
Plaintiffs-Appellees

v.

**SHAWN PAUL CALVIT, MARC PIERRE
DESGRAVES, IV, CHARLES ALEXANDER
ELLIOTT, INSULINIC OF LAFAYETTE LLC,
INSULINIC OF HIALEAH LLC, INSULINIC OF
HAWAII, LLC,**
Defendants-Appellants

**PATRICK DALE LELEAUX, INSULINIC LLC,
INSULINIC OF HAMMOND, LLC, INSULINIC OF
GRETNA, LLC,**
Defendants

2023-1229

Appeal from the United States District Court for the
Southern District of Texas in No. 4:22-cv-03062, Judge Lee
H. Rosenthal.

Decided: September 21, 2023

LEMA BARAZI, Lloyd & Mousilli, Houston, TX, argued for plaintiffs-appellees.

JAMIL ALIBHAI, Munsch Hardt Kopf & Harr, PC, Dallas, TX, argued for defendants-appellants. Shawn Paul Calvit, Insulinic of Lafayette LLC also represented by WINSTON OLIVER HUFF.

Before PROST, CHEN, and CUNNINGHAM, *Circuit Judges*.

CHEN, *Circuit Judge*.

Shawn Paul Calvit, Marc Pierre Desgraves, IV, Charles Alexander Elliott, Insulinic of Lafayette LLC, Insulinic of Hialeah LLC, and Insulinic of Hawaii, LLC (collectively, Appellants) appeal a decision of the United States District Court for the Southern District of Texas granting a motion for preliminary injunction filed by Well Cell Global LLC and Well Cell Support LLC (collectively, Well Cell). *Well Cell Glob. LLC v. Calvit*, No. CV H-22-3062, 2022 WL 16857060, at *11 (S.D. Tex. Nov. 10, 2022) (*Opinion*). The district court enjoined Appellants from, *inter alia*, infringing certain patents owned by Well Cell and using Well Cell's alleged trade secrets. On February 9, 2023, Appellants filed an emergency motion to stay the preliminary injunction pending this appeal. ECF No. 18. On March 16, 2023, we granted this motion. ECF No. 34. After full briefing and argument, we conclude 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. We *reverse and remand*.¹

¹ After oral argument, counsel for Appellants filed a motion to withdraw as counsel with respect to the following parties: Marc Pierre Desgraves, IV, Charles Alexander

BACKGROUND

I

U.S. Patent No. 10,533,990 ('990 patent)—assigned to Well Cell—is directed to an individualized therapy for infusing insulin intravenously to a patient. '990 patent at Abstract. Claim 1 reads:

1. A method for individualized intravenous exogenous insulin-based treatment, comprising the steps of:

creating a subject profile for a subject, the subject profile comprising:

- (i) a subject history;
- (ii) subject physical reports including a subject weight;
- (iii) subject name;
- (iv) subject contact information; and
- (v) subject blood test results;

assessing metabolic factors of the subject and storing the metabolic factors in the subject profile, wherein the metabolic factors include: a glucose level, an insulin-sensitivity factor, and an individual target blood glucose level;

creating a care plan with a plurality of treatment sessions for the subject and a plan goal, wherein the care plan uses the assessed metabolic factors and indicates a schedule of bolus introductions

Elliott, Insulinic of Hialeah LLC, and Insulinic of Hawaii, LLC. ECF No. 68. Well Cell submitted a response, ECF No. 72, and Appellants submitted a reply, ECF No. 73. Counsel for Appellants' motion is granted.

with at least one unequal time period and a quantity and frequency of a plurality of boluses containing saline and insulin for sequential intravenous introduction to the subject;

introducing glucose to the subject to stimulate gastrointestinal hormone production that results in a release of enzymes from the subject's liver and causing blood glucose levels of the subject to be in a therapeutic range;

testing the subject for blood glucose levels, comparing tested blood glucose levels to a plurality of therapeutic ranges, and verifying that the subject is in at least one of the plurality of therapeutic ranges;

comparing the tested blood glucose levels to a diabetic treatment model;

mapping the tested blood glucose levels and the assessed metabolic factors of the subject by using the diabetic treatment model to determine the schedule for bolus introductions;

introducing, sequentially, to the subject a plurality of boluses by using the determined schedule for bolus introductions based on the mapping;

comparing the subject profile to a plurality of weight management protocols to identify a weight management protocol for the subject based upon the assessed metabolic functions of the subject and saving the weight management protocol in the care plan; and

implementing the weight management protocol and the determined schedule of bolus introductions for the subject to improve insulin sensitivity, cellular ATP functioning, or both, of the subject.

