ORIGINAL

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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 **PUBLIC VERSION**

COMPLAINT COUNSEL'S OPPOSITION TO SCHERING'S MOTION *IN LIMINE* TO EXCLUDE TESTIMONY OF UMESH V. BANAKAR AND MARTIN J. ADELMAN

Schering has moved to exclude the testimony of Dr. Umesh V. Banakar and Mr. Martin J. Adelman, Esq. Dr. Banakar is a professor of pharmaceutics and an expert on subjects including drug product development and evaluation, and dissolution and bioavailability assessment. He is being offered to testify concerning the technical aspects of the infringement cases against Upsher and ESI in rebuttal to Schering's two experts on that subject, Gilbert S. Banker and Robert S. Langer. Mr. Adelman is a patent law professor and author. He is being offered to testify on the major legal issues that were raised in those cases in rebuttal to Schering's two patent law experts, Gerald H. Bjorge, Esq. and Charles E. Miller, Esq.

Schering's motion is entirely without merit and should be denied. Dr. Banakar and Mr. Adelman are recognized experts in their fields, and will offer reliable testimony with respect to the issues they will address. Schering's primary complaint is that the testimony does not address

what it believes to be the only relevant question -- what the outcome likely would have been of the patent infringement cases that Schering brought against Upsher and ESI. As explained below, Schering is attempting to measure the testimony of Dr. Banakar and Mr. Adelman against an improper standard of relevance for which it does not even bother to offer any support. Moreover, the testimony of the expert witnesses that Schering is offering on the patent issues flagrantly violates the very standards against which Schering judges Dr. Banakar and Mr. Adelman to be wanting.

A. Dr. Banakar and Mr. Adelman Will Offer Reliable Testimony That Is Proper Rebuttal to Schering's Expert Witnesses

The testimony of Dr. Banakar and Mr. Adelman is not offered to establish the likely outcome of the litigation. As discussed below, that inquiry is neither relevant nor reasonably possible. Rather, because Upsher and ESI no longer have any incentive to defend the positions they took in the infringement cases, the testimony is offered simply to rebut Schering's assertions that it likely would have won the lawsuits and therefore had the right to exclude the Upsher and ESI products for the full life of the patent. It is intended to establish that ************************** ** *** This is the only point to which the testimony of any of the experts concerning the underlying patent infringement cases could possibly be relevant. If a determination is made that the testimony of Schering's four patent experts does not need to be heard, then of course the expert testimony of Dr. Banakar and Mr. Adelman will not be necessary. But if the testimony offered by Schering is admitted, then so too should be the testimony of Dr. Banakar and Mr. Adelman.

Under the FTC's Rules of Practice, "relevant, material, and reliable evidence shall be admitted."[1] Both experts are clearly qualified to offer an expert opinion on the questions they address, and the work they did was sufficient to support their opinions.

1. Dr. Banakar

Dr. Banakar has a doctoral degree; his graduate work focused on pharmaceutical technology and pharmaceutical chemistry. He has served as professor of pharmaceutics at several universities and was recently Chairman of Pharmaceutical Sciences and Graduate Programs at Butler University, College of Pharmacy and Health Sciences. He has authored over 100 publications including works in the area of drug dissolution, generic drug development, advances in new drug delivery systems, and controlled release technology. He also has chaired or taught at numerous national and international conferences about drug design, development, and evaluation.[2] The materials Dr. Banakar reviewed included the patent, the prosecution history, all motions, memos, declarations, and exhibits in connection with Upsher's Motion for Summary Judgement of Noninfringement in the underlying patent litigation, expert reports filed by the parties related to patent issues, and Upsher's development report on its generic product.[3] He will testify only to two fundamental points: ••

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[1] 16 C.F.R. § 3.43(b) (emphasis added).

[2] *Curriculum Vitae* of Dr. Banakar (Attachment A).

[3] Banakar Expert Report at 2-3 (Attachment B).

finding of substantial difference defeats a claim of infringement under the "doctrine of equivalents." The material that Dr. Banakar considered is sufficient to reliably identify the main facts or data that each side intended to present in the underlying litigation and for Dr. Banakar to apply the principles and methods in which he is an expert to the facts of the case.

Schering has not pointed to any way in which Dr. Banakar's testimony fails to satisfy the requirements of Rule 702 of the Federal Rules of Evidence that expert testimony be based upon sufficient facts or data, be the product of reliable principles and methods, and reliably apply the principles and methods to the facts of the case. Schering's claim that Dr. Banakar does not offer an opinion as an expert in the relevant technical field is rather puzzling. Schering does not actually challenge Dr. Banakar's qualifications as an expert. Instead, it claims that Dr. Banakar's testimony is not based on expert knowledge but only on the viewpoint of "a person of ordinary skill in the art." As Schering very well knows, the standard for analyzing a patent is that it should be interpreted from the point of view of "a person of ordinary skill in the art" to which the patent is related. Schering's quarrel with Dr. Banakar appears to be that he expressed his opinion directly from the point of view of a person of ordinary skill in the art, rather than stating his conclusion as "*an expert opinion* regarding the viewpoints of a person of ordinary skill."[4] As is clear from a review of Dr. Banakar's report, this is a silly semantic distinction that has nothing to do with the reliability of the testimony. There can be no dispute that Dr. Banakar is in fact an expert in the art of pharmaceutical coatings and has significant expertise and experience relating to the issues to which his opinions relate.

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[4] Schering Mem. at 6 (emphasis in the original). Indeed, Schering's expert Dr. Banker also will testify about what would be understood by one of ordinary skill in the art.

Schering's contention that Dr. Banakar "made up" facts is totally disingenuous and again attempts to elevate a semantic quibble into a basis for excluding the entire testimony. A fair reading of Dr. Banakar's report and deposition testimony is that he was drawing a simple conclusion about the effect of actions that were reflected in the prosecution history, not asserting that Schering anywhere said in exactly those words that a product using ethylcellulose having a viscosity of approximately 20 cp was not within the claimed invention. The basis for such a conclusion is discussed in Mr. Adelman's report. Dr. Banakar's reliance upon or agreement with that conclusion hardly amounts to "making up" facts. Dr. Banakar stated that he reviewed the prosecution history of the '743 patent and Mr. Adelman's anticipated testimony and concluded that ••[5] Such materials taken in their entirety provide ample basis to support the specific conclusions in Dr. Banakar's report.

The other matters referred to on page 11 of Schering's memorandum also relate to conclusions or inferences that Dr. Banakar drew from facts he reviewed. Schering's quibbles with the precision with which Dr. Banakar stated the bases for his conclusions can be fully aired on cross-examination.[6]

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[5] Banakar Dep. at 108-110 (Attachment C).

[6] *International Adhesive Coating Co., Inc. v. Bolton Emerson Int'l, Inc.*, 851 F.2d 540, 544 (1st Cir. 1988) (reasoning that "[t]he burden is on opposing counsel through cross-examination to explore and expose any weakness in the underpinnings of the expert's opinions"); *Eclipse Electronics v. Chubb Corp.*, 2001 U.S. Dist. LEXIS 20884, at *18 (E.D.Pa. 2001) (denying motion *in limine* to exclude expert based on concerns about methodology as those concerns better addressed through cross-examination); *Don Motlow, Sr. v. Union Pacific R.R. Co.*, 1997 U.S. Dist. LEXIS 20687, at *2 (E.D.La. 1997) ("defendant's concern about lack of basis does not warrant exclusion of Massie's testimony, and any doubts about its accuracy or foundation can be elicited on cross-examination").

2. Mr. Adelman

Mr. Adelman is currently Professor of Law and Director of the Intellectual Property Program and Director of the Dinwoodey Center for Intellectual Property Studies at the George Washington University Law School. He has written a large number of books and articles on patent law topics, and he has testified as an expert on patent law and practice at trial or in deposition in more than 150 patent infringement cases.[7] The materials he examined included the patent and its prosecution history; all motions, memos, declarations and exhibits in connection with Upsher's Motion for Summary Judgment in the patent case; some expert reports and depositions filed in the Upsher patent case; and the reports of Schering's patent and technical experts in this case.[8] He will state two fundamental conclusions:[redacted][9] and [redacted][10] His preparation is sufficient to support the views he expresses.

Schering's objections to Mr. Adelman's testimony are without merit. Schering has not challenged Mr. Adelman's qualifications directly, since Mr. Adelman is eminently well-qualified in his field. Rather, Schering argues that Mr. Adelman's opinions should be excluded as

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[7] *Curriculum Vitae* of Mr. Adelman (Attachment D).

[8] Adelman Expert Report at 2-3 (Attachment E).

[9] *Id.* at 3.

[10] *Id.* at 3, 8.

improper legal opinions that invade the province of the court to determine the applicable law.[11] This is a startling argument, to say the least, as Mr. Adelman is being offered solely to rebut the testimony of Schering's *two* patent lawyers, who will offer their opinions on the legal issues in the patent cases. As is stated in our motion to exclude the testimony of these two experts, Mr. Miller and Mr. Bjorge, their testimony constitutes inadmissible legal opinion.[12] Should that motion be granted, there will be no need to call Mr. Adelman. But there is no basis for excluding the Adelman testimony if Schering's patent law experts are permitted to testify.

Schering's argument that Mr. Adelman's opinion is simply incorrect on one point is not a proper grounds for excluding his testimony.[13] First, Schering's objection relates to only one of three independent grounds upon which Mr. Adelman's conclusion rests.[14] Moreover, the proper interpretation of *Maxwell*, if indeed it is relevant, can be addressed in cross-examination or in post-trial briefing.

Finally, Mr. Adelman's opinions about the ESI product were based on Dr. Banakar's expert report, the reports of Schering expert witnesses Mr. Bjorge and Mr. Miller, and his reading of the patent claims and prosecution history.[15] An assessment of patent infringement

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[11] Schering Mem. at 14, 17.

[12] Memorandum in Support of Complaint Counsel's Motion to Limit or Exclude Duplicate and Improper Expert Witness Testimony at 13-14 (Jan. 3, 2002) ("Complaint Counsel's Motion to Limit or Exclude").

[13] Schering Mem. at 15-16.

[14] Adelman Expert Report at 4.

[15] Adelman Dep. at 79-80 (Attachment F).

fundamentally involves looking at the patent and its prosecution history and comparing the claims to the accused product.[16] That is what Dr. Adelman did here.

B. Schering's Asserted Relevance Standard Does Not Justify Exclusion of the Testimony

The main basis for Schering's motion to exclude the testimony of Dr. Banakar and Mr. Adelman appears to be the claim that their testimony is irrelevant because it does not address the question that Schering deems to be the only relevant one, in the precise way that Schering asserts is necessary. In numerous places in its memorandum, Schering asserts that the relevant issue is "the likely outcome of the underlying patent cases based on evidence and arguments actually of record in the *Upsher* and *ESI* cases,"[17] or "the objective assessment of the strength of the parties' positions at the time of the *Upsher* and *ESI* cases."[18] Taking this as the standard for evaluating the relevance of their testimony, Schering faults Dr. Banakar and Mr. Adelman on two grounds: (1) they did not review the *entire* record of the underlying patent cases, and (2) they offer only their "personal opinions" about the issues raised in the patent litigation rather than predicting the likely outcome of those cases. Schering's objections are misplaced because they assume a legal conclusion regarding the antitrust standard for evaluating the nature and likely effects of cash payments to the purported infringer in connection with patent settlement agreements (1) for which no legal support or even argument is offered in Schering's supporting memorandum; (2) that has never been sanctioned by any court; and (3) that already has been rejected in this court's

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[16] *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995), *aff'd*, 116 S. Ct. 1384 (1996).

[17] Schering Mem. at 2.

[18] *Id.* at 15. *See also id.* at 3-5, 7-9, 14.

ruling on Schering's motion to dismiss the complaint. Moreover, Schering's own witnesses fail to satisfy the standards articulated in its motion.

1. Schering's Asserted Standard is Ambiguous, Has No Legal Support, and is Impossible to Implement

While Schering asserts that the issue to be decided is "the likely outcome of the underlying patent cases based on evidence and arguments actually of record in the *Upsher* and *ESI* cases,"[19] *nowhere* in its memorandum is any legal citation offered to support this claim. Neither does its memorandum contain any discussion of the basis for this contention. Rather, Schering simply asserts it, as a self-evident truth, without making any effort to articulate a basis for the conclusion.

What Schering means by this proposed test is unclear. On the one hand, Schering may be arguing that the relevant legal question is what the "actual" outcome of the two cases would have been – that is, what the particular judge and jury hearing those cases at that time actually would have decided. Applying this test, however, requires more than a review of the evidence produced for those cases. It also would require determining a myriad other factors, including the skill with which each side would have presented its case, the rulings that the judge would have made on legal and evidentiary questions, and what factual determinations the judge or jury would have made. Manifestly, this is an impossible task. The case was not heard, the judge did not make those rulings, no facts were found, and there is no way to predict with any assurance how those actual cases would have turned out. Indeed, as one of Schering's own expert witnesses, James P.

[19] *Id.* at 2.

O'Shaughnessy, stresses, [redacted][20] In his expert report Mr. O'Shaughnessy, a patent trial lawyer, explains that in the cases in which he has been involved, he frequently has been

> [redacted][21]

For this reason, Mr. O'Shaughnessy states,

> [redacted][22]

Dr. William O. Kerr, one of Upsher's economic experts, made a similar point:

> [redacted][23]

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[20] O'Shaughnessy Expert Report at 4 (Attachment G).

[21] *Id.* at 6.

[22] *Id.* at 9.

[23] Kerr Expert Report at 20 (Attachment H).

Even Mr. Miller, one of Schering's patent law experts, concedes in his report that [redacted][24] This does not, strangely, deter him from offering the opinion that there was [redacted] that Schering would have won the case against Upsher. As was noted in our memorandum in support of our motion to exclude the testimony of Mr. Miller and Mr. Bjorge, these witnesses' analyses of the likely outcomes of the patent cases are not reliable admissible evidence. As we stated, "there are no known or generally accepted techniques of handicapping patent trials, no peer reviewed journals of patent case prediction techniques, no standards for controlling the methods applied by Messrs. Miller and Bjorge, and no one has attempted to quantify the success of their methods."[25]

On the other hand, sometimes it appears that the test Schering has in mind is a decision by the current factfinder, based on the evidence assembled for the patent cases, on whether the patent is infringed by the Uphser and ESI products. At page 15 of its memorandum, for example, Schering asserts that the relevant issue is "the objective assessment of the strength of the parties' positions at the time of the *Upsher* and *ESI* cases." And at page 7, Schering says that the merits of the underlying cases are relevant to 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." This suggests that the entire patent cases needs to be recreated in the present antitrust case. In that event, however, the expert

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[24] Miller Expert Report at 6 (Attachment I). *See also id.* at 30 [redacted]

[25] Complaint Counsel's Motion to Limit or Exclude at 15-16.

testimony that Schering is offering as to the likely outcome of the litigation is irrelevant. Instead, this court would be required to hear all the evidence and make a ruling on the issue of infringement.

However Schering's proposed relevance test is understood, there has been no determination by this court, or indeed by any court, that the likely outcome of the patent cases (or the strength of the parties' positions in those cases) is even a relevant factor in analyzing the antitrust claims in this case, much less that it is the only benchmark against which to assess the likely competitive impact of the payments accompanying the settlement agreements. The appropriate standard under which to evaluate respondents' agreements is, of course, one of the significant legal issues to be addressed in this case. It will be discussed extensively in our pretrial brief as well as in post-trial briefing. As will be more fully developed in our pretrial brief, establishing either the likely outcome of the patent litigation or the probability that any party would prevail in the lawsuit is not, and should not be, a necessary part of showing that a payment by the patent holder to an alleged infringer as part of a settlement agreement unreasonably restrains competition, even under the rule of reason. As we demonstrated in our responses to the motion to dismiss filed by Schering last summer,[26] the Supreme Court has held patent settlement agreements to be illegal without an analysis of the underlying patent infringement questions.[27] In addition, lower courts assessing the competitive effects of

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[26] Complaint Counsel's Response to Schering's Motion for Partial Dismissal of the Complaint (June 25, 2001).

[27] *See, e.g., U.S. v. Singer Manufacturing Co.*, 374 U.S. 174 (1963); *U.S. v. New Wrinkle Co.*, 342 U.S. 371 (1952); *U.S. v. Lime Materials Co.*, 333 U.S. 287 (1948); *U.S. v. Masonite Corp.*, 316 U.S. 265 (1942).

settlement agreements between branded pharmaceutical companies and potential generic entrants, on facts similar to those here, have found the agreements illegal without making any inquiry into the merits of the underlying patent litigation.[28]

Moreover, Schering is improperly attempting to revisit a legal issue that was already determined by this court in the Order Denying Motions of Respondents Schering-Plough and Upsher-Smith to Dismiss the Complaint (Oct. 31, 2001) ("Order Denying Motion to Dismiss the Complaint"). Schering's motion to dismiss asserted, among other things, that the complaint in this matter failed to state a claim upon which relief could be granted because it did not allege that Schering's patent was invalid or not infringed, or that the settlements were more anticompetitive than the probable outcome of the litigations. In its supporting memorandum, Schering specifically argued that "an agreement resolving patent infringement litigation cannot be held unlawful if the parties split the remaining life of the patent in a manner consistent with the parties' objective chances of prevailing in the underlying patent suit."[29] After oral argument as well as extensive briefing, this court denied the motions to dismiss, ruling that the complaint need not contain the asserted allegations, including specifically the allegation that "the settlements were more anticompetitive than the probable outcome of the litigation."[30] Schering's Motion *In Limine* does not even assert any ground for revisiting that conclusion.

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[28] *In re Terazosin Hydrochloride Antitrust Litigation*, 164 F. Supp. 2d 1340 (S.D.Fla. 2000), *appeal pending*; *In re Cardizem CD Antitrust Litigation*, 105 F. Supp. 2d 682 (E.D.Mich. 2000), *appeal docketed*, No. 00-2483 (6th Cir. Dec. 19, 2000).

[29] Memorandum in Support of Respondent Schering-Plough Corporation's Motion for Partial Dismissal of the Complaint at 7-8 (June 7, 2001).

[30] Order Denying Motion to Dismiss the Complaint at 8.

