<u>ORAL ARGUMENT NOT YET SCHEDULED</u>

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)

BRIEF OF APPELLANT FEDERAL TRADE COMMISSION

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GLOSSARY

Barr	Barr Pharmaceuticals, In@ncluding its wholly owned subsidiary, Duramed Pharmaceuticals) Inc.
BIPI	.Boehringer Ingelheim Pharmaceuticals, Inc.
Boehringer	.Boehringer Ingelheim Pharmaceuticals, Inc.
Commission	F.ederal Trade Commission
Dkt	Docket entry in district court case below (C v. Boehringer Ingelheim Pharmaceuticals, Incase 1:09-mc-00564JMF (D.D.C.))
FDA	F.ood & Drug Administration
FOIA	Freedom of Information Act, 5 U.S.C. § 552 (2006), amended b@pen Government Act of 200Pub. L. No. 110175, 121 Stat. 2524
FTC	F.ederal Trade Commission
FTC Act	Federal Trade Commission Act, U5S.C. §§45-58

INTRODUCTION

The Supreme Court recently held that "reverse

manufacturer, and it claims the two agreements were independentifiers was a settlement of patent litigation between the two companies, in which the generic manufacturer agreed to delay competitive generic entry for a periodref Thea second was a "epromotion agreement," in which Boerhinger agreed to pay the generic manufacturer to promote Boerhinger's own branded dhags. TC'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 service are they side ayments for an anticompetitive agreement to delay generic entry and share the ensuing monopoly profits? Boerhinger's internal financial and busisseanalysis of these deals directly relevant to answering these questions.

The district courbrder challenged here frustrates that investigation. The court made a sweeping, categorical ruling that Boehringer could withhold as opinion work product undeds of documents containing such financial or business analyses, including eveanalysis of the copromotion agreement. It reasoned that "the co-promotion agreement was an integral part of the litigation," Dkt. 69 at 10 [JA-153], even though Boehringerhas repeated lipsisted 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 containing of

Boehringerexecutives contradicts the conclusion the court drew from these affidavits. In the course of these rulings district court misapplied this Circuit's precedent and reached an erroneous and overbroad conclusion description.

JURISDICTION

The district court had subject-matter jurisdiction pursuant to .\$5C. §49 (authorizing district courts to enforce FTC subpoenas) and \$28C. §\$1331, 1337, and 1345. Objectember 27and October 6, 2012, the district court entered ordersthat, collectively, resolved all claims in this case, griangt in part and denying in part the FTC's subpoena enforcement petitodes. 6972 [JA-144] uro T2 0 TW () TJ TW 81 -2.2 0.008 TW 1.256 0 T2 [([J) 72].

As a panel of this Court hatready rule

ISSUES PRESENTED FORREVIEW

- 1. Whether the district court committed legal error when it treatidusiness and financial analyses request by in-house counsel as opinion work product.
- 2. Whether the district court committed legal error when it failed to examine whetherany of the documents, including documents lyzing a "freestanding," "fair armsength business arrangemënt, ould have been prepared n essentially similar form irrespective of litigation thus were not work product
- 3. Whether the TC has shown substantial need for Boehringer's factual work product and whether the district court erroneously applied a heightened standard of heed.
- 4. Whether the district court abused its discretion when it acceptedre in camera affidavits, to which the FTC has ill been denied access, without determining that they were absolutely necessar to assess Boehringer's work-product claims and that the need for secre to utweighed other crucial interests.

STATEMENT OF THE CASE

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 Bringer drug products, Aggrenox and Mirapex. Specifically, the FTC is investigating whether Boehriung arwfully paid Barr not to aunch competing eneric versions of Aggrenox and Mirapex as part of a patent litigation settlemer each ctavis 133 S. Ct. at 2237 After Boehringer failed to comply with several 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 bt. 1 [JA-10-66].

