U.S. COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 25-1831

JOHNSON & JOHNSON, a New Jersey corporation;
JANSSEN BIOTECH, INC., a Pennsylvania corporation,
Appellants

v.

SAMSUNG BIOEPIS CO. LTD., a Korean corporation.

Appeal from the U.S. District Court, D.N.J.
Judge Georgette Castner, No. 3:25-cv-01439

Before: HARDIMAN, KRAUSE, and FREEMAN,
Circuit Judges
Argued Sept. 9, 2025; Decided Apr. 14, 2026

OPINION OF THE COURT

KRAUSE, *Circuit Judge.* Rarely do courts grant injunctive relief before the plaintiff secures a judgment. And even more rarely is that relief granted in contract cases, where it is usually the case that monetary damages can later be quantified, so the plaintiff's alleged injury does not qualify as "irreparable harm." Nevertheless, in some contexts, we have recognized that the complexity or risk of permanent alteration of a given

market can make ascertaining legal loss impossible and thus render monetary damages impractical. Such is the case here, according to Appellants Johnson & Johnson and Janssen Biotech, Inc. (together Janssen). Janssen claims that Appellee Samsung Bioepis Co., Ltd. (Samsung) issued a license to a subsidiary of the Cigna Group in violation of Samsung's contract with Janssen, and that a preliminary injunction should issue against Samsung because the harms to Janssen would otherwise be irreparable. Because we agree with the District Court that Janssen failed to establish irreparable harm, we will affirm its denial of relief.

I. BACKGROUND

A. Factual Background

This case concerns the marketplace for "biologics," a "class of medications that derive from natural sources, such as living cells and entities." App. 2 (citation modified). Because these medications are "far more costly to manufacture than traditional small molecule pharmaceuticals," *id.* (citation modified), patents that cover them are closely guarded, and those that are effective and popular can generate significant profits. But patents expire, and though they are typically enforceable for a twenty-year term after the filing date, *see* 35 U.S.C. § 154(a)(2), the "effective patent life" of a biologic—the period of actual market exclusivity from the time a medication clears the post-filing clinical trials and regulatory approvals and reaches the marketplace until the expiration of the patent, *see Proveris Sci. Corp. v. Innovasystems, Inc.*, 536

F.3d 1256, 1260-61 (Fed. Cir. 2008)—is typically far shorter, *see In re Forest*, 134 F.4th 1198, 1200 n.3 (Fed. Cir. 2025). At the end of a biologic's effective patent life, manufacturers of generic versions of the medication, called "biosimilars," can enter the biologics market. Not surprisingly then, patent holders typically seek to enforce their rights for as long as possible, often obtaining related or overlapping patents so they can still require biosimilar manufacturers to obtain a license even after the original patent expires.[1]

That was the strategy pursued by Janssen after it developed and patented ustekinumab, a biologic generally referred to and marketed under the brand name "Stelara." Stelara is used to treat plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis, and over its fifteen-year effective patent life, Stelara generated sales of over $70 billion. In September 2023, however, Janssen's patent on the composition of ustekinumab—U.S. Patent No. 6,902,734 (the '734 Patent)—expired, opening the door for other manufacturers, like Samsung, to obtain FDA approval for their ustekinumab biosimilars—in Samsung's case, called ustekinumab-ttwe or "SB17." Janssen, however, claimed that SB17 would still infringe various of the patents it had obtained related to ustekinumab that were still in effect. The resulting litigation

[1] This phenomenon of obtaining multiple, overlapping patents to cover a single product or technology has been termed a "patent thicket." *See* Jeffrey Wu & Claire W. Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 Chi.-Kent J. Intell. Prop. 93, 109-10 (2020).

ended with a Settlement Agreement that acknowledged "[f]or the purpose of this Agreement only, . . . that absent [a patent license], the SB17 Product would infringe on one or more" of Janssen's patents, App. 4, postponed SB17's entry into the marketplace until February 2025, and granted Samsung a limited patent license. That limited license prohibited Samsung from sublicensing its patent rights, with a few exceptions, one of which was for sublicenses it could grant to "commercialization partners to import, sell and offer to sell SB17 Product on behalf of [Samsung]." App. 4.

