

No. 04-10688

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

SCHERING-PLOUGH CORP.,
UPSHER-SMITH LABORATORIES, INC.,
Petitioners,

v.

FEDERAL TRADE COMMISSION,
Respondent.

PETITION OF RESPONDENT
FEDERAL TRADE COMMISSION
FOR REHEARING *EN BANC*

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Schering-Plough Corp. v. FTC

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ELEVENTH CIRCUIT RULE 35-5(c) STATEMENT

I express a belief, based on a reasoned and studied professional judgment, that the panel decision is contrary to the following decision(s) of the Supreme Court of the United States or the precedents of this Circuit and that consideration by the full court is necessary to secure and maintain uniformity of decisions in this Court:

(1) *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, __ U.S. __, 125 S. Ct. 308 (2004).

(2) *Federal Trade Commission v. Indiana Federation of Dentists*, 476 U.S. 447, 106 S. Ct. 2009 (1986); and *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 71 S. Ct. 456 (1951).

I also express a belief, based on a reasoned and studied professional judgment, that this appeal involves the following questions of exceptional importance:

(1) Whether any settlement of a patent infringement litigation is shielded from antitrust scrutiny regardless of the settlement terms, so long as entry by the allegedly

infringing product is not precluded at any time subsequent to the expiration of the subject patent term.

(2) Whether the panel decision subverts Congress's expressed goal in the Hatch-Waxman Act to accelerate market entry of significantly lower-priced generic drugs by encouraging generic manufacturers to challenge weak and narrow patents.

(3) Whether the panel violated the long-standing "substantial evidence" standard of review, by resolving critical disputed facts in accordance with its own weighing of the evidence rather than upholding the Commission's reasonable resolution of such issues.

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GLOSSARY

For ease of reference, the following abbreviations and citation forms are used in this petition for rehearing en banc:

Op. - The Panel's Opinion.

Comm. Op. - The Commission's Opinion

ID - Initial Decision of the Administrative Law Judge

CX - Complaint Counsel Exhibit

SPX - Schering-Plough Exhibit

USX - Upsher-Smith Exhibit

Tr. - Transcript of Trial Testimony before the Administrative Law Judge

STATEMENT OF ISSUES MERITING EN BANC CONSIDERATION

(1) Whether the panel decision is inconsistent with *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, ___ U.S. ___, 125 S. Ct. 308 (Oct. 12, 2004), and, if not, whether the decisions properly apply the antitrust laws to patent litigation settlements in the context of the Hatch-Waxman Act.

(2) Whether the panel decision subverts Congress’s expressed goal in the Hatch-Waxman Act to accelerate market entry of significantly lower-priced generic drugs by encouraging generic manufacturers to challenge weak and narrow patents.

(3) Whether the panel violated the long-standing “substantial evidence” standard of review by resolving critical disputed facts in accordance with its own weighing of the evidence rather than upholding the Commission’s reasonable resolution of such issues.

STATEMENT OF THE CASE

This case concerns a challenge by the Federal Trade Commission (“FTC” or “Commission”) to agreements settling patent litigation between Schering-Plough Corporation (“Schering”), the manufacturer of the “K-Dur 20” potassium supplement, and two manufacturers of generic counterparts, Upsher-Smith Laboratories, Inc. (“Upsher”) and ESI Lederle Inc. (“ESI”). After a painstaking analysis, the Commission found that in those agreements the two generic manufacturers had agreed to refrain from marketing their generic drugs until future specified dates in exchange for cash payments totaling up to \$60 million to Upsher and \$15 million to ESI.

Settlements of this kind raise serious antitrust concerns if the payments from the patentee are in fact pay-offs to potential generic competitors to induce them to abandon patent challenges and delay their entry.¹ By such agreements, the patentee obtains more than its patent alone provides, and consumers continue to pay monopoly prices while the patentee shares monopoly profits with the generics.

