Nos. 18-2621, -2748, -2758

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff-Appellant,

v.

ABBVIE INC.; ABBOTT LABORATORIES; UNIMED PHARMACEUTICALS LLC; BESINS HEALTHCARE, INC.; *TEVA PHARMACEUTICALS USA, INC.,
Defendant/Cross-Appellant.

(*Dismissed Pursuant To Court's 3/12/2019 Order)

On Appeals from the United States District Court for the Eastern District of Pennsylvania in Case No. 2:14-cv-05151, Judge Harvey Bartle, III

OPENING/RESPONSE BRIEF FOR APPELLEE/CROSS-APPELLANT BESINS HEALTHCARE, INC.

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CORPORATE DISCLOSURE STATEMENT

Besins Healthcare, Inc., is a wholly owned U.S. corporate subsidiary of Belgian company Besins Healthcare, S.A. Neither Besins Healthcare, S.A. nor its parent entity Besins Healthcare Holding LTD are publically traded companies.

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JURISDICTIONAL STATEMENT

Besins adopts the jurisdictional statement in the Brief for Abbvie Inc, Abbott Laboratories, and Unimed Pharmaceuticals, LLC (collectively "AbbVie"). Besins filed a timely notice of appeal on August 7, 2018. JA179.

ISSUES ON APPEAL

Besins adopts the issues presented in the AbbVie brief and additionally raises the following:

1) Whether the district court clearly erred in finding that Besins acted with subjective baselessness based on a factual determination that Besins's in-house counsel made the decision to file the 2011 patent-infringement suits. (Raised: ECF No. 414 at 3-11 (Besins' Post Trial Brief). Decided: ECF No. 439 (JA69) at 46, 49-53 (Op.).)

2) Whether the district court erred by ordering Besins to disgorge royalty payments that Besins never received, was not entitled to receive, and did not control. (Raised: ECF No. 414 at 11-14 (Besins' Post Trial Brief). Decided: ECF No. 439 (JA69) at 95-97 (Op.).)

RELATED CASES

Besins adopts the Statement of Related Cases in the AbbVie brief.

STATEMENT OF THE CASE

Besins adopts the Statement of the Case in the AbbVie brief, but adds the following:

1. Besins Healthcare, Inc. and AndroGel

Besins Healthcare, Inc. ("Besins") is the sole Besins entity named as a defendant in this litigation. JA1247 (PLX133) (complaint); *see also* JA163 (Op.) Besins is the wholly owned U.S. corporate subsidiary of Belgian company Besins Healthcare, S.A. ("Besins SA"). JA3471 (DX304). Non-parties Laboratoires Besins International S.A.S., ("LBI") and Besins Healthcare Luxembourg SARL ("Besins SARL") are separate affiliates of Besins SA. *Id.* Besins has no ownership interest in Besins SA, LBI, or Besins SARL. JA80 (Op.).

During the 1990s, LBI's predecessor conducted research in France to develop transdermal testosterone replacement gels. Besins was not involved in that research. Under a 1995 License agreement, LBI licensed certain intellectual property and know-how regarding its testosterone gels to Unimed, with Unimed assuming responsibility for obtaining U.S. regulatory approvals and for U.S. marketing of any commercially developed testosterone gel products. JA1425, 1433 (PLX251). In return, LBI was entitled to an 8% royalty on net U.S. sales of products derived from its intellectual property and know-how. JA1428 (PLX251).

Besins was not a party to the 1995 agreement, or even mentioned in it. JA1425 (PLX251).

In 2000, Unimed and Besins jointly filed a U.S. patent application for a transdermal testosterone gel,[1] and in 2003, U.S. Patent No. 6,503,894 (the '894 patent") issued, covering testosterone gel compositions including AndroGel 1%. Besins co-owns the patent with Unimed, which today is owned by AbbVie.

When AndroGel 1% launched in 2000, Unimed began paying royalties to LBI under the 1995 agreement. When AndroGel 1.62% launched in 2011, royalties were paid either to LBI or Besins SARL. JA3472. In a July 2014 Letter of Intent ("LOI"), the royalty rate was reduced to 5% effective April 1, 2015. JA1575 (PLX269). Besins was not a party to the LOI. JA3472 (DX304). Besins has never received, and has never had any contractual right to receive or control, any royalties on any U.S. sales of AndroGel products. JA3472 (DX304); JA1428 (PLX251); JA1571 (PLX269).

