

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

INSULET CORP.,
Plaintiff-Appellee

v.

EOFLOW, CO. LTD., EOFLOW, INC.,
Defendants-Appellants

**STEVEN DIANNI, LUIS J. MALAVE, IAN G.
WELSFORD, JESSE J. KIM, FLEXTRONICS
MEDICAL SALES AND MARKETING LTD.,**
Defendants

2024-1137

Appeal from the United States District Court for the
District of Massachusetts in No. 1:23-cv-11780-FDS, Judge
F. Dennis Saylor, IV.

Decided: June 17, 2024

WILLIAM M. JAY, Goodwin Procter LLP, Washington,
DC, argued for plaintiff-appellee. Also represented by
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Before LOURIE, PROST, and STARK, *Circuit Judges*.

LOURIE, *Circuit Judge*.

EOFlow, Co. Ltd. and EOFlow, Inc. (collectively, “EOFlow”) appeal from an October 24, 2023 order of the United States District Court for the District of Massachusetts granting a preliminary injunction sought by Insulet Corp. (“Insulet”). *See Insulet Corp. v. EOFlow, Co.*, No. 1:23-cv-11780-FDS, 2023 WL 7647573 (D. Mass. Oct. 24, 2023) (“*Order*”); J.A. 38–41. The injunction enjoined EOFlow from manufacturing, marketing, or selling any product that was designed, developed, or manufactured, in whole or in part, using or relying on alleged trade secrets of Insulet. On May 7, 2024, we issued a temporary stay of the injunction pending this opinion. For the following reasons, we lift our stay and reverse the district court’s order.

BACKGROUND

Insulet and EOFlow are medical device manufacturers that make insulin pump patches. Insulet began developing the wearable insulin pump OmniPod® in the early 2000s. J.A. 190. The FDA approved the first OmniPod product in 2005, and a next-generation product, the OPI-2, came onto the market soon thereafter in 2007. *Id.* at 202. Insulet then began work on its next-generation Eros product, which obtained FDA approval in 2012 and commercially launched in 2013. *Id.* at 203.

EOFlow began developing its own flagship product, an insulin pump patch called the EOPatch®, soon after the company’s founding in 2011. J.A. 1078. The EOPatch

received regulatory approval in South Korea in 2017, after which EOFLOW began developing its next-generation EOPatch 2. *Id.* at 1747. Around that time, four former Insulet employees joined EOFLOW. *See id.* at 5, 230–31, 8979, 9079, 9744. In 2019 and 2022, respectively, the EOFLOW 2 received regulatory approval in South Korea and Europe, after which it began commercial distribution in those select geographic markets. *Id.* at 1747–51.

In early 2023, reports surfaced that Medtronic had started a diligence process to acquire EOFLOW. J.A. 1072–73, 1077–78. Soon thereafter, Insulet sued EOFLOW in the U.S. District Court for the District of Massachusetts for violations of, among other things, the Defend Trade Secrets Act (“DTSA”), seeking a temporary restraining order and a preliminary injunction to enjoin all technical communications between EOFLOW and Medtronic in view of its trade secrets claims.

On August 29, 2023, the district court temporarily restrained EOFLOW from “disclosing products or manufacturing technical information related to the EOPatch or Omni[P]od products.” J.A. 1254. On October 4, 2023, the court granted Insulet’s request for a preliminary injunction, finding that (1) “there is strong evidence that Insulet is likely to succeed on the merits of its trade secrets claim at least in part,” (2) there was “strong evidence of misappropriation” because EOFLOW hired former Insulet employees who retained “Insulet’s confidential documents” that “fall within the statutory definition of trade secret,” and (3) that irreparable harm to Insulet crystallized when EOFLOW announced an intended acquisition by Medtronic, which “would be a source of capital for EOFLOW” and increase competition with Insulet. *Id.* at 5–22.

The resulting preliminary injunction issued on October 6, 2023, and enjoined EOFLOW “from manufacturing, marketing, or selling any product that was designed, developed, or manufactured, in whole or in part, using or relying

on the Trade Secrets of Insulet.” J.A. 35–37. EOFlow moved to modify that injunction, citing concerns regarding existing patient populations in international markets. The district court subsequently amended the injunction on October 24, 2023, adding limited carveouts for certain patient populations in South Korea, the European Union, and the United Arab Emirates. EOFlow filed a notice of appeal shortly thereafter. *Order* at *1–2; J.A. 38–41.

