

IN THE MATTER OF  
THE *COMPETITION ACT*, R.S.C. 1985, c. C-34, as am.

AND IN THE MATTER OF  
A COMPLAINT CONCERNING ANTI-COMPETITIVE PRACTICES  
IN THE PHARMACEUTICAL INDUSTRY

**STATUTORY DECLARATION**

I, James Clancy, of the City of Ottawa in the Province of Ontario make oath and say as follows:

1. I am the National President of the National Union of Public and General Employees. I have prepared this document in consultation with legal counsel and verily believe the facts disclosed to be true.

2. The National Union of Public and General Employees and the Canadians it represents, are deeply concerned about the increasing cost of drugs in Canada and the impact this has on us as consumers and taxpayers.

3. I make this declaration in support of an application for inquiry, pursuant to section 9 of the *Competition Act*, R.S.C. 1985, c. C-34 (“the Competition Act”), that the Commissioner:

- (i) Cause an inquiry to be made under section 10 of the Competition Act into the practice of brand name pharmaceutical company evergreening of patents, the effects of this practice on competition and the cost to Canadian consumers, third-party payors, taxpayers and governments (collectively “Drug Purchasers”);
- (ii) Comment upon whether the *Patented Medicines (Notice of Compliance) Regulations* (“the NOC Regulations”) as interpreted by Canadian courts promote the interests of competition or whether specific provisions, such as the automatic 24-month stay, have the effect of improperly delaying the entry of generic drug products in such a way that harms competition and Drug Purchasers; and
- (iii) Take appropriate action including proceedings to prohibit anticompetitive acts contrary to the Competition Act.

## **Application for Inquiry: Eligibility and Grounds**

4. I am a Canadian resident older than eighteen years of age and am of the opinion that grounds exist for the making of an order under Part VIII of the Competition Act.

5. In recent years, some Canadian brand name pharmaceutical companies have aggressively pursued strategies aimed at extending market monopolies for certain blockbuster drugs<sup>1</sup> and at delaying consumer and patient access to lower-priced, therapeutically equivalent generic drug products.

6. One such strategy, called “evergreening” involves obtaining multiple patents relating to the same basic drug product, listing these patents on the Canadian Patent Register, and obtaining successive 24-month stays of regulatory approval of generic products.

7. Evergreening artificially extends the patent life and market monopoly of the brand name drug and delays (or even prevents) market entry of independent generic products. The obvious effect is a substantial prevention or lessening of competition in the pharmaceutical market.

8. Of particular concern to myself and the National Union of Public and General Employees is the fact that there is no remedy whatsoever to compensate Drug Purchasers when entry of a generic drug is unnecessarily delayed.

9. This matter is of grave concern to all Canadians. I have been mandated by our members to contact you to pursue this issue. We are prepared to take all necessary means to support your inquiry into these anticompetitive brand name monopoly extension strategies and help stop the ongoing economic harm being caused to all Canadians.

10. The practice of evergreening constitutes an offence under section 79 of the Competition Act. Accordingly, we make this application for inquiry under section 9(1) of the Competition Act. Below, I set out the specific grounds for the making of an order under Part VIII of the Competition Act.

## **Background: Access to Affordable Medicine**

11. The increasing cost of pharmaceuticals and access to affordable medicine have become important issues in Canada. For example, in the 20-year period between 1979 and 1999 there was an increase from 8.6% to 15.2% in the percentage of overall health care spending attributed to drugs. By 1997, drug costs (including prescription and non-prescription drugs) had overtaken spending

---

<sup>1</sup> A blockbuster drug is a drug product ranked among the top 20 drug products as determined by annual gross sales in a given year.

on physical services to become the second largest component of health expenditures.<sup>2</sup>

12. The Romanow Report reviewed the cost of pharmaceutical drug products:

In 1980, \$1.3 billion was spent on prescription drugs in Canada, about 5.8% of total spending on healthcare in the country. By 2001, the percentage had doubled to 12% and the total amount of money spent on prescription drugs had climbed dramatically to \$12.3 billion.

There is every reason to believe that the use of prescription drugs will become even more widespread in the future and that costs will continue to increase. Given this reality, provinces and territories will face serious challenges in trying to manage costs on the one hand and ensure reasonable access to medically necessary drugs on the other.<sup>3</sup>

...

