Federal Court  Cour fédérale

Date: 20170327

Docket: T-1915-15

Citation: 2017 FC 315

Ottawa, Ontario, March 27, 2017

PRESENT: The Honourable Mr. Justice Russell

BETWEEN:

APOTEX INC.

Applicant

and

MINISTER OF HEALTH AND ATTORNEY GENERAL OF CANADA

Respondents

JUDGMENT AND REASONS

I. INTRODUCTION

[1] This is an application under s 18.1 of the *Federal Courts Act*, RSC 1985, c F-7 [Act] for judicial review of a decision of the Therapeutic Products Directorate of Health Canada [TPD] made in the Fall of 2015 [Decision], to continue an earlier decision of November 17, 2014, which required Apotex Inc. [Apotex] to provide certain additional information to TPD prior to TPD completing its review of Notice of Compliance [NOC] submissions for approval of certain

new products that were manufactured or tested at two of Apotex's manufacturing facilities in India, Apotex Pharachem India Pvt. Ltd. [APIPL] and Apotex Research Private Limited [ARPL]. At this time, Apotex is seeking an order from the Court:

(a) quashing the decision of the Minister of Health [Minister] to refuse to end her prohibition on granting a NOC for products manufactured at ARPL or having active pharmaceutical ingredients sourced from APIPL;

(b) in the nature of *mandamus* that all other submissions for products manufactured at ARPL or having active pharmaceutical ingredients sourced from APIPL be reviewed without requiring Apotex to provide further evidence to refute the same purported data integrity concerns upon which the Minister relied to ground her decision to impose the Import Ban that Justice Manson quashed in his decision of August 14, 2015; and

(c) awarding Apotex its costs of the within application.

II. BACKGROUND

A. *Regulatory Regime*

[2] The *Food and Drugs Act*, RSC 1985, c F-27 [*FD Act*] and the *Food and Drugs Regulations*, CRC, c 870 [*Regulations*] govern the manufacture, import, and sale of all drug products in Canada. Various guidelines and policies of Health Canada also help to interpret the *FD Act* and *Regulations*. Pursuant to the *FD Act* and *Regulations*, a manufacturer must obtain a NOC to sell or market a new drug in Canada. The Minister issues a NOC when satisfied that the manufacturer's abbreviated new drug submission [ANDS] is in compliance with the *Regulations*, which requires the manufacturing process to adhere to mandatory standards and the new drug to be safe, effective, and adequately labelled as per the *Regulations*.

[3] In reviewing an ANDS, TPD relies on data generated by the drug manufacturer that sponsors the submission. In the event that an ANDS is deficient or lacks sufficient information,

TPD may elect to issue a Clarifax, Notice of Non-Compliance, or Notice of Deficiency. All three issuances request additional information from the sponsor and provide an opportunity to respond to concerns. Additionally, when a new generic drug is awaiting the expiry of a patent or data protection period, it may be put on intellectual property hold [IP Hold].

B. *The Parties*

[4] The Applicant, Apotex, is the largest pharmaceutical manufacturer in Canada and is affiliated with the Indian companies APIPL and ARPL. APIPL produces active pharmaceutical ingredients [APIs] and ARPL produces finished dosage form [FDF] pharmaceutical products, both of which are purchased and imported by Apotex into Canada.

[5] The Respondent Minister is responsible for administering the *FD Act* and *Regulations*. Health Canada is the delegate responsible for regulating drug products in Canada and consists of various branches, including: the Minister and Minister's Office; the Health Products and Food Branch, which includes the Inspectorate, the branch responsible for compliance and enforcement activities and oversight of establishment licensing for health products [Establishment Licence]; the Regions and Programs Bureau [RAPB], which inspects domestic and foreign facilities to evaluate Good Manufacturing Practices [GMP] compliance; and TPD, which issues NOCs.

C. *The Facts*

[6] In January 2014, the United States Food and Drug Administration [FDA] found issues concerning data integrity at APIPL during an inspection. The FDA found similar issues at ARPL

during a later inspection in June 2014, although a joint inspection conducted by Health Canada and the United Kingdom's Medicines and Health Regulatory Agency in February 2014 did not yield any data integrity issues. The issues identified by the FDA involved problematic laboratory practices; namely, investigating or reporting out-of-specification results, including re-testing a failing product until a passing result was achieved without addressing why initial test results had failed.

[7] Apotex acknowledged the data integrity issues and provided the Inspectorate with the FDA's report of the ARPL inspection, referred to as a "Form 483". The observations in the Form 483 gave rise to concerns about the reliability of test results. In response, Apotex advised the Inspectorate it would conduct a complete data review and assessment of the laboratory practices at ARPL, including retrospective reviews and unannounced internal audits.

[8] After discussions with Apotex, Health Canada concluded that all finished products containing APIs from APIPL should be re-tested in Canada to ensure health and safety. Subsequent on-site inspections in August 2014 also did not yield critical deficiencies that required immediate corrective actions. Meanwhile, TPD continued to issue NOCs for products that incorporated APIs made at APIPL, including a NOC for Apo-Linezolid issued August 18, 2014.

[9] On September 11, 2014, the Canadian media criticized APIPL and ARPL and suggested that Health Canada's failure to implement measures against the companies put the health of

Canadians at risk. As the negative publicity grew, the Minister demanded that action be taken against Apotex by relevant branches of Health Canada.

[10] TPD says it became aware of the data integrity issues at APIPL and ARPL on September 23 or 24, 2014 when the then-Director General of TPD, Barbara Sabourin, received a telephone call and an electronic copy of the Form 483 from a colleague at the Inspectorate. Shortly after, on September 30, 2014, the Inspectorate modified Apotex's Establishment Licence to include a restriction against the importation of finished commercial drug products from APIPL and ARPL [Import Ban]. However, Apotex's ANDSs were not initially affected, as TPD continued to review Apotex's submissions, including those incorporating data from APIPL and ARPL.

[11] Subsequently, a draft NOC for Apotex's Apo-Rasagiline was delivered to Ms. Sabourin. Since the ANDS for Apo-Rasagiline indicated that APIPL and ARPL would be responsible for manufacturing the drug product and release testing the substance, Ms. Sabourin declined to sign the draft NOC and telephoned the CEO and President of Apotex, Dr. Jeremy Desai, to discuss her concerns regarding the potential compromised reliability of the data in the Apo-Rasagiline ANDS on November 17, 2014. During this conversation, Ms. Sabourin informed Dr. Desai that NOCs would not be issued for submissions containing data from APIPL and ARPL until further notice [November 2014 Decision]. Further discussions took place and TPD continued to work through its reviews of ANDSs containing data from APIPL and ARPL, as indicated by a letter dated December 9, 2014 sent by TPD to Apotex that requested additional information.

[12] Meanwhile, Apotex implemented corrective and preventative action [CAPA] to address the concerns regarding data integrity at APIPL and ARPL. In May 2015, Apotex reported that it would recall 8 batches of finished commercial products as a result of unreported deviations and withdraw or amend 9 ANDSs made to the FDA due to unreported tests. Furthermore, the report acknowledged that 5 ANDSs submitted to Health Canada were affected by unreported tests. Apotex also committed to a retrospective data integrity review on its Empower 3 computer system, which contains data generated from September 2013 onwards. A review of the preceding computer system, Empower 2, has not yet been completed. The data on Empower 2 was used in two of Apotex's ANDSs for Varenicline and Sitagliptin, which have not yet received NOCs because their submissions contained data from 2013.

[13] In June 2015, TPD conducted further inspections of the APIPL and ARPL facilities for the purpose of assessing the extent to which Apotex had successfully carried out its proposed CAPA. These inspections resulted in reports indicating that although the system controls and modified procedures satisfactorily addressed the data integrity concerns, additional supervision would be necessary to demonstrate sustainability and effectiveness at times of increased production. Additionally, the reports found that oversight was required because Apotex's retrospective review of data generated before the conclusion of the June 2015 inspections were still ongoing. Overall, TPD's recommendation conveyed that the inspection did not identify any instances of data integrity violations that had been observed during the June 2014 FDA inspection.

[14] Throughout 2015, TPD continued to send individual requests to Apotex for additional information for ANDSs containing data from APIPL and ARPL. However, in January 2015, TPD had developed an overarching policy regarding its approach to managing submissions containing data from sites where the integrity of data had been called into question. All drug manufacturers were eventually formally notified of this policy on May 22, 2015.

[15] Following the sufficient progress of Apotex's CAPA, the Inspectorate advised Apotex by letter dated August 31, 2015 that it had amended the terms and conditions of Apotex's Establishment Licences [August 2015 Decision]. This amendment removed the additional information requirement for ANDSs using data performed at the two sites after the June 2015 inspection, but continued to require additional information for any data from the sites prior to June 2015 which had not been reviewed. This date was later rolled back to January 2015.

[16] In the midst of these events, Apotex sought judicial review of two decisions rendered by the Inspectorate: the Import Ban and the August 2015 Decision. In a decision dated October 14, 2015, Justice Manson found that the Import Ban was motivated by the Minister's improper purpose of quelling criticism in the media and in the House of Commons, rather than a legitimate concern for protecting Canadians' health and safety, and that it was imposed without affording the procedural fairness required in the circumstances. Consequently, the Court quashed the Minister's decision to impose the Import Ban. See *Apotex Inc v Canada (Minister of Health)*, 2015 FC 1161 at paras 95-121 [*Apotex 2015*].

[17] Similarly, the August 2015 Decision was quashed by Justice Manson in a judgment issued June 15, 2016: see *Apotex Inc v Canada (Minister of Health)*, 2016 FC 673 [*Apotex 2016*]. Justice Manson found that the decision could not stand as lawful when the close interconnection between the Import Ban and the August 2015 Decision was coupled with a dearth of evidence before the Minister that supported any reasonable belief that further restrictions on Apotex's Establishment Licences were necessary in August 2015. The August 2015 Decision was determined to be tainted by the improper purpose that led to the quashing of the Import Ban.

[18] However, TPD's additional information requirements for ANDSs involving APIPL and ARPL's 2013 data did not change in the face of the aforementioned judicial review decisions or the Inspectorate's decision to lift the restrictions on Apotex's Establishment Licences on March 14, 2016. TPD took the position that since the decisions did not address the reliability of submission data generated at APIPL or ARPL prior to the implementation of Apotex's CAPA, a change of policy was not required, which was communicated by Ms. Sabourin to Apotex at some point in the fall of 2015 [Fall 2015 Decision]. Instead, a fresh review conducted by TPD's new Director General, Marion Law, found that additional information on a case-by-case basis was still necessary. Ms. Law outlined these reasons in a letter to Dr. Desai dated July 8, 2016 [July 2016 Decision].

III. DECISION UNDER REVIEW

[19] The Decision under review is the decision of the Minister of Health made in the Fall of 2015, and continued by Ms. Law in July 2016, to refuse to end her prohibition on granting a

NOC for certain products manufactured at ARPL or having active pharmaceutical ingredients sourced from APIPL. Apotex says that the Decision continues an earlier decision made in November 2014 by TPD that was improperly made as a consequence of the Import Ban that Justice Manson struck down in *Apotex 2015*, above.

[20] In a telephone call between Ms. Sabourin and Dr. Desai on November 17, 2014, TPD informed Apotex that TPD would not be issuing NOCs for submissions containing products from APIPL or ARPL until further notice due to the data integrity concerns perceived by inspectors from the FDA. Ms. Sabourin advised Dr. Desai that TPD would work through the reviews of Apotex's ANDSs and communicate any specific questions through the normal procedure.