In proceedings before the district court, the FTC challerigeed, alia,
Boehringer's refusal to produce hundreds of financial analyses and intilear
documents based on claims of attornotion privilege and the work-product
doctrine On September 27, 2012, the district notices sued an order addressing
these claims. Inteld that all of the withheld financial analyses prepared in
connection with the settlement of the Aggrenox and Mirapex patent litigation—
including all analyses related the business agreement that Boehringer entered
into with Barr at the time of settlement enstituted opinion work products ubject
to the "virtually undiscoverable" standard, rather than the substantial-need standard
generally applied to work roduct claims the 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 sware created by neattorneys without input from legal personnel); and (2) were intended to "aid is ettlement process" even though some of the documents were prepared well before settlement negotiations began, or up to eighonths after the settlement was executed 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 accessite the thocuments withheld by Boehringerin order to further

Whena company seeks FDA approval to market a generic version of a that arred-drug before expiration of patent covering that rug, the generic applicant must certify that the patent in question is invalid or not infringly dhe 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 Atta 2234 Oncea generic files a Paragraph IV certification, the patent decompany bring suit immediately even before the generic applicant markets its product. 35 U.S.C. § 271(e)(2) Paragraph IV patent challenges sometimes result viers expayment settlements, as described above.

In 2003 Congress amended the Hatch-Waxmannee, give king, 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 lowerost drugs off the market. Rep. No. 107167, at 4 (2002). Among these changes, Congress created a mechanism for agency review and investigation of potentially anticompetitive agreements 2666 Medicare Amendments to Hatch-Waxman Act, Pub. L. No.-11073, §§ 11111118 Actavis, 133 S. Ct. at 2234As part of its antitrust enforcement mand the FTC investigates Hatch Waxman settlement agreements to determine whether they unlawfully restrain trade.

In these investigations, the FTC often relies on compaintes that financial analyses and business forecast determine whether the branded firm has compensated the generic firm for delayed entry. Compensatively takes the form of explicit cash payments; instead, the settling firms typicately de the payment in a separate business dead xecuted simultaneously with the settlement. In these cases, the Cassesses the thertheside deals an independent business transaction or instead an inducement offered to persuade the generic firm to delay entry. Financial forecasts and analyses of the als are often the only direct evidence of whether the brand firm believed the deal to be economically freestanding or whether it instead viewed the deal as worth enteriougly because of the additional profits gained through delayed generic entry. This evidence would

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² Before the FTC began investigating reverseyment settlements, payments were often madepart of the settlement. Since then, parties to these agreements have often conveyed payments via side deals. See,Fel.G.,Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Wernization Act of 2003: Summary of Agreements Filed in FY 2009 (2010) (cataloguing potentialfpaylelay agreements, including nine that included a "side deal" allable at http://www.ftc.gov/reports/mmact/MMAreport2009. cells ee als C. Scott Hemphil, An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition

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 Aggrenoxagreements

In this investigation, the FTC is examining whether a pategation settlement and a simultaneously executed co-promotion agreement between Boehringer and Barr together constitute an unlawful reversementagreement. The investigation involves two Boehringer branded products: Mirapex (pramipexole), which is used t

Underthe settlement agreements, Barr agreed not to market generic Mirapex until January 2010 and generic Aggrenox until July 2015. Dkt. 1-1[JA-23]. At the same time, the companies entered into promotion agreement in which Boehringer agreed to provide substantial compensation top Baprortedly in exchange or 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 copromotion agreement to pay Barr not to compete with Mirapex or Aggrenox.

3. FTC investigation and Boehringeprivilege c

generic entry), and documents related to the Aggrenopromotion agreement.

Dkt. 1-1 at 45 [JA-23-24]. Eight months late Boehringe still had not certified compliance with the subpoena. ad 9 [JA-28]. Accordingly, on October 23, 2009, the FTC filed a petition in the United States District Court for the District of Columbia or an order enforcing the subpoena. DktJA-10-66]. The petition alleged that Boehringer had failed to completely produce responsive documents and used inadequate search procedulates 89 [JA-17-18].

After the FTC filed its petition for enforcement of the subporting parties exchanged correspondering effort to settle outstanding issues, including their disagreements bout whethe Boehringer had egitimately withheld or redacted a large number of documents based spruted attorney client privilege and workproduct assertion See Dkt. 32, Ex. B Decl. Ex. 17 at [1/4-562]. This appeal challenges the district court's ruling only as it applies to Boehringer's workproduct claims.

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³ Boehringer asserted both work-product protection and atterlinent 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 attolinent privilege. The FTC is appealing only the court's determination that these analyses were opinion work product. The FTCs not appealing the district court's determination with regard to documents for which only attornetion privilege was claimed. Seekt. 69 at 15 [JA158].

