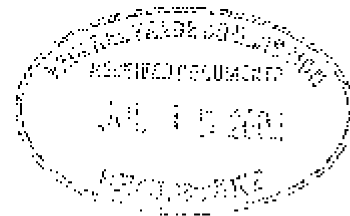
UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION



COMMISSIONERS: Timothy J. Muris, Chairman
Sheila F. Anthony
Mozelle W. Thompson
Thomas B. Leary
Orson Swindle

In the Matter of

SCHERING-PLOUGH CORPORATION,
a corporation,

UPSHER-SMITH LABORATORIES, INC.,
a corporation,

and

AMERICAN HOME PRODUCTS CORPORATION,
a corporation.

Docket No. 9297

COMPLAINT COUNSEL'S MOTION FOR LEAVE TO FILE AN APPEAL BRIEF EXCEEDING THE WORD LIMIT IN THE COMMISSION'S RULES OF PRACTICE

The complaint in this case charges that Schering-Plough Corporation paid would-be generic rivals Upsher-Smith Laboratories, Inc. $60 million and American Home Products Corporation $15 million, in exchange for agreements not to enter the market with their respective generic drug products for several years. In an initial decision served on July 5, 2002, the administrative law judge dismissed the complaint. Complaint counsel seek leave of the Commission to file an appeal brief in excess of the 18,750 word limit provided under the FTC's Rules of Practice. 16 C.F.R. § 3.52(b)(2) (2002).

Extended briefing is warranted because:

1. The extent of error in the ALJ's initial decision is extraordinary, and renders the decision wholly unreliable. ALJ Chappell applied the wrong standard of proof in reviewing the evidence, thereby invalidating all his factual findings; made

numerous errors in construing the evidence; and made fundamental mistakes of antitrust and patent law.

2. Apart from the initial decision itself, our appeal brief must address numerous erroneous procedural rulings by the ALJ that prevented us from presenting relevant, material, and reliable evidence, the effect of which is to deny the Commission the opportunity to review this important evidence on appeal.

3. Beyond the ALJ's errors, the special circumstances of the case, including the fact that it challenges two different agreements (resulting in an increased number of factual and legal issues), and the broad significance of the case, require a more extensive appeal brief than would be warranted in the typical case.

Although extensions of word count limitations are "disfavored," the circumstances here meet the test for such extensions, that is, "undue prejudice would result from complying with the existing limit." 16 C.F.R. § 3.52(k) (2002).

I. ALJ Chappell's Initial Decision Is So Fraught with Error as to Be Wholly Unreliable

In our appeal brief, we will request that the Commission, in exercising its power to review the record *de novo*,[1] throw out the ALJ's initial decision. We will not simply demonstrate that ALJ Chappell failed to properly construe the evidence or apply the law. Rather, we will show that ALJ Chappell's initial decision is so fraught with legal, factual, and economic errors as to render it wholly unreliable, and as a consequence we require extended briefing.

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[1] *See, e.g.*, *The Coca-Cola Bottling Co. of the Southwest*, 118 F.T.C. 452, 534 (1994) ("Our review of this matter is *de novo*, and our assessment of the evidence differs from that of the ALJ."); 16 C.F.R. § 3.54(a) (2002) (the Commission "will, to the extent necessary or desirable, exercise all the powers which it could have exercised if it had made the initial decision."); 16 C.F.R. § 3.54(b) (2002) (the Commission may "set aside the findings, conclusions, and rule or order contained in the initial decision").

A. ALJ Chappell Applied the Wrong Standard of Proof to the Evidence

Rule 3.51(c) of the FTC's Rules of Practice provides that initial decisions "shall be based on a consideration of the whole record relevant to the issues decided, and shall be supported by reliable and probative evidence." 16 C.F.R. § 3.51(c) (2002). The Commission has made it clear that this standard is the traditional one used in civil litigation; that is, facts are determined based on the preponderance of the evidence in the record. *See, e.g., Automotive Breakthrough Sciences, Inc.*, 126 F.T.C. 229, 306 & n.45 (1998).