While this appeal was pending, both parties moved in the district court to further modify the injunction. As a result, a second amended preliminary injunction issued on April 24, 2024, limiting the carveouts contained in the October 24, 2023 order. *Insulet Corp. v. EOFlow, Co.*, No. 1:23-cv-11780-FDS (D. Mass. Apr. 24, 2024), ECF No. 361.

Oral argument was heard at this court on May 6, 2024. On May 7, 2024, we issued a temporary stay of the October 24, 2023 preliminary injunction pending this decision and further suggested that the district court consider entering a stay of the April 24, 2024 order that is not before us. The district court subsequently stayed the April 24, 2024 order on May 8, 2024. *Id.* at ECF No. 368.

We have jurisdiction over the October 24, 2023 preliminary injunction order under 28 U.S.C. § 1292(c)(1).

DISCUSSION

A preliminary injunction is “an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.” *Winter v. NRDC, Inc.*, 555 U.S. 7, 22 (2008) (citing *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam)). To establish such entitlement, the court must find that “(1) the plaintiff has a likelihood of success on the merits of his claim; (2) the plaintiff does not have an adequate remedy at law such that it will suffer irreparable harm without the injunction; (3) this harm is greater than the injury the defendant will

suffer if the injunction is granted; and (4) the injunction will not harm the public interest.” *Concrete Mach. Co. v. Classic Lawn Ornaments, Inc.*, 843 F.2d 600, 611 (1st Cir. 1988).

We review a district court’s grant of a preliminary injunction under the law of the regional circuit. *SoClean, Inc. v. Sunset Healthcare Sols., Inc.*, 52 F.4th 1363, 1367 (Fed. Cir. 2022). Here, that is the First Circuit, which reviews grants of preliminary injunctions for an abuse of discretion. *Id.* An abuse of discretion may be established by showing that a material factor deserving significant weight has been ignored, that an improper fact was relied upon, or that the court made a serious mistake in weighing the facts. *I.P. Lund Trading ApS v. Kohler Co.*, 163 F.3d 27, 33 (1st Cir. 1998). That “deferential standard, however, applies to ‘issues of judgment and balancing of conflicting factors,’ and we still review rulings on . . . legal issues de novo and findings of fact for clear error.” *Water Keeper All. v. Dep’t of Def.*, 271 F.3d 21, 30 (1st Cir. 2001) (quoting *Cablevision of Bos., Inc. v. Pub. Improvement Comm’n*, 184 F.3d 88, 96 (1st Cir. 1999)).

EOFlow contends that the preliminary injunction was issued in error and that the district court abused its discretion by failing to consider factors relevant to Insulet’s likelihood of success on the merits and failing to meaningfully evaluate the balance of harms and the public interest. We address each argument in turn.

I

Trade secrets are an important form of intellectual property that both Congress and the states have deemed worthy of protection. *See, e.g.*, 18 U.S.C. § 1836; Mass. Gen. Laws ch. 93, §§ 42A, 42B. And even well before those laws were enacted, the Founders also recognized the value,

as well as the volatility, of an idea kept as a secret.¹ Indeed, once a trade secret has lost its secrecy, its value may be gone because others may practice it to the detriment of its owner. Trade secrets can thus deeply benefit from being the subject of preliminary injunctive relief as much as other forms of intellectual property. *See* Melvin F. Jager & Brad Lane, *Trade Secrets Law* §§ 1:1, 7:4 (2023). But establishing entitlement to such injunctive relief still requires a showing of the existence of the trade secret and misappropriation, as well as the satisfaction of the usual, established factors justifying the grant of a preliminary injunction.

Under the DTSA, the “owner of a trade secret that is misappropriated” may bring a civil action “if the trade secret is related to a product or service used in, or intended for use in, interstate or foreign commerce.” 18 U.S.C. § 1836(b)(1). Here, Insulet alleged that it owns trade secrets relating to its OmniPod product that were misappropriated by EOFlow and several individually named defendants. The district court subsequently granted its request for a preliminary injunction.

EOFlow argues that the district court abused its discretion in granting that preliminary injunction. EOFlow first notes that even if Insulet owned protectable trade secrets, and even if those trade secrets were misappropriated

¹ For example, in an August 13, 1813 letter to merchant Isaac McPherson, Thomas Jefferson wrote: “[I]f nature has made any one thing less susceptible, than all others, of exclusive property, it is the action of the thinking power called an Idea; which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of every one, and the receiver cannot dispossess himself of it.” *The Founder’s Constitution*, ed. Philip B. Kurland and Ralph Lerner (Chicago: University of Chicago Press, 1987), 3:42.

