ORAL ARGUMENT NOT YET SCHEDULED

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUBMIA CIRCUIT

NO. 12-5393

FEDERAL TRADE COMMISSION,
Petitioner-Appellant,

v.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,
Respondent-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA (NO. 1:09-MC-00564-JMF)

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

1. Parties

The Federal Trade Commission ("Commission" or "FTC") was the petitioner before the district court and appears as appellant before this Court.

Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer" or "BIPI") was the respondent before the district court and appears as appellee before this Court.

2. Ruling Under Review

The ruling under review consists of the memorandum opinion and the associated order entered by the district court on September 27, 2012, which addressed attorney work-product claims. Dkt. 69, 70 [JA-144-64]. The district court entered a companion ruling on search issues on October 16, 2012, Dkt. 71, 72 [JA-165-72].

3. Related Cases

This case has not previously been before this Court. No related cases are pending before this Court or any other court.

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GLOSSARY

Barr	Barr Pharmaceuticals, Inc. (including its wholly-owned subsidiary, Duramed Pharmaceuticals, Inc.)
BIPI	Boehringer Ingelheim Pharmaceuticals, Inc.
Boehringer	Boehringer Ingelheim Pharmaceuticals, Inc.
Commission	Federal Trade Commission
Dkt.	Docket entry in district court case below (*FTC v. Boehringer Ingelheim Pharmaceuticals, Inc.*, Case 1:09-mc-00564-JMF (D.D.C.))
FDA	Food & Drug Administration
FOIA	Freedom of Information Act, 5 U.S.C. § 552 (2006), *amended by* Open Government Act of 2007, Pub. L. No. 110-175, 121 Stat. 2524
FTC	Federal Trade Commission
FTC Act	Federal Trade Commission Act, 15 U.S.C. §§ 45-58

INTRODUCTION

The Supreme Court recently held that "reverse-payment" settlements of pharmaceutical patent litigation are subject to antitrust scrutiny and that the central question in assessing such an agreement is whether the branded drug firm's payment to the generic challenger is justified—that is, shown to be for something other than avoiding the risk of competition. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236 (2013). This appeal concerns the ability of the Federal Trade Commission ("Commission" or "FTC") to obtain the most direct evidence on that question: contemporaneous financial analyses, including analyses of purportedly independent business arrangements. In *Actavis*, the Court noted that the settling parties claimed the payments to the generic drug firms were "compensation for other services the generics promised to perform," while the FTC complaint alleged that the payments were compensation for the generics' agreement not to compete until 2015. *Id.* at 2229. The complaint in that case relied on an internal financial analysis by the branded drug manufacturer (at that time Solvay) of various settlement scenarios, which was an exhibit to the complaint.

The current inquiry probes similar antitrust concerns and gives rise to a similar need for the same types of financial records. As discussed below, branded-drug manufacturer Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer" or "BIPI") simultaneously entered into two agreements with a generic-drug manufacturer, and it claims the two agreements were independent. The first was a settlement of patent litigation between the two companies, in which the generic manufacturer agreed to delay competitive generic entry for a period of years. The second was a "co-promotion agreement," in which Boerhinger agreed to pay the generic manufacturer to promote Boerhinger's own branded drugs. The FTC's investigation focuses on whether these two agreements are indeed independent. Are the very large sums Boerhinger agreed to pay the generic manufacturer only for these promotional services? Or are they side-payments for an anticompetitive agreement to delay generic entry and share the ensuing monopoly profits? Boerhinger's internal financial and business analysis of these deals is directly relevant to answering these questions.

The district court order challenged here frustrates that investigation. The court made a sweeping, categorical ruling that Boehringer could withhold as opinion work product hundreds of documents containing such financial or business analyses, including *every* analysis of the co-promotion agreement. It reasoned that "the co-promotion agreement was an integral part of the litigation," Dkt. 69 at 10 [JA-153], even though Boehringer has repeatedly insisted that the co-promotion agreement was a freestanding business transaction, distinct from the settlement. Moreover, the district court based its decision to a significant extent on two *ex parte* affidavits from Boehringer's counsel, even though sworn testimony of

Boehringer executives contradicts the conclusion the court drew from these affidavits. In the course of these rulings, the district court misapplied this Circuit's precedent and reached an erroneous and overbroad conclusion as to the scope of work-product protection. This Court should reverse.

JURISDICTION

The district court had subject-matter jurisdiction pursuant to 15 U.S.C. § 49 (authorizing district courts to enforce FTC subpoenas) and 28 U.S.C. §§ 1331, 1337, and 1345. On September 27 and October 16, 2012, the district court entered orders that, collectively, resolved all claims in this case, granting in part and denying in part the FTC's subpoena enforcement petition. Dkts. 69-72 [JA-144-72].

As a panel of this Court has already ruled, the Court has jurisdiction over this appeal pursuant to 28 U.S.C. § 1291. The district court's September 27 and October 16, 2012, orders were final and appealable. *See FTC v. Boehringer Ingelheim Pharm., Inc.*, No. 12-5393, Order (D.C. Cir., April 12, 2013) (*per curiam*) (denying Boehringer's motion to dismiss for lack of jurisdiction); *see also FTC v. Texaco, Inc.*, 555 F.2d 862, 873 n.21 (D.C. Cir. 1977) (*en banc*); *U.S. v. Legal Services for N.Y.C.*, 249 F.3d 1077, 1081 (D.C. Cir. 2001). The Commission filed a timely notice of appeal on December 11, 2012. Dkt. 77 [JA-173-74]. *See* Fed. R. App. P. 4(a)(1)(B)(ii).

ISSUES PRESENTED FOR REVIEW

1. Whether the district court committed legal error when it treated all business and financial analyses requested by in-house counsel as opinion work product.

2. Whether the district court committed legal error when it failed to examine whether any of the documents, including documents analyzing a "freestanding," "fair arms-length business arrangement," would have been prepared in essentially similar form irrespective of litigation and thus were not work product.

3. Whether the FTC has shown substantial need for Boehringer's factual work product and whether the district court erroneously applied a heightened standard of need.

4. Whether the district court abused its discretion when it accepted *ex parte*, *in camera* affidavits, to which the FTC has still been denied access, without determining that they were "absolutely necessary" to assess Boehringer's work-product claims and that the need for secrecy "outweighed other crucial interests."

STATEMENT OF THE CASE

A. Nature of the Case, Course of Proceedings, and Disposition Below

On February 5, 2009, the FTC issued a subpoena *duces tecum* to Boehringer seeking documents relevant to an investigation into whether Boehringer, Barr

Pharmaceuticals, Inc. (“Barr”), and their affiliates engaged in unfair methods of competition in or affecting commerce, in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, with respect to the sale of two Boehringer drug products, Aggrenox and Mirapex. Specifically, the FTC is investigating whether Boehringer unlawfully paid Barr not to launch competing generic versions of Aggrenox and Mirapex as part of a patent litigation settlement. *See Actavis*, 133 S. Ct. at 2237. After Boehringer failed to comply with several of the subpoena’s terms, the FTC filed a petition for enforcement in the U.S. District Court for the District of Columbia on October 23, 2009. Dkt. 1 [JA-10-66].

In proceedings before the district court, the FTC challenged, *inter alia*, Boehringer’s refusal to produce hundreds of financial analyses and other similar documents based on claims of attorney-client privilege and the work-product doctrine. On September 27, 2012, the district court issued an order addressing these claims. It held that all of the withheld financial analyses prepared in connection with the settlement of the Aggrenox and Mirapex patent litigation—including all analyses related to the business agreement that Boehringer entered into with Barr at the time of settlement—constituted opinion work product subject to the “virtually undiscoverable” standard, rather than the substantial-need standard generally applied to work-product claims. It did so on the grounds that the analyses (1) had been prepared at the request of Boehringer’s general counsel, (notwithstanding sworn testimony that at least some were created by non-attorneys without input from legal personnel); and (2) were intended to "aid in the settlement process" even though some of the documents were prepared well before settlement negotiations began, or up to eight months after the settlement was executed.[1] The court resolved the remaining claims raised in the subpoena enforcement action in a companion decision issued October 16, 2012.

This appeal followed.

B. Statement of Facts

Commission staff sought access to the documents withheld by Boehringer in order to further the FTC's investigation of Hatch-Waxman patent settlements involving "reverse-payment" agreements. Typically, when a patentee sues an alleged infringer, a settlement may involve the alleged infringer's paying the patentee. In a reverse-payment settlement, the alleged infringer agrees not to enter the market for a period of time, and "the settlement requires the patentee to pay the alleged infringer, rather than the other way around." *Actavis*, 133 S. Ct. at 2227. This form of settlement "tend[s] to have significant adverse effects on competition," *id.* at 2231, because it can amount to a sharing of monopoly profits

[1] Boehringer stated that "the patent litigation settlements with Barr [] were negotiated and executed between March and August 2008." Dkt. 37 at 36 [JA-655]. Almost 200 withheld documents pre-date March 2008, and over 30 documents are dated up to eight months after August 2008. Dkt. 32, Ex. B Decl. Exs. 11-16 [JA-287-560].

in order to prevent the risk of competition. *Id.* at 2236; *see also* 12 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 2046c, at 338 (3d ed. 2012) ("In such cases a settlement agreement effectively 'preserves' the patent, thus giving the two firms the joint-maximizing, or monopoly, output.")

According to the Supreme Court, the antitrust analysis of reverse-payment settlements focuses on the size of, and potential justifications for, the payment. *Actavis*, 133 S. Ct. at 2236 ("Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons?"). In this investigation, Boehringer agreed to pay Barr more than $100 million, purportedly as part of a co-promotion agreement executed at the same time as the settlement. The Commission seeks to determine whether this payment was "compensation for other services that the generic has promised to perform," or if it was for Barr's agreement to forgo entry. *Id.* The withheld financial analyses are the only direct evidence of how Boehringer contemporaneously valued the co-promotion agreement.

