

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION



In the Matter of)	
)	
Schering-Plough Corporation, a corporation,)	
)	
Upsher-Smith Laboratories, a corporation,)	Docket No. 9297
)	
and)	
)	
American Home Products Corporation, A corporation.)	

**MOTION *IN LIMINE* TO EXCLUDE TESTIMONY OF
UMESH V. BANAKAR AND MARTIN J. ADELMAN**

Respondent Schering-Plough Corporation ("Schering") respectfully submits this motion for an order *in limine* to: (a) exclude the testimony of Umesh V. Banakar, Ph.D. ("Dr. Banakar") entirely or, in the alternative, exclude parts of his proffered testimony as set forth hereinafter; and (b) exclude the testimony of Martin J. Adelman ("Mr. Adelman") entirely. As more fully set forth in the accompanying memorandum, Dr. Banakar and Mr. Adelman failed to provide expert opinions based on sufficient facts and data from the underlying patent cases and opined on matters that are prohibited by Rule 702 and not relevant to the present case. Thus, their testimony are improper and must be excluded. A proposed order is attached.

Respectfully submitted,

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Schering-Plough Corporation

Dated: January 16, 2002

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Upsher-Smith Laboratories,)	Docket No. 9297
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**MEMORANDUM OF LAW IN SUPPORT OF
RESPONDENT SCHERING-PLOUGH CORPORATION'S
MOTION TO EXCLUDE TESTIMONY OF
UMESH V. BANAKAR AND MARTIN J. ADELMAN**

Respondent Schering-Plough Corporation ("Schering") respectfully submits this memorandum of law in support of its motion *in limine*, pursuant to the Federal Rules of Evidence. Schering seeks an order *in limine* to: (a) exclude the testimony of Umesh V. Banakar, Ph.D. ("Dr. Banakar") entirely or, in the alternative, exclude parts of his proffered testimony as set forth hereinafter; and (b) exclude the testimony of Martin J. Adelman ("Mr. Adelman") entirely.

I. Introduction

Complainant counsel have proffered Dr. Banakar as an expert witness in rebuttal to the testimony of Schering's technical experts, Drs. Gilbert S. Banker and Robert S. Langer. Complainant counsel have also proffered Mr. Adelman as an expert witness in rebuttal to the testimony of Schering's patent experts, Messrs. Gerald H. Bjorge and Mr.

rebuttal to the testimony of Schering's patent experts, Messrs. Gerald H. Bjorge and Mr. Charles E. Miller. All of Schering's patent experts will give testimony regarding the actual issues in the underlying patent infringement cases, *Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc.*, Civil Action No. 95-6281 (D.N.J.) ("Upsher Case") and *Key Pharmaceuticals, Inc. v. ESI-Lederle, Inc.*, Civil Action No. 96-CV-1219 (E.D. Pa.) ("ESI Case"). 16 C.F.R. § 3.31(b)(3). All but one of Schering's patent expert witnesses were also witnesses in the underlying cases.

Pursuant to Rule 3.31(b)(3) and this Court's scheduling order, Dr. Banakar and Mr. Adelman each submitted an expert report detailing the specifics of their opinions regarding their proposed testimony. A copy of "Expert Report of Umesh V. Banakar, Ph.D. on Behalf of Complainant Counsel" is attached hereto as Exhibit 1. A copy of "Expert Report of Martin J. Adelman on Behalf of Complainant Counsel" is attached hereto as Exhibit 2.

As set forth in greater detail below, an Order excluding Dr. Banakar's testimony in its entirety is warranted under Rule 702 of the Federal Rules of Evidence. Dr. Banakar eschews offering expert opinions, but instead purports to testify only as to what one of ordinary skill in the art would recognize or appreciate. Further, Dr. Banakar has not studied the complete record from the underlying patent cases and does not testify as to the likely outcome of those cases. Instead, Dr. Banakar purports to state his own views based on a scant review of selective parts of the record. As Dr. Banakar is not testifying to the likely outcome of the underlying patent cases based on the evidence and arguments actually of record in the *Upsher* and *ESI* cases, his testimony is simply not relevant to any issue in this case and should therefore be excluded.