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by the defendants, Insulet's right to bring a civil action would remain limited by 18 U.S.C. § 1836(d), which provides that such a civil action "may not be commenced later than 3 years after the date on which the misappropriation with respect to which the action would relate is discovered or by the exercise of reasonable diligence should have been discovered." A likelihood of success analysis for a claim brought under the DTSA must, according to EOFflow, contemplate whether or not that claim may be time barred under § 1836(d) when a statute of limitations challenge is raised.

The district court expressed no opinion on the matter; although there are over twelve pages of analysis on Insulet's likelihood of success, the statute of limitations is never discussed. EOFflow notes that after having moved on to an assessment of irreparable harm, the court noted that it "express[ed] no opinion about the accrual of the statute of limitations," deeming it "not the issue here." J.A. 15. It is not clear whether the court meant that the statute of limitations was irrelevant to assessing irreparable harm, or that it was irrelevant to the grant of a preliminary injunction more generally. But that distinction matters not, because, either way, the court did not assess the statute of limitations in the context of evaluating Insulet's likelihood of success on the merits. The court thus ignored a material factor deserving significant weight, which constitutes an abuse of discretion. *See I.P. Lund Trading*, 163 F.3d at 33. Indeed, if the three-year statute of limitations for filing a DTSA claim had expired, Insulet's claims would be time-barred and therefore would have no chance of success.

But even if the district court had adequately dealt with the statute of limitations issue, that would have been insufficient to support the October 24, 2023 order. As EOFflow further contends, the district court also abused its discretion in its consideration of what constitutes a trade secret.

The DTSA defines “trade secrets” as:

All forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing *if—*

(A) the *owner thereof has taken reasonable measures to keep such information secret; and*

(B) *the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information[.]*

18 U.S.C. § 1839(3)(A) (emphases added).

In contrast, the order granting this preliminary injunction broadly defines the term “trade secret” as including “any and all Confidential Information of Insulet” and “any information that contains, derives from, or incorporates such Confidential Information.” *Order* at *1; J.A. 36. The injunction further specifies that “Confidential Information’ shall mean (a) any and all information or materials that were marked ‘confidential’ by Insulet and (b) any and all CAD files, drawings, or specifications created by Insulet, whether or not they were marked ‘confidential.’” *Order* at *1; J.A. 36. That definition is severely overbroad.

Compounding the harm of that inaccurate definition was the district court’s position that “it would be unfair to require at this stage perfection as to the precise number and contours of the trade secrets at issue.” J.A. 6. We disagree. In order to secure a preliminary injunction, Insulet

had to establish the likelihood of its success on the merits for at least one, specifically defined, trade secret. It did not do so. Rather, it advanced a hazy grouping of information that the court did not probe with particularity to determine what, if anything, was deserving of trade secret protection.

Instead, the preliminary injunction broadly prohibits EOFflow from disclosing eight “items . . . , to the extent that the Trade Secrets of Insulet were used in their design, development, or creation.” *Order* at *1; J.A. 39. By way of example, we look to the first of those eight items in the analysis that follows, although our concerns run through them all. Thus, for example, the district court enjoined EOFflow from disclosing “design drawings and specifications for each physical component and subassembly” of EOFflow’s own EOPatch 2. *See Order* at *1; J.A. 39. But the court failed to assess what within the “design drawings and specifications” for those physical components was likely to have been a misappropriated trade secret.

Such an analysis requires evaluating which of the “design drawings and specifications” was alleged to have been the intellectual property of Insulet, and whether, under § 1839(3)(A), Insulet took “reasonable measures” to keep that specific information secret. Although the district court found that “at least as to some substantial set of information, Insulet took reasonable steps to protect the information” and that “[d]ocuments were marked confidential, employees were required to sign nondisclosure or confidentiality agreements, systems were password protected, and the like,” J.A. 5–6, that analysis was too general to support the preliminary injunction. Finding that Insulet took measures to protect some unidentified “set of information” is not the same as finding that Insulet took reasonable measures to protect specific information alleged to be a trade secret, such as particular “design drawings and specifications for each physical component and subassembly,” as the DTSA requires.

The district court similarly failed to adequately assess whether or not the information that Insulet sought to protect was generally known or reasonably ascertainable through proper means. As set forth in 18 U.S.C. § 1839(6)(B), proper means for ascertaining information that may otherwise constitute a trade secret include “reverse engineering, independent derivation, or any other lawful means of acquisition[.]” *See also Bonito Boats Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 155 (1989); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 476 (1974).

