IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN OF THE NORTH AMERICAN FREE TRADE AGREEMENT

AND THE UNCITRAL ARBITRATION RULES (1976)

BETWEEN:

ELI LILLY AND COMPANY

Claimant/Investor

AND:

GOVERNMENT OF CANADA

Respondent/Party

(Case No. UNCT/14/2)

SECOND WITNESS STATEMENT OF MARCEL BRISEBOIS

DECEMBER 7, 2015

Trade Law Bureau
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1. I submit this second witness statement to respond to certain assertions made by Claimant in its Reply Memorial and accompanying expert reports. In particular, I will address Claimant's patent invalidation statistics, and show that its conclusions with respect to discrimination are unreliable. I will then discuss the inquiries I believe were missing from Claimant's analyses.

A. Claimant's Conclusions on Discrimination are Unreliable because of the Flawed Data Set

2. Claimant presented Dr. Bruce Levin with a list of patent cases litigated between 1980 and 2015, which he attaches as Appendix C to his report.[1] Based on his analysis of this data, Dr. Levin identifies a 39.5% difference between utility-based invalidity rates for pharmaceutical and non-pharmaceutical patents since 2005, and concludes the difference is likely not due to chance.[2]

3. I have reviewed the data set relied on by Dr. Levin, and found that it is afflicted with at least three flaws: (1) discrepancies and inaccuracies in the data; (2) the use of cases instead of patents to measure patent invalidation rates; and (3) the inclusion of cases brought under the *Patented Medicine (Notice of Compliance)* ("PM(NOC)") regulations.

4. These flaws in the data set are crucial errors. Given the small populations considered in Dr. Levin's analysis, a single case counted in the wrong box can fundamentally alter the significance of the statistical conclusions. I asked Mr. Andrew Raven, Manager of the Biostatistics and Epidemiology Unit, Office of Science, Therapeutic Products Directorate at Health Canada, to statistically analyze a corrected data set. His analysis revealed that there has not been a statistically significant difference in utility-based invalidation rates between pharmaceutical and non-pharmaceutical patents since 2005. I have attached his analysis as Annex A to my report.

[1] Levin Report at para. 4.

[2] Levin Report at para. 5.

1. There are important discrepancies and inaccuracies in the data relied on by Dr. Levin

5. In Table 1 of his report, Dr. Levin reports that there are **25** post-2005 pharmaceutical cases wherein a patent failed a utility challenge.[3] However, only **24** post-2005 pharmaceutical cases wherein a patent failed a utility challenge are found in Appendix C to his report.

6. Dr. Levin further reports that **38** pharmaceutical cases were found useful when challenged post-2005. Appendix C to his report, however, lists **39** such cases.

7. In addition, there are several inaccuracies in the characterization of the cases provided to Dr. Levin in Annex C of his report. First, as set out in the second expert report of Mr. Ron Dimock,[4] there are at least two non-pharmaceutical patent cases that were incorrectly treated as cases in which patents were found useful: *Wenzel Downhole Tools Ltd. v. National-Oilwell Canada Ltd*., 2012 FCA 333 (*Wenzel*);[5] and *Eurocopter v. Bell Helicopter Textron Canada Ltée*, 2013 FCA 219 (*Eurocopter*).[6] The court did not find it necessary to decide on utility in *Wenzel*.[7] This case should be removed from Dr. Levin's Table 1 altogether.

8. *Eurocopter* is a case in which 15 of the helicopter landing gear patent's 16 claims were found invalid for lack of utility.[8] The patent claimed two embodiments of landing gear, one with a front cross-piece offset forwards, and one with a front cross-piece offset backwards. The court found that only the piece that was offset forwards was useful. As such, I have counted this case as one in which a non-pharmaceutical patent both won and lost a utility-based validity challenge. I note that I treated the pharmaceutical patent case *Novartis Pharmaceuticals Canada Inc. v. Teva Canada Limited*, 2015 FC 770, the same way in my data set.

[3] Levin Report at p. 5.

[4] Dimock Second Report at Annex C.

[5] *See* Levin Report at Appendix C, p. 17.

[6] *See* Levin Report at Appendix C, p. 17.

[7] *See* Dimock Second Report at Annex C, p. 1.

[8] *See* Dimock Second Report at Annex C, p. 1.

9. Second, as set out in the second expert report of Mr. Dimock, at least two pharmaceutical patent cases were also incorrectly characterized. First, *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236,[9] should be treated as a case in which a patent was held to lack utility. While the trial level court found the patent to be useful, the appellate court overturned the trial court's decision on that ground.[10] Second, and consistent with the treatment accorded to *Eurocopter*, *Novartis Pharmaceuticals Canada Inc. v. Teva Canada Limited*, 2015 FC 770 should be treated as a pharmaceutical patent that both won and lost a utility-based validity challenge because certain claims were found useful and others were found to lack utility.[11]

10. Finally, four cases should be added to Dr. Levin's Table 1. First, *Bayer Inc. v. Apotex Inc.*, 2014 FC 403, a pharmaceutical patent case in which the patent at issue was found useful is missing from the case list.[12] Second, there have been three additional cases in which a utility challenge was decided since Claimant filed its Reply Memorial, all with respect to pharmaceutical patents: *Eli Lilly Canada Inc. v. Apotex Inc*, 2015 FC 1016 (the patent was found useful); *Gilead Sciences, Inc. v. Idenix Pharmaceuticals Inc.*, 2015 FC 1156 (the patent was found to lack utility); and *Amgen Canada Inc. v. Apotex Inc.*, 2015 FC 1261 (the patent was found useful).

11. Correcting for all of these errors, and updating for the new cases, Dr. Levin's Table 1 should read:

[9] *See* Levin Report at Appendix C, p. 15.

[10] *See* Dimock Second Report at Annex C, p. 2.

[11] *See* Dimock Second Report at Annex C, p. 2: In this PM(NOC) decision, use claims 1-4 and 40-42 of patent 2,255,951 were held to lack utility and compound claims 5-37 were held to be useful.

[12] *Bayer Inc. v. Apotex Inc.*, 2014 FC 403 **(R-398)**. I note that this is a case in which the judge adopted the reasons from a separate PM(NOC) challenge brought by Cobalt Pharmaceuticals Company (*see* 2013 FC 1061). This is an example of the type of double counting that can result from including PM(NOC) cases in a comparison. Nonetheless, according to the methodology set out in Appendix C to Dr. Levin's report, the case should be counted as a separate judgment in which a patent was found useful.

Table 1: Corrections to Levin's Table 1

Type of patent	Patent found *invalid* on utility grounds	Patent found *valid* on utility grounds	Total
Pharmaceutical	27	41	68
Non-pharmaceutical	1	7	8
Total	28	48	76

12. While these modifications may appear minor at first glance, they are actually quite significant because of the small populations under consideration. With these changes, the difference between the observed proportion of pharmaceutical patents found invalid on utility grounds post-2005 and that of non-pharmaceutical patents similarly found invalid is now only 27.2 percentage points.[13]

13. Using Fisher's exact test for comparing two proportions with the one-tailed criterion of statistical significance at the 0.05 level – the same test used by Dr. Levin – Mr. Raven observed a significance level, or "P-value" of 0.1293. This is well above the acceptable 0.05 level.[14] As these results show, had Dr. Levin been provided with accurate data, he would inevitably have concluded that the difference between utility-based invalidation rates for pharmaceutical and non-pharmaceutical patents since 2005 *is within the realm of chance, i.e.* it was statistically insignificant.

2. The Data Provided to Dr. Levin Inappropriately Counts Cases Rather than Patents

14. In providing data to Dr. Levin, Claimant counted court judgments instead of the patents with respect to which the court judgment was rendered. This is problematic because a given judgment may have findings relating to more than one patent on the same grounds. According to Claimant's methodology, if more than one patent is challenged in a single proceeding on the same ground, and just one patent was found invalid on that ground, the

[13] *See* Annex A (Raven Analysis), p. 3.

[14] *See* Annex A (Raven Analysis), p. 3.

entire case should be coded invalid for that ground.[15] There is no justification for such a biased assumption.

15. Canadian patents 1,333,895 and 1,338,937 provide an example of this. Both patents were challenged in the same PM(NOC) case on the basis of utility.[16] The judge found that the allegations of lack of utility with respect to the first were justified, while the same allegations were not justified with respect to the second. Claimant counted this one case as a statistic for "patent found *invalid* on utility grounds", even though it could equally have been treated as a "patent found *valid* on utility grounds."

16. A more reliable way to assess the data is to consider, as I did in my first statement, the findings as they relate to each patent.[17] In the vast majority of cases, this accurately reflects the courts' findings as they relate to the patent as a whole or the claims at issue. In two cases where distinct claimed embodiments of a patent were found to both have and lack utility, I treated the patent itself as being found both invalid and valid on utility grounds.[18] This manner of treating cases more accurately depicts the outcomes of patent validity challenges.

17. I have updated the data I presented with my first statement, and after combining it with the corrections noted in Table 1, I obtained Table 2 below. The data is current to November 30, 2015:[19]

Table 2: Patents Involving a Decided Challenge on Grounds of Utility Post-2005

Type of patent	Patent found *invalid* on utility grounds	Patent found *valid* on utility grounds	Total
Pharmaceutical	27	50	77
Non-pharmaceutical	1	7	8
Total	28	57	85

[15] *See* Levin Report, Appendix C at p. 1 ("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.")

[16] *See Novartis Pharmaceuticals Canada Inc. v. Teva Canada Ltd.*, 2013 FC 283 (aff'd 2013 FCA 244) (**C-244**).

[17] *See* Brisebois First Statement, Annex A.

[18] *See* my discussion with respect to *Eurocopter* and *Novartis* in paras. 8-9 above.

[19] *See* Annex B for my updated list of decided validity challenges for pharmaceutical patents.

18. Table 2 shows that the difference between the observed proportion of pharmaceutical patents found invalid on utility grounds post-2005 and that of non-pharmaceutical patents similarly found invalid is now only 22.6 percentage points.[20]

19. Once again, as Mr. Raven finds, the difference of 22.6 percentage points is not statistically significant at the one-tailed 0.05 level ($P = 0.1882$).[21] This leads to the same conclusion: the difference between utility-based invalidity rates for pharmaceutical and non-pharmaceutical patents since 2005 is within the realm of chance.[22]

3. The Data Provided to Dr. Levin is Biased by the Inclusion of PM(NOC) Cases

20. In both its Memorial and Reply, Claimant included PM(NOC) cases in its data set to compare patent invalidation rates between pharmaceutical and non-pharmaceutical sectors.[23] In my view, PM(NOC) cases should not be included in any statistical inquiry into the significance of observed differences in invalidity rates between sectors for three main reasons.

21. First, as I set out in my first statement, PM(NOC) proceedings are available exclusively to the pharmaceutical sector.[24] This litigation mechanism exists in addition to the impeachment mechanism that is available to challenge all patents, pharmaceutical and non-pharmaceutical alike. Including these proceedings in a comparison between pharmaceutical and non-pharmaceutical sectors thus introduces an impermissible and inappropriate differentiation factor between two populations beyond the pharmaceutical/non-pharmaceutical distinction.

22. Second, the effect of a finding that the allegations of invalidity are justified in a PM(NOC) proceeding is not the same as the effect of a finding of invalidity in an impeachment or infringement proceeding.[25] Unlike in an impeachment or infringement decision in which a patent is declared invalid in whole or in part, a PM(NOC) decision does not declare the challenged patent invalid. It remains valid, and can be asserted in subsequent PM(NOC),

[20] *See* Annex A (Raven Analysis), p. 3.

[21] *See* Annex A (Raven Analysis), p. 3

[22] *See* Annex A (Raven Analysis), p. 3.

[23] *See, e.g.*, Claimant's Memorial at paras. 221-2; Claimant's Reply at para. 198.

[24] Brisebois Statement at paras. 31-33.

[25] *See* Brisebois Statement at paras. 27, 39-40.

infringement or impeachment proceedings.[26] While the "practical effects of a PM(NOC) finding of invalidity are real, immediate, and significant",[27] these considerations are not relevant to an objective assessment of whether there has been a disproportionate number of patents declared invalid in whole or in part in the pharmaceutical sector as compared to other sectors. A declaration of invalidity is therefore the only effect that is equally comparable between pharmaceutical and non-pharmaceutical patents.

23. Third, the inclusion of PM(NOC) proceedings introduces an inappropriate double counting factor for pharmaceutical patents. A single pharmaceutical patent could have allegations of invalidity found justified on the same grounds several times under PM(NOC) proceedings, and then be conclusively invalidated in an infringement or impeachment proceeding on the same grounds. Under Claimant's methodology, each case counts as a separate "invalidation" of the same patent.

24. For example, the allegation of lack of utility against Canadian patent 1,341,206 was found to be justified in a PM(NOC) proceeding.[28] That same patent was later invalidated on the same grounds in infringement/impeachment proceedings.[29] Claimant counted this patent twice as being found invalid for lack of utility, while it was only invalidated once. Taking into account such PM(NOC) decisions gives surplus "weight" in the overall statistics to the patents that have been challenged in more than one proceeding,[30] and ultimately skews the comparison between pharmaceutical and non-pharmaceutical patents.[31]

25. Once the PM(NOC) cases are removed from the analysis, and the corrections discussed above are applied, I obtain the following table:

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[26] *See* Dimock First Report at paras. 43-44.

[27] Claimant's Reply at para. 25.

[28] *Aventis Pharma Inc. v. Apotex*, 2006 FCA 64 **(C-212)**.

[29] *Sanofi-Aventis Canada Inc. v. Apotex Inc*, 2011 FCA 300 **(C-300)**.

[30] Although this "double counting" factor also affects findings of validity, and opposite rulings in different proceedings represent a possibility, these facts do not cure the inherent and underlying methodological problem associated with allowing for double counting.