Within the following year, Samsung invoked that exception, entering into a "Commercialization Agreement" and a "Sublicense Agreement" with Sandoz AG. According to Sandoz's press release, the Commercialization Agreement granted Sandoz "*exclusive* rights to commercialize" SB17, branded as "Pyzchiva." App. 135-41 (emphasis added); App. 6. Pyzchiva's FDA-approved packaging likewise indicated that Samsung was manufacturing SB17 for Sandoz. So far so good.

But Samsung also entered into two other agreements for the manufacture and distribution of SB17—the ones giving rise to this appeal. In November 2024, Samsung, along with Sandoz, entered a Private Label Distributor (PLD) Agreement with an entity called "Quallent Pharmaceuticals Health LLC." App. 7, 121. Quallent is a subsidiary of the Cigna Group (Cigna), a vertically integrated healthcare conglomerate that owns a healthcare provider, an insurance company, a pharmacy

benefits manager (PBM), and a network of specialty pharmacies. That PLD Agreement designated Quallent "as a commercialization partner" and provided that Samsung "shall manufacture," Sandoz "shall supply," and Quallent "shall distribute" SB17. App. 7. The same day they entered the PLD Agreement, Samsung and Quallent executed a Sublicense Agreement, under which Samsung granted that Cigna subsidiary a "non-exclusive, non-transferable sublicense" to sell SB17 "under Quallent's own label," subject to the terms of Samsung's own license with Janssen. App. 7-8. Meanwhile, the healthcare provider in Cigna's conglomerate announced that it would begin to offer a Stelara biosimilar for $0 out-of-pocket for eligible patients in early 2025.

B. Procedural History

Janssen then filed the underlying suit in this case, claiming that Samsung's sublicense to Quallent—unlike its sublicense to Sandoz—breached the Settlement Agreement between Janssen and Samsung because it did not fall within the commercialization-partner (or any other) exception to the settlement's prohibition on downstream sublicensing by Samsung. Specifically, Janssen asserted that Quallent would not be selling SB17 "on behalf of" Samsung when it sells its product under Quallent's own private label. Janssen also contended that it would be irreparably harmed by this breach because the distribution of a private-label biosimilar by a Cigna subsidiary would result in a potential loss of Janssen's market share, ability to compete, and negotiation leverage. On that basis, Janssen filed a motion for a preliminary injunction to

prevent Samsung from supplying Quallent or authorizing Quallent to distribute SB17 during the pendency of the litigation.[2]

In anticipation of the preliminary injunction hearing, the parties submitted expert declarations from economists with experience in the biologics market and focused on the issue of irreparable harm. According to Janssen's expert, Dr. Robert Popovian, Quallent's private labelling would represent "an entirely different market dynamic than Janssen faces from other biosimilars," App. 85, because the "playbook" of vertically integrated healthcare conglomerates, like Quallent's parent, Cigna, is to increase profits by steering their patients to their own private-label biosimilars, rather than the lowest-cost biosimilars, and then having the patients fill those private-label prescriptions at their own specialty pharmacies, App. 92. Because Cigna controls approximately 23% of the prescription market in the United States, Dr. Popovian explained that the entry of a private-label biosimilar by its subsidiary could commandeer nearly a quarter of potential consumers nationally.

[2] Janssen also sought to require Samsung to comply with the disclosure requirements in the Settlement Agreement, but does not challenge on appeal the District Court's determination that there is no causal nexus between Samsung's purported failure to comply with the disclosure requirements and the alleged irreparable harms to Janssen.

To substantiate the likelihood of this harm, Dr. Popovian pointed to the market effects of private-label biosimilars on another brand-label biologic, Humira. As he described it, when three large healthcare conglomerates prioritized their private-label Humira biosimilars on their formularies, six of Humira's other biosimilars were effectively shut out of 80% of the market, and Humira itself lost 31% of its market share—the vast majority of which was steered to one conglomerate's private-label. From that, Dr. Popovian concluded, "[i]f Quallent introduces its STELARA® biosimilar, the results will be similar." App. 113.

