Court File No. T-2223-14

FEDERAL COURT

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OCT 29 2014
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BETWEEN:

APOTEX INC., APOTEX PHARMACHEM INDIA PVT LTD and APOTEX RESEARCH PRIVATE LIMITED

Applicants

- and -

MINISTER OF HEALTH and ATTORNEY GENERAL OF CANADA

Respondents

NOTICE OF APPLICATION

TO THE RESPONDENTS:

A PROCEEDING HAS BEEN COMMENCED by the Applicants. The relief claimed by the Applicants appears on the following page.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the Applicants. The Applicants request that this application be heard at Toronto, Ontario.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for

you must prepare a notice of appearance in Form 305 prescribed by the *Federal Courts Rules* and serve it on the Applicants' solicitor, or where an Applicant is self-represented, on the Applicant, WITHIN 10 DAYS after being served with this notice of application.

Copies of the *Federal Courts Rules*, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

Date OCT 29 2014 Issued by ABIGAIL GRIMES REGISTRY OFFICER AGENT DU GREFFE (Registry Officer)

Address of local office: 180 Queen Street West
Suite 200
Toronto, Ontario
M5V 3L6

TO: THE REGISTRAR
Federal Court of Canada
Application Division
180 Queen Street West
Suite 200
Toronto, Ontario M5V 3L6

AND TO: MINISTER OF HEALTH and ATTORNEY GENERAL OF CANADA
130 King Street West
Suite 3400, Box 36
Toronto, Ontario M5X 1K6

APPLICATION

THIS IS AN APPLICATION for judicial review by Apotex Inc. ("Apotex"), Apotex Pharmachem India Pvt Ltd ("APIPL") and Apotex Research Private Limited ("ARPL") of the decision of the Respondent, the Minister of Health (collectively with her delegates, the "Minister"), dated September 30, 2014, to issue and implement an import ban to prevent the importation of drug products into Canada from APIPL, and ARPL (the "Import Ban").

THE APPLICANTS hereby request, pursuant Rule 317 of the *Federal Courts Rules*, all material that is relevant to the application herein that is in the possession of the Minister and/or Health Canada including, without limitation, all documents leading to or otherwise relating to the Minister's decision to impose and implement the Import Ban, to issue the press releases of Sept 30, 2014 (referred to and defined below), to issue the 4 EL Letters (described and defined below) including all drafts, all instructions, all communications with or between Health Canada and the Minister's office, and all records of the Prime Minister's Office ("PMO") and records of communications between the PMO and the Minister, her office and/or Health Canada.

THE APPLICANTS MAKE APPLICATION FOR:

1. An order declaring the decision of the Minister to issue the Import Ban to be unlawful;

2. An order quashing the decision of the Minister to issue the Import Ban;

3. An order prohibiting or restraining the Minister from implementing or carrying into effect the Import Ban including, in particular, by attempting to amend Apotex's establishment licences ("ELs") so as to prohibit the importation of drug products from APIPL and/or ARPL.

4. An order quashing four letters issued by the Minister on October 2, 2014 purporting to amend Apotex's ELs (defined below as the "4 EL Letters").

5. An order quashing the listing of APIPL and ARPL products as prohibited products by the Import Ban, first published on Health Canada's website on September 30, 2014 and maintained to this date (defined below as the "September 30 List of Products").

6. An order releasing to Apotex any property unlawfully seized by the Minister pursuant to the Import Ban;

7. An order compelling the Minister to retract the September 30 Minister's Statement (defined below).

8. An order compelling the Minister to require Health Canada to retract the September 30 Health Canada Statement (defined below).

9. One or more interim orders of the nature contemplated in subparagraphs 1 to 8, above.

10. An order, if necessary, permitting the within application to be heard on an interim basis, *ex parte* or on notice.

11. An order, if necessary, abridging the time for service and hearing of the within application, whether on an interim or a final basis.

12. Costs of this application on a scale and in amount determined by this Honourable Court to be appropriate in all of the circumstances; and

13. Such further and other relief as this Honourable Court may deem just.

THE GROUNDS FOR THE APPLICATION ARE:

Applicants

1. Apotex is the largest pharmaceutical manufacturer in Canada, with about 6,000 employees in Canada, and accounting for approximately twenty percent of all prescriptions filled in Canada.