[21] In effect, then, the subject of this judicial review comprises of three related decisions rendered by TPD that comprise a continuous course of conduct: the November 2014 Decision, the Fall 2015 Decision, and the July 2016 Decision.

[22] The November 2014 Decision consists of communications conducted via a telephone call and a face-to-face meeting. On November 17, 2014, in a telephone call between Ms. Sabourin and Dr. Desai, TPD informed Apotex that TPD would not be issuing NOCs for submissions containing products from APIPL or ARPL until further notice due to the data integrity concerns perceived by inspectors from the FDA. Ms. Sabourin advised Dr. Desai that TPD would work through the reviews of Apotex's ANDSs and communicate any specific questions through the normal procedure. In a face-to-face meeting on November 27, 2014, TPD informed Apotex that

TPD would not be issuing NOCs for submissions containing products from APIPL or ARPL unless additional information was provided to satisfy the data integrity concerns.

[23] The Fall 2015 Decision consists of two communications conducted via email and letter. In an email dated October 15, 2015, Ms. Sabourin informed Apotex that TPD would need to perform an analysis and understand the implications of *Apotex 2015* prior to moving forward. A few months later, in a letter stamped December 17, 2015, Ms. Sabourin informed Apotex that TPD would continue to require additional information for products from APIPL and ARPL manufactured prior to June 10, 2015.

[24] The July 2016 Decision refers to a letter dated July 8, 2016, in which TPD took the position that, following a fresh review, additional information on a case-by-case basis was still necessary for submissions containing data generated at APIPL or ARPL prior to Apotex's corrective and preventative actions, which was in accordance with the general policy communicated by TPD to all drug manufacturers in January 2015. In the letter, Ms. Law explained that the reason additional information would continue to be required was based on the fact that approximately 30 of Apotex's other submissions containing data from APIPL or ARPL prior to January 2015 required additional information to address data integrity concerns. As a result, retrospective data analysis for submissions containing data from APIPL or ARPL prior to January 2015 would continue to be needed.

IV. ISSUES

[25] Apotex submits that the following are at issue in this application:

1. Did the Minister act unlawfully in the fall of 2015 in refusing to end the prohibition on granting NOCs for products manufactured or tested at APIPL or ARPL unless and until Apotex provided further evidence respecting data integrity at those two facilities?

2. Is the Minister continuing to act unlawfully in refusing to grant NOCs for products manufactured or tested at APIPL or ARPL unless and until Apotex provides further evidence respecting data integrity at those two facilities?

3. If the Minister's continued requirement of further evidence respecting data integrity generated at APIPL and ARPL prior to January 2015 is not sufficiently related to the Import Ban and August 2015 decisions that were quashed or the November 14 Decision, is it reasonable?

[26] The Respondent submits the following are at issue in this application:

1. What is the nature of the administrative action under review?

2. What is the appropriate standard of review?

3. Is TPD's policy of requiring additional information to confirm the reliability of data from APIPL and ARPL reasonable?

4. Is Apotex entitled to orders in the nature of *mandamus* compelling the Minister to return certain drugs to IP Hold?

V. STANDARD OF REVIEW

[27] The Supreme Court of Canada in *Dunsmuir v New Brunswick*, 2008 SCC 9 [*Dunsmuir*] held that a standard of review analysis need not be conducted in every instance. Instead, where the standard of review applicable to a particular question before the court is settled in a satisfactory manner by past jurisprudence, the reviewing court may adopt that standard of review. Only where this search proves fruitless, or where the relevant precedents appear to be inconsistent with new developments in the common law principles of judicial review, must the reviewing court undertake a consideration of the four factors comprising the standard of review

analysis: *Agraira v Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36 at para 48.

[28] Apotex submits that the November 2014 communications between Ms. Sabourin and Dr. Desai constituted a decision that is not sufficiently independent from the Import Ban, which was quashed on October 14, 2015. An assessment of whether a decision is unlawful on the basis of its close connection to a prior decision that has been quashed is subject to the standard of correctness: *Apotex Inc v Canada (Minister of Health)*, 2016 FC 673. Alternatively, if the November 2014 Decision is sufficiently independent, Apotex submits that the November 2014 Decision and its continued enforcement is subject to the standard of reasonableness. Similarly, if TPD's current policy of additional requirements imposed on submissions containing data generated from APIPL and ARPL before January 2015 is sufficiently independent from the November 2014 Decision, Apotex submits that it is subject to the standard of reasonableness.

[29] The Respondent submits that the standard of review is reasonableness because the matter at issue is TPD's policy for submissions with data integrity concerns, which is part of the regulatory scheme governing the issue of NOCs. This is an exercise of the Minister's broad discretion under s C.08.002.1(3) of the *Regulations* and must be accorded considerable deference*: Apotex Inc v Canada (Minister of Health)*, 2009 FC 452 at para 23; *Pharmascience Inc v Canada (Attorney General)*, 2008 FCA 258 at para 4.

[30] In my view, the assessment of whether a decision under review should be unlawful based on its proximity to a quashed decision is a legal question and should be reviewed using a

correctness standard, particularly if the facts demonstrate the decision under review amends, carries forward, and maintains a decision that was quashed on the basis of unfair implementation and improper purpose: see *Apotex 2016* at para 45.

[31] If the decisions at issue are not tainted by the quashed decision, then the Minister's continuing requests for additional data should be reviewed on a reasonableness standard.

[32] When reviewing a decision on the standard of reasonableness, the analysis will be concerned with "the existence of justification, transparency and intelligibility within the decision-making process [and also with] whether the decision falls within a range of possible, acceptable outcomes which are defensible in respect of the facts and law." See *Dunsmuir*, above, at para 47, and *Canada (Minister of Citizenship and Immigration) v Khosa*, 2009 SCC 12 at para 59. Put another way, the Court should intervene only if the Decision was unreasonable in the sense that it falls outside the "range of possible, acceptable outcomes which are defensible in respect of the facts and law."

VI. STATUTORY PROVISIONS

[33] The following provisions from the *Regulations* are relevant in this proceeding:

New Drugs	**Drogues nouvelles**
C.08.002.1 (1) A manufacturer of a new drug may file an abbreviated new drug submission or an abbreviated extraordinary use new drug submission for the new drug where, in comparison with a	C.08.002.1 (1) Le fabricant d'une drogue nouvelle peut déposer à l'égard de celle-ci une présentation abrégée de drogue nouvelle ou une présentation abrégée de drogue nouvelle pour usage

Canadian reference product,

exceptionnel si, par comparaison à un produit de référence canadien :

(a) the new drug is the pharmaceutical equivalent of the Canadian reference product;

a) la drogue nouvelle est un équivalent pharmaceutique du produit de référence canadien;

(b) the new drug is bioequivalent with the Canadian reference product, based on the pharmaceutical and, where the Minister considers it necessary, bioavailability characteristics;

b) elle est bioéquivalente au produit de référence canadien d'après les caractéristiques pharmaceutiques et, si le ministre l'estime nécessaire, d'après les caractéristiques en matière de biodisponibilité;

(c) the route of administration of the new drug is the same as that of the Canadian reference product; and

c) la voie d'administration de la drogue nouvelle est identique à celle du produit de référence canadien;

(d) the conditions of use for the new drug fall within the conditions of use for the Canadian reference product.

d) les conditions thérapeutiques relatives à la drogue nouvelle figurent parmi celles qui s'appliquent au produit de référence canadien.

(2) An abbreviated new drug submission or an abbreviated extraordinary use new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

(2) La présentation abrégée de drogue nouvelle ou la présentation abrégée de drogue nouvelle pour usage exceptionnel doit contenir suffisamment de renseignements et de matériel pour permettre au ministre d'évaluer l'innocuité et l'efficacité de la drogue nouvelle, notamment :

(a) the information and material described in

a) les renseignements et le matériel visés :

(i) paragraphs C.08.002(2)(a) to (f), (j) to (l) and (o), in the case of an abbreviated new drug submission, and

(i) aux alinéas C.08.002(2)a) à f), j) à l) et o), dans le cas d'une présentation abrégée de drogue nouvelle,

(ii) paragraphs C.08.002(2)(a) to (f), (j) to (l) and (o), and subparagraphs C.08.002.01(2)(b)(ix) and (x), in the case of an abbreviated extraordinary use new drug submission;

(ii) aux alinéas C.08.002(2)a) à f), j) à l) et o) et aux sous-alinéas C.08.002.01(2)b)(ix) et (x), dans le cas d'une présentation abrégée de drogue nouvelle pour usage exceptionnel;

(b) information identifying the Canadian reference product used in any comparative studies conducted in connection with the submission;

b) les renseignements permettant d'identifier le produit de référence canadien utilisé pour les études comparatives menées dans le cadre de la présentation;

(c) evidence from the comparative studies conducted in connection with the submission that the new drug is

c) les éléments de preuve, provenant des études comparatives menées dans le cadre de la présentation, établissant que la drogue nouvelle :

(i) the pharmaceutical equivalent of the Canadian reference product, and

(i) d'une part, est un équivalent pharmaceutique du produit de référence canadien,

(ii) where the Minister considers it necessary on the basis of the pharmaceutical and, where applicable, bioavailability characteristics of the new drug, bioequivalent with the Canadian reference product as demonstrated using bioavailability studies, pharmacodynamic studies or clinical studies;

(ii) d'autre part, si le ministre l'estime nécessaire d'après les caractéristiques pharmaceutiques et, le cas échéant, d'après les caractéristiques en matière de biodisponibilité de celle-ci, est bioéquivalente au produit de référence canadien selon les résultats des études en matière de biodisponibilité, des études pharmacodynamiques ou des études cliniques;

(d) evidence that all test batches of the new drug used in any studies conducted in connection with the submission were manufactured and controlled in a manner that is representative of market

d) les éléments de preuve établissant que les lots d'essai de la drogue nouvelle ayant servi aux études menées dans le cadre de la présentation ont été fabriqués et contrôlés d'une manière représentative de la

production; and

production destinée au commerce;

(e) for a drug intended for administration to food producing animals, sufficient information to confirm that the withdrawal period is identical to that of the Canadian reference product.

e) dans le cas d'une drogue destinée à être administrée à des animaux producteurs de denrées alimentaires, les renseignements permettant de confirmer que le délai d'attente est identique à celui du produit de référence canadien.

(3) The manufacturer of a new drug shall, at the request of the Minister, provide the Minister, where for the purposes of an abbreviated new drug submission or an abbreviated extraordinary use new drug submission the Minister considers it necessary to assess the safety and effectiveness of the new drug, with the following information and material:

(3) Le fabricant de la drogue nouvelle doit, à la demande du ministre, lui fournir, selon ce que celui-ci estime nécessaire pour évaluer l'innocuité et l'efficacité de la drogue dans le cadre de la présentation abrégée de drogue nouvelle ou de la présentation abrégée de drogue nouvelle pour usage exceptionnel, les renseignements et le matériel suivants :

(a) the names and addresses of the manufacturers of each of the ingredients of the new drug and the names and addresses of the manufacturers of the new drug in the dosage form in which it is proposed that the new drug be sold;

a) les nom et adresse des fabricants de chaque ingrédient de la drogue nouvelle et les nom et adresse des fabricants de la drogue nouvelle sous sa forme posologique proposée pour la vente;

(b) samples of the ingredients of the new drug;

b) des échantillons des ingrédients de la drogue nouvelle;

(c) samples of the new drug in the dosage form in which it is proposed that the new drug be sold; and

c) des échantillons de la drogue nouvelle sous sa forme posologique proposée pour la vente;

(d) any additional information or material respecting the safety and effectiveness of the

d) tout renseignement ou matériel supplémentaire se rapportant à l'innocuité et à

new drug.	l'efficacité de la drogue nouvelle.