The district court initially held that it was “true that [the OmniPod] can be broken down and to some extent reverse engineered” and that there was “some evidence” that portions of the OmniPod were, in fact, “actually reverse engineered.” J.A. 8–9. But the court nevertheless considered any and all depictions or descriptions of those components to be trade secrets. In so doing, it held that the “mere possibility that something could be reverse engineered without more is not enough to defeat a trade secret claim.” J.A. 8–9. That holding misstates the effect that reverse engineering has on the ability of a plaintiff to assert a trade secret. To be clear: if information is “readily ascertainable through proper means” such as reverse engineering, it is not eligible for trade secret protection. *See Kewanee Oil*, 416 U.S. at 475–76 (describing reverse-engineering as “starting with the known product and working backward to divine the process which aided in its development or manufacture”). It was an error for the district court not to consider, in its analysis of likelihood of success on the merits, whether the alleged trade secrets would have been capable of being obtained through reverse engineering, particularly given the evidence of the public availability of the OmniPod, multiple tear-down videos available on the internet, and Insulet’s own publications providing “[a] look under the hood, featuring core components of the OmniPod.” *See, e.g.*, J.A. 829–39, 974–89.

The district court similarly erred in declining to assess another potential proper source for ascertaining information concerning Insulet's product: patent disclosures. Noting that it was "true" that Insulet had patents that disclosed information relating to the OmniPod, the court dismissed those disclosures as irrelevant because "[t]his is not a patent case." J.A. 9. Such an analysis was an abuse of discretion. It is "axiomatic that 'matters of public knowledge or of general knowledge in an industry cannot be appropriated' by an entity as a trade secret." *Allstate Ins. Co. v. Fougere*, 79 F.4th 172, 189 (1st Cir. 2023) (alteration omitted) (quoting *Burten v. Milton Bradley Co.*, 763 F.2d 461, 463 n.2 (1st Cir. 1985)). Although "[n]ovelty, in the patent law sense, is not required for a trade secret, . . . some novelty will be required if merely because that which does not possess novelty is usually known; secrecy, in the context of trade secrets, thus implies at least minimal novelty." *Kewanee Oil*, 416 U.S. at 476. If particular components of the OmniPod are not novel because they have become matters of public knowledge either through a patent disclosure or otherwise, then the specifications for those components are unlikely to merit trade secret protection.

The analysis under § 1839(3)(B) further requires that the information at issue have independent economic value. *See Allstate Ins.*, 79 F.4th at 190 (describing the economic value prong as "a key factor for determining whether or not . . . information may be defined as trade secrets"). Although the district court identified that the "value of a small number of secrets that solve critical problems can be greater than the sum of its parts," J.A. 11, it did not sufficiently evaluate whether or not the information that Insulet asserted deserved trade secret protection had independent economic value.

Inherent in the definition of misappropriation is that there is a trade secret to be misappropriated. 18 U.S.C. § 1839(5). Because the court failed to identify any trade

secret with sufficient particularity, its analysis of misappropriation necessarily also fails.

Still further, there is a mismatch between the court's grant of a sweeping injunction and its recognition that Insulet had failed to establish that "EOFlow had knowingly benefited from" the full swath of information covered in the injunction. *See* J.A. 10 (noting that it "may be true" that EOFlow did not knowingly benefit from "some subset of information. It's hard to tell at this point. . . . It is certainly possible that there are innocent explanations for some of this."); *see also* Dkt. No. 351 at 53–54 (acknowledging that the court's "initial preliminary injunction was sweeping, it was intended to be sweeping"). Even if the timing of EOFlow's product development seemed suspiciously accelerated following the arrival of four former Insulet employees, that does not obviate the need to prove the existence of trade secrets, or that the defendants knowingly benefited from them, or the full satisfaction of each of the four preliminary injunction factors.

In view of the failure to address the statute of limitations, the lack of a tailored analysis as to what specific information actually constituted a trade secret, as well as the finding that it was "hard to tell" what subset of that information was likely to have been misappropriated by EOFlow, we find that the district court abused its discretion in granting the October 24, 2023 preliminary injunction. *See Winter*, 555 U.S. at 22 (holding that preliminary injunctions "may only be awarded upon a *clear showing* that the plaintiff is entitled to such relief" (emphasis added)).

II

EOFlow further contends that the district court abused its discretion in reaching its findings as to irreparable harm and the public interest. We agree with EOFlow.

