In the Arbitration Under the Arbitration Rules of the United Nations Commission on International Trade Law and the North American Free Trade Agreement (Case No. UNCT/14/2)

ELI LILLY AND COMPANY

Claimant

v.

GOVERNMENT OF CANADA

Respondent

EXPERT REPORT OF BRUCE LEVIN, PH.D.
Professor of Biostatistics, Columbia University
I. **Background and Introduction.**

1. I am a Professor of Biostatistics at the Mailman School of Public Health of Columbia University in the City of New York. I hold the rank of Full Professor, with tenure, and was Chair of Biostatistics from 2000 to 2011.

2. My academic work entails teaching biostatistics to medical and public health students, mentoring junior faculty, consulting with biomedical researchers at the Columbia University Medical Center, designing randomized clinical trials, and publishing research papers in mathematical statistics. I also have expertise in analyzing claims of disparate impact (indirect discrimination) and have, on occasion, testified on behalf of both plaintiffs and defendants in such cases in U.S. courts. I am a Fellow of the American Statistical Association and a Statistics Section Award Winner from the American Public Health Association. I am co-author of, among other things, the textbooks *Statistics for Lawyers, Second Edition* (with Michael O. Finkelstein, Springer-Verlag, 2001) (hereinafter “SFL”) and *Statistical Methods for Rates and Proportions, Third Edition* (with Joseph L. Fleiss and Myunghee Cho Paik, Wiley, 2003), and the monograph, *The Biostatistics of Aging* (with Gilberto Levy, Wiley, 2014). My complete curriculum vitae is attached as Appendix A.

3. I have been asked by counsel for Eli Lilly & Co. to offer an opinion regarding certain statistical arguments raised by the Government of Canada in its Counter-Memorial of January 27, 2015.\(^1\) In this connection, I was provided with the Counter-Memorial itself, an accompanying Witness Statement of Marcel Brisebois, and Claimant’s Memorial of September 29, 2014. I have reviewed these documents with regard to the statistical issues raised therein.

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\(^1\) Other than this engagement, I have no relationship with or interest in Eli Lilly & Co.
and, in particular, Canada’s overall conclusion that “there is no ‘systemic discrimination’ against pharmaceutical patents.”

4. Subsequently, I requested and received a document (attached as Appendix C) containing detailed information concerning certain patent cases litigated between 1980 and 2015, classified by year of final decision—1980 through 2004 (“pre-2005”) or 2005 through August 10, 2015 (“post-2005”)—and by whether the patents at issue were pharmaceutical or non-pharmaceutical. In addition, the document contained the grounds of challenge raised in each case, including (1) utility, (2) non-obviousness (inventiveness) and (3) novelty. The document also includes cases involving challenges on sufficiency grounds, a basis for challenge that Mr. Brisebois included in his report. For each such basis, the document provided an outcome variable indicating whether or not the patent was held invalid on that basis in the relevant case.

5. As described in detail below, I performed a series of statistical analyses on the data provided. My key findings are the following:

- Post-2005, the 39.7 percentage point difference between utility-based invalidity rates for pharmaceutical and non-pharmaceutical patents is statistically significant (i.e., the difference is likely not due to chance). See Section II.

- Pre-2005, the 8.3 percentage point difference between utility-based invalidity rates for pharmaceutical and non-pharmaceutical patents is not statistically significant. See Section III.

- The 0.2 percentage point difference between the invalidity rates for pharmaceutical and non-pharmaceutical patents post-2005 on grounds other than utility is not statistically significant. See Section IV.

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2 See Resp. CM § II.D, at ¶¶ 140-149 (relying on Brisebois Statement §§ C.1-7 and, in particular, ¶¶ 30-40).

3 I understand from counsel that the document I received, as attached in Appendix C, listed all patent invalidity decisions issued by Canada’s Federal Courts between January 1, 1980 and August 10, 2015. This report concerns n = 217 patent cases, comprising 88 pre-2005 determinations (22 pharmaceutical + 66 non-pharmaceutical) and 129 post-2005 determinations (107 pharmaceutical + 22 non-pharmaceutical). Appendix C also lists an additional 17 cases (8 pre-2005 and 9 post-2005) which involved challenges on grounds other than utility, obviousness, novelty, or sufficiency. I did not consider these cases in my analysis.
These results are consistent with a disproportionate impact of the utility doctrine on pharmaceutical patents in the post-2005 period. Further, as explained in Section V, these results account for and do not support the alternate explanations for the increased rate of utility-based invalidations offered by Canada (specifically, the advent of PM(NOC) proceedings in 1993 and the fact that patents found to lack utility were also subject to invalidation on other grounds).

II. The difference between the proportion of pharmaceutical patents held invalid on grounds of utility and that of non-pharmaceutical patents in the post-2005 period is statistically significant.

   6. I began my analysis by first comparing the proportion of post-2005 pharmaceutical cases challenged and held invalid on the basis of utility (possibly among other grounds) with the proportion of post-2005 non-pharmaceutical cases challenged and held invalid on that basis.

   7. To address the question of whether the difference in those proportions was “statistically significant,” I considered two hypotheses, a statistical or “null” hypothesis and a substantive or “alternative” hypothesis. The null hypothesis specified that any positive difference in the proportions of pharmaceutical and non-pharmaceutical patents held invalid among post-2005 cases on grounds of inutility would be due merely to chance. The alternative hypothesis specified that the proportion of pharmaceutical patents held invalid on utility grounds is systematically greater than that for non-pharmaceutical patents, consistent with a disproportionate impact of the utility doctrine on pharmaceutical patents.

   8. I tested the null against the alternative hypothesis with Fisher’s exact test for

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4 In this report, I use the term “disproportionate impact” to mean a statistically significant difference in outcomes consistent with an identifiable cause or policy, such as the utility requirement under Canadian law. The term can be analogized to the U.S. concept of “disparate impact,” but I have not used the term “disparate impact” so as to avoid offering what may be considered a legal conclusion under U.S. law.
comparing two proportions. In this and each other hypothesis test prepared for this report I adopted the one-tailed criterion of statistical significance at the 0.05 level. (I explain what these terms mean below.) Table 1 shows the data for this hypothesis test.

### Table 1

**Patent Cases in the Post-2005 Period Involving a Decided Challenge on Grounds of Utility**

<table>
<thead>
<tr>
<th>Type of patent</th>
<th>Patent found <em>invalid</em> on utility grounds</th>
<th>Patent found <em>valid</em> on utility grounds</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical</td>
<td>25</td>
<td>38</td>
<td>63</td>
</tr>
<tr>
<td>Non-pharmaceutical</td>
<td>0</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>46</td>
<td>71</td>
</tr>
</tbody>
</table>

9. The observed proportion of pharmaceutical cases found invalid on utility grounds post-2005 was 25/63 or 39.7% whereas the observed proportion of non-pharmaceutical cases found invalid on utility grounds in the same time period was 0. The difference of 39.7 percentage points is statistically significant at the one-tailed 0.05 level. The attained significance level or “P-value” is *P*=0.0245. I therefore reject the null hypothesis of chance variation in favor of the alternate hypothesis of disproportionate impact. I conclude that the difference between the utility-based invalidity rates for pharmaceutical and non-pharmaceutical patents since 2005 is likely not due to chance.

10. To interpret the P-value, consider the following thought experiment. Suppose we were to place 71 chips into an urn, each chip representing an individual patent case, marking 25 chips with the word “invalid” and 46 chips “valid.” Suppose further that we now withdraw 63 chips at random and without replacement from the urn, leaving 8 chips in the urn. “At random” here means that of the large number of ways we might divide the 71 chips into two groups, one
of size 63 and the other of size 8, all of them would be equally likely.\(^5\) How often would we see the difference between the proportion of chips marked “invalid” among those we withdraw from the urn compared to the proportion of chips marked “invalid” among those remaining in the urn equal or exceed 39.7 percentage points? The \(P\)-value gives us the fraction of all such splits in which the difference in proportions would be as large or larger than that actually observed. In other words, the \(P\)-value tells us the probability of finding a difference in proportions as great or greater than that observed as a matter of pure chance.\(^6\)

11. The one-tailed \(P\)-value (like the two-tailed \(P\)-value) depends on two factors: the magnitude of the observed difference in proportions and the sample sizes upon which those proportions are based. In common statistical practice, if the \(P\)-value is less than or equal to 0.05, then we reject the null hypothesis and call the results statistically significant at the 0.05 level.\(^7\)

12. In the chips example, above, I “conditioned on” the observed number of cases found valid and invalid (46 and 25, respectively) – that is to say, I treated them as fixed quantities. This is appropriate because under the null hypothesis, in which the type of patent (pharmaceutical or not) has no effect on the determination of validity on grounds of utility, the outcomes of the cases may be considered to have been decided on factors other than the industry sector of the patent, and would have been decided in the ways they were irrespective of whether

\(^5\) The number of ways is given by the binomial coefficient \(\binom{71}{63} = \binom{71}{8} = 10,639,125,640.\) See SFL, p. 44 (C-395).

\(^6\) In the present instance the numerical difference between proportions cannot exceed 39.7 percentage points because all 25 cases found invalid on utility grounds are already segregated on a single side of the pharmaceutical vs. non-pharmaceutical divide. In general, however, the \(P\)-value includes the probability of all possible differences equal to, or more extreme than, the observed difference.

