IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

AMGEN INC.,

Plaintiff-Appellant,

– v. –

WATSON LABORATORIES, INC., ACTAVIS PHARMA, INC.,

Defendants-Appellees,

CIPLA LIMITED, CIPLA USA INC.,

Defendants - Amici Curiae,

AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK LLC, CADILA HEALTHCARE LTD., dba Zydus Cadila, PIRAMAL HEALTHCARE UK LIMITED, SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES, INC., SUN PHARMACEUTICAL INDUSTRIES, LTD., ZYDUS PHARMACEUTICALS (USA) INC.,

Defendants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE IN IN NOS. 1:16-CV-00853-MSG, 1:16-CV-00855-MSG, 1:16-CV-00925-MSG, 1:17-CV-00183-MSG AND 1:17-CV-00713-MSG, HONORABLE MITCHELL S. GOLDBERG, JUDGE

BRIEF FOR *AMICI CURIAE* CIPLA LIMITED AND CIPLA USA INC. IN SUPPORT OF DEFENDANTS-APPELLEES AND SEEKING DISMISSAL OR AFFIRMANCE

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NOVEMBER 4, 2019

FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Amgen Inc. **v.** Watson Laboratories, Inc., Actavis Pharma, Inc.

Case No. 2019-1650, 2019-1770

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ■ (appellee) ☐ (amicus) ☐ (name of party)

James W. Dabney (for Cipla Ltd. and Cipla USA, Inc.)

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Cipla Limited	Cipla Limited	None
Cipla USA, Inc.	Cipla USA, Inc.	Cipla USA, Inc. is an indirect subsidiary of CIpla Ltd.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court **(and who have not or will not enter an appearance in this case)** are:

K&L Gates LLP: Peter L. Giunta, Elizabeth J. Weiskopf, Anil H. Patel, Michael Freno, Harold Storey, Jenna Bruce
Kilpatrick Townsend: Joshua H. Lee
Bayard P.A.: Stephen B. Brauerman, Sara E. Bussiere
Farnan LLP: Michael Farnan
Hughes Hubbard & Reed LLP: Patrice P. Jean, Dina R. Hoffer, Lynn M. Russo

FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

Amgen Inc. v. Amneal Pharmaceuticals LLC, Nos. 18-2414, 19-1086 (Fed. Cir.)
Cipla Ltd. and Cipla USA, Inc. v. Amgen Inc., No. 19-2017 (3d Cir.)
Cipla Ltd. v. Amgen Inc., C.A. No. 19-cv-44 (D. Del.)
Amgen Inc. v. Accord Healthcare, Inc., C.A. No. 18-cv-956 (D. Del.)
Cesar Castillo, Inc. v. Amgen Inc., No. 1:19-cv-00396-LPS (D. Del.)
KPH Healthcare Servs., Inc. v. Amgen, Inc., No. 2:19-cv-01510-WB (E.D. Pa.)
Teamsters Local 237 Welfare Fund v. Amgen, Inc., No. 2:19-cv-08561-ES-CLW (D.N.J.)
UFCW Local 1500 Welfare Fund v. Amgen Inc., No. 1:19-cv-00369-LPS (D. Del.)
In re: Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig.., 1:19-md-2895-LPS (D. Del.)

11/4/2019
Date

/s/ James W. Dabney
Signature of counsel

Please Note: All questions must be answered

James W. Dabney
Printed name of counsel

cc: Counsel of Record (via CM/ECF)

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Per ECF 57, Cipla Ltd. and Cipla USA (collectively, "Cipla") submit this brief as *amici curiae* supporting the district court's judgment (Appx79-80), following a non-jury trial, that the pharmaceutical products described in Abbreviated New Drug Application No. 204377 (the "Teva Products") are outside the scope of U.S. Patent No. 9,375,405 (the "'405 Patent") as a factual matter, such that sale or use of Teva Products in the United States would not infringe the '405 Patent.

STATEMENT OF RELATED CASES

These appeals are related to *Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. 3d 386 (D. Del.), *aff'd*, 778 F. App'x 135 (3d Cir. 2019). In *Cipla*, the district court (per Stark, C.J.) and the Third Circuit both held that the judgment of non-infringement in this case (Appx79-80), coupled with a subsequent launch of Teva Products by Teva Pharmaceuticals USA, Inc. ("Teva"), entitled Cipla to sell the pharmaceutical products described in Cipla's own FDA-approved Abbreviated New Drug Application No. 208915 ("Cipla Products") under the terms of a written contract between Amgen, Inc. ("Amgen") and Cipla. 778 F. App'x at 141; 386 F. Supp. 3d at 399-400. Amgen and Teva also stand charged in the *Cipla* case with having "colluded to divide up the market for cinacalcet, in order to share supracompetitive profits and deter true generic competition." 386 F. Supp. 3d at 409 & n.25.

These appeals are also related to *In re: Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litigation*, C.A. No. 19-md-2895-LPS (D. Del.), which includes

Cesar Castillo, Inc. v. Amgen Inc., C.A. No. 19-396-LPS; *KPH Healthcare Servs., Inc. v. Amgen, Inc.*, C.A. No. 19-1460-LPS; *Teamsters Local 237 Welfare Fund v. Amgen, Inc.*, C.A. No. 19-1461-LPS; and *UFCW Local 1500 Welfare Fund v. Amgen, Inc.*, C.A. No. 19-369-LPS. In each of these cases, the plaintiffs allege that Amgen and Teva have conspired to suppress competition in violation of federal and state antitrust laws.

These appeals are tangentially related to Appeal Nos. 2018-2414 and 2019-1086 in this Court. Appeal Nos. 2018-2414 and 2019-1086 involve the '405 Patent, but the judgment of non-infringement as to the Teva Products rests on distinct factual grounds that are not raised or at issue in those earlier appeals.