[31] Canadian patent 2,139,653 is another example of "double counting" by the Claimant: *see AstraZeneca v. Apotex*, 2010 FC 714 **(C-468)** (PM(NOC) case) and *Astrazeneca Canada Inc. v. Apotex Inc.* 2015 FCA 158 **(R-399)** (infringement/impeachment case).

Table 3: Patents Involving a Decided Challenge on Grounds of Utility Post-2005 Without PM(NOC) Cases

Type of patent	Patent found *invalid* on utility grounds	Patent found *valid* on utility grounds	Total
Pharmaceutical	6	14	20
Non-pharmaceutical	1	7	8
Total	7	21	28

26. As Mr. Raven unsurprisingly finds, the difference of 17.5 percentage points in the proportion of pharmaceutical and non-pharmaceutical patents found invalid on utility grounds post-2005 is not statistically significant at the one-tailed 0.05 level ($P = 0.3274$).[32] Once again, the statistical analysis concludes that the difference between utility-based invalidity rates for pharmaceutical and non-pharmaceutical patents since 2005 is within the realm of chance.

B. Additional Analyses the Claimant Should have Carried Out Confirm that there has been No Discrimination

1. No statistically significant increase was observed in overall pharmaceutical patent invalidations

27. Claimant argues in its Reply that the higher incidence of pharmaceutical patent litigation following the introduction of PM(NOC) proceedings cannot explain the higher rate (or proportion) of invalidity findings under the utility doctrine."[33] It asserts that a similar percentage increase between pre-2005 and post-2005 inutility findings was not observed outside of the pharmaceutical sector or with respect to other patentability requirements.

28. A finding of invalidity on a single ground is sufficient to invalidate a patent. Therefore, if utility-based invalidation rates increased with statistical significance, but the rates of invalidation on grounds other than utility "remained relatively stable before and after 2005,"[34] one would expect to see a significant increase in overall patent invalidation rates for pharmaceutical patents. This is not the case.

[32] *See* Annex A (Raven Analysis), p. 4.

[33] Claimant's Reply at paras. 196-197.

[34] Claimant's Reply at para. 197.

29. As Mr. Raven has confirmed, a decrease of 22 percentage points is observed in overall patent invalidation rates for pharmaceutical patents under infringement/impeachment proceedings in the post-2005 period:

Table 4: Pharmaceutical Patents Involving a Decided Validity Challenge (All Grounds) Without PM(NOC) Cases

Period	Pharmaceutical patent found *invalid*	Pharmaceutical patent found *valid*	Total
Post-2005	7	18	25
Pre-2005	4	4	8
Total	11	22	33

30. Mr. Raven's analysis shows that this decrease is statistically insignificant ($P = 0.2333$), and thus within the realm of chance.[35]

31. If the PM(NOC) cases are inappropriately included in the same analysis, Mr. Raven observes an increase of 7.9 percentage points:

Table 5: Pharmaceutical Patents Involving a Decided Validity Challenge (All Grounds) With PM(NOC) Cases

Period	Pharmaceutical patent found *invalid*	Pharmaceutical patent found *valid*	Total
Post-2005	79	68	147
Pre-2005	11	13	24
Total	90	81	171

32. Mr. Raven concludes, once again, that this increase is statistically insignificant ($P = 0.3085$), and is therefore within the realm of chance.[36]

2. No statistically significant increase in utility-based invalidity rates was observed for pharmaceutical patents before and after 2005

33. Claimant also argues that: "only utility challenges have seen a statistically significant increase in invalidations, and only in the pharmaceutical sector since 2005."[37] However,

[35] *See* Annex A (Raven Analysis), p. 5.

[36] *See* Annex A (Raven Analysis), p. 5.

[37] Claimant's Reply at para. 197.

while there is an observed increase in utility-based invalidation rates in pharmaceutical patents before and after 2005 (shown in Tables 6 and 7), Dr. Levin has not assessed the statistical significance of this difference.

Table 6: Pharmaceutical Patent Involving a Decided Challenge on Grounds of Utility Without PM(NOC) Cases

Period	Pharmaceutical patent found *invalid* on utility grounds	Pharmaceutical patent found *valid* on utility grounds	Total
Post-2005	6	14	20
Pre-2005	0	3	3
Total	6	17	23

Table 7: Pharmaceutical Patent Involving a Decided Challenge on Grounds of Utility With PM(NOC) Cases

Period	Pharmaceutical patent found *invalid* on utility grounds	Pharmaceutical patent found *valid* on utility grounds	Total
Post-2005	27	50	77
Pre-2005	0	4	4
Total	27	54	81

34. Mr. Raven confirms that there is no statistical evidence of a difference in utility-based invalidation rates for pharmaceutical patents before and after 2005.[38] This is the case whether PM(NOC) cases are properly excluded ($P = 0.3840$) or improperly included ($P = 0.1901$).[39] The observed difference is therefore, once again, within the realm of chance.[40]

3. No statistically significant difference was observed in utility-based invalidity rates for pharmaceutical patents before and after the AZT *decision in 2002, or before and after the* Raloxifene *decision in 2008*

35. The Claimant asserts that the 2002 *AZT* decision[41] changed the law on post-filing evidence of utility,[42] and that a "heightened disclosure" rule for sound prediction cases was created in the

[38] *See* Annex A (Raven Analysis), p. 7.

[39] *See* Annex A (Raven Analysis), pp. 6.

[40] *See* Annex A (Raven Analysis), p. 6.

[41] *Apotex Inc. v. Wellcome Foundation Ltd*., [2002] 4 SCR 153 ("*AZT*"), para. 45 **(R-004)**.

[42] Claimant's Reply at paras. 93-103.

2008 *Raloxifene* decision.[43] Each of these alleged new rules, it argues, is one of the "components" of the alleged new elevated utility standard in Canadian law.[44] However, all of its statistical analyses are centered on 2005. If the alleged new post-filing evidence and "heightened disclosure" rules began to be applied against pharmaceutical patents in a new way after 2002 and 2008, respectively, one might expect to see a statistically significant increase in pharmaceutical patent invalidation rates in the periods following the *AZT* and *Raloxifene* decisions. This is not the case.

36. To determine whether the *AZT* decision had any impact on the outcomes of validity challenges on utility grounds, I looked at the proportion of pharmaceutical patents that lost a utility challenge in the period before the Supreme Court's decision in *AZT* (the pre-*AZT* period) and the proportion of the pharmaceutical patents that lost a utility challenge after *AZT* was decided by the Supreme Court (the post-*AZT* period):[45]

Table 8: Pharmaceutical Patent Involving a Decided Challenge on Grounds of Utility Before and After *AZT* Without PM(NOC) cases

Period	Pharmaceutical patent found *invalid* on utility grounds	Pharmaceutical patent found *valid* on utility grounds	Total
Pre-*AZT*	0	2	2
Post-*AZT*	6	14	20
Total	6	16	22

Table 9: Pharmaceutical Patent Involving a Decided Challenge on Grounds of Utility Before and After *AZT* With PM(NOC) cases

Period	Pharmaceutical patent found *invalid* on utility grounds	Pharmaceutical patent found *valid* on utility grounds	Total
Pre-*AZT*	0	3	3
Post-*AZT*	27	50	77
Total	27	53	80

[43] *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142 **(C-115)**; Claimant's Reply at paras. 113-114.

[44] Claimant's Reply at para. 70.

[45] *See* Annex C for the list of cases included in this analysis.

37. Mr. Raven confirms that there is no statistical evidence of a difference in the rates of utility-based invalidation rates for pharmaceutical patents before and after *AZT* in 2002.[46] This is the case whether PM(NOC) cases are properly excluded ($P = 0.5195$) or improperly included ($P = 0.2851$).[47] The observed difference is therefore, once again, within the realm of chance.[48] His conclusion does not support Claimant's argument that *AZT* changed Canada's approach to utility in a way that negatively impacted pharmaceutical patents.

38. Similarly, to determine if the allegedly unprecedented heightened disclosure rule had any impact on the outcomes of validity challenges on utility grounds, I looked at the proportion of pharmaceutical patents that lost a utility challenge in the period from 1980 until the *Raloxifene* trial decision in 2008 (the pre-*Raloxifene* period), on the one hand, and the proportion of those pharmaceutical patents that lost a utility challenge after the *Raloxifene* trial decision until November 30, 2015 (the post-*Raloxifene* period):[49]

Table 10: Pharmaceutical Patent Involving a Decided Challenge on Grounds of Utility Before and After *Raloxifene* Without PM(NOC) Cases

Period	Pharmaceutical patent found *invalid* on utility grounds	Pharmaceutical patent found *valid* on utility grounds	Total
Pre-*Raloxifene*	0	3	3
Post-*Raloxifene*	6	14	20
Total	6	17	23

Table 11: Pharmaceutical Patent Involving a Decided Challenge on Grounds of Utility Before and After *Raloxifene* With PM(NOC) cases

Period	Pharmaceutical patent found *invalid* on utility grounds	Pharmaceutical patent found *valid* on utility grounds	Total
Pre-*Raloxifene*	5	8	13
Post-*Raloxifene*	21	46	67
Total	26	54	80

[46] *See* Annex A (Raven Analysis), p. 8.

[47] *See* Annex A (Raven Analysis), pp. 7-8.

[48] *See* Annex A (Raven Analysis), p. 7-8.

[49] *See* Annex D for the list of cases included in this analysis.

39. Mr. Raven confirms that there is no statistical evidence of a difference in utility-based invalidation rates for pharmaceutical patents before and after *Raloxifene* in 2008.[50] This is the case whether PM(NOC) cases are properly excluded ($P = 0.3840$) or improperly included ($P = 0.4197$).[51] The observed difference is therefore, once again, within the realm of chance.[52] His conclusion does not support Claimant's argument that *Raloxifene* changed Canada's approach to utility in a way that negatively impacted pharmaceutical patents.

C. There is nothing unique about the "spike" in utility-based invalidations in 2005: invalidations on other grounds "peaked" at the same time

40. In its Reply Memorial, Claimant asserts that the "discriminatory pattern of utility rulings," demonstrated by a "spike" in inutility findings since 2005 can only be explained by the "dramatic change in Canada's utility standard."[53] As the following Figures 1 and 2 show, however, the same "spike" occurred around the same period for all of the main grounds of invalidity.

41. First, utility-based invalidity findings must be placed in the broader context of all pharmaceutical patent litigation. As shown in Figure 1, the Canadian courts saw an increase in the number of validity challenges directed at pharmaceutical patents on all grounds around the same time in the mid-2000s:

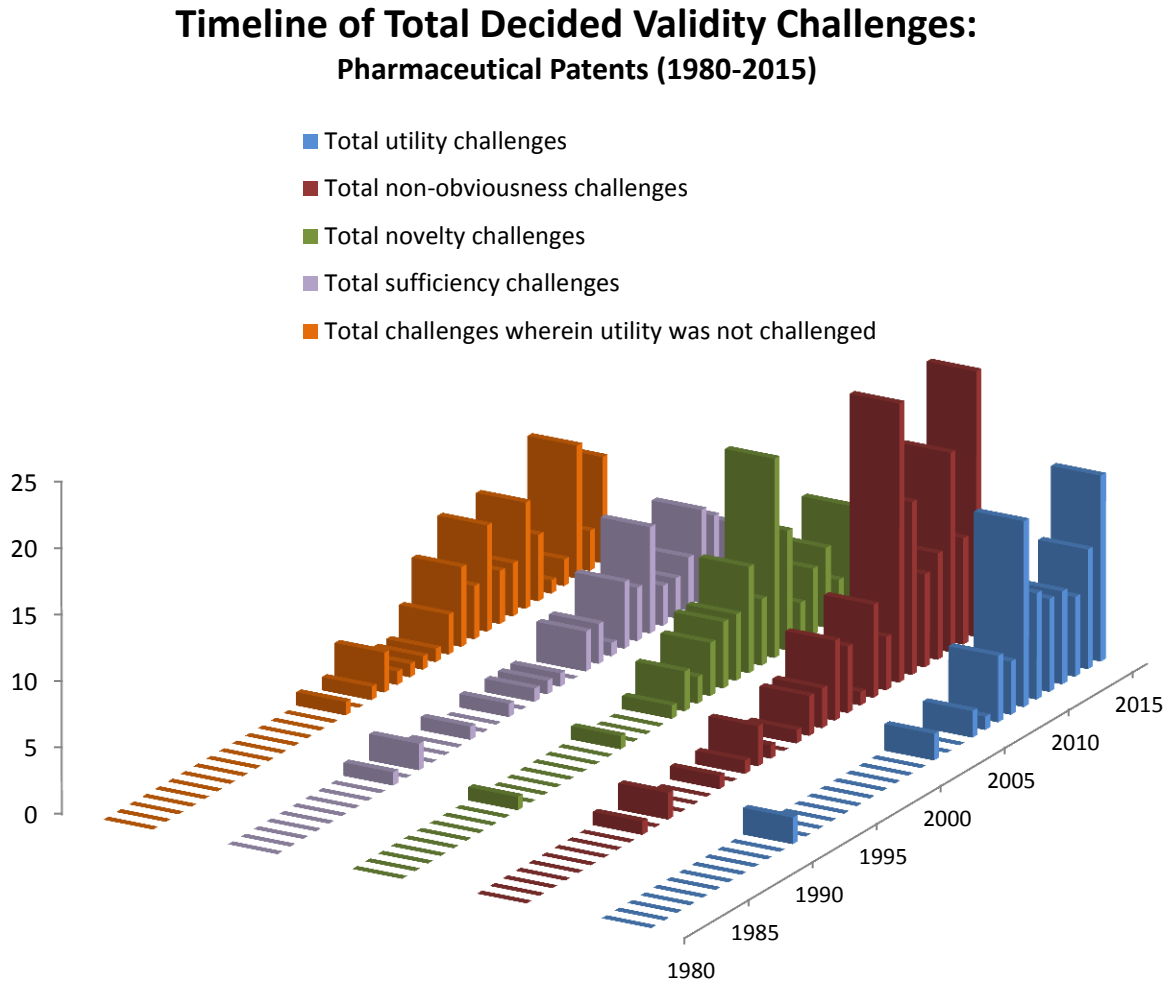
[50] *See* Annex A (Raven Analysis), p. 9.