\(^7\) See SFL, at § 4.3.2 (C-395). Note that studies constrained by limited sample sizes often do not achieve statistical significance, a shortcoming described by the phrase “low statistical power.” Conversely, it is possible for even tiny differences in proportions to be significant \((P \leq 0.05)\) if the sample sizes are sufficiently large. What can be said generally, though, is that if a difference in proportions does reach statistical significance notwithstanding relatively small sample sizes, it is generally because the difference is substantial in both statistical and substantive terms.
they were pharmaceutical patents or not. Therefore I am able to treat the case outcomes as \textit{fixed} results in the urn experiment in the manner they were actually determined in the courts. The random and equally likely nature of all possible splits in the urn experiment reflects the null hypothesis in which the division of patents into two groups (pharmaceutical or not) has no effect upon the finding of validity or invalidity based on utility grounds.\footnote{The above interpretation of the test of significance is due to R.A. Fisher in his landmark 1935 textbook, \textit{The Design of Experiments}.}

13. In the chips example above, and generally in this report, I adopt the one-sided approach (resulting in a “one-tailed” $P$-value) rather than the two-sided approach (resulting in a “two-tailed” $P$-value). A one-sided test is appropriate when the investigator is not interested in a difference in the reverse direction from that hypothesized (\textit{i.e.}, in the present case, I am not testing for discrimination in \textit{favor} of pharmaceutical patents). In contrast, in a two-sided test, the significance of differences in proportions in either direction would contribute to a finding of statistical significance. Since the hypothesis of disproportionate impact against pharmaceutical patents can only be supported by evidence in one direction, one-tailed $P$-values provide the relevant measure of statistical significance.\footnote{See \textit{SFL}, at pp. 121-122 (C-395).}

\section*{III. Among the pre-2005 cases, there is no corresponding statistically significant difference between the proportion of pharmaceutical and non-pharmaceutical patents held invalid on grounds of utility.}

14. I conducted a similar analysis among the pre-2005 cases and did not find a statistically significant difference in invalidity proportions between pharmaceutical and non-pharmaceutical cases. Table 2 presents the data.
Table 2
Patent Cases in the Pre-2005 Period Involving a Decided Challenge on Grounds of Utility

<table>
<thead>
<tr>
<th>Type of patent</th>
<th>Patent found invalid on utility grounds</th>
<th>Patent found valid on utility grounds</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical</td>
<td>0</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Non-pharmaceutical</td>
<td>2</td>
<td>22</td>
<td>24</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>25</td>
<td>27</td>
</tr>
</tbody>
</table>

15. The observed proportion of pharmaceutical cases found invalid on utility grounds pre-2005 was 0% whereas the observed proportion of non-pharmaceutical cases found invalid on utility grounds in the same time period was 8.3%. The difference of 8.3 percentage points is not statistically significant at the one-tailed 0.05 level. The one-tailed “$P$-value” is $P=1.0$, indicating no disproportionate impact in the pre-2005 period. In other words, prior to 2005, the differences in the rate of utility invalidations between pharmaceutical and non-pharmaceutical patents are consistent with an explanation of chance variation.

IV. There is no statistically significant difference between proportions of pharmaceutical and non-pharmaceutical patents held invalid on other, non-utility grounds in the post-2005 period.

16. Having concluded that the difference between invalidity rates on grounds of utility in the post-2005 period between pharmaceutical and non-pharmaceutical patents is not due to chance, I next turned to the question of specificity of the finding, that is, whether or not a similar pattern held for patents found invalid on other grounds.

17. To accomplish this I tabulated the number of cases involving a challenge or invalidation on either of the other two grounds I considered (obviousness, novelty, or both), irrespective of whether the cases were also challenged or invalidated on grounds of utility. Table 3 contains the data for the post-2005 period.
Table 3

Patent Cases in the Post-2005 Period Involving a Decided Challenge on Other Grounds
(Non-Obviousness or Novelty)

<table>
<thead>
<tr>
<th>Type of patent</th>
<th>Patent found invalid on other grounds</th>
<th>Patent found valid on other grounds</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical</td>
<td>39</td>
<td>56</td>
<td>95</td>
</tr>
<tr>
<td>Non-pharmaceutical</td>
<td>9</td>
<td>13</td>
<td>22</td>
</tr>
<tr>
<td>Total</td>
<td>48</td>
<td>69</td>
<td>117</td>
</tr>
</tbody>
</table>

18. The observed proportion of pharmaceutical cases found invalid on novelty or obviousness grounds post-2005 was 41.1% whereas the observed proportion of non-pharmaceutical cases found invalid on such grounds in the same time period was 40.9%. The difference of 0.2 percentage points is not statistically significant at the one-tailed 0.05 level; the exact one-tailed “P-value” is $P=0.59$.

19. I also considered the grounds of novelty and obviousness separately. There was no statistically significant difference in proportions of pharmaceutical vs. non-pharmaceutical patents held invalid on either ground. For obviousness, the invalidity proportions were 38.8% vs. 35.0% for pharmaceutical vs. non-pharmaceutical patents, respectively ($P=0.48$), and for novelty, the proportions were 26.2% vs. 26.3%, respectively ($P=0.63$). Thus, the statistically significant difference between the utility-based invalidation rates for pharmaceutical and non-pharmaceutical patents is not reflected in challenges involving novelty and obviousness, irrespective of whether those grounds are analyzed jointly or separately.

20. From my review of Canada’s Counter-Memorial and the witness statement of Mr.

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10 For completeness, I checked whether there were differences between invalidity proportions for pharmaceutical and non-pharmaceutical cases in the pre-2005 period on specific grounds or on all other grounds. None were significant. The $P$-values for obviousness, novelty, or a combination of those two grounds were, respectively, 0.23, 0.14 and 0.11. The $P$-value for sufficiency was 1.0, and the $P$-value for any combination of novelty, obviousness or sufficiency was 0.14.
Brisebois, I noted that Canada also discussed litigation related to a fourth ground of invalidity: sufficiency. Adding sufficiency to my analysis does not meaningfully change the results. The invalidity proportions for sufficiency alone are 13.3% vs. 25% for pharmaceutical vs. non-pharmaceutical patents, respectively \((P=0.89)\). When I included sufficiency-based invalidations along with obviousness- and novelty-based invalidations, the invalidity proportions on any of the three grounds (obviousness, novelty, and/or sufficiency in any combination) are 40.8% vs. 40.9% for pharmaceutical vs. non-pharmaceutical patents, respectively \((P=0.60)\).

21. I analyzed the question of specificity in more detail, as follows. I considered the 39.7 percentage point difference in pharmaceutical vs. non-pharmaceutical utility-based invalidation rates (the difference between 39.7% and 0%) and the 0.2 percentage point difference in pharmaceutical vs. non-pharmaceutical novelty and obviousness invalidation rates (the difference between 41.1% and 40.9%). I assessed the probability of the 39.5 percentage point difference between these differences resulting purely from chance. The \(P\)-value generated by my analysis, which is explained in detail in Appendix B, was 0.046. Thus I conclude that the specificity is statistically significant. In other words, the difference between pharmaceutical and non-pharmaceutical invalidity rates on grounds of utility as compared with other grounds is not consistent with mere chance.

V. Comments on additional statistical arguments raised in part II.D of Canada’s Counter-Memorial and Mr. Brisebois’s statement.

22. Counsel have also asked me to provide specific observations on additional arguments raised in section II.D of Canada’s Counter-Memorial.\(^{11}\)

\(^{11}\) The statistical arguments made by Mr. Brisebois on rates of invalidity findings (parts C.1-6 of his statement and, in particular, paragraphs 30-38) are incorporated into section II.D of the Counter-Memorial, at paragraphs 140-149. I have not commented on Mr. Brisebois’s arguments on “secondary” patents in part C.7 of his statement. Mr. Brisebois has not provided any data on the total number of what he terms “secondary” patents, as compared to
23. First, I note that several of the arguments raised in section II.D of the Counter-Memorial (at ¶¶ 142, 144-145) rely on comparisons of raw frequencies rather than comparisons of proportions. Raw frequencies cannot be used to meaningfully analyze the comparative impact of the utility doctrine as between pharmaceutical and non-pharmaceutical patents. To be relevant in statistical analysis, comparisons must be based on proportions rather than frequencies, because increases in the number of patent cases over time make comparisons of raw frequencies unreliable and misleading. Put differently, arguments based on raw frequencies do not take sufficient account of the wider context.

24. Second, paragraph 143 of the Counter-Memorial asserts that the overall proportion of patent validity challenges for pharmaceutical patents remained consistent between the pre-2005 and post-2005 periods. However, to determine the effect of the utility requirement in the pharmaceutical sector as compared with other sectors, one cannot look at data from the pharmaceutical sector alone. Nor can one look at the overall proportions of patent validity challenges alone. Rather, the question is a comparative one, and identifying any disproportionate impact attributable to the utility requirement necessarily involves a comparison of "primary" patents, and as such he has not provided sufficient data to enable a comparative analysis of invalidity rates for "secondary" as compared to "primary" patents.

12 These arguments rely on paragraphs 32, 35-36, 42 and 46 of the Brisebois Statement.

13 For example, suppose in a study of childhood diabetes and obesity, two communities are studied, one urban and one rural, during two consecutive 10-year time periods. The study finds that, in the urban neighborhood, there are 200 cases of diabetes among obese children in the earlier time period and 250 cases in the later time period. In the rural community, there are 100 cases of diabetes among obese children in the earlier time period and 50 in the later time period. It would be an error to conclude that the prevalence of childhood diabetes increased over time in the urban setting while it decreased in rural settings on the basis of these raw frequencies. Suppose that in the urban neighborhood, the population of obese children increased over time from 1,000 to 1,500 while in the rural community it decreased from 500 to 200 over time. In that case the prevalence of diabetes would have decreased in the urban neighborhood (from 200/1000 = 20% to 250/1500 = 16.7%) while in the rural community the prevalence would have increased (from 100/500 = 20% to 50/200 = 25%).

14 This argument relies on paragraph 34 of the Brisebois Statement.
of the effect of the utility requirement as against the effect of other requirements within like time periods. As discussed in Sections II and IV above, my analysis reveals that the proportion of cases held invalid on utility grounds increased from 0% pre-2005 to 39.7% post-2005 for pharmaceutical patents, while it decreased from 8.3% pre-2005 to 0% post-2005 for other sectors. In other words, a higher proportion of pharmaceutical patents were being found non-useful even as a somewhat lower proportion of non-pharmaceutical patents were being found non-useful. It is the joint effect of these divergences over time that contributes to the statistically significant evidence of disproportionate impact of the utility requirement against pharmaceutical patents in the post-2005 period. In other words, Canada’s arguments with respect to overall invalidity rates are off point: pharmaceutical patents face a disproportionate risk of invalidation on grounds of utility; non-pharmaceutical patents do not face a comparable risk.