2. Schering's Witnesses Do Not Meet the Standards Articulated in the Motion

The expert testimony that Schering intends to offer does not support the test that Schering relies upon in any event. The witnesses that Schering offers are hardly in a position to make an "objective" assessment of the patent cases. There is no way to make an "objective" assessment of the probabilities in a statistical sense (such as one could do with tossing a coin or throwing dice) because we cannot do a controlled experiment of the trial. What Schering appears to mean, rather, is a "disinterested" or "fair" assessment. Schering's experts are not even in a position to do that. Most were expert witnesses in the underlying cases and can hardly be relied upon to impartially assess the strength of the evidence they would have offered at the trial. Indeed, Schering suggests, at page 8 of its memorandum, that *only* experts who were employed to testify or to advise one of the parties at trial are equipped to testify in this proceeding about the merits of the patent cases.[31]

Nor do Schering's own experts meet the other tests that it expects Dr. Banakar and Mr. Adelman to satisfy. Mr. Bjorge, for example, one of Schering's patent law experts, nowhere states that he reviewed "the entire record from the underlying patent cases," and accordingly his testimony is "improper and not relevant to the issues of the case" according to the standard that Schering proposes.[32] Mr. Bjorge's report says that he based his testimony on a review of the patent, the prosecution history, the Banker report, and ••

[31] There is no reason to suppose, and Schering suggests none, that the experts Upsher intended to call in the underlying patent cases were any less qualified or "objective" than those Schering intended to call. The fact that Upsher now has no incentive to rely on those experts or to defend their work simply points out the impossibility of attempting to recreate the outcome of the aborted patent trials.

[32] Schering Mem. at 4.

[redacted] from the patent cases.[33] Nor does the report of Mr. Miller, Schering's other patent-law expert, state that he reviewed the entire record of the cases.[34]

Most indefensible of all is Schering's claim that the testimony of Dr. Banakar and Dr. Adelman should be excluded because it concerns their "personal opinions" about the issues raised in the patent cases.[35] The opinions of Dr. Banakar and Mr. Adelman represent their personal opinions or views to the same extent, and in precisely the same way, that the opinions of Schering's experts are based on their own personal opinions. Whether or not they articulate a conclusion about the likely outcome of the litigation or about a specific issue in the cases, the opinions cannot be other than a "personal opinion." It is the function of the court to determine, after hearing the testimony and the other evidence in the case, what weight should be accorded to those opinions. Unlike Dr. Banakar and Mr. Adelman, however, Schering's patent law expert Mr. Miller does not limit his personal opinions to matters arguably within the range of his expertise. Based on his conclusions about the positions of the parties in the patent cases, Mr. Miller assumes for himself the role of spokesperson for American consumers and opines that:

[redacted]

[33] Bjorge Expert Report at 2 (Attachment J). In his deposition, Mr. Bjorge stated that he relied primarily on Dr. Banker's expert report and that he had not looked at some of the documents relating to the patent litigation since the case was settled over four years ago. *See* Bjorge Dep. at 71-72, 85 (Attachment K).

[34] Miller Expert Report at 2-5 (list of materials he did consider).

[35] Schering Mem. at 2-3, 5, 7-8, 14-15.

[redacted][36]

As Mr. Miller conceded in his deposition, this conclusion is not based on a consumer survey or any other research or body of knowledge, but on his [redacted]

[redacted] [37]

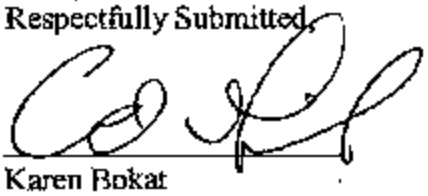
Thus, the offered rebuttal testimony of Dr. Banakar and Mr. Adelman is much more relevant, reliable, factually based, and rooted in recognized principles methods than is the testimony of some expert witnesses offered by Schering.

[36] Miller Expert Report at 6. *See also id.* at 7 [redacted]

[37] Miller Dep. at 102 (Attachment L).

For the reasons stated above, complaint counsel respectfully request that Schering's Motion *In Limine* to Exclude Testimony of Umesh V. Banakar And Martin J. Adelman be denied.

Respectfully Submitted,



Karen Bokat
Judith Moreland
Bradley S. Albert
Andrew S. Ginsburg
Karan Singh

Counsel Supporting the Complaint
Bureau of Competition
Federal Trade Commission
Washington, D.C. 20580

Dated: January 22, 2002

CERTIFICATE OF SERVICE

I hereby certify that this 22nd day of January, 2002, I caused a copy of the foregoing Public Version of Complaint Counsel's Opposition to Schering's Motion *In Limine* to Exclude Testimony of Umesh V. Banakar and Martin J. Adelman to be served upon the following person by hand delivery:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

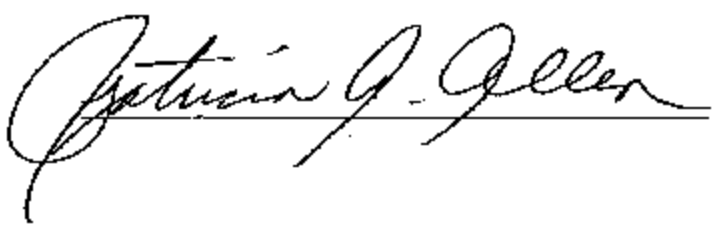
I caused one original and one copy to be served by hand delivery and one copy to be served by electronic mail upon the following person:

Office of the Secretary
Federal Trade Commission
Room H-159
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

I caused copies to be served upon the following persons by electronic mail and Federal Express:

Laura S. Shores
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Christopher Curran
White & Case LLP
601 13th St., N.W.
Washington, D.C. 20005



ATTACHMENT A

UMESH V. BANAKAR, PH.D.

BIOSKETCH

Umesh V. Banakar, Ph.D. is Professor of Pharmaceutics and President of Pharm-Assist International, a consulting company providing professional services to pharmaceutical industry and academia worldwide. He received his Bachelor of Pharmacy degree from Bombay University, Bombay, India in 1978 and Ph.D. from Duquesne University, Pittsburgh, Pennsylvania, USA in 1985. He joined Creighton University, School of Pharmacy & Allied Health in 1985 as an Assistant Professor and was promoted to Associate Professor in 1988. He joined St. Louis College of Pharmacy in 1990 as Director of Research and Section Head: Pharmaceutical Sciences where he was promoted to Professor in 1994, thus progressing from Assistant Professor to Professor in 9 years. Since 1997 through 1999, he was professor of Pharmaceutics and Chairman of Pharmaceutical Sciences and Graduate Program at Butler University, College of Pharmacy & Health Sciences in Indianapolis.

Since 1985, he has authored over 100 publications, over 80 published abstracts and presentations, numerous specialized workshop manuals, several chapters and monographs, over 45 expert book reviews and 5 guest editorials. The texts that he has authored include: Pharmaceutical Dissolution Testing, Drug Development Process: Increasing efficiency and cost effectiveness, among others. He is the co-author of an electronic text: Basic Pharmacokinetics. He is on the roster of experts with WHO, United Nations – TOKTEN program and International Executive Service Corps (IESC). He is listed in Who's Who in Biotechnology, Who's Who Among Asian Americans, and American Men and Women of Science. He is on the International Scientific Advisory Board of several pharmaceutical corporations worldwide. In 1997, he won the nomination for the distinguished **Fulbright Scholar Award for Lecturing**. He has received numerous awards for excellence in teaching, faculty development and achievement in research and scholarly activity. He is the recipient of two **Service to Country Awards** presented by IESC. He is the founding Editor-in-Chief of *International Journal of Pharmaceutical Advances* and a member of the International Editorial Boards of *International Journal of Pharmaceutical Excipients, Journal of Biomaterial Applications, Acta Pharmaceutica*, and is a referee for 8 other major pharmaceutical journals. He serves as a member and/or chairman of several NIH Study Sections. He is a member of several professional organizations worldwide including International Society for Technology Assessment in Healthcare and others. He has been an invited speaker on national and international programs and has served as chairman and coordinator for numerous international seminars and symposia. He has offered numerous national and international symposia and workshops on design, development and evaluation of conventional and advanced/specialized pharmaceutical products. He specializes in dissolution testing and technology, design and evaluation of modified release pharmaceuticals, bioavailability and bioequivalence testing, transdermal drug delivery and interfacing biotechnology with pharmaceutical product development.

Of date, he has successfully completed several Pharmaceutical Product Development Technology Transfer through education assignments sponsored by IESC and other pharmaceutical corporations worldwide. Additionally, he has served as testifying/non-testifying expert in patent litigations in the disciplines of pharmaceutical formulations, clinical investigations, dissolution testing. Furthermore, he has planned and executed the development, both *in vitro* and clinical, of over 10 ANDAs and over 5 NDAs. Providing professional service to the pharmaceutical industry and academia worldwide continues to be the focus of his professional career and further growth is expected.

Pharm-Assist International
10251 Tanmer Drive
Carmel, IN 46032 USA

Tel./Fax: 317 334 0174
email: umeshbanakar@juno.com

UMESH V. BANAKAR, PH.D.

Professor

10251 Tanmer Drive
Carmel, IN 46032 USA

Tel./Fax: 317 334 0174 **email: ubanakar@medmail.com**

Universities attended

Massachusetts Institute of Technology, 1989
Boston, MA
Advances in Controlled Release Technology

Duquesne University, Pittsburgh, PA U.S.A.
Doctor of Philosophy (Ph.D.) 1985
Major - Pharmaceutical Technology
Minor - Pharmaceutical chemistry
Thesis Title: Polyethylenes as Potential Prolonged Release Tablet Excipients

Bombay University, Bombay, India
Bachelor of Pharmacy (B. Pharm.) 1978

Professional Career

Pharm- Assist International 2000 - Present
Carmel, IN 46033
President

Butler University 1997 - 1999
College of Pharmacy and Health Sciences
Indianapolis, IN 46208-3485
Professor of Pharmaceutics 1997 - 1999
Chairman, Pharmaceutical Sciences and Graduate Program 1997 - 1999

St. Louis College of Pharmacy 1990 -1997
St. Louis, MO 63110
Professor of Pharmaceutics 1994 - 1997
Associate Professor (Pharmaceutics) 1990 - 1993
Director of Research 1990 - 1996
Section Head: Pharmaceutical Sciences 1990 - 1996

Creighton University 1985 - 1990
School of Pharmacy, Omaha, NE 68178
Department of Pharmaceutical Sciences
Associate Professor (Pharmaceutics) 1988 - 1990
Assistant Professor (Pharmaceutics) 1985 - 1987

Duquesne University 1981 - 1984
School of Pharmacy, Pittsburgh, PA U.S.A.
Instructor-in-Charge (Pharmaceutics)

School of Pharmacy 1980
J.N. Medical College, Belgaum, India
Lecturer Pharmaceutics

Roussel Pharmaceuticals (India) Ltd. 1978 - 1979
Bombay, India; Product Chemist

Pfizer (India) Ltd. 1977
Bombay, India; Trainee (App.) - Production

Scientific Advisory Board Membership

Several pharmaceutical corporations worldwide

Organizations – Professional Associations

Member of several professional organizations worldwide

Expertise (not exclusive listing)

Disciplines:

- Drug product development and evaluation, conventional and non-conventional
- Dissolution and bio-availability assessment
- Novel drug delivery systems
- Data characterization, evaluation, and model development
- Dosage form design for bio-availability /pharmacokinetic studies

ACADEMIC DISTINCTIONS

Invited to present a special 2-day program: Generic Drug Development Program – Techno-Legal Considerations, Torrent research Center, Ahmedabad, India (Nov. 2000)

Invited to present a 3-day intensive discourse: Correlating Dissolution and Bio-availability, International Pharmaceutical Technology Conference and Expo, Bangkok, Thailand (Aug. 2000)

Invited to lead and moderate Dissolution Discussion Group (DDG) Southeast Asia Meeting, Bangkok, Thailand (Aug. 2000)

Invited to serve on NIH SBIR/STTR Multidisciplinary Study Section, Bethesda, MD (July 2000)

Invited to serve on Special Emphasis review Panel by Center for Disease Control & Prevention, national Center for HIV, STD and TB Prevention, Athens, GA (March 2000)

Invited to present a 4-day Focus Program: Principles of Generic Pharmaceutical Product Development and Biopharmaceutical Evaluation, Ministry of Health, Drug Regulatory Agency, Colombo, Sri Lanka (March 2000)

Invited to present a Keynote Opening Address for the symposium on Innovations in Dissolution Testing, AAPS Ann. Mtg., New Orleans, LA (Nov. 1999)

Invited to present keynote address at the Bases Científicas y Technologicas de la Bio-equivalencia/ Normatividad Sanitaria, Seminario International FIFARMA, Association Mexicana de Industries de Investigation Farmaceutica, A.C., Mexico City, Mexico. Title of Presentation: Correlaciones In vivo-In vitro (Sept. 1999)

Recipient of the distinguished P.C. Dandiya Award/Citation for Distinguished Service to the Profession of Pharmacy. Invited to present the oration at the Indian Pharmaceutical Association, National Annual Meeting, Indore, India (Dec. 1999)

Invited to present a 2-day intensive course: Correlating Dissolution and Bio-availability – Understanding IVIVC, Intl. Adv. Instruments Expo., Mexico D.F., Mexico (Nov. 1999)

Invited to present a 3-h special technical WS session: ABCs of generic Drug Development: Case Study Approach, Interphex-USA'99, New York, NY (April 1999).

Invited to chair the opening session: Dosage Forms and Drug Delivery, Intl. Conf. Pharm. Ingred. Excip., Cphl'98, Amsterdam The Netherlands (Dec.1998).

Invited to present a 2-day specialized Intensive Seminar: Generic Drug Product Development – Bio-availability, Bio-equivalence & In Vitro Equivalence, Intl. Advanced Instruments Expo, Mexico City, Mexico (Nov. 1998).

Invited to chair NIH-SBIR/STTR, Special Multidisciplinary Study Section NIH, Bethesda, MD (Nov. 1997).

Invited to chair session 2: Drug Delivery and Drug Delivery Technology, Intl. Conf. Pharm. Ingred. Excip., London, England (Nov. 1997).

Invited to present a keynote address at the 41st International Seminar. Drug Delivery Systems, Pharmacokinetics and Pharmacodynamics, Warsaw, Poland (Nov. 1997).

Invited to present a Special 2-day Session; The Modern Dissolution Laboratory, VanKel International, London, England (July 1997).

Invited to present a Special 2-day Session. The Modern Dissolution Laboratory, AGB International Ltd., Dublin, Ireland (July 1997).

Invited to present a Special 2-day Session: El Moderno Laboratorio de Disolucion, Advanced Instruments de Mexico, Mexico City, Mexico (Feb. 1997)

Nominated for the Distinguished Fulbright Lecturing Award (Feb. 1997)

Invited to chair NIH SBIR/STTR special Multidisciplinary Study Section, NIH, Bethesda, MD (March 1997)

Invited to present Keynote Address at the 1st Int. Conf. on The Practice of Clinical Pharmacy, Univ. of Zagreb, Faculty of Pharmacy, Zagreb, Croatia (April 1997)

Invited to present a key workshop: Challenging Opportunities in the Delivery of Proteins and Peptides, Interphex USA'97, Philadelphia, PA (April 1997)

Invited to serve on the Organizing Committee (Scientific Conference Section), Reed Exhibition/Conference Companies, Inc., Norwalk, CT (April 1997-Present)

Invited to chair NIH-SBIR/STTR, Special Multidisciplinary Study Section, NIH, Bethesda, MD (June 1997).

Invited to chair Session 4: Advances in Drug Delivery Technology, Intl. Conf. Pharm. Ingred. Excip., CPhI'96, Turin, Italy (Oct. 1996)

Invited to chair NIH - SBIR/ STTR Special Multidisciplinary study section, NIH, Bethesda MD (Nov 1996).

Invited to present a keynote address to the Pharmaceutical Technology Section, VIIth Congress of Argentine Association of Industrial Pharmacy and Biochemistry, Buenos Aires, Argentina (June 1996).

Invited to present a plenary lecture at the VIIth Congress of Argentine Association of industrial Pharmacy and Biochemistry, Buenos Aires, Argentina (June 1996).

Invited to present a keynote address at the AAPS Midwest Regional Meeting, Chicago, IL (May 1996).

Invited to chair NIH-SBIR/STTR Study Section, NIH, Bethesda, MD (March 1996).

Invited to present a keynote address at the Indo-Swiss Collaborative Program and International Conference on Bioprocess Technology, Center for Biotechnology, Anna University, Madras, India; "Advances and Opportunities in the Delivery of Therapeutic Proteins and Peptides", (March 1996).

Invited to lead a UN-IESC assignment to Extractum - Pharma, Ltd., Kunfeherto, Hungary (April – May 1996)

Invited to serve on international Scientific Conference Committee, CphI'95, Miller Freeman BV, Maarssen, The Netherlands (1995-Present).

Invited to chair Session 2: Developments in Dosage Forms and Delivery Systems, Intl. Conf. Pharml. Ingred. Excip., Frankfurt, Germany (Nov. 1995).

Invited to present a keynote lecture at the Symposium: *Bio-availability / Bio-equivalence - Past, Present and Future*, Al-Azhar Intl. Pharml. Conf., Cairo, Egypt (Dec.1995).

Invited to present a 2-day session: *Development and Evaluation of Import-Substituted (Generic) Products*, University of Alexandria, Alexandria, Egypt (Dec. 1995).

Invited to serve as a Coordinator and Chairman of the 1st *International Conference on New Horizons in Drug* Delivery *and Targeting*, Basel, Switzerland (1995).

Invited to become International Scientific Advisor for Wockhardt international, Ltd., Bombay, India (1995).

Invited to present keynote (opening) address at the National Congress on Rheumatology, "Percutaneous Transport of Drugs," Paris, France (1995).

Invited to serve on NIH, SBIR/STTR Special Study Section Z (March 1995).

Invited to become the Founding Editor-in-Chief of International Journal of Pharmaceutical Advances, a scientific peer-reviewed journal, by Technomic Publishing Co., Inc., Ardsley, NY (1995).

Invited to serve on NIH-NIAID, RFP Special Review Panel (1994).

Invited to open a symposium on 'Controlled Release Dosage Form Design' and present a paper on Design Considerations and Mechanistic Evaluation of Oral Controlled Release Systems', at the AAPS Western Regional Meeting, Reno, NV (Feb. 27,1990).

Recipient of PMA (Pharmaceutical Manufacturers Association USA) Visiting Professor for 1989 Award. Sponsored by Searle Laboratories, Skokie, IL (Aug. 06-20, 1989).