The case meets both of the alternative tests for rehearing *en banc* under Fed. R. App. P. 35(a) and this Court's Rule 35-3. First, the panel discarded the framework provided by this Court in *Valley Drug* for distinguishing settlements based on a lawful exercise of the exclusionary power of a patent from settlements that *augment* the exclusionary effect of a patent and are therefore subject to antitrust scrutiny. In *Valley Drug*, this Court indicated that it is necessary to analyze whether the patentee was actually getting more protection from competition as a result of the settlement than it could reasonably expect from its patent alone. *See, e.g.*, 344 F.3d at 1311.

The panel's ruling replaces that framework with a blanket rule that a patentee is presumptively entitled to buy protection from *all* competition for the full patent term, even if there is evidence that such payments are augmenting the patent's actual exclusionary power. Op. at 21, 24. This erroneous reading of *Valley Drug* flows from

¹ *See, e.g., Valley Drug*, 344 F.3d at 1304, 1309-10; *Andrx Pharms. v. Biovail Corp. Int'l*, 256 F.3d 799, 809-10 (D.C. Cir. 2001); *see also* Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F.L. Rev. 11 (2004). Schering's in-house counsel acknowledged this potential concern. *See* Comm. Op. at 29.

the panel's assumption that a challenger has the burden of proving its product does *not* infringe the patent. *See* Op. at 21. This is not the law.² If the panel's approach stands, exclusion payments from a branded to a generic drug manufacturer in the context of a patent settlement will be *per se lawful* in this Circuit – regardless of the size of, or reason for, the payment – so long as the exclusion period does not extend beyond expiration of the patent. This result is inconsistent with *Valley Drug*.³

Second, this case is exceptionally important to all consumers of FDA-approved drugs and to those who pay for them, and it raises exceptionally important issues of patent law, antitrust law, and administrative law.⁴ Congress has spoken to this issue at least twice: first in the Hatch-Waxman Act,⁵ which modified the incentives and rewards of the parties in litigation between patentees and generic manufacturers, and more recently in the 2003 Medicare amendments, which were prompted in part by the

² *See, e.g., Kegel Co., Inc. v. AMF Bowling, Inc.*, 127 F.3d 1420, 1425 (Fed. Cir. 1997) (patent holder has the burden of proving infringement by a preponderance of the evidence); *Wolverine World Wide, Inc. v. Nike, Inc.*, 38 F.3d 1192, 1196 (Fed. Cir. 1994).

³ *See also United States v. Singer Mfg. Co.*, 374 U.S. 174, 197, 83 S. Ct. 1773, 1785 (1963) (White, J., concurring); *United States v. Masonite Corp.*, 316 U.S. 265, 279, 62 S. Ct. 1070, 1078 (1942).

⁴ The AARP and a public interest patent organization submitted amicus briefs to the Court to emphasize the importance of this case. The court refused to accept the briefs after petitioners withheld consent.

⁵ The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

very antitrust concerns raised by the FTC in this case.⁶ The principal goal of these statutes is to encourage generic drug manufacturers to challenge weak or narrow patents and enter the market as soon as possible. Every day that the statutes are thwarted because a generic is paid to stay off the market is a day that prescription drug prices remain higher than a competitive market would have provided.

The panel also violated long-standing law on the review of decisions of administrative agencies. A court should review the decision of the *agency*, not the initial decision of an administrative law judge, to determine whether the decision is supported by substantial evidence in the record.⁷ The Commission engaged in a painstaking analysis of the record and explained its findings (and the deficiencies of the ALJ's decision) in great detail. The Commission set out some 40 pages of specific factual findings, replete with dozens (if not hundreds) of citations to specific documents and testimony, to determine whether the \$60 million paid to Upsher was at least in part for

⁶ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-04, 1111-17, 117 Stat. 2066, 2461-63 (2003). *See, e.g.*, S. Rep. No. 107-167, at 4 (2002) (“the industry has recently witnessed the creation of 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. Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law that was intended to promote generic alternatives”). Congress therefore required that litigation settlements be filed with the Commission and the Department of Justice for review. *See* 117 Stat. 2461-2462. Such review, specifically mandated by Congress, would be a meaningless exercise if the panel's standard of *per se* legality becomes the law.