Prescription drugs play a growing and essential role in Canada's health care system and the health of Canadians. They are a vital component of the health care system and that reality should be reflected in how we fund, cover and ensure access to quality, safe and cost-effective prescription drugs.<sup>4</sup> [emphasis added]

13. In Canada, coverage of prescription drugs is provided both privately and publicly. The majority of costs are covered through employer-sponsored private group insurance plans. Provincial and territorial plans subsidize the cost of prescription drugs for some residents, particularly social assistance recipients and seniors.<sup>5</sup>

14. With respect to employer-sponsored private group insurance plans, employers in Canada are grappling with rising costs, propelled mainly by soaring drug costs. The escalating costs of health benefit plans, exacerbated by the practice of evergreening, is becoming a contentious issue between employers and employees, in both unionized and non-unionized workplaces across the country. Employers are attempting to shift the costs onto employees by raising worker co-payments, cutting benefits or adjusting wage increases to offset higher costs.

---

<sup>2</sup> Canadian Institute for Health Information (2000).

<sup>3</sup> The Romanow Report at 196.

<sup>4</sup> The Romanow Report at 210.

<sup>5</sup> Data from the Canadian Institute for Health Information (CIHI 2002) indicates that in 1999, private insurance plans covered approximately 34% (\$3.4 billion) of prescription drug costs, individual Canadians paid 22% (\$2.3 billion) of prescription drug costs out of their own pockets, and public insurance plans covered approximately 44% (\$4.4 billion) of prescription drug costs.

15. Given the increasing cost of prescription drugs as a portion of total health spending, and the increasing reliance of Canadians on this form of health care, and the attempt by employers to shift costs onto employees, the role of generic drugs in our managed health care system is becoming more important.

16. Generic products offer significant savings: the average discount in the price of generic products (compared to brand products), based on IMS data, is 45%. For example, in 2002 the average cost of a generic prescription was \$21.53 whereas the average cost of a brand name prescription was \$55.59.<sup>6</sup> For every day generic market entry is delayed, resources must be redirected from elsewhere to fund more expensive brand name drugs.<sup>7</sup>

### **Background: The Statutory Scheme Regulating Drug Approval – The Federal NOC Regulations**

17. The NOC Regulations were enacted to serve a dual purpose: to prevent infringement of patents, and to encourage and facilitate appropriate, timely entry of generic products. To this end, Health Canada's ability to issue a notice of compliance ("NOC") to a generic manufacturer is linked to the patent status of the brand name product to which the generic company compares its product.

18. A brand name drug company that has applied to Health Canada for approval of a new drug can submit a patent for inclusion on the Patent Register.

19. A patent listed on the Patent Register triggers the ability of the brand name company to obtain an automatic 24-month stay against approval of a generic drug product referencing the brand name medicine which is the subject of the patent.

### **The Practice of Evergreening**

#### Introduction

20. The practice of evergreening in Canada was recently described in the Romanow Report:<sup>8</sup>

...manufacturers of brand name drugs make variations to existing drugs in order to extend their patent coverage. This delays the

---

<sup>6</sup> IMS Health Canada, Compuscript, 2002.

<sup>7</sup> "For every day a generic drug is *delayed* from entering the market, resources must be redirected from other parts of the health care system to pay for the more expensive 'branded' medications, or the Canadian public must be prepared to pay more for their health care privately. Either way, generic drug products will play a fundamental role in priority setting in health care" ("Timely Access to Generic Drugs: Issues for Health Policy in Canada", Queen's University, August 2001 at p. 1)

<sup>8</sup> "Building on Values, The Future of Health Care in Canada" (Commission on the Future of Health Care in Canada, November 2002) ("The Romanow Report").

ability of generic manufacturers to develop cheaper products for the marketplace and it is a questionable outcome of Canada's patent law ... Clearly, if this is the case, the practice is not in the public interest.<sup>9</sup> [emphasis added]

21. President Bush also recently commented on the practice of evergreening:<sup>10</sup>

... some brand name drug manufacturers may have manipulated the law to delay the approval of competing generic drugs. When a drug patent is about to expire, one method some companies use is to file a brand new patent based on a minor feature, such as the color of the pill bottle or a specific combination of ingredients unrelated to the drug's effectiveness. In this way, the brand name company buys time through repeated delays, called automatic stays, that freeze the status quo as the legal complexities are sorted out.<sup>11</sup>

#### Evergreening is Anticompetitive

22. In Canada, as in the U.S., evergreening artificially and inappropriately extends a brand name company's monopoly and deprives Drug Purchasers of timely access to more affordable safe and effective generic drugs. Indeed, Recommendation 41 of the Romanow Report is:

The federal government should immediately review the pharmaceutical industry practices related to patent protection, specifically, the practices of evergreening and the Notice of Compliance Regulations. This review should ensure that there is an appropriate balance between the protection of intellectual property and the need to contain costs and provide Canadians with improved access to non-patented prescription drugs.<sup>12</sup> [emphasis added]

#### Deadweight Loss to Drug Purchasers

23. Absent action by the federal government, there is no remedy in law for Canadian Drug Purchasers to recover the damages they suffer because of brand name evergreening of patents.