2. Apotex is affiliated with APIPL and ARPL.

3. APIPL is an Indian company which primarily produces active pharmaceutical ingredients ("APIs") to be used in the manufacture of finished dosage form pharmaceutical products.

4. ARPL is an Indian company which primarily produces finished dosage form pharmaceutical products.

5. Apotex purchases and imports into Canada APIs manufactured by APIPL to be manufactured into final dosage form pharmaceutical products at Apotex's Canadian manufacturing facilities.

6. Apotex also purchases and imports into Canada finished dosage form pharmaceutical products from ARPL to be sold in Canada and other jurisdictions. For some products, the finished dosage form pharmaceutical products so purchased from ARPL are made using APIs manufactured by APIPL.

Respondent Minister of Health

7. The Respondent Minister of Health is the Honourable Rona Ambrose. Through her delegates at Health Canada, she is responsible, among other things, for administering the *Food and Drugs Act*, R.S.C. , 1985, c. F-27 (the "FD Act"), and the *Food and Drug Regulations* (the "FD Regulations") made thereunder.

Regulatory Regime

8. The manufacture and import of all drugs for sale in Canada is governed by the FD Act and the FD Regulations.

DINs

9. In order for any drug to be sold in Canada in final dosage form, it must first be assigned a drug identification number ("DIN") by the Assistant Deputy Minister, Health

Products and Food Branch, of the Department of Health (the "Director") pursuant to the provisions of Part C, Division 1 of the FD Regulations and that DIN must not have been cancelled by the Director.

10. Such a DIN may be secured from the Director upon application by the manufacturer of the drug (in Canada), its agent or, in the case of a drug that is imported, by the importer. In any such application, the applicant must set out prescribed information that, generally speaking, relates to the composition of the drug and the labelling of the drug.

11. Upon the provision of such information, the Director is under a duty to issue a DIN to the applicant unless the Director believes, on reasonable grounds, that the application is not in respect of a drug or, if it is, that its sale would cause injury to the health of the consumer or purchaser or would be a violation of the FD Act or the FD Regulations.

12. Once obtained, a DIN may only be cancelled by the Director in limited circumstances which are inapplicable herein.

NOCs

13. In the case of a new drug, the application for a DIN must also comply with the requirements of Part C, Division 8 of the FD Regulations. Pursuant to these requirements, in order to sell or advertise a new drug in Canada:

(a) a person must file with the Minister a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission or an abbreviated extraordinary use new drug submission that is satisfactory to the Minister;

(b) the Minister must have issued a notice of compliance ("NOC") in respect of the new drug;

(c) the NOC must not have been suspended; and

(d) the manufacturer of the new drug must have submitted sufficient information to the Minister regarding the labelling of the new drug.

14. The content of any such submission to the Minister is prescribed and the overall intent is to satisfy the Minister that the new drug in question is safe and effective. Once so satisfied, the Minister is under a duty to issue a NOC.

15. Once issued, a NOC may be suspended by the Minister. However, pursuant the FD Regulations, if requested to do so, the Minister must disclose the basis for suspending and must provide the holder of the NOC the ability to be heard in respect of the suspension before an independent and impartial panel.

ELs

16. In order to "fabricate", package/label or import a drug in Canada, a person must, under the FD Regulations, also hold and act in accordance with an EL (i.e. an establishment licence). In this respect, "fabricate" is defined under the FD Regulations as meaning "to prepare and preserve a drug for the purposes of sale."

17. A person obtains an EL by submitting an application for same to the Minister. Such an application and any EL issued in consequence thereof are intended to inform and satisfy the Minister with respect to, among other things, the following:

(a) the facilities in Canada in which the applicant proposes to manufacture, process and store finished dosage form drug products and/or APIs;

(b) the DINs applicable to such products;

(c) evidence that the facilities in Canada are in compliance with the Good Manufacturing Practices ("GMP") contained in Part C, Division 2 of the FD Regulations; and

(d) in the case of an importer of finished dosage form products and/or APIs, evidence that the facilities in which the drug is formulated are in compliance with GMP.

18. Once issued, an EL is subject to annual review by the Minister upon application for renewal by the holder of the EL.

19. Once issued, an EL is also subject to suspension by the Minister but only upon the following first taking place:

(a) the licensee being provided written notice of and reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;

(b) if corrective action is required, the time set out in the notice has passed without the action having been taken; and

(c) the licensee having been given an opportunity to be heard in respect of the suspension.