[51] *See* Annex A (Raven Analysis), p. 9.

[52] *See* Annex A (Raven Analysis), p. 9.

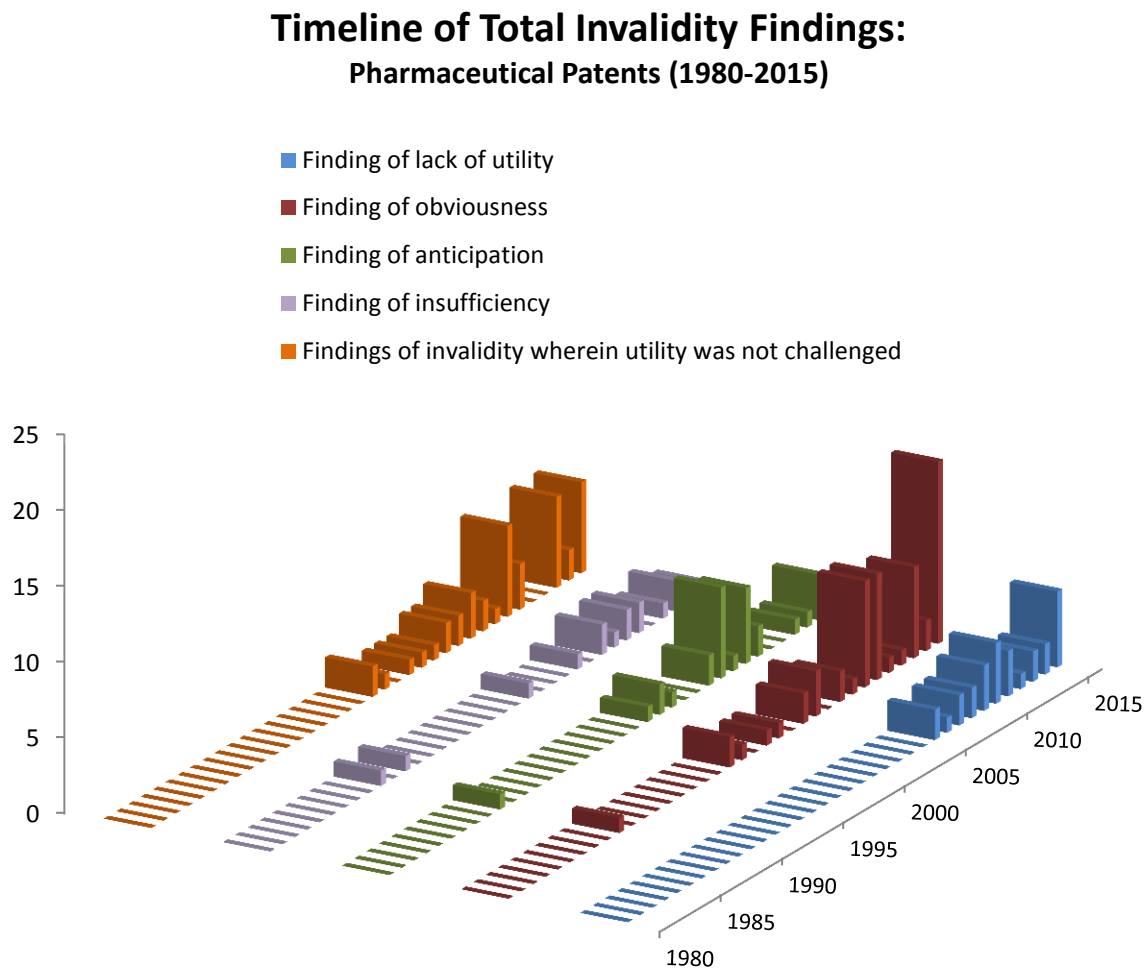
[53] Claimant's Reply at paras. 295-300; Figure 1.

Figure 1



42. Figure 2 below shows that, as one might expect, findings of invalidity on all grounds tracked the growth in decided challenges:

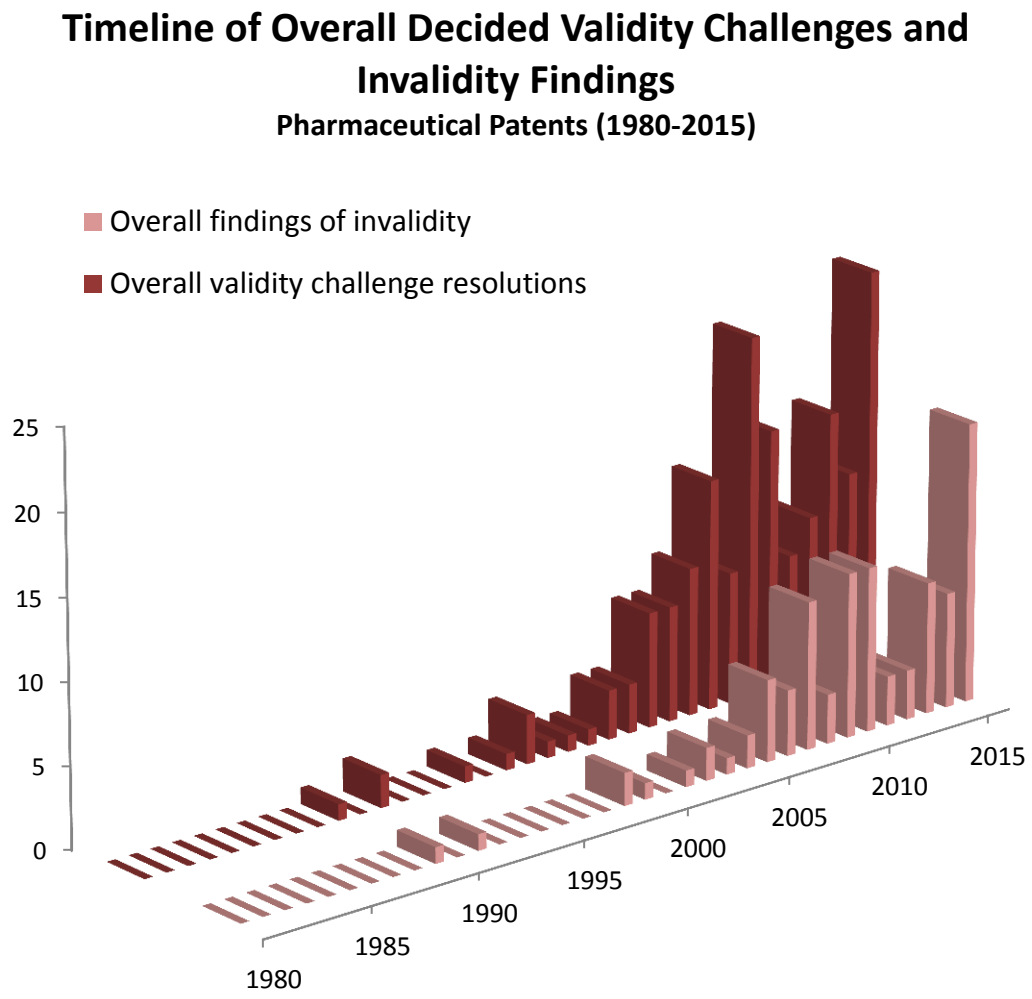
Figure 2



43. Figures 1 and 2 show that there is nothing unique or surprising about the timeframe of the statistically insignificant increase in inutility findings (blue bars) when observed in the broader context of pharmaceutical patent litigation. The number of invalidity findings in cases in which utility was not challenged (orange bars) demonstrates this point.

44. Figure 3 below shows the total number of decided validity challenges to pharmaceutical patents and the total number of pharmaceutical patents ultimately held invalid. As seen below, both increased at the same time and at a rate similar to the increase in utility-based invalidity findings that Claimant attributes to a change in the law:

Figure 3

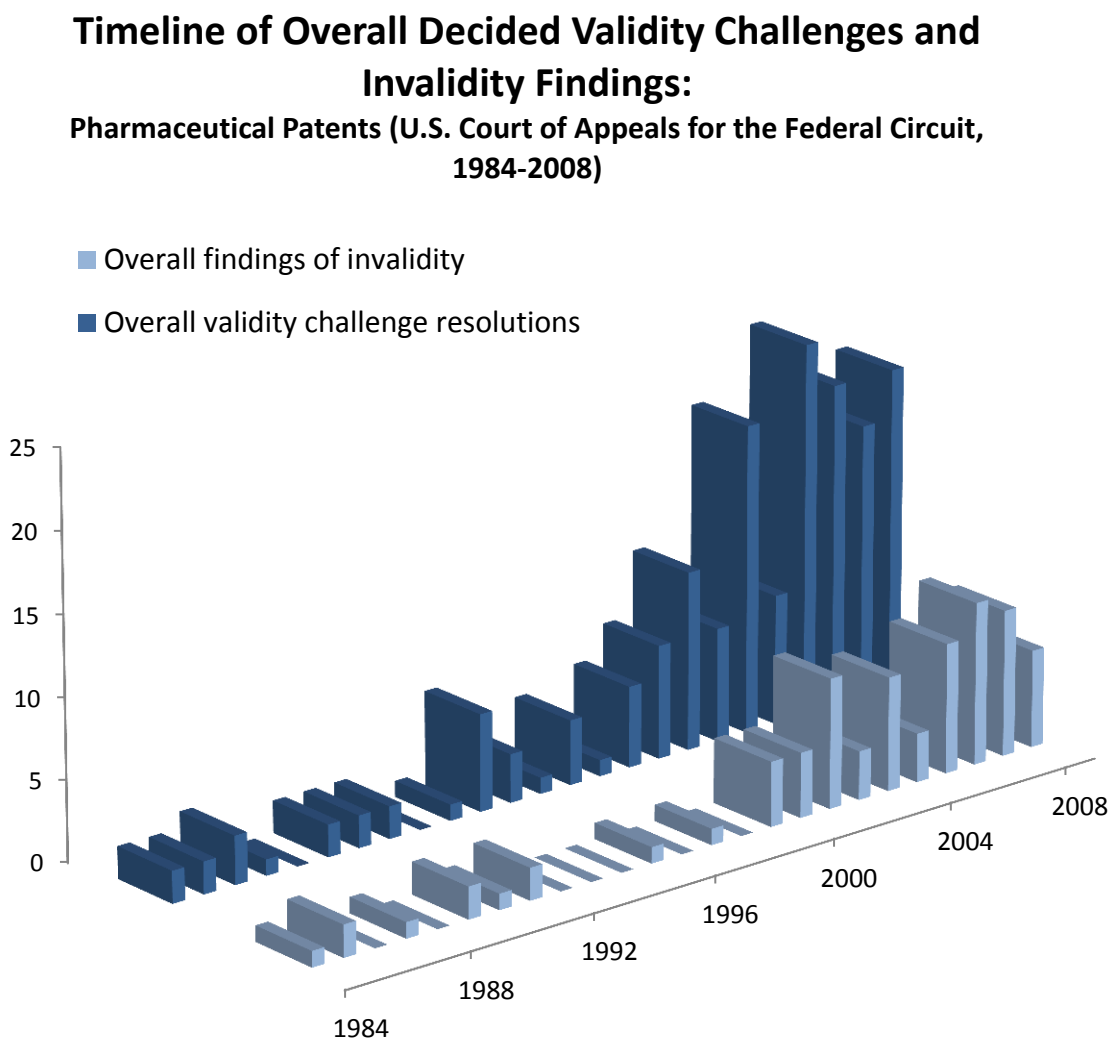


45. Importantly, all of these figures taken together show that an alleged shift in Canada's approach to utility could not have driven these "spikes" of decided challenges and corresponding findings of invalidity for other grounds.

46. This surge of pharmaceutical patent validity challenges and corresponding findings of invalidity in the mid-2000s is not unique to Canada. In fact, as shown in Figure 4 below, a

very similar surge of pharmaceutical patent invalidity challenges and findings of invalidity occurred through the US Federal Circuit:[54]

Figure 4



[54] The dataset used for Figure 4 is the same used in Alberto Galasso and Mark Schankerman ,"Patents and Cumulative Innovation: Causal Evidence from the Courts", *The Quarterly Journal of Economics*, November 21, 2014 **(R-400)**. As described in that article, the dataset includes 167 patent cases involving drug patents (patents belonging to the NBER (National Bureau of Economic Research) category 3 but not in the sub-categories of Medical Instruments and Biotechnology). I have not independently verified the data set. See Annex E for the chronological list of cases (docket number) and patents.

47. In summary, an increase in decided pharmaceutical patent validity challenges was naturally accompanied by a corresponding rise in invalidity findings post-2005, including but not limited to inutility findings. As the data shows, this increase was certainly not related to an event specific to the utility patentability requirement.

Signed at: Gatineau on: 07/12/2015

[signed]
Marcel Brisebois

Annex A

December 7, 2015

Dr. Marcel Brisebois
Canadian Intellectual Property Office
Place du Portage I
50 Victoria St
Gatineau, QC K1A 0C9

Re: *Eli Lilly and Company v. Government of Canada*, UNCT/14/2

Dear Dr. Brisebois:

You have asked me to statistically analyze a series of 2 x 2 tables relating to patent law cases in Canada to assist you in your response to the Expert Report of Dr. Bruce Levin in the *Eli Lilly and Company v. Government of Canada* NAFTA Chapter 11 arbitration. Please find below the results of my statistical analyses. I have conducted my analyses on the basis of the data you provided to me. For the purposes of my analyses, I assumed that the data was accurate, and did not conduct any independent inquiries into the reliability of the data.