Not surprisingly, Samsung's expert, Dr. DeForest McDuff, took a different view. Dr. McDuff assessed Humira's market share loss after the launch of private-label biosimilars as, in fact, "relatively modest, and at the very least . . . measurable." App. 398-99. In his opinion, any harms suffered by Janssen would not be irreparable because "[b]iosimilar entry is expected and has been authorized by Janssen"; any potential harm caused by a private-label Stelara biosimilar would be "measurable and quantifiable" and, in any event, "may not be imminent"; and Janssen would not suffer operational or reputational harm. App. 389-92, 403.

The District Court credited Dr. McDuff's opinion over Dr. Popovian's, which it "[did] not find . . . persuasive." App. 27. In a thorough opinion issued after oral argument, the District Court concluded that—even though Janssen was likely to succeed on the merits of its breach-of-contract and implied

covenant claims—it had not shown that it would suffer irreparable harm or that its "damages would be incapable of calculation," App. 21, because: "there is no . . . bright-line rule" that loss of market share equates to irreparable harm, App. 24; Janssen did not argue "that Stelara users are brand loyal" or that Quallent's private-label biosimilar would cause "reputational harm" or "price erosion," App. 29, 31; and Janssen's asserted loss of negotiating power was, in the District Court's view, "too speculative," App. 21 n.21. The District Court therefore denied Janssen's motion for a preliminary injunction and this timely appeal followed.

II. JURISDICTION AND STANDARD OF REVIEW

The District Court had jurisdiction under 28 U.S.C. § 1332, and we have jurisdiction under 28 U.S.C. § 1292(a)(1). We review the District Court's findings of fact for clear error, its conclusions of law *de novo*, and its ultimate decision to deny a preliminary injunction for abuse of discretion. *See Spring Creek Rehab. & Nursing Ctr. LLC v. Nat'l Lab. Rels. Bd.*, 160 F.4th 380, 383 (3d Cir. 2025).

III. DISCUSSION

Because a preliminary injunction "forces a party to act or desist from acting" merely "because the law *might* require it," *Del. State Sportsmen's Ass'n v. Del. Dep't of Safety & Homeland Sec.*, 108 F.4th 194, 200 (3d Cir. 2024) (citation modified), it is considered "an extraordinary remedy never awarded as of right," *id.* at 202 (quoting *Winter* v. *Nat. Res.*

Def. Council, Inc., 555 U.S. 7, 24 (2008)). Instead, to obtain a preliminary injunction, the moving party must convince the district court that four factors favor granting preliminary relief: "(1) the likelihood that the moving party will succeed on the merits; (2) the extent to which the moving party will suffer irreparable harm without injunctive relief; (3) the extent to which the nonmoving party will suffer irreparable harm if the injunction is issued; and (4) the public interest." *Siemens USA Holdings Inc. v. Geisenberger*, 17 F.4th 393, 407 (3d Cir. 2021) (citation modified).

The first two factors are the "most critical," and only if the moving party has made the requisite showing for both must the district court reach the remainder. *Del. State Sportsmen's Ass'n*, 108 F.4th at 202. Because we use a sliding scale approach, even where there is a significant likelihood of success, there still must be *some* showing of irreparable harm. *See In re Revel AC, Inc.*, 802 F.3d 558, 568-71 (3d Cir. 2015); *S.S. Body Armor I, Inc. v. Carter Ledyard & Milburn LLP*, 927 F.3d 763, 772 (3d Cir. 2019). In addition, irreparable harm is not only harm that is not "speculative," *Boynes v. Limetree Bay Ventures LLC*, 110 F.4th 604, 610 (3d Cir. 2024), but also "harm that cannot adequately be compensated after the fact by monetary damages," *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 484-85 (3d Cir. 2000). Therefore, the availability of monetary damages "typically will preclude a finding of irreparable harm," *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 n.4 (3d Cir. 2017), and thus "belie[] a claim of irreparable

injury," *Frank's GMC Truck Ctr., Inc. v. Gen. Motors Corp.*, 847 F.2d 100, 102 (3d Cir. 1988).