25. Third, paragraphs 138, 139 and 142 of the Counter-Memorial state that “patent litigation in the pharmaceutical sector . . . surged” following the introduction of “PM(NOC) proceedings” in 1993.\textsuperscript{15} Canada suggests that “[i]n this context . . . it is unsurprising that absolute numbers of court rulings on all grounds, including utility, are higher in the pharmaceutical than in other sectors.” To confirm that my results were not driven by this asserted change in law in 1993, I also performed the analysis presented in Section III above using the set of cases decided between 1994 and 2004 (inclusive) (the “1994 set”). The results were consistent with the results set out in Section III. Specifically, there were no significant differences in each of six hypothesis tests: in the 1994 set, the proportion invalidated on utility grounds was 0% for pharmaceutical patents and 9.1% for non-pharmaceutical patents ($P = 1.0$); on grounds of obviousness, the proportions were 46.2% and 34.5% ($P = 0.35$), respectively; on

\textsuperscript{15} This argument relies on paragraph 32 of the Brisebois Statement.
grounds of novelty, the proportions were 50% and 25% \((P = 0.15)\), respectively; on grounds of sufficiency, the proportions were 0% and 25% \((P = 1.0)\), respectively; on grounds of novelty or obviousness (or both), the proportions were 61.5% and 37.9% \((P = 0.14)\), respectively; and on any of the three grounds other than utility, the proportions were 57.1% and 40.0% \((P = 0.23)\), respectively. Put differently, even considering only those cases decided after the introduction of the PM(NOC) process, I found no statistically significant difference between invalidity rates for pharmaceutical and non-pharmaceutical patents on any ground (including utility) prior to 2005. Yet, such a significant difference does exist for the ground of utility post-2005. Accordingly, it is reasonable to conclude that the finding of significance is not a numerical artifact of the increase in pharmaceutical patent litigation following the introduction of PM(NOC) proceedings.

26. Finally, paragraphs 144 and 147 of the Counter-Memorial mention that: challenges based upon grounds other than utility “far outnumber” those based on utility; “only one-third of all challenges on the basis of utility were successful, reflecting outcomes on other grounds”; and many patents found not to be useful were also invalidated on other grounds. It bears emphasis that my analysis accounts for the correlations between holdings on different grounds within the same cases.\(^{16}\)

27. In particular, in paragraph 21 and Appendix B, I compared the significant surplus of cases involving a finding of inutility in the post-2005 period for pharmaceutical patents relative to non-pharmaceutical patents with the negligible surplus corresponding to other grounds in the same time period, and accounting for the multiple grounds upon which each case was challenged. Had there been similar differences between invalidity proportions for pharmaceutical and non-pharmaceutical patents when examining utility grounds first and other grounds.

\(^{16}\) These arguments rely on paragraphs 35-37 of the Brisebois Statement.
grounds second, such lack of specificity might have suggested factors were at play other than a disproportionate impact attributable to the utility requirement. In other words, if the difference in pharmaceutical vs. non-pharmaceutical invalidity rates for utility had not been significantly higher than for other grounds, that would have cast doubt on the inference of a disproportionate impact specifically attributable to Canada’s utility doctrine. The fact that those differences were significantly dissimilar, however, supports the conclusion that utility-based invalidation rates differed in a way that found no parallel in other grounds. As such, the finding accounts for each of the considered grounds of invalidity and again supports the inference of a disproportionate impact attributable to the ground of utility alone.

* * *

Done at New York City on September 7, 2015

New York, U.S.A.

[signed]

Bruce Levin
Appendix A

Curriculum Vitae
Date of preparation: 08/06/2015

Personal data:

- Birthdate: March 14, 1948
- Birthplace: New York City
- Citizenship: U.S.A.
- Marital Status: Married, two children, two grandchildren

Academic training:

Columbia University 1968 B.A. (Mathematics)
Harvard University 1972 M.A. (Mathematics)
Harvard University 1974 Ph.D. (Applied Mathematics/Statistics)

- Thesis sponsor: Arthur P. Dempster

Professional organizations and societies:

- American Public Health Association
- American Statistical Association (Fellow)
- Associate Member, CSICOP
- Institute of Mathematical Statistics
- International Biometric Society
- Sigma Xi
- Society for Clinical Trials

Academic Appointments:

- 1967–1968 Teaching Assistant, Columbia University
- 1969–1974 Teaching Fellow and Research Assistant, Harvard University
- 1974–1979 Assistant Professor of Mathematical Statistics, Columbia University
- 1976–1979 Assistant Professor of Mathematical Statistics and Public Health (Biostatistics), Columbia University
- 1979–1982 Assistant Professor of Public Health (Biostatistics)
1982–1983  Assistant Professor of Clinical Public Health (Biostatistics)
1983–1985  Associate Professor of Clinical Public Health (Biostatistics)
1985–1992  Associate Professor of Clinical Public Health (Biostatistics)
            (with tenure of title)
1992–1994  Associate Professor of Public Health (Biostatistics) (with tenure)
1993–1998  Deputy Head, Division of Biostatistics,
            Columbia University School of Public Health.
1998–2000  Acting Head, Division of Biostatistics, Columbia School of Public Health
1994–2001  Professor of Public Health (Biostatistics) (with tenure)
2001–      Professor of Biostatistics (with tenure)
2000–2011  Chair, Department of Biostatistics

**Honors**
1964–1968  Pulitzer Free Scholarship to Columbia College
1968      Phi Beta Kappa
1968      B.A. summa cum laude, Columbia College
1964–1968  New York State Regents Scholarship
1968–1970  New York State Regents College Teaching Fellowship
1968–1970  Teaching Fellowship, Harvard University
1968–1974  Woodrow Wilson Fellowship
2001      Fellow of the American Statistical Association
2008      Award Winner of the Statistics Section of the American Public Health Association
2011      Biostatistics Colloquium renamed The Levin Lecture Series in my honor
Special appointments

1990  Biostatistician on Special Review Committee for National Cancer Institute RFA 90–CA–03DCT Small Grants to Stimulate Correlative Laboratory Studies and Innovative Clinical Trials.

1991  IRG member for Tropical Medicine and Parasitology Study Section AHR (TMP–AHR–F1) (February and October sections).


1999  Consultant to National Advisory Mental Health Council’s Clinical Treatment and Services Research Workgroup, National Institute of Mental Health.

2000  National Academy of Sciences Institute of Medicine Committee on the Design and Analysis of Small Clinical Trials.

2002–  NINDS Parkinson’s Disease Neuroprotection Trials Oversight Board.


2003–  Statistical consultant for Brad H court settlement monitors.

2005–2009  Member of Federal Advisory Committee for The National Children’s Study, NICHD.


2008–  Statistician for Data and Safety Monitoring Committee for the SURE-PD (Safety of Urate Elevation in Parkinson’s Disease) Trial.

2009  Co-Chair, “Scientific Advances in Adaptive Clinical Trial Design” Workshop NIH-funded workshop, Bethesda, MD.

2009–  Scientific Review Committee, Huntington’s Study Group.

2009–2011  Chair, Data and Safety Monitoring Committee for the CHIRP (CHoline in InflammatoRY Pain) Trial.

2015 Member of NIH Special Emphasis Panel on Alzheimer’s Disease Pilot Clinical Trials.

Important invited lectureships


“Testing Odds Ratio Homogeneity for Many Fourfold Tables,” presented to the Mount Sinai School of Medicine, Department of Biomathematical Sciences, New York, NY (November 1990).


“Sampling from the Conditional Logistic Regression Model,” presented to the Nathan Kline Institute for Psychiatric Research, Statistical Sciences and Epidemiology Division, Orangeburg, NY (February, 1994).

“Clinical Trials with Assured New Treatment for Those at Greater Risk,” presented to the Statistical Methods in Epidemiology Working Seminar, Department of Biostatistics, Harvard University, Boston, MA (March, 1997)

“Randomized Designs and Alternatives,” special invited lecture presented to the Center for AIDS Prevention Studies (CAPS), San Francisco, CA (April, 1997)

“Statistical Evidence of Cheating in Large-scale, Multiple-choice Examinations,” invited paper presented to the Fourth International Conference on Forensic Statistics, North Carolina State University, Raleigh, NC (December, 1999).


“Statistical Issues in Clinical Trials.” Invited Faculty speaker at Lou Gehrig’s Centennial Birthday: ALS Clinical Trials—The Challenge of the Next Century, Tarrytown, NY (June, 2003).

“On a Family of Sequential Selection and Recruitment Procedures for Identifying the Best $b$ out of $c$ Binomials.” Invited Lecturer for the 16th Annual Charles Odoroff Memorial Lecture, Department of Biostatistics and Computational Biology, Rochester, NY (April, 2004).


“Selection Designs in Phase II Trials.” Invited speaker, Huntington’s Study Group, Boston, MA (November, 2007).

“Selection Designs.” Invited speaker, Workshop on Demonstrating Disease-modifying Effects for the Treatment of Parkinson’s Disease: Drug Development and Regulatory Issues, co-sponsored by the American Association of Pharmaceutical Scientists, the United States Food and Drug Administration, the Michael J. Fox Foundation, and the Parkinson’s Study Group, Arlington (April, 2008).


“How to Make the BKS Subset Selection Procedure Adaptive and Other Results.” Invited speaker, Department of Biostatistics, Yale University, New Haven (March, 2009).

“Selection Procedures in Clinical Trials.” Invited to present this one-day short course at the U.S. Food and Drug Administration, Center for Drug Evaluation Research (FDA/CDER) with C.-S. Leu and K. Cheung (May, 2009).


“Subset Selection in Comparative Selection Trials.” Invited speaker, Division of Statistical Sciences, New Jersey Institute of Technology, Newark (October, 2010).


Grant Support

Present Grant Support: (In parentheses are annual Direct Costs funded.)

1998–present  Principal Investigator (20% effort) of NIMH funded Statistics, Epidemiology, and Data Management Core of the HIV Center for Clinical and Behavioral Studies (A. Ehrhardt, R. Remien, Directors, B. Levin, subcontract PI, $82,373)

2003–present  Senior statistician (10% effort) on the Autism Birth Cohort study (W.I. Lipkin, PI, $2,674,377)

2009–present  Senior statistical design consultant (5% effort) on NINDS funded North American Mitochondrial Disease Consortium (NAMDC) (M. Hirano, PI, $892,039)

2013–present  Project biostatistician (8.5% effort) on NIA funded Olfactory Deficits and Donepezil Treatment in Cognitively Impaired Elderly (D. Devanand, PI, $389,341)

2014–present  Project biostatistician (5%) on NIAID funded Tissue Compartmentalization of Human Lymphocytes program project (D. Farber, PI)

2014–present  Senior statistical advisor (5% effort) on Simons’ Foundation funded Maternal and child infection and immunity in ASD (W.I. Lipkin, PI, $796,671)

Past Grant Support: (In parentheses are Total Direct Costs funded.)