A. Comments on the statistical tests used by Dr. Levin

As a preliminary matter, Dr. Levin used Fisher's exact test for comparing two proportions to conduct his primary analyses. The Fisher's exact test is well recognised and appropriate for comparing the frequencies of 2 x 2 tables – like those presented by Dr. Levin, and those you provided to me – because it calculates the precise probability of getting the results observed, as well as all other potential results that are more extreme. Fisher's exact test is preferred to other common methods (such as the Chi-square test) in this case because of the smaller counts in some of the tables.

I note that Dr. Levin used a one-sided test instead of a two-sided test to determine statistical significance in the data sets he analyzed at a significance level of 0.05. Two-sided tests at a significance level of 0.05 are generally considered to be more conservative because they provide larger p-values than their corresponding one-sided tests. As such, two-sided tests are generally preferred because they are less likely to show statistical significance. I applied a two-sided Fisher's exact test to Dr. Levin's analyses, and while all of the p-values increased, the comparisons which were statistically significant (i.e. $p<0.05$) for a one-sided test remained statistically significant for the corresponding two-sided test.

In order for my results to be as compatible as possible with those of Dr. Levin, I also use a one-sided Fisher's exact test in the direction most appropriate to the comparison (either "greater than" or "less than" depending on the direction of the values presented). As I noted above, this method increases the likelihood of declaring statistical significance for each comparison.

Dr. Levin also conducted a "difference of differences" analysis in Appendix B of his report based on approximation of the binomial distribution to the normal distribution.[1] The results of this analysis would be driven by the conclusions Dr. Levin has drawn from his Table 1, namely that there is a statistically significant difference in the rate of utility-based invalidation between pharmaceutical and non-pharmaceutical patents in the post-2005 period (discussed below). If that difference were no longer statistically significant, then there would be no statistically significant difference in the "difference of differences" analysis either. Given that I have not observed the same statistical significance as Dr. Levin on the basis of the data you provided, I did not find it necessary to carry out similar "difference of differences" analyses.

B. The Results of my Statistical Analysis of Your Corrections to Dr. Levin's Table 1

Dr. Levin concludes that there is a statistically significant difference in the rates of utility-based invalidation between pharmaceutical and non-pharmaceutical patents in the post-2005 period on the basis of his analysis of the data in his Table 1.[2] Dr. Levin observed a proportion of pharmaceutical and non-pharmaceutical cases found invalid on utility grounds post-2005 of 39.7% and 0, respectively. The difference of 39.7 percentage points led him to a p-value of 0.0245, and a conclusion that the difference is "likely not due to chance".[3]

I have analyzed the following corrected data sets relating to Dr. Levin's Table 1 that you provided. To make the results of these analyses comparable to those in Dr. Levin's report, I applied a one-sided Fisher's exact test as Dr. Levin did. Any p-value that is less than 0.05 can be considered nominally statistically significant. I found no evidence of a statistical difference in any of the tables you asked me to assess.

- **<u>Correction I to Dr. Levin's Table 1: Case Characterizations and Updates</u>**

You provided me with the following table:

Table 1: Corrections to Levin's Table 1[4]

Type of patent	Patent found *invalid* on utility grounds	Patent found *valid* on utility grounds	Total
Pharmaceutical	27	41	68
Non-pharmaceutical	1	7	8
Total	28	48	76

[1] *See* Levin Report at Appendix B. *See also* Levin Report, paras. 21, 27.
[2] *See* Levin Report at para. 9.
[3] *See* Levin Report at para. 9.
[4] *See* Brisebois Second Statement at para. 11.

The observed proportion of pharmaceutical patent cases found invalid on utility grounds post-2005 is 39.7% (27/68), while the observed proportion of non-pharmaceutical patent cases similarly found invalid is 12.5% (1/8). The difference between the two is 27.2 percentage points.

Applying a one-sided Fisher's exact test to this data set, I observed a p-value of 0.1293, which fails to meet statistical significance ($p>0.05$).

Conclusion: Based on the data you provided, the rate of utility-based invalidation for pharmaceutical patent cases is not statistically greater than those for non-pharmaceutical patent cases when considering post-2005 data. In other words, any difference between the two is within the realm of chance.

- **Correction II to Dr. Levin's Table 1: Counting Patents instead of Court Judgments**

You provided me with the following table:

Table 2: Patents Involving a Decided Challenge on Grounds of Utility Post-2005[5]

Type of patent	Patent found *invalid* on utility grounds	Patent found *valid* on utility grounds	Total
Pharmaceutical	27	50	77
Non-pharmaceutical	1	7	8
Total	28	57	85

The observed proportion of pharmaceutical patents found invalid on utility grounds post-2005 is 35.1% (27/77), while the observed proportion of non-pharmaceutical patents similarly found invalid is 12.5% (1/8). The difference between the two is 22.6 percentage points.

Applying the same one-sided Fisher's exact test to this data set, I observed a p-value of 0.1882, which fails to meet statistical significance ($p>0.05$).

Conclusion: Based on the data you provided, the rate of utility-based invalidation for pharmaceutical patents is not statistically greater than those for non-pharmaceutical patents when considering post-2005 data. In other words, any difference between the two is within the realm of chance.

[5] *See* Brisebois Second Statement, at para. 17.

- **Correction III to Dr. Levin's Table 1: Removal of PM(NOC) Cases**

You provided me with the following table:

Table 3: Patents Involving a Decided Challenge on Grounds of Utility Post-2005 Without PM(NOC) Cases[6]

Type of patent	Patent found *invalid* on utility grounds	Patent found *valid* on utility grounds	Total
Pharmaceutical	6	14	20
Non-pharmaceutical	1	7	8
Total	7	21	28

The observed proportion of pharmaceutical patents found invalid on utility grounds post-2005 is 30% (6/20), while the observed proportion of non-pharmaceutical patent cases similarly found invalid is 12.5% (1/8). The difference between the two is 17.5 percentage points.

Applying the same one-sided Fisher's exact test to this data set, I observed a p-value of 0.3274, which fails to meet statistical significance ($p>0.05$).

Conclusion: Based on the data you provided, the rate of utility-based invalidation for pharmaceutical patents is not statistically greater than those for non-pharmaceutical patents when considering post-2005 data when PM(NOC) cases are excluded. In other words, any difference between the two is within the realm of chance.

C. The Results of my Statistical Analysis of Your Additional Inquiries

- **Pharmaceutical patents held invalid on any ground before and after 2005**

You asked me to determine the statistical significance of the difference between the proportion of pharmaceutical patents held invalid on any ground before and after 2005, both with and without PM(NOC) cases. Below are my observations:

Table 4: Pharmaceutical Patents Involving a Decided Validity Challenge (All Grounds) Without PM(NOC) Cases[7]

Period	Pharmaceutical patent found *invalid*	Pharmaceutical patent found *valid*	Total
Post-2005	7	18	25
Pre-2005	4	4	8
Total	11	22	33

[6] *See* Brisebois Second Statement, at para. 25.
[7] *See* Brisebois Second Statement, at para. 29.

The observed proportion of pharmaceutical patents found invalid on any ground post-2005 is 28% (7/25), while the observed proportion of pharmaceutical patents similarly found invalid pre-2005 is 50% (4/8). The difference between the two is 22 percentage points.

Applying the same one-sided Fisher's exact test to this data set, I observed a p-value of 0.2333, which fails to meet statistical significance ($p>0.05$).

Conclusion: Based on the data you provided, the rate of pharmaceutical patent invalidation on the basis of any ground after 2005 is not statistically less than those before 2005 when PM(NOC) cases are excluded. In other words, any difference between the two is within the realm of chance.

Table 5: Pharmaceutical Patents Involving a Decided Validity Challenge (All Grounds) With PM(NOC) Cases [8]

Period	Pharmaceutical patent found *invalid*	Pharmaceutical patent found *valid*	Total
Post-2005	79	68	147
Pre-2005	11	13	24
Total	90	81	171

When PM(NOC) cases are included, the observed proportion of pharmaceutical patents found invalid on any ground post-2005 is 53.7% (79/147), while the observed proportion of pharmaceutical patent patents similarly found invalid pre-2005 is 45.8% (11/24). The difference between the two is 7.9 percentage points.

Applying the same one-sided Fisher's exact test to this data set, I observed a p-value of 0.3085, which fails to meet statistical significance ($p>0.05$).

Conclusion: Based on the data you provided, the rate of pharmaceutical patents held invalid on any ground after 2005 is not statistically greater than those held invalid on any ground before 2005 with PM(NOC) cases included in the analysis. In other words, any difference between the two is within the realm of chance.

Therefore, regardless of the inclusion of PM(NOC) cases, there is no statistical evidence of a difference in the rates of pharmaceutical patents held invalid on any ground before and after 2005 on the basis of the data you provided.

- **Pharmaceutical patents held invalid on the ground of utility before and after 2005**

You asked me to determine the statistical significance of the difference between the proportion of pharmaceutical patents held invalid on the ground of utility before and after 2005, both with and without PM(NOC) cases. Below are my observations:

[8] *See* Brisebois Second Statement, at para. 31.

Table 6: Pharmaceutical Patents Involving a Decided Challenge on Grounds of Utility Without PM(NOC) Cases [9]

Period	Pharmaceutical patent found *invalid* on utility grounds	Pharmaceutical patent found *valid* on utility grounds	Total
Post-2005	6	14	20
Pre-2005	0	3	3
Total	6	17	23

The observed proportion of pharmaceutical patents found invalid on grounds of utility post-2005 is 30% (6/20), while the observed proportion of pharmaceutical patents similarly found invalid pre-2005 is 0% (0/3). The difference between the two is 30 percentage points.

Applying the same one-sided Fisher's exact test to this data set, I observed a p-value of 0.3840, which fails to meet statistical significance ($p>0.05$).

Conclusion: Based on the data you provided, the rates of pharmaceutical patents held invalid on grounds of utility after 2005 are not statistically greater than those held invalid on grounds of utility before 2005 when PM(NOC) cases are excluded. In other words, any difference between the two is within the realm of chance.

Table 7: Pharmaceutical Patents Involving a Decided Challenge on Grounds of Utility With PM(NOC) Cases [10]

Period	Pharmaceutical patent found *invalid* on utility grounds	Pharmaceutical patent found *valid* on utility grounds	Total
Post-2005	27	50	77
Pre-2005	0	4	4
Total	27	54	81

When PM(NOC) cases are included, the observed proportion of pharmaceutical patents found invalid on grounds of utility post-2005 is 35.1% (27/77), while the observed proportion of pharmaceutical patent patents similarly found invalid pre-2005 is 0% (0/4). The difference between the two is 35.1 percentage points.

Applying the same one-sided Fisher's exact test to this data set, I observed a p-value of 0.1901, which fails to meet statistical significance ($p>0.05$).

Conclusion: Based on the data you provided, the rates of pharmaceutical patents held invalid on grounds of utility after 2005 is not statistically greater than those held invalid on grounds of utility before 2005 when PM(NOC) cases are included. In other words, any difference between the two is within the realm of chance.

[9] *See* Brisebois Second Statement, at para. 33.
[10] *See* Brisebois Second Statement, at para. 33.

Therefore, regardless of the inclusion of PM(NOC) cases, there is no statistical evidence of a difference in the rates of pharmaceutical patents held invalid on grounds of utility before and after 2005 on the basis of the data you provided.

- **Pharmaceutical patents held invalid on the ground of utility before and after *AZT* (2002)**

You asked me to determine the statistical significance of the difference between the proportion of pharmaceutical patents held invalid on the ground of utility before and after the *Apotex Inc. v. Wellcome Foundation Ltd.* ("*AZT*") decision in 2002,[11] both with and without PM(NOC) cases. Below are my observations:

Table 8: Pharmaceutical Patents Involving a Decided Challenge on Grounds of Utility Before and After *AZT* Without PM(NOC) cases[12]

Period	Pharmaceutical patent found *invalid* on utility grounds	Pharmaceutical patent found *valid* on utility grounds	Total
Pre-*AZT*	0	2	2
Post-*AZT*	6	14	20
Total	6	16	22

The observed proportion of pharmaceutical patents found invalid on grounds of utility in the pre-*AZT* period is 0%, while the observed proportion of pharmaceutical patents found invalid on grounds of utility post-*AZT* is 30% (6/20). The difference between the two is 30 percentage points.

Applying the same one-sided Fisher's exact test to this data set, I observed a p-value of 0.5195 which fails to meet statistical significance ($p>0.05$).

Conclusion: Based on the data you provided, the rate of pharmaceutical patents held invalid on grounds of utility pre-*AZT* is not statistically less than those held invalid on grounds of utility post-*AZT* when PM(NOC) cases are excluded from the data set. In other words, any difference between the two is within the realm of chance.

[11] [2002] 4 SCR 153 (**R-004**).
[12] *See* Brisebois Second Statement, at para. 36.

Table 9: Pharmaceutical Patent Involving a Decided Challenge on Grounds of Utility Before and After *AZT* With PM(NOC) cases[13]

Period	Patent found *invalid* on utility grounds	Patent found *valid* on utility grounds	Total
Pre-*AZT*	0	3	3
Post-*AZT*	27	50	77
Total	27	53	80

The observed proportion of pharmaceutical patents found invalid on grounds of utility in the pre-*AZT* period is 0%, while the observed proportion of pharmaceutical patents similarly found invalid post-*AZT* is 35.1% (27/77). The difference between the two is 35.1 percentage points.

Applying the same one-sided Fisher's exact test to this data set, I observed a p-value of 0.2851, which fails to meet statistical significance ($p>0.05$).

Conclusion: Based on the data you provided, the rate of pharmaceutical patents held invalid on grounds of utility pre-*AZT* is not statistically less than those held invalid on grounds of utility post-*AZT* when PM(NOC) cases are included in the data set. In other words, any difference between the two is within the realm of chance.

Therefore, regardless of the inclusion of PM(NOC) cases, there is no statistical evidence of a difference in the rates of pharmaceutical patents held invalid on grounds of utility before and after *AZT* on the basis of the data you provided.