2. **Perrigo's 2009 Notification**

In 2009, Besins and Unimed (the latter then owned by Solvay Pharmaceuticals) received from Perrigo Israel Pharmaceuticals, Ltd. ("Perrigo") two Paragraph IV notifications under the Hatch-Waxman Act regarding Perrigo's

[1]While the intellectual property and know-how were developed by LBI, ownership rights were assigned to Besins for purposes of filing a U.S. patent application.

intention to market in the United States a 1% testosterone gel. JA3674, 3677 (Tr: 4:59, 70) (MacAllister). Perrigo asserted that its product would not infringe the '894 patent because its product "did not contain 0.1% to about 5% isospropyl myristate," the proportion of isospropyl myristate claimed in the patent. JA1456 (PLX254). Isospropyl myristate is a transdermal penetration enhancer.

Besins and Unimed jointly retained the law firm Finnegan Henderson to evaluate Perrigo's notifications. JA3678 (Tr. 4:73) (MacAllister). Dr. Thomas MacAllister—a patent lawyer and molecular biologist who served as Besins's general counsel—also separately consulted with IP attorneys at Foley & Lardner, LLP on behalf of Besins. JA3683, 3691 (Tr. 4:95-96, 128); *see also see* JA3672-3673, 3691 (Tr. 4:52-53, 127). He also conferred with Shannon Klinger, Solvay's in-house counsel. JA3681 (Tr. 4:87); JA597 (PLX006). On July 12, 2009, MacAllister forwarded to Ms. Klinger a memorandum prepared by Foley & Lardner regarding a proposed suit against Perrigo and referenced his plans to speak with Besins's Board about the memorandum. JA597 (PLX006).

Ultimately, Solvay decided not to sue Perrigo for reasons not shared with Besins. JA3684 (Tr. 4:99). Once Solvay made that decision, Besins "stood down" from further action. JA3684 (Tr. 4:99-100).

Solvay issued a press release announcing its decision in July 2009, which MacAllister forwarded to Besins's Board members. JA3685 (Tr. 4: 94, 101-102);

JA1505-08 (PLX259). Besins was not a party to that press release. JA3685 (Tr. 4:101).

3. **2011 Suits Against Teva and Perrigo**

In March 2011, TEVA Pharmaceuticals USA, Inc. ("Teva"), sent Besins and Unimed (by then a subsidiary of Abbott Laboratories) a Paragraph IV notification for its proposed testosterone gel. JA1663 (PLX303). Teva asserted that its product would not infringe the '894 patent because it did not contain isopropyl myristate. JA1678 (PLX303). MacAllister again retained Foley & Lardner to evaluate the notification and conferred with in-house counsel at Abbott. JA3688 (Tr. 4:113-114) (MacAllister). But because MacAllister never had access to Teva's confidential information detailing the composition of its product, he remained "on the outside." JA3687 (Tr. 4:112). On April 29, 2011, Unimed, Abbott, and Besins jointly sued Teva for patent infringement. JA1247 (PLX133).

In September 2011, Besins (and Abbott) received a new Paragraph IV notification from Perrigo. JA1509 (PLX264). That notification again asserted that Perrigo's product would not infringe the '894 patent because it did not contain 0.1% to about 5% isopropyl myristate. JA1515 (PLX264); JA3689 (Tr. 4:119) (MacAllister). MacAllister followed the same steps he had taken vis-à-vis the other notifications—*i.e.*, he received analyses from outside counsel "which informed [Besins's] decision as to whether or not to proceed with the lawsuit" and

he conferred with in-house counsel at Abbott. JA3690 (Tr. 4:122). On October 31, 2011, Besins, Unimed, and Abbott jointly sued Perrigo for patent infringement. JA1366 (PLX193).

The Teva litigation settled on December 20, 2011; the Perrigo litigation settled on December 8, 2011. *See* AbbVie Br. at 16 and 20.

PROCEDURAL HISTORY

As the AbbVie brief explains (at 26 and 28), the district court entered summary judgment for the FTC on the issue of objective baselessness, and the case proceeded to trial on the issues of subjective baselessness, monopoly power, and the amount of any revenues AbbVie and Besins received from any anticompetitive behavior.

To support its claim of subjective baselessness, the FTC presented evidence regarding Solvay's 2009 decision not to sue Perrigo, as well as evidence and testimony about AbbVie's business documents prepared in 2010-2011. The FTC did not link the AbbVie documents to Besins.