1. FTC investigation of Hatch-Waxman settlements and reverse-payment agreements

Reverse-payment settlements typically arise in the context of the Hatch-Waxman Act, a streamlined regulatory framework established by Congress to encourage generic-drug entry and under which a generic-drug manufacturer may obtain approval of its product from the Food and Drug Administration ("FDA").

When a company seeks FDA approval to market a generic version of a brand-name drug before expiration of a patent covering that drug, the generic applicant must certify that the patent in question is invalid or not infringed by the generic product (a "Paragraph IV" certification). 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This system encourages challenges to patents that may be invalid. *See Actavis*, 133 S. Ct at 2234. Once a generic files a Paragraph IV certification, the patent holder may bring suit immediately, even before the generic applicant markets its product. 35 U.S.C. § 271(e)(2). Paragraph IV patent challenges sometimes result in reverse-payment settlements, as described above.

In 2003 Congress amended the Hatch-Waxman regime, seeking, in part, to eliminate the "abuse of the Hatch-Waxman law" resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market." S. Rep. No. 107-167, at 4 (2002). Among these changes, Congress created a mechanism for agency review and investigation of potentially anticompetitive agreements. *See* 2003 Medicare Amendments to Hatch-Waxman Act, Pub. L. No. 108-173, §§ 1111-1118; *Actavis*, 133 S. Ct. at 2234. As part of its antitrust enforcement mandate, the FTC investigates Hatch-Waxman settlement agreements to determine whether they unlawfully restrain trade.

In these investigations, the FTC often relies on companies' internal financial analyses and business forecasts to determine whether the branded firm has compensated the generic firm for delayed entry. Compensation rarely takes the form of explicit cash payments; instead, the settling firms typically include the payment in a separate business deal executed simultaneously with the settlement.[2] In these cases, the FTC assesses whether the side deal is an independent business transaction or instead an inducement offered to persuade the generic firm to delay entry. Financial forecasts and analyses of the deals are often the only direct evidence of whether the branded firm believed the deal to be economically freestanding or whether it instead viewed the deal as worth entering only because of the additional profits gained through delayed generic entry. This evidence would

[2] Before the FTC began investigating reverse-payment settlements, payments were often made part of the settlement. Since then, parties to these agreements have often conveyed payments via side deals. *See, e.g.*, FTC Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2009 (2010) (cataloguing potential pay-for-delay agreements, including nine that included a "side deal") (*available at* http://www.ftc.gov/reports/mmact/MMAreport2009.pdf); *see also* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 663 (2009) ("Today, side deals take two complementary forms: overpayment by the brand-name firm for value contributed by the generic firm, and underpayment by the generic firm for value provided by the brand-name firm.").

indicate the purpose and likely effect of the deal and thus help the Commission determine whether it was an anticompetitive reverse payment.

2. Mirapex and Aggrenox agreements

In this investigation, the FTC is examining whether a patent litigation settlement and a simultaneously executed co-promotion agreement between Boehringer and Barr together constitute an unlawful reverse-payment agreement. The investigation involves two Boehringer branded products: Mirapex (pramipexole), which is used to treat the symptoms of Parkinson's Disease, and Aggrenox (aspirin and extended-release dipyridamole), which is used to prevent excessive blood clotting and reduce the risk of stroke. Dkt. 1-1 at 3 [JA-22]. When Barr filed Paragraph IV certifications for both of these drugs, Boehringer promptly filed infringement suits. *Id.* [JA-22].

In August 2008, Boehringer and Barr entered simultaneous agreements settling the patent litigations. *Id.* at 4 [JA-23]. At that time, the Aggrenox litigation was still in its early stages, *id.* [JA-23], but the district court in the Mirapex litigation had declared Boehringer's patent invalid. *Boehringer Ingelheim Int'l GMBH v. Barr Labs., Inc.*, 562 F. Supp. 2d 619 (D. Del. 2008). (This decision was subsequently reversed on appeal, in litigation with a different generic firm. *Boehringer Ingelheim Int'l GMBH v. Barr Labs., Inc.*, 592 F.3d 1340 (Fed. Cir. 2010).)

Under the settlement agreements, Barr agreed not to market generic Mirapex until January 2010 and generic Aggrenox until July 2015. Dkt. 1-1 at 4 [JA-23]. At the same time, the companies entered into a co-promotion agreement in which Boehringer agreed to provide substantial compensation to Barr purportedly in exchange for its efforts promoting branded Aggrenox to women's health doctors. *Id*. [JA-23]. The FTC's investigation focuses in large part on whether Boehringer used this co-promotion agreement to pay Barr not to compete with Mirapex or Aggrenox.

3. FTC investigation and Boehringer privilege claims

On January 15, 2009, the Commission issued a Resolution Authorizing Use of Compulsory Process in Nonpublic Investigation. The Resolution authorized compulsory process to be used in connection with the investigation, to determine "whether Boehringer . . . and Barr . . . [have] engaged or [are] engaging in unfair methods of competition in or affecting commerce, in violation of Section 5 of the [FTC Act,] with respect to the sale of Aggrenox or its generic equivalents and Mirapex or its generic equivalents." Dkt. 1-2 at 2 [JA-30]. On February 5, 2009, the Commission issued the subpoena at issue in this appeal. Dkt. 1-3 [JA-31-46]. The subpoena specified 37 categories of documents, including documents related to the Aggrenox and Mirapex patent litigation, documents related to the sales, profits, and marketing plans for Aggrenox and Mirapex (including forecasts of generic entry), and documents related to the Aggrenox co-promotion agreement. Dkt. 1-1 at 4-5 [JA-23-24]. Eight months later, Boehringer still had not certified compliance with the subpoena. *Id.* at 9 [JA-28]. Accordingly, on October 23, 2009, the FTC filed a petition in the United States District Court for the District of Columbia for an order enforcing the subpoena. Dkt. 1 [JA-10-66]. The petition alleged that Boehringer had failed to completely produce responsive documents and used inadequate search procedures. *Id.* at 8-9 [JA-17-18].

After the FTC filed its petition for enforcement of the subpoena, the parties exchanged correspondence in an effort to settle the outstanding issues, including their disagreements about whether Boehringer had legitimately withheld or redacted a large number of documents based on disputed attorney-client privilege and work-product assertions. *See* Dkt. 32, Ex. B Decl. Ex. 17 at 1 [JA-562]. This appeal challenges the district court's ruling only as it applies to Boehringer's work-product claims.[3]

[3] Boehringer asserted both work-product protection and attorney-client privilege for many of the challenged documents. Because the district court found that the challenged analyses and forecasts were opinion work product, it did not resolve whether any such documents were protected by the attorney-client privilege. The FTC is appealing only the court's determination that these analyses were opinion work product. The FTC is not appealing the district court's determination with regard to documents for which only attorney-client privilege was claimed. *See* Dkt. 69 at 15 [JA-158].

Boehringer claimed attorney-client privilege or work product with regard to 3,420 documents. *See* Dkt. 32, Ex. B at 5 [JA-226]; Dkt. 32, Ex. B Decl. Ex. 17 at 1 [JA-562]. Based on Boehringer's descriptions in its log and the sworn testimony of Boehringer personnel, the FTC challenged 631 of those claims, including claims of protected status for business documents "regarding" or "prepared as a result of" patent litigation or analyzing settlement options and business documents analyzing the Aggrenox co-promotion agreement. Dkt. 32, Ex. B Decl. Ex. 17 [JA-561-69]. A number of these documents even post-dated the settlement. *Id.* at 1-2, App. A [JA-562-63, 568-69].[4] For purposes of this appeal, the challenged documents fall into two major categories:

(1) Non-legal business documents "regarding" or "prepared as a result of" patent litigation or analyzing settlement options. The FTC identified over 300 documents that the privilege log describes as "regarding" or "prepared as a result of" the patent litigation, which were circulated to business executives and prepared primarily by non-lawyers. Similarly, it identified 55 documents analyzing settlement options that appear to be non-legal business documents. *Id.* at 2, App. A [JA-563, 568-69]. These documents are primarily financial forecasts of generic entry or the financial impact of settlement options. *See* Dkt. 32, Ex. B at 6-7 [JA-

[4] *See supra* note 1.

227-28]. For example, document no. 833 is a spreadsheet sent from Tom Buckley, a non-lawyer, to Paul Fonteyne, a senior business executive, copying numerous other business executives. The privilege log, however, describes the document as "Analyses of '577 and '086/'812 Patent Litigations prepared as a result of litigation." Dkt. 32, Ex. B Decl. Ex. 11 at 60 [JA-347]. Document no. 992 is a PowerPoint found in the files of non-lawyer Steve Marlin (as to which Boehringer did not supply author information and which was not circulated) described in the privilege log as "Analysis of '577 Patent Litigations and settlement strategy prepared as a result of litigation." *Id.* at 75 [JA-362]. The FTC objected to Boehringer's withholding these and similar documents, arguing that documents created by non-lawyers for business purposes (such as informing business decisions) are not work product.

The sworn investigational hearing testimony of Boehringer personnel confirms that many of these documents consist of non-legal, financial analyses. For example, Paul Fonteyne, who is listed in the privilege log as the creator or recipient of many of the disputed documents, testified that his role was to provide "commercial input" consisting of "mostly financial analyses." Dkt. 32, Ex. B Decl. Ex. 20 at 41, 48 [JA-598-99]. Fonteyne's testimony reinforces what the privilege log suggests: many of these documents are simply business documents created to inform business decisions.