- **Pharmaceutical patents held invalid on the ground of utility before and after *Raloxifene* (2008)**

You asked me to determine the statistical significance of the difference between the proportion of pharmaceutical patents held invalid on the ground of utility before and after the *Eli Lilly Canada Inc. v. Apotex Inc.* ("*Raloxifene*") decision in 2008,[14] both with and without PM(NOC) cases. Below are my observations:

Table 10: Pharmaceutical Patents Involving a Decided Challenge on Grounds of Utility Before and After *Raloxifene* Without PM(NOC) Cases[15]

Period	Pharmaceutical patent found *invalid* on utility grounds	Pharmaceutical patent found *valid* on utility	Total
Pre-*Raloxifene*	0	3	3
Post-*Raloxifene*	6	14	20
Total	6	17	23

[13] *See* Brisebois Second Statement, at para. 36.
[14] 2008 FC 142 (**C-115**).
[15] *See* Brisebois Second Statement, at para. 38.

The observed proportion of pharmaceutical patents found invalid on grounds of utility in the pre-*Raloxifene* period is 0%, while the observed proportion of pharmaceutical patents found invalid on grounds of utility post-*Raloxifene* is 30% (6/20). The difference between the two is 30 percentage points.

Applying the same one-sided Fisher's exact test to this data set, I observed a p-value of 0.3840, which fails to meet statistical significance ($p>0.05$).

Conclusion: Based on the data you provided, the rate of pharmaceutical patents held invalid on grounds of utility post-*Raloxifene* is not statistically greater than those held invalid pre-*Raloxifene* when PM(NOC) cases are excluded from the data set. In other words, any difference between the two is within the realm of chance.

Table 11: Pharmaceutical Involving a Decided Challenge on Grounds of Utility Before and After *Raloxifene* With PM(NOC) Cases[16]

Period	Patent found *invalid* on utility grounds	Patent found *valid* on utility grounds	Total
Pre-*Raloxifene*	5	8	13
Post-*Raloxifene*	21	46	67
Total	26	54	80

The observed proportion of pharmaceutical patents found invalid on grounds of utility in the pre-*Raloxifene* period is 38.5% (5/13), while the observed proportion of pharmaceutical patents similarly found invalid post-*Raloxifene* is 31.3% (21/67). The difference between the two is 7.2 percentage points.

Applying the same one-sided Fisher's exact test to this data set, I observed a p-value of 0.4197, which fails to meet statistical significance ($p>0.05$).

Conclusion: Based on the data you provided, the rate of pharmaceutical patents held invalid on grounds of utility post-*Raloxifene* is not statistically less than those held invalid on grounds of utility pre-*Raloxifene* when PM(NOC) cases are included. In other words, any difference between the two is within the realm of chance.

Therefore, regardless of the inclusion of PM(NOC) cases, there is no statistical evidence of a difference in the rates of pharmaceutical patents held invalid on grounds of utility before and after *Raloxifene* on the basis of the data you provided.

* * *

[16] *See* Brisebois Second Statement, at para. 38.

I trust the foregoing will be of assistance.

Sincerely,

Andrew Raven
Manager, Biostatistics and Epidemiology Unit
Office of Science, Therapeutic Products Directorate
Health Canada

Annex B

Chronological List of Pharmaceutical Patent Validity Challenge Resolutions from January 1, 1980 to November 30, 2015

GREEN = A utility challenge has been won by the patent owner

BLUE = Several validity challenges have been lost by the patent owner, including a utility challenge

PURPLE = A utility challenge has been the sole validity challenge lost by the patent owner

#	Challenged Patent	Case name	Date	Citation
1	1,003,331	Apotex Inc. v. Hoffmann-La Roche Ltd.	1989-04-18	[1989] F.C.J. No. 321
2	741,825	Wellcome Foundation Ltd. v. Apotex Inc.	1991-11-14	[1991] F.C.J. No. 1136
3	907,014	Wellcome Foundation Ltd. v. Apotex Inc.	1991-11-14	[1991] F.C.J. No. 1136
4	1,275,349	Merck & Co. v. Apotex Inc.	1995-04-19	[1995] F.C.J. No. 588
5	1,181,076	Pfizer Canada Inc. v. Apotex Inc.	1997-08-18	[1997] F.C.J. No. 1087
6	1,322,334	Bayer Inc. v. Canada (Minister of National Health and Welfare)	1998-07-20	[1998] F.C.J. No. 1035
7	960,688	Wellcome Foundation Limited v. Novopharm Ltd.	1998-07-31	[1998] F.C.J. No. 1107
8	1,102,809	Hoffmann-La Roche Ltd. v. Apotex Inc.	1998-08-12	[1998] F.C.J. No. 1149
9	1,204,671	Apotex Inc. v. Syntex Pharmaceuticals International Ltd.	1999-04-23	[1999] F.C.J. No. 548
10	1,339,047	Kirin-Amgen Inc. v. Hoffmann-La Roche Ltd.	2000-12-20	[2000] F.C.J. No. 2137
11	1,332,150	Novartis Pharmaceuticals Canada Inc. v. Apotex Inc.	2001-10-18	2001 FCT 1129
12	2,178,637	Smithkline Beecham Pharma Inc v Apotex Inc	2002-05-28	2002 FCA 216
13	2,029,065	Pfizer Canada Inc v Apotex Inc	2002-11-05	2002 FCT 1138
14	1,238,277	Apotex Inc v Wellcome Foundation Ltd	2002-12-05	2002 SCC 77
15	2,214,575	GlaxoSmithKline Inc v Apotex Inc	2003-05-30	2003 FCT 687
16	1,218,067	Bayer AG v Apotex Inc	2003-10-17	2003 FC 1199
17	1,287,060	GlaxoSmithKline Inc v Genpharm Inc	2003-10-24	2003 FC 1248
18	2,212,548	GlaxoSmithKline Inc v Canada (Minister of Health)	2004-01-26	2004 FC 116
19	2,261,732	Abbott Laboratories v Canada (Minister of Health)	2004-10-01	2004 FC 1349
20	1,264,751	Apotex Inc v AB Hassle	2004-11-01	2004 FCA 369
21	1,304,080	Janssen-Ortho Inc v Novopharm Ltd	2004-11-19	2004 FC 1631

22	1,338,376	Genpharm Inc v Procter & Gamble Pharmaceuticals Canada Inc	2004-11-22	2004 FCA 393
23	1,292,693	Genpharm Inc v AB Hassle	2004-12-02	2004 FCA 413
24	1,338,377	Genpharm Inc v AB Hassle	2004-12-02	2004 FCA 413
25	2,294,595	Merck & Co Inc v Apotex Inc	2005-05-26	2005 FC 755
26	2,261,732	Abbott Laboratories v Canada (Minister of Health)	2005-08-10	2005 FC 1095
27	1,319,682	Aventis Pharma Inc v Mayne Pharma (Canada) Inc	2005-08-31	2005 FC 1183
28	2,148,071	Pfizer Canada Inc v Novopharm Ltd	2005-10-03	2005 FC 1299
29	2,148,071	Pfizer Canada Inc v Apotex Inc	2005-10-17	2005 FC 1421
30	1,340,316	Bristol-Myers Squibb Canada Co v Novopharm Ltd	2005-10-28	2005 FC 1458
31	1,246,457	Aventis Pharma Inc v Apotex	2005-11-04	2005 FC 1504
32	1,341,206	Aventis Pharma Inc v Apotex	2006-02-13	2006 FCA 64
33	1,282,006	Bayer AG v Novopharm Ltd	2006-03-24	2006 FC 379
34	1,318,590	Axcan Pharma Inc v Pharmascience Inc	2006-04-26	2006 FC 527
35	2,277,274	Abbott Laboratories v Canada (Minister of Health)	2006-05-18	2006 FCA 187
36	2,258,606	Abbott Laboratories v Canada (Minister of Health)	2006-05-18	2006 FCA 187
37	1,321,393	Pfizer Canada Inc v Canada (Minister of Health)	2006-06-09	2006 FCA 214
38	1,341,206	Pharmascience Inc v Sanofi-Aventis Canada Inc	2006-06-21	2006 FCA 229
39	1,275,350	Apotex Inc v Merck & Co	2006-10-10	2006 FCA 323
40	2,021,546	Pfizer Canada Inc v Canada (Minister of Health)	2006-12-07	2006 FC 1471
41	2,258,606	Abbott Laboratories v. Canada (Minister of Health)	2007-01-11	2006 FC 1558
42	2,393,614	Ratiopharm Inc v Canada (Minister of Health)	2007-02-23	2007 FCA 83
43	2,261,732	Abbott Laboratories v Canada (Minister of Health)	2007-04-19	2007 FCA 153
44	2,177,576	G.D. Searle & Co v Novopharm Ltd	2007-04-30	2007 FCA 173
45	2,044,748	Pfizer Canada Inc v Apotex Inc	2007-05-16	2007 FCA 195
46	1,341,206	Sanofi-Aventis Inc v Laboratoire Riva Inc	2007-05-28	2007 FC 532
47	1,341,330	Pfizer Canada Inc v Canada (Minister of Health)	2007-05-31	2007 FCA 209
48	2,041,113	Eli Lilly Canada Inc v Novopharm Ltd	2007-06-05	2007 FC 596
49	1,304,080	Novopharm Ltd v Janssen-Ortho Inc	2007-06-07	2007 FCA 217
50	2,025,668	AstraZeneca AB v Apotex	2007-06-28	2007 FC 688
51	2,133,762	AstraZeneca AB v Apotex	2007-06-28	2007 FC 688
52	2,419,729	Abbott Laboratories v Canada (Minister of Health)	2007-07-17	2007 FC 753
53	2,471,102	Abbott Laboratories v Canada (Minister of Health)	2007-07-17	2007 FC 753
54	2,220,455	Pfizer Canada Inc v Canada (Minister of Health)	2007-10-05	2007 FC 898

55	1,341,330	Pfizer Canada Inc v Canada (Minister of Health)	2008-01-02	2008 FC 11
56	2,021,546	Pfizer Canada Inc v Canada (Minister of Health)	2008-01-04	2008 FC 13
57	2,041,133	Apotex Inc v Eli Lilly Canada Inc	2008-02-04	2008 FCA 44
58	2,021,546	Pfizer Canada Inc v Canada (Minister of Health)	2008-03-20	2008 FCA 108
59	1,321,393	Pfizer Canada Inc v Canada (Minister of Health)	2008-04-17	2008 FC 500
60	2,201,967	Shire Biochem Inc v Canada (Minister of Health)	2008-04-25	2008 FC 538
61	1,340,083	GlaxoSmithKline Inc v Pharmascience	2008-05-09	2008 FC 593
62	1,336,777	Apotex Inc v Sanofi-Synthelabo Canada	2008-11-06	2008 SCC 61
63	2,163,446	Apotex v Pfizer Canada	2009-01-16	2009 FCA 8
64	1,298,288	Bristol-Myers Squibb v Apotex	2009-02-10	2009 FC 137
65	2,250,191	Eli Lilly Canada Inc v Novopharm Ltd	2009-03-19	2009 FC 235
66	2,386,527	Abbott Laboratories v Minister of Health	2009-03-20	2009 FCA 94
67	2,158,399	Eli Lilly Canada Inc v Novopharm	2009-03-23	2009 FC 301
68	2,101,356	Eli Lilly Canada v Apotex	2009-03-25	2009 FCA 97
69	2,158,399	Eli Lilly Canada Inc. v. Apotex Inc.	2009-03-26	2009 FC 320
70	1,341,196	Apotex v Adir and Servier Canada	2009-06-30	2009 FCA 222
71	2,098,738	Purdue Pharma v Pharmascience	2009-07-16	2009 FC 726
72	1,133,007	Eli Lilly and Co v Apotex	2009-10-01	2009 FC 991
73	1,146,536	Eli Lilly and Co v Apotex	2009-10-01	2009 FC 991
74	1,133,468	Eli Lilly and Co v Apotex	2009-10-01	2009 FC 991
75	1,150,725	Eli Lilly and Co v Apotex	2009-10-01	2009 FC 991
76	1,095,026	Eli Lilly and Co v Apotex	2009-10-01	2009 FC 991
77	1,132,547	Eli Lilly and Co v Apotex	2009-10-01	2009 FC 991
78	1,136,132	Eli Lilly and Co v Apotex	2009-10-01	2009 FC 991
79	1,144,924	Eli Lilly and Co v Apotex	2009-10-01	2009 FC 991
80	2,102,778	Sanofi-Aventis Canada v Hospira Health Corp	2009-10-22	2009 FC 1077
81	2,014,453	Lundbeck Canada v Ratiopharm	2009-11-23	2009 FC 1102
82	2,426,492	Lundbeck Canada v Ratiopharm	2009-11-23	2009 FC 1102
83	2,325,014	Schering-Plough Canada Inc. v. Pharmascience Inc.	2009-12-22	2009 FC 1128
84	2,267,136	Schering-Plough Canada Inc. v. Pharmascience Inc.	2009-12-22	2009 FC 1128
85	2,290,624	Biovail Corporation v The Minister of Health	2010-01-20	2010 FC 46
86	2,177,772	Sanofi Aventis Canada v Ratiopharm	2010-03-05	2010 FC 230
87	2,173,457	Merck & Co v Pharmascience	2010-05-11	2010 FC 510
88	2,324,324	Pfizer v Ratiopharm	2010-06-08	2010 FC 612
89	2,285,266	Sandoz Canada Inc v Abbott Laboratories	2010-06-22	2010 FCA 168
90	2,358,395	Sandoz Canada Inc v Abbott Laboratories	2010-06-22	2010 FCA 168
91	2,139,653	Astrazeneca Canada Inc v Apotex Inc	2010-06-30	2010 FC 714
92	1,321,393	Pfizer v Ratiopharm	2010-07-29	2010 FCA 204
93	2,111,851	Novo Nordisk Canada Inc v Cobalt Pharmaceuticals	2010-08-03	2010 FC 746