Boehringer claimed attorneylient privilege or work product with regard to 3,420 documentsSeeDkt. 32, Ex. B a5 [JA-226]; Dkt. 32, Ex. B Decl. Ex. 17 at 1 [JA-562]. Based on Boehringer's descriptionsitisnlog and the sworn testimony of Boehringer personnetletFTC challenged 631 of theclaims including claims of protected status foursiness documents "regiang" or "prepared as a result of" patent litigation or analyzing settlement opations business documents analyzing the Aggrenoperconotion agreement. Dkt. 32, Ex. B Decl. Ex. 17[JA-561-69]. A number of theedocuments even postated the settlementId. at 1-2, App.A [JA-562-63, 56869]. 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 "aegarding" or "prepared as a result of" the patent litigation which were circulated to business executives and prepared primarily by notawyers. Similarly, it identified 55 documents analyzing settlement options that appear to be fregal business documents. at 2,App. A [JA-563, 56869]. These documents are primarily financial forecasts of generic entry or the financial mpact of settlement option SeeDkt. 32, Ex. B at 67 [JA-

⁴ Seesupranote1.

227-28]. For example, document no. 8 (\$32) a spreadsheet sent from Buckley, a non-lawyer, to Paul Fonteyna senior business executival pyingnumerous other business executival privilege log, however, describes the document as "Analyses of '577 and '086 (\$12 Patent Litigations prepared as a result of litigation." Dkt. 32, Ex. B Decl. Ex. 1 (\$160 [JA-347]. Document no. 92 is a PowerPoinfound in the files of non-lawyer Steve Marlin (as to which Boehringer did not supply authorinformation and which was ot circulated) described in the privilege logas "Analysis of '577 Patent Litigations and settlemetrategy prepared as a result of litigation." (at 75[JA-362]. The FTCobjected to Boehringer's withholding these and similator cuments, arguint (hat documents created by nonlawyers for business purpos (essuch as informing business decisions) are not work product.

The sworn investigational hearing testimon Boehringer personnel confirms that many of these documents consist of leogral, financial analyse for example Paul Fonteyne, whis listed in the privilege log as those ator or recipient of many of the disputed documents, testified that his role was to provide "commercial input" consisting of "mostly financianalyses. Dkt. 32, Ex. B Decl. Ex. 20 at 41, 4 AJA-598-99]. Fonteyne's testimony reinforces what the privilege log suggests: many of these documents amply business documents created to inform business decisions.

(2) Non-legal business documents anyzing the Aggrenox copromotion agreement. The FTC alsoidentified a number of locuments, including seven submitted in camera related solely to the Aggrenox promotion agreement, which Boehringer maintains was an "artesigh business arrangement" separate from the patentitigation settlement SeeDkt. 32, Ex. B Decl. Ex. 18 at [7A-577]. For example, document no. 1090 in from non-lawyer Hanbo Hu tonon-lawyer Fonteyne, is a PowerPoint "Analysis regarding possible Aggren promotion agreement leating to '577 Patent Litigation settlement prepared as a result of litigation." Dkt. 32, Ex. B Decl. Ex. 17 at 4, App. [4A-565, 56869]. Despite its position that the copromotion was a separate economic transaction, Boehringer contended that these documents were work product because pthremation agreement "relates to" the pateiting ation settlement. Id[JA-565, 56869].

Boehringer testimonagainindicates that these documentere focused on the financial, not legal, implications of the promotion agreement. Elizabeth Cochrane, a financial executive who created many cantaleyses, testified that her role was to "quantify the Durameral 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 camerat the district court did not rule on this document. See note 1.

statement. Dkt. 32, Ex. B Decl. Ex. 3t 21:622:16[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. 2048:79 [JA-599]. Some or all of these analyses appear to have been conducted in order to evaluate the financial tather than legal implications of the Aggrenox copromotion agreement, which, aga pehringer insists was a separate economic transaction Dkt. 32, Ex. B Decl. Ex. 18 at 7 [JA77].

4. District court proceedings

Ultimately, the partiesailed to reach agreement as to the privilege claims or other issues in disputSeeDkt. 32, Ex. B Decl. Ex. QJA-282-83]; Id. Decl. Ex. 10 [JA-284-86]. Boehringernonethelessertified its compliance with the subpoena on April 19, 2010SeeDkt. 15 at 2[JA-68]; Dkt. 32, Ex. B Decl. Ex. QJA-233-39]. The parties briefed the two disputed issime 2010. After district court-supervised mediationailed to resultin settlement the district court held a status hearing on December 9, 2011. Dkt. [592-72-143]. As part of the proceeding, the parties mutually agreed on 87 sample documents to submit to the district court for in camerareview. SeeDkt. 69 at 34 [JA-146-47].