1980–1981  School of Public Health Biomedical Research Support Grant (6.5%)

1981–1983  Principal Investigator (25% effort) on NICHD Grant HD15850 Spontaneous Abortion Epidemiology – Statistical Power. (B. Levin, PI, $45,145)

1982–1983  School of Public Health Biomedical Research Support Grant (3%)

1982–1986  Biostatistician (25% effort) on NICHD Grant HD15909 Epidemiology of Early Reproductive Loss. (J. Kline, PI, $2,092,200)
1983–1992  Biostatistician (as needed) on NIH Training Grant AR07486  
Epidemiology of Bone Diseases.  
(J.L. Kelsey, PI, $68,748)

1984–1985  School of Public Health  
Biomedical Research Support Grant (4.5%)

1984–1986  Co–investigator on NICHD Grant HD18677  
Detecting Clustering – Application to Reproduction.  
(S. Wallenstein, PI, $45,758)

1986–1987  Biostatistician (15% effort) on NICHD Grant HD22820  
Spermicide Use and Adverse Pregnancy Outcome.  
(D. Warburton, PI, $341,647)

1986–1988  Senior Research Scientist Grade 31 (5% effort) on  
NIDA Grant DA04186, Epidemiology of Drug Abuse and  
Spontaneous Abortion.  
(J. Kline, PI, $121,907)

1986–1989  Biostatistician (5% effort) on NIH Grant AR34851  
Epidemiology of Prolapsed Lumbar and Cervical Disks.  
(J.L. Kelsey, PI)

1986–1990  Senior Research Scientist Grade 31 (7½%–10% effort) on  
competing continuation of NICHD HD15909, Epidemiology of  
Early Reproductive Loss.  
(J. Kline, PI, $543,575)

1987–1992  Co–investigator (10% effort) on NIH Grant HL28907  
Health Education for High Risk Urban Asthmatic Children.  
(R.B. Mellins, PI, $1,470,431)

1989–1992  Biostatistician (3% effort) on NINCDS Grant NS26612  
Somatosensory Grouped Potential in Congenital HIV Infection  
(R. Emerson, PI, $516,442)

1989–1992  Biostatistician (2.5% effort) on NIDA Grant DA05730  
Cocaine Abuse: Effects in Pregnancy and the Newborn  
(S. Ng, PI, $688,134)

1989–1991  Biostatistician (5% effort) on NIH Grant HD24659  
An Epidemiologic Study of Stress in Pregnancy  
(M. Hatch, PI, $324,920)
1989–1993  Biostatistician (3% effort) on NIH Grant HL38260
Epidemiology of Hypertensive Emergency
(S. Shea, PI, $472,754)

1989–1993  Director, Biostatistics Core (10% effort) on NIMH Grant MH43878
Center to Study Youth Depression, Anxiety, and Suicide
(D. Shaffer, PI, $3,845,138)

1990–1991  Biostatistician (5% effort) on NCI Grant CA52107
Random Digit Dialing: An Evaluation.
(J.L. Kelsey, PI, $50,000)

1990–1995  Biostatistician (10% effort) on NIH Grant HL45304
A Childhood Asthma Program in NYC Health Dept. Clinics.
(R.B. Mellins, PI, $1,650,935)

1990–1996  Co–investigator (10% effort) on NIH Grant ES505116
Biological Monitoring for Exposure to Aflatoxin.
(R. Santella, PI, $434,145)

1991–1992  Biostatistician (1% effort) ASPH–Subcontract to
Sergievsky Center / Columbia University
Maternal Stress during Pregnancy, Urinary Catecholamine
Concentrations and Selected Reproductive Outcomes.
(M. Hatch, PI, $78,210)

1991–1993  Biostatistician (5% effort) on NIH Grant HS07076
Dissemination of Prevention Guidelines to Harlem Physicians.
(D. Gemson, PI, $235,553)

1991–1995  Biostatistician (10% effort) on NIH Grant AG10251
The Epidemiology of Trisomy and Aging.
(J. Kline, PI, $892,535)

1992–1994  Director of Program (5% effort) on NIMH Training
Grant T32–MH15774, Research Training in Mental Health Statistics.
(B. Levin, PI, $842,779)

1992–1996  Co–principal Investigator (5% effort) on NIH Grant
NIA R35 AG10963, Leadership and Excellence in
Alzheimer’s Disease: Gene–Environment Interactions
in Alzheimer’s Disease.
(R. Mayeux, PI, $2,893,522)
1993–1997  Biostatistician (5% effort) on NIH Grant HL51514
Risk Factors for Asthma in Harlem.
(S.E. Findley, PI, $671,798)

1993–1998  Biostatistician (5% effort) on NIH Grant HL51492
Decreasing the Need for Emergency Asthma Care in Harlem.
(C. Felton, PI, $1,281,395)

1993–1994  Biostatistician (5% effort) on Grant U48/CCU209663
Health Promotion and Disease Prevention Center.
(A. Rosenfield, PI, $221,172)

1994–1995  Principal Investigator (10% effort) on Subcontract
to NIH Grant AG10251, The Epidemiology of Trisomy and Aging.
(B. Levin, PI, $13,455)

1995–1999  Biostatistician (10% effort) on NIH Grant 1U01CA/ES66572
Breast Cancer and the Environment on Long Island
(M. Gammon, PI, $5,180,000)

1996–2000  Senior Statistical Consultant (5% effort) on NIH Grant RR00645
General Clinical Research Center
(H.N. Ginsberg, PI, $2,565,000)

1997–1998  Senior Statistical Consultant (5% effort) to NICHD Grant HD27006
Data Coordinating Center for Reproductive Medicine Network
(R.E. Canfield, PI, $196,000)

1997–2002  Senior Statistical Consultant (10% effort) to NINDS funded
Warfarin Antiplatelet Recurrent Stroke Study.
(J.P. Mohr, PI, $338,313)

1998–2004  Principal Investigator on subcontract (10% effort) to NIA funded study
Epidemiology of Ovarian Age
(J. Kline, PI, B. Levin, subcontract, $23,285)

2002–2007  Biostatistician (5% effort) on NICHD funded study,
Spontaneous Abortion and Skewed X Chromosome Inactivation.
(D. Warburton, PI, $530,216)

2004–2007  Senior Statistical Consultant (5% effort) to NINDS funded
Clinical Trial of High Dose CoQ10 in ALS (QALS—STAT)
(J.L.P. Thompson, PI, $175,000)
2004–2009 Senior Statistical Consultant (5% effort) to NINDS funded Phase IIB Study of TNK in Acute Stroke (TNK-S2B-STAT) (J.L.P. Thompson, PI, $318,061)

2005–2010 Senior statistical consultant (2.3% effort) on NIMH funded center, Columbia Center for Homelessness Prevention (C. Caton, PI, $210,813)

2007–2010 Principal Investigator on subcontract (7.5% effort) on NIDA funded center Clinical Trials Network: Long Island Regional Node (E. Nunes, PI, $73,215)

2007–2010 Co-investigator (5% effort) on NICHD funded study of association of trisomy with maternal age as reflective of accelerated ovarian aging Trisomy and Ovarian Age: An Epidemiologic Study (J. Kline, PI, $347,007)

2002–2011 Senior Statistician (5% effort) to NICHD funded Cooperative Multicenter Traumatic Brain Injury Clinical Trials Network Data Coordinating Center (W.T. Friedewald, PI, $1,030,834).

2002–2012 Principal Investigator on subcontract (5% effort) on NIMH funded randomized clinical trial, Antipsychotic Discontinuation in Alzheimer’s Disease (D. Devanand, PI, B. Levin, subcontract $23,954)

2002–2013 Senior Statistical Consultant (20% effort) to NINDS funded study Warfarin vs. Aspirin in Reduced Cardiac Ejection Fraction–STAT. (J.L.P. Thompson, PI, $1,838,989)

2006–2014 Co-investigator (5%) on NINDS funded methodology grant to study dose escalation and treatment selection methods (K. Cheung, PI, $112,500)

University committees

2000–2007 MSPH Curriculum Committee

2008–2009 Ad Hoc Advisory Committee to the Provost for the Salary Study of Officers of Research
Teaching experience and responsibilities

A. Courses taught [approximate number of students](semester-year):

Courses taught in the Department of Mathematical Statistics:

1. Statistics C3001x-3002y [80] Introduction to Statistics (F-74, S-75).

Courses taught in the Division then Department of Biostatistics:

7. Biostatistics P6102 [40] Introduction to Statistical Inference (F-79, F-80, F-81).
15. Biostatistics P8140 [50] The Randomized Clinical Trial (S-06).
    (S-14, S-15)
    (F-91, S-93, F-95, S-00, S-01, F-01, F-03, S-08).
23. Public Health P6071 [20] The Integration of Science and Practice
    (F-13, S-14)

Other courses:
    University School of Law (S-82).
25. IPPR First Year Medical Student Short Course in Biostatistics [150]
    (F-81, S-87, S-88, S-92).
27. Selection Methods in Clinical Trials, a one-day short course delivered to the U.S.
    Food and Drug Administration, Division of Biostatistics, Center for Drug
    Evaluation Research [50] (S-09) .
B. Thesis sponsorships:


   Dissertation: A Nonparametric Analysis of Survival Data Within a Mixture of Susceptibles and Nonsusceptibles.


   Dissertation: Testing Homogeneity of Discrete Exponential Families in the Large-Sparse Case.

   Dissertation: Some theorems concerning a sequential elimination procedure for selecting the best one of several binomial populations or multinational categories.


   Dissertation: Some Statistics for Comparing Two Treatments with Placebo, with Selection of Better Treatment.

   Dissertation: An index of Aging-Relatedness with Relevance to Genetic and Environmental Contributions to Mortality and Disease Incidence in a Population (with distinction).

    Dissertation: Applying twice-weighted multiple interval estimates of a marginal structural model to analyze the cost-effectiveness of treatments provided to nursing home residents with advanced dementia.
C. Dissertation committees:

For the degree of Doctor of Philosophy:

1. Anne A. Robrock, Department of Mathematical Statistics, 1974.
   Dissertation: Detecting a Spike in a Geometric Distribution and an Algorithm for Resistant Line Fitting.

2. Teddy Seidenfeld, Department of Philosophy, 1975.
   Dissertation: The Fiducial Argument.

   Dissertation: On the Truncated Power One Test and Non-linear Renewal Theorem.

4. Wendy Worth, Department of Sociology, 1980.

   Dissertation: Linear Regression Models for Censored Occurrence Time Data.

   Dissertation: Cigarette Yield and the Outcome of Pregnancy.

7. Janet Lynn Berkeley, Division of Epidemiology, 1983.
   Dissertation: Variation in Profile of Psychological Symptom Dimensions: Effect of Gender, MF Score, and Selected Social Statuses.


    Dissertation: Some Nonparametric Two-Sample Tests with Censored Data.