STATEMENT OF JURISDICTION

These appeals should be dismissed, because they do not involve any "honest and actual antagonistic assertion of rights." *United States v. Johnson*, 319 U.S. 302, 305 (1943). As described in *Cipla*, Amgen and Teva are parties to a binding, in-force settlement agreement (the "Amgen-Teva Agreement") by which "Amgen agreed to withdraw its appeal of this Court's judgment of non-infringement by the Teva Products" (386 F. Supp. 3d at 391-92) and Amgen ceded up to approximately $212 million in sales revenues to Teva. *Id*. at 391, 409 n.25. "Amgen and Teva structured their agreement so that both make more money the longer the market remains free of other generic competition." *Id*. at 409 n.25.

On January 9, 2019, Amgen and Teva jointly moved the district court for an "indicative ruling" (Fed. R. Civ. P. 62.1) that, if this Court remanded pursuant to Federal Rule of Appellate Procedure 12.1, the district court would then reverse its judgment of non-infringement and issue a "consent judgment . . . stating, in pertinent part; that [Teva] ha[s] admitted . . . that the manufacture, use, sale, offer to sell, and distribution of [its] Products in the United States and importation of [its] Products into the United States, would infringe the ['405] Patent; and . . . [Teva] [is] enjoined . . . from infringing the ['405] Patent by making, having made, using selling, offering to sell, or distributing [its] Products in the United States, or importing [its] Products into the United States." Appx2.

Amgen's and Teva's joint motion for an "indicative ruling" was not supported by any evidence. Amgen and Teva did not provide the district court with a copy of the Amgen-Teva Agreement. Amgen and Teva did not disclose that Amgen was ceding up to approximately $212 million in sales revenue to Teva. 386 F. Supp. 3d at 391. Amgen and Teva did not disclose that they had "structured their agreement so that both make more money the longer the market remains free of other generic competition." 386 F. Supp. 3d at 391, 409 n.25. Amgen and Teva did not disclose that their settlement was designed to cut off Cipla's rights to sell the Cipla Products. *See id*. at 395-400; Appx5127-5129. And perhaps most significantly of all, Amgen and Teva did not offer any explanation for why, after Teva

had proved, with published literature and expert testimony, that the Teva Products did not embody the claimed invention of the '405 Patent, the district court should credit, as a basis for reversing prior factual findings, an unverified statement that Teva had purportedly "admitted" the contrary. Appx2.

On March 26, 2019, the district court issued an Order denying Amgen's and Teva's joint motion for an "indicative ruling." Appx1-6. Amgen then purported to appeal this Order as Appeal No. 19-1770. On April 29, 2019, this Court issued an Order (ECF 26) consolidating Appeal No. 19-1770 with the earlier-filed Appeal No. 19-1650 that Amgen had agreed to withdraw in the Amgen-Teva Agreement. *See* 386 F. Supp. 3d at 391-92 ("Amgen agreed to withdraw its appeal of this Court's judgment of non-infringement by the Teva Products.")

On June 24, 2019, despite its having "agreed to withdraw" this Appeal No. 19-1650 (*id.*), Amgen filed an opening brief in Appeal Nos. 19-1650 and 19-1770. ECF 39. On July 17, 2019, exactly one day after the Third Circuit's decision in *Cipla*, *see* 778 F. App'x 135, Amgen abruptly filed an "unopposed" motion for an Order reversing the district court's judgment of non-infringement as to the Teva Products and directing issuance of the same "consent judgment" that the district court had indicated (Appx1-6) it would not issue. *See* ECF 46. Teva filed no opposition to Amgen's motion, consistent with Teva now sharing Amgen's interest in maintaining artificially high prices for cinacalcet products and undoing the result in

Cipla. *See* 386 F. Supp. 3d at 409 & n.25 (noting "the seemingly undisputed fact that Teva stands to make approximately $200 million from its already-shipped product *if the cinacalcet market remains un-genericized*.") (emphasis added); Appx5127-5129 (noting "loophole" and "gambit" utilized by Amgen and Teva).

The existence of an "honest and actual antagonistic assertion of rights to be adjudicated" has long been recognized as "a safeguard essential to the integrity of the judicial process." *Johnson*, 319 U.S. at 305. By their voluntary action in making an agreement "fully resolving their respective infringement claims and invalidity counterclaims as to the '405 patent" (Appx5078), Amgen and Teva have eliminated any basis on which this Court could review whether the factual basis of the district court's judgment of non-infringement as to the Teva Products is, or is not, "clearly erroneous." Fed. R. Civ. P. 52(a)(6).

The Court lacks jurisdiction to hear Appeal No. 19-1770 on the separate and independent ground that there exists no statutory or non-statutory basis for review of an Order which refuses an "indicative ruling" (Fed. R. Civ. P. 62.1) and does not purport to alter any person's legal rights.

INTEREST OF AMICI CURIAE

Cipla and Amgen are parties to a contract that provides in part: "if any Third Party that has made an At Risk Launch of a Generic Cinacalcet Product . . . is not found to have infringed one or more valid and enforceable claims of the '405 pa-

tent . . . , 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." 778 F. App'x at 139. Under the district court's judgment in this case, Teva currently "is not found to have infringed" for purposes of the above-quoted language and Cipla currently is, accordingly, licensed to sell the Cipla Products. *See id*. at 141; 386 F. Supp. 3d at 399-400. Cipla is thus vitally interested in defending the district court's judgment of non-infringement in this case.

Cipla has this Court's permission to file this brief. ECF 57. No party's counsel authored this brief in whole or in part, and no party, no party's counsel, and no person (other than *amici curiae*) contributed money in support of this brief.