More than a yearfterthe parties had briefed the disputed wprkeduct issues and nothe eve of the hearing, Boehringer submittemate affidavits from Marla Persky, Boehringer's general counsel, and Pamela Taylor, who is outside

counselepreseting Boehringer in the FTC investigation who had no contemporaneous volvement in the settlements co-promotion agreements ee

Dkt. 69 at 1011 [JA-153-54]. Apparently relying on these affidavits, Boehringer argued that the withheld analyses of stettlement and the coromotion were "specifically asked for by [Persky], either directly or indirectlip. Kt. 59 at 19 [JA-90]. Because Boehringer did not disclose the affidavits or their content to the FTC, the FTC had opportunity to review or respond to the and objected to their submission. At 45 [JA-75-76].

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 ordeon Boehringer'swork-productclaims.Dkt. 69 and Ø [JA-144-64]. It held all of the withheld financial analyses weeequested by counstel assist in settlement negotiations and so weekquested by product the

⁶ The affidavits appear to have placed additional documents before the district court for in camera

disclosure of which would "necessarily evealthe attorneys' thought processes. Dkt. 69 at 12/JA-155]. The district courspecifically addressessed disputed documents containing analyses of the Aggreno promotion agreement atting that the agreement as an integraphant of the settlement." Dkt. 69 at 10 [JA53]. It acknowledged, but did not accord significant togethe tension between this conclusion and Boehringer's continuing claim that the promotion agreement was "freestanding" and independent from the settlet agreement as basis in essentier. Id. [JA-153].

As supportfor its holding that these analyses reflected Persky's mental impressions, the district court cited primarily pepair of in camera affidavits from Perskyand Taylor. Id. at 11 [JA154]. According to the court, BIPI attorneys supplied "information and frameworks" to be used in these analyses A-154] Further, it held that ny factual work product in those documents could not be segregated from the opinion work productause disclosing "any aspect" of the analyses would shed light on the nature of the attorney's retiplicated 12 [JA-155]. The court did not discuss the sworn investigational hearing testimony (which the FTC had presented in its briefs) in which Persky 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 rule the FTC had not demonstratted "overriding and compelling need required to discover this type of work produtate 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 [Brown]i was using the co-promotion agreement to pay Barr not to compete. ald.3 [JA156]. But in the court's view, the documents did not provide additional useful information beyond what the Commission already knew about the settlemenant 162-13 [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 achie ve')court declared "there are no smoking guns contained in these documents 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 of anti-competitive in intendment or result." lat 13 [JA156]. The district court announced this conclusion without addressing issues shuch atse Commission and its staff mighbnsider, or what other documents and data the Commission might be able to consider in conjunction with these calculations.

SUMMARY OF ARGUMENT

The district court applied in indiscriminate, categorical approach the work product doctrine that contradicts this ourt's precedent and established work-product principles. First, the district court erroneously concluded that every financial and generic entranalysis prepare 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" proof that standard rather than theormal standard for factual" work product. That holding contradicts settled precedent: documents prepared by any product simply because they

"factual" work producthat

contemporaneous analyses of the settlement and co-promotion agreement are highly relevant and otherwisenavailable.

Finally, the district court abused its discretion by relying on in cameera parte affidavits from Boehringer's general counsel and side counsels 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 expaniitheavits were "absolutely necessary" to decidedispute ovework-product protection, and the district court erroneous failed to require such a showing. Moreover, ord evidence casts doubt on the reliability of these affidavits. In these circumstances, it was an abuse of discretion for the district court by one Boehringer's exparte representations.

STANDARD OF REVIEW

In subpoena enforcement caeec -0.02TT2 1 82poena.Tr [(eTc -0(ctet8m)21(se(e)

of discretion." FTC v. GlaxoSmithKlin@94 F.3d 141, 146 (D.C. Cir. 2002) (quotingIn re Sealed Caşe 46 F.3d 881, 883 (D.C. Cir. 1998))

ARGUMENT

- I. THE DISTRICT COURT APPLIED AN INCORRECT LEGAL STANDARD IN RULING O N 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 Aggrenepromotion agreementRather than evaluating which of the withheld documents actually contained mental impressions of countries, court categoricallyoncluded that any analysis requested by counsel "necessarily" conveyed the mental impressions of counselDkt. 69 at 11[JA-154]:

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

Supervision v. Vinson & Elkins, LLP124 F.3d 1304, 1308 (D.C. Cir. 1997)he 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), Suv. 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 produstreserved for documents that "reveal[] the attorney's mental processed pjohn Co. v. U.Ş.449 U.S. 383, 400 (1981) All documents preparted relitigation arguably contain some clues as to an attorney's thinking, and are quest from counsel does not automatically transform all resulting documents into opinion work product. Dir., Office of Thrift Supervision, 124 F.3d \$807-08. 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

degree of editing and selection by the lar. See US 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 enhearing, 129 F.3d 637, 638)See Smith v. Life Investors Ins. Co. of Amelo, 2:07cv-681, 2009 WL 2045197at *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 district court erred in holding that an attorney sequest necessarily transforms a document into "virtually undiscoverable" opinion work product.

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

Despite the district court's blanket holding that any financial analysis requested by Boeheringerstorneys is opinion work product, the record illustrates that many of the withheld documents not reflect mental impressions of an attorney Boehringer witnesses testified that financial analyses that we substantive contribution from in-

settlement, the Aggrenox settlement, threel Aggrenox copromotion agreement.

Dkt. 32, Ex. B Decl. Ex. 19 at 113:422 [JA-592]. According to Persky, Fonteyne was the key decisionmaker regarding the terms of the Aggrenox potention agreement, and was responsible for evaluating whether the agreement with Barr made sense from tinancial [and] business perspectivel. at 61:1-23, 68:1924 [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 notativers, he conducted many of the withheld financial analyses.

Both Fonteyne and Perskeystified that the assumptions used to construct lat ngATc 0 Tw 1.504 0 T436-23o427 these analyses were generated from non-

[JA

In sum, the district court's holding that an attorney's request matter how attenuated necessarily transforms a doment 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 ally omnivorous in the range of relevant evidence it would shield from discovery. In re Sealed Case F.3d at 237This Court should thus reverse and remand for application of the appropriate standar see Comptroller of the Currency 67 F.2d a 633.

B. The District Court Committed Legal Error by Failing to Requir e

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analysis that [Boehringer] already provided" for agreements other than those entered into at the time of the patent settlements. Dkt. 59 at 25 [19-102]. 10 And the district court itself founthat the documents are "financial analyses" and "arithmetical calculations. Dkt. 69 at 13 [JA156]. Indeed, the district court ordered production with redaction for the transmittal emails and other correspondence that accompanied the financial analyses, bultiably 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 reinforcescumelusion that the court committed legal error by assuming any document resulting from counse's requestnecessarily 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.; see also Washington Bancorporation. Said, 145

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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 C OMMITTED 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/itthlheld financial analyses/wereopinion work product, the court erred by failing to consider whether any of the downents 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); aslee U.S. v. Adlman, 134 F.3d 1194, 1202 (2d Cir. 1998) worn testimony from Boehringer witnesses establishes that many of the documents/uestion/were straightforward financial analyses—a key subset of which relate only to a business agreement that Boehringerhas repeatedly claimed was fsteending Moreover, many of the withheld documents/were created well before or after settlement negotiations.

The workproductdoctrine protect only those documentseated "because of" litigation. SeeDeloitte, 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 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 re Sealed Caşe 46 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; Adman, 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 76 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 litigationse with respect to all categories of documents, including financial and generic entry analyses. This failure, however, waparticularly indefensible with regard to those ocuments analyzing the financial impact of the Aggrenox poromotion agreement, which Boehringer insists was a business transaction economically independent of settlement. Given Boehringer's position, it is implausible ith and ucted 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 products in produced.

In particular, **f** there is any truth to Boehringer's repeated assertion that this was a freestanding, arms

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necessarily presupposters the co-promotion was a vehicle to pay Barr for the delayed entry codified in the settlement. Agasophringer cannot logically maintain that the deal was economically freestanding while attribution the analyses of the deal to the settlement.