(2) Non-legal business documents analyzing the Aggrenox co-promotion agreement. The FTC also identified a number of documents, including seven submitted *in camera*, related solely to the Aggrenox co-promotion agreement, which Boehringer maintains was an "arms-length business arrangement" separate from the patent-litigation settlement. *See* Dkt. 32, Ex. B Decl. Ex. 18 at 7 [JA-577]. For example, document no. 1090, sent from non-lawyer Hanbo Hu to non-lawyer Fonteyne, is a PowerPoint "Analysis regarding possible Aggrenox co-promotion agreement relating to '577 Patent Litigation settlement prepared as a result of litigation." Dkt. 32, Ex. B Decl. Ex. 17 at 4, App. A [JA-565, 568-69].[5] Despite its position that the co-promotion was a separate economic transaction, Boehringer contended that these documents were work product because the co-promotion agreement "relates to" the patent-litigation settlement. *Id.* [JA-565, 568-69].

Boehringer testimony again indicates that these documents were focused on the financial, not legal, implications of the co-promotion agreement. Elizabeth Cochrane, a financial executive who created many of the analyses, testified that her role was to "quantify the Duramed [a Barr subsidiary] copromotion," which entailed evaluating "the financial impact to [Boehringer]'s P&L, profit and loss

[5] This document was included on the list of documents that the parties agreed would be submitted to the district court *in camera*, but the district court did not rule on this document. *See infra* note 6.

statement." Dkt. 32, Ex. B Decl. Ex. 3 at 21:6-22:16 [JA-242-43]. Paul Fonteyne, who was also closely involved in creating the analyses, testified that his role was to provide "commercial input" on the deal. Dkt. 32, Ex. B Decl. Ex. 20 at 48:7-9 [JA-599]. Some or all of these analyses appear to have been conducted in order to evaluate the financial (rather than legal) implications of the Aggrenox co-promotion agreement, which, again, Boehringer insists was a separate economic transaction. Dkt. 32, Ex. B Decl. Ex. 18 at 7 [JA-577].

4. District court proceedings

Ultimately, the parties failed to reach agreement as to the privilege claims or other issues in dispute. *See* Dkt. 32, Ex. B Decl. Ex. 9 [JA-282-83]; *Id.* Decl. Ex. 10 [JA-284-86]. Boehringer nonetheless certified its compliance with the subpoena on April 19, 2010. *See* Dkt. 15 at 2 [JA-68]; Dkt. 32, Ex. B Decl. Ex. 2 [JA-233-39]. The parties briefed the two disputed issues in 2010. After district court-supervised mediation failed to result in settlement, the district court held a status hearing on December 9, 2011. Dkt. 59 [JA-72-143]. As part of the proceeding, the parties mutually agreed on 87 sample documents to submit to the district court for *in camera* review. *See* Dkt. 69 at 3-4 [JA-146-47].

More than a year after the parties had briefed the disputed work-product issues and on the eve of the hearing, Boehringer submitted *ex parte* affidavits from Marla Persky, Boehringer's general counsel, and Pamela Taylor, who is outside counsel representing Boehringer in the FTC investigation and who had no contemporaneous involvement in the settlements or co-promotion agreement. *See* Dkt. 69 at 10-11 [JA-153-54]. Apparently relying on these affidavits, Boehringer argued that the withheld analyses of the settlement and the co-promotion were "specifically asked for by [Persky], either directly or indirectly." Dkt. 59 at 19 [JA-90]. Because Boehringer did not disclose the affidavits or their content to the FTC, the FTC had no opportunity to review or respond to them and objected to their submission. *Id.* at 4-5 [JA-75-76].[6]

On September 27, 2012, almost a year after the status hearing and more than three years after the FTC filed its enforcement petition, the district court issued its opinion and order on Boehringer's work-product claims. Dkt. 69 and 70 [JA-144-64]. It held all of the withheld financial analyses were requested by counsel to assist in settlement negotiations and so were "opinion" work product, the

[6] The affidavits appear to have placed additional documents before the district court for *in camera* review that were not part of the parties' agreement on the *in camera* submission. The district court's September 27, 2012, decision ruled on 101 documents, not the 87 agreed upon. Of the 101, 27 (nos. 1365, 1367, 1368, 902, 2918, 2919, 2920, 1580, 1984, 2250, 233, 790, 791, 2495, 2578, 2983, 780, 1008, 1016, 1001, 3327, 1364, 2917, 3057, 616, 1308, and 2945) were not covered by the agreement, and of those 27, 14 (nos. 1580, 2250, 233, 790, 2495, 2578, 2983, 780, 1001, 3327, 2917, 3057, 1308, and 2945) were not even contested by the FTC. The district court also failed to rule on 13 documents (nos. 3171, 3296, 2331, 1384, 1380, 1363, 1339, 1294, 1095, 1154, 1084, 1090, and 1029) that were jointly submitted.

disclosure of which would "necessarily" reveal the attorneys' thought processes. Dkt. 69 at 12 [JA-155]. The district court specifically addressed the disputed documents containing analyses of the Aggrenox co-promotion agreement, stating that the agreement "was an integral part of the settlement." Dkt. 69 at 10 [JA-153]. It acknowledged, but did not accord significance to, the tension between this conclusion and Boehringer's continuing claim that the co-promotion agreement was "freestanding" and independent from the settlement agreement as a business matter. *Id.* [JA-153].

As support for its holding that these analyses reflected Persky's mental impressions, the district court cited primarily the pair of *in camera* affidavits from Persky and Taylor. *Id.* at 11 [JA-154]. According to the court, BIPI attorneys supplied "information and frameworks" to be used in these analyses. *Id.* [JA-154] Further, it held that any factual work product in those documents could not be segregated from the opinion work product because disclosing "any aspect" of the analyses would shed light on the nature of the attorney's request. *Id.* at 12 [JA-155]. The court did not discuss the sworn investigational hearing testimony (which the FTC had presented in its briefs) in which Persky and other Boehringer witnesses stated that Persky did not provide input or assumptions to guide the creation of these financial analyses.

Having deemed all of the financial analyses opinion work product, the district court then ruled the FTC had not demonstrated the "overriding and compelling need" required to discover this type of work product. The court stated that it was "sympathetic to the FTC's argument that these financial analyses are the only documents that could demonstrate whether or not [Boehringer] was using the co-promotion agreement to pay Barr not to compete." *Id.* at 13 [JA-156]. But in the court's view, the documents did not provide additional useful information beyond what the Commission already knew about the settlement. *Id.* at 12-13 [JA-155-56]. ("No one is pretending that the FTC is not fully aware of the deal that was made or the economic benefits the deal makers were trying to achieve."). The court declared "there are no smoking guns contained in these documents." *Id.* at 12 [JA-155]. Further, it believed that "the arithmetical calculations of various potential scenarios … are not in any way evidence of any conspiratorial intent to violate the law" and "do not cast any light on the fundamental legal issue of whether the deal was or was not anti-competitive in intendment or result." *Id.* at 13 [JA-156]. The district court announced this conclusion without addressing issues such as how the Commission might analyze or use the financial and quantitative data in the documents as part of its investigation, what legal and economic theories the

Commission and its staff might consider, or what other documents and data the Commission might be able to consider in conjunction with these calculations.[7]

SUMMARY OF ARGUMENT

The district court applied an indiscriminate, categorical approach to the work product doctrine that contradicts this Court's precedent and established work-product principles. First, the district court erroneously concluded that every financial and generic entry analysis prepared by non-lawyers at the request of Boehringer's general counsel necessarily conveyed the mental impressions of counsel and was thus subject to the heightened "opinion" work-product standard rather than the normal standard for "factual" work product. That holding contradicts settled precedent: documents prepared by non-lawyers in response to a general request from a lawyer are *not* opinion work product simply because they might indirectly shed some weak light on the lawyer's thought processes. Because it erroneously concluded otherwise, the district court categorically suppressed all of the relevant documents in their entirety and failed to require Boehringer to evaluate whether particular documents or portions of documents contained only

[7] The parties have also disputed whether Boehringer failed to conduct centralized electronic searches of its records and improperly maintained documents. *See* Dkt. 32, Ex. B. Decl. Ex. 7 at 1 [JA-274]. On October 16, 2012, the district court issued a second opinion resolving the parties' dispute over the backup tape search, fully resolving all outstanding issues before it on that question. Dkt. 71, 72 [JA-165-72]. This appeal deals only with the district court's work-product decision.

"factual" work product that could be produced. Testimony from Boehringer witnesses, admissions from counsel, and the district court's own characterization of the documents prevent any reasonable inference that this entire category of documents amounts to opinion work product.

Second, the district court erred by failing to consider whether any of the withheld documents would have been created in essentially similar form irrespective of the litigation. Such documents were not created "because of" litigation, and are therefore not work product at all. This error was particularly significant with regard to the withheld analyses of the Aggrenox co-promotion, a purportedly freestanding, "arms-length" business deal. Record evidence, including testimony from Boehringer personnel, as well as common sense, indicates that Boehringer would have conducted ordinary-course financial analyses before entering the co-promotion agreement—a $120 million deal. Yet Boehringer has withheld every contemporaneous financial analysis of the agreement as work product.

Third, the FTC has shown substantial need for Boehringer's factual work product. To the extent that the district court required a higher showing than substantial need, it misperceived the applicable legal standard and abused its discretion by substituting the court's assessment of the investigation's merits for the FTC's own. The FTC amply demonstrated below that Boehringer's contemporaneous analyses of the settlement and co-promotion agreement are highly relevant and otherwise unavailable.

Finally, the district court abused its discretion by relying on *in camera, ex parte* affidavits from Boehringer's general counsel and outside counsel to conclude that virtually all of the over 600 documents withheld by Boehringer were created at Persky's request for the purpose of aiding the Aggrenox and Mirapex patent litigation. Boehringer made no attempt to show that the *ex parte* affidavits were "absolutely necessary" to decide a dispute over work-product protection, and the district court erroneously failed to require such a showing. Moreover, record evidence casts doubt on the reliability of these affidavits. In these circumstances, it was an abuse of discretion for the district court to rely on Boehringer's *ex parte* representations.