'990 patent at claim 1.

II

In the fall of 2021, Well Cell and Appellants entered into a license agreement regarding Well Cell’s intellectual property. *Opinion*, 2022 WL 16857060, at *4. In June 2022, Well Cell sent Appellants a “notice of default,” alleging Appellants’ billing practices breached the license agreement, and on September 8, 2022, Well Cell filed a complaint against Appellants and other parties alleging infringement of Well Cell’s patents and copyrights, as well as misappropriation of its trade secrets.² *Id.* The day after filing the complaint, Well Cell filed motions for a temporary restraining order (TRO)—which was granted—and the preliminary injunction currently on appeal.

Regarding likelihood of success on the merits of Well Cell’s patent infringement claims, the district court understood Appellants—for purposes of the preliminary injunction—to have waived validity challenges to the patents based on their representations at the preliminary injunction hearing. *Id.* at *7 (“[T]he defendants stated at the preliminary injunction hearing that they do not, at this time, challenge the validity of the patents.”) (citing J.A. 1382 at ll. 18–20).³ The court also found Well Cell showed a likelihood of infringement of the ’990 patent’s claimed method. *Id.* at *8–9. It credited the testimony of Well Cell’s CEO and sole witness Scott Hepford that “someone could perform the protocols and administer the appropriate doses of insulin to individual patients using only the information conveyed in the ’990 Patent” and that Appellants had

² In addition to the ’990 patent, Well Cell asserted U.S. Patent No. 9,652,595, but it is not germane to this appeal.

³ Not all defendants in the underlying action appealed. The “defendants” referenced by the district court here and at other points in this opinion include Appellants.

access to an “encrypted data room,” the contents of which appeared to allow a person to perform the licensed method. *Id.* at *8. The court did not find that the Appellants actually copied this information, only that the Appellants had access to the information and had to copy the information “to continue to use the Well Cell treatment after their licenses were terminated.” *Id.*

On the Appellants’ side, the court acknowledged “Calvit testified that the therapy the defendants now perform ‘[is] similar in that we are still putting IV into somebody’s veins, but the timing, the amounts, and their process is different.’” *Id.* at *9. Nonetheless, the court found “Calvit’s testimony indicate[d] that the defendants continue to perform therapies aimed at treating metabolic conditions with exogenous intravenous insulin therapy” and concluded that “Calvit’s minimal ability to differentiate the current therapy offered by the defendants does not effectively rebut the charge that the defendants are infringing the ’990 Patent.” *Id.*

The district court also found Well Cell would be irreparably harmed by Appellants’ continued actions absent an injunction. Well Cell argued that “continued infringement of its intellectual property risk[ed] doctor, patient, and consumer confusion and irreparable harm to its reputation and business goodwill.” *Id.* at *10. The district court found that these alleged harms “are paradigmatic examples of irreparable harm in the commercial context.” *Id.* The district court also found that Well Cell established a causal nexus between the alleged infringement and the alleged irreparable harm, crediting testimony from Mr. Hepford explaining that “given the past relationship between Calvit, Calvit’s Insulinic clinics, and Well Cell, if Calvit ‘does things that are illegal and improper and ultimately ends up getting in trouble for that . . . and then . . . point[s] his fingers back and say[s], but these guys, they were the ones that taught me all this stuff,’ then Well Cell is put at risk.” *Id.*

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The district court’s balancing of the equities analysis consisted of a paragraph noting the lack of argument by Appellants regarding irreparable harm to themselves during the pendency of the TRO. *Id.* at *11. The district court also disposed of the public interest question in one paragraph. *Id.* The district court issued an order broadly outlining the enjoined activities. J.A. 1–2.