COUNTER-STATEMENT OF THE ISSUES

The issues presented by these appeals are:

1. Whether these appeals should be dismissed for lack of jurisdiction. *Cf. Aqua Marine Supply v. AIM Mach., Inc*., 247 F.3d 1216, 1219-20 (Fed. Cir. 2001) (dismissing appeal as moot, despite district court refusal to vacate summary judgment of invalidity).

2. Whether, assuming that this Court has jurisdiction to consider the issue, the district court acted within its discretion in stating, in an "indicative ruling" (Fed. R. Civ. P. 62.1), that on the record then before it, the district court would not issue a certain proposed, unabashedly collusive "consent judgment." Appx2.

3. Whether, assuming that this Court has jurisdiction to consider the issue, the district court's judgment that the Teva Products fall outside the scope of the '405 Patent "is plausible in light of the record viewed in its entirety," *Anderson v. Bessemer City*, 470 U.S. 564, 574 (1985), and thus cannot be deemed "clearly erroneous." Fed. R. Civ. P. 52(a)(6).

COUNTER-STATEMENT OF THE CASE

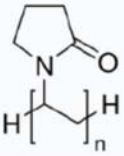
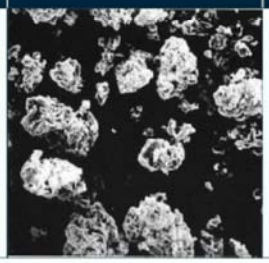
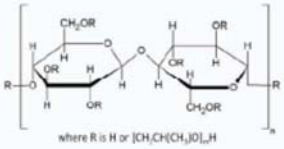
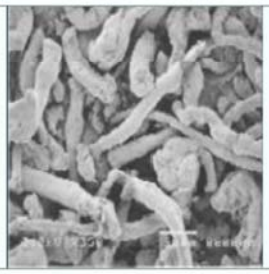
The '405 Patent discloses and claims "[a] pharmaceutical composition comprising . . . (d) from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovid[o]ne, sodium starch glycolate, croscarmellose sodium, and mixtures thereof." Appx166 Claim 1.

The claims of the '405 Patent are thus limited to compositions that comprise "at least one" of the three listed "disintegrant[s]" or equivalents thereof. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997) ("Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole.").

It is undisputed that the Teva Products do not include any of the three listed disintegrants, but comprise a disintegrant commonly known as low-substituted hydroxypropyl cellulose ("L-HPC"). Appx28. Prior to and during the trial below, Amgen contended that L-HPC was "equivalent" to one of the listed disintegrants,

crospovidone, "under the function-way-result test." Appx29; *see* D.I. 353 at 81:2-5; D.I. 355 at 552:3-10. The district court received extensive expert testimony and documentary evidence on this factual issue, including the chart below (D.I. 360 at p.51; D.I. 355 at 651:4-660:18):

Crospovidone and L-HPC are Not Equivalent

	Chemistry	Picture	Functional Category	Primary Mechanisms of Disintegrant Action
Crospovidone	Cross-linked polymer N-vinyl-2-pyrrolidinone 		disintegrant	recovery of elastic energy of deformation capillary action disruption of particle/particle bonds
L-HPC	2-hydroxypropyl ether (low-substituted) 		binder disintegrant	swelling

In post-trial submissions, Amgen put forward two alternative theories of equivalence, namely, (i) "L-HPC is equivalent to all three listed disintegrants of claim 1 under the function-way-result test"; and (ii) "L-HPC is equivalent to crospovidone under the insubstantial differences test." Appx29. With regard to crospovidone, the district court credited published literature and testimony given by

Dr. Leah Appel, Watson/Teva's technical expert,[1] and found, as a fact, that L-HPC and crospovidone were substantially different from one another in their chemistry; in their physical forms; in their primary mechanisms of action; and in their respective disintegration behaviors. Appx29-36. The district court rejected, as unsupported and non-credible, Amgen's expert's conclusory assertion that L-HPC purportedly can be characterized as a "superdisintegrant" and, by virtue of this label, was equivalent to all three of the listed disintegrants. Appx30-31.

"A finding of equivalence is a determination of fact." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950). On August 24, 2018, based on its factual finding that L-HPC was not equivalent to any of the three listed disintegrants as a factual matter, the district court entered a final judgment of non-infringement as to the Teva Products. Appx79-80.

Teva Ships $212 Million Worth of Teva Products Subject to "Shelf Stock Adjustment" Supply Provisions

"On December 28, 2018, Teva launched its generic cinacalcet product by shipping 409,128 bottles to wholesalers." *Cipla*, 386 F. Supp. 3d at 391. "In an internal email, Brendan O'Grady, Teva's Executive Vice President and Head of North America Commercial, estimated that Teva would realize about $200 million in revenue from this shipment, assuming that no other company launched a com-

[1] Watson Laboratories, Inc. is an indirect wholly-owned subsidiary of Teva. *See* 386 F. Supp. 3d at 390 n.2.

peting generic drug – and noting that Teva's revenue would 'drastically decreas[e]' if other generics entered the cinacalcet market." *Id*. "Robert G. Cunard, Cipla's expert on the pharmaceutical industry, provided opinions consistent with Mr. O'Grady's email." *Id*. "Mr. Cunard estimated Teva's revenue from its launch at $212 million, a number which might be reduced due to 'shelf stock adjustments' if other generic companies launched their products before Teva's wholesalers resold the Teva Product." *Id*.

Teva Agrees to Cease Direct Sales of the Teva Products and to Join With Amgen in Seeking a "Consent Judgment"

"On January 2, 2019, just five days after Teva launched its generic product, Amgen and Teva entered into the Amgen-Teva Agreement." *Id*. "Under this agreement, and despite having prevailed at trial and obtained a final judgment of non-infringement, Teva stipulated that the Teva Product *does infringe* the '405 patent, which Teva further stipulated was valid and enforceable." *Id*.