In its decision, the court rejected the FTC's efforts to prove subjective baselessness based on Solvay's 2009 decision not to sue Perrigo or the AbbVie 2010-2011 business documents. JA108-111 (Op). Instead, the court concluded that it was proper to "zoom in on the individuals at AbbVie and Besins who made the decisions to file the infringement actions against Teva and Perrigo and discern

what those individuals knew." JA114. No witness testified, however, as to who at Besins made the decision to join the 2011 suits, nor was that question ever posed to MacAllister, the sole Besins witness.[2] Purporting to apply a clear-and-convincing-evidence standard, but relying only on inferences, the district court nonetheless found that: i) MacAllister, an experienced patent attorney, made the decision on behalf of Besins, with no input or involvement by any Besins business professionals; ii) MacAllister testified but "he did not say a word about his reasoning for filing suit against Teva and Perrigo"; iii) MacAllister was aware of Teva's and Perrigo's Paragraph IV notifications and, therefore, knew that those companies used different penetration enhancers from AndroGel; iv) MacAllister was familiar with the '894 patent's prosecution history, which—the court believed—precluded infringement claims for penetration enhancers other than isopropyl myristate; v) MacAllister was aware of AndroGel's financial success; and vi) MacAllister knew the patent suits were baseless and knowingly filed sham litigation. JA88, 91, 114, 117-121, 164.

The district court then found that AbbVie and Besins had monopoly power in a topical testosterone gel market and used sham litigation to maintain their monopoly power.

[2]Three AbbVie witnesses testified about AbbVie's in-house counsel who acted as AbbVie's decision-makers – an issue that the court specifically pursued. *See, e.g.*, JA4096-4097 (Tr. 11:37-44) (Stewart).

As to remedy, the court found that it had that authority to order disgorgement under Section 13(b) of the FTC Act. JA141. Despite the fact that Besins never received any royalties on any AndroGel sales, the court decided it was proper to require Besins to pay a proportional share of the disgorgement award – an amount set at $31,534,540. JA163, 165-166 (Op.); JA172 (Judgment).

SUMMARY OF ARGUMENT

In addition to the grounds presented in the AbbVie brief, which are adopted by reference below, *infra* Part I, the judgment against Besins should be reversed for two independent reasons.

First, the district court erred in finding subjective baselessness as to Besins by resting its decision on a clearly erroneous factual finding. *Infra* Part II. The district court ruled that Besins's intent in suing Teva and Perrigo could be discerned from "zoom[ing] in on the individual[]" at Besins who made the decisions to sue, and that MacAllister was that decision-maker. JA88, 91, 114 (Op.). The record, however, contains no evidence—let alone clear and convincing evidence—that MacAllister made the decisions to sue. Indeed, the FTC never argued that MacAllister was Besins's decision-maker or presented any evidence on this topic. ECF No. 405 at ¶¶ 136-141, 194-199. The FTC bore the burden of presenting evidence and it failed to do so. Besins had no obligation to fill-in the

FTC's evidentiary gaps. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1368 (Fed. Cir. 2008).

What limited evidence that exists fails to satisfy the clear-and-convincing standard, which requires evidence that is "'so clear, direct, weighty and convincing as to enable the [fact finder] to come to a clear conviction, without hesitancy, of the truth of the precise facts in issue.'" *Bellardine v. Ross*, 2018 WL 3642223, at *4 (E.D. Pa. Aug. 1, 2018). Rather, at most, the trial record establishes that in both 2009 and 2011, MacAllister conferred with Besins's Board regarding Perrigo's and Teva's Paragraph IV notifications and the Hatch-Waxman statutory stay, and that MacAllister was "involved" in the 2011 decisions by getting outside counsel "up to speed" and conferring with them and with AbbVie's in-house counsel. Such evidence is neither "direct, weighty [nor] convincing." Without clear and convincing evidence against Besins, the court's reasoning collapses.

Second, the court erred in ordering Besins to disgorge royalties it never received or controlled. *Infra* Part III. Besins never received any royalties on U.S. sales of any AndroGel products and it was not entitled to receive any such royalties. Rather, all royalties were paid by AbbVie to LBI or Besins SARL pursuant to the 1995 License Agreement—an agreement to which Besins was not a party. The court nonetheless found that because Besins joined the 2011 lawsuits, it was obligated to disgorge $31,534,540 in "excess" royalties that LBI and Besins

SARL received on AbbVie's sales of AndroGel products. JA164-165 (Op.). That ruling contravenes this Court's recognition that disgorgement "may not be used punitively." *SEC v. Teo*, 746 F.3d 90, 103, 109 (3d Cir. 2014). The district court relied on the Second Circuit decision in *SEC v. Contorinis*, 743 F.3d 296 (2d Cir. 2014), but that decision has never been adopted by this Court and presented very different circumstances. Moreover, the Supreme Court recently highlighted the punitive nature of the disgorgement ordered in *Contorinis*, casting doubt on the validity of imposing disgorgement in the manner approved in that case. *See Kokesh v. SEC*, 137 S. Ct. 1635, 1645 (2017).