VII. ARGUMENTS

A. *Applicant*

(1) Connection between the November 2014 Decision and the Import Ban

(a) *Initial Submissions from November 2016*

[34] Apotex submits that the November 2014 Decision (the effects of which have been continued by TPD in its refusal to end its prohibition on granting NOCs for products manufactured or tested at APIPL or ARPL) was not sufficiently independent of the unlawful Import Ban. While Ms. Sabourin asserts that the November 2014 Decision was solely connected to significant data integrity concerns and was not attributable to the Import Ban, this evidence is not credible for several reasons and should be rejected.

[35] First, all communications between Ms. Sabourin and Apotex regarding the November 2014 Decision began with a reference to the Import Ban.

[36] Second, TPD's regulatory stance remained aligned with that of the Inspectorate's until March 14, 2016, when the Inspectorate lifted all terms and conditions, while TPD continued to enforce the additional information requirement.

[37] Third, although Ms. Sabourin claims the November 2014 Decision was based solely upon concerns in the FDA's Form 483s, other facts contradict the assertion that those concerns were serious enough to warrant a refusal to issue NOCs: TPD was aware of the FDA's Form 483s, yet did not take any regulatory action for at least six months; Ms. Sabourin's affidavit and cross-examination contradict when she first learned about the data integrity concerns; and TPD continued to grant NOCs for products manufactured at APIPL despite having knowledge of the Form 483s.

[38] Fourth, Ms. Sabourin's testimony contains further inconsistencies that cast doubt on the Respondent's position, including purporting to give evidence as to the reasons for the Import Ban when she had no involvement in the decision to impose the Import Ban.

[39] Fifth, Ms. Sabourin could not remember details and appeared to reconstruct events during her cross-examination.

[40] Sixth, despite a limited recollection of the facts and events at issue, Ms. Sabourin did not try to refresh her recollection by speaking with other TPD officials or by reviewing notes and other material related to the facts and events.

[41] Seventh, the complete lack of documentation evidencing deliberations for the November 2014 Decision indicates that Ms. Sabourin was merely following the Minister's directive to take "stronger measures" against APIPL and ARPL.

[42] As the credibility of Ms. Sabourin's evidence is disputed for the foregoing reasons, Apotex says that her assertion that the November 2014 Decision is unconnected to the Import Ban is not credible. The evidence suggests that the two decisions are linked and, since administrative decisions founded upon underlying decisions that are quashed cannot stand, neither can the Minister's refusal to rescind the November 2014 Decision: *Thambithurai v Canada (Minister of Citizenship and Immigration)*, 2006 FC 751 at paras 17 and 18.

(b) *Further Submissions in February 2017*

[43] Following the November 2016 hearing of this matter, additional evidence was produced and Apotex made further submissions regarding the connection between the November 2014 Decision and the Import Ban as well as the credibility of Ms. Sabourin's evidence.

[44] The additional evidence is as follows: Ms. Sabourin recalled two telephone calls immediately preceding the November 2014 Decision. The first call involved a conference between TPD and officials from the Assistant Deputy Minister's Office [November 10 Call], most notably Dr. Supriya Sharma, who was primarily responsible for the Import Ban. The second call involved only Ms. Sabourin and Dr. Sharma [November 14 Call]. Additionally, emails regarding this time period were also discovered.

[45] Apotex submits that the additional evidence supports a connection between the November 2014 Decision and the Import Ban. With regards to the decision-maker, Apotex contends that Dr. Sharma is responsible for both decisions. First, Dr. Sharma was significantly involved in both decisions, even though it is unusual for her to be involved in TPD's NOC

deliberations. Second, an email from one of Ms. Sabourin's senior advisors confirmed that on the day of the November 2014 Decision, "Barb talked to Supriya and was told she couldn't sign it." Third, the reasons underlying both decisions are premised on the same data integrity concerns.

[46] As for the motivation underlying the decisions, Apotex submits they are also the same. First, an analysis of the issues facing TPD with regards to the Import Ban identified adverse media reports as a potential risk; this is notable because it constitutes the improper purpose that led the Import Ban to be quashed. Second, in the same analysis, the risk to public health and safety was not considered to be a matter of serious concern. This parallels the Import Ban since this Court found that the decision-makers did not consider health and safety to necessitate the Import Ban. Third, communications between TPD officials demonstrate that there were concerns regarding the prohibition of products from sites that retained GMP-compliant ratings, which was one of the key concerns of the Import Ban.

[47] Returning to the matter of Ms. Sabourin's credibility, Apotex submits that the additional evidence further demonstrates the unreliability of the testimony that Ms. Sabourin provided. In her testimony regarding the November 2014 Decision, Ms. Sabourin did not recall either telephone call or Dr. Sharma's involvement. Apotex contends that such a material omission from evidence going to a central issue of the case should give serious doubts about the reliability of the witness' evidence. Additionally, Ms. Sabourin also did not recall other relevant conversations or events that were the subject of the new emails.

(2) Reasonableness of the November 2014 Decision

[48] Alternatively, Apotex submits that the November 2014 Decision was unreasonable.

[49] The decision was made with an overwhelmingly narrow focus and should not be considered reasonable. Despite the existence of a vast quantity of relevant evidence such as emails, memos, and letters exchanged between Apotex and Health Canada, Ms. Sabourin only reviewed the FDA's Form 483 and Health Canada's draft exit notice prior to rendering the November 2014 Decision. Ms. Sabourin also did not consult with the officials at RAPB who had conducted the inspections at APIPL and ARPL, or the officials at the Inspectorate that imposed the Import Ban.

(3) Reasonableness of the Continued Application of the 2014 Decision

[50] The Minister has not adduced any evidence as to why data integrity packages continue to be required for new products manufactured at ARPL or having active pharmaceutical ingredients sourced from APIPL. Ms. Sabourin is unable to provide insight on the matter and the Respondent has refused requests to examine other individuals who may have more knowledge on the matter, such as the current Director General of TPD. The complete lack of evidence demonstrates that there is no basis for the continued insistence on data integrity packages and, as such, the decision should be quashed as unreasonable.

B. *Respondent*

(1) Nature of the Administrative Action under Review

[51] The Respondent submits that the purported November 2014 Decision and its continuation is not a decision or administrative action that is amenable to judicial review. At the time of the telephone call between Ms. Sabourin and Dr. Desai on November 17, 2014, TPD was still developing an approach to submissions containing data from foreign sites with data integrity concerns. Policy development continued after the telephone call and was finalized in January 2015. As such, a direct challenge to the telephone call is precluded by the doctrine of prematurity, upon which courts will not interfere with ongoing administrative processes until they are complete, absent exceptional circumstances: *Canada (Border Services Agency) v CB Powell Limited*, 2010 FCA 61 at para 31.

[52] The matter at issue is actually TPD's overarching data integrity policy which requires additional information to confirm the integrity of data from APIPL and ARPL. While an ongoing policy is subject to judicial review at any time, internal departmental policies do not attract a duty of procedural fairness or a duty to give reasons and are entitled to significant deference.

(2) Reasonableness of the Data Integrity Policy

(a) *Initial Submissions in November 2016*

[53] The Respondent submits that the policy is reasonable and contains no reviewable error.

[54] The Minister, and consequently TPD as the appointed delegate, has broad discretion to request any additional information considered necessary to assess the safety and effectiveness of a proposed new drug. TPD's ongoing policy of requiring additional information to confirm the reliability of pre-January 1, 2015 data generated at APIPL and ARPL represents a reasonable response to a complex problem and does not warrant court intervention. The policy is supported by multiple reasons: the FDA made observations of problematic testing at these two sites, including re-testing failed results without reporting the prior failures; Dr. Desai acknowledged during cross-examination that only a specific, individual investigation into problematic testing could confirm whether the data was reliable, which is effectively what TPD requests in the additional data integrity packages; Apotex's review of data acknowledged 5 Canadian submissions were affected by the data integrity problems; Apotex made modifications due to issues with data integrity in submissions where data integrity confirmation was requested; and TPD is unable to independently confirm the reliability of the data in submissions that may have been affected by the problematic testing.

[55] The policy is not unreasonably onerous for Apotex. TPD employs its own resources to review submissions on a case-by-case basis and to request additional information rather than rejecting submissions outright. These additional information requests are not limited to Apotex and apply to other drug manufacturers' products as well.

[56] The requests for additional information were and are motivated by the same data integrity concerns which led to the imposition of the Import Ban, but not by the Import Ban itself. Ms. Sabourin's notes from the call do not demonstrate that TPD acted solely on the basis of the

Import Ban; instead, the notes reference "signification [*sic*] data integrity issues as perceived by inspectors from the US FDA" and Ms. Sabourin's concerns about the integrity of the data contained in Apotex's submissions. The evidence does not suggest that Ms. Sabourin was pressured by the Minister or was acting for an improper purpose. Instead, Ms. Sabourin took careful consideration of the matter: she asked her subordinates to review the matter; she convened a meeting of scientists to advise on how to handle concerns about the integrity and reliability of data in submissions; she drew her concerns regarding data integrity to Apotex's attention upon reviewing a draft NOC on November 17, 2014; and she met with Apotex to discuss the matter. Months later, these considerations culminated in a policy that provided Apotex with notice of its concerns and an opportunity to respond.

(b) *Further Submissions in February 2017*

[57] Following the second hearing, the Respondent made further submissions regarding the additional evidence, documentary production and evidence, and clarification of prior evidence.

[58] With regards to the impact of the additional evidence, the Respondent submits that it is limited, entirely consistent with the original evidence, and immaterial. The Respondent contends that the November 10 Call is consistent with Ms. Sabourin's evidence that: the analysis of the data integrity issues began in September 2014; her staff was developing a policy for submissions with data from affected sites before November 13, 2014; regular meetings concerning the policy and data integrity issues were held; and the affected sites were not limited to Apotex sites. The notes from the November 10 Call discussed data integrity concerns involving a variety of drug

companies. Additionally, Ms. Sabourin's inability to recall the November 10 Call is not surprising for the reason that her testimony was not delivered until 18 months afterwards.

[59] Likewise, the November 14 Call does not demonstrate any inappropriate influence on Ms. Sabourin's decision-making. Ms. Sabourin testified that it was not unusual to consult with Dr. Sharma on a difficult file given that Dr. Sharma had held the same position of Director General of TPD. Moreover, Ms. Sabourin believes the November 14 Call likely involved discussion of her concerns regarding issuing a NOC in the midst of data integrity issues, with Dr. Sharma counselling that she could not sign the NOC in those circumstances. This is consistent with her prior evidence that her job duties entailed briefing the Assistant Deputy Minister on "hot" files.

[60] Similarly, the emails regarding the November 10 Call do not suggest that TPD was not concerned with health and safety issues or that the adverse media coverage was a significant motivating factor. Ms. Sabourin explicitly rejected the former in her testimony and the emails actually contradict the latter because the media risk was categorized as a secondary risk factor. It is not unreasonable that reputational risk could be a factor, but the evidence does not support it was a significant motivating factor. Moreover, by November 2014, the media attention had subsided and there was no evidence to demonstrate the Minister was under political pressure at the time.