20. The Minister may suspend an EL without giving the licensee an opportunity to be heard if it is necessary to do so to prevent injury to the health of the consumer but, in such circumstances, a notice in writing must still be given that states the reason for the suspension. However, thereafter, the licensee can still request to be heard and the Minister must give the licensee such opportunity.

21. The Minister's authority with respect to issuance of ELs, inspection of establishments, and ensuring compliance with GMP is delegated by the Minister to the Director General ("DG") of the Health Products and Food Branch Inspectorate ("HPFBI"). With respect to such delegation, the responsibilities and duties of the DG and HPFBI are delineated in Health Canada's website publication "Health Products and Food Branch Inspectorate".

Apotex's Regulatory Compliance

22. At all material times relevant to this application for judicial review, and to date, Apotex held and continues to hold valid, unsuspended DINs and NOCs for the products which, as described below, became the subject of the Import Ban announced and implemented by Health Canada (the "Banned Products").

23. At all material times relevant to this application for judicial review, and to date, Apotex has held and continues to hold valid ELs in respect of its facilities in Canada and in respect of the APIPL and ARPL facilities in India in which the Banned Products were made.

24. At no time has either the Director or the Minister cancelled DINs or suspended NOCs in relation to the Banned Products nor have they taken any legitimate steps in accordance with the FD Regulations or the rules of natural justice otherwise to do so.

25. Similarly, at no time has the Minister embarked upon the necessary procedure under the FD Regulations and otherwise at law to suspend Apotex's ELs in respect of the APIPL and ARPL facilities and/or the Banned Products.

26. Instead, as further described below, the Minister has recently contrived with Health Canada to subvert the due process provisions protecting the rights to hold and maintain DINs, NOCs and ELs by issuing an "Import Ban" that is nowhere provided for in the FD Act or FD Regulations and by purporting to unilaterally "amend the terms and conditions" of Apotex's ELs all for the sake of political expediency.

APIPL GMP Compliant

27. In late January 2014, the United States Food and Drug Administration ("FDA") conducted an inspection of APIPL's manufacturing plant and advised APIPL of alleged observations with respect to "data reliability" and laboratory procedures. This was done via the issuance of a "Form 483" notice to APIPL under U.S. law.

28. The alleged observations did not suggest any problem with actual product quality. In any event, to the extent valid, the observations were addressed through procedural improvements. The issuance of a Form 483 with observations requiring improvements is very common and occurs with most inspections.

29. The U.S. appliesdifferent rules for the inspection and compliance of plants outside of the U.S. Those rules are such that non-U.S. plants are subject to more frequent and more stringent inspections by the FDA than U.S. plants, all of which is in breach of the U.S.'s North American Free Trade Agreement ("NAFTA") and World Trade Organization ("WTO") obligations.

30. The discriminatory nature of the FDA's foreign plant inspection procedure is such that many of the Form 483s and import alerts that are issued by the FDA generally result in no action by agencies of other countries, who rely on their own inspections of such facilities or on the inspections of other countries' regulatory bodies.

31. For example, with respect to Apotex's own plants, in 2009, the FDA issued warning letters and import alerts for Apotex's Etobicoke and Signet locations in the Greater Toronto Area ("GTA") and, in 2013, the FDA issued warning letters for Apotex's Richmond Hill and Signet locations in the GTA. Despite this, all other regulators, including Health Canada, have continually and continuously found the same plants to be compliant.

32. Notwithstanding the foregoing, with respect to the January Form 483 that was issued by the FDA, APIPL and Apotex voluntarily advised Health Canada of the FDA's

observations and, in an effort to properly engage and keep Health Canada aware of all steps being taken in respect of the FDA investigation, provided Health Canada representatives with copies of the FDA's observations and APIPL's response thereto.

33. Through to April 2014, Apotex submitted additional information to Health Canada on a voluntary basis to ensure that Health Canada was kept apprised of all information in respect of APIPL.

34. On April 29, 2014, Health Canada requested, by letter, that Apotex cease the sale of drugs containing API made from APIPL.

35. On April 30, 2014, Apotex responded to Health Canada's correspondence advising that there was no basis for Apotex to implement a cease of sale directive and also invited Health Canada to personally inspect APIPL.