ALJ Chappell, however, did not apply the preponderance standard. *See* ID at 81. Instead, he misquoted Rule 3.51(c)[2] and applied the "substantial evidence" standard for appellate review of Commission findings of fact, a standard that requires less than a preponderance of the evidence. *See, e.g., Gumport v. AT&T Techs.*, 89 F.3d 559, 563 (9th Cir. 1996); *Detroit Auto Dealers Ass'n., Inc. v. FTC*, 955 F.2d 457, 461 (6th Cir. 1992). Using the incorrect standard allowed the ALJ to adopt findings proposed by respondents even though not supported by a preponderance of the evidence in the record as a whole. This fundamental error infects each and every one of ALJ Chappell's findings.

In making this fundamental legal error, ALJ Chappell disregarded well-established FTC case law, as well as the Commission's clear guidance when it amended Rule 3.51(c).[3] He instead

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[2] ALJ Chappell misquotes Rule 3.51(c) to say that it expressly requires "substantive evidence," which he then interprets to mean "substantial evidence." ID at 81. Neither word is found in the current rule.

[3] *See* ID at 81. During ALJ Chappell's tenure at the agency, the Commission removed the words "substantial evidence" from Rule 3.51(c), precisely to reduce the likelihood of the very mistake ALJ Chappell makes. Moreover, the Commission specifically cited the initial decision in *Standard Oil* as an example of an ALJ incorrectly applying the appellate review standard. *See*
(continued...)

cited to superceded language in an old version of Rule 3.51(c), and quoted the ALJ decision in *Standard Oil Co. of California*, 84 F.T.C. 1401, 1446-47 (1974). This was a striking choice, inasmuch as the Commission unanimously reversed the portion of the initial decision in *Standard Oil* that ALJ Chappell quotes on page 81 of his initial decision. *See* 84 F.T.C. at 1489. Moreover, *Standard Oil* itself demonstrates that the difference in the standard of proof can be decisive in changing the outcome of a case. *Compare* 84 F.T.C. at 1458-59 (ALJ holding complaint counsel failed to meet its burden of proof based on appellate "substantial evidence" standard) *with* 84 F.T.C. at 1459, 1477, 1488 (Commission holding in favor of complaint counsel).

ALJ Chappell's reliance on a legal standard less rigorous than the preponderance of the evidence is evident throughout his opinion. For example, in making findings proposed by the respondents, he repeatedly relies on respondents' self-serving trial testimony even when that testimony is contradicted by the parties' contemporaneous business records. But as the Supreme Court made clear in *United States v. United States Gypsum Co.*, where trial testimony is contradicted by contemporaneous documentary evidence, the testimony should be given little weight.[4] Indeed, ALJ Chappell's preference for testimony over documents is so strong that key pieces of documentary evidence establishing the elements of our case are not even mentioned in

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[3](...continued)
FTC Rules of Practice, 66 Fed. Reg. 17,622, 17,626 (2001) (codified at 16 C.F.R. § 3.51(c)).

[4] 333 U.S. 364, 396 (1948). *See also Toys "R" Us, Inc.*, 126 F.T.C. 415, 567 n. 39 (1998) (rejecting "self serving" testimony that was contradicted by contemporaneous documentary evidence); *Adolph Coors Co.*, 83 F.T.C. 32, 185 (1973) ("It is well established, however, that little weight can be given to testimony which is in conflict with contemporaneous documents, particularly when the crucial issue involves mixed questions of law and fact.").

his decision.[5] For example, the ALJ's opinion makes no mention of Schering's "Executive Summary," CX 283, a document that lays out the blueprint for the eventual anticompetitive settlement with Upsher, although CX 283 was attached to our pre-trial brief, and used during our opening statement, at trial, in our closing argument, and in our post-trial briefs.