STANDARD OF REVIEW

In subpoena enforcement cases, this Court undertakes a *de novo* review of whether a district court applied the correct legal standard. *See U.S. Int'l Trade Comm'n v. ASAT, Inc.*, 411 F.3d 245, 253 (D.C. Cir. 2005); *FTC v. Texaco, Inc.*, 555 F.2d 862, 876 n.29 (D.C. Cir. 1977) (*en banc*). Where the district court misperceives the applicable legal standard, no deference is due. *See In re Subpoena Served upon the Comptroller of the Currency*, 967 F.2d 630, 633 (D.C. Cir. 1992). In other respects, a district court's decision is reviewed "for arbitrariness or abuse of discretion." *FTC v. GlaxoSmithKline*, 294 F.3d 141, 146 (D.C. Cir. 2002) (quoting *In re Sealed Case*, 146 F.3d 881, 883 (D.C. Cir. 1998)).

ARGUMENT

I. THE DISTRICT COURT APPLIED AN INCORRECT LEGAL STANDARD IN RULING ON BOEHRINGER'S WORK-PRODUCT CLAIMS

A. The District Court Erroneously Deemed All Withheld Financial and Generic Entry Analyses as Opinion Work Product Because They Were Requested by Counsel

The district court made a blanket determination that virtually all of the categories of documents challenged by the FTC were opinion work product, including Excel spreadsheets and other documents calculating the financial impact of generic entry, documents analyzing the financial impact of proposed settlement terms, and documents analyzing the profitability of the Aggrenox co-promotion agreement. Rather than evaluating which of the withheld documents actually contained mental impressions of counsel, the court categorically concluded that any analysis requested by counsel "necessarily" conveyed the mental impressions of counsel, Dkt. 69 at 11 [JA-154]:

> [A] disclosure of any aspect of the financial analyses would *necessarily* reveal the attorneys' thought processes regarding the BIPI-Barr settlement. The reports in question were prepared at the behest of BIPI attorneys, who requested that certain data be entered and manipulated to determine whether various settlement options were beneficial to BIPI. Revealing the data chosen for this analysis would *necessarily* reveal the attorneys' mental impressions, including, at a bare minimum, that the attorneys believed such analyses of that

> data was necessary or important to determining an appropriate settlement.

Id. at 12 [JA-155] (emphasis added). But such a request is not a sufficient legal basis for presuming that these analyses reveal opinion work product, particularly where, as here, counsel did not choose the inputs or assumptions that Boehringer business people used in the analyses. *See* Part I.A.2, *infra*. In effect, the district court applied a rule that extends work-product protection "to every written document generated by an attorney." *Senate of the Com. of Puerto Rico on Behalf of the Judiciary Comm. v. U.S. Dept. of Justice*, 823 F.2d 574, 586 (D.C. Cir. 1987) (internal quotation and cite omitted). That was reversible error.

1. An attorney's request for a document does not necessarily make it opinion work product

The work-product doctrine protects an attorney's legal analyses and preparations from intrusion by opposing parties and their counsel. *Hickman v. Taylor*, 329 U.S. 495, 510-11 (1947). *U.S. v. Deloitte LLP*, 610 F.3d 129, 130 (D.C. Cir. 2010) (noting that work-product doctrine protects documents created "because of" litigation). A party may still discover work product, however, based on a showing of substantial need for the materials and undue hardship in acquiring the information in any other way. Fed. R. Civ. P. 26(b)(3);[8] *Dir., Office of Thrift*

[8] While the FTC Act, 15 U.S.C. §§ 46, 49, and case law, *see, e.g., U.S. v. Morton Salt Co.*, 338 U.S. 632 (1950); *Texaco*, 555 F.2d 862, govern enforcement of

Supervision v. Vinson & Elkins, LLP, 124 F.3d 1304, 1308 (D.C. Cir. 1997). The general rule for discoverability does not apply to the narrower set of work product documents that disclose an attorney's "mental impressions, conclusions, opinions, or legal theories." Fed. R. Civ. P. 26(b)(3)(B); *U.S. v. Nobles*, 422 U.S. 225, 238 (1975). This "opinion" work product is "virtually undiscoverable." *Dir., Office of Thrift Supervision*, 124 F.3d at 1307.

The category of opinion work product is reserved for documents that "reveal[] the attorney's mental processes." *Upjohn Co. v. U.S.*, 449 U.S. 383, 400 (1981). All documents prepared for litigation arguably contain some clues as to an attorney's thinking, and a request from counsel does not automatically transform all resulting documents into opinion work product. *Dir., Office of Thrift Supervision*, 124 F.3d at 1307-08. If "every item which may reveal some inkling of a lawyer's mental impressions, conclusions, opinions, or legal theories" were to be classified as opinion work product, "the exception would hungrily swallow up the rule." *In re San Juan Dupont Plaza Hotel Fire Lit.*, 859 F.2d 1007, 1015 (1st Cir. 1988)*; see also Simon v. G.D. Searle & Co.*, 816 F.2d 397. 402 n.3 (8th Cir. 1987) ("The purpose of the work product doctrine—that of preventing discovery of a

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Commission subpoenas, the Commission recognizes work-product claims, 16 C.F.R. §§ 2.7(a)(4), 2.11, and applies federal common law concerning work product, as codified in Fed. R. Civ. P. 26(b)(3).

lawyer's mental impressions—is not violated by allowing discovery of documents that incorporate a lawyer's thoughts in . . . an indirect and diluted manner.").

"Where the context suggests that the lawyer had not sharply focused or weeded the materials," they are deemed fact work product and may be obtained on a showing of substantial need and undue burden under Fed. R. Civ. P. 26(b)(3)(A)(ii)." *In re Sealed Case*, 124 F.3d 230, 236 (D.C. Cir. 1997)*, rev'd on other grounds*, *Swidler & Berlin v. United States*, 524 U.S. 399 (1998). Although this Court has not directly articulated the "degree of selection necessary to transform facts into opinions," *Dir., Office of Thrift Supervision*, 124 F.3d at 1308, work-product cases in this and other circuits illustrate that the attorney must be more than a catalyst for the document's creation.

In the context of attorney notes memorializing witness interviews, for example, courts in this circuit have rejected the view that all such attorney notes necessarily convey the mental impressions of counsel. This Court has distinguished between "interviews conducted as part of a litigation-related investigation," in which the facts elicited "necessarily reflected a focus chosen by the lawyer," and preliminary interviews initiated by a non-lawyer that cover a wide range of topics, which may not contain opinion work product. *In re Sealed Case*, 124 F.3d at 236. Lawyer notes memorializing the second category of witness interviews are not necessarily opinion work product, even though the notes invariably involve some degree of editing and selection by the lawyer. *See U.S. v. Clemens*, 793 F. Supp. 2d 236, 252-53 (D.D.C. 2011) (discussing the degree of editing involved in *Sealed Case*, as described in Judge Tatel's dissent from the denial of *en banc* hearing, 129 F.3d 637, 638). *See also Smith v. Life Investors Ins. Co. of Amer.*, No. 2:07-cv-681, 2009 WL 2045197, at *3 (W.D. Pa. July 9, 2009) (an actuarial calculation created at the request of a lawyer was "at most, 'fact work product'" because "documents reflect only the financial calculations of [the actuary]" and "no impressions, opinions or thoughts of an attorney are revealed"). The district court erred in holding that an attorney's request necessarily transforms a document into "virtually undiscoverable" opinion work product.

2. The record indicates that few of the withheld documents actually contain the mental impressions of counsel

Despite the district court's blanket holding that any financial analysis requested by Boeheringer's attorneys is opinion work product, the record illustrates that many of the withheld documents do not reflect the mental impressions of an attorney. Boehringer witnesses testified that financial analyses lacked any substantive contribution from in-house counsel, and Persky herself testified that she provided minimal, if any, substantive input. Dkt. 32, Ex. B Dec. Ex. 19 at 117: 2-7 [JA-593]; Dkt. 37, Ex. 4 at 118:3-23 [JA-776]. She explained that she asked a senior business executive, Paul Fonteyne, to provide financial analyses that would inform the terms that would be acceptable for Boehringer for the Mirapex settlement, the Aggrenox settlement, and the Aggrenox co-promotion agreement. Dkt. 32, Ex. B Decl. Ex. 19 at 113:14-22 [JA-592]. According to Persky, Fonteyne was the key "decision-maker" regarding the terms of the Aggrenox co-promotion agreement, and was responsible for evaluating whether the agreement with Barr made sense from a "financial [and] business perspective." *Id.* at 61:1-23, 68:19-24 [JA-589-90]. Fonteyne likewise testified his role was to provide "commercial input," which consisted of "mostly financial analyses." Dkt. 32, Ex. B Decl. Ex. 20 at 48:7-16 [JA-599]. With assistance from other non-lawyers, he conducted many of the withheld financial analyses.

Both Fonteyne and Persky testified that the assumptions used to construct these analyses were generated from non-legal sources. For example, Persky testified that she had not supplied any legal assumptions about Boehringer's odds of success in the patent litigation. Dkt. 32, Ex. B Decl. Ex. 19 at 117:2-7 [JA-593]. In fact, she testified that the information flowed in the opposite direction: "I did not provide them with figures. I asked them to provide me with figures." Dkt. 37, Ex. 4 at 118:3-7 [JA-776]. And those figures concerned business, not legal matters. Fonteyne explained that he—not any legal source—was responsible for the "business constructs" of the agreement, which he considered to include: date of generic entry, royalties, Aggrenox supply (to Barr in 2015), and the Aggrenox co-promotion agreement. Dkt. 32, Ex. B Decl. Ex 20 at 64:11-21 [JA-600]. Critically, Fonteyne testified that the market information supporting the assumptions built into these financial forecasts was supplied by the marketing team. Dkt. 32, Ex. B Decl. Ex. 20 at 109:10-16 [JA-601]. The marketing team, not the legal department, supplied information on the timing of competitor launches and generic entry, including entry based on litigation. *Id.* at 109:17-110:13 [JA-601-02].

