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

[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."[2]

4. Subsequently, I requested and received a document (attached as Appendix C) containing detailed information concerning certain patent cases litigated between 1980 and 2015,[3] 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.

[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.[4] 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

[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

Type of patent	Patent found *invalid* on utility grounds	Patent found *valid* on utility grounds	Total
Pharmaceutical	25	38	63
Non-pharmaceutical	0	8	8
Total	25	46	71

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 *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.[8]

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 (*i.e.*, in the present case, I am not testing for discrimination in *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.[9]

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.

[8] The above interpretation of the test of significance is due to R.A. Fisher in his landmark 1935 textbook, *The Design of Experiments*.

[9] See *SFL*, at pp. 121-122 (C-395).

Table 2

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

Type of patent	Patent found *invalid* on utility grounds	Patent found *valid* on utility grounds	Total
Pharmaceutical	0	3	3
Non-pharmaceutical	2	22	24
Total	2	25	27

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)

Type of patent	Patent found *invalid* on other grounds	Patent found *valid* on other grounds	Total
Pharmaceutical	39	56	95
Non-pharmaceutical	9	13	22
Total	48	69	117

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).[10] 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.

[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. Brisbois'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.[12] 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.[13]

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.[14] 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

---

"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.[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

[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

[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, New York, U.S.A. on September 7, 2015

[signed]
Bruce Levin

Appendix A

Curriculum Vitae

BRUCE LEVIN – 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
Dissertation title:	Maximum Likelihood Estimation in Compound Multinomial and Compound Poisson Distributions.
Citation:	Levin, B. and Reeds, J. (1977). Compound Multinomial Likelihood Functions are Unimodal: Proof of a Conjecture of I.J. Good. *Annals of Statistics* 5:79–87.

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)
1979–1997	Senior Research Scientist, New York State Psychiatric Inst.
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).
1991	Consultant to NINDS program staff regarding preparation of a workscope for RFP/BAA #NIH–NINDS–90–06, establishing two Clinical Research Centers for Neonatal Seizure (April).
1992–2002	Consulting Editor for Statistics, American Journal of Public Health.
1998–1999	Program Chair for Spring 1999 Meetings of the International Biometrics Society, Eastern North American Region, Atlanta, GA.
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.
2003–2005	Co-editor for Chance Magazine's statistics in law column, Chance at the Bar.
2003–	Statistical consultant for Brad H court settlement monitors.
2005–2009	Member of Federal Advisory Committee for The National Children's Study, NICHD.
2006–2009	Scientific Review Committee, Parkinson's Study Group.
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.
2010–2012	Statistician for Data and Safety Monitoring Board for the Double-Blind Placebo Controlled Study Of Rifampicin In Multiple System Atrophy.

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

Important invited lectureships

"Sequential Medical Trials with Finite Patient Horizon,"
presented at New York Statistics Discussions Group (March 1978).

"Selecting the Highest Probability in Binomial and Multinomial Trials"
presented at the Rutgers Statistics Day Conference (April 1982).

"Logistic Regression,"
presented to the Bureau of Justice Statistics in Washington, DC (April 1983).

"Empirical Bayes Estimation in Heterogeneous Matched Binary Samples with Systematic Aging Effects," presented at the symposium *Adaptive Statistical Procedures and Related Topics*, in honor of Herbert Robbins' 70th birthday, Brookhaven National Laboratory (June 1985).

"Emerging Problems in Multiple Regression,"
presented at the Washington (State) Judicial Conference in Tacoma (August 1985).

"Some Statistical Issues in Employment Discrimination Litigation,"
presented at the Statistics Seminar at AT&T Bell Laboratories in Murray Hill, NJ (March 1986).

"The Saddlepoint Approximation in Conditional Logistic Likelihood Analysis,"
presented to the Harvard School of Public Health Department of Biostatistics, Cambridge, MA (April 1989).

"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).

"Tests of Odds Ratio Homogeneity with Improved Power in Sparse Fourfold Tables,"
presented to the Memorial Sloan–Kettering Cancer Center, Division of Biostatistics, New York, NY (May, 1991).

"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)

"On a New Inequality Involving Normal Densities," presented to the Division of Biostatistics, Columbia School of Public Health, New York, NY (February, 1998) and to the Department of Statistics and Operations Research, Stern School of Business, New York University, New York, NY (December, 1998).

"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).

"Mathematical Aspects of Estimating Two Treatment Effects and a Common Variance in an Assured Allocation Design," invited paper presented to the International Chinese Statistical Association Applied Statistics Symposium, Morristown, NJ (June, 2000).

"Research Design, Biostatistics, and Ethics," invited facilitator at the 13th Annual Bioethics Summer Retreat, Jiminy Peak, MA (June, 2001).

"Statistics Creates Beautiful Mathematics," invited Keynote Speaker at the 16th Annual New England Statistics Symposium, New Haven, CT (April, 2002).

"How to Tell the Truth with Statistics," invited speaker at Johnson & Johnson Pharmaceutical Research & Development, Ethics Lecture Series IV, Titusville, NJ (April, 2003).

"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 Procedures in Phase II Clinical Trials." Keynote speaker, Johnson & Johnson Pharma Stat 2005 Conference, Princeton, NJ (September, 2005).

"Innovative Statistical Designs for Small Clinical Trials." Invited speaker, Muscle Study Group 2006 Conference, Java Center, NY (June, 2006).

"Sequential Statistical Designs for Selecting from Competing Therapies." Invited speaker, ALS Association Conference on Drug Discovery, Biomarkers, and Clinical Trials for ALS, The Banbury Center, Cold Spring Harbor Laboratory, NY (September, 2007).

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

"Statistical Methods for Rates and Proportions." Invited tutorial faculty, The Sixty-Third Annual Deming Conference on Applied Statistics, Atlantic City (December, 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).

"Statistics in the Law: Some Lessons from Famous and Infamous Cases." Invited speaker with Michael O. Finkelstein, The New York Metro Area Chapter of the American Statistical Association, New York (February, 2009).

"Use of Data Collected Out of Compliance – When is it Acceptable?" Invited speaker at the Institutional Review Board Annual Educational Conference, Columbia University, New York (March, 2009).

"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).

"A Tale of Two Adaptive Trials." Invited speaker in The Use of Adaptive Designs in an NIH-Funded Clinical Trials Environment session at The Society for Clinical Trials meetings, Atlanta, (May, 2009).

"Recent Developments in Adaptive Subset Selection Procedures." Invited speaker, Statistical and Services Research Division, Nathan Kline Institute for Psychiatric Research, Orangeburg (December, 2009).

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

"Subset Selection for Comparative Clinical Selection Trials." Invited speaker, Third Annual International Workshop on Sequential Methodologies, Stanford University (June, 2011).

"Subset Selection for Comparative Clinical Selection Trials." Invited speaker, International Chinese Statistical Association, New York City (June, 2011).

"Meta-Analysis of Sparse Data—Perspectives from the Avandia Cases." Invited speaker with Michael O. Finkelstein, International Chinese Statistical Association, New York City (June, 2011).

"On an Algebraic Inequality Useful in Sequential Selection Procedures." Invited speaker, Fifth Annual International Workshop on Sequential Methodologies, Columbia University (June, 2015).

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 Biostatician (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).
2. Statistics W1111x-W1112y [85] Introduction to Statistics (F-78, S-79, S-83, F-91).
3. Mathematical Statistics W4006y [20] Principles of Statistical Inference (S-78).
4. Mathematical Statistics-Sociology G4181x-G4182y [20] Statistical Methods in Social Sciences (F-75, S-76, F-76, S-77, F-77, S-78, F-78, S-79).
5. Mathematical Statistics G6107x-G6108y [10] Theory of Statistical Inference (F-74, S-75, F-75, S-76).
6. Mathematical Statistics G8245x [2] Topics in Advanced Statistics (F-76, F-77).

Courses taught in the Division then Department of Biostatistics:

7. Biostatistics P6102 [40] Introduction to Statistical Inference (F-79, F-80, F-81).
8. Biostatistics P6104 [60] Introduction to Biostatistical Methods (F-98).
9. Biostatistics P6105 [10] Introductory Probability with Statistical Applications (F-89).
10. Biostatistics P8109 [20] Statistical Inference (S-00).
11. Biostatistics P8120 [20-100] The Analysis of Categorical Data (F-79, F-83, S-87, S-88, S-93, F-93, S-94, S-96, F-96, S-97, S-02, S-04, S-10).
12. Biostatistics P8129 [12] Theory of Multivariate Analysis (F-89).
13. Biostatistics P8133 [10] (new course) Sequential Experimentation (F-84, S-86, F-92, S-95, S-01, S-08).
14. Biostatistics P8137 [4] Seminar in the Statistics of Mental Health Research (F-92).
15. Biostatistics P8140 [50] The Randomized Clinical Trial (S-06).
16. Biostatistics P8151 [10] (new course) Methods of Statistical Adjustment (S-87, F-90, F-93).
17. Biostatistics P8160 [10] (new course) Topics in Statistical Computing with APL (S-89, F-90).

18. Biostatistics P8177 [7] (new course) Biostatistics in Legal Proceedings (S-14, S-15)

19. Biostatistics P8185 [10] Capstone Consulting Seminar (S-06, S-07).

20. Biostatistics P8190 [1] Master's Tutorial (F-91, S-93, F-95, S-00, S-01, F-01, F-03, S-08).

21. Biostatistics P9190 [1] Tutorial (Doctoral) (S-90, S-93, S-07, F-08).

22. Biostatistics P9154 [10] (new course) Discrete Statistical Analysis (S-77, S-80, S-84, S-85, F-86, F-87, F-88, S-92, S-94, S-96, S-98, F-03, S-09, S-11).

23. Public Health P6071 [20] The Integration of Science and Practice (F-13, S-14)

Other courses:

24. Law L6248x [20] Statistics for Lawyers, co-taught with M.O. Finkelstein, Columbia 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).

26. Survival Analysis, adjunct at Rutgers University [20] (F-95).

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:

1. Patricia Zybert, Ph.D. in Biostatistics, 1986.
   Dissertation: A Sequential Elimination Procedure for Selecting the Highest Binomial Probability.

2. John P. Orazem, Ph.D. in Biostatistics, 1990.
   Dissertation: A Nonparametric Analysis of Survival Data Within a Mixture of Susceptibles and Nonsusceptibles.

3. Fanhui Kong, Ph.D. in Biostatistics, 1992.
   Dissertation: Edgeworth Expansions in Generalized Linear Models and Logistic Regression Models.

4. Michael K. Parides, Ph.D. in Biostatistics, 1995.
   Dissertation: Testing Homogeneity of Discrete Exponential Families in the Large-Sparse Case.

5. Cheng-Shiun Leu, Ph.D. in Biostatistics, 1997.
   Dissertation: Some theorems concerning a sequential elimination procedure for selecting the best one of several binomial populations or multinational categories.

6. Xun Chen, Ph.D. in Biostatistics, 1999.
   Dissertation: Estimation methods for semi-parametric models in risk-based allocation trials.

7. Rosita Zawadzki, Dr.P.H. in Biostatistics, 2003.
   Dissertation: On the Truncated Levin-Robbins Sequential Selection Procedure for Three Binomials.

8. Xianhuang Zhou, Ph.D. in Biostatistics, 2006.
   Dissertation: Some Statistics for Comparing Two Treatments with Placebo, with Selection of Better Treatment.

9. Gilberto Levy, Dr.P.H. in Biostatistics, 2011.
   Dissertation: An index of Aging-Relatedness with Relevance to Genetic and Environmental Contributions to Mortality and Disease Incidence in a Population (with distinction).

10. Keith Goldfeld, Dr.P.H. in Biostatistics, 2012.
    Dissertation: Applying twice-weighted multiple interval estimates of a marginal structural modelto analyze the cost-effectiveness of treatments provided tonursing 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.

3. Hajime Takahashi, Department of Mathematical Statistics, 1978.
   Dissertation: On the Truncated Power One Test and Non-linear Renewal Theorem.

4. Wendy Worth, Department of Sociology, 1980.
   Dissertation: The Occupational Matrix: An Exploratory Analysis of the Situs-Prestige and Industry-Prestige Distributions of Four White Ethnic Groups.

5. Sonja H. Johansen, Division of Biostatistics, 1982.
   Dissertation: Linear Regression Models for Censored Occurrence Time Data.

6. Martin A. Weinstock, Division of Epidemiology, 1982.
   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.

8. David Edelman, Department of Mathematical Statistics, 1983.
   Dissertation: Empirical Permutation Bayes Estimation: Gaussian Case.

9. Bridget F. Grant, Division of Epidemiology, 1984.
   Dissertation: Preliminary Evaluation of Competing Screening Tests for Major Depression and Substance Abuse and Dependence in an Alcoholic Population: An Application of Receiver Operating Characteristic (ROC) Methodology.

10. Mai Zhou, Department of Statistics, 1986.
    Dissertation: Some Nonparametric Two-Sample Tests with Censored Data.

11. Anne L. Golden, Division of Epidemiology, 1990.
    Dissertation: Occupational Physical Demands and Risk of Prolapsed Lumbar Intervertebral Discs.

12. Mingxin Tang, Department of Statistics, 1990.
    Dissertation: Statistical Analysis for Doubly Censored Data.

13. Xiao Ou Shu, Division of Epidemiology, 1992.
    Dissertation: Obesity, Diet, Physical Activity, and the Risk of Endometrial Cancer

14. Jeanne Marie Courval, Division of Epidemiology, 1992.
    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.

16. Dawn Misra, Division of Epidemiology, 1993.
    Dissertation: The Effect of Hypertensive Disorders of Pregnancy Upon Fetal Growth.

17. Dale Cindy Hesdorffer, Division of Epidemiology, 1993.
    Dissertation: Cryptogenic Unprovoked Seizures in the Elderly: A Case-Control Study of Cerebrovascular Disease Risk Factors.

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

19. Shu-Lin Cheng, Division of Biostatistics, 1993.
    Dissertation: Nonparametric Analysis of Data Obtained Under Case-Cohort Design.

20. Cecilia Anne Hale, Division of Biostatistics, 1994.
    Dissertation: Non-null Inferences about Kappa.

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

22. Emilia Bagiella, Division of Biostatistics, 1997.
    Dissertation: Estimating a Survival Distribution from Case-Control Family Data.

23. Haiying Zhang, Division of Biostatistics, 1998.
    Dissertation: Nonparametric Method for Longitudinal Studies with Dropout.