Finally, some of the purported "facts" in Dr. Banakar's expert report are simply fabrications, made up from whole cloth and devoid of support in the record. Even if he is allowed to testify, the Court should not accept any testimony from Dr. Banakar as to conjured allegations and concocted facts contained in his reports.

Exclusion of Mr. Adelman's report in its entirety is similarly warranted under Rule 702 of the Federal Rules of Evidence. Like Dr. Banakar, Mr. Adelman has not studied the complete record from the underlying patent cases and does not purport to testify to the likely outcome of those cases. Mr. Adelman purports to offer only his personal opinion as to his view of the law, consisting of purely legal conclusions unsubstantiated by facts from the underlying patent cases. As Mr. Adelman is not testifying to the likely outcome of the underlying patent cases based on the evidence and arguments actually of record in the *Upsher* and *ESI* cases, his personal views are also irrelevant to the issues before this case, and his testimony should therefore be excluded.

II ARGUMENTS

Expert testimony in this case must comply with Rule 702 of the Federal Rules of Evidence. See December 20, 2001 Hearing Tr. at 16 (this case is governed by federal rules and case law when there is no governing FTC rules). Rule 702 was amended effective December 1, 2000, expressly *requiring* such testimony to satisfy three separate relevance and reliability criteria: "(1) the testimony [must be] based upon *sufficient facts or data*, (2) the testimony [must be] the product of *reliable principles and methods*, and (3) the witness [must have] *applied the principles and methods reliably to the facts of the case*." Fed. R. Evid. 702 (emphases added). Thus, the court must "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993)). An additional consideration under Rule 702 toward the relevance of the expert's testimony is "whether [the] expert testimony proffered in the case is sufficiently tied to the facts of the case." *Id.* at 591.

Here, Complainant Counsel has ignored these principles by asking Dr. Banakar and Mr. Adelman to provide expert opinions without reviewing the entire record from the underlying patent cases, regarding matters for which expert testimony is simply not allowed by Rule 702, and opining on issues that are simply not relevant to the present case. Thus, these opinions and testimony based thereon are improper and must be excluded.

The Supreme Court held in *Daubert* that admissible expert opinion testimony must be based on reliable foundation and relevant to the task at hand. *See Daubert v. Merrell Dow Pharma.*, 509 U.S. 579, 590 (1993). In this case, an expert attempting to offer a reasoned and informed opinion helpful to the fact finder, at a minimum, would consider the complete record of the case at issue and rely on accurate facts in formulating the opinions. *See Smelser v. Norfolk Southern Railway Co.*, 105 F.3d 299 (6th Cir. 1997)(excluding expert testimony when *inter alia* the supposed expert failed to consider plaintiff's entire medical history); *see also Wellman v. Norfolk & Western Railway, Co.*, 98 F.Supp.3d 919 (S.D. Ohio 2000)(limited scope of expert testimony by excluding outside expert's knowledge). Moreover, "[e]xpert testimony which does not relate to any issue in the case is not relevant and ergo, non-helpful" *Daubert*, at 591, (citing *United States v. Downing*, 753 F.2d 1224, 1242 (CAS 1985)). Thus, Dr. Banakar and Mr. Adelman's failure to provide opinion based on a review of the entire record from the underlying patent cases renders their testimony improper and not relevant to the issues of this case. Therefore, pursuant to the Federal Rules of Evidence, Dr. Banakar and Mr. Adelman should be prohibited from testifying as rebuttal witnesses in the upcoming trial.

A. Dr. Banakar's Testimony Should Be Excluded In Its Entirety

As noted, Complainant Counsel purports to offer Dr. Banakar's testimony as rebuttal to Schering's technical experts, Drs. Banker and Langer regarding the technical issues of the underlying patent cases.

However, Dr. Banakar's testimony is improper because he does not offer an opinion as an expert in the relevant technical field. Further, Dr. Banakar's testimony is also improper because he failed to review sufficient facts from the record of the underlying patent cases to opine on the likely outcome of those cases. Finally, Dr. Banakar's testimony is improper because he is proffering his own view of the underlying patent cases without sufficient regard for the issues actually litigated in these two cases. Thus, his views are not relevant to the issues in this case. Accordingly, Dr. Banakar's opinion testimony based on his report should be excluded.

