7-16-2019

Cipla Ltd v. Amgen Inc

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 19-2017

CIPLA LTD.; CIPLA USA, INC.

v.

AMGEN INC;
TEVA PHARMACEUTICALS USA, INC.

Amgen Inc.,
Appellant

Appeal from the United States District Court
for the District of Delaware
(D.C. No. 1-19-cv-00044)
District Judge: Hon. Leonard P. Stark

Submitted Under Third Circuit L.A.R. 34.1(a)
July 15, 2019

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

(Filed: July 16, 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.

Amgen Inc. appeals the District Court's order denying its motion to preliminarily enjoin Cipla Ltd. and Cipla USA, Inc. ("Cipla") from selling Cipla's generic version of one of Amgen's products. Amgen asserts that Cipla's launch breaches their settlement agreement. Because the Court correctly determined that Amgen fails to establish a likelihood of success on the merits of its breach of contract claim, we will affirm.

I

A

Amgen developed cinacalcet hydrochloride, known under the brand name SENSIPAR, to treat hyperparathydoirdism, hypercalcemia, and elevated calcium-phosphorous product. Amgen owns the patent for cinacalcet under U.S. Patent Number 9,375,405 ("the '405 patent"). Cipla, Teva Pharmaceuticals, and other generic drug manufacturers filed Abbreviated New Drug Applications ("ANDA") to produce generic equivalents of SENSIPAR before the '405 patent expired. Amgen sued Cipla, Teva, and other generic manufacturers in the District of Delaware, asserting that their generic cinacalcet products infringed the '405 patent.

Amgen and Cipla settled their patent infringement dispute. In their Settlement Agreement, Cipla conceded that the '405 patent is valid and enforceable and agreed not to launch[1] a generic cinacalcet until one of the following entry dates: ninety-seven days

[1] A "launch" refers to "the first sale in the United States, with regard to a Generic Cinacalcet Product." JA 458.

before the expiration of the '405 patent; the launch of generic cinacalcet by an entity other than Cipla or Amgen, except as provided in § 5.5 of the Settlement Agreement; or a "Final Court Decision" finding the '405 patent unenforceable. The Settlement Agreement defines a "Final Court Decision," in relevant part, as a federal district court's final judgment on the merits from which no timely appeal was taken or a mandate with respect to an appeal from such a judgment. Section 5.5 authorizes Cipla's launch of generic cinacalcet under specific circumstances based upon Amgen's response to a third party's launch. Section 5.6 lists circumstances under which Amgen may not seek relief if Cipla makes an at risk launch.[2]

Although Amgen settled its suit with Cipla, its claims against Teva proceeded to trial. Teva prevailed. The district court held that Teva did not infringe the '405 patent. Amgen Inc. v. Amneal Pharm. LLC, 328 F. Supp. 3d 373, 399 (D. Del. 2018). Amgen appealed to the Federal Circuit. While the appeal was pending, Teva received FDA approval and launched its generic cinacalcet. Less than a week later, Amgen and Teva entered into an agreement, in which Teva agreed that it had infringed the '405 patent, would stop selling its generic cinacalcet, and would pay Amgen up to $40 million. The district court declined to amend its noninfringement judgment.

B

[2] An at risk launch is a launch of a generic cinacalcet "without authorization from Amgen," and where "there has not been a Final Court Decision of non-infringement, unenforceability and/or invalidity of the '405 patent" for that generic company. JA 464.

Cipla then filed suit against Amgen in the District of Delaware, seeking, among other things, a declaratory judgment that it could launch its generic cinacalcet. Cipla also notified Amgen that it planned to launch its generic cinacalcet based on Teva's launch, and quickly thereafter launched its generic cinacalcet. Amgen filed a breach of contract counterclaim, asserting that Cipla's launch breached the Settlement Agreement, and moved to preliminarily enjoin Cipla's at risk launch.

In a thoughtful and thorough decision, the District Court denied Amgen's motion for a preliminary injunction. See generally Cipla Ltd. v. Amgen Inc., No. 19-44-LPS, 2019 WL 1970780 (D. Del. May 2, 2019). The Court held that Amgen did not establish a likelihood of success on the merits because, among other reasons, Cipla's at risk launch was authorized and Amgen was prevented from seeking relief under § 5.6 of the Settlement Agreement. Id. at *6-12. Even though the Court found that Cipla's sales would cause Amgen irreparable harm, id. at *14, and the balance of equities and public interest in protecting its patent narrowly favored Amgen, id. at *17-18, the Court denied the motion. Amgen appeals.