24. Xiaoping Hu, Division of Biostatistics, 1998.
    Dissertation: Survival Analysis for Competing Risks Models

25. Susan Teitelbaum, Division of Epidemiology, 2000.
    Dissertation: Reported Residential Pesticide Use and Breast Cancer on Long Island, NY.

26. Dong Xu, Department of Biostatistics, 2001.
    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.

30. Nancy Mervish, Department of Epidemiology, 2003.
    Dissertation: Lifestyle factors, ovarian response & conception in infertile women.

31. Alexander Kiss, Department of Biostatistics, 2004.
    Dissertation: Hierarchical Models: What the Data Are Really Telling Us.

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.
    Dissertation: Variance Estimation of the Cross Validation Estimator of the Generalization Error.

35. Hye-Seung Lee, Department of Biostatistics, 2006.
    Dissertation: Familial Correlation Analysis Using Regression Models.

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.
    Dissertation: Handling Missing Data in Regression Without Specifying Auxiliary Models.

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.

41. Alan C. Fisher, Division of Biostatistics, 1984.
    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.

45. Chin-Lin Tseng, Department of Biostatistics, 2001.
    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

1. "Compound Multinomial Likelihood Functions are Unimodal,"
   presented at ASA–Biometric Society–IMS meetings in Atlanta, GA (August 1975).
2. Discussant for section on Categorical Data Analysis at IMS meetings in
   Chapel Hill, NC (April 1977).
3. "Sequential Medical Trials,"
   IMS meetings in New Brunswick, NJ (May 1978).
4. "On Extending Bock's Model of Logistic Regression,"
   American Public Health Association meetings in Detroit, MI (October 1980).
5. "Remember the Dominating Measure in your Logistic Regression Programs,"
   Northern NJ Chapter of ASA Symposium on the Analysis of Discrete Data
   Morristown, NJ (May 1981).
6. "Urn Models for Regression Analysis,"
   ORSA/TIMS meetings in San Diego, CA (October 1982).
7. "The Use of Cusum Procedures in Spontaneous Abortion Epidemiology,"
   Columbia Statistics Day Conference (April 1983).
8. "Empirical Bayes Methods for Non–identically Distributed Clusters of Binary Observations,"
   Workshop on Statistical Methods in Animal Studies, Columbia University (October 1984).
9. Panelist in "The Statistician in Court: A Mock Trial," for the Panel on Statistical Assessments as Evidence in the Courts of the Committee on National Statistics and the Committee on Research on Law Enforcement and the Administration of Justice, National Academy of Sciences,
   Joint Statistical Meetings in Las Vegas, NV (August 1985).
10. "The Geometric Cusum Procedure is More Efficient Than the Sets Procedure,"
    Department of Statistics, Columbia University, New York, NY
    (October, 1995).
11. "On the Unreasonable Effectiveness of a Biased Logistic Regression Procedure in the Analysis of Pair Matched Case–Control Data,"
    Department of Statistics, Columbia University, New York, NY (March, 1996).
12. "Building on SMRP." Invited lecture for the Joseph L. Fleiss Memorial Session,
    Joint Statistical Meetings, Minneapolis, MN (August, 2005).
13. "The Risk-Based Allocation Design in Evaluation Research." Invited speaker,
    Symposium on Community Collaborative Research: Interdisciplinary, Conceptual, and Methodological Approaches, Columbia University School of Social Work, New York (May, 2009).
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
1983	Consultant and coauthor with M.O. Finkelstein and H. Robbins on Equal Employment Opportunity Commission Amicus Brief to the United States Court of Appeals for the Fourth Circuit, in EEOC, Cooper, Moore and Hannah *v*. Federal Reserve Bank of Richmond 698 F.2d 633 (4th Cir. 1983)
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.
1995–present	Senior Statistical Consultant for the Collaborative Trials of the Warfarin and Aspirin Recurrent Stroke 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*. Diapolis 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 lititgation:

A. Cases in which I testified in court:

1. Hupart vs. Board of Higher Education of the City of New York
   420 F. Supp. 1087
   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).

4. Novotny vs. Great American Federal Savings and Loan Assoc.
   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).

9. U.S. Dept. of Labor vs. Harris Trust and Savings Bank (78–OFCCP–2)
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).

12. Boylan vs. New York Times Co. (74 Civ 4891)
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
Attorney: Frederic L. Gordon and Palma Cesar Hooper,
Thorsnes, Bartolotta, McGuire & Padilla, San Diego
(1996; on behalf of Foodmaker Inc., in re statistical analysis of foodborne illness outbreak).

14. Craft, et al. v. Vanderbilt, et al.
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.
Attorney: Bruce M. Wexler, of Paul, Hastings, Janofsky & Walker, LLP, New York City, and Bradley A. Harsch and Niall D. Omurchadha of Sullivan & Cromwell, LLP, New York City.
(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 eszopliclone 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:

1. Glick, S.D., Jarvik, M.E., Levin, B. and Carley, J.L. (1970). An Automatic Multiple Choice Test of Short–Term Spatial Memory for Monkeys. *Journal of Experimental Analysis of Behavior* 13:317–318.

2. Glick, S.D., Levin, B. and Jarvik, M.E. (1970). Role of Monkeys' Spatial Preferences in Performance of a Non–spatial Task. *Journal of Comparative and Physiological Psychology* 73:56–61.

3. *Levin, B. and Reeds, J. (1977). Compound Multinomial Likelihood Functions are Unimodal: Proof of a Conjecture of I.J. Good. *Annals of Statistics* 5:79–87.

4. Hirschfeld, L., Howe, J. and Levin, B. (1978). Warfare, Infanticide, and Statistical Inference: A Comment on Divale and Harris. *American Anthropologist* 89:110–115.

5. Kline, J., Levin, B., Stein, Z.A., Susser, M.N. and Warburton, D. (1980). Epidemiologic Detection of Low Dose Effects on the Developing Fetus. *Proceedings of the First Annual Symposium on Environmental Epidemiology*, Pittsburgh, PA.

6. Lai, T.L., Levin, B., Robbins, H. and Siegmund, D. (1980). Sequential Medical Trials. *Proceedings of the National Academy of Sciences USA* 77(6):3135–3138.

7. *Levin, B. and Shrout, P.E. (1981). On Extending Bock's Model of Logistic Regression in the Analysis of Categorical Data. *Communications in Statistics* A10(2):125–147.

8. *Levin, B. (1981). A Representation for Multinomial Cumulative Distribution Functions. *Annals of Statistics* 9(5):1123–1126.

9. *Levin, B. and Robbins, H. (1981). Selecting the Highest Probability in Binomial or Multinomial Trials. *Proceedings of the National Academy of Sciences USA* 78(8):4663–4666.

10. *Levin, B. (1982). On the Accuracy of a Normal Approximation to the Power of the Mantel–Haenszel Procedure. *Journal of Statistical Computation and Simulation* 14(3):210–218.

11. Robbins, H. and Levin, B. (1983). A Note on the Underadjustment Phenomenon. *Statistics and Probability Letters* 1:137–139.

12. *Levin, B. (1983). On Calculations Involving the Maximum Cell Frequency. *Communications in Statistics*, special edition on the Analysis of Categorical Data, 12(11):1299–1327.

13. Kline, J., Levin, B., Shrout, P.E., Stein, Z.A., Susser, M.N. and Warburton, D. (1983). Maternal Smoking and Trisomy in Spontaneously Aborted Conceptions. *American Journal of Human Genetics* 35(3):421–431.

14. *Levin, B. and Robbins, H. (1983). Urn Models for Regression Analysis with Applications to Employment Discrimination Studies. *Law and Contemporary Problems* 46(4):247–267.

15. *Levin, B. (1984). On a Sequential Selection Procedure of Bechhofer, Kiefer, and Sobel. *Statistics and Probability Letters* 2(2):91–94.

16. *Levin, B. (1984). Simple Improvements on Cornfield's Approximation to the Mean of a Non–central Hypergeometric Random Variable. *Biometrika* 71(3):630–632.

17. *Levin, B. and Kline, J. (1984). Letter to the Editor Re: "The Detection of Disease Clustering in Time." *Biometrics* 40:1179–1180.

18. Levin, B. and Fleiss, J.L. (1985). Letter to the Editor Re: "Interpreting Multiple Logistic Regression Coefficients in Prospective Observational Studies." *American Journal of Epidemiology* 122(2):348.

19. *Levin, B. and Kline, J. (1985). The Cusum Test of Homogeneity with an Application in Spontaneous Abortion Epidemiology. *Statistics in Medicine* 4:469–488.

20. Weinstein, G.S. and Levin, B. (1985). The Coronary Artery Surgery Study (CASS): A Critical Appraisal. *Journal of Thoracic and Cardiovascular Surgery* 90:541–548.

21. Simberloff, D. and Levin, B. (1985). Predictable Sequences of Species Loss with Decreasing Island Area – Land Birds in Two Archipelagoes. *New Zealand Journal of Ecology* 8:11–20.

22. *Levin, B. (1987). Conditional Likelihood Analysis in Stratum–Matched Retrospective Studies with Polytomous Disease States. *Communications in Statistics* B16(3):699–718.

23. Evans, D., Clark, N.M., Feldman, C.H., Rips, J., Kaplan, D., Levison, M.J., Wasilewski, Y., Levin, B., and Mellins, R.B. (1987). A School Health Education Program for Children with Asthma Aged 8–11 Years. *Health Education Quarterly* 14(3):267–279.

24. Evans, D., Levison, M.J., Feldman, C.H., Clark, N.M., Wasilewski, Y., Levin, B., and Mellins, R.B. (1987). The Impact of Passive Smoking on Emergency Room Visits of Urban Children with Asthma. *American Review of Respiratory Diseases* 135:567–572.

25. Zybert, P. and Levin, B. (1987). Selecting the Highest of Three Binomial Probabilities. *Proceedings of the National Academy of Sciences USA* 84:8180–8184.

26. *Levin, B. (1988). Letter to the Editor Re: "Polychotomous Logistic Regression Methods for Matched Case–Control Studies with Multiple Case or Control Groups." *American Journal of Epidemiology* 128:446.

27. Fleiss, J.L. and Levin, B. (1988). Sample Size Determination in Studies with Matched Pairs. *Journal of Clinical Epidemiology* 41(8):727–730.

28. Weinstein, G.S. and Levin, B. (1989). The Effect of Crossover on the Statistical Power of Randomized Studies. *Annals of Thoracic Surgery* 48:490–495.

29. Weinstein, G.S. and Levin, B. (1990). Letter to the Editor Re: "Crossovers in Coronary Artery Bypass Grafting Trials." *Annals of Thoracic Surgery* 49:847–848.

30. Hatch, M., Kline, J., Levin, B., Hutzler, M., and Warburton, D. (1990). Paternal Age and Trisomy Among Spontaneous Abortions. *Human Genetics* 85:335–361.

31. *Levin, B. and Kong, F. (1990). Bartlett's Bias Correction to the Profile Score Function is a Saddlepoint Correction. *Biometrika* 77(1):219–221.

32. *Levin, B. (1990). The Saddlepoint Correction in Conditional Logistic Likelihood Analysis. *Biometrika* 77(2):275–285.

33. Kline, J., Hutzler, M., Levin, B., Stein, Z., Susser, M., and Warburton, D. (1991). Marijuana and Spontaneous Abortion of Known Karyotype. Pae*diatric and Perinatal Epidemiology* 5:320–332.

34. Kline, J., Levin, B., Silverman, J., Kinney, A., Stein, Z., Susser, M., and Warburton, D. (1991) Caffeine and Spontaneous Abortion of Known Karyotype. *Epidemiology* 2:409–417.

35. *Levin, B. (1991). Re: "Interpretation and Choice of Effect Measures in Epidemiologic Analyses." *American Journal of Epidemiology* 133:963–964.

36. *Levin, B. (1992). In re: "Siobhan's Problem: The Coupon Collector Revisited." *The American Statistician* 46:76.

37. Olson, S.H., Kelsey, J.L., Pearson, T.A., and Levin, B. (1992)
Evaluation of Random Digit Dialing as a Method of Control Selection in Case–Control Studies. *American Journal of Epidemiology* 135:210–222.

38. *Levin, B. (1992)
Tests of Odds Ratio Homogeneity with Improved Power in Sparse Fourfold Tables. *Communications in Statistics* 21(6):1469–1500.

39. *Kline, J. and Levin, B. (1992)
Trisomy and Age at Menopause: Predicted Associations Given a Link with Rate of Oocyte Atresia. *Paediatric and Perinatal Epidemiology* 6(2):225–239.

40. Westhoff, C., Levin, B., Ladd, G., and O'Connor, J. (1992)
Sources of Variability in Normal CA 125 Levels.
Cancer Epidemiology, Biomarkers & Prevention 1:357–359.

41. Kline, J., Levin, B., Stein, Z., Warburton, D., and Hindin, R. (1993)
Cigarette Smoking and Trisomy 21 at Amniocentesis.
Genetic Epidemiology 10:35–42.

42. Hatch, M.C., Shu, X.–O., McLean, D.E., Levin, B., Begg, M., Reuss, L., and Susser, M. (1993)
Maternal Exercise during Pregnancy, Physical Fitness, and Fetal Growth.
American Journal of Epidemiology 137(10):1105–1114.

43. Hatch, M.C., Chen, C.–J., Levin, B., Ji, B.–T., Yang, G.–Y., Hsu, S.–W., Wang, L.–W., Hsieh, L.–L., and Santella, R. (1993)
Urinary Aflatoxin Levels, Hepatitis–B Virus Infection and Hepatocellular Carcinoma in Taiwan. *International. Journal of Cancer* 54:931–934.

44. Kairam, R., Kline, J., Levin, B., Brambilla, D., Coulter, D., Kuban, K., Lansky, L., Marshall, P., Velez–Borras, J., and Rodriguez, E. (1993). Reliability of Neurologic Assessment in a Collaborative Study of HIV Infection in Children.
Annals of the New York Academy of Sciences 693:123–140.

45. *Finkelstein, M.O. and Levin, B. (1994)
Proportional Hazard Models for Age Discrimination Cases.
Jurimetrics Journal 34:153–171.

46. Olson, S., Kelsey, J.L., Pearson, T.A., and Levin, B. (1994)
Characteristics of a Hypothetical Group of Hospital Controls for a Case–Control Study. *American Journal of Epidemiology* 139(3):302–311.

47. Kline, J., Levin, B., Silverman, J., Kinney, A., Stein, Z., Susser, M., and Warburton, D. (1994).
Letter to the Editor: in re 270:2940 and 270:2973,
Journal of the American Medical Association 272(1):27–28.