With this background, we consider below Janssen's four arguments as to why the District Court erred in deciding that it failed to sufficiently establish irreparable harm: (1) loss of market share in a complex market, like that for biologics, is categorically sufficient to demonstrate irreparable injury, (2) the calculation of damages need only be difficult, not "impossible," (3) Janssen's loss of negotiating leverage against Cigna is not a speculative harm, and (4) the severity of Janssen's injury should not have factored into the District Court's analysis. None has traction.

A. Loss of Market Share as *Per Se* Irreparable Harm

Janssen's first argument is that the introduction of Quallent's private-label product into the complex biopharmaceutical market will necessarily have a permanent negative impact on Janssen's sales, customer relationships, and pricing, and that under *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co.*, 290 F.3d 578 (3d Cir. 2002), such "permanent" loss of market share *per se* constitutes irreparable harm. For this purported categorical rule, Janssen relies on our statement in *Novartis* that "loss of market share constitutes irreparable harm," Opening Br. 18 (citing 290 F.3d at 596), but that case is inapposite for three reasons.

First, in *Novartis*, the evidence supporting irreparable injury from loss of market share was far stronger. The plaintiff

there manufactured a brand-name medication for nighttime heartburn, a type of heartburn that is particularly common and often severe. *Id.* at 583-84, 588. When the defendant, a competing biopharmaceutical company marketed its over-the-counter biopharmaceutical as "made just for" nighttime heartburn and "strong enough to get rid of even your toughest nighttime heartburn," *id.* at 584, the plaintiff sought and obtained a preliminary injunction to prevent the defendant from marketing its product to suggest that it was specially formulated for nighttime heartburn, *id.* at 585. We upheld that injunction on appeal because the plaintiff had established that "the promotion and sale of [defendant's product] had already had a measurable effect on [plaintiff's product's] market share," and in "a competitive industry where consumers are brand-loyal," post-trial remedies would not suffice. *Id.* at 595-96. It was "*this* loss of market share" that we concluded "constitutes irreparable harm." *Id.* at 596 (emphasis added). Here, in contrast, the market consequences of Quallent's private-label entering the marketplace are not yet known, and biologics patients, who are often steered to the label prescribed by their doctors, are not "brand-loyal."

Second, *Novartis* arose in the distinct context of the Lanham Act during an era in which this Court and others applied a presumption of irreparable harm upon a showing of likelihood of success for trademark infringement claims. *Ferring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 211 (3d Cir. 2014) (citing *Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 726 (3d Cir. 2004)). In that era, some of our sister circuits also applied the same presumption to false advertising claims under the Lanham Act, *see id.* at 210-11 (collecting cases). That was the context in which we held that "this loss of market share" constitutes irreparable harm,

Novartis, 290 F.3d at 596, and for good reason, the presumption of irreparable harm has not been extended beyond that context. The twofold justification for the presumption was specific to false advertising and trademark infringement contexts: "(1) a misleading or false comparison to a specific competing product necessarily causes that product harm by diminishing its value in the mind of the consumer" and "(2) the harm necessarily caused to reputation and goodwill is irreparable because it is virtually impossible to quantify in terms of monetary damages." *Ferring Pharms., Inc.*, 765 F.3d at 211; *see also Kos*, 369 F.3d at 726. In contrast to the presumption that historically applied in the Lanham Act context, "damages are always the default remedy for breach of contract." *United States v. Winstar Corp.*, 518 U.S. 839, 885 (1996) (plurality op.). Simply put, the contexts are different, and the *Novartis* Court's observation in a different context does not control here.