Assuming that Dr. Banakar can be qualified as an expert in the relevant technical field, he specifically eschews relying on any specialized expert knowledge to offer the opinions set forth in his Report.

In the context of patent law, there exists a legal fiction of "a person of ordinary skill" with respect to the analysis of certain patent issues similar to that of a "reasonable

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hereto as Exhibit 3.

A copy of the transcript is attached

prudent person” in torts. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1566 (Fed. Cir. 1987)(noting that in patent law context, “a person having ordinary skill in the art” is not unlike the ‘reasonable man’ and other ghosts in the law”); *See, Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd.*, 122 F.3d 1040, 1042 (Fed. Cir. 1997)(stating that “a person of ordinary skill in the art” is a theoretical construct used in determining obviousness under §103, and is not descriptive of some particular individual). A technical expert assisting the trier of fact in determining factual interpretations must provide *an expert opinion* regarding the viewpoints of a person of ordinary skill.

Dr. Banakar’s testimony should also be excluded because Dr. Banakar failed to study sufficient facts from the record of the underlying cases to have an informed view as to the issues in either case.

This list is an incomplete list of the materials from the record of the underlying patent cases, containing only selective excerpts provided by complainant counsel. In fact, many of the relevant materials from the underlying patent cases are plainly missing.² Additionally,

As Dr. Banakar has only reviewed selective excerpts from the record in the underlying patent cases, any opinion offered as to the outcome of the issues in those cases would necessarily be improper and therefore

² For example,

inadmissible pursuant to Rule 702 of the Federal Rules of Evidence. See, *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281 (Fed. Cir. 1985)(stating that the lack of factual support for expert opinions renders the testimony of little probative value.); *W.L. Gore and Associates, Inc. v. Garlock Inc.*, 842 F.2d 1275 (Fed. Cir. 1988)(finding that where the evidence consisted merely of one expert's opinion without supporting tests and data, the district court is under no obligation to accept such opinion).

Moreover,

Thus, Dr. Banakar is only proffering his own personal views based on selective excerpts of the record. He does not purport to offer a judgement as to how the underlying cases were likely to be resolved.

The underlying merits of the *Upsher* and *ESI* patent cases are relevant here as they demonstrate that Schering had an objectively strong patent case. An objective analysis of the merits of the underlying cases is thus relevant to whether the settlement of these cases was pro-competitive. Moreover, an objective assessment of the likely outcome of the *Upsher* and *ESI* cases requires an assessment of the record from these cases. Dr. Banakar's personal views today, wholly apart from record of the underlying cases or based on selected excerpts, are simply not relevant. Thus, Dr. Banakar's proffered testimony, however, does not address the issues relevant to this case.

Dr. Banakar does not purport to opine how technical issues would have been resolved based on the record in the *ESI* and *Upsher* cases. Rather, Dr. Banakar has taken highly selective excerpts from the record, generated new arguments³ not made in the

³ One of the issues in the *Upsher* case is whether Upsher's use of sorbitan monooleate in its product is "equivalent" to the hydroxypropylcellulose claimed in claim 1 of the '743 patent for a finding of

underlying cases and opined about his personal view based on the selective excerpts at issue he studied. Dr. Banakar's subjective assessment, separated from the evidence and issues as actually found in the *Upsher* and *ESI* cases, is simply not probative of the issues before this Court. Such his testimony is simply not relevant and must be excluded in its entirety.

In addition, Dr. Banakar's testimony is also not proper as "rebuttal testimony" to Schering's technical experts, Drs. Gilbert Banker and Robert Langer.⁴ Unlike Drs. Banker and Langer, Dr. Banakar was not involved in the underlying patent infringement cases.⁵ Drs. Banker and Langer were testifying experts in the underlying case and are prepared to testify in this case the testimony they would have provided in the underlying cases if those cases had gone to trial. In contrast, Dr. Banakar was not a witness in the underlying cases and, as shown above, had not reviewed the record in its entirety. The opinions offered in the Banakar Report are simply his personal views of an outcome, based on selective excerpts from the underlying cases. As such, Dr. Banakar's testimony is not appropriate as rebuttal testimony and should be excluded.