48. *Levin, B. (1995)
Accounting for the Effects of Both Group– and Individual–Level Variables in Community–Level Studies. (Annotation)
American Journal of Public Health 85(2):163–164.

49. Kline, J., Levin, B., Kinney, A., Stein, Z., Susser, M., and Warburton, D. (1995).
Cigarette Smoking and Spontaneous Abortion of Known Karyotype: Precise Data but Uncertain Inferences. *American Journal of Epidemiology* 141:417–427.

50. Reuss, M.L., Kline, J., Santos, R., Levin, B., and Timor–Tritsch, I. (1996).
Age and the Ovarian Follicle Pool Assessed with Transvaginal Sonography.
American Journal of Obstetrics and Gynecology 174:624–627.

51. *Levin, B. (1996).
On the Holms, Simes, and Hochberg Multiple Test Procedures. (Annotation)
American Journal of Public Health 86:628–629.

52. *Finkelstein, M.O., Levin, B., and Robbins, H. (1996).
Clinical and Prophylactic Trials with Assured New Treatment for Those at Greater Risk. Part I –– Introduction.
American Journal of Public Health 86:691–695.

53. *Finkelstein, M.O., Levin, B., and Robbins, H. (1996).
Clinical and Prophylactic Trials with Assured New Treatment for Those at Greater Risk. Part II –– Examples.
American Journal of Public Health 86:696–705.

54. Kong, F. and Levin, B. (1996).
Edgeworth Expansions for the Conditional Distributions in Logistic Regression Models. *Journal of Statistical Planning and Inference* 52:109–129.

55. Wang, L.–Y., Hatch, M., Chen, C.–J., Levin, B., You, S.–L., Lu, S.–N., Wu, M.–H., Wu, W.–P., Wang, L.–W., Wang, Q., Huang, G.–T., Yang, P.–M., Lee, H.–S., and Santella, R. (1996).
Aflatoxin Exposure and the Risk of Hepatocellular Carcinoma in Taiwan.
International Journal of Cancer 67:620–625.

56. Wasilewski, Y., Clark, N., Evans, D., Levison, M., Levin, B., and Mellins, R. (1996).
Factors Associated with Emergency Department Visits by Children with Asthma: Implications for Health Education.
American Journal of Public Health 86:1410–1415.

57. Mittelman, M.S., Ferris, S.H., Shulman, E., Steinberg, G., and Levin, B. (1996).
A Family Intervention to Delay Nursing Home Placement of Patients with Alzheimer Disease: A Randomized Controlled Trial.
Journal of the American Medical Association 276:1725–1731.

58. Gammon, M., Wolff, M., Neugut, A., Terry, M., Britton, J., Greenebaum, E., Hibshoosh, H., Levin, B., Wang, Q., and Santella, R. (1996).
Treatment for Breast Cancer and Blood Levels of Chlorinated Hydrocarbons.
Cancer Epidemiology, Biomarkers, and Prevention 5:467–471.

59. Gammon, M.D., Wolff, M.S., Neugut, A.I., Terry, M.B., Papadopoulos, K., Levin, B., Wang, Q., and Santella, R. (1997).
Temporal Variation in Chlorinated Hydrocarbons in Healthy Women.
Cancer Epidemiology, Biomarkers, and Prevention 6:327–332.

60. Evans, D., Mellins, R., Lobach, K., Ramos–Bonoan, C., Pinkett–Heller, M., Wiesemann, S., Klein, I., Donahue, C., Burke, D., Levison, M., Levin, B., Zimmerman, B., and Clark, N. (1997).
Improving Care for Minority Children with Asthma: Professional Education in Public Health Clinics
Pediatrics 99:157–164.

61. *Finkelstein, M.O. and Levin, B. (1997).
Clear Choices and Guesswork in Peremptory Challenges in Federal Criminal Trials.
Journal of the Royal Statistical Society, Series A 160 (Part 2):275–288.

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.

63. Aviv, J.E., Sacco, R.L., Mohr, J.P., Thompson, J.L.P., Levin, B., Sunshine, S., Thomson, J., and Close, L.G. (1997).
Laryngopharyngeal Sensory Testing with Modified Barium Swallow as Predictors of Aspiration Pneumonia After Stroke.
Laryngoscope 107:1254–1260.

64. *Levin, B. (1997).
A Lower Bound for the Mantel–Haenszel One Degree of Freedom Chi–squared Statistic in 1:m Matched Samples.
The American Statistician 51:318–320.

65. Bigger, J.T., Parides, M.K., Rolnitzky, L.M., Meier, P., Levin, B., and Egan, D.A. (1998). Changes in Sample Size and Length of Follow–up to Maintain Power in the Coronary Artery Bypass Graft (CABG) Patch Trial.
Controlled Clinical Trials 19:1–14.

66. Hatch, M., Levin, B., Shu, X.–O., and Susser, M. (1998).
Maternal Exercise During Pregnanacy, Physical Fitness, and Timely Delivery.
American Journal of Public Health 88:1528–1533.

67. Marshall, R.S., Lazar, R.M., Mohr, J.P., Pile-Spellman, J., Hacein-Bey, L., Duong, D.H., Joshi, S., Chen, X., Levin, B., and Young, W.L. (1999).
Higher Cerebral Function and Hemispheral Blood Flow During Awake Carotid Artery Balloon Test Occlusions.
Journal of Neurology, Neurosurgery, and Psychiatry 66:734-738.

68. *Levin, B. and Chen, X. (1999).
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.

69. Mohr, J.P. for The Arteriovenous Malformation Study Group (1999).
Arteriovenous Malformations of the Brain in the Adult.
The New England Journal of Medicine 340(23):1812-1818.

70. *Leu, C.-S. and Levin, B. (1999).
On the Probability of Correct Selection in the Levin-Robbins Sequential Elimination Procedure. *Statistica Sinica* 9(3):879-891.

71. *Rottman, J.N., Levin, B., Paik, M.C., Tsai, W.-Y., and Bigger, J.T. (1999).
Using Missing Data Techniques to Explore the Lack of Survival Effect: Illustration with The CABG Patch Trial. *Statistics in Medicine* 18(15):1943-1959.

72. Varasteh, N.N., Neuwirth, R.S., Levin, B., Keltz, M.D. (1999).
Pregnancy Rates After Hysteroscopic Polypectomy and Myomectomy in Infertile Women. *Obstetics and Gynecology* 94:168-171.

73. Leu, C.-S. and Levin, B. (1999).
Proof of a Lower Bound Formula for the Expected Reward in the Levin-Robbins Sequential Elimination Procedure. *Sequential Analysis* 18(2):81-105.

74. Kline, J., Kinney, A., Levin, B., Mayeux, R., Schupf, N., and Warburton, D. (2000). Alzheimer's Disease in the Parents of Women with Trisomic Spontaneous Abortions. *Neuroreport* 11(4):795-799.

75. Kuhn, L., Kline, J., Ng, S., Levin, B., and Susser, M. (2000) Cocaine Use during Pregnancy and Intrauterine Growth Retardation: New Insights Based on Maternal Hair Tests. *American Journal of Epidemiology* 152(2):112-119.

76. Kline, J., Kinney, A., Levin, B., and Warburton, D. (2000) Trisomic Pregnancy and Earlier Age at Menopause. *American Journal of Human Genetics* 67:395-404.

77. Evans, D., Clark, N., Levison, M.J., Levin, B., and Mellins, R.B. (2001) Can Children Teach Their Parents About Asthma?" *Health Education & Behavior* 28(4):500-511.

78. Sacco, R.L., DeRosa, J.T., Haley, E.C., Levin, B., Ordronneau, P., Phillips, S.J., Rundek, T., Snipes, R.G., and Thompson, J.L.P., for the GAIN Americas Investigators (2001). Glycine Antagonist in Neuroprotection for Patients with Acute Stroke. GAIN Americas: A Randomized Trial. *Journal of the American Medical Association* 285:1719-1728.

79. *Levin, B. and Paik, M.C. (2001). The Unreasonable Effectiveness of a Biased Logistic Regression Procedure in the Analysis of Pair–Matched Case–Control Studies. *Journal of Statistical Planning and Inference* 96:371-385.

80. Mohr, J.P., Thompson, J.L.P., Lazar, R.M., Levin, B., Sacco, R.L., Furie, K.L., Kistler, J.P., Albers, G.W., Pettigrew, L.C., Adams, H.P., Jackson, C.M., and Pullicino, P., for the Warfarin-Aspirin Recurrent Stroke Study Group (2001). A comparison of Warfarin and Aspirin for the Prevention of Recurrent Ischemic Stroke. *The New England Journal of Medicine* 345(20):1444-1451.

81. Ehrhardt, A.A., Exner, T.M., Hoffman, S., Silberman, I., Leu, C.-S., Miller, S., and Levin, B. (2002). A Gender-Specific HIV/STD Risk Reduction Intervention for Women in a Health Care Setting: Short- and Long-term Results of a Randomized Clinical Trial. *AIDS Care* 14(2):147-161.

82. Mohr, J.P., Thompson, J.L.P., and Levin, B. (2002). Letter to the Editor re: Warfarin or Aspirin for Recurrent Ischemic Stroke. *New England Journal of Medicine* 346(15):1170-1171.

83. Homma, S., Sciacca, R.R., Di Tullio, M.R., Thompson, J.L., Levin, B., Sacco, R.L., and Mohr, J.P. (2002). Response to "Patent Foramen Ovale and Cryptogenic Stroke: The Controversy Continues" (Letter).
Circulation 105(22):2625-2631.

84. Silverman, R.A., Osborn, H., Runge, J., Gallagher, E.J., Chiang, W., Feldman, J., Gaeta,, T., Freeman, K., Levin, B., Mancherje, N., and Scharf, S., for the Acute Asthma/Magnesium Study Group. (2002).
IV Magnesium Sulfate in the Treatment of Acute Severe Asthma. *Chest* 122:489-497.

85. Gammon, M.D., Neugut, A.I., Santella, R.M., Teitelbaum, S.L., Britton, J.A., Terry, M.B., Eng, S.M., Wolff, M.S., Stellman, S.D., Kabat, G.C., Levin, B., Bradlow, H.L., Hatch, M., Beyea, J., Camann, D., Trent, M., Senie, R., Garbowski, G., Maffeo, C., Montalvan, P., Berkowitz, G., Kemeny, M., Citron, M., Schnabel, F., Schuss, A., Hajdu, S., Vinceguerra, V., Collman, G.W., and Obrams, G.I. (2002).
The Long Island Breast Cancer Study Project: Description of a Multi-Institutional Collaboration to Identify Environmental Risk Factors for Breast Cancer.
Breast Cancer Research and Treatment 74(3):235-254.

86. Gammon, M.D., Santella, R.M., Neugut, A.I., Eng, S.M., Teitelbaum, S.L., Paykin, A., Levin, B., Terry, M.B., Young, T.L., Wang, L.W., Wang, Q., Britton, J.A., Wolff, M.S., Stellman, S.D., Hatch, M., Kabat, G.C., Senie, R., Garbowski, G., Maffeo, C., Montalvan, P., Berkowitz, G., Kemeny, M., Citron, M., Schnabel, F., Schuss, A., Hajdu, S., and Vinceguerra, V. (2002).
Environmental Toxins and Breast Cancer on Long Island. I. Polycyclic Aromatic Hydrocarbon DNA Adducts.
Cancer Epidemiology Biomarkers & Prevention 11:677-685.

87. Gammon, M.D., Wolff, M.S., Neugut, A.I., Eng, S.M., Teitelbaum, S.L., Britton, J.A., Terry, M.B., Levin, B., Stellman, S.D., Kabat, G.C., Hatch, M., Senie, R., Berkowitz, G., Bradlow, H.L., Garbowski, G., Maffeo, C., Montalvan, P., Kemeny, M., Citron, M., Schnabel, F., Schuss, A., Hajdu, S., Vinceguerra, V., Niguidula, N., Ireland, K., and Santella, R.M. (2002).
Environmental Toxins and Breast Cancer on Long Island. II. Organochlorine Compound Levels in Blood.
Cancer Epidemiology Biomarkers & Prevention 11:686-697.

88. *Levin, B., Robbins, H., and Zhang, C.-H. (2002).
Mathematical Aspects of Estimating Two Treatment Effects and a Common Variance in an Assured Allocation Design.
Journal of Statistical Planning and Inference (Special Issue in Honor or C.R. Rao) 108(1-2):255-262.

89. Finkelstein, M.O. and Levin, B. (2003).
On the Probative Value of Evidence from a Screening Search.
Jurimetrics 43(3):265-290.

90. The APASS Investigators. (2004).
Antiphospholipid Antibodies and Subsequent Thrombo-occlusive Events in Patients with Ischemic Stroke.
Journal of the American Medical Association 291:576-584.

91. *Finkelstein, M.O. and Levin, B. (2004).
Bush v. Gore: Two Neglected Lessons from a Statistical Perspective.
Jurimetrics 44:181-199.

92. Kline, J., Kinney, A., Reuss, M.L., Kelly, A., Levin, B., Ferin, M., and Warburton, D. (2004).
Trisomic pregnancy and the oocyte pool.
Human Reproduction 19(7):1633-1643.

93. Warburton, D., Dallaire, L., Thangavelu, M., Ross, L., Levin, B., and Kline, J. (2004).
Trisomy Recurrence: A Reconsideration Based on North American Data.
American Journal of Human Genetics 75: 376-385.

94. Phelan, J.C., Link, B.G., Diez-Roux, A., Kawachi, I., and Levin, B. (2004).
"Fundamental Causes" of Social Inequalities in Mortality: A Test of the Theory.
Journal of Health and Social Behavior 45:265-285.

95. *Levin, B. (2004).
Statistical Issues.
Amyotrophic Lateral Sclerosis and other Motor Neuron Disorders 5 (Supp. 1):43-45.

96. Markatou, M. and Levin, B. (2004). Comment. *Statistical Science* 19(3):409-410. [Commenting on: Lindsay, B. G., Kettenring, J. and Siegmund, D. O. (2004), A report on the future of Statistics (with discussion), *Statistical Science*, 19(3):387-413.]

97. Gammon, M.D., Sagiv, S.K., Eng, S.M., Shantakumar, S., Gaudet, M.M., Teitelbaum, S.L., Britton, J.A., Terry, M.B., Wang, L.W., Wang, Q., Stellman, S.D., Beyea, J., Hatch, M., Kabat, G.C., Wolff, M.S., Levin, B., Neugut, A.I., and Santella, R.M. (2004). Polycyclic aromatic hydrocarbons (PAH)-DNA adducts and breast cancer: a pooled analysis.
Archives of Environmental Health 59(12):640-649.