[61] As for the concerns regarding documentary production and evidence, the Respondent contends that TPD was in compliance on the matter. If Apotex required additional documents, it

should have requested them when the opportunity arose. Instead, Apotex withdrew its motion to compel the production of a Rule 317 record and declined Ms. Sabourin's offer to fact-check her answers during her cross-examination. Nonetheless, regardless of Ms. Sabourin's recollection of specific conversations of meetings, her testimony that the main concern was data integrity has always been clear and consistent.

[62] The Respondent also seeks to clarify the prior evidence; namely, that APIPL had a non-compliant rating. Apotex had argued that both APIPL and ARPL had compliant ratings at all times, but APIPL had had a non-compliant rating since April 29, 2014. A draft compliant rating was assigned on September 25, 2014 but was never issued in final form.

(3) Request for *Mandamus*

[63] The Respondent submits that there are no grounds to grant Apotex's request for an order in the nature of *mandamus* because Apotex has not established a vested right to a NOC or to hold IP Hold status. The Minister has the discretion to revisit applications on IP Hold in light of new information that casts doubt on the initial conclusions regarding the safety and effectiveness of a drug: *Apotex Inc v Canada (Attorney General)*, 2012 FCA 322.

VIII. ANALYSIS

A. *Improper Motive*

(1) Introduction

[64] In its Memorandum of Fact and Law, Apotex asks the Court to grant the following orders:

(a) quashing the decision of the Minister to refuse to end her prohibition on granting NOCs for products manufactured at ARPL or having APIs sourced from APIPL;

(b) in the nature of *mandamus* that all other submissions for products manufactured at ARPL or having APIs sourced from APIPL be reviewed without requiring Apotex to provide further evidence to refute the same purported data integrity concerns upon which the Minister relied to ground her decision to impose the Import Ban.

[65] As confirmed by Ms. Rosenthal, acting for Apotex at the resumption of the hearing on February 13, 2017, the principal Decision under review in this application is the decision of the Minister "to continue to require data integrity packages for products from APIPL and ARPL manufactured or tested prior to" January 2015.

[66] On October 14, 2015, Justice Manson's decision quashed the Import Ban because it was not motivated by data integrity concerns, but rather "was motivated by the Minister's desire to ease pressure triggered from the media and in the House of Commons." Following this decision, Apotex felt that the underpinning for TPD's requiring additional data integrity packages had been removed. As a consequence, Apotex wrote to Ms. Sabourin of TPD and asked that TPD reconsider its earlier decision to require data integrity packages (which Apotex says was made in November 2014). Ms. Sabourin advised that she would consider the implications of

Justice Manson's decision and, after she had done so, advised Apotex that Justice Manson's decision did not affect TPD's need for additional information to deal with outstanding NOCs for products manufactured or tested at APIPL or ARPL prior to a certain date – which is now January 2015. Consequently, TPD continued that requirement for data integrity packages for NOC submissions that remained in the system and that relied upon pre-January 2015 data.

[67] Notwithstanding that the principal Decision under review was made in the fall of 2015, Apotex's focus in this application is heavily concentrated upon earlier events that took place in 2014 and, in particular, what it says was a decision made in November 2014 to suspend Apotex's NOC submissions for products manufactured or tested at APIPL or ARPL.

[68] As matters presently stand between the parties in this dispute, it appears that TPD no longer requires Apotex to provide additional information to support the integrity of submission data generated at ARPL or APIPL after January 1, 2015, because TPD has concluded that data generated after Apotex took corrective and preventive action can now be considered reliable. So we are only dealing with submissions containing data generated before January 2015.

[69] In addition, of the 30 drugs listed in the Notice of Application, Apotex has submitted to TPD the requested information for 28. Of the 28, 26 have been approved and 2 have not been approved for reasons not related to data integrity. This leaves 2 drugs whose submissions rely upon data generated before January 2015 and for which TPD is requesting data integrity packages. Those submissions are for Varenicline and Sitagliptin which contain data from stability studies conducted at ARPL in 2013.

[70] So the relief requested could only apply to Varenicline and Sitagliptin, or to some, as yet, unidentified drug that will rely upon pre-January 2015 data in its submission to TPD. This is because there is no general prohibition "on granting NOCs for products manufactured at ARPL or having API sourced from APIPL." The reality is that TPD is refusing to grant NOCs for Varenicline and Sitagliptin until such time as Apotex provides the data integrity packages requested to satisfy data integrity concerns that arise from information generated in 2013. As regards any future submissions, the Court has no record before it to determine what any concerns might be for data generated pre-January 2015. This is why, I think, Apotex is simply asking that submissions for products manufactured at ARPL or having APIs sourced from APIPL "be reviewed without requiring Apotex to provide further evidence to refute the same purported data integrity concerns *upon which the Minister relied to ground her decision to impose the Import Ban*" (emphasis added).

[71] I see nothing in this application to suggest that, in a general sense, TPD cannot request additional information to satisfy data integrity concerns identified in *any* submission, including any submission made by Apotex. Nor do I see that Apotex objects to the policy that the Minister has developed to deal with data integrity concerns and which applies to all manufacturers as set out in the notice of May 22, 2015. Apotex is only challenging decisions (at present, the withholding of NOCs for Varenicline and Sitagliptin) where Apotex alleges that TPD is relying upon data integrity concerns that were used as a justification for the Import Ban.

[72] This raises some extremely complex causal issues in this dispute. To begin with, it seems to me that Apotex needs to demonstrate that TPD's present position of requiring data integrity

packages to satisfy data integrity concerns in the Varenicline and Sitagliptin submissions is improper because it emanates from, and arises out of, the Import Ban that Justice Manson found in his decision of October 14, 2015 in T-2223-14 to have been improperly motivated:

> [107] The above facts suggest that the Import Ban was motivated by the Minister's desire to ease pressure triggered from the media and in the House of Commons – a purpose falling outside her delegated authority from the enabling legislation, which must be exercised in accordance with the rule of law. The Minister's actions were therefore *ultra vires* and she erred in her exercise of jurisdiction by implementing an Import Ban on September 30, 2014. The public statements released on September 30, 2014, by the Minister and Health Canada constituted a manifestation of this improper purpose; they were a way for the Minister to publicly convey she was taking strong action and was not weaker than her US regulatory counterpart.

[73] In the case of the Import Ban, the Minister was removing rights already enjoyed by Apotex. In the present instance, TPD is seeking additional information before it is prepared to allow Apotex the rights it seeks under NOC submissions. Even if Apotex can satisfy the Court that TPD's initial decision to require additional information from Apotex was improperly motivated by the Import Ban back in November 2014 (when, as a result of Apotex' s Apo-Rasagiline submission, TPD informed Apotex that it would require additional information), this does not mean that TPD's present requirement for additional information in relation to Varenicline and Sitagliptin is either improper or unreasonable if that information is, in fact, required so that TPD can be satisfied that the health and safety of Canadians is not at risk. In my view, this requires Apotex to show that TPD continues to be motivated by the improperly imposed Import Ban in requiring Apotex to provide additional information for these particular submissions.

[74] Another problem for the Court is that, for the most part, Apotex has provided TPD with the requested additional information for 28 of the 30 drugs listed in the Notice of Application, and only the Varenicline and Sitagliptin submissions remain unresolved. In the case of Varenicline, the submission was made on March 22, 2013 and TPD requested the additional information on July 15, 2015. In the case of Sitagliptin, the submission was made on December 16, 2013 and the request for additional information was on July 15, 2015. In the case of the Apo-Rasagiline submission that first raised the data integrity concerns under review here, the request for additional information was made on December 9, 2014. Apotex provided that information and the NOC was granted on January 11, 2016. Apotex has not asked the Court to review these requests for additional information as separate decisions, as the time for doing so has lapsed and, in the case of Apo-Rasagiline, is no longer necessary. Yet it was the Apo-Rasagiline submission on November 14, 2014 that first involved the data integrity concerns that Justice Manson referred to when considering the Import Ban.

[75] So out of 30 submissions involving data for products manufactured at ARPL or having APIs sourced from APIPL, Apotex has complied with TPD's requests for additional information rather than seek judicial review. In all likelihood, this is because Apotex considered that, if the Import Ban was found to be improper then all data integrity concerns would dissolve along with the quashing of the Import Ban. This does not, of course, mean that Apotex accepts those requests for additional information to be legitimate. However, as the evidence I will come to later shows, for Varenicline and Sitagliptin, Apotex is having difficulties in completing the internal review process that it agreed with the FDA to complete. Apotex has asked the Court to draw many inferences (dealt with below) concerning the motivation of TPD's requests for

additional information. Inferences, of course, can be drawn both ways, so that Apotex's compliance with 28 requests for additional information and its resort to judicial review for two drugs for which it has yet to complete its own agreed-upon internal review of data concerns cannot be left out of account.

B. *The November 2014 Exchanges*

[76] The linchpin for Apotex's argument that TPD's refusal to grant NOCs for products manufactured at ARPL or having APIs sourced from APIPL is improper is the exchange that took place between Dr. Desai, CEO and President of Apotex, and Ms. Sabourin, the then Director General of TPD, in November 2014, and the events that led up to that exchange.

[77] It was at this time that a draft NOC for Apo-Rasagiline came to Ms. Sabourin for signature. The submission indicated that APIPL and ARPL would be responsible for manufacturing the drug product and release testing the drug. Ms. Sabourin declined to sign the NOC and telephoned Dr. Desai on the next business day to discuss the situation.

[78] Apotex says that Ms. Sabourin's refusal to sign the NOC for Apo-Rasagiline was improperly motivated by the Import Ban. TPD says that Ms. Sabourin's actions were motivated by genuine data integrity concerns affecting the safety, quality and effectiveness of the drug.

[79] Following her telephone discussion with Dr. Desai on November 17, 2014, Ms. Sabourin summarized their conversation in an email to her colleagues on the same day. That email reads as follows:

phone call with Jeremy Desai today

Barbara J Sabourin to: karen.reynolds, Craig Simon

Cc: john.patrick.stewart

2014-11-17 05:13 PM

Hi – I spoke to Jeremy Desai today regarding Apotex's submissions for products being manufactured at ARPL or having API sourced from APIPL both in India. These sites both are subject to an import ban due to signification [*sic*] data integrity issues as perceived by inspectors from the US FDA. I told Jeremy that we would not be issuing NOCs for submissions from these sites until further notice. If we have specific questions we will ask them through normal means (clarifiax, NON, NOD) as we work through the reviews.

As a follows up, we need to send something in writing to them indicating what we are doing. Could you develop a first draft please, or delegate this to someone else to do?

We also need to develop a more formal communication to Industry as a whole, regarding how we are dealing with this type of situation. That is partly why I asked for tomorrow's internal meeting.