94	2,172,149	Merck-Frosst - Schering Pharma GP v Canada (Minister of Health)	2010-09-17	2010 FC 933
95	2,065,965	Merck & Co v Canada (Minister of Health)	2010-10-22	2010 FC 1042
96	1,329,211	Merck & Co v Canada (Minister of Health)	2010-10-22	2010 FC 1043
97	2,209,735	Eli Lilly Canada Inc v Apotex	2010-10-29	2010 FC 1065
98	2,310,950	Janssen Inc v Mylan Pharmaceuticals	2010-11-10	2010 FC 1123
99	1,339,452	Lundbeck Canada v Minister of Health	2010-11-25	2010 FCA 320
100	1,161,380	Merck & Co v Apotex	2010-12-22	2010 FC 1265
101	1,328,452	GlaxoSmithKline Inc v Pharmascience	2011-03-01	2011 FC 239
102	1,339,132	Pfizer Canada Inc v Canada (Minister of Health)	2011-03-17	2011 FCA 102
103	2,209,735	Novopharm/Teva v Eli Lilly	2011-07-05	2011 FCA 220
104	1,333,285	Hoffman-La Roche v Apotex	2011-07-13	2011 FC 875
105	1,339,132	Apotex v Pfizer	2011-08-16	2011 FCA 236
106	1,341,206	Sanofi-Aventis v Apotex895	2011-11-02	2011 FCA 300
107	2,440,764	Allergan v Minister of Health	2011-11-17	2011 FC 1316
108	2,225,626	Allergan v Minister of Health	2011-11-17	2011 FC 1316
109	1,338,808	Mylan Pharmaceuticals v Pfizer	2012-03-29	2012 FCA 103
110	1,337,420	Mylan Pharmaceuticals v Astrazeneca	2012-04-11	2012 FCA 109
111	2,195,094	Alcon Canada v Apotex	2012-04-11	2012 FC 410
112	2,163,446	Teva v Pfizer	2012-04-18	2012 SCC 60
113	2,487,054	Fournier Pharma Inc v Minister of Health and Sandoz	2012-07-05	2012 FC 740
114	2,372,576	Fournier Pharma Inc v Minister of Health and Sandoz	2012-07-05	2012 FC 741
115	2,041,113	Eli Lilly Canada v Novopharm	2012-09-10	2012 FCA 232
116	2,101,572	Bristol-Myers Squibb v Mylan Pharmaceuticals	2012-09-27	2012 FC 1142
117	2,279,198	Bristol-Myers Squibb v Mylan Pharmaceuticals	2012-09-27	2012 FC 1142
118	2,440,764	Apotex v Allergan	2012-11-23	2012 FCA 308
119	2,255,652	Pfizer Canada v Pharmascience	2013-02-04	2013 FC 120
120	2,093,203	Teva v Novartis; Apotex v Norvartis	2013-02-19	2013 FC 141
121	2,170,647	Astrazeneca Canada Inc v Ranbaxy Pharmaceuticals	2013-03-05	2013 FC 232
122	2,251,944	Astrazeneca Canada Inc v Teva Canada	2013-03-07	2013 FC 245
123	2,251,944	Astrazeneca Canada Inc v Teva Canada	2013-03-07	2013 FC 246
124	1,339,452	Apotex Inc v H Lundbeck A/S	2013-03-12	2013 FC 192
125	1,338,895	Novartis Pharmaceuticals Canada v Teva Canada	2013-03-19	2013 FC 283
126	2,154,721	Hoffman-La Roche v Apotex	2013-07-12	2013 FC 718
127	1,336,777	Sanofi-Aventis v Apotex	2013-07-24	2013 FCA 186
128	1,338,937	Teva Canada Ltd v Novartis	2013-10-15	2013 FCA 244
129	2,261,619	Gilead Sciences v Minister of Health and Teva	2013-12-20	2013 FC 1270
130	2,298,059	Gilead Sciences v Minister of Health and Teva	2013-12-20	2013 FC 1270
131	2,261,619	Gilead Sciences v Minister of Health and Teva	2013-12-20	2013 FC 1271
132	2,298,059	Gilead Sciences v Minister of Health and Teva	2013-12-20	2013 FC 1271
133	2,261,619	Gilead Sciences v Minister of Health and Teva	2013-12-20	2013 FC 1272

134	2,298,059	Gilead Sciences v Minister of Health and Teva	2013-12-20	2013 FC 1272
135	2,365,281	Abbvie Corporation v Janssen Inc	2014-01-17	2014 FC 55
136	2,163,446	Pfizer Ireland Pharmaceuticals v. Apotex Inc.	2014-01-22	2014 FCA 13
137	2,410,201	Novartis Pharmaceuticals v Cobalt Pharmaceuticals	2014-01-27	2014 FCA 17
138	2,177,576	Pfizer Canada and GD Searle & Co v Mylan Pharmaceuticals	2014-01-28	2014 FC 38
139	2,447,924	Alcon Canada Inc v Cobalt Pharmaceuticals Company	2014-02-14	2014 FC 149
140	2,177,576	Pfizer Canada Inc v Apotex Inc	2014-04-15	2014 FC 314
141	2,179,728	Bayer Inc v Apotex Inc	2014-05-01	2014 FC 403
142	2,382,426	Bayer Inc v Apotex Inc	2014-05-07	2014 FC 436
143	2,290,531	Pharmascience Inc v Canada (Minister of Health)	2014-05-22	2014 FCA 133
144	2,585,691	Allergan Inc v Minister of Health	2014-06-13	2014 FC 566
145	2,129,287	Alcon Canada Inc v Apotex Inc	2014-08-08	2014 FC 699
146	2,606,370	Alcon Canada Inc v Apotex Inc	2014-08-25	2014 FC 791
147	2,226,784	Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC	2015-01-07	2015 FC 17
148	2,371.684	Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC	2015-02-02	2015 FC 125
149	2,435,146	Janssen Inc. v. Teva Canada Limited	2015-02-16	2015 FC 184
150	2,629,670	Laboratoires Servier and Servier Canada Inc. v. Canada (Health)	2015-02-16	2015 FC 108
151	2,379,948	Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC	2015-02-23	2015 FC 178
152	2,203,936	Janssen Inc. v. Teva Canada Limited	2015-02-26	2015 FC 247
153	1,292,693	Astrazeneca Canada Inc. v. Apotex Inc.	2015-03-16	2015 FC 322
154	2,388,322	Takeda Canada Inc. v. Canada (Health)	2015-05-01	2015 FC 570
155	2,388,325	Takeda Canada Inc. v. Canada (Health)	2015-05-01	2015 FC 570
156	2,538,419	Takeda Canada Inc. v. Canada (Health)	2015-05-01	2015 FC 570
157	2,179,728	Cobalt Pharmaceuticals Company v. Bayer Inc.	2015-05-04	2015 FCA 116
158	2,382,426	Cobalt Pharmaceuticals Company v. Bayer Inc.	2015-05-04	2015 FCA 116
159	2,585,691	Apotex Inc. v. Allergan Inc.	2015-06-03	2015 FCA 137
160	2,341,031	Takeda Canada Inc. v. Canada (Health)	2015-06-15	2015 FC 751
161	2,255,951 (claims 1-4)	Novartis Pharmaceuticals Canada Inc. v. Teva Canada Limited	2015-06-19	2015 FC 770
162	2,255,951 (claims 5-37)	Novartis Pharmaceuticals Canada Inc. v. Teva Canada Limited	2015-06-19	2015 FC 770
163	2,139,653	Astrazeneca Canada Inc. v. Apotex Inc.	2015-07-06	2015 FCA 158
164	2,226,784	Eli Lilly Canada Inc. v. Apotex Inc	2015-07-20	2015 FC 875
165	2,379,948	Eli Lilly Canada Inc. v. Apotex Inc.	2015-09-11	2015 FC 1016
166	2,342,211	Alcon Canada Inc. v. Actavis Pharma Company	2015-09-16	2015 FCA 191
167	1,340,114	Actavis Pharma Compagny v. Alcon Canada Inc.	2015-09-16	2015 FCA 192

168	2,490,191	Gilead Sciences, Inc. v. Idenix Pharmaceuticals Inc.	2015-11-02	2015 FC 1156
169	2,527,657	Gilead Sciences, Inc. v. Idenix Pharmaceuticals Inc.	2015-11-02	2015 FC 1156
170	2,202,879	Amgen Canada Inc. v. Mylan Pharmaceuticals ulc.	2015-11-03	2015 FC 1244
171	1,341,537	Amgen Canada Inc. v. Apotex Inc.	2015-11-10	2015 FC 1261

Annex C

Chronological List of Pharmaceutical Patent Validity Challenge Resolutions Considered for Before/After *AZT* Decision Analysis (1980 – November 30, 2015)[1]

PM(NOC) cases included:

Date	Decision	Patent challenged	Utility met
19911114	39 C.P.R. (3d) 289	741825	Yes
19911114	39 C.P.R. (3d) 289	907014	Yes
20020528	2002 FCA 216	2178637	Yes
20021205	2002 SCC 77	1238277	Yes
20050526	2005 FC 755	2294595	No
20050810	2005 FC 1095	2261732	No
20060213	2006 FCA 64	1341206	No
20070419	2007 FCA 153	2261732	No
20070430	2007 FCA 173	2177576	Yes
20070516	2007 FCA 195	2044748	No
20070528	2007 FC 532	1341206	Yes
20070531	2007 FCA 209	1341330	Yes
20080102	2008 FC 11	1341330	Yes
20080417	2008 FC 500	1321393	Yes
20080425	2008 FC 538	2201967	No
20080509	2008 FC 593	1340083	No
20090319	2009 FC 235	2250191	No
20090325	2009 FCA 97*	2101356	No
20090630	2009 FCA 222	1341196	Yes
20090716	2009 FC 726	2098738	Yes
20091001	2009 FC 991	1133007	Yes
20091001	2009 FC 991	1146536	Yes
20091001	2009 FC 991	1133468	Yes
20091001	2009 FC 991	1150725	Yes
20091001	2009 FC 991	1095026	Yes
20091001	2009 FC 991	1136132	Yes
20091001	2009 FC 991	1144924	Yes
20091123	2009 FC 1102	2014453	Yes
20091123	2009 FC 1102	2426492	No
20091222	2009 FC 1128	2325014	Yes
20100305	2010 FC 230	2177772	No

[1] *Apotex Inc. v. Wellcome Foundation Ltd*., 2002 SCC 77 ("*AZT*") was excluded from the figures in Tables 8 and 9 of my second statement.

20100608	2010 FC 612	2324324	No
20100622	2010 FCA 168	2358395	Yes
20100630	2010 FC 714	2139653	No
20100729	2010 FCA 204	1321393	No
20101029	2010 FC 1065	2209735	Yes
20101125	2010 FCA 320	1339452	Yes
20101222	2010 FC 1265	1161380	Yes
20110301	2011 FC 239	1328452	Yes
20110317	2011 FCA 102	1339132	Yes
20110705	2011 FCA 220	2209735	No
20110713	2011 FC 875	1333285	Yes
20110816	2011 FCA 236	1339132	No
20111102	2011 FCA 300	1341206	No
20111117	2011 FC 1316	2225626	Yes
20120329	2012 FCA 103	1338808	Yes
20120411	2012 FCA 109	1337420	Yes
20120418	2012 SCC 60	2163446	Yes
20120705	2012 FC 740	2487054	Yes
20120705	2012 FC 741	2372576	Yes
20120910	2012 FCA 232	2041113	No
20120927	2012 FC 1142	2101572	Yes
20130204	2013 FC 120	2255652	No
20130219	2013 FC 141	2093203	Yes
20130312	2013 FC 192	1339452	Yes
20130319	2013 FC 283	1338895	No
20130724	2013 FCA 186	1336777	Yes
20131015	2013 FCA 244	1338937	Yes
20140117	2014 FC 55	2365281	Yes
20140214	2014 FC 149	2447924	No
20140501	2014 FC 403	2179728	Yes
20140522	2014 FCA 133	2290531	No
20140613	2014 FC 566	2585691	Yes
20140808	2014 FC 699	2129287	Yes
20140825	2014 FC 791	2606370	Yes
20141030	2014 FCA 250	2177576	Yes
20141030	2014 FCA 250	2177576	Yes
20150107	2015 FC 17	2226784	Yes
20150202	2015 FC 125	2371684	No
20150216	2015 FC 108	2629670	No
20150316	2015 FC 322	1292693	Yes
20150504	2015 FCA 116	2179728	Yes

20150504	2015 FCA 116	2382426	Yes
20150603	2015 FCA 137	2585691	Yes
20150619	2015 FC 770	2255951	No
20150619	2015 FC 770	2255951	Yes
20150706	2015 FCA 158	2139653	No
20150911	2015 FC 1016	2379948	Yes
20150916	2015 FCA 192	1340114	Yes
20151102	2015 FC 1156	2490191	No
20151110	2015 FC 1261	1341537	Yes

PM(NOC) cases excluded:

Date	Decision	Patent challenged	Utility met
19911114	39 C.P.R. (3d) 289	741825	Yes
19911114	39 C.P.R. (3d) 289	907014	Yes
20021205	2002 SCC 77	1238277	Yes
20090630	2009 FCA 222	1341196	Yes
20091001	2009 FC 991	1133007	Yes
20091001	2009 FC 991	1146536	Yes
20091001	2009 FC 991	1133468	Yes
20091001	2009 FC 991	1150725	Yes
20091001	2009 FC 991	1095026	Yes
20091001	2009 FC 991	1136132	Yes
20091001	2009 FC 991	1144924	Yes
20100729	2010 FCA 204	1321393	No
20101222	2010 FC 1265	1161380	Yes
20110705	2011 FCA 220	2209735	No
20111102	2011 FCA 300	1341206	No
20120910	2012 FCA 232	2041113	No
20130219	2013 FC 141	2093203	Yes
20130312	2013 FC 192	1339452	Yes
20130724	2013 FCA 186	1336777	Yes
20140117	2014 FC 55	2365281	Yes
20150316	2015 FC 322	1292693	Yes
20150706	2015 FCA 158	2139653	No
20151102	2015 FC 1156	2490191	No