ARGUMENT

I. Besins Adopts The Arguments Set Forth In The AbbVie Brief

Pursuant to Federal Rule of Appellate Procedure 28(i), Besins adopts by reference the arguments presented in the AbbVie brief that: (1) the 2011 suits against Teva and Perrigo were not objectively baseless; (2) the suits were not subjectively baseless; (3) the district court erred in finding monopoly power; and (4) Section 13(b) of the FTC Act does not authorize disgorgement, and even if it did, the court abused its discretion in awarding disgorgement here. *See* AbbVie Br. at 31-85. In response to the FTC's appeal, Besins adopts by reference the arguments in the AbbVie brief that the district court did not abuse its discretion in:

(1) denying the FTC additional disgorgement, and (2) denying injunctive relief. *See id.* at 93-106.

II. The District Court's Decision Regarding Besins's Subjective Intent Rests On A Clearly Erroneous Factual Finding

1. Standard of Review

The district court's factual findings from a bench trial are reviewed for clear error. *Vici Racing, LLC, v. T-Mobile USA, Inc*., 763 F.3d 273, 283 (3d Cir. 2014). *Cf. Trinity Indus. Inc. v. Greenlease Holdings Co.*, 903 F.3d 333, 356 (3d Cir. 2018) (district court abuses its discretion when decision depends on a clearly erroneous factual finding).

2. Quantum of Evidence Required To Prove Intent Under Clear and Convincing Standard

To establish that Besins engaged in sham litigation, the FTC had to prove by clear and convincing evidence that Besins's "subjective motivation" was to "'interfere directly with the business relationships of a competitor,' … through the 'use [of] the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon.'" JA107 (Op.); *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993)).

To satisfy that standard by clear and convincing evidence, the FTC's evidence had to be "so clear, direct, weighty and convincing so as to enable the court to make its decision with a clear conviction." *Polselli v. Nationwide Mut.*

Fire Ins. Co., 23 F.3d 747, 752 (3d Cir.1994) (citations and quotation marks omitted). *See also Berg Chilling Sys., Inc. v. Hull Corp.*, 369 F.3d 745, 754 (3d Cir. 2004) (factual finding clearly erroneous where it is devoid of a minimum of evidentiary support and bears no rational relationship to evidence offered). Although intent may be inferred from circumstantial evidence, the clear-and-convincing standard requires more than insinuation. *Amica Mutual Insur. Co. v. Fogel*, 656 F.3d 167, 179 (3d Cir. 2011). As the Federal Circuit explained in the analogous context of inequitable patent conduct:

> [B]ecause direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence. … But such evidence must still be clear and convincing, and inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement. … [T]he inference must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.

Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008) (citations and quotation marks omitted). The Federal Circuit emphasized that "[t]he need to strictly enforce the burden of proof and elevated standard of proof . . . is paramount because the penalty for inequitable conduct is so severe, the loss of the entire patent . . . ." *Id*. at 1365.

At the trial below, the FTC failed to present "clear, direct, weighty and convincing" evidence of Besins's subjective motivation or even ask the necessary

questions to establish what the district court considered to be the key facts—*i.e.*, who were the decision-makers for Besins and what did they know. That lack of evidence dooms the district court's factual finding, which is "completely devoid of [a] minimum [of] evidentiary support." *Id.* at 1368 (clear and convincing evidence absent when questions about key topic never asked); s*ee also Vici Racing*, 763 F.3d at 283; *Sabinsa Corp. v. Creative Compounds, LLC*, 609 F.3d 175, 182 (3d Cir. 2010) (court errors in making ultimate factual finding without subordinate factual foundation). And a decision resting on a clearly erroneous finding should be reversed. *Id.* at 183.

Moreover, the Federal Circuit's rationale for requiring strict enforcement of the burden of proof is equally applicable here. Sham-litigation claims implicate a party's "precious" First Amendment rights to petition a court for redress. *See PRE*, 508 U.S. at 69 (Stevens, J. concurring). The loss of those rights would be even more severe than the loss of a patent and, thus, the need for strict enforcement here too is "paramount."