The district court's factual characterization of the withheld documents is entirely consistent with this evidence:

> From my review, there are no smoking guns contained in these documents; rather, they are the sort of *financial* analyses one would expect a company exercising due diligence to prepare when contemplating settlement options. They yield nothing more than the *arithmetical calculations* of various potential scenarios and are not in any way evidence of any conspiratorial intent to violate the law.

Dkt. 69 at 12-13 (emphases added) [JA-155-56]. The withheld documents—a series of spreadsheets, financial analyses, and forecasts—would thus appear to be "nothing but straightforward calculations from raw data, making it difficult to imagine what 'mental impressions' were involved." *In re Six Grand Jury Witnesses*, 979 F.2d 939, 945 (2d Cir. 1992).

Moreover, some withheld documents appear to have been requested by Persky only indirectly, if at all. For example, document 3058, described in the privilege log as a PowerPoint presentation authored by non-lawyer Elizabeth Cochrane and containing "Analyses of settlements of '086/'812 and '577 Patent Litigations prepared at the direction of attorney," Dkt. 32, Ex. B Decl. Ex. 15 at 13

[JA-520], was attached to a cover email sent by Persky (document 3057).[9] That cover email, sent to Dr. Alessandro Banchi, a non-lawyer member of Boehringer's Board of Directors, responded to his "request for information on the effect a co-promotion agreement with Barr would have on our financial projections." The cover email makes clear that document 3058 was requested by the Board of Directors, not Persky, and that it was created to provide financial information.

Boehringer's counsel at the status hearing admitted that some of the analyses were not directly requested by counsel. *See* Dkt. 59 at 19:22-24 [JA-90] (claiming that Persky asked for the financial analyses "either directly *or indirectly*"), 20:11-12 [JA-91] (asserting that financial analyses were "directed *at some level* by counsel"), 20:13-19 [JA-91] (admitting that the financial analyses were "delegated" to people who had no direct involvement with counsel) (emphasis added). And even those documents that were in fact requested by Persky cannot be presumed to reflect the mental impressions of counsel, given her role as the company's lead negotiator on "business terms" and "the broad economic arrangement" for "all the agreements." Dkt. 37, Ex. 4 at 70:2-12 [JA-755]; *see also id*. at 71:10-12 [JA-756] (Persky negotiated "key business terms of co-promotion agreement").

[9] The cover email, which the district court ordered to be produced to the FTC, Dkt. 69 at 13 [JA-156], was included in the *in camera* submission to the district court.

In sum, the district court's holding that an attorney's request—no matter how attenuated—necessarily transforms a document into opinion work product would extend protection "to every written document generated by an attorney," and even beyond. *Senate of Com. of Puerto Rico*, 823 F.2d at 586. As this Court and others have recognized, that approach would be "virtually omnivorous" in the range of relevant evidence it would shield from discovery. *In re Sealed Case*, 124 F.3d at 237. This Court should thus reverse and remand for application of the appropriate standard. *See Comptroller of the Currency*, 967 F.2d at 633.

B. The District Court Committed Legal Error by Failing to Require Boehringer to Redact Any Opinion Work Product

The district court's failure to order production of any work-product materials that do not include opinion, or with opinion work product redacted, underscores that its conclusion was based on a categorical presumption rather than an individualized review of the documents. It is simply implausible that the entire contents of the hundreds of withheld documents are opinion work product, or that any opinion work product is so intertwined with fact work product (or non-work product) that all of the documents must be withheld in their entirety. The district court should thus have required Boehringer to produce the documents with any opinion work product redacted.

In fact, counsel for Boehringer admitted that there was a "segregable factual portion" to the financial analyses that would be "similar to the ordinary course analysis that [Boehringer] already provided" for agreements other than those entered into at the time of the patent settlements. Dkt. 59 at 31:19-25 [JA-102].[10] And the district court itself found that the documents are "financial analyses" and "arithmetical calculations." Dkt. 69 at 13 [JA-156]. Indeed, the district court ordered production with redaction for the transmittal emails and other correspondence that accompanied the financial analyses, but inexplicably failed to require the same level of scrutiny for the analyses themselves. Dkt. 69 at 17 [JA-160].

Given this record, even protected documents "likely … include[] other information that is not work product." *Deloitte LLP*, 610 F.3d at 139. The district court's failure to require individual review and redaction reinforces the conclusion that the court committed legal error by assuming that any document resulting from counsel's request necessarily merited protection as opinion work product. Accordingly, this Court should remand the case to the district court "for the purpose of independently assessing whether the document[s were] entirely [opinion] work product, or whether a partial or redacted version of the document[s] could have been disclosed." *Id.*; *see also Washington Bancorporation v. Said*, 145

[10] He went on to state that the segregable portions would be meaningless out of context, but this is not Boehringer's decision to make.

F.R.D. 274, 278 n.7 (D.D.C. 1992) (notes and commentary constituting opinion work product can be protected with redactions).

II. THE DISTRICT COURT COMMITTED LEGAL ERROR BY FAILING TO EVALUATE WHETHER ANY OF THE WITHHELD DOCUMENTS WOULD HAVE BEEN CREATED IRRESPECTIVE OF THE LITIGATION

In addition to the district court's erroneous conclusion that all withheld financial analyses were opinion work product, the court erred by failing to consider whether any of the documents would have been created in essentially similar form irrespective of the litigation and are therefore not work product at all. *See Willingham v. Ashcroft*, 228 F.R.D. 1, 4 (D.D.C. 2005); *see also U.S. v. Adlman*, 134 F.3d 1194, 1202 (2d Cir. 1998). Sworn testimony from Boehringer witnesses establishes that many of the documents in question were straightforward financial analyses—a key subset of which relate only to a business agreement that Boehringer has repeatedly claimed was freestanding. Moreover, many of the withheld documents were created well before or after settlement negotiations.

The work-product doctrine protects only those documents created "because of" litigation. *See Deloitte*, 610 F.3d at 129. A document is prepared "because of" litigation if, "in light of the nature of the document and the factual situation in the particular case, the document can fairly be said to have been prepared or obtained because of the prospect of litigation." *Senate of the Com. of Puerto Rico*, 823 F.2d at 586 n.42 (quoting 8 C. Wright & A. Miller, Federal Practice and Procedure §

2024 at 198 (1970)). Thus, documents prepared in the ordinary course of business are not work product. *See In re Sealed Case*, 146 F.3d 881, 887 (D.C. Cir. 1998). Similarly, "if documents would have been created in essentially similar form irrespective of the litigation, it cannot fairly be said that they were created 'because of' actual or impending litigation." *Willingham*, 228 F.R.D. at 4; *Adlman*, 134 F.3d at 1202. "Even if such documents might also help in preparation for litigation, they do not qualify for protection." *Adlman*, 134 F.3d at 1202. The district court recited this standard, Dkt. 69 at 6-7 [JA-149-50], but then wholly failed to apply it.

The district court's failure to consider whether any withheld documents would have been created irrespective of the litigation arose with respect to all categories of documents, including financial and generic entry analyses. This failure, however, was particularly indefensible with regard to those documents analyzing the financial impact of the Aggrenox co-promotion agreement, which Boehringer insists was a business transaction economically independent of the settlement. Given Boehringer's position, it is implausible that it conducted financial analyses of this purportedly freestanding transaction only because of the litigation settlement. Any analyses that would have been conducted to evaluate the deal regardless of a contemporaneous settlement are not work product and must be produced.

Boehringer is taking inherently inconsistent positions on the subject of those co-promotion documents, and that inconsistency renders Boehringer's work-product claims not only untenable, but also inequitable. While the FTC continues to investigate whether the co-promotion agreement was an anticompetitive vehicle to pay Barr for delayed entry, Boehringer has repeatedly asserted that it was not, and that it instead represented an economically separate business transaction. *See* Dkt. 37 Ex. 4, at 113:3-6 [JA-772] (Aggrenox co-promotion agreement not "a vehicle to pay Barr not to compete on generic"); Dkt.32, Ex. B Decl. Ex. 18 at 7 [JA-577] (stating that the co-promotion "stands by itself" and is a "fair arms-length business arrangement"). These assertions undermine any plausible work-product claim that documents related solely to the co-promotion agreement were created "because of" the litigation settlement. Boerhinger cannot have it both ways: because it maintains that these two deals are economically separate, it must face up to the logical implication of that position in this work-product dispute.[11]

[11] If, on the other hand, Boehringer's *ex parte* affidavits represented to the district court—contrary to its court filings and sworn testimony—that the co-promotion *was* part of the consideration for the settlement, then it has advanced conflicting positions in order to gain an unfair litigation advantage, and this Court should take the appropriate remedial action. *See Recycling Solutions, Inc. v. District of Columbia*, 175 F.R.D. 407, 408 (D.D.C. 1997) ("As the adage states, privilege cannot be used both as a sword and as a shield."); *see also In re Echostar Commcns. Corp.*, 448 F.3d 1294, 1302 (Fed. Cir. 2006) (district court should "balance the policies to prevent sword-and-shield litigation tactics with the policy to protect work product"). Moreover, the FTC's inability to examine this

In particular, if there is any truth to Boehringer's repeated assertion that this was a freestanding, arms-length business transaction, a sophisticated company like Boehringer would have performed analyses to determine the financial value of the co-promotion agreement, which required payment from Boehringer in excess of $100 million.[12] Indeed, we know that Boehringer performed such analyses, but it has withheld every contemporaneous analysis of the co-promotion agreement as work product.[13] The premise of the district court's holding is that Boehringer conducted each and every one of these financial analyses only because the co-promotion agreement was being considered simultaneously with the patent litigation settlement. But that premise crashes headlong into the position Boehringer has taken in this case. Any conclusion that these analyses would *not* have been created in essentially similar form in the absence of litigation

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possibility provides further reason to question the district court's uncritical reliance on *ex parte* affidavits. *See* Part IV, *infra*.