DISCUSSION

While “we review a grant or denial of a preliminary injunction using the law of the regional circuit,” we acknowledge our “body of precedent applying the general preliminary injunction considerations to a large number of factually variant patent cases” and thus give “dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues.” *Murata Mach. USA v. Daifuku Co.*, 830 F.3d 1357, 1363 (Fed. Cir. 2016) (internal quotations omitted). Our review of a district court’s grant of a preliminary injunction is the same as in the Fifth Circuit—we both review such an order for an abuse of discretion. *Compare id.*, with *Jiao v. Xu*, 28 F.4th 591, 598 (5th Cir. 2022). In the context of a preliminary injunction, an abuse of discretion necessarily exists if the district court made an error of law or a clearly erroneous factual finding. *Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1203 (Fed. Cir. 2017).

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, a balance of hardships tipping in its favor, and the injunction’s favorable impact on the public interest.” *Murata*, 830 F.3d at 1363.

I

The party seeking a preliminary injunction must prove it likely would be irreparably harmed absent an injunction. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008);

Koninklijke Philips N.V. v. Thales DIS AIS USA LLC, 39 F.4th 1377, 1380 (Fed. Cir. 2022). Well Cell failed to make that showing, and the district court clearly erred in finding otherwise.

Well Cell at best provided evidence of speculative harm, not likelihood that such harm would occur as required to establish irreparable harm for a preliminary injunction. *See Winter*, 555 U.S. at 22 (2008) (noting the proper standard for irreparable harm is “likely” irreparable harm, not simply the “possibility” of such harm); *Koninklijke*, 39 F.4th at 1380 (“Evidence of speculative harms, such as customers merely expressing concern that a potential future ITC exclusion order could affect Thales’ ability to deliver products down the road, is insufficient to show a likelihood of irreparable harm.”). Well Cell argued—and the district court found—that Well Cell’s reputation *risks* being damaged *if* Appellants performed the claimed methods illegally or improperly *and* Well Cell was blamed for such behavior. *Opinion*, 2022 WL 16857060, at *10–11.

Well Cell’s argument rests on two levels of speculation—first that Appellants would perform the claimed methods illegally or improperly and second that Well Cell would then get pinned with the blame for Appellants’ misconduct. But Well Cell never explained or proved why there was reason to believe Appellants would likely misuse Well Cell’s intellectual property, or, if they had, how and why the public would assume Well Cell was at fault. Because Well Cell’s irreparable harm allegations rested on unsubstantiated assertions, the court clearly erred by finding that Well Cell sufficiently established a likelihood of irreparable harm.

II

“To establish a likelihood of success on the merits, a patentee must show that it will likely prove infringement of the asserted claims and that its infringement claim will likely withstand the alleged infringer’s challenges to

patent validity and enforceability.” *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1364 (Fed. Cir. 2017). “A preliminary injunction should not issue if the accused infringer raises a substantial question concerning either infringement or validity.” *Id.* (internal quotations omitted). As with irreparable harm, Well Cell failed to make a case for establishing a likelihood of success on the merits.

A

We first address whether the district court abused its discretion in finding Appellants waived their invalidity argument based on 35 U.S.C. § 101. *See Columbia Sportswear N. Am., Inc. v. Seirus Innovative Accessories, Inc.*, 942 F.3d 1119, 1132 (Fed. Cir. 2019) (“We review a district court’s decision to exercise or, as here, not exercise its inherent power to find waiver for an abuse of discretion.”). In Appellants supplemental response brief to Well Cell’s preliminary injunction motion, Appellants only addressed the second step of the two-step *Alice* inquiry and did so in an entirely conclusory manner. J.A. 564–65 (only addressing the “inventive concept” inquiry and not whether the asserted claims were “directed to” an abstract idea); *see Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 217–18 (2014). In addition, at the oral hearing, Appellants’ counsel stated they were not challenging the validity of the asserted patents. *Opinion*, 2022 WL 16857060, at *7 (“[T]he defendants stated at the preliminary injunction hearing that they do not, at this time, challenge the validity of the patents.”) (citing J.A. 1382 at ll. 18–20). Based on this record, we find the district court did not abuse its discretion in finding this argument waived for purposes of the preliminary injunction. *See Opinion*, 2022 WL 16857060, at *7; *cf. Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 582 F.3d 1288, 1296 (Fed. Cir. 2009) (“[I]f a party fails to raise an argument before the trial court, or presents only a skeletal or undeveloped argument to the trial court, we may deem that argument waived on appeal.”). We accordingly decline to hear this

argument on appeal. *See Conoco, Inc. v. Energy & Env't Int'l, L.C.*, 460 F.3d 1349, 1358–59 (Fed. Cir. 2006).