3. Evidence About Besins's Intent Was Not Clear And Convincing

The FTC presented very limited evidence regarding Besins, particularly regarding Besins's intent in 2011. The FTC called only one Besins witness—Dr. MacAllister—and sought to show Besins's intent in 2011 by linking it to Solvay's

2009 decision not to sue Perrigo. The district court rightly found that the 2009 decision as "not probative" of Besins's (or AbbVie's) subjective intent in 2011.[3]

The district court "zoom[ed] in" instead on who in 2011 were the decision-makers at Besins (and AbbVie) and what those people knew. JA114. As to Besins, the FTC presented no evidence on those questions. The limited evidence the FTC elicited about Besins at trial established only that:

- MacAllister was a patent attorney and worked at Besins in a general-counsel-type role. JA3672, JA3691 (Tr. 4:52-53, 127) (MacAllister).
- In 2009, MacAllister emailed Besins's Board members to inform them of Perrigo's Paragraph IV notification and to point out that the notice triggered a forty-five-day window in which to decide whether to sue. JA3673 (Tr. 4:66); JA2708 (DX256).
- In 2009, MacAllister jointly retained one law firm with Solvay and separately retained Foley & Lardner to assess Perrigo's Paragraph IV notification. JA3678, JA3682, JA3691 (Tr. 4:73; 95-96, 128).
- MacAllister sent Solvay's in-house counsel a memorandum from Foley & Lardner about a proposed suit against Perrigo. He stated that he would be speaking with Besins's Board the next morning and that he hoped the memorandum provided information sufficient for Solvay's counsel to do the same. JA3683 (Tr. 4:94); JA597 (PLX6).
- When Solvay issued its 2009 press release announcing its decision not to sue Perrigo, MacAllister emailed a copy to Besins's Board. JA3685-3686 (Tr. 4:101-102); JA1505 (PLX259).

[3]JA108-109 (Op.). The FTC's other subjective-intent evidence focused on AbbVie documents that bore no link to Besins. Even as to AbbVie, the district court rejected the FTC's reliance on those materials, finding it neither persuasive nor "even relevant." JA110-111.

- In 2011, MacAllister followed the same course of conduct. He was "involved" in the decisions to file the 2011 suits to the extent that he took steps "akin" to what occurred with Perrigo in 2009. He assisted Besins's outside counsel in getting up to speed and conferred with counsel to the extent possible given that he was "on the outside" of the confidential portions of Teva's and Perrigo's notifications. He also conferred with AbbVie's in-house counsel. JA3687-3690 (Tr. 4:112, 113, 122); JA2710 (DX271).

- MacAllister informed the Besins's Board after the Teva suit was filed and noted that the filing triggered the 30-month stay "that we discussed." JA3688 (Tr. 4:115); JA2710 (DX271).

That testimony neither addressed nor established who made the 2011 decisions to sue. Nor did the FTC ask MacAllister who at Besins made those decisions. Neither did the district court. By failing to question Besins on the single issue the district court deemed pivotal to determining subjective intent, the FTC failed to meet its burden of proof. In the face of that failure, it was not Besins's obligation to fill in the FTC's evidentiary gap. *Star Scientific*, 537 F.3d at 1368 (when party bearing burden fails to ask core questions about subjective intent, other party need not offer evidence).

Moreover, the FTC never took the position that MacAllister was Besins's decision-maker. Rather, the FTC cited only to the spotty testimony that MacAllister was "involved" and then made no argument about the significance of that testimony in determining who was Besins's decision-maker. ECF No. 405 at ¶¶ 136-141, 194-199.

With no direct evidence establishing MacAllister's role as the decision-maker, the district court was left with indirect, circumstantial evidence of Besins's intent. However, that evidence could not establish intent unless it was "clear, direct, weighty and convincing." *Bellardine v. Ross*, 2018 WL 3642223, at *4 (E.D. Pa. Aug. 1, 2018). And any inference drawn by the court needed to be "the single most reasonable inference able to be drawn" to satisfy the clear-and-convincing evidence standard. *Star Scientific*, 537 F.3d at 1366; *cf. Sabinsa*, 609 F.3d at 187-88 (factual decision on intent clearly erroneous because it failed to acknowledge contrary evidence). The court's decision does not meet these requirements.

The limited evidence does not show MacAllister acting as Besins's "decision-maker." It shows that in 2009 and 2011, MacAllister, consistent with his general-counsel role, communicated with Besins's Board about developments associated with the Perrigo and Teva notifications. Otherwise, the evidence shows only that MacAllister consulted with outside counsel and with his counterparts at Solvay and AbbVie. Such evidence is not "clear, direct, weighty and convincing." Nor is that conclusion "the single most reasonable inference to be drawn." *Star Scientific*, 537 F.3d at 1366. To the contrary, it is equally reasonable, if not more

so, to conclude that MacAllister gave the Board members privileged legal advice and information that the Board considered in coming to *its* decisions.[4]

In sum, the district court's inferential evidentiary findings are not based on evidence that satisfies the clear and convincing standard. *Vici Racing,* 763 F.3d at 283. Without that evidentiary basis, the court's decision must be reversed. *See Araujo v. New Jersey Transit Rail Ops., Inc.*, 708 F.3d 152, 163 (3d Cir. 2013); *Citizens Financial Group, Inc. v. Citizens Nat. Bank of Evans City*, 383 F.3d at 129-30.