After the District Court denied Amgen's motion for an injunction pending appeal, Amgen renewed its request before this Court and, alternatively, sought an expedited briefing schedule. This Court granted Amgen's alternative request, scheduling its appeal for the first possible sitting and has considered the parties' comprehensive briefs.

II[3]

[3] The District Court had jurisdiction under 28 U.S.C. § 1331, 1337, and 1367. We have jurisdiction under 28 U.S.C. § 1292(a)(1).

A

The decision to grant or deny a preliminary injunction is within the sound discretion of the district court.[4] Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 24, 33 (2008). 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 [nonmovant] more than denying relief would harm the [movant] 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) (quoting Tenafly Eruv Ass'n v. Borough of Tenafly, 309 F.3d 144, 157 (3d Cir. 2002)); see Fed. R. Civ. P. 65. To establish a likelihood of success, a party must show "a reasonable chance, or probability, of winning."[5] In re Revel AC, Inc., 802 F.3d 558, 568 (3d Cir. 2015) (quoting Singer Mgmt. Consultants, Inc. v. Milgram, 650 F.3d 223, 229 (3d Cir. 2011) (en banc)).

B

[4] "We employ a tripartite standard of review for . . . preliminary injunctions. We review the District Court's findings of fact for clear error. Legal conclusions are assessed de novo. The ultimate decision to grant or deny the injunction is reviewed for abuse of discretion." K.A. ex rel. Ayers v. Pocono Mountain Sch. Dist., 710 F.3d 99, 105 (3d Cir. 2013) (omission in original) (internal quotation marks and citations omitted).

[5] Amgen incorrectly asserts that the District Court applied a heightened standard by requiring "certainty" of success rather than a reasonable likelihood of success. In its opinion, the Court recited and applied the correct standard of review. See Cipla, 2019 WL 1970780, at *4, *8, *10, *12, *13. The Court only spoke of certainty when it addressed whether indirect sales of Teva's generic cinacalcet meant that Teva was still selling its product within the terms of the Settlement Agreement, and resolved this ambiguity in nonmovant Cipla's favor, as movant Amgen bears the burden of proof when seeking injunctive relief and failed to meet its burden. See id. at *11-12.

We first consider whether Amgen has established a likelihood of success on its claim that Cipla breached the Settlement Agreement. A breach of contract claim under Delaware law[6] requires proof of (1) a contract, (2) "breach of an obligation imposed by that contract," and (3) damage to the non-breaching party. VLIW Tech., LLC v. Hewlett-Packard Co., 840 A.2d 606, 612 (Del. 2003). To determine whether Cipla breached the Settlement Agreement, we must analyze the language as it would "be understood by an objective, reasonable third party. If a contract is unambiguous, extrinsic evidence may not be used to interpret the intent of the parties, to vary the terms of the contract, or to create an ambiguity."[7] Exelon Generation Acquisitions, LLC v. Deere & Co., 176 A.3d 1262, 1267 (Del. 2017) (internal quotation marks, footnotes, and citations omitted). When reviewing contractual language, we "must read the specific provisions of the contract in light of the entire contract," Chi. Bridge & Iron Co. N.V. v. Westinghouse Elec. Co., 166 A.3d 912, 913-14 (Del. 2017), "and, if possible, reconcile all the provisions of the instrument." Alta Berkeley VI C.V. v. Omneon, Inc., 41 A.3d 381, 386 (Del. 2012) (citation omitted).

Amgen contends that Cipla's launch breached the Settlement Agreement, while Cipla asserts that § 5.6 of the Agreement bars Amgen from obtaining relief and,

[6] The parties agree that Delaware law governs this contract dispute. See Cipla, 2019 WL 1970780, at *5 n.8.

[7] We consider de novo whether a contract is ambiguous. Wayne Land & Mineral Grp. v. Del. River Basin Comm'n, 894 F.3d 509, 528 (3d Cir. 2018). "If the court determines that a contract is . . . unambiguous, then it construes the contract as a matter of law." Allegheny Int'l, Inc. v. Allegheny Ludlum Steel Corp., 40 F.3d 1416, 1424 (3d Cir. 1994).

therefore, that the launch does not constitute a breach. The second sentence of § 5.6 provides

> [n]otwithstanding anything to the contrary in this Settlement Agreement, if any Third Party that has made an At Risk Launch of a Generic Cinacalcet Product (where such At Risk Launch is before or after an at risk launch by [Cipla]) is not found to have infringed one or more valid and enforceable claims of the [']405 patent or has not ceased or agreed to cease selling such Generic Cinacalcet Product following an At Risk Launch, then Amgen shall not be entitled to seek or recover any relief from [Cipla] for [Cipla's] at risk sales, offers for sale, distribution, or importation of [Cipla's] product.