---

<sup>9</sup> The Romanow Report at 209.

<sup>10</sup> These comments by the President were made in the context of discussion about anti-competitive abuse of regulatory laws by American brand name pharmaceutical companies (Remarks by the President on Prescription Drugs, The Rose Garden (October 21, 2002)).

<sup>11</sup> Remarks by the President on Prescription Drugs, The Rose Garden (October 21, 2002).

<sup>12</sup> The Romanow Report at 208.

24. The NOC Regulations contain a damages provision for generic companies who successfully defend a patent infringement suit brought by the brand name company.<sup>13</sup> The generic is entitled to recover its lost profits for the period of time its market entry was inappropriately delayed.

25. However, monopoly profits are always greater than generic profits and in every case the brand name company's profits earned during the improper market delay will be greater than the damages suffered by the generic company, and as set out above, these are unrecoverable by Drug Purchasers.

26. Thus, there is always a windfall to the brand name company, which corresponds to a deadweight loss borne directly by Drug Purchasers who have paid monopoly prices when a lower-cost generic product should have been available. There is no remedy in law for these deadweight losses.<sup>14</sup>

27. Brand name companies never have to account for the excess windfall profits accumulated during a period of improper delay of generic market entry, and as a result there is a substantial incentive for brand name companies to continue to game the system.

28. In my view, investigation by the Bureau into the practice of evergreening is an appropriate, and perhaps the only, mechanism available to seek to address the problem of evergreening. In addition to the possibility that orders be made in respect of specific brand name companies, a strong message would be sent to all brand name companies that monopoly extension strategies will no longer be tolerated.

---

<sup>13</sup> Note that it is estimated that generic companies win 75% of these cases. This is similar in the United States, where the Federal Trade Commission found "of all the patent infringement cases ... in which there has been a decision of a court as of June 1, 2002, generic applicants prevailed in 73 percent of these cases ("Generic Drug Entry Prior to Patent Expiration: An FTC Study", Federal Trade Commission (July 2002) at p. 13). Note too that no generic company has yet been awarded damages under the NOC Regulations.

<sup>14</sup> Canadian courts have declined to certify classes in potential class action suits where anticompetitive behaviour is alleged. In one such case, the Ontario Superior Court refused to certify a class in a proceeding where the plaintiffs alleged a conspiracy to unduly prevent or lessen competition in the Canadian market for iron oxide. The Court held there was no real common issue which would move the litigation forward, other than in a theoretical sense. In addressing the plaintiffs' argument that the certification would serve the goal of behaviour modification (one of the objectives of certification), the Court said:

In the case at bar, there is a specialized statutory authority, the Competition Bureau, that is responsible for the administration and enforcement of the very provisions of the Competition Act the respondents allege the appellants violated. Therefore, it cannot be said that a class proceeding would be the preferable procedure for the resolution of the common issues when the primary object of the action would be to modify the behaviour of the appellants and potential wrongdoers. There is another procedure better-suited to achieving this goal.<sup>14</sup> [emphasis added]

## Specific Examples of Evergreening in Canada

### Omeprazole

29. Omeprazole is sold in Canada by Astra Zeneca Pharma Inc. (“Astra”) under the brand name Losec.

30. Omeprazole is a widely prescribed drug used to treat ulcers and acid reflux, with annual sales in Canada in 2002 of \$424 million. Omeprazole is the second highest selling drug product in Canada based on sales dollars.

31. Despite the fact that the original patent on Losec expired on July 6, 1999, and the fact that generic omeprazole is available in the United States and Europe, there is no generic omeprazole marketed in Canada.

32. Sale of generic omeprazole in Canada has been successfully blocked by the evergreening of patents by Astra. After generic companies filed submissions with Health Canada in respect of omeprazole, Astra switched its omeprazole product from a capsule to a tablet and acquired new 20-year patents on the tablet form.