36. On June 10, 2014, Apotex representatives met with Health Canada personnel in Ottawa. The meeting was chaired by Ms. Robin Chiponski, Director General, Health Products and Food Branch Inspectorate, Health Canada. At that time, Apotex presented a progress status on its global quality systems enhancement plan that was sent to FDA for all of its global API sites, including APIPL.

37. On June 18, 2014, Ms. Chiponski conveyed to Apotex's representative that *"she felt that Apotex has taken drastic action to address the APIPL"* and that she was *"leaning towards conducting their own inspection of the facility"*. Ms. Chiponski further conveyed that

"the 'Apotex Evidence' contradicts the FDA evidence" flowing from the January 2014 FDA inspection.

38. As a precaution, Health Canada requested that Apotex implement a lot release protocol for all finished product batches using API made at APIPL as an interim approach until an inspection of the site could be scheduled to verify the corrective actions that had been implemented. Apotex, in an effort to ensure that Health Canada's concerns were addressed, submitted a Supporting Documentation Protocol to Health Canada on June 25, 2014 (the "Protocol").

39. Pursuant to and in accordance with the Protocol, since July 24, 2014, Apotex has submitted documentation to Health Canada with respect to all batches of drug products imported into Canada, for ultimate sale here, made with APIs manufactured at APIPL. At no time was Apotex advised of any concerns by Health Canada with respect to the documentation submitted.

40. Between August 7, 2014 and August 14, 2014, Health Canada and the Australian Therapeutic Goods Administration ("TGA") inspected APIPL. Neither Apotex nor APIPL was advised of any significant concerns by Health Canada or the TGA inspectors regarding GMP at that time.

41. In July and August 2014, Apotex regularly communicated with Health Canada in respect of APIPL (and ARPL), including providing copies of materials submitted to the FDA as

part of the FDA's ongoing investigations. Health Canada did not bring any concerns to the attention of Apotex or APIPL in this period.

42. On September 25, 2014, Health Canada provided Apotex with confirmation that APIPL would be assigned a Compliant (C) rating, and that no observations had been made of issues related to data integrity (which had purportedly been found by the FDA).

ARPL GMP Compliant

43. Between February 16, 2014 to February 20, 2014, Health Canada and the United Kingdom Medicines and Healthcare Products Regulatory Agency ("MHRA") conducted planned, detailed inspections of ARPL.

44. On May 6, 2014, the MHRA issued a GMP Certificate of Compliance for ARPL following the February 2014 inspection. The GMP Certificate of Compliance is valid for 3 years.

45. On or about May 6, 2014, Health Canada similarly recognized that ARPL was GMP compliant pursuant to the above joint MHRA/Health Canada inspection.

The Toronto Star

46. On September 11, 2014, the Toronto Star published an article titled "***Canadians kept in dark about defective drugs***". The article impugned Indian manufacturing facilities generally and Apotex's facilities specifically. The focus of the article was on the fact that, while the FDA had taken steps to rectify problems with overseas manufacturing facilities, Health Canada had not.

47. On September 16, 2014, the Minister responded to vigorous questioning in Parliament regarding the Toronto Star article.

48. That evening, prompted by the Toronto Star article, Health Canada sent correspondence to various pharmaceutical companies requesting a "voluntary" quarantine of any products made at certain Indian facilities.

49. Apotex responded to Health Canada's September 16, 2014 correspondence and proposed an approach whereby certain protocols would be adopted whereby additional documentation evidencing the safety and efficacy of the products in question, thereby ensuring that there would not be market shortages. Health Canada had, in fact, previously adopted this approach for API being delivered from APIPL.

50. On September 18, 2014, Apotex notified Health Canada that it would voluntarily quarantine six products being made using API sourced from a third party Indian supplier, IPCA.

51. On September 19, 2014, the Toronto Star published another article titled "***Feeble Health Canada can't block dodgy drug imports***" and an editorial titled "***End secrecy around prescription drugs***". On September 21, 2014, the Toronto Star published another editorial titled "***Health Canada needs to show backbone with drug companies.***"

52. Following the Toronto Star publications of September 19, 2014 and September 21, 2014, the Minister again was compelled to respond to vigorous questioning in Parliament about the Toronto Star article and editorials.