[12] The terms of the co-promotion agreement reveal that it was a significant financial transaction. Under the agreement, Boehringer agreed to pay Barr a one-time fee plus annual, increasing royalties on total U.S. Aggrenox sales for a period of years. Dkt. 37, Ex. 19 at 14-15 [JA-903-04]. In 2008, Aggrenox had total U.S. sales of about $366 million. Dkt. 1-1 at 3 [JA-22]. At this level of sales, the FTC estimates that the deal would ultimately cost Boehringer over $120 million in royalties.

[13] The district court noted that "BIPI insists any freestanding non-litigation-based financial analyses were already disclosed to the FTC," Dkt. 69 at 11 [JA-154], but although it has produced some ordinary-course financial forecasts, Boehringer has not produced any such financial analyses for the co-promotion agreement.

necessarily presupposes that the co-promotion was a vehicle to pay Barr for the delayed entry codified in the settlement. Again, Boehringer cannot logically maintain that the deal was economically freestanding while attributing all of the analyses of the deal to the settlement.

In any event, *whatever* the relationship between the patent litigation settlement and the co-promotion agreement, the district court should have considered whether any of the analyses would have been created in essentially similar form irrespective of the litigation. Any such documents are not work product.

Testimony from Boehringer personnel confirms that their analyses were a standard part of the evaluation of a transaction of this sort. Persky testified that "[w]e negotiated with Barr the co-promote agreement … as a freestanding agreement." Dkt. 33, Ex. 2 at 112:15-23 [JA-991]. She testified that the decision to enter the agreement was a business one, *id.* at 67:16-22, 68:6-16 [JA-989-90], and said that whether the co-promotion agreement made sense from a "financial business perspective" was a "business" decision, *id.* at 68:19-24 [JA-990]. Not surprisingly, the business people who conducted the analyses testified that their role was to perform routine financial projections of the transaction.

Elizabeth Cochrane, a Boehringer executive involved in creating the withheld analyses, stated that her role was to "quantify the Duramed [Barr] copromotion," which entailed evaluating "the financial impact to [Boehringer]'s P&L, profit and loss statement." Dkt. 32, Ex. B Decl. Ex. 3 at 21:6-22:16 [JA-242-43]. The P&L analyses amounted to "simply doing the math for, if this changes, this is what it means to our P&L, a lot of adding and subtracting." *Id.* at 26:5-9 [JA-244]. The analyses described by Cochrane are precisely the kind of financial forecasts one would expect Boehringer to conduct before entering a $120 million business transaction. Indeed, Cochrane testified that when Boehringer has entered co-promotion agreements with other companies, it has conducted similar financial analyses. Dkt. 33, Ex. 3 at 72:21-23 [JA-1008].[14]

Paul Fonteyne, a Boehringer business executive, is listed as the author of many of the withheld co-promotion analyses. Dkt. 32, Ex. B Decl. Ex. 11 at 58 [JA-345] (no. 815); 82 [JA-369] (nos. 1085-88); 103 [JA-390] (no. 1341); 10 [JA-297] (no. 135); 53 [JA-340] (no. 758); 57 [JA-344] (no. 800); 59 [JA-346] (no. 819). He testified that his role was to provide "commercial input"—as opposed to legal input—on the co-promotion agreement. Dkt. 32. Ex. B Decl. Ex. 20 at 48:7-9 [JA-599]. He elaborated that commercial input consisted primarily of providing financial analysis, *id.* at 48:10-21 [JA-599] and stated that he worked with the data

[14] Since those agreements were global, the analyses were conducted at Boehringer's headquarters in Germany rather than in the U.S., and Cochrane had no specific knowledge of what they entailed. *Id.* at 72:6-20 [JA-1008].

he received from Cochrane, Dkt. 37, Ex. 6 at 49:18-23, 62:10-14 [JA-802, 806]. The testimony thus shows that Fonteyne examined the profit and loss forecasts produced by Cochrane in order to determine whether the co-promotion made commercial sense for Boehringer. These documents were standard financial projections that likely would have been created in essentially similar form irrespective of the litigation.

Analyses of the co-promotion are the most obvious documents that would likely have been prepared irrespective of litigation. However, the district court's error is not limited to these documents. Many of the other withheld documents are standard financial analyses that may have been created even in the absence of litigation. The district court acknowledged that "similar reports are prepared for BIPI executives as a matter of regular business." Dkt. 69 at 11 [JA-154]. Additionally, many of the withheld documents were created before settlement negotiations began or after the negotiations concluded, strongly suggesting that their creation was not due to the settlement negotiations.[15] The district court should

[15] *See supra* note 1 (over 200 of the over 600 documents at issue in this case fall into this category). The district court's opinion contains no analysis articulating why these pre- and post-settlement documents are entitled to work product protection. Its finding that "[i]nformation used to assess settlement option [sic] clearly falls within the ambit of the work product doctrine," Dkt. 69 at 11 [JA-154],—the sole basis for the court's work product ruling—simply does not apply to roughly one-third of the documents at issue in this case.

have ordered Boehringer to produce any documents that would have been created in essentially similar form irrespective of the litigation.

United States v. Adlman, 134 F.3d 1194, on which Boehringer relied extensively in the proceedings below, does not support the applicability of work product to the challenged documents. *Adlman* held that "[w]here a document is created because of the prospect of litigation, analyzing the likely outcome of that litigation, it does not lose protection under this formulation merely because it is created in order to assist with a business decision." *Id.* at 1202. As the *Adlman* holding makes clear, a work-product document must first have been "created because of the prospect of litigation" in order to qualify for protection. *Id.* Further, *Adlman*'s holding refers to "documents analyzing *anticipated* litigation, but prepared to assist in a business decision rather than to assist in the conduct of litigation." *Id.* at 1201-02 (emphasis added). Thus, if a company contemplating a business deal asks its counsel to evaluate litigation that might arise from the deal, that analysis may be protected as work product under *Adlman*. *Id.* at 1199.[16] But if a business deal is simply part of the consideration offered in settlement, documents created to assess the commercial value of the deal are "financial analyses one

[16] Similar examples include an analysis by in-house counsel of a potential merger partner's prospects in its existing litigation or a prediction of litigation outcomes prepared to aid in a financial forecast. *Adlman*, 134 F.3d at 1199-1200.

would expect a company exercising due diligence to prepare" (Dkt. 69 at 12-13 [JA-155-56]), and do not become work product simply because an attorney was involved or due to the temporal connection to the settlement. Again, that conclusion follows with particular force if, as Boehringer insists, the business deal is economically independent of the settlement.

The record evidence supports the common-sense conclusion that many of the withheld documents, particularly the analyses of the co-promotion agreement, would have been created in essentially similar form irrespective of the litigation. The district court failed to consider this possibility, and Boehringer continues to insist that all such documents were prepared "because of" the Barr settlement. This Court should order Boehringer to produce any documents that would have been created in essentially similar form in the absence of litigation, especially those documents related solely to the co-promotion agreement. Alternately, this Court should remand to the district court for an individualized assessment of the documents.

III. THE FTC DEMONSTRATED A SUBSTANTIAL NEED FOR FACT WORK PRODUCT AND AN UNDUE BURDEN IN OTHERWISE OBTAINING IT

As seen in the foregoing sections, Boehringer has not shown that all of the financial analyses and other documents at issue in this appeal reflect opinions of counsel; those materials constitute—at most—*fact* work product. Under established work product standards, "[a] party can discover fact work product upon showing a substantial need for the materials and an undue hardship in acquiring the information any other way." *Dir., Office of Thrift Supervision*, 124 F.3d at 1307; Fed. R. Civ. P. 26(b)(3)(A)(ii). In the proceedings below, the FTC demonstrated substantial need for any factual work product in the withheld documents and undue hardship in acquiring the underlying financial projections elsewhere. While the district court did not disagree, it held that the FTC had not shown an "overriding and compelling need" to discover the withheld documents, which it thought necessary on the basis of its erroneous conclusion that all of them were opinion work product. Dkt. 69 at 12-13 [JA-155-56].

The court below erred to the extent that it applied this "overriding and compelling" standard to ordinary factual work product, and compounded its error—and usurped the Commission's investigatory function—by purporting to determine what kinds of evidence are needed to advance the investigation. The district court's discussion of substantial need reflects a fundamental misperception of the context in which this case arose and the legal standards for enforcing agency investigative subpoenas. Thus, this Court should ensure that the district court on any remand properly applies the correct "substantial need" standard, under which the Commission has a patent need for, and thus is entitled to obtain, the materials withheld here.

A. To the Extent That the District Court Applied a Heightened Standard for the Discovery of Ordinary Fact Work Product, This Was Legal Error

As discussed below, the district court apparently recognized that the FTC had demonstrated substantial need for withheld factual work product. It went on, however, to opine that the Commission had no "overriding and compelling need" for the withheld documents because they contained "no smoking guns," Dkt. 69 at 12 [JA-155], were "not in any way evidence of any conspiratorial intent to violate the law," *id*. at 13 [JA-156], "add[] nothing to what is already known about what the involved companies intended in settling their suit," *id*. [JA-156], and did "not cast any light on the fundamental legal issue of whether the deal was or was not anti-competitive in intendment or result," *id*. [JA-156]. Despite being "sympathetic to the FTC's argument that these financial analyses are the only documents that could demonstrate whether or not BIPI was using the co-promotion agreement to pay Barr not to compete," the district court concluded that the documents "cast no light of [sic] whether that intendment existed." *Id*. [JA-156].