As shown, Dr. Banakar eschewed offering expert opinions and the opinions offered were his personal views of the underlying cases based on selective excerpts from those cases. Thus, the opinions contained in the report and any testimony regarding those opinions are improper. Additionally, as Dr. Banakar is not testifying to the likely

infringement under the doctrine of equivalents.

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⁵ In fact, with respect to Dr. Langer's experiments,

outcome of the underlying patent cases based on the evidence actually of record in the *Upsher* and *ESI* cases, his testimony is simply not relevant to any issue in this case. Hence, Dr. Banakar's report should be excluded in its entirety.

B. Dr. Banakar Should Be Prohibited From Testifying As To Facts He Made Up

Even if Dr. Banakar is allowed to testify during the upcoming trial, the Court should not accept any testimony from Dr. Banakar as to conjured allegations based on fabricated facts.

In these paragraphs, Dr. Banakar attempted to address one of the issues in the *Upsher* case involving the impact of changes made to claim 1 of the '743 patent during the prosecution of the patent. Generally, changes to the claims of a patent application could impact the patent coverage afforded by the claim upon issues of the patent and, hence, the patent infringement analysis. See, *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997). In particular, in the *Upsher* case, one of the issues is whether the *Upsher* product infringes the claims of the '743 patent under what is called the "doctrine of equivalents." An infringement under the doctrine of equivalents occurs where "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Id.* at 21. An inquiry under the doctrine of equivalents is whether an element

⁶ The "prosecution history" of a patent contains the final text of the patent as issued by the United States Patent and Trademark Office ("PTO"), any documents presented to the PTO, any correspondence between the attorney for the applicant and the PTO examiner, and any amendments made to the patent application during the patent procuring process.

of the accused device is insubstantially different from the element of the patent claim.⁷
Id. at 39-40.

This

statement is simply untrue.

The prosecution history of the '743 patent does not discuss ethylcellulose having a viscosity of 20 cp. In fact, "ethylcellulose having a viscosity of approximately 20 cp" is not found anywhere in the '743 patent or its prosecution history. Thus, Schering could not have made any representation during the patent prosecution process regarding any product using ethylcellulose having a viscosity of approximately 20 cp. Any factual assertion to the contrary,

, is not supported by the record.

It is therefore not surprising that Dr. Banakar

⁷ Another way of making this inquiry is to determine whether the element in the alleged infringer's product functions substantially the way to obtain the same result as the claimed element. *See, Warner-Jenkinson*, at 39-40.

⁸ "cp" is an abbreviation for centipoise, a measure of viscosity.

⁹ According to Upsher's Development Report, Upsher's product contained ethylcellulose having a viscosity between 18-22 cp.

Accordingly, _____, are mere allegations unsubstantiated by facts and must be excluded. Accordingly, even if Dr. Banakar is allowed to testify, he should not be permitted to testify as to the matters contained in these paragraphs.

In reality, there is no indication in the '743 patent or its prosecution history relating to hydroxypropylcellulose creating channels or holes in the ethylcellulose. In fact, the words "channels" or "holes" or any similarly related concepts are not found in the '743 patent or its prosecution history.

Thus, _____, must be excluded and the Court should prohibit Dr. Banakar from testifying as to the matters contained in these paragraphs.

Accordingly, even if Dr. Banakar is allowed to testify during the upcoming trial, the Court should prohibit testimony consisting of conjured allegations based on fabricated facts he made up by prohibiting Dr. Banakar from offering opinion testimony