53. Again prompted by the Toronto Star publicationsand under increasing pressure from Parliament, on September 23, 2014, Health Canada wrote to Apotex asking it to confirm that, by the next morning at 10:00 a.m., it would voluntarily quarantine products made at ARPL.

54. As a sign of its intention to work with Health Canada, Apotex complied with Health Canada's request to quarantine select materials from ARPL so that Health Canada could independently review the various FDA inspection reports and its own report from the February 2014 inspections to ensure that APIPL and ARPL products were safe, effective and GMP compliant.

55. On September 24, 2014, Health Canada issued a press release stating that Apotex would voluntarily quarantine select products made at ARPL. Health Canada's press release confirmed and publicly acknowledged that it had given ARPL a Compliant rating following its February 2014 inspection.

56. Accordingly, at all times up to September 29, 2014, there had been no indication from Health Canada of any significant concern about GMP compliance at either APIPL or ARPL. To the contrary, as result of recent inspections done jointly with TGA and MHRA, done after the inspections by US FDA, and with full knowledge of same, Health Canada had explicitly confirmed that both plants were and are compliant.

Health Canada's reaction to additional Toronto Star publications

57. Between September 25, 2014 and September 29, 2014, three additional articles and one additional editorial, titled "***Apotex to quarantine suspect drugs from factory in India***",

"Health Canada is not protecting health of Canadians", ***"Would it be safer for us abolish Health Canada?"*** and ***"Health Canada must inform Canadians about suspect drugs"***, respectively, were published by the Toronto Star.

58. Then, without prior notification, on September 30, 2014, Apotex was requested to attend two telephone calls with Health Canada representatives. During those calls, Health Canada, without warning, advised that the Canadian Border Services Agency ("CBSA") had been instructed to restrict importation of APIs from APIPL and finished product from ARPL, and that the CBSA would defer to Health Canada to make a determination of action.

59. In effect, Health Canada was imposing the Import Ban in respect of products coming into Canada from APIPL and ARPL.

60. In the evening of September 30, 2014, Health Canada posted on its website and issued a press release in connection with the Import Ban which read, in part, as follows (the "September 30 Health Canada Statement"):

> *Health Canada took action today to stop the import of health products from the following sites in India:*
>
> *Apotex Pharmachem India Pvt Ltd (APIPL)*
>
> *Apotex Research Private Limited (ARPL)*
>
> *IPCA Laboratories*
>
> *The action applies to finished products from ARPL, as well as active pharmaceutical ingredients (APIs) and products made with APIs from APIPL and IPCA. Health Canada has compiled an initial list of products affected by the import ban. The list will be updated as new information becomes available.*
>
> ...

> *Consumers should be aware that no specific safety issues have been identified with products currently on the market from the list. To date, neither the FDA nor Health Canada has requested a recall of these products. Health Canada has stopped imports as a temporary precautionary measure until it is satisfied of the processes followed at these sites. Consumers should not make any change to their medication without first consulting with a healthcare professional.*

61. As indicated in the September 30 Health Canada Statement, at the same time, Health Canada posted on its website a list of products affected by the Import Ban (the "September 30 List of Products").

62. The September 30 List of Products contained significant inaccuracies about the products said to be manufactured at ARPL and APIPL.

63. Also in the evening of September 30, 2014, the Minister issued a separate press release (the "September 30 Minister's Statement") which stated, in part:

> *To that end, Health Canada has taken decisive action today to stop the import into Canada of all drug products from three plants in India. They are:*
>
> - *Apotex Pharmachem India Pvt Ltd*
> - *Apotex Research Private Limited*
> - *IPCA Laboratories*
>
> *The Department has ordered an import ban after it received new information yesterday from the United States Food and Drug Administration (US FDA). This latest information puts into question Health Canada's trust in the reliability of data that all three plants are required by law to provide to demonstrate the safety and quality of their products.*
>
> ...
>
> *But when trust between a regulator and a company is broken, strong actions are required. The import ban will remain in place until such time as the Department is satisfied that the data integrity problems have been resolved.*

64. Later in the evening of September 30, 2014, Apotex sent correspondence to the Minister requesting, *inter alia*, details of the "new information" that was said by the Minister to have been the basis for the Import Ban.