In so doing, the court below compounded its basic error of categorically deeming all of these financial analyses to be opinion work product by also failing to take proper account of the context in which the Commission seeks this information. The present proceeding is for the enforcement of an investigatory subpoena, for which the Commission has broad authority under Section 9 of the

FTC Act, 15 U.S.C. § 49. This Court has repeatedly acknowledged that a district court's "role in a proceeding to enforce an administrative subpoena is a strictly limited one." *Texaco, Inc.*, 555 F.2d at 871-72; *Linde Thomson Langworthy Kohn & Van Dyke, P.C. v. Resolution Trust Corp.*, 5 F.3d 1508, 1513 (D.C. Cir. 1993). "[T]he scope of issues which may be litigated in an enforcement proceeding must be narrow, because of the important governmental interest in expeditious investigation of possible unlawful activity." *Texaco, Inc.*, 555 F.2d at 872. "[I]it is sufficient if the [agency's] inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant." *Id.* (quoting *U.S. v. Morton Salt Co.*, 338 U.S. 632, 652 (1950)). "The district court is not free to speculate about the possible charges that might be included in a future complaint, and then to determine the relevance of the subpoena requests by reference to those hypothetical charges." *Id*. at 874; *see also Linde Thomson*, 5 F.3d at 1512 (court not to make "an *ex ante* determination of what claims, if any, may eventually be pursued by an agency undertaking a broad investigation pursuant to its clear statutory mandate").

Thus, in assessing the Commission's "substantial need" for the material in question, the district court should have taken into account the investigatory context, in which the Commission is entitled to materials of "reasonable relevance" to an investigation that may itself properly be open-ended. The court erred in ignoring these principles, and instead relying upon its own assessment of whether the documents "cast any light on the fundamental legal issue" (Dkt. 69 at 13 [JA-156]) of the existence of a violation of the FTC Act.

Moreover, both factually and institutionally, the district court could not have any basis for concluding that the "arithmetic of various potential scenarios adds nothing to what is already known about what the involved companies intended in settling their suit." *Id*. [JA-156]. By definition, the proceeding was summary, with no discovery. *See* Fed. R. Civ. P. 81(a)(5); *FTC v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980). There was no complaint defining any potential FTC claims that Boehringer's conduct violated the FTC Act. *Texaco, Inc.*, 555 F.2d at 874. The district court did not have access to the full evidentiary file that the FTC would use to determine the existence of a violation. The district court did not and could not consider all the possible legal theories that the FTC had under consideration or the possible conclusions to be drawn from the evidence gathered by the agency. In light of the record before it, the district court could not have determined whether or not the withheld documents added to what the FTC did or did not know. In light of its limited role in enforcing the subpoena, the court's determination that the documents did not add to the FTC's knowledge was both legally erroneous and an abuse of the court's discretion. *Texaco, Inc.,* 555 F.2d at 874, 885.

B. The Information in the Withheld Documents is Highly Relevant to the FTC's Investigation and Available Only from Boehringer

Under a proper legal standard, there is no question that the Commission has established a substantial need for any of the materials in question that constitute fact work product. The district court itself indicated that the FTC had shown a substantial need for fact work product that can be segregated from opinion work product. Although the court's treatment of the generic entry and financial analyses was dominated by its erroneous categorical conclusion that fact work product could not be excised from opinion work product (Dkt. 69 at 13 [JA-156]), it elsewhere recognized the existence of genuine need. Addressing work product contained in transmittal emails, for example, the district court concluded that the FTC is entitled to fact work product "that can be reasonably excised from any indication of opinion work product." Dkt. 69 at 13 [JA-156]; *see also id.* at 17 [JA-160]; *see also* Dkt. 71 at 6 [JA-170] (holding that if a document found through search of Boehringer's back-up tapes "contains some factual work product and some opinion work product, and the opinion work product can be excised from the rest of the document, BIPI should redact the privileged material and disclose the rest").

In any event, the FTC amply demonstrated "a substantial need for the materials and an undue hardship in acquiring the information any other way." *Dir., Office of Thrift Supervision*, 124 F.3d at 1307. The Commission's investigation seeks to determine whether Boehringer agreed to share its monopoly profits on two branded drugs with its potential rival, Barr, in exchange for Barr's agreement to delay entry with lower-priced generic products. Among other things, the Commission seeks to assess whether Boehringer is using the Aggrenox co-promotion deal, entered contemporaneously with the patent settlement, as a way to pay Barr not to enter, and to understand any potential justifications for such a payment.

Notably, in its recent *Actavis* decision, the Supreme Court considered an FTC complaint containing allegations that rely on the same kinds of contemporaneous internal financial analyses of settlement options and business deals that are at issue in this appeal. As the Supreme Court noted, the settling parties claimed the payments to the generic drug firms were "compensation for other services the generics promised to perform," while the FTC complaint alleges that the payments were compensation for the generics' agreement not to compete until 2015. *Actavis*, 133 S. Ct. at 2229. The FTC complaint in that case prominently features an internal financial analysis by the branded drug manufacturer (at the time Solvay) of various settlement scenarios. *FTC v. Actavis, Inc*., Case No. 1:09-cv-00955-TWT (N.D. Ga.), Second Amended Complaint ¶¶

57-59[17] & Exhibit A.[18] That is precisely the kind of document the Commission seeks here.

The *Actavis* exhibit contains various mathematical calculations showing that, if Solvay paid its potential competitors, the parties would have more profit to divide the longer they delayed competition. *Id.* Ex. A at 3, 10-12; Joint Appendix at 105, 112-14. Solvay thus calculated in concrete dollar amounts how paying its potential generic competitors to agree to a later entry date increased the total pool of profits available to all the manufacturers. The financial analysis also contains Solvay's calculation that possible side business arrangements with the generic challengers would result in net costs rather than profits, which is evidence that those agreements made economic sense only as a mechanism for Solvay to pay the generic firms to delay competing. *Id.* at 12; Joint Appendix at 114, *Actavis* Compl. ¶ 82.

The relevance of a branded company's financial analysis reflected in *Actavis* is particularly striking here, given the district court's characterization of the withheld financial analysis documents as mere "arithmetical calculations of various

[17] The Second Amended Complaint is available at http://www.ftc.gov/os/caselist/0710060/090528androgelfinalcmpt.pdf.

[18] Exhibit A to the Second Amended Complaint is reproduced in Volume 2 of the Joint Appendix filed in the Supreme Court and is available at http://www.ftc.gov/os/caselist/0710060/130122watsonappendix2.pdf.

potential scenarios" that "do not cast any light on the fundamental legal issue of whether the deal was or was not anti-competitive in intendment or effect." Dkt. 69 at 13 [JA-156]. In fact, as shown by the complaint in *Actavis*, such mathematical calculations go directly to "the relevant antitrust question" in an antitrust investigation of a reverse-payment settlement: the reasons the parties used such payments. *Actavis*, 133 S. Ct at 2237. As the Eleventh Circuit recently observed in ordering that Exhibit A be part of the public record in *Actavis*, the financial analysis "had a direct bearing on the economic advantages that Solvay reaped by entering into a reverse-payment settlement." *FTC v. AbbVie Prods. LLC*, 713 F.3d 54, 64 (11th Cir. 2013).

Boehringer contended below that the FTC did not need the withheld documents because the FTC could re-construct the company's analyses based on the agreements themselves and the FTC's own financial calculations. Dkt. 37 at 24 [JA-643]. This is incorrect for a number of reasons.

First, the inputs, assumptions and formulas for those analyses came from Boehringer's business people. Dkt. 37, Ex. 4 at 118:3-23 [JA-776]. That information is not available to the FTC. Without access to Boehringer's documents, the FTC cannot question the business people during investigational hearings about the specific inputs and assumptions used in the withheld analyses. Indeed, the district court declared itself "sympathetic to the FTC's arguments that these financial analyses are the only documents that could demonstrate whether or not BIPI was using the co-promotion agreement to pay Barr not to compete." Dkt. 69 at 13 [JA-156].

Second, even if the FTC could run its own calculations using available data, such calculations could not replace Boehringer's own. Courts routinely consider evidence of the parties' purpose in order to "interpret facts and to predict consequences." *Chi. Bd. of Trade v. U.S.*, 246 U.S. 231, 238 (1918); *see also Broad. Music Inc. v. CBS, Inc.*, 441 U.S. 1, 20 (1979) ("[O]ur inquiry must focus on whether the effect and, here because it tends to show effect, … the purpose of the practice are to threaten the proper operation of our predominantly free-market economy"); *U.S. v. Brown Univ.*, 5 F.3d 658, 672 (3d Cir. 1993) ("[C]ourts often look at a party's intent to help it judge the likely effects of challenged conduct."). Moreover, "in cases of ambiguity we presume that the defendants, who are in the best position to know their business, are also rational actors. As a result, knowledge of their own expectations can aid a tribunal in determining whether the likely effects of restraints are competitive or anticompetitive." 11 Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1912g, at 367 (3d ed. 2011).

Third, an objective assessment conducted years later is no substitute for Boehringer's contemporaneous assessment of its business justifications for the settlement. *See Polk Bros., Inc. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir.

1985) (conduct under the antitrust laws to be evaluated at the time of contract). Courts have made clear the importance of contemporaneous documents, particularly where they contradict testimony. *See U.S. v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948) (trial testimony contradicted by contemporaneous documents entitled to little weight).