Annex D

Chronological List of Pharmaceutical Patent Validity Challenge Resolutions Considered for Before/After *Raloxifene* Decision Analysis (1980 – November 30, 2015)[1]

PM(NOC) cases included:

Date	Decision	Patent challenged	Utility met
19911114	39 C.P.R. (3d) 289	741825	Yes
19911114	39 C.P.R. (3d) 289	907014	Yes
20020528	2002 FCA 216	2178637	Yes
20021205	2002 SCC 77	1238277	Yes
20050526	2005 FC 755	2294595	No
20050810	2005 FC 1095	2261732	No
20060213	2006 FCA 64	1341206	No
20070419	2007 FCA 153	2261732	No
20070430	2007 FCA 173	2177576	Yes
20070516	2007 FCA 195	2044748	No
20070528	2007 FC 532	1341206	Yes
20070531	2007 FCA 209	1341330	Yes
20080102	2008 FC 11	1341330	Yes
20080205	2008 FC 142 (Ralox. Dec)	2101356	No
20080417	2008 FC 500	1321393	Yes
20080425	2008 FC 538	2201967	No
20080509	2008 FC 593	1340083	No
20090319	2009 FC 235	2250191	No
20090325	2009 FCA 97*	2101356	No
20090630	2009 FCA 222	1341196	Yes
20090716	2009 FC 726	2098738	Yes
20091001	2009 FC 991	1133007	Yes
20091001	2009 FC 991	1146536	Yes
20091001	2009 FC 991	1133468	Yes
20091001	2009 FC 991	1150725	Yes
20091001	2009 FC 991	1095026	Yes
20091001	2009 FC 991	1136132	Yes
20091001	2009 FC 991	1144924	Yes
20091123	2009 FC 1102	2014453	Yes

[1] Both *Eli Lilly Canada Inc. v. Apotex Inc*, 2008 FC 142 (*Raloxifene* trial decision) and *Eli Lilly Inc. v. Apotex Inc.*, 2009 FCA 97 (*Raloxifene* appeal decision) were excluded from the figures in Tables 10 and 11 of my second statement.

20091123	2009 FC 1102	2426492	No
20091222	2009 FC 1128	2325014	Yes
20100305	2010 FC 230	2177772	No
20100608	2010 FC 612	2324324	No
20100622	2010 FCA 168	2358395	Yes
20100630	2010 FC 714	2139653	No
20100729	2010 FCA 204	1321393	No
20101029	2010 FC 1065	2209735	Yes
20101125	2010 FCA 320	1339452	Yes
20101222	2010 FC 1265	1161380	Yes
20110301	2011 FC 239	1328452	Yes
20110317	2011 FCA 102	1339132	Yes
20110705	2011 FCA 220	2209735	No
20110713	2011 FC 875	1333285	Yes
20110816	2011 FCA 236	1339132	No
20111102	2011 FCA 300	1341206	No
20111117	2011 FC 1316	2225626	Yes
20120329	2012 FCA 103	1338808	Yes
20120411	2012 FCA 109	1337420	Yes
20120418	2012 SCC 60	2163446	Yes
20120705	2012 FC 740	2487054	Yes
20120705	2012 FC 741	2372576	Yes
20120910	2012 FCA 232	2041113	No
20120927	2012 FC 1142	2101572	Yes
20130204	2013 FC 120	2255652	No
20130219	2013 FC 141	2093203	Yes
20130312	2013 FC 192	1339452	Yes
20130319	2013 FC 283	1338895	No
20130724	2013 FCA 186	1336777	Yes
20131015	2013 FCA 244	1338937	Yes
20140117	2014 FC 55	2365281	Yes
20140214	2014 FC 149	2447924	No
20140501	2014 FC 403	2179728	Yes
20140522	2014 FCA 133	2290531	No
20140613	2014 FC 566	2585691	Yes
20140808	2014 FC 699	2129287	Yes
20140825	2014 FC 791	2606370	Yes
20141030	2014 FCA 250	2177576	Yes
20141030	2014 FCA 250	2177576	Yes
20150107	2015 FC 17	2226784	Yes
20150202	2015 FC 125	2371684	No

20150216	2015 FC 108	2629670	No
20150316	2015 FC 322	1292693	Yes
20150504	2015 FCA 116	2179728	Yes
20150504	2015 FCA 116	2382426	Yes
20150603	2015 FCA 137	2585691	Yes
20150619	2015 FC 770	2255951	No
20150619	2015 FC 770	2255951	Yes
20150706	2015 FCA 158	2139653	No
20150911	2015 FC 1016	2379948	Yes
20150916	2015 FCA 192	1340114	Yes
20151102	2015 FC 1156	2490191	No
20151110	2015 FC 1261	1341537	Yes

PM(NOC) cases excluded:

Date	Decision	Patent challenged	Utility met
19911114	39 C.P.R. (3d) 289	741825	Yes
19911114	39 C.P.R. (3d) 289	907014	Yes
20021205	2002 SCC 77	1238277	Yes
20080205	2008 FC 142 (Ralox. Dec)	2101356	No
20090630	2009 FCA 222	1341196	Yes
20091001	2009 FC 991	1133007	Yes
20091001	2009 FC 991	1146536	Yes
20091001	2009 FC 991	1133468	Yes
20091001	2009 FC 991	1150725	Yes
20091001	2009 FC 991	1095026	Yes
20091001	2009 FC 991	1136132	Yes
20091001	2009 FC 991	1144924	Yes
20100729	2010 FCA 204	1321393	No
20101222	2010 FC 1265	1161380	Yes
20110705	2011 FCA 220	2209735	No
20111102	2011 FCA 300	1341206	No
20120910	2012 FCA 232	2041113	No
20130219	2013 FC 141	2093203	Yes
20130312	2013 FC 192	1339452	Yes
20130724	2013 FCA 186	1336777	Yes
20140117	2014 FC 55	2365281	Yes
20150316	2015 FC 322	1292693	Yes
20150706	2015 FCA 158	2139653	No
20151102	2015 FC 1156	2490191	No

Appendix E

List of Pharmaceutical Patent Validity Challenge Resolutions, U.S. Court of Appeals for the Federal Circuit, 1984-2008 (from Alberto Galasso and Mark Schankerman, "Patents and Cumulative Innovation: Causal Evidence form the Courts," *The Quarterly Journal of Economics*, November 21, 2014)

year	patent	docket	invaliditydummy	inst
1984	4107292	83-1417	1	0
1984	3672371	83-1066	0	1
1984	3950529	83-1401	0	0
1984	3178820	83-660	0	1
1984	3228741	84-591	0	1
1985	4327709	85-812	1	1
1985	4261339	85-812	0	1
1985	4293654	84-1766	1	0
1985	4189534	84-1766	1	0
1985	3368280	84-818	0	1
1986	4194814	85-2578	0	1
1986	4261339	85-2671	0	1
1986	4376110	86-531	0	0
1986	3902501	85-2645	0	1
1986	3815586	85-2779	0	1
1986	3541581	85-2191	0	0
1986	3863006	85-2607	0	0
1987	4278080	87-1137	0	1
1987	4345606	87-1082	0	1
1987	3789832	86-1005	0	1
1987	4103001	86-1682	1	0
1987	4166469	87-1082	0	1
1987	4243050	87-1082	0	1
1988	4460363	88-1265	0	1
1988	3842841	87-1445	0	1
1989	4261339	88-1266	0	1
1989	3807409	88-1609	0	1
1989	3882246	89-1046	1	0
1989	3781430	88-1513	1	0
1989	3934274	88-1641	1	1
1990	3789841	90-1013	1	1
1990	3794732	89-1076	1	0
1990	3541581	90-1320	0	0

YEAR= year of Federal circuit decision

PATENT= US patent number in decision

DOCKET= court reference number

INVALIDITYDUMMY = dummy variable equal one if there is invalidation

INST= dummy equal one if medical instrument patent

These are all pharma patents (drugs+medical instruments),

if you need to focus on drugs compile the table setting inst=0.

1990	3717140	89-1619	0	1
1991	4691694	91-1062	1	1
1991	4628910	91-1062	0	1
1991	4194509	90-1444	0	1
1991	4677195	90-1273	1	0
1991	4703008	90-1273	1	0
1991	4568329	90-1528	0	1
1991	4280489	90-1232	0	1
1991	4692141	90-1528	0	1
1991	4465074	90-1159	0	1
1992	4667661	91-1428	0	1
1992	4502479	91-1428	0	1
1992	4695278	92-1011	1	1
1992	4422459	91-1091	0	1
1992	4159546	91-1343	0	1
1992	4601720	92-1216	1	1
1992	4909804	92-1198	1	1
1993	4356170	93-1076	0	0
1993	4475910	92-1428	1	1
1994	4828838	93-1503	0	0
1994	4818538	93-1507	0	0
1994	4837208	93-1506	0	0
1994	4724232	93-1504	0	0
1994	4833130	93-1505	0	0
1994	4551146	94-1055	0	1
1994	4415330	93-1426	0	1
1994	5118602	93-1253	0	0
1994	4354490	94-1056	0	1
1994	4810241	94-1058	0	1
1994	3972123	94-1004	0	1
1994	4655762	94-1057	0	1
1995	4521431	94-1026	0	0
1995	4583968	94-1242	0	1
1995	4002746	94-1209	0	0

1995	4762129	94-1317	0	1
1995	4616039	93-1138	1	0
1996	4588580	95-1367	0	0
1996	4626210	96-1103	0	1
1996	4830014	95-1494	0	1
1996	4888023	96-1082	0	1
1996	4808155	95-1225	0	1
1997	5144345	95-1093	0	1
1997	4952207	95-1322	0	1
1997	4772112	96-1167	0	1
1997	4896955	96-1167	0	1
1997	4521431	96-1466	0	0
1997	4536516	96-1364	0	0
1997	4741611	96-5089	0	1
1997	5098303	97-1162	0	1
1997	5234342	97-1162	0	1
1997	5376006	97-1162	0	1
1997	5100420	94-1386	1	1
1997	5084057	94-1386	1	1
1997	4652525	96-1175	1	0
1997	4431740	96-1175	0	0
1997	5156547	96-1298	1	1
1997	5423679	96-1298	1	1
1997	5269748	96-1101	1	1
1997	5298013	96-1101	1	1
1997	4579530	97-1115	0	1
1997	4978344	95-1322	0	1
1998	4944308	96-1165	1	1
1998	5186938	98-1067	0	0
1998	5308336	97-1526	0	1
1998	5385553	97-1526	0	1
1998	5209737	97-1526	0	1
1998	4743262	97-1117	1	1
1998	4330891	96-1463	1	1

1999	5648080	98-1446	0	0
1999	4774941	98-1106	0	1
1999	4487829	98-1341	1	0
1999	5208149	98-1438	1	0
1999	5190931	98-1438	1	0
1999	5433717	97-1365	0	1
1999	4916163	98-1360	1	0
1999	5306285	98-1512	1	1
1999	5059192	99-1038	1	1
2000	5144345	99-1093	0	1
2000	5521911	99-1093	0	1
2000	5264446	99-1365	0	0
2000	4530901	99-1251	0	0
2000	4626549	99-1262	1	0
2000	5401629	99-1381	1	0
2000	4916163	99-1092	0	0
2000	4283408	99-1521	1	0
2000	5672360	99-1416	1	0
2000	4560381	00-1033	0	1
2000	4652259	99-1397	0	1
2000	4653490	98-1317	1	1
2001	4696290	00-1163	0	1
2001	5670537	00-1304	1	0
2001	5641803	00-1304	1	0
2001	4535060	00-1218	0	0
2001	4711880	01-1122	0	0
2001	4626549	99-1262	1	0
2001	4601980	00-1223	0	0
2001	5562925	00-1166	1	0
2001	5302169	00-1106	0	1
2001	5400806	00-1106	0	1
2001	5573780	00-1272	1	0
2001	5690962	00-1272	1	0
2001	5500365	00-1002	1	0

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2008	5740801	2007-1353	1	1
2008	5411474	2007-1420	0	1

Annex F

Chronological List of Pharmaceutical Patent Validity Challenge Resolutions from January 1, 1980 to December 31, 2013

RED = Finding of invalidity

#	Challenged Patent	Case name	Type of proceeding	Citation
1	1,003,331	Apotex Inc. v. Hoffmann-La Roche Ltd.	Imp./infring.	[1989] F.C.J. No. 321
2	741,825	Wellcome Foundation Ltd. v. Apotex Inc.	Imp./infring.	[1991] F.C.J. No. 1136
3	907,014	Wellcome Foundation Ltd. v. Apotex Inc.	Imp./infring.	[1991] F.C.J. No. 1136
4	1,275,349	Merck & Co. v. Apotex Inc.	Imp./infring.	[1995] F.C.J. No. 588
5	1,181,076	Pfizer Canada Inc. v. Apotex Inc.	PM(NOC)	[1997] F.C.J. No. 1087
6	1,322,334	Bayer Inc. v. Canada (Minister of National Health and Welfare)	PM(NOC)	[1998] F.C.J. No. 1035
7	960,688	Wellcome Foundation Limited v. Novopharm Ltd.	Imp./infring.	[1998] F.C.J. No. 1107
8	1,102,809	Hoffmann-La Roche Ltd. v. Apotex Inc.	PM(NOC)	[1998] F.C.J. No. 1149
9	1,204,671	Apotex Inc. v. Syntex Pharmaceuticals International Ltd.	Imp./infring.	[1999] F.C.J. No. 548
10	1,339,047	Kirin-Amgen Inc. v. Hoffmann-La Roche Ltd.	Imp./infring.	[2000] F.C.J. No. 2137
11	1,332,150	Novartis Pharmaceuticals Canada Inc. v. Apotex Inc.	PM(NOC)	2001 FCT 1129
12	2,178,637	Smithkline Beecham Pharma Inc v Apotex Inc	PM(NOC)	2002 FCA 216
13	2,029,065	Pfizer Canada Inc v Apotex Inc	PM(NOC)	2002 FCT 1138
14	1,238,277	Apotex Inc v Wellcome Foundation Ltd	Imp./infring.	2002 SCC 77
15	2,214,575	GlaxoSmithKline Inc v Apotex Inc	PM(NOC)	2003 FCT 687
16	1,218,067	Bayer AG v Apotex Inc	PM(NOC)	2003 FC 1199
17	1,287,060	GlaxoSmithKline Inc v Genpharm Inc	PM(NOC)	2003 FC 1248
18	2,212,548	GlaxoSmithKline Inc v Canada (Minister of Health)	PM(NOC)	2004 FC 116