33. In addition, several other subsequent patents were listed on the Register in respect of minor modifications to the drug, including patents on a new coating, different dosages and the inactive chemicals used in tablets.

34. The Patent Register now contains at least 10 additional patents in respect of Losec.

35. One generic manufacturer, Apotex Inc. was subjected to two 24-month stays in respect the original patent on Losec, and has been subjected to at least four subsequent stays.

36. The accumulated deadweight loss to Drug Purchasers since expiry of the original patent on July 6, 1999 (to April 1, 2003) is approximately \$537 million.

37. This loss continues to mount by approximately \$502,000 per day (or \$3.5 million per week). If a generic version of omeprazole had been available in 2001, for just this one drug, the average employer’s total drug benefit cost would have dropped by 1.6%.<sup>15</sup>

### Paroxetine

38. Paroxetine is sold in Canada by GlaxoSmithKline (“Glaxo”) (formerly SmithKline Beecham), under the brand name Paxil.

---

<sup>15</sup> Greenshield Canada’s submission to the Commission on the Future of Health Care in Canada, April 23, 2002.

39. Paroxetine is an antidepressant with annual Canadian sales in 2002 of \$227.5 million. Paroxetine is the sixth highest selling drug product in Canada based on sales dollars.

40. The listing of patents by Glaxo has resulted in seven-and-a-half years of automatic stays. The first stay was triggered on December 4, 1996 and expired May 4, 1999. The last stay currently expires on June 6, 2004, however there is no guarantee that this is the final automatic stay in respect of Paxil, as Glaxo has filed many patent applications relating to Paxil, which it may attempt to list.

41. Accordingly, there is currently no generic paroxetine available for sale in Canada. This is despite the fact that Health Canada's review of Apotex' submission was complete in October, 1999, and as of that date it was determined that Apotex' product was a safe and effective alternative to the brand name product.

42. Therefore, between October 31, 1999 and April 1, 2003, Drug Purchasers have likely incurred a deadweight loss in the amount of approximately \$258 million. This loss continues to mount by approximately \$269,000 per day (or \$1.9 million per week).

### **The Automatic Stay in Canada and the United States**

43. Evergreening by brand name companies in the United States has been met by a flurry of legislative and regulatory developments.

44. The NOC Regulations, although different in some respects, were modeled on the drug approval scheme in the United States under the Hatch-Waxman Act. Accordingly, regulation of drug approval is similar in both countries:

- (i) The listing of a patent in both the Orange Book (the U.S. equivalent to the Patent Register) and the Patent Register can give rise to an automatic stay;
- (ii) The supervising agency in both countries (the Food and Drug Administration and Health Canada), consider that they have no obligation to remove improperly listed patents, and in neither country does a private citizen have the right to seek the delisting of a patent;
- (iii) There is an economic incentive to game the system, as brand name companies will not be required to fully account for improper gains realized during improper periods of market monopoly;



- (iv) Brand name companies in both countries evergreen patents to extend market monopolies;
- (v) Evergreening of patents results in a significant deadweight loss which is borne by Drug Purchasers in both countries; and
- (vi) There is no remedy in either country to compensate these parties for the deadweight losses suffered.

45. At the time the Hatch-Waxman Act was introduced in 1984, most brand name companies listed patents for the active ingredient (pioneer patent), simple formulations, processes and intermediates, and primary uses. Now, brand name companies in Canada and the U.S. systematically seek and obtain patents on each and every chemical form of a chemical compound, on every manner of formulating the product, and every indication that is possible for the product. Some companies even obtain patents on the colour of the pill, or the colour of the pill bottle.

46. The Federal Trade Commission (“FTC”) in the United States examined the problem of evergreening and has taken assertive and broad measures to stop the practice. Timothy Muris, Chairman of the FTC, discussed the increasing prevalence of brand name strategies aimed at delaying generic entry:

Since 1998, two new phenomena appear to be emerging in relation to patent listing practices that affect patent litigation: (1) an increase in the number of patents listed in the Orange Book for “blockbuster” drug products; and (2) the listing of patents after an ANDA has been filed for the particular drug product.