Recipient of the Distinguished Leadership Award and inclusion in the International Directory of Distinguished Leadership for outstanding service to the teaching profession (1989).

Included in the list of experts with International Executive Service Corps (IESC) for Assignments (educational or otherwise) organized and administered through IESC worldwide (November 1988).

Recipient of the distinguished Dr. Pete Ellerbeck Memorial Award for outstanding faculty service to students and School of Pharmacy (1988).

Recipient of the Rho Chi National Pharmacy Honor Society award for "Excellence in Teaching" (1988).

Recipient of Travel Grant for attendance and participation at 7th Pharm. Tech. Conf., London, UK (April 1988). Sponsored by Marion Laboratories, Kansas City, MO (1988).

Nominated for Burlington Northern Foundation Scholar of the Year Award for the academic year 1986-87.

Recipient of James M. Keck, Faculty Development Award granted by Health Future Foundation, 1986 (September 10,1987).

Invited by American Chemical Society (ACS) to develop, establish and instruct an intensive course in Theory and Practice of Controlled Release, (September, 1987).

Name included in the list of experts with World Health Organization (WHO) for future short-term assignments organized and administered by WHO worldwide (August, 1987).

Invited to become a Book Review Editor for BioPharm Manufacturing Journal (1987).

Recipient of PMA (Pharmaceutical Manufacturers Association, USA) Visiting Professor for 1987 Award. Sponsored by Marion Laboratories, Kansas City, MO (June 15-26, 1987).

Selected for inclusion in "Who's Who in Technology", 5th. ed. Biotechnology Section (1986).

Solicited for preparation of a profile for Pralidoxime Chloride for inclusion in vol.17 of Analytical Profiles of Drug Substances, Academic Press, NY.

Recipient of Health Futures Foundation Young Faculty Award (1986).

Recipient of NARD Northrop-Thayer Foundation Gram Award (1986).

Invited to prepare a full-length monograph (book) entitled "Pharmaceutical Dissolution Technology", by Marcel Dekker, Inc., New York, New York (1986).

Recipient of Biomedical Research Support Grant Award (1985).

Above average academic record throughout graduate curriculum.

First class academic record throughout undergraduate curriculum.

Fifth rank in Bombay University at I B. Pharm. (1976).

Fourth rank in Bombay University at II B. Pharm. (1977).

First class first at I and II B. Pharm in Goa College of Pharmacy, Panaji-Goa, India.

Always in TOP FIVE PERCENT of the class, both at school and university levels.

SCHOLARLY ACTIVITY

Electronic Texts

"Basic Pharmacokinetics", Makoid MC, Vuerrec P and Banakar UV, Eds., Virtual University Press, http://kiwi.creighton.edu/pkin.book/ (1996).

Texts

"Pharmaceutical Dissolution Testing," 2nd Edition (in preparation) Marcel Dekker, Inc., New York, NY (2000)

"Drug Development Process: Increasing Efficiency and Cost Effectiveness", Welling PG, Lasagna L and Banakar UV, Eds., Marcel Dekker, Inc., NY (1996).

"Zdravilni Sistemi". Slovensko Farmacevtsko Drustvo, Ljubljana ,Slovenia (1994). ISBN 961-90099-0-8.

"Pharmaceutical Dissolution Testing", Marcel Dekker, Inc., New York, NY (1992); 2nd printing (1995).

"Computer Assisted Data Analysis of Sustained Release Formulations", Interphex-USA'92, WS7, New York (1992).

"Characterization and Enhancement of Transdermal Drug Uptake", Interphex-USA'92, WS14, New York (1992).

"In Search of an Ideal Oral Sustained Release Dosage Form", Interphex-USA'91, WSQ7, New York (1991).

"Computer-Assisted Mathematical Modeling of Modified Drug Release", Interphex-USA'91, WS13, New York (1991).

"Educating Older Americans and Children about Prescription (Rx) and Over-the-Counter (OTC) Drugs: A Ready Reference Booklet", NARD Foundation, Alexandria, VA (1990).

"Pharmaceutics I & II, Theory and Practice", Creighton University. Omaha, NE 68178 (1986).

Chapter(s)/Monograph(s) in Texts

Banakar UV. "Dissolution Method Development for Pharmaceutical Dosage Forms", VanKel Technology Group, Cary NC (2000)

Banakar UV. "Principles of Generic Pharmaceutical Product Development and Biopharmaceutical Evaluation. Ministry of Health, Drug Regulatory Agency, Colombo, Sri Lanka (March 2000)

Banakar UV. "Generic Drug Development Program – Techno-Legal Considerations", TRC Press. Ahmedabad, India (2000)

Banakar UV. "Correlating Dissolution and Bioavailability; Understanding IVIVC, "VanKel Technology Group, Cary, NC (1999)

Banakar UV. "Fundamentals of Drug Product Development with Special Emphasis on the Development and Evaluation of Generic Pharmaceuticals, "Novartis Enterprises Pvt. Ltd., Mumbai, India (1999)

Banakar UV. "Beyond Traditional Non-conventional Drug Delivery Systems." Ch. in Drug Delivery Systems, Pharmacokinetics and Pharmacodynamics. ICB, Warsaw, Poland (1998)

Banakar UV. "Generic Drug Product Development: Bio-availability, Bio-equivalence and In Vitro Equivalence." Advanced Instruments de Mexico, Mexico DF, Mexico (1998)

Banakar UV. "Fundamentals of Generic Drug Product Development and Evaluation: In Vitro Perspective." Synthon BV, Nijmegen, The Netherlands (1998)

Banakar UV and Makoid MC. "Pharmacokinetics in Drug Development," Technomic Publishing Co., Inc., Ardsley, NY (1997)

Banakar UV. "The Modern Dissolution Laboratory: Theory and Practice," Vankel Technology Group, Cary, NC (1997)

Banakar UV and Kristina Kumar. "Validation of Bioanalytical Methods and Fundamentals of Phase I Bio-availability/ Bio-equivalence Investigations." BIA d.o.o., Ljubljana, Slovenia (1997)

Banakar UV. "Challenging Opportunities in the Delivery of Therapeutic Proteins and Peptides"," Reed Publications, Norwalk, CT (1997)

Banakar UV and Ghignone AA. "Generic Pharmaceutical Product Development; Regulatory considerations", PLIVA d.d., Zagreb, Republic of Croatia (1996).

Banakar UV and Makoid MC. "Clinical Pharmacokinetics and The Practice of Pharmacy ", Faculty of Farmacia, Univ. of Ljubljana, Ljubljana, Slovenia (1996).

Banakar UV Dasgupta AK and Makoid MC. In Vitro - In Vivo Correlations. some recent thoughts. Ch. 6, Bio-availability and Bio-equivalence: An Uptade, Tiptis HP, ed., New Age, Publishers, New Delhi, India (1996) pp 31-61.

Banakar UV and Murty R. "Generic Pharmaceutical Markets. Opportunities and Pitfalls", PLIVA d.d., Zagreb, Republic of Croatia (1996).

Banakar UV. "Generic Drug Product Development and Bio-equivalence Assessment". Technomic Publishing AG, Basel, Switzerland (1996).

Banakar UV. "Contemporary Issues in Bio-equivalence Assessment", Interphex-USA'96, New York, NY (1996).

Banakar UV. "Advances in Oral Rate Controlled Drug Delivery Systems: Meeting the Challenges", Interphex-USA '96, New York, NY (1996)

Banakar UV. "Pharmaceutical Issues", Ch. in Drug Development Process: Increasing Efficiency, and Cost Effectiveness, Welling PG, Lasagna L and Banakar UV, eds , Marcel Dekker, Inc., NY (1996).

Banakar UV. "Development and Evaluation of Import-Substituted Products (Generics)" - University of Alexandria, Alexandria, Egypt and Pharco Pharmaceuticals, Alexandria, Egypt (1995).

Banakar UV, "Principles of Pharmaceutical Dosage Forms Development and Bio-pharmaceutical Evaluation". PLIVA Research Institute, Zagreb, Republic of Croatia (1995).

Banakar UV and Tharp PC. "Advances in New Drug Delivery Systems: Technological and Marketing Considerations". Technomic Publishing AG, Basel, Switzerland (1995).

Banakar UV and Makoid MC. "Principles of Pharmaceutical Product Development and Evaluation". Technomic Publishing Co., Inc., Ardsley, NY (1995).

Banakar UV. Rate-Controlled Drug Delivery Technology and Novel Oral Rate-Controlled Drug Delivery System. PLIVA Research Institute, Zagrab Republic of Croatia (1995).

Banakar UV and Makoid MC. Generic Drug Product Development and Current Issues in Bio-equivalence Evaluation. Association Argentina de Farmacia y Bioquimica Industrial, Buenos Aires, Argentina (1995).

Banakar UV. "Bioavailability. Bio-equivalence and Therapeutic Substitution" - Technomic Publishing Co., Inc., Ardsley, NY (1995).

Banakar UV and Osborne DW. "Transdermal Drug Product Development". Technomic Publishing Co , Inc., Ardsley, NY (1994).

Banakar UV. "Materials Used in Controlled Release Technology - A Primer". Ch. 8 in Advances in Controlled Delivery of Drugs, Kofrodic, MA, Ed., Technomic Publishing Co., Inc., Lancaster, PA (1994); pp 132-154.

Banakar UV. "Sodium Starch Glycolate", invited monograph in 'Handbook of Pharmaceutical Excipients', Amer. Pharm. Assoc., Washington, DC (1994); 462-466.

Banakar UV. "Excipients in New Drug Delivery System". PhLA Intl. Conf., Expo consult, The Netherlands (1994).

Banakar UV, Snycher M and Tharp PC. "New Drug Delivery Systems: Developmental and Marketing Considerations", Technomic Publishing Co., Inc., Ardsley, NY (1994).

Banakar UV. "Role of Pharmaceutical Ingredients and Excipients in Development of Pharmaceuticals", CPhI'93, Intl. Conf., Turin, Italy (1993).

Banakar UV and Makoid MC. "Drug Dissolution and Bio-availability: Critical Considerations Including Simulations & Predictions", Technomic Publishing Co., Inc., Ardsley, NY (1993)

Banakar UV and Makoid MC, "Modelling of Modified Release Systems". Technomic Publishing Co., Inc., Ardsley, NY (1993).

Banakar UV and Osborne D. "Dermatological Product Development and Drug Delivery". Technomic Publishing Co. Inc., Ardsley, NY (1993).

Banakar UV and Suryanarayanan. "Controlled Release Using Polymers: Characterization of Solid Drugs and Excipients'. Technomic Publishing Co., Inc., Ardsley, NY (1992).

Banakar UV and Mueller LG. 'Transdermal Drug Delivery; Contemporary Issues and New Directions'. Technomic Publishing Co., Inc., Ardsley, NY (1992).

Banakar UV and Makoid MC. "Drug Dissolution and Bioavailability". Technomic Publishing Co., Inc., Ardsley, NY (1991).

Banakar UV and Makoid MC. 'Controlled Release: Theory and Practice'. American Chemical Society, Washington DC (1990).

Banakar UV, et al. "Introduction to Specialized Drug Delivery Systems: Laboratory Research to Production", Ch. 1 in 'Specialized Drug Delivery Systems: Manufacturing & Production', P. Tyle, ed., Marcel Dekker, Inc., NY (1989) pp 3-36.

Editor-in-Chief

Invited to become the Founding Editor-in-Chief of International Journal of Pharmaceutical Advances by Technomic Publishing Co., Inc, Ardsley, NY (1994-1996).

Editor-at-Large

Invited to become the Editor-at-Large in the area of Pharmaceutical Technology by Marcel Dekker, Inc., New York, NY 10016 (1990).

International Editorial Advisory Board

Journal of Biomaterials Applications, Lancaster, PA

Acta Pharmaceutica &, Ljubljana. Republic of Slovenia

International Journal of Pharmaceutical Excipients, Mumbai, India

Book Review Editor

BioPharm Manufacturing, Aster Publications, 859 Willamette Street, Eugene, OR 97440.

Guest Editorial

Invited to contribute an Expert Guest Editorial. "Intrinsic Dissolution" Practical Solutions, vol. 2 (Sept. 1999)

Invited to contribute an editorial-commentary: " Oral Rate-Controlled drug administration". Chemica-oggi, (1996)

Invited to write a conference report/guest editorial by Pharmaceutical Technology Magazine. "Interphex USA'92: Business-Technology Interface", Pharm. Tech. 16 (June 1992

Invited to write a conference report/guest editorial by Pharmaceutical Technology Magazine. "Interphex USA'91: Blending Academics and Technology", Pharm. Tech., 15, (June 1991).

Invited to write a guest editorial by Pharmaceutical Technology Magazine. "IUC-Pharm. Sci. '87: A step in the Right Direction', Pharm. Tech., 12, (Feb. 1988).

Reviewer for:

S.T. P. Pharma Sciences, Chateney-Malabry, Cedex, France.

Annals of Pharmacotherapy, Cincinnati, OH 45242.

Intl. J. of Pharm. Technol. Prod. Mfr., Childwall University Press, London, England.

Trends in Biotechnology, Elsevier Trends Journals, Cambridge, England.

Journal of Pharmaceutical Sciences, Amer. Pharm. Assoc., Amer. Chem. Soc., Washington, D.C.

Pergamon Press Scientific & Medical Health Publications, Elmsford, New York.

American Pharmacy, APhA, 2215 Constitution Ave. NW, Washington, DC

Pharmaceutical Research, Alexandria, VA.

VCH Publishers, 2 Sidney Place, Brooklyn, NY.

Publications

Chopade AJ, Shelly C, Pandit NK and Bamakar UV. Liposphere Based Lipoprotein-Mimetic Delivery System for 6-Mercaptopurine. *J.* Biomater. Applin., 14(2), 389-399 (2000)

Deswoolkar AV, Soni R and Bamakar UV. Sodium Starch Glycolate. A Contemporary Review. Ind. J. Pharm Excip., 1(1), 4-9 (1999)

Bamakar UV. Fractional System Response as Basis for Establishing IVIVC, Proc. Cphi '98, Manuf. Chemist, 69, 88106 (1998)

Bamakar UV. Frontiers in Delivery of Therapeutic Proteins. Exer. Pharm. 40, 21-28 (1997)

Bamakar UV. Advances and Opportunities in Delivery of Proteins and Peptides. J. Biomater. Applin., 11(4), 377429 (1997).

Deo MR, Sant VP, Parekh SR, Khopade and Bamakar UV. Proliposome-based Transdermal Delivery of Levonorgestel, J. Biomater. Applin., 12(1), 77-88 (1997)

Makoid MC and Bamakar UV, Modeling of Pharmacological Response for Simulation and Data Analysis. II. Single Receptor Interaction. Int. J. Pharm. Adv., (3), 285-297 (1996)

Makoid MC and Bamakar UV. Modelling of Pharmacological Response for Simulation and Data Analysis. III. Multiple Receptor Site Interactions. Acta Pharm., 46(4), 265-278 (1996).

Bamakar UV. Specialized Drug Delivery Responding to Physiological Demands Proc. CPhI'95, Manuf. Chemist 67, 49 61 (1996).

Kulshreshtha R, Pampalis H and Bamakar UV. Effect of Phase Inversion on Physical Stability of o/w Emulsions, Int. J. Pharm. Adv., 1(1), 73-83 (1995).

Duman G, Baykara T and Bamakar UV. Dissolution and Bioavailability of Bioadhesive Dosage Form of Lidocaine, Int. J. Pharm. Adv., 1(2), 101-111 (1995).

Makoid MC and Bamakar UV. Modelling of Pharmacological Response for Simulation and Data Analysis. I: Basic Concepts, Int. J. Pharm. Adv., 1(2), 170-187 (1995).

Bamakar UV. Percutaneous Transportation of Drugs, Acta Ther., 1, 11-22 (1994)

Walgren RA and Bamakar UV, in Vitro Release of Selected Cardiac Drugs from Reservoir-Type Transdermal Formulations. Acta Pharm., 45(1), 1-7 (1995).

Bamakar UV. Excipients in New Drug Delivery Systems, Proc. PhIA; Manuf. Chmst., Expoconsult, The Netherlands (1994).

Bamakar, UV, Role of Pharmaceutical Ingredients and Excipients in the Development of Pharmaceuticals. Manuf. Chemist, CPhI'93, Conf. Issue, 88-107 (1994).

Bamakar UV. Oral Rate-Controlled Drug Administration. Part I. Manuf. Chmst. 65(1), 14-17 (1994).

Bamakar UV. Oral Rate-Controlled Drug Administration, Part II., Manuf. Chmst, 65(2), 30-34 (1994).

Bamakar UV. Synthetic Polymers as Excipients, Part I., Manuf. Chmst., 68(9), (1994).

Bamakar UV. Synthetic Polymers as Excipients, Part II., Manuf. Chmst., 68(10), 27-29 (1994).

Nitsch MJ and Bamakar UV. Implantable Drug Delivery, J. Biomat. Applin., 8, 247-284 (1994).

Doubek D, Makoid MC and Banakar UV. In Vitro Transcutaneous Uptake of Theophylline from Topical Reservoir Formulations; Eastern Pharmacist XXXVI(428), 161-165 (1993).

Makoid, MC, Dufoure, A and Banakar, UV. Modelling Dissolution Behavior of Controlled Release Dosage Forms. STP Pharma. 3,49-58(1993).

Saxena, J, Sharma, N. and Banakar, UV. Ultrasonically Mediated Drug Delivery. J. Biomat. Appln. 7(3),277-296 (1993).

Banakar, UV, Dissolution and Bio-availability of Drug Delivery Systems: Are Predictable Correlations Dependable? CPhI'92 Manuf. Chem., 64,145-155 (1993).

Chotiloke, C, Elking, P and Banakar, UV. Issues in Contemporary Drug Delivery. VIII: Treatment of Rheumatoid Arthritis. J. Pharm. Tech., 9, 52-62 (1993).

DeSimone, E. and Banakar, UV. Issues in Contemporary Drug Delivery. VII: Sunscreens as Therapeutic Agents, J. Pharm. Tech., (1 993).

Singh, G, Sharma, SN and Banakar, UV. Release Kinetics of Propranolol from Polymeric Matrices. Acta Pharmaceutica, 42, 225-230 (1993).