"Teva also agreed to pay Amgen up to $40 million dollars, depending (in part) on how long the cinacalcet market remains free of non-Amgen and non-Teva generic products, and appears to have agreed to stop selling the Teva Product." *Id*. In view of Teva's having admittedly shipped between $200-$212 million worth of Teva Products prior to January 2, 2019 (*see id*.), Teva's contingent agreement to pay Amgen up to $40 million was a disguise for the reality that "Teva stands to make approximately $200 million." *Id*. 409 n.-25.

"For its part, Amgen agreed to withdraw its appeal of this Court's judgment of non-infringement by the Teva Products." *Id*. at 391-92. Importantly, Amgen's undertaking to withdraw this Appeal No. 19-1650 and Teva's undertaking to cease direct sales of Teva Products were *not* contingent on any further action by either party or the district court. In *Cipla,* Amgen persuaded the district court to hold that the Amgen-Teva Agreement was binding and currently obligates Teva to cease direct sales of Teva Products. *See* 386 F. Supp. 3d at 401 ("[I]n Amgen's view, the Amgen-Teva Agreement imposes current restrictions on Teva's conduct. The Court agrees."); ECF 56 at 26:17-18 ("the parties were bound upon signing.").

"Restrictions on price and output are the paradigmatic examples of restraints of trade that the Sherman Act was intended to prohibit." *NCAA v. Bd. of Regents of Univ. of Okla*., 468 U.S. 85, 107-08 (1984). The pendency of this Appeal No. 19-1650 had no effect on the preclusive effect of the district court's judgment of non-infringement. *See Pharmacia & Upjohn Co. v. Mylan Pharm. Inc.,* 170 F.3d 1373, 1381 (Fed. Cir. 1999) ("The law is well settled that the pendency of an appeal has no effect on the finality or binding effect of a trial court's holding.").

Insofar as the Amgen-Teva Agreement obligated Teva to cease direct sales of Teva Products, as Amgen successfully argued in *Cipla* (*see* 386 F. Supp. 3d at 401), that agreement was subject to strict scrutiny under 15 U.S.C. § 1 and imposed on Amgen and Teva "a heavy burden of establishing an affirmative defense

which competitively justifies this apparent deviation from the operations of a free market." *NCAA*, 468 U.S. at 113. Such an affirmative defense would require evidence that the Amgen-Teva Agreement "promotes competition." *Nat'l Soc'y of Prof. Eng'rs v. United States*, 435 U.S. 679, 691 (1978). It is "well settled that good motives will not validate an otherwise anticompetitive practice." *NCAA*, 468 U.S. at 101 n.23.

The Amgen-Teva Agreement did not, however, call for the submission of evidence of pro-competitive effects to the district court, but merely for filing a joint motion seeking reversal the district court's judgment of non-infringement and issuance of a new and different judgment of infringement having the force of law, without any proof or adversary submissions. Appx2; Appx5078; Appx5083.

The District Court Denies Amgen's and Teva's Joint Motion for an "Indicative Ruling."

On January 9, 2019, Amgen and Teva jointly moved the district court to issue an "indicative ruling" (Fed. R. Civ. P. 62.1) that, if this Court remanded pursuant to Federal Rule of Appellate Procedure 12.1, the district court would then issue a "consent judgment" reversing its earlier non-infringement finding with respect to the Teva Products. Appx5077-5094. At the time Amgen and Teva made this motion, the district court lacked jurisdiction to issue any Order concerning "those aspects of the case involved in the appeal." *Griggs v. Provident Consumer Disc. Co.* 459 U.S. 56, 58 (1982). Further, Amgen and Teva withheld from the district court

both the Amgen-Teva Agreement and the huge sums (386 F. Supp. 3d at 391, 409 n.25) that Amgen had ceded to Teva to induce Teva's so-called "infringement admission." ECF 39 at 2.

On March 26, 2019, the district court denied Amgen's and Teva's joint motion for an "indicative ruling." Appx1-6. The Order denying an "indicative ruling" did not purport to alter any party's legal rights.

ARGUMENT

I. THESE APPEALS SHOULD BE DISMISSED FOR MOOTNESS AND FOR LACK OF JURISDICTION.

Amgen purports to raise two merits issues in these appeals: (i) whether the district court erred in declining to issue a certain "indicative ruling" (Fed. R. Civ. P. 62.1); and (ii) whether the district court's judgment of non-infringement as to the Teva Products is "clearly erroneous." Fed. R. Civ. P. 52(a)(6). The Court lacks jurisdiction to decide either of these issues by reason of a binding, in-force settlement agreement between Amgen and Teva.

The facts here are very similar to those that confronted the Court in *Aqua Marine*. There, as here, a district court had issued a merits judgment that was unfavorable to the patentee. 247 F.3d at 1218. There, as here, the parties had subsequently entered into a comprehensive settlement agreement, one of whose terms called for the parties to file "a joint proposed order" that would have vacated the district court's merits judgment. *Id*. at 1218-19. There, as here, the district court

indicated that it would not vacate its prior judgment. *Id*. at 1219. And there, as here, the patentee attempted to have this Court review the correctness of the district court's merits decision even though the appellee had joined with the patentee in seeking vacatur of the decision in its favor. *Id*. at 1219-20.