⁷ *See, e.g., NLRB v. Dell*, 283 F.2d 733, 735 (5th Cir. 1960).

an entry date or for side-licenses. *See* Comm. Op. at 39-79. The panel rejected these findings out of hand, with virtually no factual or evidentiary analysis or citation to the record.⁸

Course of Proceedings and Disposition of the Case

The Commission issued its administrative complaint on March 30, 2001, charging that Schering's agreements with Upsher and ESI violated the FTC Act, 15 U.S.C. § 45.⁹ ESI entered a consent agreement with the FTC in April 2002. After a trial, the ALJ's Initial Decision ("ID") dismissed the complaint. The Commission reversed, concluding on *de novo* review that the ALJ erred in numerous key factual conclusions, as well as in his legal analysis.

⁸ The panel also fundamentally mischaracterized what the Commission did in its opinion. It appeared to believe that the Commission has declared *per se* unlawful all settlements in which payments of more than \$2 million flow from a patentee to a generic challenger. *See, e.g.*, Op. at 41-42. The Commission could not have been clearer that that was *not* its ruling. *See* Comm. Op. at 10-14, 25-29. Evidently the panel confused the terms of the Commission's cease and desist order, aimed at "fencing-in" future conduct of the named parties after a finding that they had entered into an illegal agreement that harmed consumers, *see FTC v. National Lead Co.*, 352 U.S. 419, 430, 77 S. Ct. 502, 510 (1957), with its ruling in the case. There was no issue in this appeal about the scope of the order apart from the challenge to the finding of illegality. The "rule of law" the panel said it "fear[ed] and reject[ed]," Op. at 43, was not a rule the Commission had articulated, and the panel was therefore vacating a decision the Commission did not make.

⁹ The FTC Act violation here is analogous to a violation of Section 1 of the Sherman Act.

On Schering's and Upsher's petitions for review, the panel set aside the Commission's decision and vacated its cease and desist order.

Statement of the Facts

Schering's "K-Dur 20" is a potassium supplement. The active ingredient, potassium chloride, is in common use and is unpatentable. Schering owns a *formulation* patent (the '743 patent) that relates only to the material coating the active ingredient. A generic manufacturer can therefore develop a generic version of K-Dur 20 without infringing Schering's patent if the generic uses a non-infringing coating. Upsher and ESI certified to the FDA and consistently maintained in patent litigation that their products were such non-infringing generic substitutes.

Following the filing by Upsher and ESI of their applications for approval of their generic product, Schering sued both firms for patent infringement. Those suits were settled. Schering's settlement with Upsher contains an unconditional \$60 million payment that was described to Schering's Board of Directors as a guaranteed income stream to replace Upsher's lost revenue for the time the generic agreed to stay off the market. CX 338 at SP1200270. Schering contended before the FTC that the \$60 million was in fact consideration for licenses relating to a niacin product, Niacor, that was under development at Upsher. Schering's settlement with ESI includes payments totaling \$15 million in order to secure ESI's agreement not to market any generic version of K-Dur 20 before January 2004. Comm. Op. 80, 82.

ARGUMENT

I. THE PANEL’S DECISION APPLIES A *PER SE* LEGALITY RULE, DIRECTLY CONTRAVENING THE *VALLEY DRUG* DECISION

Valley Drug held that a reviewing court must consider “the scope of the exclusionary potential of the patent” in order to determine whether a settlement agreement is anticompetitive. *See Valley Drug*, 344 F.3d at 1311. Without prescribing a fixed formula for all cases, *Valley Drug* expressly instructed that the relevant inquiry should be whether the exclusionary power of the patent was “bolstered by the exit payments,” *id.*, and that “[a]ny provisions of the Agreements found to have effects beyond the exclusionary effects of [the] patent may then be subject to traditional antitrust analysis.” *Id.* at 1312. The Court recognized that the size, purpose, and terms of the “reverse payment” are probative of the “exclusionary power of the patent,” *id.* at 1309-11, and that the parties’ economic positions and incentives should also inform the reviewing court’s analysis. *Id.* at 1310. It discussed all these factors even though only the patent’s *validity* was at issue there – a situation where the patentee enjoys a favorable presumption and the challenger carries the burden of proof.