    Dissertation: Occupational Physical Demands and Risk of Prolapsed Lumbar Intervertebral Discs.

   Dissertation: Obesity, Diet, Physical Activity, and the Risk of Endometrial Cancer

   Dissertation: Estimating the Impact of Malarial Control on Mortality in Infants and Children

15. Sara H. Olson, Division of Epidemiology, 1992. 
   Dissertation: The Selection of Control Groups in Case-Control Studies: Evaluation of Control Groups Selected by Random Digit Dialing and from Hospitals.


17. Dale Cindy Hesdorffer, Division of Epidemiology, 1993. 

18. Mary Northridge, Division of Epidemiology, 1993. 
   Dissertation: Home Hazards, Physical Functioning, and Non-Syncopal Falls at Home in Older Persons.

   Dissertation: Nonparametric Analysis of Data Obtained Under Case-Cohort Design.

   Dissertation: Non-null Inferences about Kappa.

21. Suzanne Margaret Leal, Division of Epidemiology, 1994. 
   Dissertation: Etiologic/Genetic Heterogeneity.

   Dissertation: Estimating a Survival Distribution from Case-Control Family Data.


   Dissertation: Survival Analysis for Competing Risks Models

   Dissertation: Reported Residential Pesticide Use and Breast Cancer on Long Island, NY.
   Dissertation: Optimal Path-Dependent Estimator for Bivariate Survival Functions.

27. Hoi-Jeong Lim, Department of Biostatistics, 2001. 
   Dissertation: Saddlepoint Approximations to P-values for Comparisons of Density Estimates.

28. Min Wu, Department of Biostatistics, 2002. 
   Dissertation: Adjusting for Population Admixture in Multipoint Linkage Analysis with Missing Parental Haplotypes.

29. Ruei-Che Liu, Department of Biostatistics, 2003. 
   Dissertation: The Distance-Based Framework for Model Assessment in Regression.

   Dissertation: Lifestyle factors, ovarian response & conception in infertile women.


32. Yuqing Yang, Department of Biostatistics, 2005. 
   Dissertation: Some Statistical Methods for Diagnostic Accuracy with Correlated Data.

33. Mei-Yin Chen, Department of Biostatistics, 2006. 
   Dissertation: Two-stage Stepwise Procedures for Dose-Finding in Clinical Trials with a Biological Endpoint.

34. Hong Tian, Department of Biostatistics, 2006. 

35. Hye-Seung Lee, Department of Biostatistics, 2006. 

36. Xiaodong Luo, Department of Biostatistics, 2006. 
   Dissertation: Analysis of Failure Time Data with Interval Censoring and Bivariate Truncation.

37. Hui Zhang, Department of Biostatistics, 2007. 
For the degree of Doctor of Public Health:

38. Michelle Kiely, Division of Epidemiology, 1985.
   Dissertation: Use of Multinomial Capture-Recapture and Log-linear Analysis to
   Estimate the Prevalence of Developmental Disabilities.

39. Deborah Shapiro, Division of Biostatistics, 1986.
   Dissertation: Survival Models with Concomitant Variables in Long Term
   Maintenance Drug Therapy of Recurrent Bipolar Affective Illness.

40. Carol A. Bodian, Division of Biostatistics, 1983.
   Dissertation: Risk of Carcinoma of the Breast Subsequent to Various Benign Breast
   Diseases.

   Dissertation: Utilization of a Nonparametric Estimator to Test for Group
   Differences and Interaction Across Strata.

42. Eric Dulberg, Division of Epidemiology, 1987.
   Dissertation: An Evaluation of the Effectiveness of Iodized Oil Injections in
   Preventing Endemic Cretinism and Milder Developmental Delay.

43. Diana Hartell, Division of Epidemiology, 1993.
   Dissertation: Methadone Maintenance for Treatment of Opiate Addiction and
   Reduction of Injection Drug Use.

44. Beatriz Staghezza Jaramillo, Division of Epidemiology, 1996.
   Dissertation: Cross-Cultural Comparison of Behavior Problems Among Toddlers in
   the USA and Yugoslavia.

   Dissertation: Analysis of Two-Wave Multi-Stage Survey Data: The Contextual
   Effect of Unemployment on Mental Health.

46. Michelle Norton, Department of Biostatistics, 2002.
   Dissertation: Repeated Measures Analysis of Continuous Data: An Application to
   Assess Blood Pressure Variability Buffering Effects of Cardiac Autonomic Control
   During Psychological and Orthostatic Challenge.
Other invited presentations not listed under Honors


2. Discussant for section on Categorical Data Analysis at IMS meetings in Chapel Hill, NC (April 1977).


14. Panelist in a discussion of the new NIMH guidelines for R34 pilot grant awards, Division of Biostatistics Colloquium Series, New York State Psychiatric Institute, New York (October, 2010).
Other professional activities

1967–72  Computer Programmer and Statistical Consultant, Albert Einstein College of Medicine

1974–79  Statistical Consulting Service, Department of Mathematical Statistics, Columbia University

1975–79  Consultant, Employment Rights Project, Columbia Law School


1984–92  Director of Research, Statistica Consulting, Inc.

1987–88  Advisor to Institute of Medicine’s Committee to Review the CDC Vietnam Veterans Agent Orange Study.


1996–97  Senior Statistical Consultant for the CABG Patch Trial

2000–present  Consultant for Oxford Health Plans

2001  Member of Institute of Medicine Committee on Strategies for Small-Number-Participant Clinical Research Trials

2009–2010  Consultant and coauthor on Amicus Brief to the United States Supreme Court, in re Mary Berghuis, Warden, Petitioner v. Diopolis Smith, Respondent, for social scientists, statisticians, and law professors, Jeffrey Fagan, et al., as Amici Curiae supporting respondent.
Testimony as an expert statistical witness in litigation:

A. Cases in which I testified in court:

1. Hupart vs. Board of Higher Education of the City of New York
   U.S. District Court, Southern District of New York, Judge Frankel
   Attorneys: Victor J. Herwitz, 22 East 40th Street, NYC, NY 10016
   (1976; testified for plaintiff in a reverse race discrimination case).

2. Huertas vs. East River Housing Corp.
   U.S. District Court, Southern District of New York, Judge Carter
   Attorneys: Kenneth Kimmerling, Puerto Rican Legal Defense and Educational
   Fund, 95 Madison Avenue, NYC, NY 10016
   (2/81; testified for plaintiff in housing race discrimination case).

3. Berkman vs. City of New York
   U.S. District Court, Eastern District of New York, Judge Sifton
   Attorneys: Robert King, Debevoise, Plimpton, Lyons & Gates, 299 Park Avenue,
   NYC, NY 10017; Laura Sager, Women’s Rights Clinic of the Washington Square
   Legal Services, Inc., 40 Washington Square South, NYC, NY 10012
   (9/81; testified for plaintiff in firefighters' sex discrimination case).

   U.S. District Court, Western District of Pennsylvania, Judge Cohill
   Attorneys: Stanley M. Stein, Felstein, Grinberg, Stein & McKee, Seventh Floor,
   Law and Finance Building, Pittsburgh, PA 15219
   (11/81; testified for plaintiff in sex discrimination case).

5. Brinks, Inc. vs. City of New York
   U.S. District Court, Southern District of New York, Judge E. Weinfeld
   Attorneys: Robert Meister, Milgram, Thomajan, Jacobs & Lee, Chrysler Building,
   NYC, NY 10714
   (6/82; testified for plaintiff in a jury trial concerning parking meter revenue trends).

6. Lewis vs. NLRB
   U.S. District Court, District of Texas – Houston, Judge Black
   Attorneys: Gail J. Wright, Legal Defense and Educational Fund, 10 Columbus
   Circle, NYC, NY 10019
   (6/82; testified for plaintiff in a race discrimination case involving promotion
   through GS system).
7. Sobel vs. Yeshiva University  
U.S. District Court, Southern District of New York, Judge Goettel  
Attorneys: Daniel Riesel and Mark A. Chertok, Winer, Neuberger & Sive, 425 Park Avenue, NYC, NY 10022  
(9/82; testified for defendant in a sex discrimination case against the Albert Einstein College of Medicine).

8. Mississippi Council on Human Relations vs. State of Mississippi  
J76 Civ 118R  
U.S. District Court, Southern District of Mississippi – Jackson, Judge J. Countiss  
Attorneys: Jeffrey N. Drummond, Debevoise & Plimpton, 875 Third Avenue, NYC, NY 10022  
(11/83; testified on behalf of plaintiff in race discrimination suit against Attorney General's office).

Judge Nahum Litt  
Administrative hearing, U.S. Department of Labor – Washington  
Attorneys: Deborah Millenson, Richard Gilman and Diane Heim, Office of the Solicitor  
(12/85–1/86; testified on behalf of plaintiffs in race and sex discrimination suit).

10. Auxilium Pharmaceuticals, Inc. and FCB I, LLC v. Watson Laboratories, Inc.  
Attorneys: Isaac Ashkenazie and Bruce Wexler of Paul, Hastings, Janofsky & Walker, LLP.  
(2014: on behalf of plaintiff in re statistical appropriateness of bioequivalence studies supporting differences between Testim and AndroGel in a patent dispute).

B. Cases in which my deposition was taken (cases settled before trial):

11. Smith vs. Readers Digest Association (73 Civ 4883)  
U.S. District Court, Southern District of New York, Judge Frankel  
Attorneys: Harriet Raab, George Cooper and Howard Rubin, Employment Rights Project, Columbia University Law School, NYC, NY 10027  
(1977; on behalf of plaintiff in sex discrimination case).

U.S. District Court, Southern District of New York, Judge Werker  
Attorneys: Harriet Raab, George Cooper and Howard Rubin, Employment –Rights Project, Columbia University Law School, NYC, NY 10027  
(1978; on behalf of plaintiff in sex discrimination case).
13. **The Hamburger Patties Cases**  
   U.S. District Court, San Diego, California  
   (1996; on behalf of Foodmaker Inc., in re statistical analysis of foodborne illness outbreak).

   Attorney: A.H. Wilcox, of Pepper, Hamilton & Scheetz, Philadelphia, and Michael O. Finkelstein, of Patterson, Belknap, Tyler & Webb, New York City  
   (1997; on behalf of defendant in re statistical evidence of cancer causation from a post-war radiolabelled iron nutritional uptake study).

15. **Eisai Co., Ltd., and Eisai, Inc. v. Dr. Reddy’s Laboratories, Ltd., et al.**  
   (2005; on behalf of plaintiff in re statistical analysis of animal experiment data concerning stomach acid reduction of rabeprazole compared with omeprazole in a patent challenge case).