19	2,261,732	Abbott Laboratories v Canada (Minister of Health)	PM(NOC)	2004 FC 1349
20	1,264,751	Apotex Inc v AB Hassle	PM(NOC)	2004 FCA 369
21	1,304,080	Janssen-Ortho Inc v Novopharm Ltd	PM(NOC)	2004 FC 1631
22	1,338,376	Genpharm Inc v Procter & Gamble Pharmaceuticals Canada Inc	PM(NOC)	2004 FCA 393
23	1,292,693	Genpharm Inc v AB Hassle	PM(NOC)	2004 FCA 413
24	1,338,377	Genpharm Inc v AB Hassle	PM(NOC)	2004 FCA 413
25	2,294,595	Merck & Co Inc v Apotex Inc	PM(NOC)	2005 FC 755
26	2,261,732	Abbott Laboratories v Canada (Minister of Health)	PM(NOC)	2005 FC 1095
27	1,319,682	Aventis Pharma Inc v Mayne Pharma (Canada) Inc	PM(NOC)	2005 FC 1183
28	2,148,071	Pfizer Canada Inc v Novopharm Ltd	PM(NOC)	2005 FC 1299
29	2,148,071	Pfizer Canada Inc v Apotex Inc	PM(NOC)	2005 FC 1421
30	1,340,316	Bristol-Myers Squibb Canada Co v Novopharm Ltd	PM(NOC)	2005 FC 1458
31	1,246,457	Aventis Pharma Inc v Apotex	PM(NOC)	2005 FC 1504
32	1,341,206	Aventis Pharma Inc v Apotex	PM(NOC)	2006 FCA 64
33	1,282,006	Bayer AG v Novopharm Ltd	PM(NOC)	2006 FC 379
34	1,318,590	Axcan Pharma Inc v Pharmascience Inc	PM(NOC)	2006 FC 527
35	2,277,274	Abbott Laboratories v Canada (Minister of Health)	PM(NOC)	2006 FCA 187
36	2,258,606	Abbott Laboratories v Canada (Minister of Health)	PM(NOC)	2006 FCA 187
37	1,321,393	Pfizer Canada Inc v Canada (Minister of Health)	PM(NOC)	2006 FCA 214
38	1,341,206	Pharmascience Inc v Sanofi-Aventis Canada Inc	PM(NOC)	2006 FCA 229
39	1,275,350	Apotex Inc v Merck & Co	Imp./infring.	2006 FCA 323
40	2,021,546	Pfizer Canada Inc v Canada (Minister of Health)	PM(NOC)	2006 FC 1471
41	2,258,606	Abbott Laboratories v. Canada (Minister of Health)	PM(NOC)	2006 FC 1558
42	2,393,614	Ratiopharm Inc v Canada (Minister of Health)	PM(NOC)	2007 FCA 83
43	2,261,732	Abbott Laboratories v Canada (Minister of Health)	PM(NOC)	2007 FCA 153
44	2,177,576	G.D. Searle & Co v Novopharm Ltd	PM(NOC)	2007 FCA 173
45	2,044,748	Pfizer Canada Inc v Apotex Inc	PM(NOC)	2007 FCA 195
46	1,341,206	Sanofi-Aventis Inc v Laboratoire Riva Inc	PM(NOC)	2007 FC 532
47	1,341,330	Pfizer Canada Inc v Canada (Minister of Health)	PM(NOC)	2007 FCA 209

48	2,041,113	Eli Lilly Canada Inc v Novopharm Ltd	PM(NOC)	2007 FC 596
49	1,304,080	Novopharm Ltd v Janssen-Ortho Inc	Imp./infring.	2007 FCA 217
50	2,025,668	AstraZeneca AB v Apotex	PM(NOC)	2007 FC 688
51	2,133,762	AstraZeneca AB v Apotex	PM(NOC)	2007 FC 688
52	2,419,729	Abbott Laboratories v Canada (Minister of Health)	PM(NOC)	2007 FC 753
53	2,471,102	Abbott Laboratories v Canada (Minister of Health)	PM(NOC)	2007 FC 753
54	2,220,455	Pfizer Canada Inc v Canada (Minister of Health)	PM(NOC)	2007 FC 898
55	1,341,330	Pfizer Canada Inc v Canada (Minister of Health)	PM(NOC)	2008 FC 11
56	2,021,546	Pfizer Canada Inc v Canada (Minister of Health)	PM(NOC)	2008 FC 13
57	2,041,133	Apotex Inc v Eli Lilly Canada Inc	PM(NOC)	2008 FCA 44
58	2,021,546	Pfizer Canada Inc v Canada (Minister of Health)	PM(NOC)	2008 FCA 108
59	1,321,393	Pfizer Canada Inc v Canada (Minister of Health)	PM(NOC)	2008 FC 500
60	2,201,967	Shire Biochem Inc v Canada (Minister of Health)	PM(NOC)	2008 FC 538
61	1,340,083	GlaxoSmithKline Inc v Pharmascience	PM(NOC)	2008 FC 593
62	1,336,777	Apotex Inc v Sanofi-Synthelabo Canada	PM(NOC)	2008 SCC 61
63	2,163,446	Apotex v Pfizer Canada	PM(NOC)	2009 FCA 8
64	1,298,288	Bristol-Myers Squibb v Apotex	PM(NOC)	2009 FC 137
65	2,250,191	Eli Lilly Canada Inc v Novopharm Ltd	PM(NOC)	2009 FC 235
66	2,386,527	Abbott Laboratories v Minister of Health	PM(NOC)	2009 FCA 94
67	2,158,399	Eli Lilly Canada Inc v Novopharm	PM(NOC)	2009 FC 301
68	2,101,356	Eli Lilly Canada v Apotex	PM(NOC)	2009 FCA 97
69	2,158,399	Eli Lilly Canada Inc. v. Apotex Inc.	PM(NOC)	2009 FC 320
70	1,341,196	Apotex v Adir and Servier Canada	Imp./infring.	2009 FCA 222
71	2,098,738	Purdue Pharma v Pharmascience	PM(NOC)	2009 FC 726
72	1,133,007	Eli Lilly and Co v Apotex	Imp./infring.	2009 FC 991
73	1,146,536	Eli Lilly and Co v Apotex	Imp./infring.	2009 FC 991
74	1,133,468	Eli Lilly and Co v Apotex	Imp./infring.	2009 FC 991
75	1,150,725	Eli Lilly and Co v Apotex	Imp./infring.	2009 FC 991
76	1,095,026	Eli Lilly and Co v Apotex	Imp./infring.	2009 FC 991
77	1,132,547	Eli Lilly and Co v Apotex	Imp./infring.	2009 FC 991
78	1,136,132	Eli Lilly and Co v Apotex	Imp./infring.	2009 FC 991
79	1,144,924	Eli Lilly and Co v Apotex	Imp./infring.	2009 FC 991
80	2,102,778	Sanofi-Aventis Canada v Hospira Health Corp	PM(NOC)	2009 FC 1077
81	2,014,453	Lundbeck Canada v Ratiopharm	PM(NOC)	2009 FC 1102

82	2,426,492	Lundbeck Canada v Ratiopharm	PM(NOC)	2009 FC 1102
83	2,325,014	Schering-Plough Canada Inc. v. Pharmascience Inc.	PM(NOC)	2009 FC 1128
84	2,267,136	Schering-Plough Canada Inc. v. Pharmascience Inc.	PM(NOC)	2009 FC 1128
85	2,290,624	Biovail Corporation v The Minister of Health	PM(NOC)	2010 FC 46
86	2,177,772	Sanofi Aventis Canada v Ratiopharm	PM(NOC)	2010 FC 230
87	2,173,457	Merck & Co v Pharmascience	PM(NOC)	2010 FC 510
88	2,324,324	Pfizer v Ratiopharm	PM(NOC)	2010 FC 612
89	2,285,266	Sandoz Canada Inc v Abbott Laboratories	PM(NOC)	2010 FCA 168
90	2,358,395	Sandoz Canada Inc v Abbott Laboratories	PM(NOC)	2010 FCA 168
91	2,139,653	Astrazeneca Canada Inc v Apotex Inc	PM(NOC)	2010 FC 714
92	1,321,393	Pfizer v Ratiopharm	Imp./infring.	2010 FCA 204
93	2,111,851	Novo Nordisk Canada Inc v Cobalt Pharmaceuticals	PM(NOC)	2010 FC 746
94	2,172,149	Merck-Frosst - Schering Pharma GP v Canada (Minister of Health)	PM(NOC)	2010 FC 933
95	2,065,965	Merck & Co v Canada (Minister of Health)	PM(NOC)	2010 FC 1042
96	1,329,211	Merck & Co v Canada (Minister of Health)	PM(NOC)	2010 FC 1043
97	2,209,735	Eli Lilly Canada Inc v Apotex	PM(NOC)	2010 FC 1065
98	2,310,950	Janssen Inc v Mylan Pharmaceuticals	PM(NOC)	2010 FC 1123
99	1,339,452	Lundbeck Canada v Minister of Health	PM(NOC)	2010 FCA 320
100	1,161,380	Merck & Co v Apotex	Imp./infring.	2010 FC 1265
101	1,328,452	GlaxoSmithKline Inc v Pharmascience	PM(NOC)	2011 FC 239
102	1,339,132	Pfizer Canada Inc v Canada (Minister of Health)	PM(NOC)	2011 FCA 102
103	2,209,735	Novopharm/Teva v Eli Lilly	Imp./infring.	2011 FCA 220
104	1,333,285	Hoffman-La Roche v Apotex	PM(NOC)	2011 FC 875
105	1,339,132	Apotex v Pfizer	PM(NOC)	2011 FCA 236
106	1,341,206	Sanofi-Aventis v Apotex895	Imp./infring.	2011 FCA 300
107	2,440,764	Allergan v Minister of Health	PM(NOC)	2011 FC 1316
108	2,225,626	Allergan v Minister of Health	PM(NOC)	2011 FC 1316
109	1,338,808	Mylan Pharmaceuticals v Pfizer	PM(NOC)	2012 FCA 103
110	1,337,420	Mylan Pharmaceuticals v Astrazeneca	PM(NOC)	2012 FCA 109
111	2,195,094	Alcon Canada v Apotex	PM(NOC)	2012 FC 410
112	2,163,446	Teva v Pfizer	PM(NOC)	2012 SCC 60
113	2,487,054	Fournier Pharma Inc v Minister of Health and Sandoz	PM(NOC)	2012 FC 740

114	2,372,576	Fournier Pharma Inc v Minister of Health and Sandoz	PM(NOC)	2012 FC 741
115	2,041,113	Eli Lilly Canada v Novopharm	Imp./infring.	2012 FCA 232
116	2,101,572	Bristol-Myers Squibb v Mylan Pharmaceuticals	PM(NOC)	2012 FC 1142
117	2,279,198	Bristol-Myers Squibb v Mylan Pharmaceuticals	PM(NOC)	2012 FC 1142
118	2,440,764	Apotex v Allergan	PM(NOC)	2012 FCA 308
119	2,255,652	Pfizer Canada v Pharmascience	PM(NOC)	2013 FC 120
120	2,093,203	Teva v Novartis; Apotex v Norvartis	Imp./infring.	2013 FC 141
121	2,170,647	Astrazeneca Canada Inc v Ranbaxy Pharmaceuticals	PM(NOC)	2013 FC 232
122	2,251,944	Astrazeneca Canada Inc v Teva Canada	PM(NOC)	2013 FC 245
123	2,251,944	Astrazeneca Canada Inc v Teva Canada	PM(NOC)	2013 FC 246
124	1,339,452	Apotex Inc v H Lundbeck A/S	Imp./infring.	2013 FC 192
125	1,338,895	Novartis Pharmaceuticals Canada v Teva Canada	PM(NOC)	2013 FC 283
126	2,154,721	Hoffman-La Roche v Apotex	PM(NOC)	2013 FC 718
127	1,336,777	Sanofi-Aventis v Apotex	Imp./infring.	2013 FCA 186
128	1,338,937	Teva Canada Ltd v Novartis	PM(NOC)	2013 FCA 244
129	2,261,619	Gilead Sciences v Minister of Health and Teva	PM(NOC)	2013 FC 1270
130	2,298,059	Gilead Sciences v Minister of Health and Teva	PM(NOC)	2013 FC 1270
131	2,261,619	Gilead Sciences v Minister of Health and Teva	PM(NOC)	2013 FC 1271
132	2,298,059	Gilead Sciences v Minister of Health and Teva	PM(NOC)	2013 FC 1271
133	2,261,619	Gilead Sciences v Minister of Health and Teva	PM(NOC)	2013 FC 1272
134	2,298,059	Gilead Sciences v Minister of Health and Teva	PM(NOC)	2013 FC 1272