98. Kaufmann, P., Levy, G., Thompson, J.L.P., DelBene, M., Battista, V., Gordon, P.H., Rowland, L.P., Levin, B., and Mitsumoto, H. (2005).
The ALSFRSr Predicts Survival Time in an ALS Clinic Population.
Neurology 64:38-43.

99. Haley, E.C., Thompson, J.L.P., Levin, B., Davis, S., Lees, K., Pittman, J.G., DeRosa, J.T., Ordronneau, P., Brown, D.L., and Sacco, R.L., for the GAIN Americas and GAIN International Investigators (2005).
Gavestinel Does Not Improve Outcome Following Acute Intracerebral Hemorrhage: An Analysis From the GAIN International and GAIN Americas Studies.
Stroke 36:1006-1010.

100. Finkelstein, M.O. and Levin, B. (2005).
Compositional Analysis of Bullet Lead as Forensic Evidence.
Journal of Law and Policy 13(1):119-142.

101. Shantakumar, S., Gammon, M.D., Eng, S., Sagiv, S.K., Gaudet, M.M., Teitelbaum, S.L., Britton, J.A., Terry, M.B., Paykin, A., Young, T.L., Wang, L.W., Wang, Q., Stellman, S.D., Beyea, J., Hatch, M., Camann, D., Prokopczyk, B., Kabat, G.C., Levin, B., Neugut, A.I., and Santella, R.M. (2005).
Residential Environmental Exposures and other Characteristics Associated with Detectable PAH-DNA Adducts in Peripheral Mononuclear Cells in a Population-Based Sample of Adult Females.
Journal of Exposure Analysis and Environmental Epidemiology 15:482-490.

102. Kline, J., Kinney, A., Kelly, A., Reuss, M.L., and Levin, B. (2005).
Predictors of Antral Follical Count During the Reproductive Years.
Human Reproduction 20:2179-2189.

103. Kinney, A., Kline, J., Levin, B. (2005). Alcohol, caffeine and smoking in relation to age at menopause. *Maturitas* 54:27-38.

104. Sacco, R.L., Prabhakaran, S., Thompson, J.L.P., Murphy, A., Sciacca, R.R., Levin, B., Mohr, J.P., on behalf of the WARSS investigators (2006).
Comparison of Warfarin versus Aspirin for the Prevention of Recurrent Stroke or Death: Subgroup Analyses from The Warfarin-Aspirin Recurrent Stroke Study.
Cerebrovascular Diseases 22:4-12.

105. Pullicino, P., Thompson, J.L.P., Barton, B., Levin, B., Graham, S., and Freudenberger, R.S., on behalf of the WARCEF investigators (2006).
Warfarin Versus Aspirin in Patients with Reduced Cardiac Ejection Fraction (WARCEF): Rationale, Objectives, and Design.
Journal of Cardiac Failure 12:39-46.

106. Kline, J., Kinney, A., Levin, B., Kelly, A., Chih-Yu, J., Brown, S., and Warburton, D. (2006). X-chromosome Inactivation and Ovarian Age During the Reproductive Years. *Fertility and Sterility* 85:1488-1495.

107. *Levy, G., Kaufmann, P., Buchsbaum, R., Montes, J., Barsdorf, A., Arbing, R., Battista, V., Zhou, X., Mitsumoto, H., Levin, B., Thompson, J.L.P. (2006). A Two-stage Design for a Phase II Clinical Trial of Coenzyme Q10 in ALS. *Neurology* 66:660-663.

108. *Levin, B., Thompson, J.L.P., Levy, G., Mitsumoto, H., and Kaufmann, P. (2006). Pentoxifylline in ALS: A double-blind, randomized, multicenter, placebo-controlled trial (letter). *Neurology* 66:1786-1787.

109. *Finkelstein, M.O., Levin, B., McKeague, I.W., and Tsai, W.-Y. (2006). A Note on the Censoring Problem in Empirical Case-Outcome Studies. *Journal of Empirical Legal Studies* 3(2):375-395.

110. *Finkelstein, M.O. and Levin, B. (2006). A comment on bullet lead identification and screening searches. *Jurimetrics* 47:89-97.

111. Cheung, Y.K., Gordon, P.H., and Levin, B. (2006). Selecting promising ALS therapies in clinical trials. *Neurology* 67:1748-1751.

112. Kaufmann, P., Levy, G., Montes, J., Buchsbaum, R., Barsdorf, M.A., Battista, V., Arbing, R., Gordon, P.H., Mitsumoto, H., Levin, B., and Thompson, J.L.P. (2007). Excellent inter-rater, intra-rater, and telephone-administered reliability of the ALSFRS-R in a multicenter clinical trial. *Amyotrophic Lateral Sclerosis* 8:42-46.

113. Teitelbaum, S.L., Gammon, M.D., Britton, J.A., Neugut, A.I., Levin, B., and Stellman, S.D. (2007). Reported Residential Pesticide Use and Breast Cancer Risk on Long Island, NY. *American Journal of Epidemiology* 165(6):643-651.

114. Kinney, A., Kline, J., Kelly, A., Reuss, M.L., and <B>Levin, B.</B> (2007). Smoking, alcohol and caffeine in relation to ovarian age during the reproductive years. *Human Reproduction* 22:1175-1185.

115. Mitsumoto, H., Uluğ, A.M., Pullman, S.L., Gooch, C.L., Chan, S., Tang, M.-X., Mao X., Hays, A.P., Floyd, B.A. Battista, V., Montes, J., Hayes, S., Dashnaw, S., Kaufmann, P., Gordon, P.H., Hirsch, J., Levin, B., Rowland, L.P., and Shungu, D.C. (2007). Quantitative Objective Markers for Upper and Lower Motor Neuron Dysfunction in Amyotrophic Lateral Sclerosis.
Neurology 68:1402-1410.

116. Morin, S.F., Chesney, M.A., Ehrhardt, A.A., Kelly, J.A., Pequegnat, W., Rotheram-Borus, M.J., Afifi, A.A., Benotsch, E.G., Brondino, M.J., Catz, S.L., Charlebois, E.D., Cumberland, W.G., DesJarlais, D.C., Duan, N., Exner, T.M., Goldstein, R.B., Gore-Felton, C., Hirky, A.E., Johnson, M.O., Kertzner, R.M., Kirshenbaum, S.B., Kittel, L.E., Klitzman, R., Lee, M., Levin, B., Lightfoot, M., Pinkerton, S.D., Remien, R.H., Rhodes, F., Song, J., Steward, W.T., Tross, S., Weinhardt, L.S., Weiss, R., Wolfe, H., Wolfe, R., Wong, F.L., Batterham, P., Comulada, W.S., Rogers, T., Zhao, Y., Correale, J., Hackl, K., Hong, D., Huchting, K., Mickalian, J.D., Peterson, M., Gordon, C.M., Rausch, D., and Stover, E. (2007).
Effects of a Behavioral Intervention to Reduce Risk of Transmission among People Living with HIV: The Healthy Living Project Randomized Controlled Study.
Journal of Acquired Immune Deficiency Syndromes 44(2):213-221.

117. *Levin, B. and Leu, C.-S. (2007).
A Comparison of Two Procedures to Select the Best Binomial Population with Sequential Elimination of Inferior Populations.
Journal of Statistical Planning and Inference 137(1):245-263.

118. *Leu, C.-S. and Levin, B. (2008).
A Generalization of the Levin-Robbins Procedure for Binomial Subset Selection and Recruitment Problems. *Statistica Sinica* 18: 203-218.

119. *Finkelstein, M.O. and Levin, B. (2008).
Re "Barrett, Bruce E. (2007), Detecting Bias in Jury Selection, The American Statistician 61, 296-301" (Letter to the Editor).
The American Statistician 62(1):95.

120. *Leu, C.-S. and Levin, B. (2008).
On a Conjecture of Bechhofer, Kiefer, and Sobel for the Levin-Robbins-Leu Binomial Subset Selection Procedures. *Sequential Analysis* 27:106-125.

121. Gordon, P.H., Cheung, Y.-K., Levin, B., Andrews, H., Doorish, C., Macarthur, R.B., Montes, J., Bednarz, K., Florence, J., Rowin, J., Boylan, K., Mozaffar, T., Tandan, R., Mitsumoto, H., Kelvin, E.A., Chapin, J., Bedlack, R., Rivner, M., McCluskey, L., Pestronk, A., Graves, M., Sorenson, E., Barohn, R.J., Belsh, J.M., Lou, J.-S., Levine, T., Saperstein, D., Miller, R.G., Scelsa, S.N., and the Combination Drug Selection Trial Study Group (2008).
A Novel, Efficient, Randomized Selection Trial Comparing Combinations of Drug Therapy for ALS. *Amyotrophic Lateral Sclerosis* 9(4):212-222.

122. Pullicino P., Thompson, J.L.P., Mohr, J.P., Sacco, R.L., Freudenberger, R., Levin, B., and Homma, S. (2008).
Oral Anticoagulation in Patients with Cardiomyopathy or Heart Failure in Sinus Rhythm. *Cerebrovascular Diseases* 26:322-327.

123. *Gordon, P.H., Cheung, Y.-K., Levin, B., Andrews, H., and Mitsumoto, H. (2009).
Response to 'Commentary on a novel, efficient, randomized selection trial comparing combinations of drug therapy for ALS' (Letter to the Editor).
Amyotrophic Lateral Sclerosis 10(1):61.

124. Buchsbaum, R., Kaufmann, P., Barsdorf, A.I., Arbing, R., Montes, J., and Thompson, J.L.P. for the QALS Study Group (2009).
Web-based Data Management for a Phase II Clinical Trial in ALS.
Amyotrophic Lateral Sclerosis 10(5&6):374-377 (plus an online appendix).

125. Ventuneac, A., Carballo-Diéguez, A., Leu, C.-S., Levin, B., Bauermeister, J., Woodman-Maynard, E., Giguere, R. (2009). Use of a Rapid HIV Home Test to Screen Sexual Partners: An Evaluation of its Possible Use and Relative Risk.
AIDS and Behavior 13(4):731-737.

126. Kaufmann, P., Thompson, J.L.P., Levy, G., Buchsbaum, R., Shefner, J., Krivickas, L.S., Katz, J., Rollins, Y., Barohn, R.J., Jackson, C.E., Tiryaki, E., Lomen-Hoerth, C., Armon, C., Tandan, R., Rudnicki, S.A., Rezania, K., Sufit, R., Pestronk, A., Novella, S.P., Heiman-Patterson, T., Kasarskis, E.J., Pioro, E.P., Montes, J., Arbing, R., Vecchio, D., Barsdorf, A., Mitsumoto, H., and Levin, B.; for the QALS Study Group (2009).
Phase II Trial of CoQ10 for ALS Finds Insufficient Evidence to Justify Phase III.
Annals of Neurology 66:235-244.

127. Warburton, D., Kline, J., Kinney, A., Yu, C.-Y., Levin, B., and Brown, S. (2009).
Skewed X Chromosome Inactivation and Trisomic Spontaneous Abortion: No Association. *American Journal of Human Genetics* 85(2):179-193.

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., Kieburtz, K., Shoulson, I., Kaufmann, P., Khan, J., Simpson, E., Shefner, J., Levin, B., Cwik, V., Schoenfeld, D., McDermott, M.P., Aggarwal, S., and Miller, R. (2010).
Toward More Efficient Clinical Trials for Amyotrophic Lateral Sclerosis.
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.

131. Kline, J., Kinney, A., Levin, B., Kelly, A., Ferin, M., and Warburton, D. (2011) Trisomic Pregnancy and Elevated FSH: Implications for the Oocyte Pool Hypothesis. *Human Reproduction* 26(6):1537–1550.

132. Leu, C.-S., Ventuneac, A., Levin, B., and Carballo-Diéguez, A. (2011).
Use of a Rapid HIV Home Test to Screen Sexual Partners: A Commentary on Ventuneac, Carballo-Diéguez, Leu, et al., 2009. *AIDS and Behavior* 16(1):1-4.

133. *Leu, C.-S., Cheung, Y.-K., and Levin, B. (2011).
Subset selection in comparative selection trials. Chapter 15 in: Bhattacharjee, M., Dhar, S.K., and Subramanian, S. (eds.) *Recent Advances in Biostatistics: False Discovery, Survival Analysis, and Other Topics*. Series in Biostatistics, 4:271-288. World Scientific.

134. *Levin, B., Thompson, J.L.P., Chakraborty, B., Levy, G., MacArthur, R.B., Haley, E.C. (2011). Statistical Aspects of the TNK-S2B Trial of Tenecteplase versus Alteplase in Acute Ischemic Stroke: An Efficient, Dose-Adaptive, Seamless Phase II/III Design. *Clinical Trials* 8:398-407.

135. Devanand, D.P., Mintzer, J., Schultz, S., Sultzer, D., de la Pena, D., Gupta, S., Colon, S., Schimming, C., Pelton, G.H., Andrews, H., and Levin, B. (2012). The Antipsychotic Discontinuation in Alzheimer Disease Trial: Clinical Rationale and Study Design. *American Journal of Geriatric Psychiatry* 20(4):362-373.

136. ½*Finkelstein, M.O. and Levin, B. (2012).
Meta-Analysis of "Sparse" Data: Perspectives from the Avandia Cases.
Jurimetrics 52(2):123-153.

137. Kline, J., Kinney, A., Brown, S., Levin, B., Oppenheimer, K., and Warburton, D. (2012). Trisomic pregnancy and intermediate CGG repeat length at the *FMR*1 locus. *Human Reproduction* 27(7):2224-2232.

138. Homma, S., Thompson, J.L.P., Pullicino, P.M., Levin, B., Freudenberger, R.S., Teerlink, J.R., Ammon, S.E., Graham, S., Sacco, R.L., Mann, D.L., Mohr, J.P., Massie, B.M., Labovitz, A.J., Anker, S.D., Lok, D.J., Ponikowski, P., Estol, C.J., Lip, G.Y.H., Di Tullio, M.R., Mejia, V., Gabriel, A.P., del Valle, M.L., Buchsbaum, R., Sanford, A.R., and Moy, C.S., for the WARCEF Investigators (2012). Warfarin and Aspirin in Heart Failure Patients in Sinus Rhythm.
New England Journal of Medicine 366:1859-1869.

139. Devanand, D.P., Mintzer, J., Schultz, S.K., Andrews, H.F., Sultzer, D.L., de la Pena, D., Gupta, S., Colon, S., Schimming, C., Pelton, G.H., and Levin, B. (2012). Relapse Risk after Discontinuation of Risperidone in Alzheimer's Disease.
New England Journal of Medicine 367:1497-1507.