By the timely listing of additional patents in the Orange Book after a generic applicant has filed its ANDA (“later issued patents”), brand-name companies can obtain additional 30-month stays of FDA approval of the generic applicant’s ANDA. In eight instances, brand-name companies have listed later-issued patents in the Orange Book after an ANDA has been filed for the drug product. For those eight drug products, the additional delay of FDA approval (beyond the first 30-months) ranged from four to 40 months. In all of the four cases so far with a court decision on the validity or infringement of a later-issued patent, the patent has been found either invalid or not infringed by the ANDA.<sup>16</sup>

47. In hearings held by the U.S. Senate, the practice of evergreening was commented upon by Senator Edward Kennedy as follows:

---

<sup>16</sup> The prepared statement of the Federal Trade Commission before the Committee on Energy and Commerce Subcommittee on Health, United States House of Representatives, Washington D.C. (October 9, 2002).

Each and every day pharmaceutical companies exploit loopholes in the law to maintain a monopoly over their drugs and keep more affordable generic drugs off the market. America's consumers are paying the price... the pharmaceutical companies game the system by listing spurious patents with FDA – patents on unapproved uses, unapproved compounds or formulations that they don't even market. Then they get automatic 30-[month] stays delaying approval of generic drugs.<sup>17</sup>

48. In July 2002, the FTC released an extensive study which examined, among other things, the anti-competitive effects of improper patent listings.<sup>18</sup> The FTC observed that these strategies cost consumers and third-party payors billions of dollars per year,<sup>19</sup> and that there is no viable mechanism for compensating these parties.

49. The FTC specifically considered the case of GlaxoSmithKline's drug product Paxil,<sup>20</sup> which was discussed above as a specific example of evergreening in Canada. In the United States, after the original patents in respect of Paxil expired, nine additional patents were listed in the Orange Book, and four consecutive 30-month stays have been triggered. The brand name company has effectively prevented generic competition for approximately 65 months.

50. Shortly after the FTC Study was released, Senate Bill 812 was passed in the Senate. This Bill, among other things, limits the eligibility of patents which trigger entitlement to the 30-month stay to only those patents listed within 30 days of the approval of a new drug application.

51. In addition, anti-trust lawsuits have been filed in the United States in cases where brand name companies have abused the automatic stay provisions of the legislation. Twenty-nine state governments have filed suits against Bristol-Myers Squibb Company ("BMS") in respect of the drugs Taxol and BuSpar, and FTC investigated the matter. BMS was charged with engaging in a series of unlawful acts to delay competition from generic versions of three of its major drug

---

<sup>17</sup> United States Senate, Committee on Health, Education, Labor and Pensions, Closing the Gaps in Hatch-Waxman: Assuring Greater Access to Affordable Pharmaceuticals, Senator Edward Kennedy (D-MA), Chairman (May 8, 2002).

<sup>18</sup> This study is titled: "Generic Drug Entry Prior to Patent Expiration: An FTC Study," Federal Trade Commission (July 2002).

<sup>19</sup> And according to President Bush on the same subject, "By cutting out delays and maneuvering, our reforms will yield cost savings of more than \$3 billion a year" (Remarks by the President on Prescription Drugs, The Rose Garden, October 21, 2002).

<sup>20</sup> See "Generic Drug Entry Prior to Patent Expiration: An FTC Study," Federal Trade Commission (July 2002) at p. 51.

products: BuSpar, an anti-anxiety agent, and two anti-cancer drugs, Taxol and Platinol.<sup>21</sup>

52. In January 2003, BMS announced that it would pay \$670 million to settle these state suits, and on March 7, 2003 BMS and the FTC announced a settlement. In part, the settlement eliminates BMS' ability to obtain an automatic stay on later-listed patents<sup>22</sup>, and bars an automatic stay, regardless of when the patent was listed, in cases where BMS has engaged in certain types of misconduct in connection with obtaining and listing the patent.

53. The same activity by the same companies occurs in Canada, yet there has been no action by the Canadian government to challenge this unlawful, anti-competitive conduct.

#### The Story of Paclitaxel in Canada

54. A recent example of the inactivity of the Canadian government in a situation in which U.S. federal agencies have acted is the case of Paclitaxel, an anti-cancer drug manufactured in Canada by Biolyse Pharma Corporation ("Biolyse"). Attached to this Declaration and marked as Exhibit "A" is a copy of an article published in the Ottawa Citizen on April 26, 2003 titled "How a Generic Drug Firm Lost to the Big Guys: The Story of What Happened to Biolyse Gives Fresh Insight into the High Stakes and Litigious World of Pharmaceutical Making".

55. Biolyse developed a new paclitaxel product from a new botanical source. After consultation with Health Canada regarding what form its drug submission should take, Biolyse submitted a new drug submission in respect of its Paclitaxel product.