Third, even if the presumption at play in *Novartis* had applied more generally, we subsequently disavowed it. Several years after *Novartis*, the Supreme Court decided *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), which rejected a categorical presumption of irreparable harm upon a showing of infringement in patent cases, and *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7 (2008), which rejected the notion that a more lenient standard for showing irreparable harm should apply in any category of cases. Because we recognized that the logic of *eBay* and *Winter* "is equally applicable in other contexts, including cases arising under the Lanham Act," we held in *Ferring Pharmaceuticals, Inc. v. Watson Pharmaceuticals, Inc.*, that "there is no presumption of irreparable harm afforded to parties seeking injunctive relief in Lanham Act cases," 765 F.3d 205, 214, 216

(3d Cir. 2014), even if that presumption "might survive as [a] 'lesson[] of . . . historical practice' that might inform the district courts' equitable discretion," *id.* at 213 n.7 (quoting *eBay*, 547 U.S. at 396 (Kennedy, J., concurring)).

The handful of other cases on which Janssen relies are also unavailing. Some are patent infringement cases from other Courts of Appeals, which had historically applied a presumption of irreparable harm,[3] and the remainder are antitrust cases, in which market share is tied to the elements of the claim so a preliminary injunction may be necessary to

[3] *See TEK Glob., S.R.L. v. Sealant Sys. Int'l, Inc.*, 920 F.3d 777, 793 (Fed. Cir. 2019) (patent case); *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010), *aff'd*, 564 U.S. 91 (2011) (same); *Abbott Lab'ys v. Sandoz, Inc.*, 544 F.3d 1341, 1362 (Fed. Cir. 2008) (same); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006) (same)). The cited cases from district courts within this Circuit similarly involve claims in the contexts where a presumption of irreparable harm previously applied. *See* Opening Br. 23 n.5 (citing *LKRB Indus., LLC v. xuzhouaiyaxundianzishangwuyouxiangongsi*, No. 2:24-cv-1601, 2025 WL 531845, at *14 (W.D. Pa. Feb. 18, 2025) (patent and false advertising case); *Fresenius Kabi USA, LLC v. Fera Pharms., LLC*, No. 15-CV-3654, 2016 WL 5348866, at *13 (D.N.J. Sept. 23, 2016) (patent case); *Allergan Sales LLC v. Sandoz, Inc.*, No. 2:17-cv-10129, 2018 WL 3675235, at *9 (D.N.J. July 13, 2018), *aff'd*, 935 F.3d 1370 (Fed. Cir. 2019) (same); *Indivior Inc. v. Dr. Reddy's Lab'ys S.A.*, No. 17-7111, 2018 WL 3496643, at *12 (D.N.J. July 20, 2018), *vacated on other grounds*, 752 F. App'x 1024 (Fed. Cir. 2018) (same)).

preserve a district court's ability to grant relief.[4] *See Del. State Sportsmen's Ass'n*, 108 F.4th at 200-01 (explaining that the "primary purpose" of preliminary injunctions is "to ensure that, at the end of the case, the court can still grant an adequate remedy"). Those two categories of cases share commonalities inapposite to contract cases: just as patent infringement claims seek to preserve a patent holder's exclusivity in a competitive market, antitrust claims seek to avoid monopolization of a competitive market, and in both contexts, likelihood of success on the merits would also support a finding of irreparable harm. The same cannot be said of breach of contract claims where "damages are always the default remedy." *Winstar Corp.*, 518 U.S. at 885.

Perhaps recognizing the dearth of authority for its position, Janssen pivots in its Reply Brief, where it asserts that it is not proposing that "loss of market share is *categorically* irreparable," but rather that "such losses are irreparable where defendant's unlawful conduct significantly changes the relevant market in ways that are irreversible or otherwise make damages difficult to quantify." Reply Br. 12 (citation modified). Although that narrows the scope of Janssen's proposed categorical rule, it is still contrary to the "case-by-case" analysis required by this Court. *Groupe SEB United States, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 205 (3d Cir. 2014). And, as discussed below, mere difficulty calculating damages from loss of market share is not the standard, nor does mere complexity of an industry obviate the

[4] *See Boardman v. Pac. Seafood Grp.*, 822 F.3d 1011, 1023 (9th Cir. 2016) (antitrust case); *Collins Inkjet Corp. v. Eastman Kodak Co*., 781 F.3d 264, 279 (6th Cir. 2015) (same).

need for a case-by-case approach when assessing requests for equitable relief.