65. On October 1, 2014, representatives of Apotex spoke with Ms. Chiponski who advised that Health Canada would be responding to Apotex's September 30, 2014 correspondence, and in particular would be addressing what the "new information" referred to in the Minister's September 30 Statement. Ms. Chiponski also advised that Health Canada was carefully reviewing the information provided by Apotex to it in relation to ARPL's and APIPL's GMP compliance.

66. Approximately two hours after the conversation with Ms. Chiponski took place, Health Canada responded to Apotex's September 30, 2014 correspondence. No information whatsoever was presented about the "new information" nor was any other attempt made to justify the Import Ban.

67. Instead, on October 2, 2014, Health Canada transmitted four letters to Apotex (the "4 EL Letters") pursuant to which Health Canada purported to "amend" the terms and conditions of Apotex's ELs by prohibiting the import of APIs and finished dosage forms from APIPL and ARPL.

68. On October 2, 2014, a telephone conversation took place between Ms. Chiponski and Apotex's President and Chief Executive Officer, Dr. Jeremy Desai. In that conversation, Dr. Desai pressed Ms. Chiponski for further details about the "new information" that had formed

the basis of Import Ban. The only further details forthcoming from Ms. Chiponski was a suggestion that there was a discrepancy between a listing of APIPL products that been provided by Apotex to Health Canada in June 2014 and those products that were included in the September 30 List of Products.

69. On October 3, 2014, Apotex sent further correspondence to Ms. Chiponski addressing this supposed "discrepancy" and demonstrating how it could not possibly constitute "new information" nor form any basis for the Import Ban. Health Canada had simply erroneously listed products on the September 30 List of Products.

70. On October 6, 2014, Ms. Chiponski responded to Apotex's October 3, 2014 correspondence. The response still did not provide any disclosure regarding the "new information" despite Apotex's explicit request for same in its October 3, 2014 correspondence and earlier.

71. On October 7, 2014, Apotex's solicitors wrote a detailed letter to the Minister and Ms. Chiponski which, among other things, pointed out the unjustified and illegitimate nature of the Import Ban. In that letter, Apotex's solicitors yet again demanded disclosure of the "new information" that was said to be the basis for the Import Ban.

72. As of the date of the institution of this application for judicial review, no response has been received in respect of Apotex's solicitors' October 7, 2014 letter nor has there been any disclosure of the "new information".

73. As of the date of the institution of this application for judicial review, contrary to the actions of the Minister and Health Canada, none of TGA, MHRA or any other European regulatory authority has taken any steps against any of Apotex, APIPL and APRL or their products. To the contrary, these regulatory agencies have accepted that products emanating from Apotex, APIPL and ARPL continue to meet all requisite safety and quality standards.

4 EL Letters

74. On October 11, 2014, Apotex's solicitors responded on Apotex's behalf to the Minister's transmittal of the 4 EL Letters. In their letter, Apotex's solicitors:

(a) communicated Apotex's objection to the Minister's attempt to unilaterally amend the terms and conditions of Apotex's EL so as to prohibit the import of products from APIPL and ARPL;

(b) objected to the regulatory mechanism through which the Minister was attempting to implement the Import Ban;

(c) demonstrated why the Minister could not have any *bona fide* concern about the health and safety of Canadians with respect to drug products being imported from APIPL and ARPL, especially in light of Health Canada's own findings of compliance with respect to APIPL and ARPL discussed above;

(d) complained about the lack of transparency with respect to the "new" and "recent" information that had purportedly caused Health Canada to implement the Import Ban;

(e) asked for full disclosure of all such information; and

(f) demanded confirmation, by October 14, 2014, that the proposed amendments to Apotex's EL would not be implemented.

75. No substantive response or comment was received from the Minister to the letter of October 11, 2014. Instead, on October 17, 2014, the Minister transmitted amended ELs which purported to contain the contested amendments despite the protest contained in the letter of October 11, 2014. By letter dated October 21, 2014, Apotex's solicitors wrote to the Minister reiterating Apotex's position that the contested amendments were unlawful and therefore of no force or effect. No response to this letter has been received.

76. In the period from September 30, 2014 to October 28, 2014, Dr. Jeremy Desai, President of Apotex, was in frequent communication with the DG, endeavouring to ensure that the DG had all necessary information to enable the DG to confirm that Apotex's plants remained in compliance and that the Import Ban and EL restrictions would be rescinded. Dr. Desai advised the DG that, if Apotex did not have such confirmation by October 29, 2014, Apotex would have no alternative but to proceed with the within Application. The DG repeatedly indicated that she was working to achieve a resolution before October 29. As late as October 27, the DG indicated that she expected to be able to confirm same by October 29.