B

As to likelihood of proving patent infringement or trade secret misappropriation, Well Cell's presentation was simply too conclusory. For a preliminary injunction motion, "[t]he burden is always on the movant to show that it is likely to succeed on the merits." *BlephEx, LLC v. Myco Indus., Inc.*, 24 F.4th 1391, 1398 (Fed. Cir. 2022). "[W]hether performed at the preliminary injunction stage or at some later stage in the course of a particular case, infringement and validity analyses must be performed on a claim-by-claim basis." *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). But the record shows Well Cell never identified any particular claim of the '990 patent in its likelihood of infringement arguments, and the district court's opinion never analyzed any particular claim either. Nor did Well Cell ever establish on the record what particular steps and procedures Appellants perform when providing their insulin therapy. Instead of comparing one of the patent claims to Appellants' established procedures, Well Cell and the district court appeared to assume the Appellants must have performed at least one of the claimed methods during the pendency of the license, and Appellants must have continued practicing the same procedures without a license unless Appellants could prove otherwise. *Opinion*, 2022 WL 16857060, at *9 ("Calvit's minimal ability to differentiate the current therapy offered by the defendants does not effectively *rebut* the charge that the defendants are infringing the '990 Patent.") (emphasis added). Despite some Appellants having been former licensees, Well Cell's infringement theory still rests on assumptions, not proof. On the facts of this case, this argument cannot support a finding of a likelihood of success on the merits for infringement.

With respect to the trade secret misappropriation allegation, both the district court and Well Cell failed to identify the alleged trade secrets and these failures are fatal to Well Cell's case. "To succeed on the merits of its misappropriation of trade secrets claim, [the moving party] must show that: (1) a trade secret existed, (2) the trade secret was acquired through a breach of a confidential relationship or discovered by improper means, and (3) the defendant *used* the trade secret without authorization from the plaintiff." *CAE Integrated, L.L.C. v. Moov Techs., Inc.*, 44 F.4th 257, 262 (5th Cir. 2022). The district court's discussion of Well Cell's alleged trade secrets never explained what they were. *Opinion*, 2022 WL 16857060, at *9–10. The entirety of Well Cell's attempt below to identify its trade secret came at the preliminary injunction hearing. *See* Appellee's Br. at 34–35 (citing J.A. 1453, J.A. 1490, J.A. 1559, J.A. 1561–62, J.A. 1595, J.A. 1642). At most, these passages identify a "four- to eight-minute dynamic dosing" as a trade secret. J.A. 1561–62. However, this was publicly disclosed in the '990 patent and thus cannot constitute a trade secret. *See Accent Packaging, Inc. v. Leggett & Platt, Inc.*, 707 F.3d 1318, 1329 (Fed. Cir. 2013); *see also* '990 patent at FIG. 1A & 1B (noting an unequal time period of 240–480 secs between bolus introductions) and J.A. 1605 at ll. 6–19. At oral argument, Well Cell could not explain what its alleged trade secrets are. Oral Arg. at 24:24–26:44. As Well Cell cannot describe its alleged trade secrets, it cannot show a likelihood of success on its misappropriation claim.

CONCLUSION

Because we conclude there was a failure of proof of irreparable harm and likelihood of success on the merits, we find the district court abused its discretion in granting the preliminary injunction. We thus reverse the district court's

order and remand for further proceedings consistent with this opinion.⁴

REVERSED AND REMANDED

COSTS

Costs to Appellants.

⁴ We note Appellants' concern that the district court's injunction was overly broad without specifying the methods enjoined. On remand, should a new injunction issue later in the case, the district court must describe the methods enjoined with specificity consistent with our case law. *See Int'l Rectifier Corp. v. IXYS Corp.*, 383 F.3d 1312 (Fed. Cir. 2004).