The panel here acknowledged none of these factors. After castigating the Commission for supposedly refusing to assess the power of the ‘743 patent,¹⁰ it itself

¹⁰ The panel was incorrect. Virtually the entire 88-page Commission Decision analyzes in multiple ways whether Schering was buying more protection from competition than it thought it would get from its patent alone.

studiously avoided any specific analysis of the exclusionary power of Schering's patent, as *Valley Drug* would require. Instead, it relied on a series of presumptions, one of which reflects a fundamental, fatal legal error, and the others of which mischaracterize the record and the legal theories of the case. *See Op.* at 20-24.

The panel's reasoning appears to have been as follows: based on the statutory presumption of validity – a rebuttable presumption – the panel stated:

By virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products, Klor-Con and Micro-K 20, respectively, did not infringe Schering's patent.

Op. at 21. It went on to say that the Commission had conceded it was unable to prove that Upsher or ESI could enter before patent expiration, and that there was no allegation that the patent was invalid or that the infringement suits were shams. *Op.* at 24. The panel's unstated conclusion evidently was that, absent the settlement, Schering would have excluded Upsher and ESI from the market for the full term of its patent.

The first, fundamental legal error in this reasoning is that the panel *assumed Upsher and ESI's products infringed the '743 patent*, when it is black-letter patent law that the patentee bears the burden of proof on this issue. *See note 2, supra.* In the underlying litigation, infringement was vigorously contested. If any assumption is appropriate, it is that the competing products did *not* infringe Schering's patent.

Second, neither Complaint Counsel nor the Commission ever conceded that Upsher and ESI could not have entered earlier than the agreed dates. To the contrary,

the Commission cited abundant evidence showing that the parties understood the payments were tied to a delayed entry date. *See, e.g.* Comm. Op. at 26-27, 41-52, 78-79. Indeed, Upsher had asked the court in its patent case to shorten the statutory Hatch-Waxman stay (which would otherwise expire by May 1998) because it was ready to enter the market immediately, even while the patent litigation was ongoing. Comm. Op. at 34. The panel evidently misunderstood the Commission's point, also made in *Valley Drug*, that it was impossible and inappropriate to predict the outcome of patent litigation, and instead agreements had to be assessed as of the time they were made. *See Valley Drug*, 344 F.3d at 1306; Comm. Op. at 32-33. What the Commission did say in its opinion was that it was unnecessary for purposes of a Commission cease and desist order to specify exactly what date the competitors would have entered absent the payments. That question might well be an issue in a damages action, but damages were not at issue before the Commission. Comm. Op. at 31-32.

It is also striking that the panel viewed the settlements as genuine compromises because the challengers "obtained less than what they would have received from successfully defending the lawsuits (the ability to immediately market their generics)." Op. at 38. Not so. Schering's payments provided Upsher *all* the revenues it lost by staying off the market, putting it in the *same or better* position than if it had successfully defended the lawsuits: the only difference is that consumers were forced to continue paying supra-competitive prices. Schering was willing and able to make these

payments because its monopolistic profits substantially exceeded the entrants' expected revenues, making it profitable for it to pay off potential competitors.¹¹

II. THE PANEL HAS SUBVERTED THE GOALS OF THE HATCH-WAXMAN ACT

The panel appears to have found it necessary to jettison basic principles of antitrust law – *i.e.*, that one may not pay a competitor to stay out of a market – out of deference to its view of what the patent laws require. Op. at 15-16, 19-20. This analysis was not only bad antitrust law: the panel's result is also utterly at odds with Congress's specific goals in adjusting the patent laws as they apply in the generic drug context. In the Hatch-Waxman Act, Congress exercised its constitutional authority to redefine the parameters of patent law in order to accomplish the explicit goal of controlling the soaring costs of health care. It struck a carefully considered balance between maintaining the incentives for innovation and promoting significantly lower-priced generic drugs. Important elements in this balance were provisions that made it easier and more lucrative for generics to challenge the validity and scope of pharmaceutical patents. *See* 21 U.S.C. § 355(j)(5)(B)(iv); 35 U.S.C. § 271(e)(2).