This Court held, in *Aqua Marine*, that it lacked jurisdiction because "as a result of the Agreement, Aqua Marine and the defendants [were] no longer adversaries." *Id*. at 1220. The same is true here. Amgen and Teva jointly told the district court that they had "executed a Litigation Settlement Agreement . . . *fully resolving* their respective infringement claims and invalidity counterclaims as to the '405 patent." Appx5078 (emphasis added). Amgen and Teva *jointly* moved the district court to indicate that it would enter a "consent judgment" reversing its prior judgment. Appx5077-5094. Amgen represented in *Cipla* that "the parties were bound upon signing." ECF 56 at 26:17-18. Amgen filed an *unopposed* motion for summary reversal in this Court. ECF46. And as the *Cipla* decisions make clear, Amgen and Teva now have common interests in seeking reversal of the district court's judgment of non-infringement to (i) undermine Cipla's ability to sell Cipla Products (386 F. Supp. 3d at 395-400); and (ii) confect a patent-based defense to antitrust and unfair competition claims now pending against them.

The absence of jurisdiction here is clearer than it was in *Aqua Marine*; for in that case, the appellee had merely "lost interest" (247 F.3d at 1220) in the legal is-

sue that the patentee had asked this Court to review. Here, in contrast, Teva has purported to *flip-flop* on a *factual* issue and, for legal and pecuniary reasons of its own (*see* 386 F. Supp. 3d at 391, 409 & n.25), Teva has *joined* with Amgen in seeking *reversal* of the district court's judgment of non-infringement and issuance of a new and different judgment of infringement. Amgen has cited no case, and Cipla is aware of none, in which a federal court has ever knowingly issued such a collusive judgment. *Cf. Cont'l Wallpaper Co. v. Louis Voight & Sons Co.*, 212 U.S. 227, 262 (1909) ("a court will not lend its aid, in any way, to a party seeking to realize the fruits of an agreement that appears to be tainted with illegality.").

Where, as here, it appears that litigants have cooperated in seeking issuance of a judgment, federal courts have repeatedly held that jurisdiction is lacking. For example, in *Johnson*, the appellee was a landlord who engaged and paid counsel to represent one of his tenants in a suit challenging the validity of a rent control regulation. 319 U.S. at 303-04. The suit was held to be "collusive because it [was] not in any real sense adversary" and did not "assume the honest and actual antagonistic assertion of rights to be adjudicated – a safeguard essential to the integrity of the judicial process." 319 U.S. at 305 (internal quotation omitted).

So here, Amgen and Teva have jointly sought, for their mutual gain, a "consent judgment" that would constitute an exercise of federal judicial power having the force of law and reverse, outside of any adversary process, a district court find-

ing and judgment of non-infringement rendered following a non-jury trial. Appx2. Amgen and Teva's collusion is more visible (*see* Appx5127-5129) than was that of the *Johnson* litigants, but the unabashed nature of Amgen's and Teva's joint conduct renders these appeals no less "collusive."

As Amgen itself notes, "the Court is 'dependent . . . on the adversarial process for sharpening the issues for decision,' without which it could issue an 'improvident or ill-advised decision.'" ECF 39 at 23 (quoting *Carbino v. West*, 168 F.3d 32, 34-35 (Fed. Cir. 1999)). But because Teva, at this stage, stands to *benefit* from reversal of the district court's judgment of non-infringement (*see* 386 F. Supp. 3d at 409 n.25; Appx5127-5129), this Court can have no more confidence in a brief filed by Teva than 1919 World Series spectators could have confidence in efforts of White Sox players. Again to quote Amgen, "it is unclear whether [Teva] will even participate in these appeals, never mind how [Teva] will try to navigate its admission of infringement on the merits if it does." ECF 39 at 23-24.

In *Lord v. Veazie*, 49 U.S. (8 How.) 251 (1850), the Court dismissed an appeal where, as here, litigants having the same interest in an issue (in that case, navigation rights that were subject to conflicting claims) sought a judgment that would benefit them but injure rival third-party claimants. The Court stated:

> The objection in the case before us is, not that the proceedings were amicable, but that there is no real conflict of interest between them; that the plaintiff and defendant have the same interest, and that interest adverse and in conflict with the interest of third persons, whose rights would be

> seriously affected if the question of law was decided in the manner that both of the parties to this suit desire it to be.

Id. at 255.

In *Cleveland v. Chamberlain*, 66 U.S. (1 Black) 419 (1861), the Court dismissed an appeal where, as here, the litigants were shown to have been pursuing a common interest designed to prejudice the rights of third-parties, similarly to how Amgen and Teva seek a "consent judgment" that would purport to impair Cipla's rights to sell Cipla Products. The Court stated:

> [I]t appearing to the court here, from affidavits and other evidence filed in this case in behalf of persons not parties to this suit, that this appeal is not conducted by parties having adverse interests, but for the purpose of obtaining a decision of this court, to affect the interests of persons not parties—it is therefore now here ordered and adjudged by this court, that the appeal in this case be and the same is hereby dismissed, with costs.

66 U.S. (1 Black) at 426.

As in the above cases, Amgen's and Teva's conduct in jointly seeking reversal of the district court's judgment demonstrates, clearly, that these appeals are, in law, "collusive," 319 U.S. at 305, and must be dismissed. Dismissal of Appeal No. 19-1770 is required on the separate and independent ground that there exists no statutory or non-statutory basis for appellate review of the district court's refusal of an "indicative ruling." Fed. R. Civ. P. 62.1.

The district court's Order (Appx1-6) did not purport to alter any person's legal rights; it did not grant or refuse an injunction; and it was issued at a time when

jurisdiction had passed to this Court. *See* 386 F. Supp. 3d at 392 n.6. A mere utterance, not purporting to adjudicate or vary legal rights, does not qualify as "an invasion of a legally protected interest" as could support federal court jurisdiction. *Spokeo, Inc. v. Roberts*, 136 S. Ct. 1540, 1549 (2016) (internal quotation omitted).