16. **Sunovion Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.**  
   Attorneys: Bruce M. Wexler and Mark Koehn, of Paul, Hastings, Janofsky & Walker, LLP.  
   (2011: on behalf of plaintiff in re statistical appropriateness of clinical trials supporting differences between zopiclone and eszopiclone in a patent challenge case).

C. **Other testimony:**

17. Testified before F.T.C. commissioners in re Sominex 2 hearings.  
   Attorney: J. Halvorsen, Shearman & Sterling, NYC.  
   (1984; on behalf of respondent Beecham Products).

18. Testified in an administrative hearing in re Butler v. NYS Civil Service.  
   (1985; on behalf of plaintiff alleging disparate racial impact in police examinations).

19. Testified in New York City Police Dept. proceeding, Case No. 64261/90.  
   Attorney: Lieut. Michael Gorman, One Police Plaza, NYC.  
   (1990; on behalf of Department Advocate’s Office in re statistical sampling methodology for random drug testing).
20. Testified in New York City Police Dept. proceeding, Case No. 67061/92.
    Attorney: Rosemarie DeBellis, One Police Plaza, NYC.
    (1993; on behalf of Department Advocate's Office in re pseudorandom number
generation and statistical sampling methodology for random drug testing).

21. Testified in New York City Police Dept. proceeding, Case No. 69758/95 et al.
    Attorney: Harry Peters, One Police Plaza, NYC.
    (1997; on behalf of Department Advocate’s Office in re statistical evidence of
    cheating on a standardized multiple choice examination for promotion to sergeant).

22. Testified at arbitration hearings on behalf of Oxford Health Plans.
    Attorney: Joe Clasen, Robinson & Cole
    (2000--; in re upcoding practices by participating physicians).
Publications: An asterisk (*) indicates senior authorship.

A. Original, peer reviewed articles:


62. The WARSS, APASS, PICSS, HAS, and Genesis Study Groups (1997). The Feasibility of a Collaborative Double–Blind Study Using an Anticoagulant: the Warfarin–Aspirin Recurrent Stroke Study (WARSS), the Antiphospholipid Antibodies and Stroke Study (APASS), the Patent Foramen Ovale in Cryptogenic Stroke Study (PICSS), the Hemostatic System Activation Study (HAS), and the Genes in Stroke Study (GENESIS). *Cerebrovascular Diseases* 7:100–112.

   A Lower Bound for the Mantel–Haenszel One Degree of Freedom Chi–squared Statistic in 1:m Matched Samples.

   *Controlled Clinical Trials* 19:1–14.

    Maternal Exercise During Pregnancy, Physical Fitness, and Timely Delivery.

    Higher Cerebral Function and Hemispheral Blood Flow During Awake Carotid Artery Balloon Test Occlusions.

    Is the One–Half Continuity Correction Used Once or Twice to Derive a Well Known Approximate Sample Size Formula to Compare Two Independent Binomial Distributions? *The American Statistician* 53:62-66.

    Arteriovenous Malformations of the Brain in the Adult.


119. *Finkelstein, M.O. and Levin, B. (2008).*


128. Zafonte, R., Friedewald, W.T., Lee, S.M., Levin, B., Diaz-Arrastia, R., Ansel, B.,
Eisenberg, H., Timmons, S.D., Temkin, N., Novack, T., Ricker, J., Merchant,
R., and Jallo, J. (2009). The Citicoline Brain Injury Treatment (COBRIT) Trial:
Design and Methods. 
Journal of Neurotrauma 26:2207-2216.

129. Cudkowicz, M., Katz, J., Moore, D.H., O’Neill, G., Glass, J.D., Mitsumoto, H.,
Appel, S., Ravina, B., Kieburzt, K., Shoulson, I., Kaufmann, P., Khan, J.,
Simpson, E., Shefner, J., Levin, B., Cwik, V., Schoenfeld, D., McDermott, M.P.,
Amyotrophic Lateral Sclerosis 11: 259–265.

130. Haley, E.C., Thompson, J.L.P., Grotta, J.C., Lyden, P.D., Hemmen, T.G., Brown,
D.L., Fanale, C., Libman, R., Kwiatkowski, T.G., Llinas, R.H., Levine, S.R.,
Johnston, K.C., Buchsbaum, R., Levy, G., and Levin, B., for the Tenecteplase in
Stroke Investigators (2010). Phase IIb/III Trial of Tenecteplase in Acute Ischemic
Stroke: Results of a Prematurely Terminated Randomized Clinical Trial. 
Stroke 41:707-711.


135. Devanand, D.P., Mintzer, J., Schultz, S., Sultzer, D., de la Pena, D., Gupta, S.,


B. Books:


(Third edition in preparation.)


C. Reviews, chapters, proceedings, abstracts, and editorials:


   (Member of Institute of Medicine Committee on Strategies for Small-Number-Participant Clinical Research Trials)


    The Effect of Intradialytic Vasopression Infusion on Chronic Blood Pressure Control in Hypertensive Patients with ESRD: A Program to Develop a Decisive Randomized Controlled Trial. (Abstract for American Society of Nephrology)


   *Chance*, 16(3):30-36, Summer 2003.

   *Chance*, 16(4):37-40, Fall 2003.


5. Bullet Lead As Forensic Evidence.


7. Statistical Evidence in an Education Finance Case.

E. Technical Reports:


Appendix B

Difference of Differences Analysis

As explained in paragraph 21 of my report, I considered whether the difference between the proportions of pharmaceutical and non-pharmaceutical patents found invalid on utility grounds discussed in Section II of my report was significantly different from the corresponding difference on novelty and obviousness grounds discussed in Section IV.

This “difference of differences” analysis is common in studies where the effect of a study condition, when compared to a control condition, is examined with respect to different outcome variables. In the present case, the study condition is “pharmaceutical patent” which is compared to “non-pharmaceutical patent.” Differences in invalidity rates between the pharmaceutical patent group and the non-pharmaceutical patent group are the “effects” that are of interest. The outcome variables are the invalidity holdings based on utility or other grounds. As discussed in Sections II and IV, I found a significant difference of 39.7% between the treatment of pharmaceutical and non-pharmaceutical on grounds of utility but a non-significant difference of 0.2% on grounds of novelty and obviousness. So the “effect” appears to depend on whether utility or another ground is the basis of a challenge.

The question I now turn to is whether we can conclude that the specificity observed as such could have arisen purely by chance or, in the alternative, that the specificity is statistically significant, consistent with the hypothesis of disproportionate impact between pharmaceutical patents versus non-pharmaceutical patents localized on grounds of utility.

A different statistical procedure is required for this hypothesis test because two fourfold tables are involved and because there is overlap in the cases represented in the two tables (those
that were challenged on grounds of utility as well as obviousness, novelty, or both).\(^1\) I specify
the statistical method I used later in this appendix.

The one-tailed \(P\)-value generated by my analysis is 0.046. I therefore rejected the null hypothesis that the positive difference of 39.5 percentage points between the two differences of 39.7 and 0.2 percentage points in the post-2005 period was due to chance at the 0.05 level. I conclude that the observed specificity of the disproportionate impact of utility-based invalidations is statistically significant and is likely not due to chance. In other words, the disproportionate impact of the utility doctrine on the pharmaceutical sector is unique and finds no parallel in other grounds.

I note that repeating the test with the inclusion of sufficiency alongside novelty and obviousness does not meaningfully change the results. The positive difference of 39.8 percentage points between the two differences of 39.7 and –0.1 percentage points in the post-2005 period has a significant one-tailed \(P\)-value of 0.045.

What follows is the technical description of the method for obtaining the \(P\)-values for this test.

\* \* \*

Let \(i=1,\ldots,n\) index the \(n\) cases under consideration, where \(n=88\) for pre-2005 cases and \(n=129\) for post-2005 cases. Let \(W_i=1\) if the \(i^{th}\) case was challenged on grounds of utility or 0 if utility was not challenged (irrespective of whether the case was challenged on other grounds).

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\(^1\) There were 61 such cases (53 pharmaceutical and 8 non-pharmaceutical). Of the pharmaceutical patents, 10/53 or 18.9\% were held invalid on both utility and novelty or obviousness (or both). Of the non-pharmaceutical patents, none were held invalid on both utility and other grounds, consistent with the fact that none were held invalid on utility grounds irrespective of other grounds.
Similarly, let $W_{i2}=1$ if the $i^{th}$ case was challenged on other grounds (obviousness, novelty, sufficiency, or combinations of these) or 0 if not (irrespective of whether the case was challenged for utility). Also, for $i=1,...,n$ and $j=1,2$, let $Y_{ij}=1$ if the patent in the $i^{th}$ case was held invalid on ground $j$ or 0 if the challenge on that ground (or those grounds) was not successful. The value of $Y_{ij}$ will be needed in the analysis only if $W_{ij}=1$, i.e., only if the patent was challenged on ground(s) $j$. Our analysis will condition on the set of observed values of $W_{ij}$.

For patents of a given type (pharmaceutical or non-pharmaceutical) in a given time period (pre- or post-2005), let $P_j = P[Y_{ij}=1|W_{ij}=1]$ denote the probability of finding the patent invalid on ground $j=1$ or 2, assumed constant for all cases of the given type in the given time period. Also let $P_{12} = P[Y_{i1}=Y_{i2}=1|W_{i1}=W_{i2}=1]$ denote the joint probability of holding the patent invalid on both grounds, among those challenged on grounds of both utility and at least one other ground.