Key points from my conversation with Jeremy are:

- our inspectors plus those from MHRA went through their labs after seeing the US FDA's 483 letter, and found no issues. Australia stood behind their inspectors and did not institute an Import ban

- October 22 – an internal audit of their own qc. labs found no issues

- November 27 – a 3rd party sign off of data reviews will be completed

- They have been requested to use 3rd party testing for all imported products from these sites, and cannot even use their own Canadian labs

- companies who do not sell to the USA will never have a 483, and therefore those who do sell to the USA are being treated unfairly by Canada

> - This will add to their damage claim against Health Canada
>
> He also indicated that he would appreciate knowing what we need to assure ourselves there is nothing wrong with the integrity of the files. He pointed out that if there was something wrong with the products, that it would be found as they test in their Canadian labs as well for all imported products. He also indicates that the level of scrutiny is already very high for all companies, very different than in previous years.
>
> Jeremy also mentioned that their QC labs have been accepted to do additional testing / full release testing (my notes are not good on this point).
>
> I committed to having a follow up call with him next Monday, November 24 2014.
>
> …

[80] Apotex argues that by halting the issuance of NOCs for products produced at APIPL or ARPL, the Minister was aligning TPD's approach to regulatory submissions with the Inspectorate's approach to products already on the market, as implemented by the Import Ban. Apotex sees the November 17, 2014 exchange as yet another politically-motivated move against Apotex by the Minister, so that suspending NOCs "until further notice" was simply part of the Minister's response to the media and political pressure that motivated the Import Ban (eventually found to be improper by Justice Manson in his decision of October 14, 2015) and the Minister's August 31, 2016 decision that varied the terms of Apotex's Drug Establishment Licenses for APIPL and ARPL, which Justice Manson declared unlawful in his decision of June 15, 2016 in file no. T-1653-15:

> [57] The question before the Court here is not whether the Minister had the jurisdiction to amend terms and conditions to a drug manufacturer's Els, or of the Minister improperly specifying the source of her jurisdiction. In fact, it is quite evident that the power to amend or impose terms and conditions falls squarely within the Minister's mandate. Instead, the issue is whether the

August 2015 Decision was unlawful on the basis that the amendment, in effect, sustained a decision quashed by this Court by maintaining in part, the 2014 Terms and Conditions in the 2015 Terms and Conditions.

[58] In essence, the lawfulness of the August 2015 Decision depends upon (i) whether it is a sufficiently independent decision from the 2014 Import Ban, and (ii) whether it could nonetheless be justified in the evidence, such that the Minister's improper purpose in imposing the Import Ban did not also taint this subsequent and related decision.

[59] It is evident that the August 2015 Decision was not implemented as, nor intended to be, a new and independent decision from the 2014 Import Ban. I disagree with the Respondents that the characterization of the August 2015 Decision as an amendment is immaterial. The two decisions are inextricably interconnected, and the facts before me suggest the August 2015 Decision was neither in substance or form a free-standing and uninfluenced decision, such that it was not also infected by the improper purpose that motivated the Import Ban.

…

[65] I find that the August 2015 Decision cannot stand as lawful when the close interconnection between this Decision and the Import Ban is coupled with the lack of evidence before the Minister that supports any reasonable belief an Import Ban was necessary in August of 2015. The Respondents have pointed to no evidence, either of any affiant or circumstantial, to persuade me that even though the August 2015 Decision was an amendment and closely connected to the 2014 Decision, it was nonetheless justified on the facts.

…

[69] Fundamentally, it is not simply the Minister's *reference* to a certain provision of the *FD Regulations* or to a decision subsequently set aside that, in my view, makes the August 2015 Decision unlawful. Rather, it is the perpetuation of a decision found to have been motivated by a purpose falling outside the Minister's delegated authority, and thus a decision not made in accordance with, or respecting the supremacy of the rule of law (*Apotex v Canada*, above, at para 107).

[70] According to the Respondents, it is fundamentally important that the decision in the First Judicial Review did not

> undermine the legitimate data integrity concerns Health Canada had about the facilities in question. I note that neither the First Judicial Review, nor these reasons suggest that Health Canada did not have data integrity concerns, or that Health Canada is not entitled to consider information from international regulatory counterparts. However, I disagree on these facts that any existing data integrity concerns, which the evidence demonstrates had only improved since September of 2014, justified the continuation of an Import Ban in the August 2015 Decision, without more.
>
> …
>
> [74] This case involves a very unique set of circumstances where an underlying decision of the Minister, found to have been made for an improper purpose and carried out unfairly, has been perpetuated in identical form in a subsequent decision without an evidentiary or lawful basis to do so.
>
> (emphasis in original)

[81] Likewise, the question before the Court in the present application is not whether the Minister (in this case acting through TPD) has the jurisdiction to request additional information before granting NOCs or returning to IP Hold. It seems to me, and I don't believe Apotex questions this, that the power to request additional information falls squarely within the Minister's mandate under C.08.002.1 (3) of the *Regulations*. The issue is whether, by requesting data integrity packages for Varenicline and Sitagliptin from Apotex in this case, TPD is acting unlawfully because that request is so inextricably interconnected with the improper Import Ban that it is fatally infected by the improper purpose that motivated the Import Ban and for which the Import Ban was quashed by Justice Manson.

[82] As was the case before Justice Manson in his June 15, 2016 decision, the lawfulness of the continuing request for data integrity packages depends upon: (a) whether it is a sufficiently independent decision from the 2014 Import Ban; and (b) whether it can nonetheless be justified

on the evidence, such that the Minister's improper purpose in imposing the Import Ban did not also taint this subsequent and related action by TPD to continue to withhold NOCs for Varenicline and Sitagliptin until Apotex has provided the additional information.

[83] On its face, and viewed in isolation, I don't think it can be said that the decision communicated verbally to Dr. Desai on November 14, 2014 and summarized in Ms. Sabourin's email to her colleagues of the same date is not a sufficiently independent decision. It has to be borne in mind that it was not the Import Ban, *per se*, that was improper. It was the motivation behind it, *i.e.* the Minister imposed the Import Ban in response to media and political pressure and not to protect the health and safety of Canadians. Ms. Sabourin, in her email to colleagues on November 17, 2014 refers to "an import ban due to significant data integrity issues as perceived by inspectors from the US FDA." The Import Ban is referred to, but the email makes is clear that it is the "significant data integrity concerns" behind it that are her concern. It seems to me that TPD decided to put Apotex's APIPL- and ARPL- related NOC submissions on hold until such time as TPD could find a way to determine that it had the information it needed to satisfy itself that those submissions did not give rise to health, safety or efficacy concerns. Ms. Sabourin's email refers to the Import Ban but it clearly sees that ban as being "due to significant data integrity issues as perceived by inspectors from the US FDA." And this, in my view, is consistent with Ms. Sabourin's later evidence. There is no suggestion in the email that TPD is acting at the behest of, or under pressure from, the Minister herself, or responding to media pressure. That is why, until the recent disclosure of further evidence from Ms. Sabourin (which I shall come to later) Apotex placed great reliance upon circumstantial and contextual issues to

convince the Court of the true motivation behind the decision by TPD to suspend Apotex's NOC applications and request more information.

C. *Stronger Measures*

[84] Apotex alleges, in effect, that TPD, like the Inspectorate, was given its marching orders to implement "stronger measures" with regard to Apotex's NOC submissions because of the political pressure on the Minister that caused her to impose the improper Import Ban.

[85] The record shows that, on September 23, 2014, Mr. Clarke Olsen, the Minister's Director of Issues Management, sent an email to the Inspectorate that made it clear that the Minister was not pleased with the way the Inspectorate was dealing with Apotex and that the Minister wished to move to "stronger measures" against the company. The Inspectorate had asked Apotex to voluntarily quarantine ARPL products without pointing to any particular safety concerns with those products, but Mr. Olsen wanted quicker action against Apotex. As a result, the Inspectorate accelerated the deadline the following day from 5 p.m. to 10 a.m., which was barely one hour from the time the letter accelerating the deadline was sent. Hence, there was clear evidence that the Minister made direct contact with the Inspectorate and that the Inspectorate responded with "stronger measures."

[86] Before additional evidence disclosed by Ms. Sabourin following the hearing of this application in November 2016, (as discussed below) there was no direct evidence that Mr. Olsen, or anyone else acting for the Minister, contacted TPD directly and urged TPD to take "stronger

measures." The evidence was that Ms. Sabourin was contacted by phone by Sharon Mullin, a senior official at the Inspectorate.

[87] Ms. Sabourin's evidence was that she had a two-minute telephone conversation with Ms. Mullin who alerted her "to the situation with the two Apotex facilities in India" and that "there were possible implications for submissions."

[88] Apotex originally argued before me that:

> 36. The obvious conclusion is that, just as the Inspectorate officials were being given their marching order to impose "stronger measures", so too was Ms. Sabourin. And indeed Ms. Sabourin wasted no time in passing on those orders to her subordinates. Upon finishing her call with Ms. Mullin, Ms. Sabourin immediately contacted the two most senior officials responsible for reviewing and making recommendations in respect of submissions: Karen Reynolds and Craig Simon. Again, no notes, memos or emails of this discussion have been produced.
>
> (footnotes omitted)

[89] There was, in fact, no direct evidence to support this conclusion. The only direct evidence came from Ms. Sabourin who said that she was alerted to a situation which could have possible implications for submissions, but she acted upon the basis of data integrity concerns that had been identified in the FDA Form 483s, and acknowledged by Apotex. Apotex was asking the Court to infer that Ms. Sabourin was, in fact, given her "marching orders" by Ms. Mullin, or by the Minister through Ms. Mullin. It wasn't all that surprising that there were no notes of this brief telephone call, and the inference that Apotex wanted the Court to draw (*i.e.* that Ms. Sabourin deliberately began to ensure that there would be no paper trail) was speculation.

[90] There is no evidence that Ms. Sabourin was urged or asked to do anything by Ms. Mullin. She was "alerted to the situation." Having been so alerted, it was Ms. Sabourin's duty to consult with her senior officials about "the situation" to see if anything needed to be done about NOC submissions. So, once again, in my view, there was nothing untoward in Ms. Sabourin's immediate contact with her own senior officials.

[91] Alerting someone to a situation so that they can assess the implications in terms of their own statutory obligations is not "marching orders," and it is not improper interference. Justice Manson has found that the Minister's contact with the Inspectorate did amount to improper interference and compromised the action taken by the Inspectorate. But this does not automatically mean that Ms. Sabourin and the TPD were told to do anything more than assess the situation for themselves, which they quickly set about doing.

[92] The decision to impose the Import Ban was communicated to Apotex in a conference call on September 30, 2014. However, Apotex was not contacted about any NOC submission issues until Ms. Sabourin contacted Dr. Desai by telephone on November 17, 2014. Given the displeasure expressed by Mr. Olsen to the Inspectorate and the immediate response he required and received from the Inspectorate, it does not look as though TPD was being pushed to do anything quickly. In fact, the more obvious inference is that TPD took a few weeks to internally review the whole "situation" and work out what their response should be before contacting Dr. Desai.

[93] However, following the initial hearing of this application in November 2016, and in the course of discussions about the related damages action commenced by Apotex, Ms. Sabourin remembered that, in addition to Dr. Craig Simon, she may also have spoken to Dr. Patrick Steward on November 14, 2014, and that she had spoken to Dr. Sharma, prior to her decision not to sign the NOC for Apo-Rasagiline on November 14, 2014.

[94] Further cross-examinations of Ms. Sabourin then took place during which she recalled that she and Dr. Sharma had both participated in a conference call concerning data integrity concerns with other employees of TPD and the Assistant Deputy Minister's Office on November 10, 2014. Neither Ms. Sabourin or Dr. Sharma retained notes of the November 10 Call, but four other participants did, and those notes have been located and were placed before the Court in the resumption hearing on February 13, 2017.