In particular, the district court began by holding that, under *EEOC v. Astra USA, Inc.*, 94 F.3d 738 (1st Cir. 1996), “when [the] likelihood of success on the merits is great, a movant can show somewhat less in the way of irreparable harm.” J.A. 12. But to the extent the district court was indicating that a strong showing on likelihood of success meant the plaintiff did not also have to establish irreparable harm, that is incorrect. In *Winter*, the Supreme Court held that even if the plaintiff demonstrates a strong likelihood of prevailing on the merits, a preliminary injunction may only be entered if the plaintiff further establishes that irreparable injury is likely in the absence of an injunction. 555 U.S. at 21–22; *see also Sosa v. Mass. Dep’t of Corr.*, 80 F.4th 15, 25 (1st Cir. 2023) (confirming that “a plaintiff ‘must establish’” all four preliminary injunction factors in view of *Winter*). Here, the court found that the irreparable harm prong had been satisfied “particularly [] because the evidence of likely success on the merits is strong.” J.A. 21–22. That conclusion was based on an error of law.

But even if the district court had provided a more fulsome analysis on irreparable harm, such a finding “must be grounded on something more than conjecture, surmise, or a party’s unsubstantiated fears of what the future may have in store.” *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004). Here, the alleged harm that the court deemed irreparable was not the acquisition, use, or disclosure of trade secrets but instead a potential commercial transaction. In particular, the court held that “[w]hat is immediate or reasonably immediate is the acquisition by Medtronic that would be a source of capital for EOFlow, and, again, not just money but all the other things that come with it, regulatory expertise, marketing expertise, manufacturing expertise, customer support networks, the panoply of things that are required to be a real competitor.” J.A. 20. But neither a generalized fear of a larger competitor nor any theoretical sale that can

be remedied with damages constitutes a cognizable irreparable harm. The district court found that the relevant competitive harm was “losing market share and having your pricing undercut by a competitor who did not have to spend the same time and money on research and development.” J.A. 21. But the court cites no evidence to support that finding. The Medtronic acquisition may have been expected to cause these or other harmful results – but on the record before the court such a finding was nothing more than mere “conjecture.”

Finally, we share EOFLOW’s view that the district court failed to meaningfully engage with the public interest prong, holding only that it “s[aw] little impact one way or the other.” J.A. 22. That type of cursory analysis is generally deficient. *See Winter*, 555 U.S. at 26 (“Despite the importance of assessing the balance of equities and the public interest in determining whether to grant a preliminary injunction, the District Court addressed these considerations in only a cursory fashion.”).

Insulet nevertheless suggests that even if the district court’s rationales for granting the preliminary injunction were lacking, under the law of the First Circuit, we could nevertheless affirm “on any grounds supported by the record.” Appellee’s Br. at 36 (quoting *SEC v. Fife*, 311 F.3d 1, 8 (1st Cir. 2002)). But that alternative path to affirmance is inaccessible here. The record simply does not support an injunction. *See New Comm Wireless Servs., Inc. v. Sprint-Com, Inc.*, 287 F.3d 1, 13 (1st Cir. 2002) (First Circuit “ordinarily will not uphold a preliminary injunction on a ground that was not fully addressed by the trial court”). Moreover, the concerns that Insulet raised as likely to cause immediate irreparable harm have since been mooted. During the pendency of this appeal, EOFLOW confirmed that the Medtronic acquisition deal “has since been killed.” Appellants’ Reply Br. at 23. Although Insulet questions the veracity of this representation, *see, e.g.*, Appellee’s Br. at 57–58, the record is one on which none of the purported

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rationales for irreparable harm remain, and without such harm, there can be no injunction. *See Charlesbank Equity Fund II*, 370 F.3d at 162 (“[I]rreparable harm constitutes a necessary threshold showing for an award of preliminary injunctive relief.”).

CONCLUSION

We conclude by noting what we have not decided. We have not found that Insulet has failed to adequately allege misappropriation of trade secrets or that it cannot succeed on the merits of its claims. We are asked here only whether Insulet has proven a likelihood of success on the merits (and the other factors for a preliminary injunction) and we find that, to date, it has not shown such a likelihood. The ultimate disposition of Insulet’s claims will have to be determined through further proceedings.

We have considered Insulet’s remaining arguments and find them unpersuasive. For the foregoing reasons, we lift our stay of the October 24, 2023 preliminary injunction enjoining EOFlow, reverse the grant of that preliminary injunction, and remand for further proceedings consistent with this opinion.²

REVERSED AND REMANDED

COSTS

No costs.

² The April 24, 2024 second amended preliminary injunction is not before us as part of this appeal, but to the extent it relies on reasoning similar to that which resulted in the October 24, 2023 order, the district court should consider retracting the April 24, 2024 order in view of this opinion.