Then an unbiased estimate of $P_j$ is given by $p_j = \frac{\sum_{i=1}^{n} W_{ij} Y_{ij}}{\sum_{i=1}^{n} W_{ij}}$ and its variance is given by

$$Var(p_j) = \sum_{i=1}^{n} W_{ij}^2 P_j (1-P_j) \left/ \left( \sum_{i=1}^{n} W_{ij} \right)^2 \right. = \sum_{i=1}^{n} W_{ij} P_j (1-P_j) \left/ \left( \sum_{i=1}^{n} W_{ij} \right)^2 \right. = \left( \sum_{i=1}^{n} W_{ij} \right) P_j (1-P_j) \left/ \left( \sum_{i=1}^{n} W_{ij} \right)^2 \right.$$ 

$$= P_j (1-P_j) \left/ \sum_{i=1}^{n} W_{ij} = P_j (1-P_j)/n_j, \right.$$

where $n_j = \sum_{i=1}^{n} W_{ij}$ is the number of cases challenged on ground $j=1$ or 2 and we have used the fact that $W_{ij}$ is a zero-one indicator so that $W_{ij}^2=W_{ij}$. It follows that the standard error (s.e.) of the estimated proportion $p_j$ is given by $s.e.(p_j) = \sqrt{p_j (1-p_j)/n_j}$. 
Next, the covariance between the two ground-specific estimates is given by

\[
\text{Cov}(p_1, p_2) = \text{Cov}\left(\frac{\sum_i W_{i1} Y_{i1}}{n_{12}}, \frac{\sum_i W_{i2} Y_{i2}}{n_{12}}\right) = \frac{n_{12}}{n_1 n_2} \left(\sum_i W_{i1} W_{i2} \text{Cov}(Y_{i1}, Y_{i2})\right)
\]

where \( n_{12} = \sum_i W_{i1} W_{i2} \) is the number of cases challenged on both grounds 1 and 2 (utility and any other ground). The joint probability \( P_{12} \) may be estimated unbiasedly by

\[
P_{12} = \frac{\sum_i W_{i1} W_{i2} Y_{i1} Y_{i2}}{n_{12}},
\]

which is the observed proportion of cases found invalid on both grounds among cases challenged on both grounds. It follows that a consistent estimator of \( \text{Cov}(p_1, p_2) \) is given by

\[
\hat{\text{Cov}}(p_1, p_2) = \{n_{12}/(n_1 n_2)\} (P_{12} - P_1 P_2),
\]

In order to compare pharmaceutical cases with non-pharmaceutical cases, we extend the notation using superscripts \( \phi \) (the Greek letter phi) for pharmaceutical cases and \( \nu \) (the Greek letter nu) for non-pharmaceutical cases. To keep the notation simple, here we consider only post-2005 cases. We denote the estimated difference between pharmaceutical and non-pharmaceutical proportions held invalid on ground \( j \) by \( d_j = p_j^{(\phi)} - p_j^{(\nu)} \) and estimate its standard error (s.e.) by

\[
s.e.(d_j) = \sqrt{s.e.\cdot^2(p_j^{(\phi)}) + s.e.\cdot^2(p_j^{(\nu)})}
\]

due to the statistical independence of the two types of cases. The covariance between the two differences \( d_1 \) and \( d_2 \) is given by

\[
\text{Cov}(d_1, d_2) = \text{Cov}(p_1^{(\phi)} - p_1^{(\nu)}, p_2^{(\phi)} - p_2^{(\nu)}) = \text{Cov}(p_1^{(\phi)}, p_2^{(\phi)}) + \text{Cov}(p_1^{(\nu)}, p_2^{(\nu)}),
\]
again by statistical independence. It follows that the standard error of the difference \( d = d_1 - d_2 \) is given by

\[
s.e.(d) = \sqrt{s.e.^2(d_1) + s.e.^2(d_2) - 2\text{Cov}(d_1, d_2)}
\]

\[
= \sqrt{s.e.^2(p_{1}^{(v)}) + s.e.^2(p_{2}^{(v)}) + s.e.^2(p_{1}^{(w)})} - 2\text{Cov}(p_{1}^{(v)}, p_{2}^{(w)}) - 2\text{Cov}(p_{1}^{(w)}, p_{2}^{(w)}).
\]

If an estimated invalidity proportion \( p_j \) equals zero, the standard error formula \( \sqrt{p_j(1 - p_j)/n} = 0 \) is clearly an underestimate of the true but unknown standard error unless the true \( P_j \) happens to equal 0 as well, which we do not assume. In such cases we replace the zero point estimate with the one-sided upper 95% confidence limit for the true but unknown \( P_j \) in the formula for \( s.e.(p_j) \) and in the formula for \( \text{Cov}(p_1, p_2) \) if that limit is less than 0.5, or by 0.5 if not. We do not replace a zero estimate of \( P_{12} \) in the formula for \( \text{Cov}(p_1, p_2) \). This procedure is conservative in the sense that it allows for more uncertainty in the statistical testing procedure. For \( p_{1}^{(v)} \) in the post-2005 period we replaced the observed zero proportion by the one-sided upper 95% confidence limit for \( p_{1}^{(v)} \) of 0.3123. As just noted, the statistical significance of \( d \) would be greater (and the corresponding \( P \)-value would be smaller) without the specified replacements.

Finally, the central limit theorem\(^2\) implies that the standardized difference \( z = d / s.e.(d) \) is distributed approximately as a standard normal random variable. An approximate one-tailed \( P \)-value is given by the area under the standard normal probability density function to the right of \( z \).

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\(^2\) See SFL, at §4.3 (C-395).
Appendix C

Canadian Federal Court Patent Validity Cases (1980-Present)
Federal Court Patent Validity Cases from 1980-Present

The chart that follows shows all patent validity cases heard in the Federal Court of Canada and decided between January 1, 1980 and August 10, 2015.

Cases are coded for their outcome on four grounds of validity: utility, non-obviousness, novelty and sufficiency.

- “---” denotes that the relevant ground was not ruled upon.
- “Y” denotes that the relevant ground was ruled upon, and that the patent was found valid as to that ground.
- “N” denotes that the relevant ground was ruled upon, and that the patent was found invalid as to that ground.

Coding is based on the outcome of the final available appeal. Where rulings were split by claim within a patent, such that some claims were found valid and others invalid, a coding of “Y” was applied for the relevant ground. Where a case involved multiple patents, and at least one patent was challenged on a given ground, then the case is coded as either “Y” or “N” for the relevant ground, as appropriate. Where a case involved multiple patents challenged on the same ground, and at least one patent was invalidated on a given ground, a coding of “N” was applied for the relevant ground.
### Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