[95] This new evidence, and the way it has been characterized, is important in various ways. First of all, in presenting it to the Court, Apotex appears to concede that there was no "direct" evidence to support its case until this new evidence was revealed:

> 3. This late-breaking information, along with a few related documents, effects a significant change in the evidence in the within proceedings. It provides, for the first time, a clear and direct link between the architect of the Import Ban – Dr. Sharma – and the November 2014 decision that is at issue herein. It also provides, for the first time, direct evidence that the same concerns that motivated the Import Ban, namely, concerns about adverse reports in the media, continued to motivate the responsible Health Canada officials in November 2014.

[96] More important, however, is what the new evidence tells us about what took place in November 2014 concerning the Import Ban and Ms. Sabourin's decision not to sign the NOC for

Apo-Rasagiline and to raise data integrity concerns for Apotex's submissions that involved products manufactured or tested at APIPL and/or ARPL. From Apotex's perspective, the conclusions are obvious:

> 15. Unfortunately, at the time that the foregoing arguments were advanced, the parties did not have the benefit of certain key documents. Those documents – which were produced to Apotex only after the conclusion of the hearing – are notable for two main reasons. First, they provide clear evidence that the November 2014 decision was based upon the Import Ban. They demonstrate that, not only were the same people behind the November 2014 decision as were behind the Import Ban, but also that the November 2014 decision was motivated by the same type of media-related concerns that led to the imposition of the Import Ban. Second, the documents highlight still further reasons as to why Ms. Sabourin's evidence is not credible and should be rejected.
>
> (emphasis in original)

[97] As Apotex points out, on the very same day that Ms. Sabourin informed Apotex that Apotex's NOC submissions were to be suspended, Dr. Craig Simon, who was the Associate Director of the Bureau of Pharmaceutical Sciences and a senior advisor to Ms. Sabourin, wrote in an email to Karen Reynolds that "Barb [Ms. Sabourin] talked to Supriya [Dr. Sharma] and was told she couldn't sign it [*i.e.* the Apo-Rasagiline NOC submission]."

[98] Apotex argues that Dr. Sharma's involvement at this juncture in the process is "highly significant" for the present application:

> 19. Dr. Sharma's involvement in the November 2014 decision - hitherto unknown to Apotex - is highly significant. Dr. Sharma was one of the key personnel involved in the decision to implement the Import Ban. If she was not the actual decision-maker (and that point remains unclear), she was unquestionably a leader of the very small circle of senior Health Canada personnel who collectively decided to impose the Import Ban.

> 20. For Dr. Sharma to be involved in TPD's deliberations in respect of new drug submissions (such as the Apo-Rasagiline submission that allegedly prompted the November 2014 decision) was very unusual. This was confirmed by Ms. Sabourin on cross-examination and, indeed, is evident from the fact that neither in her affidavit nor in her original cross-examination did Ms. Sabourin suggest any role being played by Dr. Sharma specifically or by members of the Assistant Deputy Minister's Office more generally in TPD's review and approval of new drug submissions.
>
> 21. Moreover, as is made clear by the new documents, Dr. Sharma was not merely involved in the November 2014 decision, she was the actual decision-maker, telling Ms. Sabourin that the NOC for Apo-Rasagiline could not be signed.
>
> 22. Moreover, it is notable that, in Court File No. T-2223- 14, Dr. Sharma gave evidence that was strikingly similar to that given by Ms. Sabourin in the within application. Like Ms. Sabourin herein, Dr. Sharma gave evidence in T-2223-14 that her decision (in that case, to impose the Import Ban) was motivated by a concern that the data integrity problems identified by the US FDA and the resulting risk to the health and safety of Canadians were so significant as to justify her decision.
>
> 23. However, the evidence given by Dr. Sharma in T-2223-14 as to her motives in imposing the Import Ban was rejected by Justice Manson. He found that the Import Ban was not, in fact, motivated by a desire to protect health and safety, but rather by a desire to deflect "intense media criticism" and by a "desire to ease pressure triggered from the media and in the House of Commons".
>
> 24. There is no evidence to suggest that these motivations that underlay Dr. Sharma's actions in September 2014 had changed by the time she was directing Ms. Sabourin barely six weeks later in November 2014. On the contrary, the new documents reveal that these same factors were motivating TPD and Ms. Sabourin in the days leading up to the November 2014 decision.
>
> (footnotes omitted)

[99] The fact that Ms. Sabourin was "told she couldn't sign it" is not inconsistent with Ms. Sabourin's evidence that she was concerned about the Apo-Rasagiline NOC because of data integrity concerns at APIPL and ARPL, the FDA Form 483s and missing test results.

Ms. Sabourin has testified in her continued cross-examination that it was not out of the ordinary for her to consult with Dr. Sharma on a difficult file. The reason she did this was because Dr. Sharma had previously filled the same role at TPD as Ms. Sabourin (Director General) and Dr. Sharma is a senior medical officer. She was an obvious person to consult if Ms. Sabourin was having difficulties in dealing with a NOC submission. And if Ms. Sabourin, as she has testified, had concerns about data integrity, FDA Form 483s and missing test results, then Dr. Sharma's advice that she couldn't sign the NOC seems entirely reasonable. It is the kind of advice that any knowledgeable person might give. Dr. Simon's email doesn't say that Dr. Sharma contacted Ms. Sabourin and told her not to sign the NOC. The evidence is that "Barb talked to Supriya and was told she couldn't sign it." It is worth bearing in mind that, at this juncture, Ms. Sabourin could not know that the Court would find the Import Ban to be improper. There was no reason for her not to talk to Dr. Sharma and seek her advice, as she had on other occasions.

[100] In my view, this evidence does not establish, as Apotex alleges, that the November decision was "made by an official in the Assistant Deputy Minister's Office – the very same official who had been the architect of the Import Ban – Dr. Supriya Sharma." The evidence establishes that Ms. Sabourin consulted with Dr. Sharma – as she had consulted with her on other occasions – about the data integrity concerns she had about the Apo-Rasagiline NOC submission and was told she couldn't sign it.

[101] It may be that, in giving Ms. Sabourin this advice, Dr. Sharma was motivated by the improper influences behind the Import Ban, and this is a possible inference. But there is no

evidence that Dr. Sharma was the person who made the November 2014 Decision or that Ms. Sabourin did not have genuine data integrity concerns when she made the decision, or that Ms. Sabourin refused to sign the NOC because of "marching orders" from Dr. Sharma or anyone else.

[102] Apotex has not established before me that in November 2014 there were no genuine data concerns at APIPL or ARPL, as identified on the FDA Form 483s. An Import Ban that Justice Manson later found to be improper, does not mean that there were no genuine data integrity concerns identified by TPD that had to be dealt with. And the fact that the Inspectorate was improperly influenced by the Import Ban, as found by Justice Manson, does not again mean that TPD was improperly influenced. And even if TPD was prompted or galvanized to take action on data integrity concerns (that had existed for some time) by the Import Ban, this does not mean that such action was not entirely appropriate given the existence (as Apotex has acknowledged) of data integrity concerns at APIPL and/or ARPL.

[103] The fact that Justice Manson rejected Dr. Sharma's evidence that she was motivated in relation to the Import Ban by data integrity problems identified by the United States FDA, and the resulting risk to the health and safety of Canadians, does not mean that the Court must reject Ms. Sabourin's evidence. As Apotex's own dealings with the FDA and its actions at APIPL and ARPL demonstrate, those data integrity concerns were real and were not simply an excuse for TPD to succumb to media and political pressure, or to accept "marching orders" from the Minister. It seems inconsistent to me that Apotex would take such forceful action itself to address the data integrity concerns at APIPL and ARPL but now argue that there was no reason

for TPD to address those concerns other than the improper influence brought to bear by the Import Ban and those officials involved in the Import Ban. This position asks the Court to leave out of account TPD's subsequent dealings with Apotex over submissions for drugs connected to APIPL and ARPL, TPD's prior concerns about data integrity at APIPL and/or ARPL, the development and implementation of a general policy to deal with data integrity concerns that TPD has applied to all drug manufacturers, and not just Apotex, and to accept that in the Fall of 2015 when TPD desired to continue to ask for data integrity packages for Varenicline and Sitagliptin, (which is the decision under review) that it did so because it was still motivated by the Import Ban and the Minister's "marching orders." It seems to me that this is a bit of a stretch.

[104] Similar considerations apply to the use that Apotex seeks to make of the new evidence concerning an Issues Management Report that Karen Reynolds was asked to prepare:

> 25. Thus, on November 7, 2014, when Karen Reynolds (the head of the Bureau of Pharmaceutical Sciences) was asked to prepare an analysis - known as an "Issues Management Report" - of the issue facing TPD with regard to "submission s in cue [sic] that are implicated by the Import Ban", she identified three potential risks, one of which was the risk of adverse media reports:
>
> > Reputational/media related risks could result from the approval of new products from the implicated sites.
>
> 26. Thus, despite the fact that September's media storm had died down, it would appear that Health Canada officials continued to view the risk of possible negative stories in the media as a source of real concern.
>
> 27. It should also be noted that the second risk identified by Ms. Reynolds in her "Issues Management Report" was the risk to public health and safety that would result if TPD were to grant an NOC to a product from APIPL or ARPL. But, tellingly, as is made clear by the new documents, Ms. Reynolds did not consider the potential health and safety risk to be a matter of serious concern.

Rather, in her view, such a risk was satisfactorily mitigated by the Import Ban itself. Ms. Reynolds wrote:

> Potential risks to the health and safety of Canadians would be mitigated by the import ban.

28. No documents have been produced to suggest that anyone at TPD or elsewhere in Health Canada disagreed with Ms. Reynolds' assessment of the relevant risks.

29. The parallels with the Import Ban are manifest. As with the Import Ban, the November 2014 decision was orchestrated by Dr. Sharma. And, as was the case with the Import Ban, concerns about potentially adverse media coverage were a significant motivating factor. And, as was the case with the Import Ban, the responsible Health Canada officials did not believe that the November 2014 decision was needed in order to protect health and safety.

30. These parallels are to be expected, given that the Import Ban was the foundation upon which the November 2014 decision was based. That foundation is further evidenced by the new documents wherein senior TPD officials repeatedly describe the issue before them as arising out of the Import Ban. Thus, on November 7, 2014, Rita Beregszaszy, who was the issues manager in Ms. Sabourin's office, wrote to Karen Reynolds as follows:

> Hi Karen,
>
> I spoke to Pat [i.e., John Patrick Stewart - Ms. Sabourin's second-in-command] and he's on board with engaging ADMO [i.e., the Assistant Deputy Minister's Office] asap on <u>TPD's issue with submissions in cue [sic] which are implicated by the import ban.</u> [emphasis added]

31. Similarly, in her "Issues Management Report", Karen Reynolds summarized the issue facing TPD as follows:

> TPD has identified a number of drug submissions which contain data from sites from which the import of already approved products has been banned.