Hilleman, DE, and Banakar, UV. Issues in Contemporary Drug Delivery. VI. Advanced Cardiac Drug Formulations. J. Pharm. Tech., 8, 203-211 (1992).

Banakar, UV and Makoid, MC. Dissolution and Bio-availability: Are In Vitro-in Vivo Correlations Possible? Eastern Pharm., XXXV(416),17-28 (1992).

Berba, J. Makoid, MC, and Banakar, UV. Treatment of Diabetes: Insulin Delivery Systems. Pharma Times, 10(8); 72-86 (1992).

Banakar, UV and Makoid, MC. Bio-availability and Dissolution. Pharm. Tech., vol 1, 149-181 (1992).

Makoid, MC, Sylvestri, MF and Banakar, UV. Oral Sustained Release Theophylline Products: Should Manufacture Recommend Dosage Modification Upon Conversion from IV Therapy? Proc. Interphex-USA'92, vol 1, 318(1992).

Sylvestri, MF, Banakar, UV and Makoid, MC. In Vitro - In Vivo Correlation with 7 Commercial Phenobarbital Formulations. Interphex-USA'92, vol 1, 19-24 (1992).

Banakar, UV. Global Pharmaceutical Industry Tradewinds and Drug Delivery System Research. Proc. CPhI'91 Manuf. Chem., 63, 84-91 (1992)

Mohler, P and Banakar, UV. Issues in Contemporary Drug Delivery. V. Total Parenteral Nutrition (TPN). J. Pharm. Tech., 8 (1992).

Chan, D-M, Sylvestri, MF, Snyder, S, Banakar, UV and Makoid, MC. Release Kinetics of Polymeric Prodrugs of Pindolol, Drug Dev. Indus. Pharm. 17, 1279-1294 (1991).

Sanghvi, P and Banakar, UV. Ultrasonic: Principles and Biomedical Application. BioPharm Manuf., 4(5) 32-38 (1991).

Makoid MC, Whitmore CK, MacDonald. NC and Banakar, UV, Influence of pH and Ionic Strength on the Stability of Methacholine Chloride Solutions. Proc. Interphex-USA, vol.1, 205-218 (1991).

Makoid, MC, Vogel, J, Sylvestri, MF and Banakar UV., Dissolution Characteristics of Two Formulations of Sustained Release Theophylline. Proc, Interphex-USA, vol. 1, 219-234 (1991).

Nitsch, MJ and Banakar, UV, In Vitro Transcutaneous Uptake of Diltiazem from Reservoir-Type Topical Formulations, S.T.P. Pharma, 1, 64-69 (1991).

Berba, J. Huff, S, Langle, J and Banakar, UV. In Vitro Release of Selected Nonsteroidal Antiinflammatory Analgesics (NSAIA) from Reservoir-Type Transdermal Formulations, Drug Dev. Indus. Pharm. 17, 55-66 (1991).

Kirchain, W and Banakar, UV. Issues in Contemporary Drug Delivery. IV. Insulin Therapy, J. Pharm Tech., 7 19-28 (1991).

Berba, J and Banakar, UV. Clinical Assessment of Current Transdermal Drug Delivery Systems (TDDS): A Retrospective evaluation. Amer. Pharm., NS30, 33-41 (1990).

Speake, W and Banakar, UV. Fats and Waxes in Pharmaceuticals. I: As Excipients and Therapeutic Agents, Manuf. Chem.,

61(8), 33-38 (1990).

Speake, W and Banakar, UV, Fats and Waxes in Pharmaceuticals. II: Manufacturing Process Considerations, Manuf. Chem., 61(9), 43. (1990).

Patel, UN and Banakar, UV. Comparative In Vitro Dermatokinetics of Ibuprofen (IBP), Il Farmaco, Sci. Ed., 45, 559-568 (1990).

Banakar UV, Block, LH and Galinsky, AM. Bio-availability Evaluation and In Vitro - In Vivo Correlation of Polyethylenes as Potential Prolonged Release Tablet Excipients, Proc. 9th Pharm Tech. Conf., Vol. 1, 135-151 (1990).

Ertner, K and Banakar, UV. In Vitro Transcutaneous Uptake of Metronidazole from Topical Reservoir Formulations. Proc. 9th Pharm. Tech. Conf., Vol. 2, 197-214 (1990).

Banakar, UV. In Vitro Release of Metoprolol (MTP) from Various Transdermal Formulations, Pharmazie, 45/2, 121-123 (1990).

Banakar, UV. Issues in Contemporary Drug Delivery. I : Fundamental Considerations, J. Pharm. Tech, 6, 75-81 (1990).

Banakar, UV Issues in Contemporary Drug Delivery II : In Vitro Release and Biopharmaceutical Considerations, J. Pharm. Tech., 6,122-131 (1990).

Athani, A, Maknid, MC and Banakar, UV, Issues in Contemporary Drug Delivery. III : Pharmacokinetics/Pharmacodynamic Modelling, J. Pharm. Tech., 6,200-211 (1990).

Athani, A and Banakar, UV, The Development and Potential Uses of Biosensors, BioPharm Manuf., 3(1), 23 (1990).

Banakar, SU and Banakar UV, Japan's Pharmaceutical Industry: A Threat to the United States?, Drug Dev. Indus. Pharm., 15, 1555 (1989).

Benedict, MK, Roche, VF, Banakar, UV and Hilleman, DE. visual Compatibility of Amiodarone Hydrochloride with Various Antimicrobial Agents during Simulated Y-Site Injection, Amer. J. Hosp., 45, 1117 (1988).

Block, LH and Banakar, UV. Further Considerations in Correlating In Vitro-In Vivo Data Employing Mean-Time Concept Based on Statistical Moments, Drug Dev. Indus. Pharm, 14, 2143 (1988).

Patel, UN and Banakar, UV. Pralidoxime Chloride, Anal. Prof. Drug Subst., vol. 17, 533 (1988).

Kaura, S, Banakar, UV and Galinsky, AM. A Study of the Effects of Sucrose Concentration, Lacquer Concentration and Coating Time on the Formulation of Stable and Effective Carbenicillin Indanyl Sodium Microcapsules, Drug Dev. Indus. Pharm., 14, 925 (1988).

Young, WW and Banakar, UV, Pharmaceutical Technology Information on the National Pharmacy Bulletin Board Service (NPBBS), J. Pharm. Technol., 3(4),159 (1987)

Banakar, UV, Block, LH and Galinsky, AM. Evaluation of a Low Density and a High Density Polyethylene as Potential Prolonged Release Tablet Excipients, Pharm. Technol., Controlled Drug Release, Vol. 1, Ellis Horwood Ltd., London, England (1987) pp 17-33.

Banakar, UV. Drug Delivery Systems of the 90s; Innovations in Controlled Release, Amer. Pharm., 27(2), 39 (1987).

Banakar, UV. Microcomputers in Basic Pharmaceutical Sciences, Issues in Higher Edn., Vol. XXI, 19 (1986).

Banakar, UV. A Closer Look at the Mean Residence Time (MRT) Concept Based on Statistical Moments, Drug Dev. Indus. Pharm., 12,1675-(1986).

Banakar, UV. Pharmaceutics I & II: Theory and Practice, Creighton University, Omaha, NE (1986). Adopted as a required text for Pharmaceutics Lab. Course.

Lathia, CD and Banakar, UV. Advances in Dissolution Technology. Design, Prot and Cons, Drug Dev. Indus. Pharm., 12 (1-2),71 (1986)

Banakar, UV. Drug Delivery Systems of the Future. Med. Device & Diag. Indus., Conf./Expo Proc., (June 1985).

Banakar, UV. Drug Release Mechanisms of Membrane-Moderated Drug Delivery System, Pharm. Manuf., 1 36 (1984).

Bansal, UV and Block, LH. Beyond Bioavailability Testing, Pharm. Technol., 7, 107 (1983).

Bansal, UV. Microencapsulation - A Recent Tool in Pharmacy Practice, Sanjeevani, 1 (1980).

Bansal, UV, Sterility Testing, Goa Pharmacist, Vol. -, (1977).

Abstracts/Invited Presentations

"Biorelevant Dissolution Testing", Int. Conf. on Dissolution Testing, Inst. Int. Res., Philadelphia, PA (Feb. 2001)

"Correlating Dissolution and Bioavailability: Understanding IVIVC", 3-day, VanKel Int. London, England (Nov. 2000)

"Generic Drug Development Program: Techno-Legal Considerations", 2-day invited program, Torrent Research Center, Ahmedabad, India (Nov. 2000)

"Correlating Dissolution and Bioavailability: Understanding IVIVC", 3-day, VanKel Technology Group, Cary, NC (Oct. 2000)

"Advanced Dissolution Testing: Theory & Practice", 2-day, VanKel Technology Group, Cary, NC (Oct. 2000).

"Correlating Dissolution with Bioavailability," invited 3-day special intensive course, International Conference on Pharmaceutical Product Development, Bangkok, Thailand (Aug. 2000)

"Correlating Dissolution and Bioavailability: Understanding IVIVC", 3-day, Cromatec Ltd, Sao Paulo, Brazil (Sept. 2000)

"Fundamentals & Advanced Dissolution Testing: Theory & Practice", 2-day, J & J, Morristown, NJ (Aug. 2000)

"Dissolution Method Development for Pharmaceutical Dosage Forms", 3-day VanKel Technology Group, Cary, NC (July 2000)

"Advanced Dissolution Testing: Theory & Practice", 2-day, Suffern, NY (July 2000)

"Advanced Dissolution Testing: Theory & Practice", 2-day, Advanced Instruments de Mexico, San Juan, PR (June 2000).

"Correlating Dissolution and Bioavailability: Understanding IVIVC", 3-day, Unitlex Company, Ltd., Tokyo, Japan (May 2000)

"Correlating Dissolution and Bioavailability: Understanding IVIVC", 3-day, Unitlex Company, Ltd., Kyoto, Japan (May 2000)

"In Vitro Dissolution Testing of Selected Modified Release Theophylline Solid Dosage Forms", AAPS Midwest reg. Mtg., Chicago, IL (April 2000)

"Principles of Generic Pharmaceutical Product Development and Biopharmaceutical Evaluation", 4-day, Ministry of Health, Drug Regulatory Agency, Colombo, Sri Lanka (March 2000)

"Advanced Dissolution Testing: Theory & Practice", 2-day, Pfizer Inc., Groton, CT (Feb. 2000)

"Dissolution Rediscovered", AAPS Ann. Mtg., New Orleans, LA (Nov. 1999).

"Correlating Dissolution and Bio-availability. Understanding IVIVC, "invited 2-day session, Advanced Instruments de Mexico, International Expo, Mexico City, Mexico (Nov. 1999).

"Modern Dissolution Testing: Theory and Practice," 2-day technical session, Merck, Inc., West Point, PA (Oct. 1999).

"Advanced Dissolution Testing, " Cromatec Com. Instr. Analytics Ltda., San Paulo, Brasil, two 2-day sessions (Sept. 1999).

"Correlaciones In Vivo-In Vitro," Seminario Internacional FIFARMA, Assoc. Mexicana Indust. Invest. Farm. A.C. Mexico D.F, Mexico (Sept. 1999).

"Dissolution Testing in Pharmaceutical Product Development, "VanKel Technology Group, Cary, NC, 2 day seminar, IRI Training Center, Newark, NJ (Sept. 1999).

"Correlating Dissolution and Bio-availability. Understanding IVIVC," VanKel Technology Group, Cary, NC. 2-day intensive course, Morristown, NJ (Aug. 1999).

"Fundamentals of Pharmaceutical Product Development with Special Emphasis on the Development and Evaluation of Generic Pharmaceuticals," invited 4-day intensive training program, Novartis Enterprises Pvt. Ltd., Mumbai, India (Aug. 1999),

"Advanced Dissolution Testing, "VanKel Technology Group, Cary, NC. 2-day seminar, Philadelphia, PA (June 1999).

"Modern Dissolution Testing. Theory and Practice, "VanKel Technology Group/Aims Corp. Ltd., Sydney, Australia, 2-day seminar (May 1999).

"ABCs of Generic Drug Product Development: A Case Study Approach," Interphex-USA'99, New York, NY (April 1999).

"Advanced Dissolution Testing: Theory and Practice, "VanKel Technology Group, Cary, NC. 2-day intensive course, Miami Lakes, FL (April 1999).

"Modern Dissolution Testing: Theory and Practice," VanKel Technology Group, Cary, NC. 2-day course, Cary, NC (April 1999).

"Dissolution Testing and Pharmaceutical Product Development," invited 2-day session, Pfizer, Inc., Groton, CT (April 1999).

"Advanced Dissolution Testing, "VanKel Technology Group/VanKel UK Limited, London, England. 2-day seminar. PLIVA Research Institute. Zagreb, Croatia (March 1999).

"The Modern Dissolution Laboratory.. Theory and Practice, "Invited 2-day session Indian Pharmaceutical Congress, Golden Jubilee Meeting, VanKel Technology Group/Chrome Line Limited, Mumbai, India (Dec. 1998).

"Clinical Conduct in BA/BE Investigations," Specialized 1 -day session, Wockhardt Limited, Mumbai, India (Dec. 1998).

"Generic Drug Product Development: Bio-availability, Bio-equivalence and In Vitro Equivalence," Intl. Advanced Instruments Expo, Mexico City, Mexico (Nov. 1998).

"Exploring IVIVC for Generic Drug Products: Fractional System Response Correlation, "1-h special seminar, Universidad National Autonoma de Mexico, Facultad de Quimica, Departmento de Farmacia, Mexico City, Mexico (Nov. 1998).

"Modern Dissolution Laboratory: Theory and Practice, "VanKel UK Limited, London, England. 2-day seminar, Ljubljana, Slovenia (Nov. 1998).

"Dissolution and Bio-availability in Generic Drug Development - Case Study Approach, "specialized 3-h technical session, PLIVA Research Institute. Zagreb, Croatia (Nov. 1998).

"The Modern Dissolution Laboratory: Theory and Practice, "VanKel Technology Group, Cary, NC. 2-day technical session, Cary, NC (Oct. 1998).

"Advanced Dissolution Testing, "2-day invited session, Geneva Pharmaceuticals, Inc., Broomfield, CO (Sept.1998).

"Advanced Dissolution Testing," 2-day technical session, Proctor & Gamble, Inc., Cincinnati, OH (Aug. 1998).

"The Modern Dissolution Laboratory. Theory and Practice," 2-day technical session, VanKel Technology Group/Unitlex Company Ltd., Tokyo, Japan (Aug. 1998).

"Advanced Dissolution Testing," 2-day technical session Boots Healthcare International Nottingham England (July 1998).

"The Modern Dissolution Laboratory: Theory and Practice," VanKel UK Limited, London, England. 2-day seminar, Goteberg, Sweden (June 1998).

"The Modern Dissolution Laboratory: Theory and Practice." VanKel UK Limited, London, England. 2-day seminar, Copenhagen, Denmark (June 1998).

"Basic Pharmacokinetics for the Pharmaceutical Scientist," 2-day technical, short course, Institute for Scientific Exchange, Baltimore, MD (June 1998).

"Advanced Pharmacokinetics: Simulations and Clinical Implications," 2-day intensive short course, Institute for Scientific Exchange, Baltimore, MD (June 1998).

"Simulation of Dissolution Performance in Drug Product Development," 2-h keynote seminar, Pfizer Inc., Groton, CT (May 1998).

"The Modern Dissolution Laboratory: Theory and Practice," VanKel Technology Group, Cary, NC. 2-day technical session, San Juan, PR (May 1998).

"Advanced Dissolution Testing," 2-day special invited session, Eli Lilly, Inc., Indianapolis, IN (April 1998).

"The Modern Dissolution Laboratory: Theory and Practice, "2-day technical session, VanKel Technology Group/Analytical

Instruments Ltd., Toronto, Canada (April 1998).

"Advanced Dissolution Testing," 2-day technical session, Whitehall-Robins Laboratories, Inc., Richmond, VA (March 1998).

"Advanced Dissolution Testing," 2-day technical session, Eli Lilly Canada Ltd., Toronto, Canada (March 1998).

"The Modern Dissolution Laboratory: Theory and Practice," 2-day technical session, VanKel Technology Group/Advanced Instruments de Mexico, Mexico DF, Mexico (Feb.1998).

"Fundamentals of Generic Drug Product Development: In Vitro Perspective," 2-day focus session, Synthon BV, Nijmgen, The Netherlands (Feb. 1998)

"The Modern Dissolution Laboratory: Theory and Practice," VanKel Technology Group, Cary, NC. 2-day technical seminar, Baltimore, MD (Feb.1998).

"The Modern Dissolution Laboratory: Theory and Practice," 2-day special invited session, Eli Lilly, Inc., Indianapolis, IN (Dec. 1997).

"Theory and Practice of Pharmaceutical Dissolution Testing, "1-day short intensive training session Andrx Pharmaceuticals, Inc., Ft. Lauderdale, FL (Nov. 1997)

"The Modern Dissolution Laboratory: Theory & Practice," VanKel Technology Group, Cary, NC. San Francisco, CA (Feb 1997).

"Simulation of Dissolution Performance in Drug Product Development," Lederle Laboratories, Pearl River, NY (Feb. 1997)

"Challenging Opportunities in the Delivery of Therapeutic Proteins and Peptides," Interphex-USA'97, Philadelphia, PA (April 1997).

"Transdermal Clonidine in Smoking Cessation: A Meta-Analysis," St. Louis College of Pharmacy Poster Day, St. Louis, MO (April 1997).

"Emerging Concepts in the Education and Competencies Required of a Clinical Pharmacist," 1st Intl. Conf. on The Practice of Clinical Pharmacy, Faculty of Pharmacy, Univ. of Zagreb, Zagreb, Croatia (April 1997).

"Key Success Factors in Generic Drug Development," Management Board, PLIVA, d.d., Zagreb, Croatia (April 1997).

"Advanced Drug Delivery System: Technology and Marketing,

& Practice," VanKel Technology Group, Cary, NC. London, England (July 1997).

"Clinical Pharmacokinetics and The Practice of clinical Pharmacy", Faculty of Farmacija, University of Ljubljana, Slovenia (Nov. 1996).

"Delivery of Therapeutic Proteins and Peptides", Int. Conf. Pharm. Ingred. Excip., CPhI '96, Turin, Italy (Oct. 1996).

"Generic Pharmaceutical Product Development: Regulatory Considerations", PLIVA d.d., Zagreb, Croatia (Oct.1996).