II. THE DISTRICT COURT PROPERLY REFUSED TO INDICATE THAT IT WOULD ISSUE A COLLUSIVE CONSENT JUDGMENT.

To the extent that this Court considers it appropriate to review whether the district court erred in refusing to "indicate" that it would, in the event of a remand under Federal Rule of Appellate Procedure 12.1, issue a collusive "consent judgment" (Appx2), the Court should affirm.

As noted above, Amgen's and Teva's joint motion for an "indicative ruling" was not supported by any evidence. Amgen and Teva did not provide the district court with a copy of the Amgen-Teva Agreement.[2] Amgen and Teva did not disclose that Amgen had ceded up to approximately $212 million in sales revenues to Teva. 386 F. Supp. 3d at 391, 409 n.25. And Amgen and Teva did not provide the

[2] Although Amgen and Teva did not provide district court with a copy of the Amgen-Teva Agreement, Amgen's opening brief to this Court (ECF 39) purports to submit a copy of that Agreement as an "Addendum" and Amgen's "unopposed" motion for summary reversal (ECF 46) asked this Court to consider that extra-record material in a factual vacuum. "[T]he record on appeal is generally limited to that which was before the district court." *Moore U.S.A., Inc. v. Standard Register Co.*., 229 F.3d 1091, 1116 (Fed. Cir. 2000) (citing Fed. R. App. P. 10(a)). "We are especially reluctant to expand the record on appeal where, as here, the party seeking expansion of the record offers no reasonable basis for its failure to produce the preferred evidence at an earlier time." *Id*.

district court with any evidentiary basis for crediting, as a basis for reversing factual findings made after trial, an unverified statement that Teva had purportedly "admitted" that its prior non-infringement position was false. Appx2.

The district court appropriately declined to "indicate" that it would exercise federal judicial power to issue the highly unusual, if not unprecedented, "consent judgment" sought by Amgen and Teva. Even assuming that the district court had the power to issue such a collusive "judgment" (which it did not), any such "judgment" would be "tainted with illegality." *Cont'l Wallpaper*, 212 U.S. at 262.

The conduct of Amgen and Teva is analogous to that held illegal in *United States v. Singer Manufacturing Co.*, 374 U.S. 174, 192-97 (1963), cited and quoted with approval in *FTC v. Actavis, Inc.*, 570 U.S. 136, 149 (2013). In *Singer*, as here, business competitors acted in concert to "settle" litigation to support issuance of broader patent claims than might have issued in the absence of their collusion, and did so for the purpose of using the broader patent claims to exclude competition by third-party rivals. *Id*. The illegality of the Amgen-Teva Agreement is a subject of the antitrust litigations cited on pp. 1-2 *supra*.

Amgen's invocation of 28 U.S.C. § 2106 is misplaced for two independent reasons. First, Amgen and Teva sought, not mere "vacatur" of the district court's judgment of non-infringement as to the Teva Products, but issuance of an entirely new judgment of infringement that would have the force of law (Appx2) and prej-

udice legal rights of third parties including Cipla. Amgen cites no case, and Cipla is aware of none, which holds that 28 U.S.C. § 2106 authorizes a court to direct issuance of a collusive judgment having the force of law.

Second, and laying aside that Amgen and Teva do not seek mere "vacatur" of the district court's judgment, their request for an "indicative ruling" was properly denied on the basis that "[j]udicial precedents are presumptively correct and valuable to the legal community as a whole." *U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship*, 513 U.S. 18, 26 (1994) (internal quotation omitted). "They are not merely the property of private litigants and should stand unless a court concludes that the public interest would be served by a vacatur." *Id*. This is especially so in patent cases. *See Hazel-Atlas Glass Co. v. Hartford-Empire Co*., 322 U.S. 238, 246 (1944) ("There are issues of great moment to the public in a patent suit.").

Amgen and Teva did not even purport to demonstrate, in the district court, that "the public interest would be served by a vacatur." *Id*. Citing footnote 1 in *Aqua Marine*, 247 F.3d at 1221 n.1, Amgen asserts (ECF 39 at 2) that Teva purportedly has "now recognized that the non-infringement judgment was in 'error' through its infringement admission." Amgen's assertion is unsupported by evidence and sharply disputed.

Teva's so-called "infringement admission" (ECF 39 at 3) is fully consistent with Amgen and Teva having corruptly "colluded to divide up the market for ci-

nacalcet, in order to share supracompetitive profits and deter true generic competition." 386 F. Supp. 3d at 409. Insofar as Amgen and Teva might claim to have had some other, more benign, motive for seeking the requested "indicative ruling" (Fed. R. Civ. P. 62.1), they elected not to present any evidence of any such benign motive to the district court. They even withheld the Amgen-Teva Agreement from the district court. In these circumstances, this Court must reject Amgen's attempt to introduce extra-record materials (*see* p. 18 n.2 *supra*) and assert, for the first time on appeal, that Teva purportedly now "recognized" (ECF 39 at 3) that the Teva Products purportedly embody the claimed invention of the '405 Patent.

Amgen's heavy reliance on *Major League Baseball Properties, Inc. v. Pacific Trading Cards, Inc.*, 150 F.3d 149 (2d Cir. 1998), is misplaced. *Major League Baseball* involved a defendant-appellee who could not afford a security bond that an appellate court had threatened to impose pending oral argument and determination of a preliminary injunction appeal. The parties reached a settlement that, unlike the Amgen-Teva Agreement, was contingent on vacatur of the district court's interlocutory order denying preliminary injunctive relief, which the appellee had been unable to defend for financial reasons. 150 F.3d at 152.