JA 469. The Settlement Agreement therefore makes clear that under certain circumstances, Amgen is not entitled to seek relief against Cipla for the launch.

The second sentence of § 5.6 has two components that inform our analysis of Cipla and Amgen's rights under the Settlement Agreement: (1) the second sentence's "notwithstanding" clause and (2) the use of "or" between the two circumstances that prohibit Amgen from obtaining relief from Cipla for its launch.

First, "[t]he use of . . . a 'notwithstanding' clause clearly signals the drafter's intention that the provisions of the 'notwithstanding' section override conflicting provisions of any other section." In re Estate of Crist, 863 A.2d 255, 258 (Del. Ch. 2004) (quoting Cisneros v. Alpine Ridge Grp., 508 U.S. 10, 18 (1993)); see NLRB v. SW Gen., Inc., 137 S. Ct. 929, 940 (2017) ("A 'notwithstanding' clause . . . shows which of two or more provisions prevails in the event of a conflict."). Therefore, although we must read a contract as a whole and in accordance with other provisions, the notwithstanding clause clearly signals precedence. It sets the second sentence of § 5.6 apart from the remaining

provisions and authorizes Cipla's launch free from Amgen's interference, despite other provisions in § 5.5 that limit Cipla's activities.[8]

It is clear that the parties intentionally included the notwithstanding clause. The agreement before us is different from the other settlement agreements Amgen entered with generic manufactures because it includes the second sentence of § 5.6, where the others do not. The intentional inclusion of the second sentence here is thus dispositive and binding. Delaware law holds sophisticated parties like Cipla and Amgen to the bargain they actually struck, rather than the one in hindsight they realize they should have made. See NAF Holdings, LLC v. Li & Fung (Trading) Ltd., 118 A.3d 175, 181 & n.14 (Del. 2015).

Second, the use of "'or' is almost always disjunctive." Encino Motorcars, LLC v. Navarro, 138 S. Ct. 1134, 1141 (2018) (internal quotation marks omitted) (quoting United States v. Woods, 571 U.S. 31, 45 (2013)). The word "or" in the second sentence identifies two circumstances that would allow Cipla to launch without Amgen's interference. The clause states that Amgen cannot seek relief from Cipla if Cipla launches when a third party "is not found to have infringed" the '405 patent or has not

[8] In its reply brief, Amgen revives its argument that the first sentence's use of "[n]othing in Section 5.5 or in this Settlement Agreement shall be construed"—like the second sentence's use of "[n]otwithstanding anything to the contrary"—signals an intent to override contrary language in the Settlement Agreement. The text strongly favors Cipla's reading because "[n]otwithstanding anything to the contrary" is more clearly preemptory, and the placement of the "notwithstanding" sentence immediately following the "nothing in Section 5.5 or in this Settlement Agreement" sentence connotes an exception to the first sentence. See Sage Software, Inc. v. CA, Inc., No. C.A. 4912-VCS, 2010 WL 5121961, at *8 & n.74 (Del. Ch. Dec. 14, 2010), aff'd, 27 A.3d 552 (Del. 2011) (Strine, V.C.).

stopped or agreed to stop selling a generic cinacalcet product. JA 469. Amgen argues that both a noninfringement finding and refusal to stop selling are required before Amgen loses its ability to seek relief, but its argument is not supported by the text or its context. "Whether requirements in a [contract] are to be treated as disjunctive or conjunctive does not always turn on whether the word 'or' is used; rather it turns on context." United States v. One 1973 Rolls Royce, V.I.N. SRH-16266, 43 F.3d 794, 815 (3d Cir. 1994); see Stockman v. Heartland Indus. Partners, L.P., No. CIV.A. 4227-VCS, 2009 WL 2096213, at *14 & n.64 (Del. Ch. July 14, 2009). The use of "or" appears to be an intentional choice as shown by the presence of the words "and" and "but has not" elsewhere in § 5.6.[9] Because the context of the clause and the contract as a whole reflect a deliberate choice of when the parties used "and" versus "or," there is no basis to read the "or" in the second sentence of § 5.6 as an "and."