32. Moreover, in her analysis, Ms. Reynolds - whether knowingly or not - highlighted the one aspect of the Import Ban that immediately raised doubts as to its bona fides - namely, the fact that it banned the import of products from sites despite the fact

> that those sites retained GMP compliant ratings from the Inspectorate. That highly questionable feature of the Import Ban would raise the same concerns in respect of the November 2014 decision. Ms. Reynolds wrote:
>
> > As the implication sites continue to have compliant GMP ratings, it would be standard practice for the Directorate to accept the validity of the data from these sites and approve the submissions should they be determined to meet established scientific standards for approval…. It would set a precedent to reject a submission from a site that remains GMP compliant.
>
> 33. In fact, Ms. Reynolds was so concerned about this issue, that she featured it as the third risk identified in her "Issues Management Report":
>
> > Rejection of submissions from sites which remain GMP compliant would set a precedent.
>
> 34. Ultimately, however, Ms. Reynolds concerns about setting such a questionable "precedent" were overridden by Dr. Sharma's directive to follow the lead established by the Import Ban.
>
> (footnotes omitted)

[105] If Karen Reynolds did not consider the potential health and safety risks to be a matter of serious concern because they could be mitigated by the Import Ban, the direct evidence before me is that Ms. Sabourin did, and she was the one who made the decision. Apotex asks the Court not to accept Ms. Sabourin's evidence because she had difficulty in recalling significant emails and her telephone calls with Dr. Sharma. Apotex has made it clear in oral argument that it does not regard Ms. Sabourin as being dishonest; it just doesn't think she has a memory that can be trusted on the central issue before the Court, *i.e.*, why she decided in November 2014 to suspend Apotex's NOCs and to go on to request data integrity packages. However, I see no reason to mistrust Ms. Sabourin's evidence that she consults with Dr. Sharma and looks for guidance on

decisions she has to make. If Ms. Sabourin is being honest about this, as Apotex concedes, then it goes a long way to explaining why she went to Dr. Sharma for advice in November 2014.

[106] But the central issue before the Court is why did TPD decide in the Fall of 2015 that it would continue to require data integrity packages for products from APIPL and ARPL manufactured or tested prior to June 10, 2015, a date that was later pushed back to January 2015. The Court is being asked to accept that behind this decision are not genuine data integrity concerns for the health and safety of Canadians, but rather actions taken by the Minister back in 2014 in response to adverse media and political criticism. For reasons already given, I regard this as too much of a stretch. TPD has worked with Apotex and others to ensure that data integrity concerns associated with NOC submissions are resolved and overcome and, in the case of Apotex, there are only two drugs in dispute, and both of them have 2013 data integrity concerns that Apotex has itself been attempting to resolve but, according to the evidence of Dr. Desai, this has not yet been possible.

[107] When Apotex says that the central issue before the Court is why Ms. Sabourin decided in November 2014 to suspend Apotex's NOCs with connections to APIPL and ARPL, it is, in effect conceding, that apart from the events surrounding November 2014, there is little to suggest that the decision under review, which was made in the Fall of 2015, was made for anything other than legitimate concerns for the health and safety of Canadians.

[108] Apotex also argues that Ms. Sabourin's late disclosure of this documentation means that her memory cannot be trusted: "[T]he new documents clearly demonstrate the unreliability of the

testimony that Ms. Sabourin gave in her affidavit and on her cross-examination last fall" because she "completely forgot about both the November 10, 2014 conference call, as well as the crucial November 14, 2014 phone call with Dr. Sharma. In fact, she had forgotten about Dr. Sharma's involvement entirely."

[109] Apotex has made it clear that it does not question Ms. Sabourin's honesty. It questions the reliability of her memory. In essence, Apotex is saying that the Court should not accept Ms. Sabourin's evidence that the actions of November 2014 were prompted by data integrity concerns that arose from the Form 483s, and not by the Import Ban and those responsible for the Import Ban.

[110] In my view, the best test of Ms. Sabourin's memory on this central issue are the objective facts that we do know:

a) There were genuine data integrity concerns at APIPL and ARPL;

b) The Form 483s are evidence of genuine data concerns at APIPL and ARPL;

c) TPD had data integrity concerns before the Import Ban and was looking for a way to deal with them;

d) Apotex acknowledged that there were genuine data concerns at APIPL and ARPL to the FDA and went about vigorously addressing those concerns;

e) The Import Ban – whatever its motivation – was an obvious wake-up call to TPD that it needed to address data integrity concerns for Apotex's NOC submissions that relied upon products manufactured at ARPL or having APIs sourced from APIPL;

f) TPD implemented a process of internal review that eventually resulted in a policy to deal with data integrity concerns that was applicable to all NOC submissions and not just to those belonging to Apotex;

g) TPD continued to work with Apotex to overcome the APIPL and ARPL data integrity concerns and continued to accept and deal with Apotex's NOC submissions;

h) The date for data integrity concerns was eventually pushed back to January 2015;

i) There are now only two relevant drugs for which TPD is requesting data integrity packages and the submissions for these drugs involve data from APIPL and/or ARPL that goes back to 2013; and

j) Dr. Desai has given evidence that Apotex itself has not resolved the problems associated with this 2013 data.

[111] Apotex has focused upon one of the trees in this forest (the exchanges that occurred in November 2014) to convince the Court that Ms. Sabourin's memory cannot be trusted when she says that she was genuinely concerned with data integrity as evidenced by the FDA Form 483s, and was not acting in response to "marching orders" from the Minister (by way of Dr. Sharma). If we take a look at the forest, Ms. Sabourin's account seems pretty convincing to me, although I do think that the Import Ban played a role. Its effect was to prompt TPD in November 2014 to put its own house in order and to devise a means of dealing with data integrity concerns that arose from Apotex's NOC submissions, as well as the submissions of others. In my view, this was not an improper purpose, even though it might have been prompted by an Import Ban that was imposed for an improper purpose.

D. *Alignment*

[112] Apotex argues further that:

> [45] By halting the issuance of NOCs for products produced at APIPL or ARPL, the Minister was aligning TPD's approach to regulatory submissions with the Inspectorate's approach to products already on the market, as implemented by the Import Ban.

[113] Having been alerted by Ms. Mullin that there were problems with the two Apotex facilities in India with possible implications for submissions, Ms. Sabourin was duty-bound to ensure that TPD assessed the situation for itself, which it proceeded to do. It would indeed be strange if these two bureaus of Health Canada did not alert each other to any situation that could have implications for their respective mandates. But this does not mean that either the Minister or Ms. Mullin interfered with TPD's own assessment of what was required for Apotex's NOC submissions. The fact that the Import Ban and the Inspectorate's actions eventually turned out to be improper, did not relieve TPD of the responsibility for assessing the implications for NOC submissions. It was TPD's statutory mandate to do this. The only issue is whether TPD's decision to impose a temporary halt to issue NOCs to Apotex was an improper response to pressure from the Minister (either directly or indirectly), or was an independent assessment of what the data integrity concerns at APIPL and ARPL meant for NOC submissions. It seems clear that Ms. Mullin's call and other factors at play may have prompted TPD's internal assessment, but this does not mean that the assessment and the conclusions were not independent or were not justified.

E. *Lack of Documentation*

[114] Apart from the documentation that has emerged following our November 2016 hearing, Apotex points to the lack of documentation and asks the Court to draw an adverse inference:

> 47. Not a single document has been produced evidencing any of the internal Health Canada deliberations or discussions leading up to this decision and Ms. Sabourin provides virtually no information as to any deliberative process. Even for those very few meetings or phone calls (one of each, to be precise) that took place, no notes or memos have been produced. Indeed, Ms. Sabourin acknowledged that she didn't know whether any of

> the participants had even taken notes - presumably because she did not make inquiries.
>
> 48. This utter lack of any documents evidencing TPD's deliberations is striking. One is left to conclude either that the documents exist but do not support the Minister's case herein, or that no such documents exist. If no such documents exist, the question arises as to whether the deliberations leading up to the November 2014 decision were so cursory as to involve no documents at all or, alternatively, whether the lack of a paper record was a deliberate choice to shield from scrutiny TPD's deliberations over the Minister's desired "stronger measures".
>
> (emphasis added, footnotes omitted)

[115] This is a serious accusation. It asks the Court to find that TPD officials, as part of their deliberations about the "situation," made a "deliberate choice" to hide the fact that they were improperly responding to the Minister's request for "stronger measures" rather than assessing the situation for themselves. This would mean that Ms. Sabourin was lying under oath when she indicated this was not the case and that TPD was assessing data integrity concerns that had arisen out of the FDA's actions. Apotex is asking the Court to rely upon speculation and a conspiracy theory that has no evidence to support it. It is not as though there were no data integrity concerns at APIPL or ARPL, as is made clear by Dr. Desai's own evidence and the measures that Apotex agreed with the FDA to implement. The fact that the Import Ban and the Inspectorate's actions were improperly influenced by media and political pressure does not mean that there were no data integrity concerns that TPD needed to assess from the perspective of NOC submissions. In fact, there were – and are – concerns that TPD is legally obliged to assess and deal with. The Court cannot favour the allegation of an improper conspiracy over facts that are established.

[116] This concern has also been allayed to a considerable extent by the additional evidence produced by Ms. Sabourin and others following the hearing and which I have referred to above. Ms. Sabourin has also provided a plausible explanation as to why she failed to find that evidence as part of her initial searches. Apotex has also confirmed to the Court at the February 13, 2017 hearing of this application that it does not now believe that Ms. Sabourin was being dishonest in any way, although it continues to question the reliability of her memory.

F. *Other Links with the Import Ban*

[117] Apotex points to other evidence which it says establishes that TPD's decision to require additional "data integrity packages" was inextricably entwined with the Import Ban:

> 49. In any event, in the months that followed the November 2014 decision, TPD sent Apotex correspondence with respect to 30 different submissions. That correspondence confirmed what Ms. Sabourin had advised in November - i.e., that NOCs would not issue for products made at APIPL or ARPL without further evidence (commonly referred to as "data integrity packages") to establish the reliability of the data contained in the submissions.
>
> 50. The letters sent by TPD, which all contain virtually identical language, made it abundantly clear that the demand for data integrity packages was linked to and dependent upon the Import Ban. Thus, for example, a letter sent with respect to Apo-Doxylamine/B6 stated:
>
> > I would like to draw your attention to the Health Canada notice of September 30, 2014... As you are already aware, this notice concerns the action that Health Canada has taken to restrict the import of health products from three sites including ARPL in India because of data integrity concerns. The same data integrity concerns that have led to import restrictions have also given rise to significant concerns with the manner in which data are collected and reported at this site....

> > ... [S]hould [you] wish to address these issues now, you should provide evidence satisfactory to the Minister to establish that the data contained in this submission could be relied upon to support the safety, effectiveness and quality of your product prior to issuance of a Notice of Compliance.
>
> 51. The identical language is found in correspondence sent regarding Apo-Sitagliptin and Apo-Varenicline. And very similar language was used in a Notice of Deficiency sent with respect to Apotex's submission for Apo-Dabigatran:
>
> > It is noted that the proposed manufacturing sites for the drug substance (APIPL) and drug (ARPL) and the proposed stability testing site are the subject of oversight measures for imports of health products from these sites. You are advised that the data integrity issues that led to these oversight measures could impact the determination of the reliability of the submitted data to support the safety, efficacy, and quality of this product. Additional information may be required to substantiate the safety, quality, and efficacy of this product ...
>
> 52. Thus, as with Ms. Sabourin's initial communication of the decision on November 17, the letters sent by TPD invariably linked the requirement for data integrity packages to the imposition of the Import Ban and the imposition of the Import Ban to data integrity concerns. However, a judicial determination was about to make that linkage problematic.
>
> (footnotes omitted)

[118] Until Justice Manson decided that the Import Ban was improper, TPD had no reasons not to refer to it in its correspondence with Apotex or anyone else and, as the examples cited by Apotex clearly indicate, TPD was not focussed on the Import Ban; it was focussed on the "data integrity concerns" that "could impact the determination of the reliability of the submitted data to support the safety, efficacy, and the quality of this product." Given the Import Ban and the FDA's actions, TPD was duty-bound to assess the underlying data integrity concerns and their

implications for Apotex's NOC submissions. References to the Import Ban (not yet declared improper by Justice Manson) are not evidence that TPD was improperly pressured or directed by anyone outside TPD to assess data integrity concerns for itself. The letters cited above by Apotex, in my view, are strong support for the Respondent's position in this application that TPD's requests for additional information were motivated by the same data integrity concerns which led to the imposition of the Import Ban, but not the Import Ban itself.