In any event, whateven relationship between the patentitigation settlement and the co-promotion agreement, the district court should have considered whether any of the analyses would have be at each essentially similar form irrespective of the litigation and such documents are not work product.

copromotion," which entailed evaluating "the financial impact to [Boehringer]'s P&L, profit and loss statemehDkt. 32, Ex. B DeclEx. 3 at 21:622:16[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 at 1265-9 [JA-244]. The analyses described by Cochrane are precisely the kind of financial forecast one would expect Boehring 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. 3at 72:2123 [JA-1008]¹⁴

Paul Fonteyne, aDkt. 32snc-iTw [(a)1 [(Dkt)-Tdij 0.004 h iTw [(34010 Tw 0.949 0

he received from Cochran (https://docs.com/https://docs.c

Analysesof the copromotion 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 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." Dkat 69 [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 documents district court should

¹⁵ See supra note (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 preand postsettlement 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.a69 1[JA-154],—the sole basis for the court's work producting—simply does not apply to roughly onethird 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 productto the challenged document admanheld 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 decisional 1202. Ashe Adlman holding makes clear, a workroduct document must first have been "created" because of the prospect of litigation" order to qualify for protectiond. Further, Adlmans holding refers to "documents analyzing intated litigation, but prepared to assist in a business decision rather than to assist in the conduct of litigation." Id. at 120102 (emphasis added). Thus, if a company contemplating a business deal asks its counsel to evaluate litigation that mightform the deal, that analysis may be rotected as work producted and analysis may be rotected as work producted and analysis may be rotected as work producted analysis. a business deal is simply part of the consideration offered in settlements created to assess the commercial value of the deal are "financial analyses one

¹⁶ Similar examples include an analysis byhimuse 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. Adlm 1894 F.3d at 1199200.

would expect a comparexercising due diligence to prepare" (Dkt. 69 at182-[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 commense conclusion that manfy o the withheld documents, particularly the analyses of the consideration agreement, would have been created in essentially similar form irrespective of the litigation. The district court failed to consider this possibility, and Boehringetinues to insist that all such documents were prepared "because of" the Barr settlement. This Court should order Boehringer to produzery documents that would have been createdn essentially similar form the absence of litigation specially those dis

FTC Act, 15 U.S.C. §49.

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 vidian 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 in estimates their suit." Id. [JA-156]. By definition, the proceeding was summary, with no discoverySeeFed. R. Civ. P. 81(a)(5); FTC v. Carter

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 substantized 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 treat meet the generic entry and financianalyses was dominated by its erroneous categorical conclusion that fact work product could not be excised from opinion work product (Dkt. 69 at 13156), it elsewhere recognized the existence of genuine needes sailed work product contained in transmittal emails, for example, the district court concluded that the FTC is entitled to dact work product "that can be reasonably excised from any indication of opinion work product." Dkt. 69 at 13A-156]; see alsoid. at 17[JA-160]; see also Dkt. 71 at 6 [JA170] (holding that if a document found through search of Boehringer's back 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 Supersion, 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 lowericed generioroducts. 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 uch a payment.

Notably, in its recentactavisdecision, 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 area 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 par

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57-59¹⁷ & Exhibit A. ¹⁸ That is precisely the kind of document the Commission seeks here.

The Actavisexhibit contains various mathematical calculations showing that,

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.69 at 13 [JA156]. In fact, as shown by the complaint in Actasisch mathematical calculations go directly to "the relevant antitrust question" in an antitrust investigation of a reverseayment settlement: the reasons the parties used such paymentsActavis 133 S. Ct at 2237. As the Eleventh Circuit recently obscirve ordering that Exhibit A be part of the public record in Actasise financial analysis "had a direct bearing on the economic advantages that Solvay reaped by entering into a reverseayment settlement." FTC v. AbbVie Prods. LEC3 F.3d 54, 64 (11thCir. 2013).

Boehringer contededbelow that the FTC did not need the withheld documents because the FTC could be struct the company's analyses based on the agreements themselves and the FTC's own financial calculations. Dkt. 37 at 24 [JA-643]. This is incorrector a number of reasons.

First, the inputs, assumptions and formulas for those analyses came from Boehringer's business people. Dkt. 37, Ex. 4 at 128: [JA-776]. That information is not available to the FT0/ithout access to Boehringer's documents, the FTC annot question the business people during investigational hearings about the specific inputs and assumptions in the business 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 expromotion agreement to pay Barr not to compete." Dkt. 69 at 13 [JA156].

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 consequencesChi. Bd. of Trade v. U.S., 246 U.S. 231, 2381(3)) See also Broad. Music Inc.v. CBS, Inc.,

1985) (conducunder the antitrust laws to be evaluated at the time of	contract)

that the statements imply [Persky's] questions from which inferences might be drawn as to [her] thinking, the inferences merely disclose the concerns a layman would have as well as a lawyer in these particultationstances, and in no way reveal anything worthy of the description 'legal theory.'" John Doe Conto F.2d at 493.