B. The Standard for When Damages Are Unavailable

Janssen next argues that the District Court erred as a matter of law in requiring that the calculation of damages be "impossible" or the damages be "incapable of calculation" to obtain a preliminary injunction, Opening Br. 28, when it should have been sufficient for Janssen to establish that the calculation of damages was merely "*difficult* to calculate," *id.* at 29 (quoting *BP Chems. Ltd. v. Formosa Chem. & Fibre Corp.*, 229 F.3d 254, 263 (3d Cir. 2000)).[5] Janssen, however, takes the *BP Chemicals* language out of context. What we said in that case was that "injuries *to reputation* are difficult to calculate, and thus money damages are an inadequate remedy." *BP Chems. Ltd.*, 229 F.3d at 263 (emphasis added). That observation is consistent with our many cases recognizing that damages may be inadequate when parties allege intangible

[5] This is an odd argument, to say the least, given that Janssen itself embraced "impossibility" as the proper standard below. Of the five instances in which the District Court's opinion used the word "impossible," two are direct quotes from Janssen's expert witness, Dr. Popovian, one is a direct quote from a district court opinion on which Janssen relied, and the remaining two reflect the District Court paraphrasing "their position," App. 28—per Dr. Popovian—that calculating damages here would be impossible.

harms, *see, e.g.*, *Novartis*, 290 F.3d at 596 (customer relationships); *Groupe SEB USA, Inc.*, 774 F.3d at 204-05 (reputation and goodwill); *Pappan Enters. v. Hardee's Food Sys., Inc.*, 143 F.3d 800, 805 (3d Cir. 1998) (same). Here, however, Janssen does not allege intangible harms, but rather lost sales and market share. *See* App. 22.[6] And we are wary when "a plaintiff in a breach of contract case" attempts to "convert monetary harm into irreparable harm" by claiming indirect "harm [to] the plaintiff's reputation." *Bennington Foods LLC v. St. Croix Renaissance Grp., LLP*, 528 F.3d 176, 178-79 (3d Cir. 2008).

[6] Although Janssen includes "[c]ustomer relationships" and "negotiation status" in its list of purported injuries, those phrases are used merely as labels for lost sales to the 23% of patients nationwide who are in Cigna's network due to Stelara's potential exclusion from its PBM's formulary. Opening Br. 22. Janssen's alleged injury to customer relationships does not implicate the loss of "brand-loyal" consumers discussed in *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co.*, where those customers' purchasing decisions were influenced by the defendant's false statements. 290 F.3d 578, 594-96 (3d Cir. 2002). Instead, Janssen's patients can be steered to use the medication prescribed by their doctors and covered by their insurance. And since Janssen declined to allege injury via price erosion, *see* App. 21 n.21, 31 & n.27, its asserted injury to "negotiation status" translates to the possibility of lost sales to Cigna's network if its PBM chooses to purchase Quallent's private-label biosimilar instead.

What Janssen calls the "impossibility" standard, Opening Br. 18 (citation modified), on the other hand, comes directly from our case law. In *ECRI v. McGraw-Hill, Inc.*, we held that when a claim for preliminary injunctive relief "is based on a breach of contract, irreparable injury may be found in two situations: (1) where the subject matter of the contract is of such a special nature of peculiar value that damages would be inadequate; or (2) where because of some special and practical features of the contract, it is impossible to ascertain the legal measure of loss so that money damages are impracticable." 809 F.2d 223, 226 (3d Cir. 1987). Only the latter could conceivably apply here because the Settlement Agreement does not involve subject matter of a special nature or peculiar value, like unique goods with sentimental worth or real estate. *See* Restatement (Second) of Contracts § 360 cmts. c, e (A.L.I. 1981). The District Court was not requiring that calculation of monetary damages be truly impossible, but rather, as described in *ECRI*, that the calculation be "impracticable," 809 F.2d at 226, meaning "*practically* impossible"[7] or "incapable of being performed or accomplished by the means employed or at