"Dissolution Testing and Pharmaceutical Product Development" Murty Pharmaceuticals Inc., Lexington, KY (Dec.1996).

"Simulation of Dissolution Performance in Drug Product Development", St. Louis College of Pharmacy, St. Louis, MO. (Oct.1996).

"Generic Pharmaceutical Markets: Pitfalls and Opportunities", PLIVA d.d., Board of Directors, Zagreb, Croatia (April 1996).

"Advances and Opportunities in Delivery of Proteins and Peptides", Indo-Swiss Collaborative Program, Intl. Conf. Biotechnology, Madras, India (March 1996)

"Advances in Oral Rate Controlled Drug Delivery", Institute for Drug Research, Budapest, Hungary (May 1996).

"Dermal and Trans dermal Drug Uptake", Semmelweis Medical Univ., Budapest, Hungary (May 1996).

"Beyond Traditional Non-conventional Drug Delivery Systems", Keynote address, Pharmaceutical Technology Section, VIIth Argentine Assoc. Indus. Pharm. and Biochem. (SAFYBI), Buenos Aires, Argentina (June 1996).

"Percutaneous absorption and Transdermal Drug Delivery Systems", Plenary Lecture, VIIth Argentine Assoc. Indus. Pharm. and Biochem. (SAFYBI), Buenos Aires, Argentina (June 1996).

"In Vitro-In Vivo Correlations for Modified Release Dosage Forms", Keynote presentation, AAPS Midwest Regional Meeting, Chicago, IL (May 1996).

"Advances in Oral Rate Controlled Drug Delivery Systems: Meeting the Challenges", Interphex '96, NY (April 1996).

"Contemporary Issues in Bio-equivalence Assessment", 1-day session, Interphex '96, NY (April 1996).

"Development and Evaluation of Import-Substituted (Generic) Products", 2-day session, Alexandria University, School of Pharmacy, Alexandria, Egypt (Dec.1995).

"Understanding the Current Requirements of In Vitro-In Vivo Correlations". Bio-availability/Bio-equivalence: Past, Present and Future, Symposium Al-Azhar 1st Intl. Conference on Pharm. Technol. & Bio. Sci., Cairo, Egypt (Dec. 1995).

"Principles of Dosage Form Development and Evaluation", 3-day intensive course, Technomic Publishing Co., Inc., NY (St. Louis, Dec.1995).

"Specialized Drug Delivery Responding to Physiological Demands". Intl. Conf. Pharml. Ingred. Excip., Frankfurt, Germany (Nov. 1995).

"Current Advances in Drug Delivery Systems Research", Keynote opening address, 1st Int. Conf. on New Horizons in Drug Delivery and Targeting, Basel, Switzerland (Nov. 1995).

"Principles of Pharmaceutical Dosage Form Development and Biopharmaceutical Evaluation", 4-day session, PLIVA Research Institute, Zagreb, Croatia (Nov. 1995).

"Bio-availability, Bio-equivalence and Therapeutic Substitution". 2-day intensive course, Technomic Publishing Co., Inc., NY (Chicago, Nov. 1995)

"Principles of Dosage Form Development and Evaluation", 3-day intensive course, Technomic Publishing AG, Basel, Switzerland (Oct. 1995).

"Transdermal Drug Product Development", 2-day intensive course, Technomic Publishing AG, Basel, Switzerland (Oct. 1995).

"Generic Drug Product Development & Current Issues in Bio-equivalence Evaluation". Association Argentina de Farmacia y Bioquimica Industrial, Buenos Aires, Argentina (Sept. 1995).

"Similarities and Differences in US and Indian Pharmacy Curricula". College of Pharmacy, Solapur, India (Aug. 1995).

"Insights into GATT and its impact on Indian Pharmaceutical Industry". Rotary Club of Solapur, Rotary Dist. 3031, Solapur, India (Aug. 1995).

"Meeting Physiological Demands through Specialized Drug Delivery". Keynote address - Magyar Biokemiai Egyesulet. Gyogyszerbiokemiai Szakosztalya, Transzmitter Rendszerek, Korszeru Technikak, Balatonaszod, Hungary (May 1995).

"Current concepts in Pharmaceutical In Vitro-In Vivo Correlations". 1st Intl. Mtg. on Pharmacy & Pharm. Sci., Istanbul, Turkey (Sept.1994).

"Dissolution and Bio-availability: Principles and Practices". 2-day course, Marmara University, Faculty of Pharmacy, Istanbul, Turkey (Sept.1994).

"Pharmaceutical Bio-equivalence Testing: Critical and Contemporary Considerations". CPhI'94 Convention and Exposition, Paris, France (Sept.1994).

"Principles in Biopharmaceutical Drug Product Development". Center for Biotechnology, Madras, India (Aug. 1994).

"Drug Product Development in Post-GATT Era: Lessons for Indian Small-Scale Industry". DST-CSIR-SSIB Workshop, Bombay, India (Aug. 1994).

"Rational Basis of Import-Substituted Drug Product Development". 2-day session, U.S. Vitamins, Ltd., Bombay, India (Aug. 1994).

"In Vitro Release of Selected Cardiac Drugs from Reservoir-Type Transdermal Formulations". APhA Ann. Mtg., Seattle, WA (March 1994).

"Percutaneous Transporation of Drugs", IBSA Symposium - Transdermal Congress, Lugano, Switzerland (June 1994)

"New Drug Delivery Systems - Developmental and Effective Marketing Considerations", 3-day seminar, Technomic Publishing Co., Inc., Ardsley, NY (April 1994).

"Drug Product Development through Modelling of Dissolution", Ankara University, Faculty of Pharmaceutical Technology, Ankara, Turkey (April 1994).

"Principles of Bio-equivalence and Strategies for Development of Generic Products", Hacettepe University, Faculty of Pharmacy, Ankara, Turkey (April 1994).

"Determination of In Vitro-In Vivo Correlations: Current Thoughts", Ankara University, Faculty of Pharmaceutical Technology, Ankara, Turkey (April 1994).

"Drug Dissolution and Bio-availability: A Preview", FAKO Pharmaceuticals, Istanbul, Turkey (April 1994).

"Principles of Bio-equivalence and Strategies for Development of Generic Products", FAKO Pharmaceuticals, Istanbul, Turkey (April 1994).

"Bio-availability, Bio-equivalence and Therapeutic Substitution". 2-day course, University of Ljubljana, Ljubljana, Republic of Slovenia (May 1994).

"Excipients in New Drug Delivery Systems". Pharmaceutical Ingredients Asia, International Conference and Exposition, Hong Kong (June 1994).

"Dissolution & Bio-availability Considerations in Drug Product Development", 3-day intensive course, Turkish Pharmaceutical Congress, Istanbul, Turkey (Sept.1994).

"Drug Product R&D: Characterization of Solid Drugs and Excipients", 2-day intensive course, Technomic Publishing Co., Inc., NY (St. Louis, Dec. 1993).

"Drug Dissolution & Bio-availability: Critical considerations including simulations and Predictions", 3-day intensive course, Technomic Publishing AG, Basel. Switzerland (Oct. 1993).

"Drug Product R&D: Characterization of Solid Drugs and Excipients", Technomic Publishing AG, Basel, Switzerland (Oct. 1993).

"Drug Product Development through Modelling of Dissolution Behavior", University of Pavia, Pavia, Italy (Sept.1993).

"Critical Consideration in Drug Product Development", 1-day special session, Cipla Labs., Ltd., Bombay, INDIA (April 1993).

"Role of Pharmaceutical Ingredients and Excipients in Development of Pharmaceuticals", CPhI'93 Conference and Exposition, Turin, Italy (Sept.1993).

"Dermatological Product Development and Drug Delivery", 2-day Short Intensive Course, Technomic Publishing AG, Basel, Switzerland (June 1993).

"Pharmaceutical Materials in Controlled Release Technology", 1-day intensive course, Pharmaceutical faculty, Univ. of Ljubljana, Republic of Slovenia (June 1993).

"Drug Product Development: Dissolution and Bio-availability Considerations", 2-day intensive course, Pharmaceutical Faculty, Univ. of Ljubljana, Republic of Slovenia (May 1993).

"Correlations Between In Vitro and In Vivo Results", Mallinckrodt Specialty Chemicals Co., St. Louis, MO 63147 (May 1993).

"Dermatological Product Development and Drug Delivery", 2-day Short Intensive Course, Technomic Publishing Co., Inc., Ardsley, NY (May 1993).

"Individual Bio-equivalence (R_i) Versus Average Bio-equivalence (R_a)". Intl. Sym. Bio-availability and Bio-equivalence, Bombay, India (April 1993).

"In Vitro-In Vivo Correlations: Some Recent Thoughts". Intl. Sym. Bio-availability and Bio-equivalence, Bombay, India (April 1993).

"Significance of Dissolution and Bio-availability Assessment in Drug Product Development", National Chemical Labs. (NCL), Pune, India (Jan.1993).

"Dissolution and Bio-availability of Drug Delivery Systems: Are predictable Correlations Dependable?", 3rd Intl. Conf Pharm. Ingred. Excip., Weisbaden, Germany (Nov. 1992).

"Evaluation of a Membrane Permeation Controlled Transdermal (MPCT) Drug Delivery System for Glibenclamide (GB)", 7th Amer. Assoc. Pharm. Sci., Ann. Mtg., San Antonio, TX (Nov. 1992).

"Release-Kinetics of Propranolol from Polymeric Matrices", 7th Amer. Assoc. Pharm. Sci., Ann. Mtg., San Antonio, TX (Nov - 1992).

"Transdermal Drug Delivery: Contemporary Issues and New Directions", 2-day short intensive course. Technomic Publishing Co., Inc., Ardsley, NY (Basel, Switzerland, Nov. 1992).

"Drug Dissolution and Bio-availability", 2-day International Seminar, Technomic Publishing Co., Inc., Ardsley, NY (Basel, Switzerland, Nov. 1992).

"Dissolution and Bio-availability Assessment in Drug Product Development", Mallinkrodt, Specialty Chemicals Co., St. Louis, MO (Oct.1992).

"Pharmaceutical Systems: Development and Evaluation", 2-day intensive course, KV Pharmaceutical Co., St. Louis, MO (Oct. 1992).

"In Vitro - In Vivo Correlations in Drug Development Process", Improving the Drug Development Process Conference, Institute for International Research, Princeton, NJ (Sept.1992).

"Bio availability and Dissolution", Pharm. Tech. Conf. and Expo. East Brunswick, New Jersey (Sept. 1992)

"Controlled Release Using Polymers: Characterization of Solid Drugs and Excipients", 2-day symposium, Technomic Publishing Co., Inc., New York, (Atlanta, March 1992).

"Oral Sustained Release Theophylline Products: Should Manufacturers recommend Dosage Modification upon Conversion from Intravenous Therapy", Interphex-USA'92, New York, (March-April 1992).

In Vitro-In Vivo Correlations with 7 Commercial Phenobarbital Formulations", Interphex-USA'92, New York (March-April 1992).

"Characterization and Enhancement of Tran dermal Drug Uptake", Workshop, Interphex –USA '92, New York (March-April 1992).

"Computer-Assisted Data Analysis of Sustained Release Formulations", Workshop, Interphex-USA'92, New York (March-April 1992).

"Dissolution and Bio-availability: Importance of in Vitro-In Vivo Correlations", 43rd Indian Pharmaceutical Congress, Panaji, Goa, INDIA (Dec. 1991).

"Dissolution Assessment of Novel Dosage Forms", European Symposium on Buccal and Nasal Administration as an Alternative to Parenteral Administration, Paris, France (December 1991).

"Trans dermal Drug Delivery", 2-day Symposium Technomic Publishing Co., NY (San Diego, Dec, 1991).

"Drug Dissolution and Bio-availability", 2-day International Symposium, Technomic Publishing Co., NY (Basel, Switzerland, Oct. 1991).

"Drug Dissolution and Bio-availability", 2-day Symposium, Technomic Publishing Co., NY (San Diego, Oct 1991).

"Specialized Drug Delivery Systems: Laboratory Research to Production", CPhI'91, International Exhibition and Conference on Pharmaceutical Excipients & Ingredients, Milano, Italy (Sept. 1991).

"Potential of Reservoir and Matrix Systems in In Vitro Transcutaneous Delivery of Diltiazem (DTZ)", Pharm. World Cong., Washington, DC (Sept 1991).

"Theory and Practice of Controlled Release Technology. II: Micro encapsulation Techniques and Dissolution Assessment", Tennessee Valley Authority, NFERC, Muscle Shoals, AL (June 1991).

"In Search of an Ideal Oral Sustained Release Dosage Form, Workshop", Interphex-USA'91, New York (April 1991).

"Computer Assisted Mathematical Modelling of Modified Drug Release", Workshop, Interphex-USA'91, New York (April 1991).

"Dissolution Characteristics of Two Formulations of Sustained Release Theophylline", Interphex-USA'91, NY (April 1991).

"Influence of pH and Ionic Strength on the Stability of Methacholine Chloride Solution", Interphex-USA '91, New York (April 1991).

"In Vitro Release of Piroxicam (I) from Reservoir-Type Topical Formulations", 138th Amer. Pharm. Assoc., Ann. Mtg., New Orleans, LA (March 1991).

"In Vitro Transcutaneous Uptake of Diltiazem (I) from Matrix-Type Topical Formulations", 138th Amer. Pharm. Assoc., Ann. Mtg., New Orleans, LA (March 1991).

"Comprehensive Evaluation of Parameters Influencing Transcutaneous Uptake of a Drug I: Drug Load, Agitation Intensity and Receptor Fluid", Amer. Soc. Hosp. Pharm., Midyear Mtg., Las Vegas, NV (Dec. 1990).

"In Vitro Release of Clonidine (I) from Reservoir-Type Topical Formulations", AAPS 5th Ann. Mtg., Las Vegas, NV (Nov. 1990).

"Evaluation of Bio-availability and In Vitro-In Vivo Correlation of Polyethylenes as Potential Prolonged Release Tablet Excipients, 9th Pharm. Technol. Conf., Veldhoven, Holland (April 1990).

"In Vitro Transcutaneous Uptake of Metronidazole from Topical Reservoir Formulations", 9th Pharm. Technol. Conf., Veldhoven, Holland (April 1990).

"Release Kinetics of Polymeric Prodrugs of Pindolol", 9th Pharm. Technol. Conf., Veldhoven, Holland (April 1990).

"In Vitro Transcutaneous Uptake of Theophylline (I) from Topical Reservoir Formulations", 137th Amer. Pharm. Assoc., Ann. Mtg., Washington, DC (March 1990).

"In Vitro Release of Naproxen (I) from Reservoir-Type Transdermal Formulations", 137th Amer. Pharm. Assoc., Ann. Mtg., Washington, DC (March 1990).

"Design Considerations and Mechanistic Evaluation of Oral Controlled Release Systems" AAPS Western Regional Meeting, Reno, NV (Feb. 1990).

"Clinical Efficacy of Current Transdermal Drug Delivery Systems (TDDS). A Retrospective Evaluation", Amer. Soc. Hosp. Pharm, Midyear Mtg., Atlanta, GA (Dec.1989).

"Potential of Reservoir Systems in the Transcutaneous Delivery of Diltiazem", Amer. Assoc. Pharm. Scientists, Ann. Mtg., Atlanta, GA. (Oct. 1989).

"Drug Release from Granules containing Acrylic Resin - Eudragit RL", Amer. Pharm. Assoc., Ann. Mtg., Anaheim, CA (April 1989).

Potential of (F_{oral}):: Dermal : Oral (F::D:O) in the Development of Dermal Products for Selected Non steroidal Anti-inflammatory Agents (NSAIAs)", Amer. Pharm. Assoc., Ann. Mtg., Anaheim, CA (April 1989).

"Transdermal Controlled Systemic Medications: In Vitro Release of Metoprolol from Transdermal Formulations", Ranbaxy Laboratories. New Delhi, India (Dec. 1988).

"Long-Acting Sub-dermal Contraceptive Drug Delivery Devices", Central Drug Research Institute, Lucknow, India (Dec.1988).

"In Vitro and In Vivo Considerations in the Design of Oral Sustained Release Dosage Forms", Institute of Medical Sciences, Banaras Hindu University, Varanasi, India (Dec. 1988).

"In Vitro-In Vivo Correlations: A Simplistic Approach", Institute of Medical Sciences, Banaras Hindu University, Varanasi, India (Dec. 1988).

"Fundamental Considerations in Transdermal Drug Delivery: In Vitro Release of Metoprolol from Transdermal Formulations", Institute of Medical Sciences, Banaras Hindu University, Varanasi, India (Dec. 1988).

"In Vitro Dermatokinetics of Selected Non steroidal Anti-inflammatory Analgesics (NSAIAs)", Amer. Assoc. Pharm. Scientists,

Ann. Mtg., Orlando, FL (Nov. 1988).

"Career Opportunities in Academia", Invited panel speaker for ASP Mid-Year Regional Meeting, APhA, (Oct.1988).

"Further Considerations in Correlating In Vitro/ In Vivo Data Employing Mean-Time Concept Based on Statistical Moments", 7th Pharm. Technol. Conf., London, England (April, 1988).

"Comparative In Vitro Dermatokinetics of Ibuprofen (IBP)", 7th Pharm. Technol. Conf., London, England (April 1988).

"In Vitro Release of Metoprolol (MTP) from Various Transdermal Formulations", 7th Pharm. Tech. Conf, London, England (April, 1988).

"Evaluation of Inwnto® as a Prolonged Release Formulation Excipient", Japan-United States Congress of Pharmaceutical Sciences Intl. Conf, Honolulu, Hawaii (Dec.1987).

"In Vitro Release of Salicylic Acid (SA) from Polymethacrylate (Eudragit L 100)-Polyethylene Glycol (PEG 6000) Films", Amer. Pharm Assoc., Ann. Mtg., Chicago, IL (March 1987).

"Biomedical Approaches to Controlled Drug Delivery", Med. Device & Diagnos. Indust., National Conference/Expo., Anaheim, CA (Jan. 12-13, 1987).

"Impending Crisis of Personnel in Pharmaceutical Sciences", SAPhA Gen. Mtg., Creighton Univ. School of Pharm., (Sept. 1986).

"Pharmaceutical Technology Information on the National Pharmacy Bulletin Board Service (NPBBS)", 5th Pharm. Technol. Conf., England, (April 1986).