Because the ALJ's findings were based on the incorrect standard of proof and ignore significant aspects of the record, the Commission will need to undertake a comprehensive review of the entire record -- testimony *and* documents -- and adopt new findings. To assist the Commission, our appeal brief will need to include an unusually extensive discussion of and citation to significant amounts of record evidence disregarded by the ALJ. We cannot adequately do this, and undue prejudice would result, absent an extension of the word limit.

B. ALJ Chappell's Findings of Fact Contain Numerous Errors

In addition to the fundamental legal error that infects all of his findings, ALJ Chappell made numerous errors in the findings that need to be addressed in our brief. Indeed, although we have not yet had an opportunity to conduct a systematic check of all of his findings, it is readily apparent that ALJ Chappell's findings of fact are no more reliable than his description of the Commission's rules and case law relating to the legal standard he was required to use in making those findings.

- *ALJ Chappell relied on evidence that was expressly not offered or admitted "for the truth of the matter asserted."* For example, an important reason advanced by ALJ Chappell for disregarding evidence that other potassium chloride products did not constrain the pricing of

[5] *See* Prehearing Conference (Jan. 18, 2002), Tr. 114 ("I will let you know, I prefer live testimony. I cannot judge the credibility of a document. I cannot judge the demeanor of a document.").

K-Dur 20 was that these products were "therapeutically equivalent" to K-Dur 20.[6] ALJ Chappell's finding of therapeutic equivalence, in turn, was based in part on IDF 47:

> Dr. Addanki looked at whether there were side effect differences between different potassium chloride products that affected their substitutability for each other. (Addanki, Tr. 5693). The primary side effect associated with potassium chloride products is the possibility of gastrointestinal (GI) irritation. (Addanki, Tr. 5693-95). Gastrointestinal irritation is not a substantial problem, however, as its incidence is low for all oral potassium chloride supplements. (Addanki, Tr. 6163). K-Dur 20 does not eliminate this potential GI side effect. (Addanki, Tr. 5693-95). Thus, potential side effect issues do not affect the substitutability of other potassium chloride products for K-Dur 20. (Addanki, Tr. 5695).

In support of this finding, ALJ Chappell cited only to Dr. Addanki. Dr. Addanki, however, is a "doctor" only in the sense that he has a Ph.D. -- in economics. During the trial, ALJ Chappell purported to recognize that an economist is not qualified to testify regarding the medical side effects of potassium chloride products, and assured complaint counsel that the cited testimony would not be considered for purposes of establishing any medical facts. *See* Tr. 24:5688-89 (ALJ Chappell stating "I'm not accepting this as a medical opinion."). By relying on this evidence now for purposes for which it was not admitted, ALJ Chappell has created an erroneous record that complaint counsel must correct before the Commission.

The error the ALJ made in relying on Dr. Addanki's testimony is not an isolated case. For example, ALJ Chappell wrote that "[c]ustomers viewed K-Dur 20 and other potassium chloride products as interchangeable" (ID at 10), in part based on the finding that "[p]harmacists were substituting two Klor Con 10s for one K-Dur 20." IDF 59. The basis for that finding is the

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[6] *See, e.g.*, ID at 90 (distinguishing *Smith-Kline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978), because other potassium chloride products are "therapeutically equivalent"); ID at 91 (presence of "therapeutically equivalent" products provides "sufficient alternative choices to defeat an *Indiana Federation* claim").

testimony of Upsher witness Phillip Dritsas at Tr. 4834. Upon complaint counsel's hearsay objection at trial, however, that testimony was expressly offered by Upsher's counsel *not* for the truth of the matter asserted, but only to show Upsher's "state of mind." The testimony was thus admitted solely on that basis. *See* Tr. 20:4834-35. Plainly Upsher's state of mind does not establish the pharmacy practice ostensibly found by ALJ Chappell.