The panel found that these statutory provisions, designed to *promote* patent challenges, justify substantial pay-offs to competitors to *avoid* patent challenges and

¹¹ The \$60 million that Schering paid Upsher, for example, equaled approximately 8 months of Schering's profits, Bresnahan, Tr. 607-08; *see also* Tr. 532-33, but four years of Upsher's forecasted lost profits. CX 283.

“caustic” litigation. Op. at 41. As the Commission opinion pointed out, however, Congress has the right to shift incentives and encourage litigation if it chooses, and it did so here. Comm. Op. at 28-29. Patentees should not be allowed to pay off challengers just because they no longer have accustomed bargaining power.¹² Moreover, exclusion payments by patentees are not needed to settle patent cases. The settlements filed with the Commission in 2004, after the Commission’s decision in this case, show that legitimate patent settlements continued to be reached without hindrance from the Commission decision.¹³ Indeed, the Commission pointed out in its merits brief that Schering itself had entered into at least four settlements with generic competitors in which Schering granted its challenger a license.¹⁴

¹² In fact, the panel misperceives the effect of the statute. If, for example, Schering had feared losing bargaining leverage if it sued Upsher and ESI before they entered, and thus before there was a potential damages claim to bargain with, *Schering did not need to bring its suit at that time*. Instead, Schering could have waited until the generics entered the market and then initiated a traditional patent infringement suit. A patentee is not required to sue within 45 days of receiving an ANDA; rather, it has the *option* to do so if it wants to benefit from the statutory stay that generally keeps generic competition off the market for 30 months. See 21 U.S.C. § 355(j)(5)(B)(iii).

¹³ See Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004: A Report by The Bureau of Competition <<http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>>.

¹⁴ See Schering press releases at <http://www.schering-plough.com/schering_plough/news/release.jsp?releaseID=380214>; *id.* at ID=394601; *id.* at ID=463286; Andrx press release at <<http://phx.corporate-ir.net/phoenix.zhtml?c=65308&p=irol-newsArticle&ID=462357&highlight=>>>.

III. THE COMMISSION'S FINDINGS ARE DUE A HIGH DEGREE OF DEFERENCE AND THE PANEL'S UNSUPPORTED ADOPTION OF THE ALJ'S FINDINGS CONTRAVENES THE SUBSTANTIAL EVIDENCE RULE

The principal factual question in this case was whether at least some of Schering's payments to Upsher were *quid pro quo* for the latter's promise to defer market entry, or merely up-front royalties for product licenses. Under the established *de novo* standard of review, *see* 5 U.S.C. § 557(b), which petitioners concede is the applicable standard for Commission review of ALJ decisions, and based on "the cumulative impact of the extensive record evidence in this case," the Commission found that at least a substantial part of Schering's \$60 million payment was to secure Upsher's agreement to the entry date of September 2001. Comm. Op. 39-79.

This Court must, of course, "accept the Commission's findings of fact if they are supported by such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *FTC v. Indiana Federation of Dentists* ("IFD"), 476 U.S. 447, 454, 106 S. Ct. 2009, 2015-16 (1986) (quotation omitted).¹⁵ The issue on appeal is *not* whether the reviewing court would appraise that evidence differently or draw different inferences from the evidence. *Id.* Instead of following these well-established standards, the panel simply adopted a version of events that it preferred.