140. Alter, H.J., Mikovits, J.A., Switzer, W.M., Ruscetti, F.W., Lo, S.-C., Klimas, N., Komaroff, A.L., Montoya, J., Bateman, L., Levine, S., Peterson, D., Levin, B., Hanson, M.R., Genfi, A., Bhat, M., Zheng, H.-Q., Lee, L.L., Sameroff, S., Heneine, W., Hornig, M., Lipkin, W.I. (2012).
Multicenter Blinded Analysis Indicates No Association Between Chronic Fatigue Syndrome/Myalgic Encephalomyelitis and Either XMRV or pMLV.
mBio 3(5):e00266-12.

141. Coffey, C.S., Levin, B., Clark, C., Timmerman, C., Wittes, J., Gilbert, P., and Harris, S. (2012). Overview, Hurdles, and Future Work in Adaptive Designs: Perspectives from an NIH-funded Workshop.
Clinical Trials 9(6):671-680.

142. *Levin, B. and Leu, C.-S. (2013). Note on an Identity Between Two Unbiased Variance Estimators for the Grand Mean in a Simple Random Effects Model.
The American Statistician 67(1):42-43.

143. *Levin, B. and Leu, C.-S. (2013). On an Inequality That Implies the Lower Bound Formula for the Probability of Correct Selection in the Levin-Robbins-Leu Family of Sequential Binomial Subset Selection Procedures.
Sequential Analysis 32(4):404-427.

144. Gorroochurn, P. and Levin, B. (2013). On Two Historical Aspects of Buffon's Needle Problem. *Electronic Journal for History of Probability and Statistics* 9:1-20.

145. Kline, J.K., Kinney, A.M., Levin, B., Brown, S.A., Hadd, A.G., and Warburton, D. (2014). Intermediate CGG Repeat Length at the *FMR1* Locus is Not Associated with Hormonal Indicators of Ovarian Age. *Menopause* 21(7):740-748.

146. Gao, B., Moore, C., Porcheray, F., Rong, C., Abidoglu, C., DeVito, J., Paine, R., Girouard, T.C., Saidman, S.L., Schoenfeld, D., Levin, B., Wong, W., Elias, N., Schuetz, C., Rosales, I., Fu, Y., and Zorn, E. (2014). Pretransplant IgG Reactivity to Apoptotic Cells Correlates With Late kidney Allograft Loss. *American Journal of Transplantation* 14:1581-1591.

147. Voors, A.A., Davison, B.A., Teerlink, J.R., Felker, G.M., Cotter, G., Filippatos, G., Greenberg, B.H., Pang, P.S., Levin, B., Hua, T.A., Severin, T., Ponikowski, P., Metra, M, for the RELAX-AHF Investigators. (2014). Diuretic Response in Patients with Acute Decompensated Heart Failure. *European Journal of Heart Failure* 16(11):1230-1240.

148. *Levin, B. (2014). "Punctured Poisson" and the Strong Birthday Problem. *Significance* 11(4):50-51 (Letter).

149. ½*Caplan, A., Plunkett, C., and Levin, B. (2015). Selecting the Right Tool for the Job (invited paper). *American Journal of Bioethics* 15(4):4-10 (with open peer commentaries, pp. 33-50).

150. ½*Caplan, A., Plunkett, C., and Levin, B. (2015). The Perfect Must Not Overwhelm the Good: Response to Open Peer Commentaries on "Selecting the Right Tool For the Job". *American Journal of Bioethics* 15(4):W8-W10.

151. Zuber, J., Rosen, S., Shonts B., Sprangers, B. Savage, T.M., Richman, S., Yang, S., Lau, S.P., DeWolf, S., Farber, D., Vlad, G., Zorn, E., Wong, W., Emond, J., Levin, B., Martinez, M., Kato, T., Sykes, M. (2015). Macrochimerism in Intestinal Transplantation: Association with Lower Rejection Rates and Multivisceral Transplants, Without GVHD. *American Journal of Transplantation* [doi: 10.1111/ajt.13325 Epub ahead of print]

152. Graham S., Ye S., Qian M., Sanford A.R., Di Tullio M.R., Sacco R.L., Mann D.L., Levin B., Pullicino P., Freudenberger R.S., Teerlink J.R., Mohr J.P., Labovitz A.J., Lip G.Y.H., Estol C.J., Lok D.J., Ponikowski P., Anker S.D., Thompson J.L.P., and Homma S. for the WARCEF Investigators. (2014). Cognitive Function in Ambulatory Patients with Systolic Heart Failure: Insights from the Warfarin versus Aspirin in Reduced Cardiac Ejection Fraction (WARCEF) Trial. *PLOS One* (in press).

153. Homma, S., Thompson, J.L.P., Qian, M., Ye, S., Di Tullio, M.R., Lip, G.Y.H., Mann, D.L., Sacco, R.L., Levin, B., Pullicino, P.M., Freudenberger, R.S., Teerlink, J.R., Graham, S. Mohr, J.P., Labovitz, A.J., Buchsbaum, R., Estol, C.J., Lok, D.J., Ponikowski, P., and Anker, S.D., for the WARCEF Investigators. (2015). Quality of Anticoagulation Control in Preventing Adverse Events in Heart Failure Patients in Sinus Rhythm: A Warfarin Aspirin Reduced Cardiac Ejection Fraction Trial (Warcef) Substudy.
Circulation: Heart Failure (in press).

154. Ye S., Cheng, B., Lip, G.Y.H., Buchsbaum, R., Sacco, R.L., Levin, B., Di Tullio, M.R., Qian, M., Mann, D.L., Pullicino, P.M., Freudenberger, R.S., Teerlink, J.R., Mohr, J.P., Graham, S., Labovitz, A.J., Estol, C.J., Lok, D.J., Ponikowski, P., Anker, S.D., Thompson, J.L.P., Homma, S. (2015).
Bleeding Risk and Antithrombotic Strategy in Patients with Sinus Rhythm and Heart Failure with Reduced Ejection Fraction Treated with Warfarin or Aspirin.
American Journal of Cardiology (in press).

B. Books:

1. ½* Finkelstein, M.O. and Levin, B. (1990). *Statistics for Lawyers*. New York: Springer–Verlag (608 pp. with 39 illustrations).

   ½**Statistics for Lawyers, 2nd Edition* (2001), (617 pp. with 55 illustrations).

   (Third edition in preparation.)

2. *Fleiss, J.L., Levin, B., and Paik, M.C. (2003). *Statistical Methods for Rates and Proportions*, *3rd edition*. New York: Wiley (760 pp. with 16 illustrations).

3. ½* Levy, G. and Levin, B. (2014). *The Biostatistics of Aging: From Gompertzian Mortality to an Index of Aging-Relatedness*. New York: Wiley (258 pp. with 36 illustrations).

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

1. *Levin, B. (1985). Comment: A Question of Theft. In: M. DeGroot, S. Fienberg and J. Kadane (eds), *Statistics in Law*, pp. 240–246, New York: John Wiley & Sons.

2. *Levin, B. (1986). Empirical Bayes Estimation in Heterogeneous Matched Binary Samples with Systematic Aging Effects. In: J. Van Ryzin (ed), *Adaptive Statistical Procedures and Related Topics*, Institute of Math. Stat. Lecture Notes – Monograph Series, Vol. 8, pp. 179–194.

3. *Levin, B. (1987). Review of "Mathematical Methods in Medicine: Part 1 and Part 2," D. Ingram and R. Bloch (eds), *Journal of the American Statistical Association* 82(399):958.

4. Finkelstein, M.O. and Levin, B. (1996). Reference Guide on Statistics: Non Lasciare Esperanza. (Review of the Federal Judicial Center Reference Guide on Statistics). *Jurimetrics* 36:201–212.

5. *Northridge, M.E., Levin, B., Feinleib, M., and Susser, M. (1997) Editorial: Statistics in the Journal––Significance, Confidence, and All That. *American Journal of Public Health* 87:1092–1095.

6. Susser, M.W. and Levin, B. (1999) Ordeals for the Fetal Programming Hypothesis. (Editorial) *British Medical Journal* 318:885-886.

7. *Small Clinical Trials–Issues and Challenges* (2001)
Evans, C.H. and Ildstad, S.T., eds. Washington, D.C.: National Academy Press. (Member of Institute of Medicine Committee on Strategies for Small-Number-Participant Clinical Research Trials)

8. *Levin, B. (2003).
No, Not Another IRB. Review of "Data Monitoring Committees in Clinical Trials: A Practical Perspective" by Ellenberg, S.S., Fleming, T.R., and DeMets, D.L. *IRB: Ethics and Human Research* 25(1):17-18.

9. *Levin, B. (2005).
The Utility of Futility (Editorial). *Stroke* 36:2331-2332.

10. Leu, C.-S. and Levin, B. (2009).
A Modification of the Bechhofer, Kiefer, and Sobel Sequential Binomial Subset Selection Procedure. Proceedings of the Second International Workshop in Sequential Methodologies.
<http://mat.izt.uam.mx/profs/anovikov/data/IWSM2009/invited_sessions.htm>

11. Ganda, A., Thompson, J.L.P., Schwartz, J., Valeri, A., Oliver, J.A., Sanford, A., Buchsbaum, R., Bigger, J.T., Levin, B., Landry, D.W. (2011).
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)

12. Levin, B. (2012).
Selection and Futility Designs. Chapter 8 in: *Clinical Trials in Neurology*, ed. B. Ravina, J. Cummings, M.P. McDermott, and M. Poole. Cambridge: Cambridge University Press.

13. Levin, B. (2015). The Futility Study—Progress Over the Last Decade.
Contemporary Clinical Trials (in press).

D. Columns: The following pieces, co-edited with Michael O. Finkelstein, appeared in Chance Magazine's column, *Chance at the Bar*, between 2003 and 2005.

1. *Bush v. Gore: Two Neglected Lessons from a Statistical Perspective.
   Chance, 16(3):30-36, Summer 2003.

2. A Statistical Portrait of the Handgun Industry.
   Chance, 16(4):37-40, Fall 2003.

3. *Statistical Proof of Discrimination in Peremptory Challenges.
   Chance, 17(1):36-39, Winter 2004.

4. *Epidemiologic Evidence in the Silicone Breast Implant Cases.
   Chance, 17(2):39-43, Spring 2004.

5. Bullet Lead As Forensic Evidence.
   Chance, 17(3):45-48, Summer 2004.

6. Stopping Rules in Clinical Trials.
   Chance, 17(4):39-42, Fall 2004.

7. Statistical Evidence in an Education Finance Case.
   Chance, 18(1):44-47, Winter 2005.

8. *The Machinery of Death.
   Chance, 18(3):34-37, Summer 2005.

E. Technical Reports:

1. *Levin, B. (1978). Sequential Medical Trials. Technical Report B–01, Division of Biostatistics, Columbia University.

2. *Levin, B. (1979). Locally Optimal Design for Estimation of the Slope in One– and Two–Stage Linear Logistic Regression. Technical Report B–04, Division of Biostatistics, Columbia University.

3. *Levin, B. (1980). An Introduction to Logistic Regression Analysis with LREG (an interactive APL Program). Technical Report B–05, Division of Biostatistics, Columbia University.

4. *Levin, B. (1982). On a Statistic Designed to Detect Multinomial Spikes. Technical Report B–22, Division of Biostatistics, Columbia University.

5. *Levin, B. (1984). Computing Algorithms Related to the Cusum Test of Homogeneity in Poisson and Binomial Trials. Technical Report B–37a, Division of Biostatistics, Columbia University.

6. *Levin, B. (1984). Tables of 5% Critical Values for the Cusum Statistic with Effect Size 2 and Known Baseline Rate in Poisson and Binomial Series. Technical Report B–37b, Division of Biostatistics, Columbia University.

7. *Levin, B. (1985). On Calculating Maximum Rank One Underapproximations for Positive Arrays. Technical Report B–48, Division of Biostatistics, Columbia University.

8. *Levin, B. (1987). Algorithms for the Exact Distribution of the Cusum Statistic for Testing Homogeneity in Ordered Multinomial and Compound Multinomial Sequences. Technical Report B–64, Division of Biostatistics, Columbia University.

9. *Levin, B. (1990). Testing Odds Ratio Homogeneity Across Many Fourfold Tables. Technical Report B–70, Division of Biostatistics, Columbia University.

10. *Levin, B. (1994). The Geometric Cusum Procedure is More Efficient than the Sets Procedure.
Technical Report B–81, Division of Biostatistics, Columbia University.

11. Leu, C.-S. and Levin, B. (2004). Selecting the Best Subset of b out of c Coins with the Levin-Robbins Sequential Elimination Procedure: Proof of the Lower Bound Formula for the Probability of Correct Selection in the Case $b=2$ and $c=4$. Technical Report B–91, Department of Biostatistics, Columbia University.

12. *Leu, C.-S. and Levin, B. (2004). Formulas for the Exact Probability of Correct Selection in the Binomial Levin-Robbins Sequential Selection Procedure in the Cases $b=2$, $c=3$ and $b=2$, $c=4$ for $r=1$. Technical Report B–92, Department of Biostatistics, Columbia University.

13. *Leu, C.-S. and Levin, B. (2004). A Generalization of the Levin-Robbins Procedure for Binomial Subset Selection and Recruitment Problems. Technical Report B–93, Department of Biostatistics, Columbia University.

14. *Levin, B. (2004). Formulas for Correcting the Mean and Variance of the Full-data Sample Mean of the Primary Endpoint Under the Dose Selected at Stage One in a Two-stage Trial with Selection Between Two Active Doses. Technical Report B-95, Department of Biostatistics, Columbia University.

15. Leu, C.S. and Levin, B. (2006). Proof of the lower bound formula for the probability of correct binomial subset selection with the Levin-Robbins-Leu sequential elimination and recruitment procedure in the case $b = 2$, $c = 4$. Technical Report #B-98, Department of Biostatistics, Columbia University

16. *Levin, B. (2006). On Minimizing the Lower Bound for the Probability of θ-acceptable Subset Selection. Technical Report B-99, Department of Biostatistics, Columbia University.

17. *Levin, B. and Leu, C.-S. (2013). On Two Lemmas Used to Establish a Key Inequality that Implies the Lower Bound Formula for the Probability of Correct Selection in the Levin-Robbins-Leu Family of Sequential Binomial Subset Selection Procedures. Technical Report B-148, Department of Biostatistics, Columbia University.

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,...,n index the n cases under consideration, where n=88 for pre-2005 cases and n=129 for post-2005 cases. Let W_{i1}=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).