- *ALJ Chappell made findings that clearly are not supported by the evidence he cites.* Complaint counsel will be required to spend considerable time correcting the many findings that are entirely without support in the record. As one example, IDF 402 -- cited four times in the ALJ's analysis of monopoly power (ID at 118) -- states that "[t]he market share of generic potassium chloride rose as fast or faster than K-Dur 20 in every year from 1997 through 2000." The only evidence cited to support this finding is CX 62 at SP 089326. This page, however, only provides data for 1996 and 1997. Moreover, even that data only relates to increases in each product's sales relative to its own prior sales -- *not* their market shares. Finally, the same document on the very next page shows that K-Dur 20's share of overall potassium chloride sales increased *more* than the increase in share represented by all generic potassium chloride sales for the time period covered (1996-97).[7] The ALJ's finding thus simultaneously: (1) is incomplete; (2) misinterprets the cited data; and (3) is contradicted by the very exhibit cited.

- *ALJ Chappell made findings that contradict one another.* For example, IDF 106 says "K-Dur 20 lost some market share to other potassium chloride products"; but this is directly

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[7] CX 62 at 089327 (showing that K-Dur 20's share of overall potassium chloride sales increased by 2.1 percentage points, while all generic potassium chloride ("Generic KCl" plus "Generic KCl - Other Forms") grew by only 1.8 percentage points).

contradicted by IDF 400. The data in IDF 400 show K-Dur 20's share *rising each year*, as well as increasing faster than the generic share. In fact, K-Dur 20's share of total prescriptions did increase each year -- all while Schering was raising its price. Neither of the documents ALJ Chappell cites for the statement in IDF 106 supports the finding. The only other evidence he cited, trial testimony by Upsher executive Phillip Dritsas, also fails to support the finding.

C. ALJ Chappell Made Fundamental Mistakes of Antitrust and Patent Law

Discussion of the legal errors in the ALJ's opinion is properly a subject for our appeal brief. The pervasiveness of these errors is relevant to this motion, however, because of the space we will need to devote in our appeal brief to addressing them.

For example, ALJ Chappell mangles basic patent law principles. Oblivious to the distinction between patent validity and patent infringement, he repeatedly states that an alleged infringer has the burden of proving non-infringement. *See, e.g.*, ID at 103-104 ("Schering had the legal right under its '743 patent to exclude ESI from the market until ESI either proved that the '743 patent was invalid, or that its product, Micro-K20, did not infringe Schering's patent."). But it has *never* been the case that an infringer has the burden of proving non-infringement, as even a cursory review of any patent treatise would establish. *See, e.g.*, Robert L. Harmon, *Patents and the Federal Circuit* (5th ed. 2001) at 300 ("It is axiomatic that the patentee bears the burden of proving infringement.").

ALJ Chappell's erroneous readjustment of the burden of proof is compounded by his fundamental misunderstanding of the nature of patent rights. His opinion suggests, for example, that the patent holder has an absolute right to exclude an alleged infringer by any means of self-help, unless and until there has been a judicial determination of non-infringement or invalidity.

See ID at 103 ("Under its '743 patent, Schering had the legal right to exclude Upsher-Smith from the market until Upsher-Smith either proved that the '743 patent was invalid or that its product, Klor Con M20, did not infringe Schering's patent.").

In fact, however, the Supreme Court has made it clear that: "The heart of [the patent-holder's] legal monopoly is the right *to invoke the State's power* to prevent others from utilizing his discovery without his consent." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) (emphasis added). Tellingly, in quoting *Zenith* in his decision, ALJ Chappell deleted the italicized words. *See* ID at 99. As we will discuss in our appeal brief, this misconception of the nature of patent rights underlies the ALJ's erroneous conclusion that complaint counsel had to prove that Upsher's and AHP's products did not infringe Schering's patent.