77. At about 6:00 p.m. on October 28, 2014, the DG phoned Dr. Desai, and advised him that her recommendations to lift the Import Ban and rescind the EL restrictions had been rejected by unidentified persons who had sent her "back to the drawing board." She further

advised Dr. Desai that there were two concerns standing in the way of rescinding the Import Ban and EL restrictions, as follows:

(a) How the Minister would explain to the public that she was now satisfied, in light of the announcement of September 30; and

(b) The FDA was now inspecting an Apotex plant in Winnipeg and was scheduled to also inspect an Apotex plant in Brantford next month. It would be problematic for the Minister to confirm compliance of Apotex's APIPL and ARPL plants, if it were then to occur that FDA were to allege deficiencies in either of these Canadian plants, despite the fact that Health Canada has itself inspected both plants and found them compliant, as was the case for the APIPL and ARPL plants.

78. In the conversation of October 28, 2014, the DG mentioned only the two issues noted in paragraph 77 above. There was no suggestion of any doubt that the Apotex plants were in fact compliant with all regulatory requirements.

The Minister's Unlawful Conduct

79. The Minister's decision to implement the Import Ban was unlawful and unreasonable for the following reasons which are presently known to Apotex.

80. There is no statutory authority, either under the FD Act, the FD Regulations or otherwise for the Minister to have imposed and implemented the Import Ban.

81. As indicated above, none of Apotex's DINs or NOCs for any of the Banned Products has been cancelled or suspended and, more importantly, neither the Director nor the

Minister has taken any legitimate steps to cancel or suspend in accordance with FD Regulations and otherwise in accordance with the law.

82. Similarly Apotex's EL has not been suspended with respect to any facilities listed thereon or with respect to any of the Banned Products and, again, more importantly, the Minister has failed to take any legitimate steps in this regard in accordance with FD Regulations and otherwise in accordance with the law.

83. Instead, the Minister and Health Canada have contrived to subvert the procedural safeguards accorded by the FD Regulations by arrogating to themselves a remedy that does not legitimately exist in law, i.e. the "Import Ban", and they have attempted to secure it through the inappropriate mechanism of "amending" the "terms and conditions" of Apotex's EL.

84. Pursuant to the FD Regulations, once an EL is duly applied for and received, the licensee has the right to import drugs unless and until the licence has, in whole or in part, been suspended or subsequently cancelled in connection with that activity.

85. In order to suspend an EL, the Minister must follow the procedures set out in section C.01A.016 or C.01A.017 of the FD Regulations. The Minister has not followed those procedures, nor has she purported to do so.

86. The Minister cannot, under the guise of amending "terms and conditions", effectively suspend or cancel the right to import.

87. Similarly, the Minister's attempt to amend the terms and conditions of Apotex's EL appears to be a thinly veiled attempt to suspend Apotex's NOCs for the numerous products that would be affected by the implementation of the proposed amendments.

88. When those NOCs were issued, the Minister approved the safety and efficacy of the products in question and also approved the sites of manufacture for the APIs and finished dosage forms for those products. Any attempt to change or suspend the Minister's approval as such requires the Minister to comply with the natural justice safeguards contained in section C.08.009 of the FD Regulations which include the NOC holder's right to be notified of the reasons for the suspension and the right to be heard in respect of same.

89. Before one's rights are negatively affected by a decision maker, that person is entitled to reasonable notice of the intended adverse action, to reasonable notice of the grounds therefor, to a reasonable opportunity to make a response thereto and to a reasonable opportunity to be heard in respect thereof. As further detailed below, Apotex (and APIPL, ARPL and IPCA) have been denied all of these in connection with the 4 EL Letters.

90. In any event, at all material times, there was no reasonable or any basis upon which the Minister or Health Canada could have based a decision to impose the Import Ban. Health Canada had previously found both APIPL and ARPL to be compliant with all regulatory requirements, and had raised no issues sufficient or at all to warrant the Import Ban.