¹⁵ *Accord Colonial Stores Inc. v. FTC*, 450 F.2d 733, 739 (5th Cir. 1971); *Foremost Dairies, Inc. v. FTC*, 348 F.2d 674, 676 (5th Cir. 1965); *see also Equifax, Inc. v. FTC*, 678 F.2d 1047, 1052 (11th Cir. 1982).

The Commission had relied on critical contemporaneous documentary evidence, including the terms of the agreements themselves (which contained no affirmative obligations for Upsher except to stay off the market until September 2001), Schering's presentation to its board of directors that explained that the guaranteed payments represented lost revenue for the period Upsher stayed off the market, CX 338 at SP1200270, and the internal memorandum of a key Schering executive explaining, only a week before the Upsher settlement, why pursuing a comparable niacin drug was not worth *any* up-front Schering investment, let alone \$60 million. CX 558. But the panel did not even *mention* this evidence, much less explain why it found it unreasonable as support for the Commission's findings.

The panel instead misstated which evidence the Commission relied on, calling the Commission's factual analysis "forced," *compare* Op. at 28-29 *with* Comm. Op. at 41-82, and proceeded to adopt its own view of the facts without explaining why the Commission's view was unreasonable. A reviewing court may not, however, "make its own appraisal of the [evidence], picking and choosing ... among uncertain and conflicting inferences." *IFD*, 476 U.S. at 454, 101 S. Ct. at 2015 (quotation omitted); *see also Alabama Pub. Svc. Comm'n. v. I.C.C.*, 765 F.2d 1516, 1521 (11th Cir. 1985) (court may not "substitute its own conclusions") (quotation omitted); *Foremost Dairies, Inc. v. FTC*, 348 F.2d 674, 676 (5th Cir. 1965) ("it is not our function to weigh the evidence"). Even if there were two reasonable interpretations of the record, one

made by the Commission and the other by the ALJ (and petitioners), a reviewing court must in those circumstances accept the agency's conclusions. *See Arkansas v. Oklahoma*, 503 U.S. 91, 113, 112 S. Ct. 1046, 1060 (1992); *Colonial Stores*, 450 F.2d at 739; *Texas Aluminum Co., Inc. v. NLRB*, 435 F.2d 917, 919 (5th Cir. 1970).

The panel's return to the discredited findings of the ALJ is itself an indication of its erroneous approach to judicial review. The Commission explained in great detail the flaws in the ALJ's analysis. In order to revive the ALJ's view of the case, therefore, the panel would have had to review the Commission's findings and explain why the Court disagreed. It did not do so. The Supreme Court has made clear that the substantial evidence standard "is not modified in any way when the [agency] and its [ALJ] disagree." *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496, 71 S. Ct. 456, 469 (1951). The agency has *de novo* review responsibility over decisions of ALJs, and it is the agency's decision that is entitled to deference, not that of the ALJ.¹⁶

To further compound its error, the panel justified its preference for the ALJ's view on the ground that "[t]he ALJ made credibility findings based upon his observations of the witnesses' demeanor," when in fact, the ALJ made no findings based on demeanor. There is a distinction between determining truthfulness (i.e., whether the traffic light was red or green when an accident took place), for which personal

¹⁶ *See, e.g. Zoltanski v. Federal Aviation Administration*, 372 F.3d 1195, 1200 (10th Cir. 2004); *Swan Creek Communications, Inc. v. FCC*, 39 F.3d 1217, 1221 (D.C. Cir. 1994).

observation may be important, and determining what weight a particular testimony should be given in the face of other, contradictory evidence. The latter was the relevant question in this case, and the panel fails to identify any evidence that compels a finding that the Commission's weighing of the evidence was unreasonable.

In short, the panel has "misapprehended" and "grossly misapplied" the relevant standard of review. *See Universal Camera*, 340 U.S. at 491, 71 S. Ct. at 466. The *en banc* Court should correct this error, in keeping with Supreme Court precedent.

CONCLUSION

For the reasons discussed above, the panel's decision should be vacated and the case re-heard by the Court *en banc*.

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CERTIFICATE OF SERVICE

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APPENDIX A
THE PANEL OPINION