<table>
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<tr>
<th>Style of Cause</th>
<th>Trial Court</th>
<th>Appeals</th>
<th>Pharma case</th>
<th>Useful</th>
<th>Non-Obvious</th>
<th>Novel</th>
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<tr>
<td>Saunders v. Airglide Deflectors Ltd.</td>
<td>(1980) 50 C.P.R. (2d) 6</td>
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<td>Congoleum Corp. v. Mannington Mills Inc.</td>
<td>(1980) 47 C.P.R. (2d) 33</td>
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<td>Cooper &amp; Beatty Co. v Alpha Graphics Ltd.</td>
<td>(1980) 49 C.P.R. (2d) 145</td>
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<td>Beloit Canada Ltée/Ltd. v. Valmet Oy</td>
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<td>Corning Glass Works v. Canada Wire &amp; Cable Ltd.</td>
<td>(1984) 81 C.P.R. (2d) 39</td>
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<td>Ductmate Industries Inc. v. Exanno Products Ltd.</td>
<td>(1984) 2 C.P.R. (3d) 289</td>
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<td>Tinsel Manufacturing Ltd. v. Noma Canada Inc. et al.</td>
<td>(1985) 3 C.P.R. (3d) 433</td>
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<td>Services et Produits Hospitaliers Confort &amp; Inc. v. W. Laframboise Ltee</td>
<td>(1985) 6 C.P.R. (3d) 238</td>
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<td>W.H. Brady Co. v. Letraset Canada Ltd.</td>
<td>(1985) 7 C.P.R. (3d) 82</td>
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<td>Kramer v. Lindsay Specialty Products Ltd.</td>
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<td>Invacare Corp. v. Everest &amp; Jennings Canadian Ltd.</td>
<td>(1987) 14 C.P.R. (3d) 156</td>
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<td><em>Cabot Corp v. 318602 Ontario Ltd.</em></td>
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<td><em>Control Data Canada Ltd. v. Senstar Corp.</em></td>
<td>(1989) 23 C.P.R. (3d) 449</td>
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<td><em>M &amp; I Door Systems Ltd. v. Indoco Industrial Door Co.</em></td>
<td>(1989) 25 C.P.R. (3d) 477</td>
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<td><em>AT &amp; T Technologies Inc. v. Mitel Corp.</em></td>
<td>(1989) 26 C.P.R. (3d) 238</td>
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<td>Standal Estate v. Swecan International Ltd.</td>
<td>(1989) 28 C.P.R. (3d) 261</td>
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<td>Energy Absorption Systems Inc. v. Y. Boissoaneault &amp; Fils Inc.</td>
<td>(1990) 30 C.P.R. (3d) 420</td>
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<td>Stiga Aktiebolag v. S.L.M. Canada Inc.</td>
<td>(1990) 34 C.P.R. (3d) 216</td>
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<td>Martinray Industries Ltd. v. Fabricants National Dagendor Manufacturing Ltd.</td>
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<td>Cochlear Corp. v. Cosem Neurostim Ltée</td>
<td>(1995) 64 C.P.R. (3d) 10</td>
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<td>Pfizer Canada Inc. v. Apotex Inc.</td>
<td>(1997) 77 C.P.R. (3d) 547</td>
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<td>(1999) 1 C.P.R. (4th) 22</td>
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<td>Pfizer Canada Inc. v. Apotex Inc.</td>
<td>(2002) 22 C.P.R. (4th) 466</td>
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<td>2003 FC 899</td>
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<td>Bayer AG v. Apotex Inc.</td>
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<td>Affirmed by 2007 FCA 243</td>
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<td>Reversed by 2006 FCA 275 (on obviousness)</td>
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<td>Wessel v. Energy Rentals Inc.</td>
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<td>2004 FC 1631</td>
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<td>2004 FC 1767</td>
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<td>2005 FC 9</td>
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<td>Merck &amp; Co. Inc. v. Apotex Inc.</td>
<td>2005 FC 755</td>
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<td>Emmanuel Simard &amp; Fils (1983) Inc. v. Raydan Manufacturing Ltd.</td>
<td>2005 FC 973</td>
<td>Reversed by 2006 FCA 293 (as to costs only)</td>
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<td>Abbott Laboratories v. Canada (Minister of Health)</td>
<td>2005 FC 1093</td>
<td>Affirmed by FCA. (2006), 56 C.P.R. (4th) 387</td>
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<td>2005 FC 1095</td>
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<td>Aventis Pharma Inc. v. Mayne Pharma (Canada) Inc.</td>
<td>2005 FC 1183</td>
<td>No appellate history</td>
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<td>Pfizer Canada Inc. v. Canada (Minister of Health)</td>
<td>2005 FC 1205</td>
<td>Reversed by 2007 FCA 209 (on different grounds than inutility)</td>
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<td>Aventis Pharma Inc. v. Apotex Inc.</td>
<td>2005 FC 1283</td>
<td>Affirmed by 2006 FCA 64 Leave to appeal to SCC ref'd: Aug. 3, 2006</td>
<td>Y</td>
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<td>Pfizer Canada Inc. v. Novopharm Ltd.</td>
<td>2005 FC 1299</td>
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<td>Abbott Laboratories v. Canada (Minister of Health)</td>
<td>2005 FC 1332</td>
<td>Affirmed by 2007 FCA 153</td>
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<td>Pfizer Canada Inc. v. Apotex Inc.</td>
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<td>Bristol-Myers Squibb Canada Co. v. Novopharm Ltd.</td>
<td>2005 FC 1458</td>
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<td>Aventis Pharma Inc. v. Apotex Inc</td>
<td>2005 FC 1504</td>
<td>Affirmed by 2006 FCA 328</td>
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<td>Abbott Laboratories v. Canada (Minister of Health)</td>
<td>2006 FC 69</td>
<td>Affirmed by 2007 FCA 83</td>
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<td>Pfizer Canada Inc. v. Canada (Minister of Health)</td>
<td>2006 FC 220</td>
<td>Reversed by 2006 FCA 214</td>
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<td>Bayer AG v Novopharm Ltd</td>
<td>2006 FC 379</td>
<td>Appeal commenced but discontinued (A-175-06)</td>
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<td>Merck &amp; Co. v. Apotex Inc.</td>
<td>2006 FC 524</td>
<td>Varied by 2006 FCA 323</td>
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<td>Axcan Pharma Inc. v. Pharmascience Inc.</td>
<td>2006 FC 527</td>
<td>No appellate history</td>
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<td>Dimplex North America Ltd. v. CFM Corp</td>
<td>2006 FC 586</td>
<td>Affirmed by 2007 FCA 278</td>
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<td>Janssen-Ortho Inc. v. Novopharm Ltd.</td>
<td>2006 FC 1234</td>
<td>Affirmed by 2007 FCA 217</td>
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<td>Calgon Carbon Corp. v. North Bay (City)</td>
<td>2006 FC 1373</td>
<td>Affirmed by 2008 FCA 81</td>
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<td>Pfizer Canada v Canada</td>
<td>2006 FC 1471</td>
<td>Appeal heard but discontinued (A-10-07)</td>
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<td>Abbott Laboratories v Canada</td>
<td>2006 FC 1558</td>
<td>Appeal dismissed 2007 FCA 187</td>
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<td>Pfizer Canada Inc. v. Apotex Inc.</td>
<td>2007 FC 26</td>
<td>Affirmed by 2007 FCA 195</td>
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<td>G.D. Searle &amp; Co. v. Novopharm Ltd.</td>
<td>2007 FC 81</td>
<td>Reversed by 2007 FCA 173 (on obviousness)</td>
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<td>Pfizer Canada Inc. v. Canada (Minister of Health)</td>
<td>2007 FC 91</td>
<td>Reversed by 2008 FCA 108</td>
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<td>Jay-Lor International Inc. v. Penta Farm Systems Ltd.</td>
<td>2007 FC 358</td>
<td>No appellate history</td>
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<td>Eli Lilly Canada Inc. v. Apotex Inc.</td>
<td>2007 FC 455</td>
<td>Affirmed in 2008 FCA 44</td>
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<td>Sanofi-Aventis Inc. v. Laboratoire Riva Inc.</td>
<td>2007 FC 532</td>
<td>No appellate history.</td>
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<td>M.K. Plastics Corp. v. Plasticair Inc.</td>
<td>2007 FC 574</td>
<td>No appellate history</td>
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<td>Eli Lilly Canada Inc. v. Novopharm Ltd.</td>
<td>2007 FC 596</td>
<td>Appeal dismissed as moot: 62 C.P.R. (4th) 161 (FCA) Leave to appeal to SCC ref’d: March 13, 2008</td>
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<td>AstraZeneca AB v Apotex</td>
<td>2007 FC 688</td>
<td>No appellate history</td>
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<td>Abbott Laboratories v Canada</td>
<td>2007 FC 753</td>
<td>Appeal commenced but dismissed (A-440-07)</td>
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<td>Pfizer Canada Inc. v. Canada (Minister of Health)</td>
<td>2007 FC 898</td>
<td>No appellate history</td>
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<td>Pfizer Canada Inc. v. Apotex Inc.</td>
<td>2007 FC 971</td>
<td>Affirmed by 2009 FCA 8</td>
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<td>McKay v. Weatherford Canada Ltd.</td>
<td>2007 FC 1233</td>
<td>Affirmed by 2008 FCA 369</td>
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<td>Pfizer Canada Inc. v. Canada (Minister of Health)</td>
<td>2008 FC 11</td>
<td>No appellate history.</td>
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<td>Pfizer Canada Inc. v. Canada (Minister of Health)</td>
<td>2008 FC 13</td>
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<td>Eli Lilly Canada Inc. v. Apotex Inc.</td>
<td>2008 FC 142</td>
<td>Affirmed by 2009 FCA 97 Leave to appeal to SCC ref’d: Oct. 22, 2009</td>
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<td>2008 FC 308</td>
<td>No appellate history</td>
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<td>Pfizer Canada Inc. v. Canada (Health)</td>
<td>2008 FC 500</td>
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<td>Shire Biochem Inc. v. Canada (Minister of Health)</td>
<td>2008 FC 538</td>
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<td>Johnson &amp; Johnson Inc. v. Boston Scientific Ltd.</td>
<td>2008 FC 552; additional reasons in 2008 FC 817</td>
<td>No appellate history</td>
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<td>GlaxoSmithKline Inc. v. Pharmascience Inc.</td>
<td>2008 FC 593</td>
<td>No appellate history.</td>
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<td>Janssen-Ortho Inc. v. Apotex Inc.</td>
<td>2008 FC 744</td>
<td>Reversed by 2009 FCA 212 (on different grounds than inutility)</td>
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<td>Laboratoires Servier v. Apotex Inc.</td>
<td>2008 FC 825</td>
<td>Affirmed by 2009 FCA 222 Leave to appeal to SCC ref’d: March 25, 2010</td>
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<td>Abbott Laboratories v. Canada (Minister of Health)</td>
<td>2008 FC 1359</td>
<td>Affirmed by 2009 FCA 94</td>
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<td>Uview Ultraviolet Systems Inc. v. Brasscorp Ltd.</td>
<td>2009 FC 58</td>
<td>No appellate history.</td>
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<td>Bristol-Myers Squibb Canada Co. v. Apotex Inc.</td>
<td>2009 FC 137</td>
<td>No appellate history</td>
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<td>Lundbeck Canada Inc. v. Canada (Minister of Health)</td>
<td>2009 FC 146</td>
<td>Affirmed by 2010 FCA 320 Leave to appeal to SCC ref’d: Aug. 25, 2011</td>
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<td>Eli Lilly Canada Inc. v. Novopharm Ltd.</td>
<td>2009 FC 235</td>
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<td>Hershkovitz v. Tyco Safety Products Canada Ltd.</td>
<td>2009 FC 256</td>
<td>Affirmed by 2010 FCA 190</td>
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<td>Eli Lilly Canada Inc. v. Novopharm Ltd.</td>
<td>2009 FC 301</td>
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<td>Eli Lilly Canada Inc. v. Apotex Inc</td>
<td>2009 FC 320</td>
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<td>Pfizer Canada Inc. v. Novopharm Ltd.</td>
<td>2009 FC 638</td>
<td>Affirmed by 2010 FCA 242</td>
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<td>Abbott Laboratories v. Canada (Minister of Health)</td>
<td>2009 FC 648</td>
<td>Reversed in part by 2010 FCA 168</td>
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<td>Sanofi-Aventis Canada Inc. v. Apotex Inc.</td>
<td>2009 FC 676</td>
<td>Affirmed 2011 FCA 300</td>
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<td>Ratiopharm Inc. v. Pfizer Ltd.</td>
<td>2009 FC 711</td>
<td>Affirmed by 2010 FCA 204</td>
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<td>Purdue Pharma v. Pharmascience Inc.</td>
<td>2009 FC 726</td>
<td>No appellate history</td>
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<td>Eli Lilly and Co. v. Apotex Inc.</td>
<td>2009 FC 991</td>
<td>Affirmed by 2010 FCA 240</td>
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<td>Y</td>
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<td>Sanofi-Aventis Canada Inc. v. Hospira Healthcare Corp.</td>
<td>2009 FC 1077</td>
<td>No appellate history</td>
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<td><strong>Lundbeck Canada Inc. v. Ratiopharm Inc.</strong></td>
<td>2009 FC 1102</td>
<td>No appellate history</td>
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<td><strong>Schering-Plough Canada Inc. v. Pharmascience Inc.</strong></td>
<td>2009 FC 1128</td>
<td>No appellate history</td>
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<td><strong>Pfizer Canada Inc. v. Canada (Minister of Health)</strong></td>
<td>2009 FC 1294</td>
<td>Affirmed by 2011 FCA 102</td>
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<td><strong>Biovail Corporation v. Canada (Health)</strong></td>
<td>2010 FC 46</td>
<td>No appellate history</td>
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<td><strong>Bridgeview Manufacturing Inc. v. 931409 Alberta Ltd.</strong></td>
<td>2009 FC 50</td>
<td>Allowed re obviousness in 2010 FCA 188</td>
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<td><strong>Sanofi-Aventis Canada Inc. v. Ratiopharm Inc.</strong></td>
<td>2010 FC 230</td>
<td>No appellate history.</td>
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<td><strong>Bauer Hockey Corp. v. Easton Sports Canada Inc.</strong></td>
<td>2010 FC 361</td>
<td>Affirmed by 2011 FCA 83</td>
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<td><strong>Pfizer Canada Inc. v. Canada (Minister of Health)</strong></td>
<td>2010 FC 447</td>
<td>Reversed by 2011 FCA 236 Application for leave to appeal to Supreme Court of Canada dismissed on February 2, 2012.</td>
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<td><strong>Merck &amp; Co. v. Pharmascience Inc.</strong></td>
<td>2010 FC 510</td>
<td>No appellate history.</td>
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<td><strong>Weatherford Canada Ltd. v. Corlac Inc.</strong></td>
<td>2010 FC 602</td>
<td>Allowed in part (re infringement only) 2011 FCA 228</td>
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<td><strong>Pfizer Canada Inc. v. Ratiopharm Inc.</strong></td>
<td>2010 FC 612</td>
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<td>Teva Canada Ltd. v. Novartis AG</td>
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