Fourth, as indicated by Persky's testimony, Dkt. 33, Ex. 2 at 133:23-134:4 [JA-995-96], Boehringer has not produced any other documents that are equivalent to those it has withheld. It has not produced any contemporaneous financial analyses of the settlement agreements or side deal that lie at the heart of the FTC's investigation. Dkt. 59 at 41:8-14 [JA-112] (noting that none of the financial analyses prepared by Fonteyne, the decision-maker for the co-promotion agreement, had been produced). During the hearing before the district court, counsel offered a carefully worded assertion that Boehringer had produced 270,000 pages of "ordinary course" documents, Dkt. 59 at 35:10 [JA-106], but failed to mention that Boehringer has withheld on privilege and work-product grounds every contemporaneous analysis of the relevant transaction. In particular, Boehringer has not produced *any* "ordinary course" analysis for the Aggrenox co-promotion agreement, nor has it produced in redacted form the "segregable factual portion" of the analyses that it has admitted to have conducted. Dkt. 59 at 31:14 [JA-102].

And fifth, Boehringer is withholding the very documents that it claims justify its conduct. "BIPI is asserting that the terms of the Co-Promotion Agreement executed between the parties, when evaluated using BIPI's financial information relating to Aggrenox that the FTC has in its possession, are not anticompetitive." Dkt. 37 at 23 [JA-642]. Yet Boehringer is claiming work-product protection for the evaluations that purportedly demonstrate that the settlement is not anticompetitive. *Id*. [JA-642]. Persky testified similarly that the co-promotion agreement was not "a vehicle to pay Barr not compete on generic Aggrenox," Dkt. 33, Ex. 2 at 113:3-6 [JA-992], and that the financial analysis of that agreement supported her testimony, *Id*. at 127:12-15 [JA-993]. When asked to identify the document that would support the proposition that the co-promotion agreement was a fair business deal, Persky identified the financial analysis that Boehringer refuses to produce. *Id.* at 133:23-134:4 [JA-995-96].

The FTC thus made a highly persuasive showing of the need for and unavailability of the analyses and information withheld by Boehringer. Moreover, production of the withheld documents "will not trench upon any substantial interest protected by the work-product immunity." *In re John Doe Corp.,* 675 F.2d 482, 493 (2d Cir. 1982). As shown above, Persky provided little substantive input into the documents and appears to have used them not as an attorney but in her role as lead business negotiator. Dkt. 37, Ex. 4 at 70:2-71:12 [JA-755-56]. "To the extent that the statements imply [Persky's] questions from which inferences might be drawn as to [her] thinking, those inferences merely disclose the concerns a layman would have as well as a lawyer in these particular circumstances, and in no way reveal anything worthy of the description 'legal theory.'" *John Doe Corp.*, 675 F.2d at 493.

IV. THE DISTRICT COURT ABUSED ITS DISCRETION WHEN IT ACCEPTED AND RELIED ON *IN CAMERA, EX PARTE* AFFIDAVITS

On the eve of the hearing and long after the parties had filed their respective status reports that served as briefs in the proceeding below, Boehringer submitted the two *ex parte* affidavits of Persky and Taylor. Dkt. 69 at 10-11 [JA-153-54]. The affidavits were presumably submitted to lay the factual foundation for the work-product claims based on Persky's request for analyses, even though Persky directly requested very few of the withheld documents, Dkt. 59 at 5:19-6:7 [JA-76-77], and Taylor was apparently not involved with the patent litigation or settlements, *id.* at 5:10-11 [JA-76]. Boehringer sent the affidavits directly to chambers, but did not file them with the district court. The company told the FTC only that the two affidavits had been submitted but provided no information other than the names of the affiants. At the hearing, the FTC objected to the affidavits, *id.* at 4:21-5:18 [JA-75-76], but the district court nevertheless heavily relied on them in ruling that Boehringer could withhold the documents. In particular, these affidavits seem to be the only evidence supporting the district court's conclusion that the documents were prepared using "information and frameworks provided by BIPI attorneys," Dkt. 69 at 11 [JA-154], given the sworn testimony that Persky did not provide the key inputs for many of the financial analyses. *See* Part I.A.2, *supra*.

The district court abused its discretion by allowing Boehringer to submit the affidavits on an *ex parte*, *in camera* basis and then relying on them in its ruling. Though a district court has the discretion to accept *ex parte* affidavits under some circumstances, *see Halkin v. Helms*, 598 F.2d 1, 5 (D.C. Cir. 1978), this Court has long expressed reservations about the practice, especially in cases that do not involve national security issues:

> The legitimacy of accepting *in camera* affidavits (as opposed to *in camera* review of withheld documents) has troubled this court in the past. Although *in camera* review of withheld documents is permissible (and even encouraged), we have held that a trial court should not use *in camera* affidavits unless necessary and, if such affidavits are used, it should be certain to make the public record as complete as possible.

Lykins v. U.S. Dep't of Justice, 725 F.2d 1455, 1465 (D.C. Cir. 1984) (addressing the use of *in camera* affidavits in FOIA case involving national security exemption).[19] *In camera* affidavits are problematic because our judicial system requires "providing as much information as possible to [an opposing party], so that

[19] In the cited cases, as here, the *in camera* affidavits were submitted *ex parte* and withheld from the other party.

the adversary system can function effectively in assisting the trial court to make a determination and producing a record that is susceptible to appellate review." *Id.*

The Court has stressed that "*in camera* proceedings should be preceded by as full as possible a public debate over the basis and scope of a privilege claim." *Ellsberg v. Mitchell*, 709 F.2d 51, 63 (D.C. Cir. 1983) (non-FOIA case involving documents withheld on state secret grounds during discovery).

> The more specific the public explanation, the greater the ability of the opposing party to contest it. The ensuing arguments assist the judge in assessing the risk of harm posed by dissemination of the information in question. This kind of focused debate is of particular aid to the judge when fulfilling his duty to disentangle privileged from non-privileged materials—to ensure that no more is shielded than is necessary to avoid anticipated injuries.

Id.

In light of these concerns, a district court permitting *in camera* affidavits "must both make its reasons for doing so clear and make as much as possible of the *in camera* submission available to the opposing party." *Armstrong v. Executive Office of the President*, 97 F.3d 575, 580 (D.C. Cir. 1996). Such affidavits should be used only where "absolutely necessary" and where "the interests of the adversary process are outweighed by other crucial interests." *Lykins*, 725 F.2d at 1465 (internal quotes and cites omitted).

That is not the case here. Boehringer submitted the affidavits without any justification, and the district court met none of the requirements for acceptance of *in camera* affidavits. Additionally, it failed to examine whether the affidavits contained *any* unprivileged information that should have been disclosed to the FTC.

In fact, there could be no justification for the use of *in camera* affidavits here. The facts necessary to lay the foundation for a work-product claim are not themselves protected. Edna Selan Epstein, *The Attorney-Client Privilege and the Work-Product Doctrine,* Vol. II at 1123-24 (5th ed. 2007); *see also GlaxoSmithKline*, 294 F.3d at 145-48 (relying on corporate affidavit that was filed publicly); *B.F.G. of Illinois, Inc. v. Ameritech Corp.*, 2001 U.S. Dist. LEXIS 18930, at *10 (N.D. Ill. Nov. 8, 2001). In addition, this case does not involve the kind of subject matter as to which courts have endorsed *in camera* affidavits, principally national security, *e.g.*, *Ellsberg*, 709 F.2d 51; *Hayden v. NSA*, 608 F.2d 1381 (D.C. Cir. 1979), state secrets, *e.g.*, *Halkin*, 598 F.2d 1, or grand jury testimony, *e.g.*, *Gordon v. U.S.*, 722 F.2d 303 (6th Cir. 1983).

Boehringer's conduct and the district court's acquiescence harmed both the adversarial process and the FTC's ability to pursue this investigation effectively. Despite the FTC's objection, the district court relied on these affidavits for critical aspects of its work-product analysis. Boehringer's central argument was that the withheld analyses "were prepared not in the ordinary course of business, but for the specific purpose of informing counsel whether the proposed BIPI-Barr settlement offers should be accepted." Dkt. 69 at 9 [JA-152]. The district court "credit[ed] the declarations of Persky and [Taylor] … that the various financial analyses were prepared for the client during settlement discussions and involved discussions among the attorneys and their agents who were handling the settlement negotiations." *Id.* at 11 [JA-154]. It further explained that Persky's *in camera* affidavit claimed "that the documents were created by BIPI or Boehringer Ingelheim employees in response to her personal requests for financial and other information." *Id.* [JA-154]. The affidavits appear to be the primary factual basis on which the district court concluded that "[t]his was information [Persky] needed in order to provide her client, BIPI, with legal advice regarding the potential settlement between BIPI and Barr." *Id.* [JA-154].

The district court's decision, thus, relies in substantial part on *in camera* testimony "unaided by the benefits of adversarial proceedings which buttress the validity of judicial decisions." *Mead Data Cent., Inc. v. U.S. Dep't of Air Force*, 566 F.2d 242, 260 (D.C. Cir. 1977); *see also U.S. v. Sepenuk*, 864 F.Supp. 1002, 1007 (D.Or.1994) (rejecting privilege claims after reviewing *in camera* affidavits and stating that "[t]he government raises a valid objection to the *in camera* affidavits which have made it impossible for them to respond in fairness to respondent's claim of privilege"), *aff'd sub nom U.S. v. Blackman*, 72 F.3d 1418, 1425 (9th Cir. 1995) (upholding without analysis review of *in camera* affidavits in these circumstances). It should be reversed as an abuse of discretion. If the Court remands the case for any further proceedings, it should also instruct the district court not to permit any further use of *in camera* affidavits.

CONCLUSION

The Court should reverse the district court and hold that Boehringer has not proven that the withheld documents should be shielded by the work-product doctrine or, in the alternative, remand the case to the district court for further proceedings consistent with the Court's decision.

Respectfully submitted,

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<u>Certificate of Compliance and Service</u>

I hereby certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because the brief contains 13,501 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

I hereby certify that copies of the foregoing Brief were served upon the following counsel of record, via the Court's CM/ECF system, this 30th day of September, 2013.

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