III. The District Court Erred In Ordering Disgorgement Against Besins

1. Standard of Review

This Court reviews the district court's conclusions of law de novo. *Vici Racing, LLC,* 763 F.3d at 283 (2014). Where disgorgement is permitted by statute, the Court reviews the award of disgorgement for abuse of discretion. *Commodity*

[4]There is no evidence about what, if anything, MacAllister told the Besins Board about the merits or risks of filing suit or the legal intricacies of prosecution-history estoppel. In any case, those communications would be privileged, and no negative inference can be drawn from privileged communications or a refusal to waive privilege. JA117 (Op.) (citing *Freedom Card, Inc. v. JPMorgan Chase & Co.*, 432 F.3d 46, 479-80 n.25 (3d Cir. 2005)). Even if the court could have inferred what MacAllister shared with the Board, there is no evidence about how the Board reacted. *Citizens Financial Group, Inc. v. Citizens Nat. Bank of Evans City*, 383 F.3d 110, 129-30 (3d Cir. 2004) (clear and convincing evidence lacking where record "not clear" how executives reacted to advice).

Futures Trading Com'n v. American Metals Exchange Corp., 991 F.2d 71, 76 (3d Cir. 1993).

2. The Punitive Disgorgement Award Should Be Reversed

As the AbbVie brief explains (at 73-79), disgorgement is not legally authorized, and its imposition here against Besins and AbbVie was improper. In addition—and independent of those errors—the district court erred as a matter of law by ordering Besins to disgorge $31.5 million where it is uncontested that Besins never received any royalties on or revenues from U.S. sales of AndroGel.

"Disgorgement is an equitable remedy designed to deprive a wrongdoer of his unjust enrichment" by divesting ill-gotten gains. *SEC v. Hughes Capital Corp.*, 124 F.3d 449, 455 (3rd Cir. 1997). As this Court noted in *SEC v. Teo*, 746 F.3d 90 (3d Cir. 2014), there also is "an equitable requirement that the amount to be disgorged must be remedial rather than punitive." *Id.* at 107 n.31; *see also id.* at 103, 109. A disgorgement award that does not rest on a financial benefit the defendant reaped from unlawful conduct could be an impermissibly punitive "penalty assessment." *CFTC v. American Metals Exchange Corp.*, 991 F.2d 71, 78 (3d Cir. 1993); *see also U.S. ex. rel. Doe v. Heart Solution, PC*, 923 F.3d 308 (3d Cir. 2019) (unjust enrichment "*requires showing that defendant received a benefit*") (italics in original).

In *Kokesh v. SEC*, 137 S. Ct. 1635 (2017), the Supreme Court considered when disgorgement amounts to a penalty. Significantly, the Court particularly noted that where disgorgement "exceeds the profits gained as a result of the violation"—such as when an insider trader is ordered to disgorge "the benefit that accrues to third parties whose gains can be attributed to the wrongdoer's conduct'"—disgorgement does not simply restore the status quo; "it leaves the defendant worse off." *Id.* at 1644-1645 (discussing *SEC v. Contorinis*, 743 F.2d 296, 302 (2d Cir. 2014)).

Under those principles, the imposition of the disgorgement award against Besins was impermissibly punitive. It is uncontested that Besins received no royalties for U.S. AndroGel sales. The FTC so stipulated. JA3472 (DX304). It is also uncontested that, pursuant to the 1995 agreement—to which Besins was not a party—only LBI was contractually entitled to royalties. *Id.* Accordingly, only LBI received royalties on AndroGel 1%'s sales, and only LBI and/or Besins SARL received royalties on U.S. sales of AndroGel 1.62%. *Id.*

Moreover, there is no evidence that Besins ever received any other benefit related to U.S. AndroGel sales.[5] The FTC introduced no evidence about the

[5]While Besins sued Teva and Perrigo, it did so because it is the sole Besins entity holding rights in the '894 patent. By suing Teva and Perrigo on their Paragraph IV notifications—exactly as the Hatch-Waxman Act encourages given that such notification constitutes infringement (*In re Wellbutrin XL Antitrust Litig. Indirect*

business relationships between Besins and its European affiliates or even if such relationships exist beyond the mere fact of their corporate affiliations.[6]

As Besins never received any benefit from the sales of AndroGel products, the district court's decision ordering Besins to disgorge tens of millions of dollars was improperly punitive. The court first sought to justify its decision by noting that it was Besins that joined the 2011 suits, and that it was Besins's experienced and knowledgeable in-house counsel who made the decision to do so. JA163-64. As discussed above, however, the finding that MacAllister was Besins's "decision-maker" is clearly erroneous and cannot support the disgorgement award.