"A Closer Look at the Mean Residence Time (MRT) Concept Based on Statistical Moments", 5th Pharm. Technol. Conf., England, (April 1986).

"Evaluation of a Low Density and a High Density Polyethylene as Potential Prolonged Release Tablet Excipients", 5th Pharm. Technol. Conf., England, (April 1986).

"Microcomputers in Basic Pharmaceutical Sciences", Issues in Higher Education Conf., Kansas City, (March 1986).

"Prolonged Release Solid Dispersions of Glyceryl Guaiacolate (GG) Employing Methacrylate Polymer (Eudragit L)", Amer. Pharm. Assoc. Ann. Mtg., San Francisco, (March 1986).

"Industrial Pharmacy on the National Pharmacy Bulletin Board Service (NPBBS)", Amer. Pharm. Assoc. Ann. Mtg., San Francisco, (March 1986).

"A Simple Model Independent Method for the Determination of Dosing Interval (τ) for Drugs with Short Biological Half-Lives (T1/2) Administered in Sustained Release Formulations", Amer. Pharm. Assoc. Natl. Mtg., Minneapolis, (Oct.1985).

"Bio-pharmaceutics and Pharmacokinetics on the National Pharmacy Bulletin
vice & Diag. Indus. Conf./Expo, Chicago, (June 1985).

"Influence of pH on In Vitro Drug Release Characteristics", Amer. Pharm. Assoc. Ann. Mtg., San Antonio, (Feb. 1985).

"Polyethylene as Potential Prolonged Release Tablet Excipients", Amer. Pharm. Assoc. Ann. Mtg., San Antonio, (Feb.1985).

"Advances in Dissolution Technology: Design, Pros and Cons", Amer. Pharm. Assoc. Natl. Mtg., Philadelphia, (Oct.1984).

"A Study of the Effects of Sucrose Concentration, Lacquer Concentration and Coating Time on the Development of Stable and Effective Carbenicillin Indanyl Sodium Microcapsules", Amer. Pharm. Assoc. Natl. Mtg., Philadelphia, (Oct.1984).

"Beyond Bio-availability Testing". XIV Ann. Grad. Stud. Pharm. Res. Mtg., Morgantown, WV, (June 1982).

Book Reviews

"Therapeutic Peptides and Proteins", Technomic Publishing Co., Inc., NY (1995). Reviewed for Ann. Clin. Pharmacother. (1996).

"International Pharmacopoeia", 3rd Edn., WHO, Geneva, Switzerland (1994). Reviewed for Ann. Clin. Pharmacother, (1995).

"Polymeric Biomaterials", S. Dumitriu, Ed., Marcel Dekker, Inc., NY (1994). Reviewed for Pharmaceutical Technology (1994).

"Drug Permeation Enhancement", D. Hiesch, Ed., Marcel Dekker, Inc., NY (1994). Reviewed for Pharmaceutical Technology (1994).

"The Process of New Drug Discovery and Development", C.G. Smith, CRC Press, Inc., Boca Raton, FL (1993). Reviewed for Pharmaceutical Technology (1994).

"Drug Master Files: Global Harmonization of Quality Standards", H. Moller and W.H. Oeser, Eds., CRC Press, Inc., Boca Raton, FL (1993). Reviewed for Pharmaceutical Technology (1994).

"Liposome Technology", 2nd Ed., Vols. I-III, G. Gregoriadis, Ed., CRC Press, Inc., Boca Raton FL (1993). Reviewed for Pharmaceutical Technology (1993).

"Prodrugs", K.B. Sloan, Ed., Marcel Dekker, Inc., New York (1992). Reviewed for Pharmaceutical Technology (1993).

"Polymer Applications for Biotechnology", D.S. Soane Ed., Prentice Hall, Englewood Cliffs, NJ (1992). Reviewed for BioPharm Manuf. (1992).

"Protein Stability and stabilization through Protein Engineering", Y. Nosoh and T. Sekiguchi, Ellis Harwood, New York, NY (1992). Reviewed for BioPharm Manuf. (1992).

"Liquid Chromatography/Mass Spectrometry", M.A. Brown, Ed., American Chemical Society, Washington, DC (1991). Reviewed for Pharm. Technol. (1992).

"Pharmaceutical Bio-equivalence", P.G. Welling, F.S.L. Tse and S. Dighe, Eds., Marcel Dekker, Inc., New York, NY (1991). Reviewed for Pharm. Technol. (1992).

"Biosensors", E.A.H. Hall, Prentice Hall, Englewood Cliffs, NJ (1991). Reviewed for BioPharm (1991).

"Biomstrumentation and Biosensors", D.L. Wise, Ed., Marcel Dekker, Inc., New York, NY (1991). Reviewed for BioPharm(1991).

"Natal Systemic Drug Delivery", Y.W.Chien, K.S.E. Su and S-F. Chang, Marcel Dekker, Inc., NY (1989). Reviewed for Biopharm Manuf. (1990).

"Applied Biosensors", D. Wise, Ed., Butterworths Publications, Stoneham, MA (1989). Reviewed for BioPharm Manufacturing, (1989).

"Bio separations: Downstream Processing for Biotechnology", P.A.Belter, E.L. Cussler and W-S Hu, John Wiley & Sons, NY (1988). Reviewed for BioPharm Manufacturing, (1989).

"Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms", J. McGinity, Ed., Marcel Dekker, Inc., NY (1989). Reviewed for Pharmaceutical Technology, (1989).

"Fundamentals of Biotechnology", P.Prave, U. Faust, W. Sitting and D.A. Sukatsch, Eds., VCH Publishers, NY (1987). Reviewed for BioPharm Manufacturing, (1989).

"Techniques of Biocompatibility Testing", Vol. I.D.F. Williams, Ed., CRC Press, Inc., Boca Raton, FL (1987). Reviewed for BioPharm Manufacturing (1988).

"Techniques of Biocompatibility Testing" Vol. II.D.F. Williams, Ed., CRC Press, Inc., Boca Raton, FL (1987). Reviewed for BioPharm Manufacturing (1989).

"Antibody-Mediated Delivery Systems", J.D. Rodwell, Ed., Marcel Dekker, Inc., NY (1988). Reviewed for BioPharm Manufacturing (Oct.1988).

"Protein Purification: Principles and Applications", 2nd ed., R.K. Scopes, Springer-Verlag, New York (1987). Reviewed for BioPharm Manufacturing (Oct.1988).

"Nuclear Pharmacy", H.M. Chilton and R.L. Witcofski, Lea & Febiger, Philadelphia, PA (1986). Reviewed for Journal of Pharmaceutical Sciences (June 1988).

"Transdermal Delivery of Drugs", A.F. Kydonieus and B. Berner, Eds., Vol. I, (1987), CRC Press, Inc., Boca Raton, FL. Reviewed for Pharmaceutical Technology (June 1988).

"Rate-Controlled Drug Administration and Action", H.A.J. Struyker-Boudier, Ed., (1987) CRC Press, Inc., Boca Raton, FL. Reviewed for Journal of Pharmaceutical Sciences (Mar.1988).

"Polymeric Nanoparticles and Micro-spheres", P. Guiot and P. Couvreur, Eds., (1987) CRC Press, Inc., Boca Raton, FL. Reviewed for Journal of Pharmaceutical Sciences (Jan.1988).

"Bio-reversible Carriers in Drug Design", E.B. Roche, Ed., Pergamon Books; Maxwell House, Elmsford, New York (1987). Reviewed for BioPharm Manufacturing, (Sept. 1987).

"Theory and Practice of Industrial Pharmacy", 3rd. ed., (1986), Lachman, Lieberman and Kanig, Lea & Febiger, Philadelphia, PA. Reviewed for Journal of Allied Health.

"Extended-Release Dosage Forms", L. Krowczynski, Vols. I-II, CRC Press, Inc., Boca Raton, FL, Reviewed for Pharmaceutical Technology.

Grants/contracts

"Development and Evaluation of Lotions as a Topical Formulation," Faculty Fellowship Grant, Butler University, Indianapolis, IN (1999). $3000

"Do Generics Full fill the Promise of Clinical Equivalence Worthy of Therapeutic Substitution," Butler Summer Institute, Butler University, Indianapolis, IN (1999). $2,000

"Advanced Professional Training," Education grant, PLIVA d.d., Zagreb, Croatia (1998) $56,250

Unrestricted Equipment Grant/Donation of a Cary UV.VIS Spectrophotometer, VanKel Technology Group, Cary, NC (1998). Estimated value $ 25,000

Unrestricted Equipment Grant/Donation of a VK7010: Six Spindle USP Dissolution Testing Apparatus, VanKel Technology Group, Cary, NC (1998). Estimated value $18,000

"Emerging Concepts in the Education and Competencies Required of a Clinical Pharmacist," 1st Intl. Conf. on the Practice of Clinical Pharmacy. Faculty of Pharmacy, Univ. of Zagreb, Zagreb, Croatia (April 1997) Travel grant from PLIVA d.d., Zagreb, Croatia $5500.

"Feasibility of Transdermal Anticonvulsants", NIH-SBIR, Bethesda, MO. (1995) $78,000. (Approved for funding, but not funded)

"Preliminary Characterization of PLIO", PLIVA Research Institute, Zagreb, Republic of Croatia (1996). $15000

"Evaluation of a HDPE for its Potential as a Prolonged Release Tablet Excipient", Egyptian Ministry of Higher Education, Cairo, Egypt (1996). $12000

"Cost Analysis of Thin-Layer Chromatography of Selected USP Drugs". The USP, Rockville, MD 20852. (1995) $8000.00.

"Understanding the Current Requirements of In Vitro-In Vivo Correlations", Bio availability/Bio-equivalence: Past, Present and Future, Symposium, Al-Azhar Univ., 1st Int. Conf. Pharm. Technol. & Bio. Sci., Cairo, Egypt (1995). Travel grant from Torrent Pharmaceuticals Ltd., India. $ 6000.

Unrestricted equipment Grant-Cum-Donation-Undergraduate Research Institute, Hanson Research Corp., Chatsworth, CA (1995). Estimated value $28,900.00.

Recipient of Research Equipment gift from Mallinckrodt Specialty Chemical Co., St. Louis, MO (1995). $20,000 value.

Unrestricted Grant towards StLCOP - Undergraduate Research Institute. Mallinckrodt Specialty Chemicals Co., St. Louis, MO (1994) $5000.00

"In Vitro Transcutaneous Uptake of Glibenclamide", NIH-AREA, Approved for funding (1994). $80,840.70.

"Critical Consideration in Pharmaceutical Bio-equivalence Testing:, Technical Course Presentation at PhIA, Hong King (1994): Travel grant from Torrent Pharmaceuticals Ltd., Ahmedabad, India. $2500.

"Modelling of Dissolution Behavior of a Modified Release Dosage Form", VanKel Industries, Inc., Edison, NJ (1993) $ 2000.00

Unrestricted Grant towards StLCOP-Undergraduate Summer Research Institute, Viro Tex Inc., Houston, TX (1993) $5000.00

"*Analyse Pratique du Medicament*", Translation from French to English. VCH Publishers, Inc., NY (1993) $15880.00

"Pharmaceutical Systems: Development and Evaluation", KV Pharmaceutical Co., St. Louis, MO (1992) $5000.00

"Formulation, Formulae and Formularies: Cost Containment and Parenteral Nutrition". Education grant in support of a CE program, Abbott Laboratories, Chicago, IL (1992). $1500+,

"Issues in the Treatment of Diabetes", Education grant in support of a CE program, The Upjohn Company, Kalamazoo, MI (1991). $5000.00

"Pro-drugs of Acyclovir and AZT for Trans dermal Delivery", NIH-AREA (1991). Approved for funding. $82,500.

"Contemporary Issues in Geriatric Medicine", Educational Grant to support a continuing education program, Marion-Merrell-Dow, Kansas City, MO (1991), $5200.00

"Design and Evaluation of a Flow-Through Modified Franz Diffusion Cell", Crown Glass Company, Somerville, *NJ* (1991). $8992.00

"A Comprehensive Evaluation of Parameters Affecting Transdermal Uptake of Salicylic Acid (SA) and Ibuprofen (IBF)", ASP Research Grant (1990). $500.00

"Educating Older Americans and Children about Prescription (RX) and Over The Counter (OTC) Drugs: An Instructional Approach", NARD Foundation Smith Kline Beecham Grant (1990). $1200.00

"Percutaneous Absorption of Iodochlorothydroxyquin", NIH-AREA (1989). Approved for funding. $97,956.

"Potential of Reservoir and Matrix-Type Delivery Systems in Transcutaneous Uptake of Diltiazem", Health Futures Foundation, Omaha, NE (1989). $8000.00

"In Vitro Dermatokinetics of Ibuprofen and Determination of Relative In Vitro Availability [$F_{a\ vitro}$ :: Dermal: Oral]", Marion Laboratories, Inc., Kansas City, MO (1989). $11919.00

Recipient of Financial support from pharmaceutical company(ies) towards 'ASP Research Grants' program promoting undergraduate research. $4000.00 (This program was established in 1988/89 by Dr.Banakar.

Recipient of Faculty Development Grant for attendance and participation in a course: Advances in Controlled Release Technology, offered by Mass. Inst Tech., Boston, MA (July 23-29,1989). $2500.00

"Tran dermal Theophylline (TPE)! A Plausible Route of Administration in Paediatric Patients", ASP Research Grant (1989). $-500.00

Recipient of research equipment gift from Crown Glass Company, Somerville, NJ (1988). $5000.00 value.

Recipient of Travel Grant for attendance and participation at 7th Pharm. Tech. Conf., London, UK (April 12-14, 1988). Sponsored by Marion Laboratories, Kansas City, MO (1988). $1000.00

"Design and Evaluation of a Matrix Type Transdermal Delivery System for Metoprolol" supported by Health Futures Foundation Young Faculty Award (1986-1987). $8500.00

"In Vitro Equivalence Testing of Commercial Ibuprofen Products" supported by NARD Norcliff-Thayer Foundation Grant (1986-1987). $1200.00

"Permeation Kinetics of Propranolol through Polymer Films as Potential Transcutaneous Drug Delivery System" supported by BRSG grant (1985-1986). $2000.00

"Development of an Unique Guaifenesin Dosage Form", supported by a cash grant from Reid-Provident Labs., Inc., Atlanta, GA (1982-1984).$5000.00

"A Study of the Effects of Sucrose Concentration, Lacquer Concentration and Coating Time in the Formulation of Stable and Effective Carbenicillin Indanyl Sodium Microcapsules", supported by grant from Roerig Inc., (1982-1984). $3000.00 value.

Doctoral Dissertation - Expert Review

"Phytochemical, Pharmacological and Toxicological Studies on Various Extracts and Principles Derived from Leaves of *Aegle Marmelos Corr.*," V. Arul, Dissertation submitted to University of Madras, Chennai, India (1999).

Formulation and Evaluation of Oral Sustained Release Drug Delivery Systems Using Tamarind Seed Polyose," D. Kulkarni, Dissertation submitted to Birla Institute of Technology, Mesra, Ranchi, Bihar, India (1998)

"Studies on the Application and Limitations of Direct Compression Technology to Potent, Medium and High Dosage Drugs," K. Abbulu, Dissertation submitted to Andhra University, Vishaka Pattnam, Andhra Pradesh, India (1997).

"Phytochemical, Pharmacological and Toxicological Studies of Coleus Aromaticus, Benth." K.Kumaravel, dissertation submitted to Madras University, Chennai, Tamilnadus. India (1997)

Directing Thesis Projects.

"In Vitro Release of Metoprolol from reservoir-type Compositions as Potential Transdermal Drug Dermal Delivery Systems" by Amrya Deweolkar, , thesis towards fulfillment of the requirements of the degree of Master of Science, Butler Univ., Indianapolis. IN (2000). Project advisor.

"In Vitro Dissolution Testing of Selected Modified Release Theophylline Solid Dosage Forms" by Nutinee Dheeraradha , thesis towards fulfillment of the requirements of the degree of Master of Science, Butler Univ., Indianapolis, IN (2000). Project advisor.

"In Vitro Permeation Across Caco-2 Mono Layer: Effect of Surfactants, Ethanol, Structurally Diverse Test Compounds and the FDA Proposed Bio-pharmaceutics-Classification System" by Syed Hasan, thesis towards fulfillment of the requirements of the degree of Master of Science, Butler Univ., Indianapolis, IN (1998). Project advisor.

"Mucus: Characterization, Rheology and Role in Oral Drug Delivery", by Nilesh P.Rao, dissertation, in progress, towards the fulfillment of the requirements of the degree of Doctor of Science (D.Sc.), Washington Univ., Dept Of Chem. Engg., St. Louis, MO. (1998) Member of Dissertation /Research Project Committee.

"Transdermal Clonidine for Smoking Cessation: A Meta-Analysis", by P.Thakker, Research project for completing the requirements for the degree of Doctor of Pharmacy (1996-1997). Project advisor.

"Prospective Design of Solid Non-conventional Dosage Form: A Non-classical Approach", by Sudhir Vadvalkar, dissertation in progress. Babasahib Ambedkar University, Nanded, India. Primary project advisor.

"Pharmaceutical Development and Evaluation of a Bio-adhesive Drug Delivery System for Lidocaine", (1994) by G. Duman, a dissertation completed towards the fulfillment of the requirements of the degree of Doctor of Philosophy (Ph.D.), University of Ankara, Faculty of Pharmaceutical Technology, Ankara, Turkey. Member of dissertation committee.

"Effect of Phase Inversion on Physical Stability of o/w Emulsions", (1992) by R. Kulshreshtra, MS thesis, Birla Institute of Technology, Mesra, Ranchi, INDIA. Member of thesis project committee.

"Evaluation of Possible Incompatibilities following Mixing of I.V. Amiodarone HCl with Injectable Antibiotics", (1987) by M. Benedict, a thesis project completed towards the fulfillment of the requirements for the degree of Doctor of Pharmacy, Creighton University, School of Pharmacy, Omaha, NE 68178. Member of thesis committee.

"Synthesis of 3,11c-ethano-10-methoxy-1,2,3,3a,11b,11c-hexa-hydroaporphine", thesis submitted by N.D. Tran in partial fulfilment of the requirement for the degree of Doctor of Pharmacy, Creighton University, School of Pharmacy, Omaha, NE 68178 (April 1986). Member of thesis committee.