91. The Minister's decision to implement the Import Ban was politically motivated and, in particular, was calculated to deflect public and Parliamentary criticism of the Minister as a result of the Toronto Star articles referenced in paragraphs 46, 51 and 57.

92. This is evidenced by the fact that the Import Ban did not require a recall of goods manufactured by APIPL, ARPL and IPCA. The Minister's decision to implement the Import Ban while allowing the same pharmaceuticals which were already in Canada to continue to be sold, both by Apotex and by distributors, wholesalers and pharmacies, is transparent.

93. The political expediency of the Minister's decision to announce and implement an Import Ban is further evidenced by the fact that the Minister did so without warning or notice to Apotex or without any reasonable explanation after the fact. The Minister's decision was designed to have maximum publicity while, at the same time, attempting to foreclose input from those most directly affected.

94. Despite repeated requests by Apotex to obtain disclosure of the "new information" which supposedly formed the basis for the Import Ban, the Minister and Health Canada have refused to provide same.

95. Each of the September 30 Health Canada Statement, the September 30 List of Products and the September 30 Minister's Statement were and are defamatory, were actuated by malice and/or wanton recklessness and were calculated to injure Apotex, ARPL and APIPL and to deflect criticism from the Minister.

96. At the time of the implementation of the Import Ban, and to date, neither the Minister nor Health Canada provided Apotex, ARPL or APIPL with formal notice of same and, in particular, with notice of the legal and factual basis upon which the Import Ban was implemented.

97. Both prior and subsequent to the implementation of the Import Ban, the Minister and Health Canada have failed and refused to:

(a) fully inform Apotex, ARPL and APIPL of the legal and factual basis for the implementation of the Import Ban;

(b) provide Apotex, ARPL and APIPL with a reasonable opportunity to be heard so as to prevent the imposition and implementation of the Import Ban;

(c) provide Apotex, ARPL and APIPL with a reasonable opportunity to be heard so as to expedite the removal of the Import Ban;

(d) act impartially;

(e) act in good faith;

(f) act free from external political interference;

(g) act free from other external influence; and

(h) act free of extraneous and irrelevant considerations.

98. In implementing the Import Ban, the Minister erred in her interpretation of the provisions of the FD Act and the FD Regulations made thereunder.

99. In addition, the Minister has acted in an unlawful and discriminatory manner for improper purposes against Apotex, ARPL and APIPL in issuing the Import Ban and purporting to amend the ELs.

100. The Minister and Health Canada have also erred in law and have denied Apotex, APRL and APIPL natural justice and procedural fairness by:

(a) depriving Apotex, ARPL and APIPL of their reasonable enjoyment of property without due process of law; and

(b) depriving Apotex, ARPL and APIPL of the right to a fair hearing in accordance with the principles of fundamental justice for the determination of their rights

all contrary to the law, including the *Canadian Bill of Rights,* S.C. 1960, c. 44.

101. In addition to all of the foregoing, the Minister has acted unlawfully in refusing to lift the Import Ban and in refusing to restore the ELs to their unamended form. Apotex, APIPL and ARPL have satisfied the Director General, Health Products and Food Branch, Health Canada, the Minister's delegate, that there are (and were) no safety or quality concerns regarding products from APIPL, ARPL and IPCA. Despite this fact, the Minister unlawfully, for improper political motives, countermanded the Director General's decision that the Import Ban be lifted and that the ELS be restored. The Minister had no authority to do so.

102. Such other grounds as the parties may advise and this Honourable Court may consider.

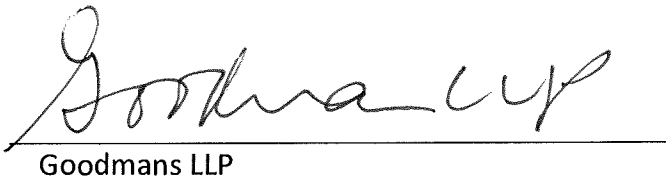
THIS APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

1. The Affidavit of Dr. Jeremy Desai to be affirmed;

2. Other Affidavits to be sworn or affirmed; and

3. Such further and other material as counsel may advise and this Honourable Court may permit.

October 29, 2014



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SERVICE OF A TRUE COPY ADMITTED ON

OCT 29 2014

ON BEHALF OF THE
DEPUTY ATTORNEY GENERAL OF CANADA
WILLIAM F. PENTNEY
per: _____
Department of Justice