[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 $p_j = \sum_{i=1}^{n} W_{ij}Y_{ij} \Big/ \sum_{i=1}^{n} W_{ij}$ and its variance is given by

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

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

$$Cov(p_1, p_2) = Cov\left(\sum_i W_{i1}Y_{i1}, \sum_i W_{i2}Y_{i2}\right) \Big/ n_1 n_2 = \sum_i W_{i1}W_{i2}Cov(Y_{i1}, Y_{i2}) \Big/ n_1 n_2 = \sum_i W_{i1}W_{i2}(EY_{i1}Y_{i2} - P_1P_2) \Big/ n_1 n_2$$
$$= \{n_{12}/(n_1 n_2)\}(P_{12} - P_1P_2),$$

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

$$p_{12} = \sum_i W_{i1}W_{i2}Y_{i1}Y_{i2} \Big/ n_{12},$$

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 $Cov(p_1, p_2)$ is given by

$$\hat{Cov}(p_1, p_2) = \{n_{12}/(n_1 n_2)\}(p_{12} - p_1 p_2).$$

In order to compare pharmaceutical cases with non-pharmaceutical cases, we extend the notation using superscripts φ (the Greek letter phi) for pharmaceutical cases and ν (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 $d_j = p_j^{(\varphi)} - p_j^{(\nu)}$ and estimate its standard error (*s.e.*) by

$$s.e.(d_j) = \sqrt{s.e.^2(p_j^{(\varphi)}) + s.e.^2(p_j^{(\nu)})}$$

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

$$Cov(d_1, d_2) = Cov(p_1^{(\varphi)} - p_1^{(\nu)}, p_2^{(\varphi)} - p_2^{(\nu)}) = Cov(p_1^{(\varphi)}, p_2^{(\varphi)}) + Cov(p_1^{(\nu)}, p_2^{(\nu)}),$$

again by statistical independence. It follows that the standard error of the difference $d = d_1 - d_2$ is given by

$$s.e.(d) = \sqrt{s.e.^2(d_1) + s.e.^2(d_2) - 2Cov(d_1, d_2)}$$
$$= \sqrt{s.e.^2(p_1^{(\varphi)}) + s.e.^2(p_1^{(\nu)}) + s.e.^2(p_2^{(\varphi)}) + s.e.^2(p_2^{(\nu)}) - 2C\hat{o}v(p_1^{(\varphi)}, p_2^{(\varphi)}) - 2C\hat{o}v(p_1^{(\nu)}, p_2^{(\nu)})}.$$

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 $C\hat{o}v(p_1, p_2)$ 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 $C\hat{o}v(p_1, p_2)$. This procedure is conservative in the sense that it allows for more uncertainty in the statistical testing procedure. For $p_1^{(\nu)}$ in the post-2005 period we replaced the observed zero proportion by the one-sided upper 95% confidence limit for $P_1^{(\nu)}$ 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*.

---

[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)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Saunders v. Airglide Deflectors Ltd.	(1980) 50 C.P.R. (2d) 6	No appellate history	N	----	Y	----	Y
Congoleum Corp. v. Mannington Mills Inc.	(1980) 47 C.P.R. (2d) 33	No appellate history	N	Y	----	Y	Y
Cooper & Beatty Co. v Alpha Graphics Ltd.	(1980) 49 C.P.R. (2d) 145	No appellate history	N	Y	Y	Y	Y
Baxter Travenol Laboratories of Canada Ltd. v. Cutter (Canada) Ltd.	(1980) 52 C.P.R. (2d) 163	Varied: 68 C.P.R. (2d) 179 (FCA)	N	----	Y	----	Y
Proctor & Gamble Co. v Calgon Interamerican Corp.	(1981) 56 C.P.R. (2d) 214	Affirmed: 61 C.P.R. (2d) 1 (FCA) Leave to appeal to SCC ref'd: 63 C.P.R. (2d) 260 (May 10, 1982)	N	Y	Y	Y	----
Johnson Controls Inc. v. Varta Batteries Ltd.	(1981) 57 C.P.R. (2d) 132	Affirmed: 80 C.P.R. (2d) 1 (FCA)	N	Y	N	N	----
Amfac Foods Inc. v. Irving Pulp & Paper Ltd.	(1984) 80 C.P.R. (2d) 59	Affirmed: 12 C.P.R. (3d) 193 (FCA)	N	----	----	----	----
Beloit Canada Ltée/Ltd. v. Valmet Oy	(1984) 78 C.P.R. (2d) 1	Reversed: 8 C.P.R. (3d) 289 (FCA)	N	----	N	N	----
Corning Glass Works v. Canada Wire & Cable Ltd.	(1984) 81 C.P.R. (2d) 39	No appellate history	N	Y	Y	Y	----
Ductmate Industries Inc. v. Exanno Products Ltd.	(1984) 2 C.P.R. (3d) 289	No appellate history	N	----	N	----	N
Windsurfing International Inc. v. Trilantic Corp.	(1984) 3 C.P.R. (3d) 95	Reversed: [1985] F.C.J. No. 1147, 8 C.P.R. (3d) 241 (FCA), additional reasons 8 C.P.R. (3d) 270 (FCA)	N	----	Y	Y	Y

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Tinsel Manufacturing Ltd. v. Noma Canada Inc. et al.	(1985) 3 C.P.R. (3d) 433	No appellate history	N	----	Y	Y	Y
Services et Produits Hospitaliers Confort & Inc. v. W. Laframboise Ltee	(1985) 6 C.P.R. (3d) 238	No appellate history	N	----	N	Y	----
W.H. Brady Co. v. Letraset Canada Ltd.	(1985) 7 C.P.R. (3d) 82	No appellate history	N	----	N	N	----
Sandvik, A.B. v. Windsor Machine Co.	(1986) 8 C.P.R. (3d) 433	No appellate history	N	----	Y	Y	----
Reading & Bates Construction Co. v. Baker Energy Resources Corp.	(1986) 13 C.P.R. (3d) 410; 9 C.P.R. (3d) 158	Affirmed: 18 C.P.R. (3d) 180 (FCA)	N	----	N	Y	----
Kramer v. Lindsay Specialty Products Ltd.	(1986) 9 C.P.R. (3d) 297	No appellate history	N	----	Y	Y	----
Riello Canada Inc. v. Lambert	(1986) 9 C.P.R. (3d) 324	No appellate history. Additional reasons in (1987) 86 C.P.R. (3d) 356.	N	----	N	N	----
TRW Inc. v. Walbar of Canada Inc.	(1986) 10 C.P.R. (3d) 184	Reversed: (1991) 39 C.P.R. (3d) 176 (FCA). Leave to appeal to SCC ref'd: June 25, 1992.	N	N	----	----	N
Crila Plastic Industries Ltd. v. Ninety-Eight Plastic Trim Ltd.	(1986) 10 C.P.R. (3d) 226	Affirmed:, 18 C.P.R. (3d) 1 (FCA)	N	----	N	Y	----
Atlas Copco AB v. CIL Inc.	(1986) 10 C.P.R. (3d) 145	Revised: (1992) 41 C.P.R. (3d) 348 (FCA)	N	----	N	N	N
Invacare Corp. v. Everest & Jennings Canadian Ltd.	(1987) 14 C.P.R. (3d) 156	No appellate history	N	----	Y	Y	----
Apotex Inc. v. Hoffmann-La Roche Ltd.	(1987) 15 C.P.R. (3d) 217	Affirmed: (1989) 24 C.P.R. (3d) 289 (FCA)	Y	----	N	N	----

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Diversified Products Corp. v. Tye-Sil Corp.	(1987) 16 C.P.R. (3d) 207	Affirmed: (1991) 35 C.P.R. (3d) 350 (FCA)	N	----	Y	Y	Y
Mahurkar v. Vas-Cath of Canada Ltd.	(1988) 18 C.P.R. (3d) 417	Affirmed: 32 C.P.R. (3d) 409 (FCA)	N	Y	Y	Y	Y
Cabot Corp v. 318602 Ontario Ltd.	(1988) 20 C.P.R. (3d) 132	No appellate history	N	Y	Y	Y	Y
Eli Lilly & Co. v. O'Hara Manufacturing Ltd.	(1988) 20 C.P.R. (3d) 342	Reversed: (1989) 26 C.P.R. (3d) 1 (FCA) (appeal only re infringement)	Y	----	Y	----	Y
Creations 2000 Inc. v. Canper Industrial Products Ltd.	(1988) 22 C.P.R. (3d) 389	Affirmed: (1990) 34 C.P.R. (3d) 178 (FCA)	N	----	N	N	----
Brushtech Inc. v. Liberty Home Products Corp.	(1988) 23 C.P.R. (3d) 370	No appellate history	N	----	N	N	----
Control Data Canada Ltd. v. Senstar Corp.	(1989) 23 C.P.R. (3d) 449	No appellate history	N	Y	----	----	Y
Gorse v. Upwardor Corp.	(1989) 25 C.P.R. (3d) 166	Affirmed: (1992) 40 C.P.R. (3d) 479 (FCA)	N	Y	Y	Y	Y
Pro-Vertic (1987) Inc. c. International Diffusion Consommateur S.A.	(1989) 26 C.P.R. (3d) 528	No appellate history	N	----	Y	Y	----
M & I Door Systems Ltd. v. Indoco Industrial Door Co.	(1989) 25 C.P.R. (3d) 477	No appellate history	N	----	----	N	----
AT & T Technologies Inc. v. Mitel Corp.	(1989) 26 C.P.R. (3d) 238	No appellate history	N	----	Y	N	Y

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Standal Estate v. Swecan International Ltd.	(1989) 28 C.P.R. (3d) 261	No appellate history	N	----	Y	Y	----
Dec International Inc. v. A.L. LaCombe & Associates Ltd.	(1989) 26 C.P.R. (3d) 193	No appellate history	N	----	N	Y	N
Reliance Electric Industrial Co. v. Northern Telecom Ltd.	(1989) 28 C.P.R. (3d) 397	Reversed: (1992) 44 C.P.R. (3d) 161 (FCA)	N	----	----	----	----
Nekoosa Packaging Corp. v. AMCA International Ltd.	(1989) 27 C.P.R. (3d) 153	Affirmed: (1994) 56 C.P.R. (3d) 470 (FCA)	N	----	----	Y	----
J.M. Voith GmbH v. Beloit Corp.	(1989) 27 C.P.R. (3d) 289	Reversed: (1991) 36 C.P.R. (3d) 322 (FCA). Leave to appeal to SCC ref'd March 9, 1992.	N	----	----	Y	Y
Energy Absorption Systems Inc. v. Y. Boissoneault & Fils Inc.	(1990) 30 C.P.R. (3d) 420	No appellate history	N	Y	Y	Y	----
Lubrizol Corp. v. Imperial Oil Ltd.	(1990) 33 C.P.R. (3d) 1	Affirmed (on validity): (1992) 45 C.P.R. (3d) 449 (FCA) Leave to appeal to SCC ref'd: Oct. 7, 1993	N	Y	Y	Y	Y
Computalog Ltd. v. Comtech Logging Ltd.	(1990) 32 C.P.R. (3d) 289	Reversed: (1992) 44 C.P.R. (3d) 77 (FCA) on infringement only	N	----	Y	----	----
Stiga Aktiebolag v. S.L.M. Canada Inc.	(1990) 34 C.P.R. (3d) 216	No appellate history	N	Y	Y	Y	----
Rothmans, Benson & Hedges Inc. v. Imperial Tobacco Ltd./Ltée	(1991) 35 C.P.R. (3d) 417	Affirmed: (1993) 47 C.P.R. (3d) 188 (FCA)	N	----	Y	----	----
Martinray Industries Ltd. v. Fabricants National Dagendor Manufacturing Ltd.	(1991) 41 C.P.R. (3d) 1	No appellate history	N	----	Y	Y	----

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Procter & Gamble Co. v. Kimberly-Clark of Canada Ltd.	(1991) 40 C.P.R. (3d) 1	No appellate history	N	----	Y	Y	----
Wellcome Foundation Ltd. v. Apotex Inc.	(1991) 39 C.P.R. (3d) 289, supp reasons at (1992) 40 C.P.R. (3d) 361	Reversed (on other grounds): (1995) 60 C.P.R. (3d) 135 (FCA) Leave to appeal to SCC ref'd: Sept. 28, 1995	Y	Y	Y	----	Y
Reliance Electric Industrial Co. v. Northern Telecom Ltd.	(1993) 47 C.P.R. (3d) 55	Affirmed: (1994) 55 C.P.R. (3d) 299 (FCA)	N	----	N	N	----
Unilever PLC v. Procter & Gamble Inc.	(1993) 47 C.P.R. (3d) 479	Affirmed: (1995) 61 C.P.R. (3d) 499 (FCA)	N	Y	Y	Y	Y
CFM Inc. v. Wolf Steel Ltd.	(1993) 50 C.P.R. (3d) 215	Affirmed: (1995) 64 C.P.R. (3d) 75 (FCA)	N	----	N	N	----
AlliedSignal Inc. v. DuPont Canada Inc.	(1993) 50 C.P.R. (3d) 1	Reversed: (1995) 61 C.P.R. (3d) 417 (FCA). Leave to appeal to SCC ref'd: Nov 30, 1995.	N	----	Y	----	Y
Dableh v. Ontario Hydro	(1993) 50 C.P.R. (3d) 290	Reversed (on other grounds than utility) by FCA: [1996] 3 F.C. 751 Leave to appeal to SCC ref'd Feb. 27. 1997	N	----	----	----	----
Airseal Controls Inc. v. M & I Heat Transfer Products Ltd.	(1993) 53 C.P.R. (3d) 259	Affirmed: (1997) 77 C.P.R. (3d) 126 (FCA)	N	----	----	----	----
Hi-Qual Manufacturing Ltd. v. Rea's Welding & Steel Supplies Ltd.	(1994) 55 C.P.R. (3d) 224	Affirmed: (1995) 61 C.P.R. (3d) 270 (FCA)	N	----	Y	Y	Y
Mobil Oil Corp. v. Hercules Canada Inc.	(1994) 57 C.P.R. (3d) 488	Reversed (on other ground than utility): (1995) 63 C.P.R. (3d) 473 (FCA) Leave to appeal to SCC ref'd: May 16, 1996	N	Y	----	----	Y