TEACHING

RX321:	Pharmaceutics I	(1998 - 1999)
RX421:	Pharmaceutics II	(1999 - 1999)
PR357:	Bio-pharmaceutics/Pharmacokinetics	(1997 - 1999)
PR557:	Clinical Pharmacokinetics	(1997 - 1999)
RX753:	Adv. Biopharm & Pharmacokinetics	(1997 – 1999)
PH4101:	Bio-pharmaceutics	(1990 - 1997)
PH2102:	Pharmaceutics	(1991 - 1997)
PH3001:	Pharmaceutics II	(1994 - 1997)
PH4102:	Pharmacokinetics	(1991 - 1997)
PH4720	Transdermal Drug Delivery	(1992 - 1997)
PH4740	Manufacturing Pharmacy	(1996 - 1997)
PH4732:	Drug Delivery Systems	(1991 - 1997)
CP4732:	Research Methodology	(1991 - 1997)

PSC 111:	Pharmaceutics I	(1985 - 1990)
PSC112:	Pharmaceutics II	(1985 - 1990)
PSC475:	Theory of Solid Systems	(1986 - 1987)
PSC478:	Principles of Modified Drug Delivery	(1988,1989)
PSC231:	Basic Pharmacokinetics	(1985 - 1990)
PSC495:	Directed independent Study	(1985 - 1990)
PSC497:	Directed Independent Research	(1985 -1990)

Physical Pharmacy I	(1981 - 1984) - Instructor-in-Charge
Physical Pharmacy II	(1981 - 1984) - Instructor-in-Charge
Manufacturing Pharmacy	(1983) - Instructor

Courses Fabricated and Instructed

As of date, over 40 courses have been developed. Partial listing is provided

PH 4101:	Bio-pharmaceutics
PH 4720:	Transdermal Drug Delivery
PH 3001:	Pharmaceutics II
PSC 111:	Pharmaceutics I
PSC 112:	Pharmaceutics II
PSC 475:	Theory of Solid Systems
PSC 476:	Theory of Disperse Systems
PSC 478:	Principles of Modified Drug Delivery

Principles of Pharmaceutical Dosage Forms Development and Evaluation
Development and Evaluation of Import-Substituted Products (Generics)
Transdermal Drug Product Development
Bio-availability, Bio-equivalence and Therapeutic Substitution
Bio-availability and Bio-equivalence: Evaluation of a Submitted Protocol and/or Report
New Drug Delivery Systems: Developmental and Effective Marketing Considerations
Drug Dissolution & Bio-availability: Critical considerations including simulations and data analysis
Topical Drug Delivery: Dermatology and Product Development
Computer Applications to Controlled Release Delivery Systems: Simulation and Data Analysis
Controlled Release Technology & its Applications. Part II: Microencapsulation Techniques & Dissolution Assessment
Drug Dissolution and Bio-availability
Transdermal Drug Delivery: Contemporary Issues and New Directions
Controlled Release Using Polymers: Characterization of Solid Drugs and Excipients
Modelling Modified Drug Release: Practical and Time-saving Techniques
Controlled Release Technology: Theory and Practice
Advanced Dissolution Testing: Theory and Applications
Correlating Dissolution and Bioavailability: Understanding IVIVC
Dissolution Method Development for Pharmaceutical Dosage Forms
Principles of Generic Pharmaceutical Product Development and Biopharmaceutical Evaluation
Generic Drug Development Program: Techno-Legal Considerations
Biorelevant Dissolution Testing: Reality or Fallacy !!

SERVICE

Academic Service

College of Pharmacy, Butler Univ., Indianapolis, IN 1997 - 1999
Chairman – Pharmaceutical Sciences Division
Chairman – Graduate Program
Administrative Council
Promotion & Tenure Committee
Curriculum Committee – Pharmaceutics Section
Strategic Planning Committee
AACP Evaluation – Subcommittee
Others

St. Louis College of Pharmacy
Strategic Planning: External Environment 1996
Peer Reviews Committee (CPT) 1996 - 1997

Promotion &Tenure Committee (Chairman '95-'96)	1994 - 1996
Curriculum Committee 1993 - 1996	
Admissions Committee	1993 - 1996
STLCOP-UMKC Joint UG Research Program (founder)	1996 - 1997
Strategic Planning: Internal Environment	1992 - 1993
(Research Subcommittee)	
Innovative Teaching Awards Committee	1993 - 1996
Undergraduate Summer Research Institute (Founder)	1992
Animal Use Committee (Chairman)	1991 - 1995
Institutional Review Board (Chairman '92-'96)	1990 - 1995
Scholarship Research committee (Chairman '90-'92)	1990 - 1996
Rho Chi (Faculty Advisor)	1993 - 1996

Creighton University, Omaha, NE 68178

Partners in Excellence Program	1987 - 1990
Committee on Committees	1987 - 1989
University Statutes and Faculty Handbook	1988 - 1989
Advising Committee - Financial Aid	1986 - 1987

School of Pharmacy Creighton University

Admissions Committee (Chairman)	1988–1990
Academy of Students of Pharmacy (ASP) (Advisor)	1988 –1990
ASP Research Grants Committee (Chairman)	1988 -1990
Executive Committee (Elected)	1989
Curriculum Committee	1989
Continuing Education Committee	1989 - 1990
AACP Delegate (Elected)	1987 - 1988
Rho Chi Delegate to Natl. Convn.	1987, 1989
Biotechnology Subcommittee	1987 - 1988
Faculty Teaching Evaluation Subcommittee	1986 - 1987
Scholarship & Awards Committee	1985 - 1986
Student Advising Committee	1985 - 1990

Bombay University, Bombay, India

Ad-hoc Committee on Revision of Syllabus	1976

<u>National</u>

National Institutes of Health – NIAID, NINDS, SBIR/STTR
Center for Disease Control & Prevention
Institute for International Research
American Pharmaceutical Association - Acad. Pharm. Res. Sci.
Reed Exhibition /Conference Cos., Inc - Member-Organizing committee (Scientific Section)

<u>International</u>

United Nations – IESC
International Journal of Pharmaceutical Advances
International Journal of Pharmaceutical Excipients
International Executive Service Corps, Connecticut, USA
United Nations, TOKTEN Program, New York
World Health Organization, Geneva, Switzerland
Miller Freeman Publishers, London, England
Marcel Dekker Inc., New York, New York
Centre for Biotechnology (CBT) Anna University, Madras, INDIA
DGHHS Adhoc Advisor to Drug Controller of India, New Delhi, INDIA
Pragati Charitable Trust Founder and Member Board of Trustees INDIA
Torrent Pharmaceuticals Ltd., Ahmedabad – INDIA
ENAR Research Foundation, Scientific Advisory Board Bombay, INDIA
Lotus Labs Private Limited, Bangalore, INDIA
Several pharmaceutical corporations worldwide

<u>Personal Data for Umesh Banakar, Ph.D.</u>

Date of Birth: Dec. 04, 1956
Health: Excellent

Married to Saneeta Banahar

ATTACHMENT B

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

EXPERT REPORT OF UMESH V. BANAKAR, Ph.D.
ON BEHALF OF
COMPLAINT COUNSEL

The remaining pages of the expert report have been redacted.

ATTACHMENT C

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of:	:	
SCHERING-PLOUGH CORPORATION, a corporation,	:	CONFIDENTIAL
	:	Deposition of:
UPSHER-SMITH LABORATORIES, a corporation,	:	UMESH BANAKAR
and	:	
AMERICAN HOME PRODUCTS CORPORATION, a corporation.	:	

TRANSCRIPT of testimony as taken by and before PATRICIA M. MULLIGAN, a Certified Shorthand Reporter and Notary Public of the State of New Jersey, at the MADISON HOTEL, One Convent Road, Morristown, New Jersey, on Friday, December 7, 2001, commencing at 8:10 in the forenoon.

REPORTING SERVICES ARRANGED THROUGH
VERITEXT/NEW JERSEY REPORTING COMPANY, L.L.C.
Kabot Battaglia & Hammer - Suburban Shorthand
Waga and Spinelli - Arthur J. Frannicola CSR
25B Vreeland Road, Suite 301
Florham Park, New Jersey 07932
Tel:(973) 410-4040 Fax:(973) 410-1313

The remaining pages of the transcript have been redacted.

ATTACHMENT D

George Washington University
Professional Record

Name: Martin J. Adelman
Office Address:
George Washington University Law School
720 20th St. N.W.
Washington, D.C. 20052
Phone: (202) 994-7703
madelman@main.nlc.gwu.edu

Date Prepared: June, 2001
Home Address:
29820 Woodland Drive
Southfield, MI 48034
Phone: (248)356-7553
Fax: (248)356-7554

Present Position:
Professor of Law, Director of the Intellectual Property Program and Director of the Dean Dinwoodey Center for Intellectual Property Studies, George Washington University Law School.

Date and Place of Birth:
February 22, 1937, Detroit, Michigan.

Citizen of: U.S.A.

Education

High School: Central High School, Detroit, Michigan, June 1954.

Baccalaureate: A.B., University of Michigan, Ann Arbor, Michigan, June, 1958.

Graduate: M.S. (Physics), University of Michigan, Ann Arbor, Michigan, August, 1959.

Law Degree: University of Michigan, Ann Arbor, Michigan, June, 1962.

Other Faculty Appointments

Professor of Law, Wayne State University Law School, Detroit MI, 1973-1999, Professor Emeritus 1999--.

Visiting Professor of Law, University of Michigan Law School, Ann Arbor, Michigan, Winter 1982.

Visiting Professor of Law and Acting Director of the Intellectual Property program, George Washington University Law School, 1998-99.

Professional Experience

Assistant Editor Michigan Law Review (1960-1962).

Research Assistant to Professor Samuel D. Estep (1960-1962).

Law Clerk, Chief Judge Theodore Levin, Federal District Court, Detroit, Michigan (1962-1963)

Associate, Honigman, Miller, Schwartz & Cohn, Detroit, Michigan (1963-64).

Patent Attorney, Burroughs Corp., Washington, D.C. (1964-1965).

Associate, Barnard, McGlynn & Reising, Birmingham, Michigan (1965-1968), Partner (1968-1973) in charge of patent, patent-antitrust, and related litigation.

Professional Society Memberships:

American Bar Association,
American Intellectual Property Law Association,
Michigan Bar Association,
International Association for the Advancement of Teaching and Research in Intellectual Property.

Service at Wayne State University

Acting Dean, Law School (1974-75).
President, Faculty Senate (1976-1979).
Chair, Personnel Committee, Law School (1987-88).

Professional Consultation

Testified as an expert on patent law and practice either at trial or by way of deposition in more than 150 patent infringement cases.

Journal/Editorial Activity

Editorships

Book Review Editor, The Antitrust Bulletin, 1980-1986.

Publications

Scholarly Books

Patent Law Perspectives, 2d Ed., Matthew Bender (eight volumes)(continuously updated)(available through LEXIS).

Cases and Materials on Patent Law (with Randall R. Rader, John R. Thomas and Harold C. Wegner), West Group 1998.

Chapter 63, *Patents*, in *Business and Commercial Litigation in Federal Courts* (six volumes)(continuously updated)(with Randall R. Rader and Harold C. Wegner) West Group 1998 (available through WESTLAW).

Journal Articles

Refereed Papers:

An Antitrust Decision: *Lear v. Adkins*, 58 A.B.A.J. 45 (1972).

Territorial Restraints in International Technology Agreements after *Topco*, 17 Antitrust Bull. 763 (1972) (with Brooks), reprinted at 5 Pat. L. Rev. 457 (1973).

The Supreme Court, Market Structure, and Innovation: Chakrabarty, Rohm and Haas, 27 Antitrust Bull. 457 (1982).

Invited Articles:

Secrecy and Patenting: Some Proposals for Resolving the Conflict, 1 A.P.L.A. Quarterly J. 296 (1973), reprinted at 5 Pat. L. Rev. 57 (1973).

Relevant Market Paradox - Attempted and Completed Patent Fraud Monopolization, 28 Ohio State L.J. 289 (1977), reprinted at 10 Intellectual Property L. Rev. 115 and 8 J. of Reprints for Antitrust L. and Econ. 709.

Use of Industrial Property as a Clandestine Cartel, 30 (Supplement) Am. J. Comp. L. 1701 (1982).

Forward, Symposium: Perspectives on the General Motors-Toyota Joint Venture, 31 Wayne L. Rev. 1163 (1985).

The New World of Patents Created by the Court of Appeals for the Federal Circuit, 20 U. of Mich. J. L. Ref. 979 (1988).

Patents and the Seventh Amendment, Molengrafica, Eenvormig en vergelijkend privaatrecht 357 (1993).

Damages and other financial remedies for Patent Infringement, AIPPI Annuaire 1995/IX,

274 (1995).

Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India, 29 Vand. J. Tranat'l L. 507 (1996)(with Baldia).

The Effect of the Seventh Amendment on Substantive American Patent Law, Molengrafica, Europees Privaatrecht 173 (1996).

The Exhaustion Doctrine in American Patent Law, Molengrafica, Europees Privaatrecht 247 (1997).

NonRefereed Papers:

State Control of Radiation Hazards: An Intergovernmental Relations Problem, 60 Mich. L. Rev. 41 (1961) (with Estep).

Trade Secrets and Federal Pre-exemption - The Aftermath of Sears and Compco, 49 J. Pat. Off. Soc'y 713 (1967).

Inventions and the Law of Trade Secrets after *Lear v. Adkins*, 16 Wayne L. Rev. 77 (1969) (with Jaress), reprinted at 3 Pat. L. Rev. 231 (1971).

Patent-Antitrust Law: A New Theory, 17 Wayne L. Rev. 1 (1971) (with Jaress), reprinted at 3 Pat. L. Rev. 231 (1971).

The Integrity of the Administrative Process, Sherman Section 2 and the Per Se Rules - Lessons of Fraud on the Patent Office, 19 Wayne L. Rev. 1 (1972) (with Brooks), reprinted at 55 J. Pat. Off. Soc'y 255 (1973) and 5 Pat. L. Rev. 413 (1973).

Patent-Antitrust: Patent Dynamics and Field of Use Licensing, 50 N.Y.U. L. Rev. 273 (1975) (with Juenger), reprinted at 7 Pat. L. Rev. 495, and 8 J.of Reprints for Antitrust L. and Econ. 429.

Property Rights Theory and Patent-Antitrust: The Role of Compulsory Licensing, 52 N.Y.U. L. Rev. 77 (1977), reprinted at 10 Intellectual Property L. Rev. 77 and 8 J. of Reprints for Antitrust L. and Econ. 287.

The Doctrine of Equivalents in Patent Law: Questions Pennwalt did not Answer, 137 U. of Penn. L. Rev. 673 (1989) (with Francione).

Is the Use of the Doctrine of Equivalents to Fix Mistakes a Mistake?, 27 N. Ky. L. Rev. 1021 (2000).

Book Reviews

Academic Journals

Book Review, 25 Antitrust Bull. 891 (1980).
Book Review, 26 Antitrust Bull. 447 (1981).
Book Review, 27 Antitrust Bull. 275 (1982).
Book Review, 28 Antitrust Bull. 491 (1983).