C. Dr. Adelman's Testimony Should Be Excluded In Its Entirety

Exclusion is similarly warranted of Mr. Adelman's testimony. Although Rule 704(a) of the Federal Rules allow expert opinion testimony that "embrace[s] an ultimate issue to be decided by the trier of fact" in civil cases, courts have guarded against experts offering opinions embodying purely legal conclusions. *See United States v. Scop*, 846 F.2d 135, 139 (2d Cir. 1988); *Dunn v. Hovic*, 1 F.3d 1362, 1367 (3d Cir. 1993); *Endress + Hauser, Inc. v. New Hawk Measurement Systems, Pty, Ltd.*, 122 F.3d 1040,1042 (Fed. Cir. 1997)(noting the impropriety of patent lawyers testifying as expert witnesses providing only legal conclusions). In patent infringement cases, however, courts have recognized that the technical complexity of these cases counsels in favor of admitting expert testimony to assist in reaching the proper result. *See, Mars, Inc. v. Coin Acceptors, Inc.*, 1996 U.S. Dist. LEXIS 21514 (D.N.J. 1996)(citing *Mendenhall v. Cedarpaids, Inc.*, 5 F.3d 1557, 1574 (Fed. Cir. 1993).

Schering's expert, Mr. Bjorge, was involved in both of the underlying patent cases as Schering's patent law expert. In this capacity, Mr. Bjorge reviewed all the relevant evidence from the underlying patent cases in formulating his expert opinions in those cases as well as this proceeding. Based on his involvement with the underlying patent cases and his specialized knowledge in patent law, Mr. Bjorge is proffering expert opinions that will assist this Court in the application of patent law to the specific factual controversies presented in the underlying patent cases. Mr. Bjorge's testimony is additionally helpful to this Court because he is prepared to provide the testimony he would have provided in the underlying cases if those cases had gone to trial. Such

opinion is highly valuable to the Court in assessing the issues in the present case. See, *Yarway Corp. v. Eur-Control USA, Inc.*, 775 F.2d 268, 274 (Fed. Cir. 1985)(noting with approval that in the manner not unusual in patent law cases, opinions of patent law experts are helpful when "testifying about questions of patent law as if it were foreign law.")

Similarly, Schering's expert, Mr. Miller is opining on the likely outcome of the underlying patent cases based on his review of all the relevant evidence from the entire record of the those cases. In particular, Mr. Miller's opinions are based on an objective assessment of the entire record from the underlying patent cases to determine whether the split of the patent term remaining for the '743 patent at the time of the respective settlements fairly reflected the relative strengths of the parties' positions. Based on this review of and his specialized knowledge in patent law, Mr. Miller is proffering expert opinions that will assist this Court in the application of patent law to the specific factual controversies presented in this case. Such opinion is also highly relevant and valuable to this Court.

Unlike Mr. Bjorge, Mr. Adelman was not involved the underlying patent cases. Unlike Mr. Miller, Mr. Adelman has not reviewed all the relevant evidence from the underlying patent cases in formulating his expert opinions regarding the likely outcome of those cases. In contrast, the opinions proffered in Mr. Adelman's report are only legal conclusions with minimal factual considerations.

Mr. Adelman simply has not reviewed the materials from the underlying cases necessary to offer factually substantiated testimony. Mr. Adelman was not involved in the underlying patent cases.

¹⁰
transcript is attached hereto as Exhibit 4.

*
*
A copy of the deposition

With such limited consideration of the facts from the underlying cases, Mr. Adelman is unqualified to provide factually substantiated expert opinions. Thus, the opinions in Mr. Adelman's report are improper as legal conclusions and must therefore be excluded. *See, Bausch & Lomb, Inc. v. Alcon Lab., Inc.* 79 F. Supp. 2d 252, 258 (excluding expert testimony as impermissible where the expert was not involved in any of the relevant events and was only opining on legal conclusions.)

Exclusion of the Adelman Report is also necessary pursuant to Rule 702 because Mr. Adelman is not proffering testimony relevant to any issue in this case. Mr. Adelman simply did not review sufficient facts to provide opinions that are relevant to this case.

Thus, Mr. Adelman's attempt to proffer opinions regarding the likely outcome of the underlying cases without considering evidence from these cases cannot possibly be helpful to this Court and must therefore be excluded.

In fact, the opinions offered in the Adelman Report are simply his personal opinions as to his view of the law. As such, his opinions are neither rebuttal to the

Schering case nor are they even relevant to any issue in the case.

Setting aside the merit of the argument, Mr. Adelman's proposition of the argument itself demonstrates that he is merely proffering his personal views of the underlying cases instead of evaluating the strength and weakness of each case based on the facts from those cases.