56. After many years of review by Health Canada, Biolyse's new product was approved in September, 2001. Biolyse's Paclitaxel offered significant savings to Drug Purchasers as an alternative to BMS' similar, higher-priced product, Taxol.

57. In November, 2002 BMS asked the Federal Court of Canada to strike Biolyse's NOC for Paclitaxel on the grounds that Biolyse did not provide notice to BMS (in the form of a Notice of Allegation) that it would challenge two patents BMS had listed on the Patent Register in respect of Taxol. BMS argued that

---

<sup>21</sup> According to the complaint, when confronted with imminent competition to these drugs through generic entry, BMS undertook a course of conduct that includes: paying a would-be competitor \$72.5 million to abandon its challenge to a BMS patent and stay off the market until the patent expired, abusing FDA regulations to block generic entry, making false statements to the FDA in connection with the listing of patents in the Orange Book, engaging in inequitable conduct before the U.S. Patent and Trademark Office to obtain patents, and filing baseless patent infringement suits.

<sup>22</sup> In part, the purpose of this is to reduce BMS' incentive to engage in improper behaviour to obtain and list a patent for the purpose of obtaining an unwarranted automatic stay.

notice was required despite the fact that Biolyse sought approval of a new drug through the new drug submission process, as opposed to approval of a generic drug through the abbreviated new drug submission process.

58. On April 7, 2003, the Federal Court of Appeal released a decision effectively agreeing with BMS that Biolyse was required to notify BMS, and because it had not, the Court quashed the Biolyse NOC.

59. Ironically, the equivalent patents in the United States to those at issue in this proceeding were found by the FTC to be unlikely to be valid because most of the innovation claimed in the patents was done by the National Cancer Institute, a publicly funded agency. Furthermore, the FTC found that BMS made false and misleading material statements to the patent office in its applications for the two patents.

60. In Canada, to my knowledge no governmental authority, including the Competition Bureau has investigated BMS' actions or has taken any action in respect of these patents. At a minimum, one would expect that the Bureau would contact the FTC and at least determine the basis for the investigation and BMS' agreement to settle proceedings in respect of Taxol. It appears that much of the legwork has been completed by the FTC and the Bureau could easily initiate and conclude a similar investigation in Canada.

61. In the meantime, from public reports it appears that Biolyse has shut down production in Canada and laid off most of its staff. In the end result, Drug Purchasers have lost access to a safe and more affordable paclitaxel product.

### **Requested Action**

62. The NOC Regulations provide a cause of action for generic companies to recover damages suffered as a result of improper patent listings, however I am unaware of any case to date in which damages have been awarded. In any event, there is no cause of action for Drug Purchasers to recover damages suffered by them because of improper patent listings.

63. Because brand name never have to account for improper gains accumulated through evergreening (i.e. because the damages suffered by generic companies are always less than brand name profits), there is a powerful economic incentive for the continued use of evergreening tactics.

64. Brand name evergreening of patents causes significant economic loss to Drug Purchasers, as set out above, and constitute a substantial prevention or lessening of competition in the pharmaceutical market.

65. I respectfully request that the Bureau take the following action:

- (i) Section 10 of the Competition Act states that the Commissioner shall, on application made under section 9, cause an inquiry to be made into all such matters as the Commissioner considers necessary to inquire into with the view of determining the facts. In my view, once a complaint is made, the Commissioner is required to cause an inquiry to be made into all such matters as the Commissioner considers necessary to inquire into with the view of determining the facts. This would include a study of the practice of evergreening, its effects on competition and the cost to consumers, third-party payors and governments.
- (ii) Based upon the facts as found, comment upon whether the NOC Regulations as interpreted by Canadian courts are promoting the interests of competition or whether specific provisions, such as the automatic 24-month stay provision, have the effect of improperly delaying the entry of generic drug products in such a way that harms competition and consumers.
- (iii) As a further step, if as a result of this investigation specific anticompetitive acts are found, take appropriate action including proceedings to prohibit anticompetitive acts contrary to the Competition Act.

**SWORN BEFORE ME** in the City )  
of , in the Province )  
of , this day of )  
, 2003 )  
) )  
) )  
**(original witnessed by a Commissioner)**  
A Commissioner, etc.

**(original signed by)**  
\_\_\_\_\_  
National President  
National Union of Public and  
General Employees (NUPGE)