[7] *Impracticable*, Oxford English Dictionary Online, https://www.oed.com/dictionary/impracticable_adj?tab=meaning_and_use#888292 [https://perma.cc/J5ZP-9JXV] (last visited Mar. 26, 2026) (emphasis added).

command."[8] So even if the District Court had imposed an "impossibility" standard by referencing Janssen's failure to show damages were "incapable of calculation," App. 21, that standard, as explicated in *ECRI*, would not have run afoul of our case law, *see* 809 F.2d at 226.

C. Janssen's Asserted Loss of Negotiating Leverage

Janssen next argues that the District Court erred by "essentially ignoring an entire category of irreparable harm," namely its loss of negotiating leverage against Cigna and other industry participants if Quallent's private-label biosimilar entered the market. Opening Br. 36. But while a district court's complete disregard of evidence may constitute legal error, *see Inwood Lab'ys, Inc. v. Ives Lab'ys, Inc.*, 456 U.S. 844, 857 n.19 (1982), that is not what happened here. Instead, the District Court *did* consider Janssen's evidence of potential loss of negotiation leverage and the cases to which it cited—none of which found such harm "sufficient to support preliminary injunctive relief"—and it determined as a factual matter that Janssen's claimed loss of negotiating leverage against Cigna was "too speculative." App. 21 n.21.

[8] *Impracticable*, Merriam-Webster's Unabridged Dictionary Online, https://unabridged.merriam-webster.com/unabridged/impracticable (last visited Mar. 26, 2026).

We review that finding for clear error, *see Novartis*, 290 F.3d at 586, and see none. Because "[a]n inability to precisely measure financial harm does not make that harm irreparable or immeasurable," our precedent requires "[m]ore than a risk of irreparable harm." *Acierno v. New Castle Cnty.*, 40 F.3d 645, 655 (3d Cir. 1994) (citation modified). A movant "must demonstrate an injury that is neither remote nor speculative, but actual and imminent." *In re Revel AC, Inc.*, 802 F.3d at 571 (citation modified). The bald assertion of irreparable harm from a loss of negotiating leverage and the "domino effect" that loss allegedly would have on a movant's business does not clear that threshold. *Acierno*, 40 F.3d at 655.

Yet bald assertions of lost negotiating leverage are all that Janssen has presented. Beyond asserting that it is "already in ongoing, quarterly negotiations with" Cigna's PBM, Reply Br. 9, and that it is Cigna's "playbook" to feature its private-label biosimilar and exclude brand-name biologics from its formulary, Opening Br. 38-39, Janssen did not provide any evidence to support the requisite "clear showing of immediate irreparable injury" to those negotiations, *ECRI*, 809 F.2d at 226 (citation modified). If anything, its evidence—consisting of Dr. Popovian's case study of Humira—indicated the opposite. Dr. Popovian described how the maker of Humira reached a co-branding agreement whereby its healthcare-conglomerate competitor "could reap a percentage of [its] profits in exchange for" returning Humira to its formulary at a higher out-of-pocket rate, App. 110, and how Janssen would likely make similar concessions. But Dr. McDuff—whom the District Court found

more persuasive—countered that the percentage of Humira sales lost to biosimilar competitors was "relatively modest" and, most importantly, quantifiable. App. 399. He also pointed out that the need for preliminary relief was speculative because, if Cigna waited many months after the entry of the private-label biosimilar to change its formula in the case of Quallent's biosimilar, as Cigna had done in the case of its Humira biosimilar, any alleged injury "may not be imminent." App. 403.