Mr. Adelman's legal arguments, wholly apart from arguments made in the underlying cases, are simply not relevant to this case. As noted previously, the relevant issue in this case is the objective assessment of the strength of the parties' positions at the time of the *Upsher* and *ESI* cases and not Mr. Adelman's subject view of these cases today. Thus, Mr. Adelman's personal views regarding the underlying patent cases are improper and not helpful to this Court.

Notwithstanding the fact his testimony advocating new legal arguments is not relevant to the issues in this case, admission of Mr. Adelman's testimony regarding this argument is also improper for it is legally wrong.

With respect to the ESI case, Mr. Adelman's vague and unsupported opinions demonstrate his lack of factual knowledge of the ESI case and are also unhelpful to a determination of the outcome of the underlying patent case.

¹¹ Claim 1 of the '743 patent was originally filed in the application without an ethylcellulose-viscosity limitation. Claims 8 and 9 of the application as filed contained the ethylcellulose viscosity limitation that Mr. Adelman is now arguing as never having been claimed.

Thus, these opinions are merely unsupported, conclusory legal opinions at best without any probative value, and as such, they are improper and must be excluded. *See, J.G. Peta, Inc. v. Club Protection, Inc.*, 2000 U.S. Dist. LEXIS 20315 (N.D.N.Y. 2000)(excluding expert opinion where the expert's opinion on infringement is conclusory and inaccurate.); *See also, Brooke Group Ltd., v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1993)(finding expert opinion evidence insufficient as a matter of law when the experts opinion is not supported by sufficient facts); *Bailey v. Allgas, Inc.*, 148 F. Supp. 2d 1222, 1238 (U.S.D.C. Ala., 2000) (granting motion to strike expert's testimony because he did not review all facts, because "[e]xpert testimony is useful as a guide to interpreting market facts, but is not a substitute for them.").

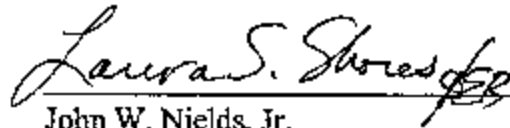
It is clear from above that the legal conclusions set forth in the Adelman Report are impermissible. *See, Bausch & Lomb, Inc. v. Alcon Lab.*, 79 F. Supp. 2d 252, 258 (W.D.N.Y 2000)(finding impermissible expert opinions that are purely legal opinions "clearly calculated to invade the province of the court to determine the applicable law.")(citing cases).

Thus, Mr. Adelman's testimony is of no probative value to this Court and must be excluded in its entirety.

III. CONCLUSION

For the foregoing reasons, Schering respectfully requests that the Court grant the motion directing an order, *in limine*, to (a) exclude Dr. Banakar's expert report in its entirety or, in the alternative, exclude in part as set forth above; (b) exclude Mr. Adelman's expert report in its entirety; and (c) prohibit Dr. Banakar and Mr. Adelman from offering expert testimony during trial.

Respectfully submitted,



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Attorneys for Respondent
Schering-Plough Corporation

Dated: January 16, 2002

CERTIFICATE OF SERVICE

I hereby certify that this 16th day of January 2002, I caused an original, one paper copy and an electronic copy of Respondent's Motion *In Limine* to Exclude Testimony of Umesh V. Banakar and Martin J. Adelman and accompanying memorandum to be filed with the Secretary of the Commission, and that two paper copies were served by hand upon:

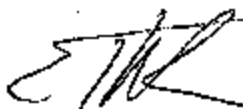
Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
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and one paper copy was hand delivered upon:

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Erik T. Koons

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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**(PROPOSED) ORDER *N IN LIMINE* TO EXCLUDE TESTIMONY OF
UMESH V. BANAKAR AND MARTIN J. ADELMAN**

IT IS HEREBY ORDERED THAT:

Pursuant to Rule 702 of the Federal Rules of Evidence, Complainant counsel is hereby precluded from offering (a) testimony Umesh V. Banakar, Ph.D. ("Dr. Banakar") entirely or, in the alternative, prohibiting Dr. Banakar from offering opinion testimony regarding matters

("Mr. Adelman") entirely.

The Honorable D. Michael Chappell
Administrative Law Judge