The ALJ's mistakes regarding antitrust law are no less fundamental. They range from legal mistakes, *see, e.g.*, ID at 87-88 ("functional interchangeability" is "the primary indicator of a product market") to economic mistakes, such as not knowing what price elasticity means, *see, e.g.*, IDF 422 (complaining that Professor Bresnahan did not study the "direct price elasticity between K-Dur 20 and other potassium products," something ALJ Chappell apparently believed was different from cross-elasticity of demand). These mistakes, too, will require additional space in order to properly address them before the Commission.

II. ALJ Chappell Made Numerous Rulings That Excluded Relevant, Material, and Reliable Evidence and That Require Correction

The ALJ's primary function is to assemble an evidentiary record for the Commission's review. In addition to the numerous errors in the initial decision, our appeal brief will also need to address several of the ALJ's rulings that improperly excluded relevant, material, and reliable

evidence. These rulings rest on, *inter alia*, erroneous concepts of the proper scope of rebuttal evidence; the meaning of the "good cause" standard for exceptions from pre-trial scheduling order deadlines; and the proper foundations for expert testimony.

For example, at trial ALJ Chappell made two rulings that excluded rebuttal evidence offered to attack claims by respondents' witnesses that there was substantial substitution of Upsher's Klor Con 10 for Schering's K-Dur 20. First, ALJ Chappell denied complaint counsel's request to add a rebuttal witness from Walgreens, the largest chain drugstore in the nation, after an Upsher witness gave unexpected and incorrect trial testimony that Walgreens had mandated or promoted what is often referred to as "therapeutic interchange."[8] While "generic substitution" refers to a pharmacist dispensing an AB-rated generic version when presented with a prescription for a brand name drug, "therapeutic interchange" refers to the dispensing of an alternative for the branded drug specified in the prescription that is not an AB-rated generic, but that the pharmacist deems to be therapeutically equivalent. Complaint counsel sought to present rebuttal testimony from William Groth, a knowledgeable Walgreens executive, that:

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[8] Uphser witness Phillip Dritsas put the therapeutic interchange policies of Walgreens directly at issue, claiming that:

> [Upsher] had customers, for example, like Walgreens and Rite Aid who were actually switching every K-Dur [20] prescription for two 10s, because they had the two 10s in the warehouse, they couldn't get any K-Dur 20 product, but they were getting prescriptions for K-Dur 20.
>
> . . . .
>
> Walgreens simply mandated that they substitute the product, because they didn't have any of the 20 milliequivalent. I can't say whether or not each pharmacist called the doctor. Our understanding was the pharmacists were simply dispensing two 10s for a 20.

Tr. 20:4682-83.

- Walgreens never instituted any policy to mandate substituting two Klor Con 10 tablets when K-Dur 20 was prescribed.
- Walgreens' policy is not to promote therapeutic interchange, because state laws require a pharmacist to obtain approval from the physician before instituting a therapeutic interchange. Obtaining such approval is costly for the pharmacist, because of the time the pharmacist must devote to the task, and due to the risk of loss of physician good will.[9]

ALJ Chappell denied a motion to add Mr. Groth as a rebuttal witness, holding that because complaint counsel had touched on "the issue of substitution" at Mr. Dritsas's deposition, "[t]his issue was not a surprise" and accordingly no "good cause" had been shown to add Mr. Groth as a rebuttal witness. Tr. 31:7491-92. Awareness that substitution was an issue in the case, however, would provide no basis to anticipate that testimony of a pharmacy chain would be needed to correct faulty assertions made by Mr. Dritsas for the first time at trial.