CASES IN WHICH MARTIN J. ADELMAN WAS DEPOSED AS A PATENT EXPERT

1. Sandvik v. Waukesha,* 640 F. Supp. 1139 (E.D. Wisc. 1986).

2. Coleco* v. Mattel, 79 Civ 4909 (S.D.N.Y.).
(Davis Hoxie, New York, N.Y.)

3. Hemstreet v. Burroughs,* 1988 WL 93121 (Fed. Cir. 1988).

4. Ransburg v. Behr,* No. 80 74003 (E.D. Mich.).

5. Anthes v. Aluma,* No. 81-1877 (E.D. Pa.).

6. Horiba v. Beckman,* (E.D. Mich.).

7. Norfin* v. A.M., Case No. 82-B-4922 (N.D. Ill.).

8. Johns-Manville* v. Guardian, 13 U.S.P.Q.2d 1684
(E.D. Mich. 1989).

9. Multi-Arc* v. Vac-Tec Systems, Inc., Civil No. H-85-6893 (D. Minn.).
(Arnold White, Houston, Texas)

10. Afros, S.p.A.* v. Krauss-Maffei, 671 F. Supp. 1402
(D. Del. 1987).

11. Truswal v. Gang-Nail,* discussed at 2 U.S.P.Q.2d 1034 (Fed. Cir. 1987).

12. Qume v. Toma* (ITC).
(Baker & McKenzie, Washington, D.C.)

13. Abbott Laboratories v. Brennan,* 21 U.S.P.Q.2d 1192 (Fed. Cir. 1991).

14. Hughes Aircraft v. Ford Aerospace,* discussed in 8 U.S.P.Q.2d 1989 (Cl. Ct. 1989).

15. Lubrizol* v. Ethel (D. Del).
(Jones Day, Cleveland, Ohio)

16. Bilgutay v. NCR*
(Davis Hoxie, New York, N.Y.)

17. Deuer* v. Kent, 1990 WL 78997 (Fed. Cir. 1990).

18. Lever Bros.* v. Proctor & Gamble, 5 U.S.P.Q.2d 1239 (D.N.J. 1987).

CASES IN WHICH MARTIN J. ADELMAN WAS DEPOSED AS A PATENT EXPERT

19. Paramount v. Weyerhauser*

20. Pall* v. Cuno, 14 U.S.P.Q.2d 1815 (E.D.N.Y. 1989).

21. DuPont v. Polaroid Graphics,* 10 U.S.P.Q.2d 1579 (D.Del 1989).

22. ICI* v. Barr, 22 U.S.P.Q.2d 1906 (S.D.N.Y. 1992).

23. Rohm & Haas v. NL*
(Burns Doane, Washington D.C.)

24. Weldotron* v. Hobart
(Davis Hoxie, New York, N.Y.)

25. Information Resources* v. Test Marketing, 19 U.S.P.Q.2d 1743 (S.D. Ohio 1991).

26. Leonard Studio* v. Desmar Corp., discussed at 18 U.S.P.Q.2d 1565 (Fed. Cir. 1991).

27. Advanced Cardiovascular Systems v. Scimed Life Systems,* 12 U.S.P.Q.2d 1539 (Fed. Cir. 1989).

28. Baxter v. Abbott*
(Jones Day, Chicago, Illinois)

29. Smith v. Amerson*
(Christie Parker, Pasadena, California)

30. Hercules v. B.F. Goodrich*
(Jones Day, Cleveland, Ohio)

31. Cadtrak v. Commodore*
(Fish & Neave, New York, N.Y.)

32. Mabuchi* v. Johnson Controls, 1992 WL 276680 (Fed. Cir. 1992).

33. Burroughs-Wellcome v. Novopharm,* 29 U.S.P.Q.2d 1721 (E.D.N.C. 1993).

34. Gambro v. Baxter*
(McAndrews, Held & Malloy, Chicago, Illinois)

CASES IN WHICH MARTIN J. ADELMAN WAS DEPOSED AS A PATENT EXPERT

35. Cyrix* v. Intel, 846 F. Supp. 522 (E.D. Tex. 1994).

36. Merck v. Alcon*
(Fish & Neave, New York, N.Y.)

37. Nellcor* v. BOC Health Care
(Fish & Neave, New York, N.Y.)

38. General Electric* v. Emerson
(Welsh & Katz, Chicago, Illinois)

39. Lemelson v. Ford*
(Fish & Neave, New York)

40. Lockwood* v. American Airlines
(Lyon & Lyon, Costa Mesa, California)

41. Medical Graphics v. SensorMedics*
(Lyon & Lyon, Los Angeles, California)

42. Stark* v. Advanced Magnetics
(Goodwin, Procter, Boston, Mass.)

43. Abbott* v. Alra
(Jones Day, Chicago)

44. Cury* v. Philip Morris
(Pennie & Edmonds, New York, N.Y.)

45. Cochlear v. Advanced Bionics*
(Fish & Neave, New York, N.Y.)

46. Lyndex v. Richmill*
(Loeb & Loeb, Los Angeles, California)

47. Pitney Bowes, Inc. v. Sudbury Systems*
(Nutter, McClennen & Fish, LLP, Boston, Mass.)

48. C.S. Telecom v. Hewlett-Packard*
(Pennie & Edmonds, New York, N.Y.)

49. Nagel v. Ford Motor*
(Rader, Fishman & Grauer, Bloomfield Hills, MI)

50. Motorola* v. Rockwell
(Fish & Neave, New York, N.Y.)

CASES IN WHICH MARTIN J. ADELMAN WAS DEPOSED AS A PATENT EXPERT

51. Ampex* v. Mitsubishi
(Fish & Neave, New York, N.Y.)

52. Altera* v. Xilinx
(Sullivan & Cromwell, New York, N.Y.)

53. Abbott* v. Geneva and Novopharm
(Jones, Day, Chicago, Illinois)

54. Pitney-Bowes v. Hewlett-Packard*
(Pennie & Edmonds, New York, N.Y.)

55. Varian* v. Lamb
(Fish & Neave, New York, N.Y.)

56. Lockheed* v. Silicon Graphics
(Scully, Scott, Murphy & Presser, Garden City, N.Y.)

57. Upjohn v. Mova Pharmaceutical*
(Burns, Doane, Swecker & Mathis, Alexandria, Virginia)

58. PLC v. Cardiogenesis*
(Lyon & Lyon, Los Angeles, CA.)

59. Berlex v. Biogen*
(Hale & Dore, Boston, Mass.)

60. Hitachi v. Samsung*
(Foley & Lardner, Washington, D.C.)

61. Fischer v. Trex*
(Fish & Richardson, Boston, Mass)

62. Shell Oil v. ICI*
(Scully, Scott, Murphy & Presser, Garden City, New York)

63. Process Resources v. Delta*
(Orrick, Herrington & Sutcliffe, New York, N.Y.)

64. Amazon.com v. Barnesandnoble.com*
(Pennie & Edmonds, New York, N.Y.)

65. Kensey Nash v. Perclose*
(Townsend and Townsend and Crew, San Francisco, CA)

CASES IN WHICH MARTIN J. ADELMAN WAS DEPOSED AS A PATENT EXPERT

66. Cordis* v. Boston Scientific
(Patterson, Belknap et al. New York, N.Y.)

67. Advanced Energy Industries v. Astec America*
(Fish & Neave, New York, N.Y.)

68. In the Matter of Hoechst Marion Roussel, Inc.
(FTC, Washington DC)

69. Oxford Gene v. Affymetrix*
(Orrick, Herrington & Sutcliffe, Palo Alto, CA)

70. U.S. Filter* v. Ionics
(Hale and Dorr, Boston, MA)

71. Proctor & Gamble* v. Brita
(Dorsey & Whitney LLP, Minneapolis, Minn.)

ARBITRATIONS

72. Acrison* v. Hyer Industries (Special Master James F. Davis)
(Davis Hoxie, New York, N.Y.)

73. Kaiser* v. Government of Israel, (arbitration before Messrs Robert Rifkind, Evan Davis and Thomas Munno involving a comparison of Israeli and United States infringement law)
(Collette & Erickson, San Francisco, California)

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1. Calderon v. G.M.,* 206 U.S.P.Q. 782 (E.D. Mich. 1980).

2. Oakwood Mfg., v. Novi American,* 212 U.S.P.Q. 261 (E.D. Mich. 1981), 213 U.S.P.Q. 1014 (E.D. MI. 1982).

3. Mead Digital Systems* v. A.B. Dick, 213 U.S.P.Q. 328 (S.D. Ohio 1981).

4. General Battery v. Gould,* 215 U.S.P.Q. 1007 (D.Del. 1982).

5. RCA v. Applied Digital Data Systems,* 217 U.S.P.Q. 421 (D.Del. 1983), rev'd 221 U.S.P.Q. 385 (Fed. Cir. 1984).

6. Alco Standard v. Westinghouse,* 1 U.S.P.Q.2d 1337 (Fed. Cir. 1987).

7. Litton v. Whirlpool,* 221 U.S.P.Q. 97 (Fed. Cir. 1984).

8. Multifastener* v. MacLean-Fogg, 219 U.S.P.Q. 1074 (E.D. Mich. 1983).

9. Jackson-Jordan* v. Plasser American, 219 U.S.P.Q. 922 (E.D. Va. 1983).

10. Foseco International* v. Fireline, 226 U.S.P.Q. 33 (N.D. Ohio 1984).

11. Shatterproof* v. L.O.F., 225 U.S.P.Q. 634 (Fed. Cir. 1985).

12. Independent Die Association v. Ford Motor,* (E.D. Mich.). (Brooks & Kushman, Southfield, Michigan)

13. Stewart-Warner* v. City of Pontiac, 226 U.S.P.Q. 676 (Fed. Cir. 1985).

14. Witco Chemical v. Mobay,* 229 U.S.P.Q. 188 (Fed. Cir. 1986).

15. Tiegel Mfg v. Farmer Mold & Machine Works,* 225 U.S.P.Q. 1051 (N.D. Fla. 1984).

16. Windsurfing* v. Bic Leisure, 227 U.S.P.Q. 927 (S.D.N.Y. 1985).

17. A.B.Dick v. Burroughs,* 230 U.S.P.Q. 849 (Fed. Cir. 1986).

CASES IN WHICH MARTIN J. ADELMAN HAS APPEARED IN COURT AS A PATENT EXPERT

18. Vieau v. Japax,* 230 U.S.P.Q. 500 (E.D. Mich. 1985).

19. Kaepa v. Payless Shoesource,* (W.D. Tex. 1985).
(Cox & Smith, San Antonio, Texas)

20. Hybritech* v. Monoclonal Antibodies, 227 U.S.P.Q. 215 (N.D. Cal. 1985).

21. Key Tronic v. Burroughs,* 861 F.2d 729 (Fed. Cir. 1988).

22. Ricon* v. Adaptive Driving Systems, 229 U.S.P.Q. 731 (C.D. Cal.1986).

23. United States of America v. Telectronics,* 3 U.S.P.Q.2d 1571 (D.Col. 1987).

24. Andrew* v. Gabriel, 6 U.S.P.Q.2d 2011 (Fed. Cir. 1988).

25. ZMI v. Cardiac Resuscitator,* 2 U.S.P.Q.2d 1985
(D. Ore. 1987).

26. Napp* v. BASF, (S.D. Cal.).
(Lyon & Lyon, Los Angeles, California)

27. Gabriel v. Andrew,* 2 U.S.P.Q.2d 1792 (D. Maine 1987).

28. Carl Cooper v. Harris,* 902 F.2d 43 (Fed. Cir. 1989).

29. Dana* v. IPC, 8 U.S.P.Q.2d 1692 (Fed. Cir. 1988).

30. Gemveto Jewelry* v. Cooper, 694 F. Supp. 1085 (S.D.N.Y. 1988).

31. Gould v. Control Laser,* 9 U.S.P.Q.2d 1718 (Fed. Cir. 1989).

32. Haworth* v. Steelcase, 8 U.S.P.Q. 2d 1001 (W.D. Mich 1988).

33. Dana* v. NOK, 11 U.S.P.Q.2d 1883 (Fed. Cir. 1989).

34. Freeman* v. Minnesota Mining & Manufacturing, 9 U.S.P.Q.2d 1111 (D.Del. 1988).

35. Laitram v. IBM,* (E.D. Va.).
(Cravath, Swaine & Moore, New York, N.Y.)

CASES IN WHICH MARTIN J. ADELMAN HAS APPEARED IN COURT AS A PATENT EXPERT

36. Hughes v. United States,* 31 Fed. Cl. 481 (Cl. Ct. 1994).

37. Pioneer Research v. Wilson Laboratories,* 12 U.S.P.Q.2d 1432 (M.D. Cal.1989).

38. T.T.I.-Vend A. Video* v. Flixcorp of America, (S.D. Cal. 1989).

39. Standard Manufacturing v. United States,* 25 Cl. Ct. 1 (Cl. Ct. 1991).

40. National Semiconductor Corp. v. Linear Technology Corp.,* (N.D. Cal.).
(Fish & Neave, New York, N.Y.)

41. Ralston Purina v. A. E. Staley,* 909 F.2d 1494
(Fed. Cir. 1990).

42. Polaroid* v. Kodak, 16 U.S.P.Q.2d 1481 (D. Mass. 1990).

43. Lemelson v. General Mills,* 968 F.2d 1202 (Fed. Cir. 1992).

44. Kearns v. Ford Motor,* 19 U.S.P.Q. 2d 1838
(E.D. Mich. 1990).

45. Envirotech* v. Amstar, (D. Utah).
(Carl A. Rowold, Baker Hughes, Houston, Texas)

46. Corning Glass* v. Lightwave, 19 U.S.P.Q.2d 1838
(S.D.N.Y. 1991)

47. Arrow* & Howes v. Medcomp & AHS 16 U.S.P.Q.2d 1671
(E.D. Pa. 1990).

48. Ortho Pharmaceutical* v. American Home Products,
18 U.S.P.Q.2d. 1977 (E.D. Pa. 1990).

49. Solarex v. Arco Solar and Siemens Solar,* 805 F. Supp. 252
(D. Del. 1992).

50. Minnesota Mining & Manufacturing v. Johnson & Johnson,* 22 U.S.P.Q.2d 1401 (D. Minn. 1991).

CASES IN WHICH MARTIN J. ADELMAN HAS APPEARED IN COURT AS A PATENT EXPERT

51. Kingsdown v. Hollister,* 1992 U.S. Dist. LEXIS 11882 (N.D. Ill. 1992).

52. Molins PLC and Smith v. Textron,* 26 U.S.P.Q.2d 1889 (D. Del. 1992).

53. Smith Corona v. Pelikan,* 784 F. Supp. 452 (M.D. Tenn. 1992). (Reed Smith, Pittsburg, Pennsylvania)

54. Stx, Inc.* v. Franklin Sports Indus., 1991 WL 114385 (Fed. Cir. 1991).

55. Chesebrough-Pond's USA* v. Benjamin Anschl, 32 U.S.P.Q.2d 1225 (Fed. Cir. 1994).

56. American Cyanamid* v. U.S. Surgical, 30 U.S.P.Q.2d 1561 (D. Conn. 1992).

57. Kearns v. Chrysler,* 31 U.S.P.Q.2d 1746 (Fed. Cir. 1994).

58. ORC* v. Time-Warner, discussed in 26 U.S.P.Q.2d 1718 (D. Del. 1992).

59. Scripps v. Baxter,* 729 F. Supp. 1473(D. Del. 1990).

60. Exxon v. Lubrizol,* 26 U.S.P.Q.2d 1871 (S.D. Tex. 1993).

61. Baxter v. Spectramed,* (C.D. Cal. 1993). (Lyon & Lyon, Los Angeles, California)

62. Diasonics* v. Acuson, 1993 U.S. Dist. LEXIS 8871 (N.D. Cal. 1993).

63. Concept Design* v. Duplitronics, 1995 U.S. App. LEXIS 848.

64. Gentex* v. Donnelly, 27 U.S.P.Q.2d 1714 (W.D. Mich. 1993).

65. Sanders* v. Summagraphics, 19 U.S.P.Q.2d 1859 (D. Conn 1991).

CASES IN WHICH MARTIN J. ADELMAN HAS APPEARED IN COURT AS A PATENT EXPERT

66. Refac v. Lotus Development,* 1995 U.S. Dist. LEXIS 4678 (S.D.N.Y. 1995).

67. Glaxo v. Novopharm,* 29 U.S.P.Q.2d 1126 (E.D. N. C. 1993).

68. Transmatic v. Mark IV,* 29 U.S.P.Q.2d 1541 (E.D. Mich. 1993).

69. Schneider v. Scimed,* 852 F. Supp. 813 (D. Minn. 1993).

70. Teradyne v. Hewlett-Packard,* 1994 U.S. Dist. LEXIS 4806 (N.D. Cal. 1994).

71. Motor Wheel* v. Superior (E.D. Mich. 1994).
(Jones Day, Cleveland, Ohio)

72. InterDigital Technology* v. QUALCOMM, 30 U.S.P.Q.2d 1205 (E.D. Pa. 1994).

73. Terumo* v. Cook and Wilson-Cook, (E.D. Va. 1994).
(Fish & Richardson, Washington D.C.)

74. A & L v. ReSound,* (N.D. Cal. 1995).
(Pillsbury Madison, San Francisco, California)

75. InterDigital Technology* v. Motorola, (D.Del. 1995).
(Dickstein Shapiro, Washington, D.C.)

76. Enzo Biochem v. Calgene,* 27 U.S.P.Q.2d 1636 (D. Del 1993).

77. Hewlett-Packard* v. GenRad, (D. Mass 1995).
(Pennie & Edmonds, New York, N.Y.)

78. Johns-Hopkins University v. Cellpro* (jury verdict for Cellpro), (D. Del. 1995).
(Lyon & Lyon, Los Angeles, California)

79. Varian* v. Lam, (N.D. Cal. 1995).
(Fish & Neave, New York, N.Y.)

80. Weatherchem Corp. v. J.L. Clark, Inc.,* (U.S.P.Q.2d (N.D. Ohio 1996).

81. Odetics v. Storage Technology* (E.D. Va. 1996).

CASES IN WHICH MARTIN J. ADELMAN HAS APPEARED IN COURT AS A PATENT EXPERT

(Pennie & Edmonds, Menlo Park, Cal.)

82. Emerson v. General Electric.* (E.D. Missouri 1996).
(Welsh & Katz, Chicago, Illinois)

83. Akro Corp.* v. Ken Luker, (N.D. Ohio 1996).
(Bell, Seltzer, Raleigh, North Carolina)

84. Bard v. Boston Scientific,* (D. Del. 1997).
(Fish & Richardson, Boston, Mass.)

85. Labatt v. Molson* (E.D. MI 1997).
(Fitzpatrick, Cella, Harper & Scinto, New York, N.Y.)

86. R2* v. Ketcho (N.D. Ill. 1997)
(Fish & Neave, New York)

87. Novo Nordisk* v. Genencor (D. Del. 1998)
(Darby & Darby, New York, N.Y.).

88. Forest Labs* v. Abbott and Tokyo Tanabe
(Fish & Neave, New York, N.Y.)

ATTACHMENT E

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

EXPERT REPORT OF PROFESSOR MARTIN J. ADELMAN
ON BEHALF OF
COMPLAINANT

I Background

The remaining pages of the expert report have been redacted.

ATTACHMENT F

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of:	:	
SCHERING-PLOUGH CORPORATION,	:	CONFIDENTIAL
a corporation,	:	Deposition of:
UPSHER-SMITH LABORATORIES,	:	MARTIN J. ADELMAN
a corporation,	:	
and	:	
AMERICAN HOME PRODUCTS	:	
CORPORATION,	:	
A corporation.	:	

TRANSCRIPT of testimony as taken by and before LEZLIE A. SETCHELL, CSR-2404, RPR, CRR and Notary Public of the State of Michigan, at Detroit Metro Marriott, Romulus, Michigan, on Thursday, December 13, 2001, commencing at 9:10 in the forenoon.

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ATTACHMENT G

UNITED STATES OF AMERICA
BEFORE THE 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	)	

Expert Report of James P. O'Shaughnessy
on Behalf of
Schering-Plough Corporation

The remaining pages of the expert report have been redacted.

ATTACHMENT H

United States of America
Federal Trade Commission

In the matter of
Schering-Plough Corporation
Upsher-Smith Laboratories, Inc.
and American Home Products Corporation

Docket No. 9297

Expert Report

by

William O. Kerr, Ph.D.

October 8, 2001

Restricted Confidential,
Attorney's Eyes Only

The remaining pages of the expert report have been redacted.

ATTACHMENT I

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

EXPERT REPORT OF CHARLES E. MILLER, ESQ.

The remaining pages of the expert report have been redacted.

ATTACHMENT J

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

EXPERT REPORT OF GERALD H. BJORGE, ESQ.

The remaining pages of the expert report have been redacted.

ATTACHMENT K

In The Matter Of:

SCHERING-PLOUGH CORP. & UPSHER-SMITH LABS
MATTER NO. D09297

GERALD H. BJORGE
November 29, 2001

For The Record, Inc.
Court Reporting and Litigation Support
603 Post Office Road
Suite 309
Waldorf, MD USA 20602
(301) 870-8025 FAX: (301) 870-8333

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ATTACHMENT L

In The Matter Of:

SCHERING-PLOUGH CORP. & UPSHER-SMITH LABS
MATTER NO. D0929

CHARLES MILLER
December 5, 2001

For The Record, Inc.
Court Reporting and Litigation Support
603 Post Office Road
Suite 309
Waldorf, MD USA 20602
(301) 870-8025 FAX: (301) 870-8333

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