The court next reasoned that "it is of no import that Besins may have chosen to direct profits from its wrongdoing to affiliated foreign entities LBI SAS and BHL SARL." JA165. That justification also has no evidentiary basis. The record is devoid of evidence that Besins "chose[] to direct profits" to its affiliates, that it received any royalties or other profits that it could have so directed, or that its decision to sue was linked to a desire or mandate to serve the financial interests of

Purchaser Class, 868 F.3d 132, 144 (3d Cir. 2017)) —Besins did not stand to gain financially.

[6]The FTC asked a single question of MacAllister relating to the financial relationship between Besins and then dropped the subject entirely. JA3673 (Tr. 4:56) (MacAllister).

its foreign affiliates.[7] The evidence shows only that as a co-owner of the patent, Besins had the right to sue to protect its intellectual property, and that its foreign affiliates have certain royalty rights under the 1995 agreement.

The district court's chief justification for imposing disgorgement against Besins was that a "wrongdoer may be ordered to disgorge not only the unlawful gains that accrue to the wrongdoer directly, but also the benefit that accrues to third parties whose gains can be attributed to the wrongdoer's conduct." JA164-165. Citing *SEC v. Contorinis*, 743 F.3d 296 (2d Cir. 2014), the court maintained that forgoing disgorgement "would be tantamount to allowing Besins to enrich unjustly its corporate affiliate through the filing of sham lawsuits." JA165 (citing *Contorinis*, 743 F.3d at 301-304, 307).

But *Contorinis* is neither controlling nor persuasive here. *Contorinis* was a civil case the SEC pursued after obtaining a criminal conviction of fund manager Joseph Contorinis. Both the criminal and civil matters involved Contorinis's use of inside information to direct certain trades in a fund he managed. Contorinis did not benefit personally from those trades, other than earning additional

[7]Piercing corporate separateness requires strict proof and is "notoriously difficult." *Trinity Indus., Inc. v. Greenlease Holding Co.*, 903 F.3d 333, 366 and 367 (3d Cir. 2018). The FTC made no showing that Besins was an alter ego of its foreign affiliates or otherwise was controlled or directed by them. *See* ECF No. 414 at 12-13 n.19 (Besins' Post Trial Brief); *Lieberman v. Corporacion Experienca Unica, S.A*, 226 F. Supp. 3d 451, 465-471 (E.D. Pa. 2016) (veil piercing valid only when corporate separation abused and used for illegitimate purposes).

compensation, but the fund generated over $7,000,000 in illicit profits for its investors.

The SEC sought disgorgement from Contorinis of the $7,000,000 in investor profits. The district court granted the award and the Second Circuit affirmed, stating that a tipper in an insider trading case may be ordered to disgorge not only unlawful gains the tipper received but also benefits the tippee gained from the tipper's unlawful conduct. *Contorinis*, 743 F.3d at 301. The Second Circuit noted that a tipper obtains various benefits even if those benefits are not pecuniary, including "self-aggrandizement, psychic satisfaction from benefitting a loved one, or future profits by enhancing one's reputation as a successful fund manager." *Id.* at 303. There was therefore "no injustice … in making [Contorinis] responsible for the profits he made for others, as well as for himself, through his fraudulent insider trades." *Id.* at 304; *see also id.* at 307 ("[t]here is nothing inequitable about requiring a person who created an unjust gain … and allocated that gain … to beneficiaries that he chose, to return the gain to the public").

Contorinis does not support the disgorgement award here. First, the Supreme Court in *Kokesh* explicitly noted the punitive aspect of the *Contorinis* decision. *Kokesh*, 137 S. Ct. at 1644-45. The same is true here, as Besins received no royalties, yet has been ordered to disgorge $31.5 million that it never received

or controlled. Besins is thus suffering a "punishment" that the rules of disgorgement do not allow.

Contorinis is also factually distinguishable on its face. Even in the context of a tipper's misconduct, a tipper cannot be held financially liable for the tippee's gains unless it is first established that the tipper benefited. *See U.S. v. Salman*, 137 S. Ct. 420, 427 (2016) (disclosure of confidential information by a tipper without personal benefit does not support imposing responsibility on the tipper). Here, there is no evidence that Besins benefitted within the meaning of *Contorinis* or *Salman* from the suits it filed in 2011.

Moreover, this Court has never adopted or endorsed *Contorinis* or its reasoning in any context.[8] Especially given the doubt cast over *Contorinis* by the Supreme Court, the Court should not do so here. Taking that step would extend the law of disgorgement without warrant and would undermine this Court's decisions emphasizing that disgorgement awards must not be punitive.