IV. THE DISTRICT COURT A BUSED ITS DISCRETION

affidavits seem to be the one-widence supporting district court's conclusion that the documents were prepared using "information and frameworks provided by BIPI attorneys," Dkt. 69 at 11 [JA54], given the swormestimony that Persky did not provide the key inputs formany of the financial analyse ePart IA.2, supra

The district court abused its discretion by allowing Boehringer to submit the affidavits on anex parte in camerabasis and then relying on them in its ruling. Though a district court habe discretion to accept ex partification and circumstances, ee Halkin v. Helm, \$598 F.2d 1, 5 (D.C. Cir. 1978), ish Court has long expressed reservations about the practice, especially in cases that do not involve national security issues:

The legitimacy of acceptining camera affidavits (as opposed to camerareview of withheld documents) has troubled this court in the past. Although in camera eview of withheld documents is permissible (and even encouraged), we have held that a trial court should not use in camera fidavits 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 Justic 25 F.2d 1455, 1465 (D.C. Cir. 1984) (addressing the use of in cameraffidavits in FOIAcase involving ational security exemption). ¹⁹ In camera affidavits are problematic because our judicial system requires "proShhexiing 0 Td [(aAC /P <i4()s)-9ford41(a)4(tic)4(n)]TJ (s po)8(se)12eble

the adversary system can function effectively instantial the trial court to make a determination and prouding a record that is susceptible to appellate review." Id.

The Court has stressed that camera proceedings should be preceded by as full as possible a public debate over the basis and scope of experiolaim."

Ellsberg v. Mitchell, 709 F.2d 51, 63 (D.C. Cir. 1983) r(FOIA case involving documents withheld n state secret grounds ring discover).

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 kid 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 shiedthan is necessary to avoid anticipated injuries.

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In light of these concerns, astriict court permitting incameraaffidavits "must both make its reasons for doing so clear and make as much as possible of the in camerasubmission available to the opposing party." Armstrong v. Executive Office of the Presiden 197 F.3d 575, 580 (D.C. Cir. 1996) uch affidavits should be used only where "absolutely necessary" and where "the interests of the adversary process are outweighed by other crucial interests." LTRES.2d at 1465 (internal quotes and cites omitted).

That is not the case he centringer submitted the affidavits without any justification, and the district court met none of the requirements for acceptance of

in cameraaffidavits. 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 use of camera affidavits here. The facts necessary to lay the foundation for a-pword uct claim are not themselves protected and Sela Epstein The Attorney Client Privilege and the Work-Product Doctrine, Vol. II at 112-324 (5th ed. 2007) see also GlaxoSmithKline294 F.3 at 145-48 (relying on corporate affidavit that was filed publicly); B.F.G. of Illinois, Inc. v. Ameritech Corp2001 U.S. Dist. LEXIS 18930, at *10 (N.D. III. Nov. 8, 2001) addition, this case does not involve the kind of subject matter as to which courts handorsed camera affidavits, principally national security, e.g. Ilsberg 709 F.2d51; Hayden v. NSA608 F.2d 1381 (D.C. Cir. 1979) state secrets, e.g. Ialkin, 598 F.2d 1or grand jury testimony, e.g., Gordon v. U.S.722 F.2d 303 (6ttir. 1983).

Boehringer's conduct and the district court's acquiescence harmed both the adversarial process and the CF

settlement offers should be accepted." Dkta69[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 Pers's in camera affidavit claimed "that the documents were atted 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." [dA-154].

The district court's decision, thus, relies in substantial paint coamera 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. 197;7) ee also U.S. v. Sepenuk864 F.Supp. 1002, 1007 (D.Or.1994) (rejecting privilege claims after reviewim gamera affidavits and stating that "[t]he government raises a valid objection ton ton tone affidavits which havenade it impossible for them to respond in fairness to respondent's claim of privilege"), aff'd sub non SUv. Blackman 72 F.3d 1418, 1425 (9th Cir. 1995) upholding without analysis review of in came affidavits in

these circumstances)

Certificate of Compliance and Service

I hereby certify that this brief complies with the typedumelimitation of Fed.R. App. P. 32(a)(7)(B) because the brief contain,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 Brixefre served upon the following counsel of ecord, via the Court's CM/ECF system, tableth day of September 2013.

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