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Anderson v. Machineries Yvon Beaudoin Inc.	(1994) 58 C.P.R. (3d) 449	No appellate history	N	----	Y	Y	----
Feherguard Products Ltd. v. Rocky's of B.C. Leisure Ltd.	(1994) 53 C.P.R. (3d) 417	Affirmed: (1995) 60 C.P.R. (3d) 512 (FCA)	N	N	----	----	----
Merck & Co. v. Apotex Inc.	(1994) 59 C.P.R. (3d) 133	Reversed by FCA: [1995] 2 F.C. 723 re infringement	Y	----	Y	----	Y
Risi Stone Ltd. v. Groupe Permacon Inc.	(1995) 65 C.P.R. (3d) 2	No appellate history	N	Y	Y	Y	----
Cochlear Corp. v. Cosem Neurostim Ltée	(1995) 64 C.P.R. (3d) 10	No appellate history	N	----	Y	Y	----
Almecon Industries Ltd. v. Nutron Manufacturing Ltd.	(1996) 65 C.P.R. (3d) 417	Affirmed: 72 C.P.R. (3d) 397 (FCA) Leave to appeal ref'd: Sept. 25, 1997	N	----	Y	Y	Y
Hoffmann-La Roche Ltd. v. Apotex Inc.	(1997) 72 C.P.R. (3d) 480	Affirmed: (1998) 82 C.P.R. (3d) 384 (FCA)	Y	----	Y	----	Y
Pfizer Canada Inc. v. Apotex Inc.	(1997) 77 C.P.R. (3d) 547	No appellate history	Y	----	Y	Y	----
Whirlpool Corp. v. Camco Inc.	(1997) 76 C.P.R. (3d) 150	Affirmed by FCA (1999) 85 C.P.R. (3d) 129; Affirmed by 2000 SCC 67	N	----	Y	Y	----
Bourgault Industries Ltd. v. Flexi-Coil Ltd.	(1998) 80 C.P.R. (3d) 1	Affirmed by FCA (1999) 86 C.P.R. (3d) 221 (FCA) Leave to appeal ref'd Mar 23, 2000	N	----	Y	Y	Y
Apotex Inc. v. Wellcome Foundation Ltd.	(1998) 79 C.P.R. (3d) 193	Varied by FCA [2000] F.C.J. No. 1770 FCA decision affirmed by 2002 SCC 77	Y	Y	Y	----	Y

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Avant-Garde Engineering (1994) Inc. c. Gestion de Brevets Fraco Ltée	(1998) 87 C.P.R. (3d) 437	Reversed (on infringement only) by FCA 1998 CarswellNat 2569; can find decision by searching case name on FCA website.	N	Y	Y	----	----
Bayer Inc. v. Canada (Minister of National Health & Welfare)	(1998) 82 C.P.R. (3d) 359	Affirmed by FCA (2000) 6 C.P.R. (4th) 285	Y	----	N	----	----
Wellcome Foundation Ltd. v. Novopharm Ltd.	(1998) 82 C.P.R. (3d) 129	Affirmed by FCA (2000) 7 C.P.R. (4th) 330	Y	----	N	----	----
Kirin-Amgen Inc. v. Hoffmann-La Roche Ltd. / Hoffmann-La Roche Ltée	(1999) 87 C.P.R. (3d) 1	Affirmed by FCA (2000) 11 C.P.R. (4th) 78	Y	----	----	----	Y
Apotex Inc. v. Syntex Pharmaceuticals International Ltd.	(1999) 1 C.P.R. (4th) 22	No appellate history	Y	----	N	----	----
Visx Inc. v. Nidek Co.	(1999) 3 C.P.R. (4th) 417	Affirmed by 2001 FCA 215	N	----	Y	y	----
Merck Frosst Canada Inc. v. Canada (Minister of Health)	(2000) 8 C.P.R. (4th) 87	Affirmed: 2001 FCA 192	Y	----	----	----	----
Monsanto Canada Inc. v. Schmeiser	(2001) 12 C.P.R. (4th) 204	Affirmed by 2002 FCA 309; FCA decision reversed by 2004 SCC 34. Validity upheld by SCC	N	----	----	----	----
SmithKline Beecham Pharma Inc. v. Apotex Inc.	[2001] 4 F.C. 518, 14 C.P.R. (4th) 76	Affirmed in 2002 FCA 216 Leave to appeal to SCC ref'd: March 20, 2003	Y	Y	Y	N	----
Baker Petrolite Corp. v. Canwell Enviro-Industries Ltd.	[2002] 2 F.C. 3, 13 C.P.R. (4th) 193	Reversed by 2002 FCA 158	N	----	Y	N	Y

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
671905 Alberta Inc. v. Q'Max Solutions Inc.	(2001) 14 C.P.R. (4th) 129	Reversed (on other grounds than utility): 27 C.P.R. (4th) 385 (FCA) Leave to appeal to SCC ref'd: April 29, 2004	N	Y	Y	Y	Y
Novartis AG v. Apotex Inc.	(2001) 15 C.P.R. (4th) 417	Affirmed by 2002 FCA 440	Y	----	N	N	----
Almecon Industries Ltd. v. Anchortek Ltd.	(2001) 17 C.P.R. (4th) 74	Affirmed by 2003 FCA 168	N	Y	----	----	----
Norac Systems International Inc. v. Prairie Systems & Equipment Ltd.	(2002) 19 C.P.R. (4th) 360	Reversed by 2003 FCA 187	N	Y	Y	Y	----
Illinois Tool Works Inc. v. Cobra Fixations Cie / Cobra Anchors Co.	(2002) 20 C.P.R. (4th) 402	Affirmed by 2003 FCA 358	N	Y	Y	----	----
Pfizer Canada Inc. v. Apotex Inc.	(2002) 22 C.P.R. (4th) 466	No appellate history	Y	----	N	N	----
Westaim Corp. v. Royal Canadian Mint	(2002) 23 C.P.R. (4th) 9	No appellate history	N	Y	N	----	----
Canamould Extrusions Ltd. v. Driangle Inc.	(2003) 25 C.P.R. (4th) 343	Affirmed by 2004 FCA 63	N	----	Y	----	----
GlaxoSmithKline Inc. v. Apotex Inc.	(2003) 27 C.P.R. (4th) 114	No appellate history	Y	----	Y	N	----
AB Hassle v. Apotex Inc.	(2003) 27 C.P.R. (4th) 465	Affirmed by 2004 FCA 369 Leave to appeal to SCC ref'd: April 21, 2005	Y	----	Y	Y	----
GlaxoSmithKline Inc. v. Canada (Minister of Health)	2003 FC 899	No appellate history	Y	----	N	Y	----
Bayer AG v. Apotex Inc.	2003 FC 1199	Affirmed by 2007 FCA 243	Y	----	Y	----	----

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
GlaxoSmithKline Inc. v. Genpharm Inc.	2003 FC 1248	No appellate history	Y	----	Y	Y	----
AB Hassle v. Genpharm Inc.	2003 FC 1443	Affirmed by 2004 FCA 413	Y	----	Y	Y	Y
Pfizer Canada Inc. v. Apotex Inc.	2003 FC 1428	Affirmed by 2004 FCA 398	Y	----	----	----	----
Halford v. Seed Hawk Inc.	2004 FC 88	Reversed by 2006 FCA 275 (on obviousness)	N	Y	N	Y	Y
Procter & Gamble Pharmaceuticals Canada Inc. v. Canada (Minister of Health)	2004 FC 204	Affirmed 2004 FCA 393; Leave to appeal ref'd Apr 21, 2005	Y	----	Y	----	----
Wessel v. Energy Rentals Inc.	2004 FC 791	No appellate history	N	----	Y	Y	----
Abbott Laboratories v. Canada (Minister of Health)	2004 FC 1349	Affirmed by 2005 FCA 250	Y	----	----	----	----
Janssen-Ortho Inc. v. Novopharm Ltd.	2004 FC 1631	No appellate history	Y	----	N	Y	Y
Stonehouse v. Batco Manufacturing Ltd.	2004 FC 1767	No appellate history	N	Y	Y	Y	Y
Biovail Pharmaceuticals Inc. v. Canada (Minister of National Health and Welfare)	2005 FC 9	No appellate history	Y	----	----	----	----
Aventis Pharma Inc. v. Pharmascience Inc.	2005 FC 340	Affirmed by 53 C.P.R. (4th) 453 (FCA).	Y	----	----	----	----
Sanofi-Synthelabo Canada Inc. v. Apotex Inc.	2005 FC 390	Affirmed by 2006 FCA 59 Affirmed by SCC (2008) 69 C.P.R. (4th) 251	Y	----	Y	Y	----
Merck & Co. Inc. v. Apotex Inc.	2005 FC 755	No appellate history.	Y	N	N	Y	Y

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Emmanuel Simard & Fils (1983) Inc. v. Raydan Manufacturing Ltd.	2005 FC 973	Reversed by 2006 FCA 293 (as to costs only)	N	----	Y	Y	----
Abbott Laboratories v. Canada (Minister of Health)	2005 FC 1093	Affirmed by FCA. (2006), 56 C.P.R. (4th) 387	Y	----	Y	N	----
Abbott Laboratories v. Canada (Minister of Health)	2005 FC 1095	No appellate history	Y	N	----	Y	----
Aventis Pharma Inc. v. Mayne Pharma (Canada) Inc.	2005 FC 1183	No appellate history	Y	----	----	----	----
Pfizer Canada Inc. v. Canada (Minister of Health)	2005 FC 1205	Reversed by 2007 FCA 209 (on different grounds than inutility)	Y	Y	Y	Y	----
Aventis Pharma Inc. v. Apotex Inc.	2005 FC 1283	Affirmed by 2006 FCA 64 Leave to appeal to SCC ref'd: Aug. 3, 2006	Y	N	----	----	Y
Pfizer Canada Inc. v. Novopharm Ltd.	2005 FC 1299	No appellate history	Y	----	Y	Y	----
Abbott Laboratories v. Canada (Minister of Health)	2005 FC 1332	Affirmed by 2007 FCA 153	Y	N	----	N	----
Pfizer Canada Inc. v. Apotex Inc.	2005 FC 1421	No appellate history.	Y	----	N	Y	Y
Bristol-Myers Squibb Canada Co. v. Novopharm Ltd.	2005 FC 1458	No appellate history	Y	----	Y	----	----
Aventis Pharma Inc. v. Apotex Inc	2005 FC 1504	Affirmed by 2006 FCA 328	Y	----	N	Y	----
Abbott Laboratories v. Canada (Minister of Health)	2006 FC 69	Affirmed by 2007 FCA 83	Y	----	Y	----	----

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Pfizer Canada Inc. v. Canada (Minister of Health)	2006 FC 220	Reversed by 2006 FCA 214	Y	----	----	Y	----
Bayer AG v Novopharm Ltd	2006 FC 379	Appeal commenced but discontinued (A-175-06)	Y	----	----	----	----
Merck & Co. v. Apotex Inc.	2006 FC 524	Varied by 2006 FCA 323	Y	----	----	----	----
Axcan Pharma Inc. v. Pharmascience Inc.	2006 FC 527	No appellate history	Y	----	----	Y	----
Dimplex North America Ltd. v. CFM Corp	2006 FC 586	Affirmed by 2007 FCA 278	N	----	Y	Y	----
Janssen-Ortho Inc. v. Novopharm Ltd.	2006 FC 1234	Affirmed by 2007 FCA 217	Y	----	Y	Y	Y
Calgon Carbon Corp. v. North Bay (City)	2006 FC 1373	Affirmed by 2008 FCA 81	N	Y	----	N	----
Pfizer Canada v Canada	2006 FC 1471	Appeal heard but discontinued (A-10-07)	Y	----	Y	Y	----
Abbott Laboratories v Canada	2006 FC 1558	Appeal dismissed 2007 FCA 187	Y	----	----	N	----
Pfizer Canada Inc. v. Apotex Inc.	2007 FC 26	Affirmed by 2007 FCA 195 Leave to appeal to SCC ref'd: Nov. 1, 2007	Y	N	----	----	----
G.D. Searle & Co. v. Novopharm Ltd.	2007 FC 81	Reversed by 2007 FCA 173 (on obviousness) Leave to appeal to SCC ref'd: Nov. 1, 2007	Y	Y	Y	----	Y
Pfizer Canada Inc. v. Canada (Minister of Health)	2007 FC 91	Reversed by 2008 FCA 108	Y	----	Y	Y	Y

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Jay-Lor International Inc. v. Penta Farm Systems Ltd.	2007 FC 358	No appellate history	N	----	Y	Y	----
Eli Lilly Canada Inc. v. Apotex Inc.	2007 FC 455	Affirmed in 2008 FCA 44	Y	----	Y	Y	----
Sanofi-Aventis Inc. v. Laboratoire Riva Inc.	2007 FC 532	No appellate history.	Y	Y	----	----	----
M.K. Plastics Corp. v. Plasticair Inc.	2007 FC 574	No appellate history	N	----	Y	Y	----
Eli Lilly Canada Inc. v. Novopharm Ltd.	2007 FC 596	Appeal dismissed as moot: 62 C.P.R. (4th) 161 (FCA) Leave to appeal to SCC ref'd: March 13, 2008	Y	----	Y	Y	N
AstraZeneca AB v Apotex	2007 FC 688	No appellate history	Y	----	N	N	----
Abbott Laboratories v Canada	2007 FC 753	Appeal commenced but dismissed (A-440-07)	Y	----	N	----	----
Pfizer Canada Inc. v. Canada (Minister of Health)	2007 FC 898	No appellate history	Y	----	----	----	Y
Pfizer Canada Inc. v. Apotex Inc.	2007 FC 971	Affirmed by 2009 FCA 8	Y	----	Y	Y	----
McKay v. Weatherford Canada Ltd.	2007 FC 1233	Affirmed by 2008 FCA 369	N	----	Y	----	----
Pfizer Canada Inc. v. Canada (Minister of Health)	2008 FC 11	No appellate history.	Y	----	----	----	----
Pfizer Canada Inc. v. Canada (Minister of Health)	2008 FC 13	No appellate history	Y	----	----	N	----