Here, in sharp contrast, nothing prevented Amgen from pressing its Appeal No. 19-1650 or seeking an injunction pending appeal as was done in *Major League Baseball*. Amgen chose, instead, to settle its claims against Teva; Amgen has con-

ceded that "the parties were bound upon signing" (ECF 56 at 26:17-18); and Amgen simply regrets the settlement terms it agreed to. No more than could the patentee in *Aqua Marine,* Amgen could not require a district court to reverse itself and issue a collusive "consent judgment." The district court's refusal to "indicate" that it would do so was entirely just and proper.

Amgen cites *Agostini v. Felton*, 521 U.S. 203, 215 (1997) and *Rufo v. Inmates of Suffolk County Jail*, 502 U.S. 367, 384 (1992), but those prison cases demonstrate what is totally lacking here: a factual record showing that continued enforcement of a judgment "is no longer equitable." Fed. R. Civ. P. 60(b)(5). Unlike in *Agostini* and *Rufo*, the record here contains no competent or credible evidence as could support a factual finding that "applying" the district court's judgment of non-infringement as to the Teva Products "prospectively is no longer equitable." Fed. R. Civ. P. 60(b)(5). The sole "evidence" that Amgen cites in support of its position is what it calls Teva's "infringement admission." ECF 39 at 2. But the district court was clearly not required to credit this unverified "admission" which, even without the expedited discovery that supported the *Cipla* decisions, is consistent with corruption and illegality.

III. THE NON-INFRINGEMENT FINDING IS NOT CLEARLY ERRONEOUS

The district court's judgment of non-infringement as to the Teva Products (Appx79-80) rests on a finding of fact, namely, that L-HPC was not equivalent to

any of the three disintegrants recited in the asserted claims. "A finding of equivalence is a determination of fact," *Graver*, 339 U.S. at 609-10, and "must not be set aside unless clearly erroneous." Fed. R. Civ. P. 52(a)(6).

To establish that a substituted element is "equivalent" to a recited element, this Court's precedents require "particularized testimony and linking argument." *AquaTex Indus., Inc. v. Techniche Sols.*, 479 F.3d 1320, 1328 (Fed. Cir. 2007); *see Texas Insts., Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996); *Lear Siegler, Inc. v. Sealy Mattress Co.*, 873 F.2d 1422, 1426 (Fed. Cir. 1989). Such "particularized testimony" must articulate each of the three function-way-result elements, *Lear*, 873 F.2d at 1425-27, and the reasons for insubstantial differences. *Texas Insts.*, 90 F.3d at 1567.

A. No Function-Way-Result Equivalence Proven

Far from being "fatal" (ECF 39 at 46, 48), the bioequivalence of Teva Products and Amgen's Sensipar® is fully consistent with L-HPC, the *ingredient*, being substantially different from the recited disintegrants. "[B]ioequivalency and equivalent infringement are different inquiries." *Abbott Labs., Inc. v. Sandoz, Inc.*, 566 F.3d 1282, 1298 (Fed. Cir. 2009). Regardless of whether, considered as entireties, Teva Products are bioequivalent to Sensipar® branded products, "the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." *Warner-Jenkinson*, 520 U.S. at 29.

Evidence introduced at trial showed that the members of the recited disintegrant Markush group each function as "superdisintegrants." Teva's expert provided detailed testimony and corroborating evidence that L-HPC, a traditional disintegrant, was "not as effective" or "potent" as the "more efficient" and "much more effective" disintegrants recited in the asserted claims. *See* D.I. 355 at 664:9-670:6; JTX12/DTX322 at p.2155 stating (emphases added):

> The ***earlier*** known disintegrants are starch- and cellulose-based excipients such as . . . low-substituted hydroxypropyl cellulose (***L-HPC***). Later, ***more efficient disintegrants*** were developed by chemical modifications of starch, cellulose, and povidone. These are sometimes referred to as ***superdisintegrants***. Examples of superdisintegrants include ***croscarmellose***, ***crospovidone***, and ***sodium starch glycolate*** (SSG).

See also DTX334 at pp.218, 235 (superdisintegrants "much more effective and used at lower concentrations"); *id.* at p.240 stating (emphasis added):

> [L-HPC] has been evaluated as a tablet disintegrant and has disintegrant activity, but ***it is not as effective as sodium starch glycolate, croscarmellose sodium, or crospovidone***.

Teva also contended that L-HPC also has multiple potential functions—it can act as a binder or disintegrant. (D.I. 355 at 656:15-22, 671:14-16; DTX324 at p.1 ("L-HPC is praised for its multi-functionality.")). Amgen's expert agreed that the claimed disintegrants are classified as "superdisintegrants" but disagreed with Teva's expert and contended that L-HPC is also a "superdisintegrant." D.I. 353 at 187:8-14, 203:1-6, D.I. 354 at 295:11-19. Even if there were "two permissible views" of the evidence, the district court's factual finding that L-HPC would not be

viewed as a "superdisintegrant" by a person skilled in the art (essentially, a pharmaceutical formulator (D.I. 353 at 182:10-183:4; D.I. 356 at 939:17-940:4)) is not clearly erroneous. *Anderson*, 470 U.S. at 573-74; Appx30-31.

The district court's finding that Amgen failed to show L-HPC acted in the same way as the recited disintegrants also was not clearly erroneous. Appx31-32. Amgen's expert contended that the mechanism of action of the claimed disintegrants and L-HPC was swelling, but he provided no corroboration of this as to the claimed disintegrants (D.I. 353 at 305:9-12); whereas Teva's expert "gave persuasive testimony, corroborated by scientific literature," that at least the claimed disintegrant in Amgen's Sensipar® product (*i.e.*, crospovidone) worked a different way, by strain recovery. Appx31-32; D.I. 354 at 658:8-659:4, 668:3-20; JTX12/DTX322 at p.2155 ("strain recovery is the dominant mechanism for the disintegrant action of crospovidone"). The trial court reviewed published literature on the mechanism of action of L-HPC and the claimed disintegrants in light of the parties' respective experts' testimony, and "accept[ed] and credit[ed] this updated literature" in Teva's favor. Appx32; *Warner-Jenkinson*, 520 U.S. at 37 ("the proper time for evaluating equivalency . . . is at the time of infringement, not at the time the patent was issued.").