Second, ALJ Chappell prevented complaint counsel from presenting rebuttal testimony from our economic expert, Stanford University Professor (and former Chief Economist at the Department of Justice's Antitrust Division) Timothy Bresnahan, to explain data showing that the filling of a K-Dur 20 prescription with Klor Con 10 (which respondents claimed was frequent) was in fact extremely rare. ALJ Chappell barred Professor Bresnahan from testifying about CX 43, a document that had already been admitted in evidence and which contains data on prescription and substitution patterns compiled by IMS Health. The ALJ excluded this testimony on the ground that Professor Bresnahan was "not qualified to proffer an opinion on specific

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[9] *Complaint Counsel's Motion for Leave to Call William Groth as a Rebuttal Witness* (March 8, 2002) at 2, 3; *see also* CX 1778 at ¶¶ 11-14 (Declaration of William E. Groth) (proffered but not admitted).

substitutability." *See* Tr. 34:8052, 8122-23.[10] As we will explain on appeal, however, Professor Bresnahan was amply qualified to testify about this widely-used industry data.

The public interest is best served when the Commission has a complete record upon which assess the merits of each side's case. It is therefore important to have adequate space in our appeal brief to address these and a number of other evidentiary and procedural rulings where ALJ Chappell clearly abused his discretion.

III. The Special Circumstances of This Case Justify an Extension

A third reason to grant leave to file an appeal brief with additional words is that, even apart from the ALJ's errors, the special circumstances of this case require a more extensive appeal brief than would be warranted in the typical FTC administrative adjudication. This case involves two separate agreements with different terms and different parties. Not only is the record voluminous, but the existence of two agreements necessarily means that there are more factual and legal issues to be resolved on appeal than would be the case if only one agreement were at issue. Moreover, this matter presents the Commission with its first opportunity to address, on the basis of an adjudicative record, important issues relating to alleged anticompetitive agreements to delay generic competition. Given the national importance of, and attention focused on, such matters, the public interest would be better served by permitting a more complete presentation of the legal and factual issues than would be possible under the word limit for appeal briefs prescribed in the FTC's Rules of Practice.

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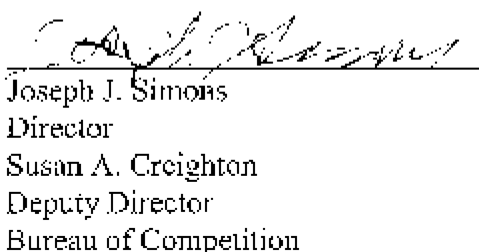
[10] The ALJ had initially also ruled that the document could not be used in Professor Bresnahan's rebuttal testimony on the ground that it was not cited in his expert report, but this basis for exclusion of the testimony was later withdrawn. *See* Tr. 34:8122-23.

IV. Conclusion

We respectfully request leave of the Commission to file an appeal brief with an additional 9,375 words (a 50% increase), bringing the brief's total to 28,125 words. We believe that any one of the bases set forth above is sufficient to find that complaint counsel would face undue prejudice from having to comply with the word limit set forth in the FTC's Rules of Practice.

We have consulted with counsel for the respondents about this request (but not the reasons therefore). Schering's counsel does not oppose the request for additional words, provided that it is permitted to file its answering brief with the same number of additional words. Upsher's counsel does not consent to our request.

Respectfully submitted,



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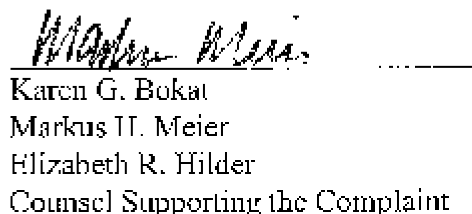

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July 15, 2002

CERTIFICATE OF SERVICE

I, Clifton L. Smith, hereby certify that on the 15th day of July, 2002:

I caused one original and twelve copies of "Complaint Counsel's Motion for Leave to File an Appeal Brief Exceeding the Word Limit in the Commission's Rules of Practice" to be served by hand delivery and one copy to be served by electronic mail upon the following person-

Office of the Secretary
Federal Trade Commission
Room H-159
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Washington, D.C. 20580

I caused one copy of "Complaint Counsel's Motion for Leave to File an Appeal Brief Exceeding the Word Limit in the Commission's Rules of Practice" to be served upon the following person by hand delivery -

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