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Eli Lilly Canada Inc. v. Apotex Inc.	2008 FC 142	Affirmed by 2009 FCA 97 Leave to appeal to SCC ref'd: Oct. 22, 2009	Y	N	Y	Y	----
Solvay Pharma Inc. v. Apotex Inc	2008 FC 308	No appellate history	Y	----	----	----	----
Pfizer Canada Inc. v. Canada (Health)	2008 FC 500	No appellate history.	Y	Y	----	----	Y
Shire Biochem Inc. v. Canada (Minister of Health)	2008 FC 538	No appellate history	Y	N	N	N	----
Johnson & Johnson Inc. v. Boston Scientific Ltd.	2008 FC 552; additional reasons in 2008 FC 817	No appellate history	N	----	N	Y	----
GlaxoSmithKline Inc. v. Pharmascience Inc.	2008 FC 593	No appellate history.	Y	N	Y	Y	----
Janssen-Ortho Inc. v. Apotex Inc.	2008 FC 744	Reversed by 2009 FCA 212 (on different grounds than inutility)	Y	Y	Y	Y	----
Laboratoires Servier v. Apotex Inc.	2008 FC 825	Affirmed by 2009 FCA 222 Leave to appeal to SCC ref'd: March 25, 2010	Y	Y	Y	----	----
Abbott Laboratories v. Canada (Minister of Health)	2008 FC 1359	Affirmed by 2009 FCA 94	Y	----	N	N	----
Uview Ultraviolet Systems Inc. v. Brasscorp Ltd.	2009 FC 58	No appellate history.	N	Y	Y	Y	----
Bristol-Myers Squibb Canada Co. v. Apotex Inc.	2009 FC 137	No appellate history	Y	----	N	Y	----
Lundbeck Canada Inc. v. Canada (Minister of Health)	2009 FC 146	Affirmed by 2010 FCA 320 Leave to appeal to SCC ref'd: Aug. 25, 2011	Y	Y	Y	Y	Y

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Eli Lilly Canada Inc. v. Novopharm Ltd.	2009 FC 235	No appellate history.	Y	N	Y	----	----
Hershkovitz v. Tyco Safety Products Canada Ltd.	2009 FC 256	Affirmed by 2010 FCA 190	N	----	N	N	----
Eli Lilly Canada Inc. v. Novopharm Ltd.	2009 FC 301	No appellate history	Y	----	N	N	----
Eli Lilly Canada Inc. v. Apotex Inc	2009 FC 320	No appellate history	Y	----	N	N	----
Pfizer Canada Inc. v. Novopharm Ltd.	2009 FC 638	Affirmed by 2010 FCA 242 Reversed 2012 SCC 60 (on other grounds than inutility)	Y	Y	Y	----	N
Abbott Laboratories v. Canada (Minister of Health)	2009 FC 648	Reversed in part by 2010 FCA 168 (on different grounds than inutility)	Y	Y	Y	----	----
Sanofi-Aventis Canada Inc. v. Apotex Inc.	2009 FC 676	Affirmed 2011 FCA 300 Application for leave to appeal to SCC dismissed (July 12,2012).	Y	N	N	----	----
Ratiopharm Inc. v. Pfizer Ltd.	2009 FC 711	Affirmed by 2010 FCA 204	Y	N	N	----	N
Purdue Pharma v. Pharmascience Inc.	2009 FC 726	No appellate history	Y	Y	Y	Y	----
Eli Lilly and Co. v. Apotex Inc.	2009 FC 991	Affirmed by 2010 FCA 240 Leave to appeal to SCC ref'd May 5, 2011	Y	Y	Y	Y	Y
Sanofi-Aventis Canada Inc. v. Hospira Healthcare Corp.	2009 FC 1077	No appellate history	Y	----	N	Y	Y

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Lundbeck Canada Inc. v. Ratiopharm Inc.	2009 FC 1102	No appellate history	Y	N	N	N	----
Schering-Plough Canada Inc. v. Pharmascience Inc.	2009 FC 1128	No appellate history	Y	Y	N	N	----
Pfizer Canada Inc. v. Canada (Minister of Health)	2009 FC 1294	Affirmed by 2011 FCA 102	Y	Y	Y	Y	Y
Biovail Corporation v. Canada (Health)	2010 FC 46	No appellate history	Y	----	N	Y	----
Bridgeview Manufacturing Inc. v. 931409 Alberta Ltd.	2009 FC 50	Allowed re obviousness in 2010 FCA 188	N	----	Y	----	----
Sanofi-Aventis Canada Inc. v. Ratiopharm Inc.	2010 FC 230	No appellate history.	Y	N	----	Y	----
Bauer Hockey Corp. v. Easton Sports Canada Inc.	2010 FC 361	Affirmed by 2011 FCA 83	N	Y	Y	Y	----
Pfizer Canada Inc. v. Canada (Minister of Health)	2010 FC 447	Reversed by 2011 FCA 236 Application for leave to appeal to Supreme Court of Canada dismissed on February 2, 2012.	Y	Y	Y	Y	----
Merck & Co. v. Pharmascience Inc.	2010 FC 510	No appellate history.	Y	----	Y	N	----
Weatherford Canada Ltd. v. Corlac Inc.	2010 FC 602	Allowed in part (re infringement only) 2011 FCA 228	N	----	Y	Y	----
Pfizer Canada Inc. v. Ratiopharm Inc.	2010 FC 612	No appellate history.	Y	N	N	----	----

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
AstraZeneca Canada Inc. v. Apotex Inc.	2010 FC 714	No appellate history.	Y	N	N	Y	----
Novo Nordisk Canada Inc. v. Cobalt Pharmaceuticals Inc.	2010 FC 746	No appellate history.	Y	----	N	Y	----
Novopharm Ltd. v. Eli Lilly and Co.	2010 FC 915	Affirmed 2011 FCA 220 Leave to appeal to SCC ref'd: Dec 8, 2011	Y	N	Y	Y	----
Merck-Frosst-Schering Pharma GP v. Canada (Minister of Health)	2010 FC 933	No appellate history	Y	----	Y	----	----
Merck & Co. v. Canada (Minister of Health)	2010 FC 1042	No appellate history	Y	----	N	Y	----
Merck & Co. v. Canada (Minister of Health)	2010 FC 1043	No appellate history	Y	----	----	----	----
Eli Lilly Canada Inc. v. Apotex Inc.	2010 FC 1065	No appellate history.	Y	Y	Y	Y	----
Janssen Inc. v. Mylan Pharmaceuticals ULC	2010 FC 1123	Dismissed as moot: 2011 FCA 16	Y	----	----	----	----
Merck & Co. v. Apotex Inc.	2010 FC 1265	Leave to appeal to SCC ref'd: Jul. 12, 2012	Y	Y	----	Y	Y
GlaxoSmithKline Inc. v. Pharmascience Inc.	2011 FC 239	No appellate history.	Y	Y	----	----	Y
Valence Technology, Inc. v. Phostech Lithium Inc.	2011 FC 174	Affirmed 2011 FCA 237	N	----	----	N	N
Pfizer Canada Inc. v. Mylan Pharmaceuticals ULC	2011 FC 547	Affirmed 2012 FCA 103	Y	Y	----	----	----
AstraZeneca Canada Inc. v. Mylan Pharmaceuticals ULC	2011 FC 1023	Affirmed 2012 FCA 109	Y	Y	Y	----	----

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Eli Lilly Canada Inc. v. Novopharm Ltd.	2011 FC 1288	Affirmed 2012 FCA 232 (see also: 2009 FC 1018, rev'd and remanded 2010 FCA 197) Leave to appeal to SCC refused (May 16, 2013).	Y	N	----	----	Y
Allergan Inc. v. Canada (Minister of Health)	2011 FC 1316	No appellate history.	Y	Y	Y	----	----
Wenzel Downhole Tools Ltd. v. National-Oilwell Canada Ltd.	2011 FC 1323	Affirmed 2012 FCA 333	N	Y	N	N	----
Apotex Inc. v. Sanofi-Aventis	2011 FC 1486	Reversed 2013 FCA 186 (FCA held patent useful) Leave to appeal to SCC to be heard in November 2014 (appeal discontinued)	Y	Y	Y	Y	----
Eurocopter v. Bell Helicopter Textron Canada Ltée	2012 FC 113	Affirmed: 2013 FCA 219	N	Y	Y	Y	Y
Alcon Canada Inc. v. Apotex Inc.	2012 FC 410	No appellate history	Y	----	N	----	----
Fournier Pharma Inc. v. Canada (Minister of Health)	2012 FC 740	No appellate history	Y	Y	Y	Y	Y
Fournier Pharma Inc. v. Canada (Minister of Health)	2012 FC 741	No appellate history.	Y	Y	Y	Y	Y
Allergan Inc. v. Canada (Minister of Health)	2012 FC 767	Affirmed 2012 FCA 308	Y	----	Y	Y	----
Hoffmann-La Roche Ltd. v. Apotex Inc.	2011 FC 875	No appellate history.	Y	Y	Y	----	----
Bristol-Myers Squibb Canada Co. v. Mylan Pharmaceuticals ULC	2012 FC 1142	No appellate history.	Y	Y	Y	Y	----

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
AstraZeneca Canada Inc. v. Phamascience Inc.	2012 FC 1189	FCA rev'd trial judge (2014 FCA 133), finding inutility allegation justified.	Y	N	Y	----	Y
Pfizer Canada Inc. v. Pharmascience Inc.	2013 FC 120	No appellate history.	Y	N	Y	----	----
Teva Canada Ltd. v. Novartis AG	2013 FC 141 2013 FC 142	Appeal heard 5 Feb 2014, but no decision reached. Re-appeal to be heard May 20, 2015.	Y	Y	----	----	Y
Apotex Inc. v. H. Lundbeck A/S	2013 FC 192	No appellate history.	Y	Y	Y	Y	Y
AstraZeneca Canada Inc. v. Ranbaxy Pharmaceuticals Canada Inc.	2013 FC 232	No appellate history. Appellant filed Notice of Discontinuance.	Y	----	Y	----	----
AstraZeneca Canada Inc. v. Teva Canada Ltd.	2013 FC 245 2013 FC 246	No appellate history.	Y	----	N	----	----
Novartis Pharmaceuticals Canada Inc. v. Teva Canada Ltd.	2013 FC 283	Affirmed 2013 FCA 244	Y	N	Y	----	N
Zero Spill Systems (Int'l) Inc. v. 614248 Alberta Ltd.	2013 FC 616	Appeal allowed (2015 FCA 115), matter remitted back to Federal Court to determine validity of 064 and 265 Patents. Appeal confirmed validity of 375 Patent.	N	----	N	N	----
Hoffman-La Roche Ltd. v. Apotex Inc.	2013 FC 718	No appellate history	Y	----	N	N	----
Varco Canada Limited v. Pason Systems Corp.	2013 FC 750	No appellate history.	N	Y	Y	Y	----
ABB Technology AG v. Hyundai Heavy Industries Co., Ltd.	2013 FC 947	Appeal heard May 14, 2014 and reserved (A-379-13)	N	----	N	----	----

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Novartis Pharmaceuticals Canada Inc v. Cobalt Pharmaceuticals Company	2013 FC 985	Affirmed: 2014 FCA 17	Y	----	Y	----	----
Distrimedic inc. c. Dispill Inc	2013 FC 1043	No appellate history	N	----	Y	Y	----
Bayer Inc. v. Cobalt Pharmaceuticals Company	2013 FC 1061	Appeals with respect to both patents dismissed, 2015 FCA 116	Y	Y	Y	----	Y
Gilead Science Inc. v. Canada (Health) Bristol-Myers Squibb & Gilead Sciences LLC v Canada	2013 FC 1270 2013 FC 1271 2013 FC 1272	Notice of Appeal filed January 17, 2014 (A-62-14)	Y	----	N	----	----
Abbvie Corporation v. Janssen Inc.	2014 FC 55	Matter remitted for new trial on appeal: 2014 FCA 242	Y	Y	Y	----	----
Pfizer Canada Inc. v. Mylan	2014 FC 38	Affirmed 2014 FCA 250	Y	Y	----	----	----
Alcon Canada Inc. v. Cobalt Pharmaceuticals Company	2014 FC 149	No appellate history.	Y	N	Y	----	Y
E. Mishan & Sons, Inc. v. Supertek Canada Inc.	2014 FC 326	Appeal dismissed 2015 FCA 163	N	----	N	Y	----
Pfizer Canada Inc. v. Apotex Inc.	2014 FC 314	Affirmed 2014 FCA 250	Y	Y	----	----	Y
Bayer Inc. v. Apotex Inc.	2014 FC 436	No appellate history	Y	----	----	Y	Y
Alcon Canada Inc. v. Cobalt Pharmaceuticals	2014 FC 462	Notices of appeal filed by both Alcon and Cobalt (A-284-14, A-286-14). Heard jointly May 27, 2015 - reserved	Y	Y	N	----	----

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Allergan Inc v Cobalt Pharmaceuticals Company	2014 FC 566	Appeal discontinued – A-321-14	Y	Y	Y	Y	----
Allergan Inc v Apotex Inc	2014 FC 567	Appeal unsuccessful: 2015 FCA 137	Y	Y	Y	Y	----
AstraZeneca Canada Inc v Apotex Inc	2014 FC 638	Appeal unsuccessful: 2015 FCA 158	Y	N	Y	Y	----
Alcon Canada Inc v Apotex Inc	2014 FC 699	No appellate history.	Y	Y	N	N	----
Alcon Canada Inc v Apotex Inc	2014 FC 794 (public reasons 2014 FC 791)	No appellate history.	Y	Y	N	----	----
The Dow Chemical Company et al. v. Nova Chemicals Corporation	2014 FC 844	Notice of appeal filed by Nova (A-379-14)	N	Y	Y	Y	Y
Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC	2015 FC 17	Notice of Appeal filed (A-47-15)	y	y	y	----	----
Les Laboratories Servier v. Apotex Inc.	2015 FC 108	No appellate history	Y	N	N	----	----
Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC	2015 FC 125	Notice of Appeal filed (A-120-15)	Y	N	N	N	----
Janssen Inc. v. Teva Canada Limited	2015 FC 184	No appellate history	Y	----	N	----	----
Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC	2015 FC 178	Notice of Appeal filed (A-139-15)	Y	----	N	----	----
Janssen Inc. v. Teva Canada Limited	2015 FC 247	No appellate history	Y	----	N	----	----
Astrazeneca Canada Inc. v. Apotex Inc.	2015 FC 322	Notice of Appeal filed (A-201-15)	Y	Y	Y	Y	----

Federal Court Patent Validity Cases from 1980-Present (as of 10 August 2015)

Style of Cause	Trial Court	Appeals	Pharma case	Useful	Non-Obvious	Novel	Sufficient
Takeda Canada Inc. v. Canada (Health)	2015 FC 570	No appellate history	Y	----	N	----	----
Novartis Pharmaceuticals Canada v. Teva Canada Limited	2015 FC 770	None yet	Y	Y	Y	----	Y
Eli Lilly Canada Inc. v. Apotex Inc	2015 FC 875	Notice of Appeal filed (A-330-15)	Y	----	----	----	Y
Takeda Canada Inc. v. Canada (Health)	2015 FC 751	No appellate history	Y	----	----	N	----