"To no type of case" is Rule 52(a)(6) "more appropriately applicable than to the one before us, where the evidence is largely the testimony of experts as to

which a trial court may be enlightened by scientific demonstrations." *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 336 U.S. 271, 274 (1949). "Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous." *Anderson*, 470 U.S. at 574.

The finding that Amgen failed to prove L-HPC achieved Amgen's claimed result— "rapid tablet disintegration"— also cannot be deemed "clearly erroneous." Fed. R. Civ. P. 52(a)(6). Inconsistencies in data sponsored by Amgen led the court to conclude, as a fact, that "L-HPC does not necessarily disintegrate at substantially the same rate as the superdisintegrants," and that to prove it did, Amgen would have needed to present testing data for comparable cinacalcet hydrochloride formulations, which it did not have. Appx33-34 & n.10; D.I. 354 at 433:10-19; D.I. 355 at 685:14-688:10, 693:17-23. *See also, e.g.*, DTX334 at p.240 (L-HPC "is not as effective as sodium starch glycolate, croscarmellose sodium, or crospovidone"). "It is not for this Court to even essay an independent evaluation of this evidence. This is the function of the trial court." *Graver*, 339 U.S. at 611.

B. No Proof of Insubstantial Differences

There is also no clear error in the district court's finding that Amgen failed to show equivalence under the insubstantial differences test. *Anderson*, 470 U.S. at 573-76; Appx34-36. Amgen's expert did not offer any opinion on insubstantial differences for the Teva Products (D.I. 355 at 551:15-552:10), and for the first time

in post-trial briefing (Appx29), Amgen attempted to rely on unsubstantiated attorney argument. Such argument has no evidentiary value in this context. *See Suffolk Techs., LLC v. AOL Inc.*, 752 F.3d 1358, 1367 (Fed. Cir. 2014) ("Without expert testimony, however, Suffolk's position is mere attorney argument. And here, those attorney arguments are insufficient to undermine the credible testimony from Google's expert"). It certainly does not constitute "particularized testimony and linking argument." *Texas Insts.*, 90 F.3d at 1567.

Amgen cited Teva internal disintegration testing of a cinacalcet formulation comprising L-HPC with another cinacalcet formulation comprising crospovidone; however, as Teva's expert pointed out, the two formulations included different amounts of other excipients, all of which could affect disintegration, and she saw them as two entirely different pharmaceutical formulations. D.I. 355 at 740:3-741:1; PTX368 at WTS-CNCLT-00000270, WTS-CNCLT-00000293; PTX391 at WTS-CNCLT-00173157, WTS-CNCLT-00173159.

Teva's expert further explained why crospovidone and L-HPC are vastly different to persons of skill in the art. D.I. 355 at 647:18-648:10, 649:11-672:1. Crospovidone and L-HPC are, respectively, synthetic and natural materials (D.I. 355 at 663:11-17); they have vastly different physical shapes ("marbles" vs. "spaghetti noodles," D.I. 355 at 655:10-656:14; PTX438 at 209, 323); vastly different material handling characteristics (flows well vs. less well (D.I. 355 at 655:10-656:14;

DTX324 at p.1)); and vastly different chemical structures (cross-linked polymer of five-membered rings with four carbons and one nitrogen vs. non-cross-linked polymer of six-membered rings with five carbons and one oxygen (D.I. 355 at 651:7-654:7, 661:3-664:5, PTX438 at 208, 322).

Dr. Appeal testified that a person skilled in the art would not consider those two materials "equivalent chemically" (D.I. 355 at 652:22-653:15), equivalent functionally (single functionality vs. multi-functionality (D.I. 355 at 656:16-658:7, 671:1-16; DTX324 at p.1)), or equivalent in terms of disintegration potencies (higher vs. lower (D.I. 355 at 665:14-667:7; JTX12/DTX322 at p.2155; DTX334 at pp.239-40)).

CONCLUSION

The Court should dismiss these appeals for lack of jurisdiction. Alternatively, the district court's judgment of non-infringement as to the Teva Products should be affirmed.

Dated: November 4, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), I certify the following:

1. This brief complies with the type-volume limitation of Rules 29(a)(5) and 32(a) of the Federal Rules of Appellate Procedure and Federal Circuit Rule 32(a) because this brief contains 6,689 words, excluding the parts of the brief exempted by Rule 32(f) of the Federal Rules of Appellate Procedure and Federal Circuit Rule 32(b), as determined by the word-count function of Microsoft Word 2017.

2. This brief complies with the typeface and type style requirements of Rules 32(a)(5) and 32(a)(6) of the Federal Rules of Appellate Procedure because this brief has been prepared in a proportionally spaced typeface using the 2017 version of Microsoft Word in 14 point Times New Roman font.

Dated: November 4, 2019

/s/ James W. Dabney
James W. Dabney

CERTIFICATE OF SERVICE

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by HUGHES HUBBARD & REED, Attorneys for Amici Curiae to print this document. I am an employee of Counsel Press.

On **November 4, 2019**, Counsel for Amici Curiae has authorized me to electronically file the foregoing **Brief for Amici Curiae Cipla Limited and Cipla USA Inc. in Support of Defendants-Appellees and Seeking Dismissal or Affirmance** with the Clerk of Court using the CM/ECF System, which will send notice of such filing to the following registered CM/ECF users:

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