As for the cases on which Janssen relies, we—like the District Court—do not find them persuasive. None held that loss of negotiating power alone was sufficient to support a preliminary injunction, and some did not address the irreparable harm factor at all, *see, e.g.*, *Disney Enters., Inc. v. VidAngel, Inc*., 869 F.3d 848, 866 (9th Cir. 2017) (determining that irreparable harm resulted from the combination of injuries to the plaintiff's "copyrighted works, their 'windowing' business model, and their goodwill and negotiating leverage"); *Brady v. Nat'l Football League*, 640 F.3d 785, 793 (8th Cir. 2011) (analyzing harm to the non-movant under the third factor of the preliminary injunction test—balance of the equities—not the second, irreparable harm factor); *United States v. Colorado*, 937 F.2d 505, 506, 508-09 (10th Cir. 1991) (reviewing a denial of a motion to modify a consent decree, not a motion for preliminary injunction, and applying the corresponding tripartite test).

Sanofi-Synthelabo v. Apotex, Inc., on which Janssen relies most heavily, upheld a preliminary injunction not simply because of lost negotiating power leading to concessions and price erosion, but because the plaintiff's losses included "loss of good will, the potential reduction in work force, and the discontinuation of clinical trials." 470 F.3d 1368, 1382-83 (Fed. Cir. 2006). Janssen, on the other hand, did not argue price erosion or other types of intangible losses, nor could it "establish that [Quallent] was the 'but for' cause of [any] claimed price erosion" given that at least four other biosimilars were being offered on the market at a cheaper price than Stelara. *Nichia Corp. v. Everlight Ams., Inc.*, 855 F.3d 1328, 1343 (Fed. Cir. 2017) (citation modified); *see also SmartSky Networks, LLC v. Gogo Bus. Aviation, LLC*, No. 2023-1058, 2024 WL 358136, at *5 (Fed. Cir. Jan. 31, 2024) (rejecting claims for price erosion where, as here, there is not yet "concrete evidence of reduced price").

In short, neither the evidence nor the case law casts doubt on the District Court's rejection of lost negotiating power as irreparable harm.

D. Consideration of the Severity of Janssen's Alleged Harms

Janssen next argues that the District Court erred as a matter of law by subjecting Janssen's loss of market share to a specific "severity" threshold. Opening Br. 20 (emphasis omitted). We do not share that reading of the Court's opinion. When the District Court stated that it was "not persuaded that Quallent's

introduction of its private label biosimilar will 'crush the market,'" App. 30, the Court was simply distinguishing *Abbott Laboratories v. Sandoz, Inc.*, an out-of-circuit district court case where the plaintiff had alleged it would "face a 90% decline in market share" if a generic drug entered the market. 500 F. Supp. 2d 807, 843 (N.D. Ill. 2007), *aff'd*, 544 F.3d 1341 (Fed. Cir. 2008).[9] It was not adopting a particular percentage threshold for lost market share. In any event, at the extremes, the severity of harm does have a role to play in the irreparable harm inquiry in breach of contract cases. We have considered, for example, whether "despite the adequacy of money damages there, nonetheless, is irreparable injury since [the movant] may no longer be in existence to collect any money damages it is awarded." *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 802 (3d Cir. 1989). But Janssen has not established that it is so reliant on Stelara sales that it would not be able to "easily absorb any short-term harm before a trial on the merits." App. 404. The District Court thus correctly determined that the severity of financial harm in this case did not entitle Janssen to a preliminary injunction.

[9] Before distinguishing *Abbott Laboratories* on the facts, the District Court noted that the case "is not binding precedent in this breach of contract case," App. 30, so the District Court's comparison of the facts in *Abbott Laboratories* and the present case was not essential to the District Court's ruling, nor subject to this Court's review, *see Drelles v. Metro. Life Ins. Co.*, 357 F.3d 344, 347-48 (3d Cir. 2003).

IV. CONCLUSION

In sum, the District Court applied the correct legal standards when assessing Janssen's purported injuries absent a preliminary injunction, considered all the parties' evidence, and reasonably concluded that Janssen was not likely to suffer irreparable harm. Because Janssen failed to meet its burden to satisfy that "gateway factor[]," *Reilly*, 858 F.3d at 179, we will affirm the District Court's denial of Janssen's motion for preliminary injunctive relief.

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