Finally, the district court's concern over "allowing Besins to enrich unjustly its affiliates through the filing of sham lawsuits," JA165, ignores that the FTC had available to it a legal mechanism to attempt to recover monies received by Besins's affiliates, but it failed to pursue that path. Where a government agency seeks

[8]Other than the decision below, *Contorinis* has been cited only once within this Circuit – for an ancillary point not relevant here. *SEC v. Huang*, 2016 WL 775764, at *3 nn.2 & 4 (E.D. Pa. 2016).

disgorgement of monies in the possession of a third party not responsible for wrongdoing, the agency names the party as a "relief defendant." The FTC is quite familiar with this procedure. *See, e.g., FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 311 (D. Mass. 2008); *FTC v. Transnet Wireless Corp.*, 506 F. Supp. 2d 1247, 1273 (S.D. Fla. 2007); *FTC v. AmeriDebt*, 343 F. Supp.2d 451, 464 (D. Md. 2004); *FTC v. Think Achievement Corp.*, 144 F. Supp. 2d 1013, 1020 (N.D. Ind. 2000). The FTC chose not to do so here, however, instead proceeding solely against Besins to reach royalties that AbbVie paid to Besins's European affiliates.

Courts "may only require disgorgement of the assets of a relief defendant upon a finding that [the relief defendant] lacks a legitimate claim" to the assets sought. *FTC v. LeadClick Media LLC*, 838 F.3d 158, 177 (2d Cir. 2016). If the relief defendant has a legitimate claim, the monies sought can be obtained only if the relief defendant is made a full defendant and the agency shows that it participated in the wrongdoing. *See, e.g., SEC v. Ross*, 504 F.3d 1130, 1142, 1145 (9th Cir. 2007). For example, where a relief defendant provided valuable consideration in good faith for the money—such as extending a loan to the defendant—the money is beyond the reach of disgorgement. *LeadClick*, 838 F.3d at 177-78. *See also Janvey v. Adams*, 588 F.3d 831, 835 (5th Cir. 2009) (debtor-creditor relationship constitutes legitimate ownership interest defeating

disgorgement); *SEC v. Quan*, 2014 U.S. Dist. LEXIS 131618 (D. Minn. Sept. 19, 2014) (defendant's wife had independent, legitimate interest in jointly owned home).

Here, the royalties sought by the FTC were at all times in the hands of non-party foreign Besins affiliates and paid pursuant to the 1995 License Agreement. To recover royalties contractually paid by AbbVie to Besins's European affiliates, the FTC could have named LBI and Besins SARL as relief defendants and sought to prove that they lacked legitimate claims to the money. Instead, the district court accepted the FTC's invitation to hold Besins financially responsible for royalties AbbVie paid the Besins European affiliates, regardless of whether those affiliates had legitimate interests in the royalties received. That truncated procedure, which essentially treated Besins and its non-party affiliates as one entity for recovery purposes, improperly relieved the FTC of its burden to show that the royalties did not represent legitimate consideration under the 1995 agreement and improperly punished Besins by requiring it to disgorge monies it never received or controlled. That result violates this Court's directive that equitable relief must not descend to punitive retribution.

CONCLUSION

For the reasons stated here and in the AbbVie brief, the FTC's appeal should be rejected, and the judgment against Besins should be reversed.

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June 5, 2019

CERTIFICATE OF BAR MEMBERSHIP (LAR 46.1)

Pursuant to Third Circuit Local Appellate Rule 46.1, I, Melinda F. Levitt, hereby certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

/s/ Melinda F. Levitt
MELINDA F. LEVITT

Pursuant to Third Circuit Local Appellate Rule 46.1, I, Paul H. Saint-Antoine, hereby certify that I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

/s/ Paul H. Saint-Antoine
PAUL H. SAINT-ANTOINE

June 5, 2019

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 28.1(e)(2)(B)(i) as modified by this Court's May 22, 2019 Order.

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(f), the brief contains 5,737 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(g), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

3. In addition, pursuant to Third Circuit Local Appellate Rule 31.1(c), I certify that the text of the brief filed with the Court via CM/ECF is identical to the text of the paper copies. I further certify that the electronic version of the brief has been scanned for viruses by Microsoft System Center Endpoint Protection Version 1.295.40.0 (updated continuously) and is, according to that program, free of viruses.

/s/ Melinda F. Levitt
MELINDA F. LEVITT

June 5, 2019

CERTIFICATE OF SERVICE

I hereby certify that on this 5th Day of June, 2019, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Third Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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