Finally, there are two reasons why the phrase "following an At Risk Launch" modifies only the second condition—that a third party "has not ceased or agreed to cease selling." JA 469. There is no textual support for Amgen's assertion that the clause "is not found to have infringed" conveys that such a finding must occur "following an At

[9] In the first sentence of § 5.6, the parties limited Amgen's right to seek relief if a third party launches "and" if each third party was later found to or admits to infringing "and" it pays damages to Amgen. JA 468-69. In the last sentence of § 5.6, Amgen's right to seek enhanced damages is limited to circumstances in which a third party was later found to have infringed due to its at risk launch "and" the third party paid increased damages for willful infringement. JA 469. Finally, the parties also use "but has not" to convey limitation, curtailing Amgen's right to seek relief if a third party who made an at risk launch agreed to cease selling "but has not agreed to pay Amgen any damages." JA 469.

Risk Launch." JA 469. The clause deprives Amgen of the ability to seek relief from Cipla if a third party either "is not found to have infringed" or has not stopped selling. JA 469. A third party can be found not to have infringed even before it sells the product if, for example, a court concludes that its ANDA itself does not infringe—as was the case here. Thus, this "is not found to have infringed" language does not convey a sequence of events, because in the context of an ANDA, a finding of infringement or noninfringement can occur without a launch, see Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1567-68 (Fed. Cir. 1997) (describing infringement actions under 35 U.S.C. § 271(e)(2), prior to a launch and "based solely upon the filing of an ANDA" and "focused on the product that is ultimately to be sold"), and therefore, the phrase "following an At Risk Launch" would incorrectly limit the circumstances under which infringement could be found.

Moreover, this interpretation is consistent with the contract. Elsewhere in the contract, the parties explicitly state when there is a temporal component to the noninfringement finding. For instance, earlier in the same paragraph of § 5.6, a third party's at risk launch is expressly conditioned on a subsequent finding of infringement. See JA 468-69 (authorizing Amgen's right to seek relief "if each Third Party with respect to its respective Third Party At Risk Launch (which At Risk Launch is either before or after an at risk launch by [Cipla]) is later found to infringe, or admits to infringing").[10]

[10] Because we consider the context and the clear language of the Settlement Agreement, it is unnecessary for us to rely on canons such at the last antecedent rule or the series-qualifier canon.

Based on our reading of the second sentence of § 5.6, Amgen was not authorized to seek relief against Cipla for its launch. The parties agree that (1) Teva, a Third Party under the Settlement Agreement, made an at risk launch of its generic cinacalcet, and (2) the district court found that Teva did not infringe the '405 patent.[11] Therefore, a condition in the second sentence of § 5.6 was satisfied when Cipla launched its generic cinacalcet, and thus, Amgen may not seek relief against Cipla for its at risk launch, which consequently was not prohibited by the Settlement Agreement. As a result, Amgen has not demonstrated a likelihood of success on its breach of contract claim.[12]

Because a failure to establish a likelihood of success is fatal to obtaining a preliminary injunction, Ass'n of N.J. Rifle & Pistol Clubs, Inc. v. Att'y Gen. N.J., 910 F.3d 106, 115 (3d Cir. 2018), the District Court appropriately denied Amgen's motion.

III

For the foregoing reasons, we will affirm.

[11] Amgen claims that this judgment does not satisfy the condition in § 5.6 because it is not a "Final Court Decision," JA 458, but unlike other provisions, such as § 5.5, this sentence requires only that a third party "is not found to have infringed" and does not say that the finding of noninfringement must be a "Final Court Decision"—a defined term in the Settlement Agreement. Moreover, this judgment remains undisturbed because the district court denied Amgen and Teva's joint motion for an indicative ruling under Federal Rule of Civil Procedure 62.1 to change the court's finding of noninfringement to infringement based on Amgen and Teva's settlement agreement. Therefore, the district court's order finding that Teva did not infringe on the '405 patent satisfies this requirement of § 5.6.

[12] Because we have determined that Amgen is precluded from seeking relief for Cipla's launch under § 5.6 and because we may affirm on any grounds, Hassen v. Gov't of the Virgin Islands, 861 F.3d 108, 114 (3d Cir. 2017), we need not analyze whether Amgen may seek relief under the other condition in the second sentence of § 5.6, or whether the launch was authorized under §§ 5.3 or 5.5.