G. *The Response to Justice Manson's October 14, 2015 Decision*

[119] Apotex cites TPD's response to Justice Manson's decision of October 14, 2015 as further evidence that TPD was improperly motivated by the Import Ban:

> 55. Then, on October 14, 2015, the Federal Court released its judgment quashing the 2014 Import Ban. Justice Manson held that the Import Ban was not motivated by "data integrity concerns", but rather "was motivated by the Minister's desire to ease pressure triggered from the media and in the House of Commons".
>
> 56. Now that the underpinning for TPD's November 2014 decision and the resulting demands for data integrity packages had been destroyed, Apotex moved quickly to have TPD rescind its decision. On the evening that Justice Manson's decision was released, Apotex wrote to Ms. Sabourin and asked that the Minister reconsider the November 2014 decision:
>
> > In light of the Judgment and, in particular, in light of the Court's clear findings that, in imposing the Import Ban, the Minister acted unfairly and for an improper purpose, we ask that you now immediately cooperate in retracting all requests for "data integrity packages"; in issuing the NOC's that have been withheld; and in restoring patent hold status and/or completing processing of all ANDS's that have been affected.
>
> 57. The next day, Ms. Sabourin responded, saying that she needed to "do some analysis and understand the implications before moving forward".

> I have received the decision as well as your emails. We will need to do some analysis and understand the implications of the decision before moving forward.
>
> 58. In a phone call the following week, Ms. Sabourin advised that she was still "reviewing [her] position".
>
> 59. At some point later in the fall of 2015, Ms. Sabourin purportedly completed her re-consideration and, acting as the Minister's delegate, concluded that no effect would be given to Justice Manson's quashing of the Import Ban. Accordingly, she decided that TPD would continue to require data integrity packages for products from APIPL and ARPL manufactured or tested prior to June 10, 2015. No reasons for this decision were provided to Apotex.
>
> (footnotes omitted)

[120] Apotex's email of October 14, 2015 is based upon the assumption that TPD's requests for additional data integrity packages was nothing more than TPD's reaction to the Import Ban. The evidence before me, however, is that this is not so. Following the November 17, 2014 exchange with Dr. Desai, TPD went on to complete an internal review of the data integrity issues from the perspective of Apotex's NOC submissions. Over time, TPD came to the conclusion that the only solution was to request additional information to establish safety, quality, and efficacy where data integrity from APIPL and ARPL could not be relied upon. Eventually, the approach became a policy of TPD that was applied to other manufacturers as well as Apotex and which was formally communicated to the industry in a notice of May 22, 2015.

[121] Justice Manson's decision of October 14, 2015 does not find that no data integrity concerns existed at ARPL or APIPL. He found that the "Minister implemented an Import Ban that was motivated by an improper purpose and without affording Apotex the procedural

protections required by law" (para 158). This does not mean there were no data integrity problems at APIPL or ARPL, and Apotex's dealings with the FDA and Dr. Desai's evidence before me in this application provide a full acknowledgement of what those concerns were and continue to be.

[122] Apotex may be able to argue that TPD's continuation of its policy was unreasonable, given Justice Manson's findings (and I will come to this later) but such continuation is not evidence that TPD was improperly motivated to require that Apotex provide additional information. In fact, it is evidence that TPD saw itself as operating independently of the Import Ban and for a different purpose. In order to find otherwise, I would have to accept Apotex's conspiracy theory that TPD has been acting in a clandestine way throughout by continuing to respond to the Minister's motives for imposing the Import Ban, and has deliberately implemented measures to conceal what it is really doing. In my view, this is a theory without any evidence to support it.

H. *Dependence Upon Inspectorate's Approach*

[123] Apotex argues that TPD's dependence upon the Inspectorate's approach to the importation of products is confirmed by the events of 2016:

> 61. On March 4, 2016, while the Inspectorate was in the process of finalizing its decision, Marion Law, who was the newly-appointed Director General of TPD, wrote to Apotex. In that letter, Ms. Law reconfirmed that TPD's approach to the review of Apotex's submissions was dependent upon the Inspectorate's approach to the importation of products:
>
> > [B]ecause the new decision will replace the 2015 Terms and Conditions, Health Canada will review its requirements for these submissions to confirm

> whether any changes are required for the requested information once the decision is finalized. We will notify you if there are any modifications to the requested information following the release of the final regulatory decision.

62. Approximately one week later, on March 14, 2016, the Inspectorate advised Apotex that it had decided to remove all terms and conditions related to APIPL and ARPL from Apotex's Establishment Licences. Given that all terms and conditions had now been lifted, which meant that the Inspectorate no longer had any concerns with the integrity of data for products produced at APIPL and ARPL, Apotex wrote to Ms. Law and asked her to confirm that TPD would no longer insist upon data integrity packages.

63. Ms. Law wrote back the following morning to "assure" Apotex that "TPD [was] moving ahead to address this issue with minimum delay". Three more days elapsed without a substantive response. So, Apotex sent a follow-up email. Still no response.

64. Finally, on March 21, 2016, Ms. Law provided her response. For reasons that remain opaque, Ms. Law's view of the importance of the Inspectorate's decision had changed markedly since she sent her letter of March 4, 2016. Suddenly and for the first time, she was taking the position that TPD's approach to the review of submissions was entirely independent from, and uninfluenced by, the Inspectorate's approach to the importation of products:

> As you are aware, the objective of the final regulatory decision was to make a new decision with respect to how we treat drugs that were fabricated at APIPL and ARPL before and after June 10, 2015. It did not concern any current or future submissions containing data from these sites.

65. Apotex asked for an explanation as to why TPD was maintaining the data integrity package requirement in the face of the Inspectorate's removal of all terms and conditions related to APIPL and ARPL. However, despite repeated requests, no explanation was ever provided. Instead, Ms. Law stalled for time, advising that she was "continuing to work through this issue" and that she "hoped" to have a response to Apotex "soon".

(emphasis in original, footnotes omitted)

[124] I see no evidence of dependency or inconsistency in these exchanges. TPD's actions in November 2014 were prompted by a telephone call made by Ms. Mullin to Ms. Sabourin and, we now know, after taking advice from Dr. Sharma, but the evidence is that TPD conducted its own internal review to see if the data concerns should impact NOC submissions. The outcome of this review was a request that Apotex provide additional information to deal with those concerns and, eventually, a new policy that applied to other manufacturers besides APIPL and ARPL.

[125] Ms. Law's letter of March 4, 2016 continues this approach. It shows that as the Inspectorate modified its position, TPD conducted its own review of "its requirements for these submissions to confirm whether any changes are required for the requested information once the decision is finalized." Apotex is suggesting that TPD acted throughout in lockstep with decisions of the Inspectorate, and the Inspectorate was improperly influenced by the Import Ban. Once again, however, this means that the Court has to accept that what Ms. Law says about reviewing submission requirements cannot be taken at face value. But there is no evidence to suggest that TPD did anything more than it indicated in the March 4, 2016 letter: it noted what was happening at the Inspectorate and then reviewed the Apotex situation in accordance with its own requirements. It has to be borne in mind that on March 4, 2016, Justice Manson had yet to release his second decision of June 15, 2016 dealing with the actions of the Inspectorate. There was no reason in March 2016 for TPD to assume that decisions of the Inspectorate were tarnished by the improper Import Ban.

[126] Once again, I think it is open to Apotex to argue that it was unreasonable of TPD to maintain the data integrity package requirement given decisions made by the Inspectorate, but I do not think this is evidence of an improper purpose.

I. *Justice Manson's Decision of June 15, 2016*

[127] Apotex alleges further evidence of improper motive by TPD in TPD's response to Justice Manson's decision of June 15, 2016:

> 66. Then, on June 16, 2016, Justice Manson released his decision on the second judicial review that had been commenced by Apotex bearing Court File No. T-1653-15, challenging the Minister's August 31, 2015 decision. In his decision, Justice Manson quashed the 2015 decision just as he had quashed the Import Ban.
>
> 67. The next day brought yet a further change of course from Ms. Law. On June 17, 2016, she wrote to Apotex and advised that she was embarking on a "fresh review of whether the information in [Apotex's] submissions is sufficient to meet the regulatory requirements or whether additional information is required". This was the first Ms. Law had ever advised of any such "fresh review". More importantly, Ms. Law still refused to provide any explanation as to why data integrity packages would be required in the interim, an explanation that was called for, given that both the 2014 Import Ban and its relaxed 2015 version had been quashed by judgment of this Honourable Court and given that the Inspectorate had determined that that it had no concerns with the integrity of data - whether current or historic - from APIPL or ARPL.
>
> 68. To this date, no explanation has been provided, and no witness has been put forward who is capable of providing one. Moreover, Apotex's request for evidence from Ms. Law herself - who would, presumably, be in a position to provide a justification for the decision, if such a justification existed - was rejected by the Minister.

[128] In his decision of June 15, 2016, Justice Manson dealt with Apotex's challenge to the Inspectorate's August 31, 2015 decision that varied the terms and conditions of Apotex's Establishment Licenses for APIPL and ARPL. Justice Manson accepted Apotex's improper purpose arguments on this issue and declared the August 2015 decision to be unlawful:

> [74] This case involves a very unique set of circumstances where an underlying decision of the Minister, found to have been made for an improper purpose and carried out unfairly, has been perpetuated in identical form in a subsequent decision without an evidentiary or lawful basis to do so.
>
> (emphasis added)

[129] On his way to reaching this conclusion, Justice Manson set out certain background details that are relevant to the present application before me:

> [5] The media criticism was prompted by the United States Food and Drug Administration's [FDA] "import alert" imposed against products from those very facilities on the basis of data integrity concerns unveiled during FDA inspections in early 2014. Notably, Health Canada's own inspections, carried out in conjunction with European and Australian regulatory counterparts, had not uncovered critical deficiencies that required immediate action for either ARPL or APIPL.
>
> [6] In June of 2015, Health Canada conducted further inspections of the ARPL and APIPL facilities with the limited purpose of assessing the extent to which Apotex had successfully carried out its proposed Corrective and Preventative Action Plan [CAPA], implemented to address deficiencies noted by the FDA [June CAPA Inspections].
>
> [7] Records of Decision were prepared for each facility, which included the inspectors' reports and Health Canada's analysis [CAPA Inspection Reports]. The CAPA Inspection Reports note that while the system controls and modified procedures satisfactorily addressed data integrity concerns, additional supervision would be necessary to demonstrate sustainability and CAPA effectiveness at times of increased production. Oversight was also needed because Apotex's retrospective review of data generated before the conclusion of the on-site June CAPA

Inspections was still ongoing. Importantly however, overall the inspection team recommendation conveyed that "Health Canada Inspectors did not identify any instances of data integrity (DI) violations observed during the June 2014 FDA Inspection".

[8] By letter dated August 31, 2015, Health Canada advised Apotex it had amended the terms and conditions on Apotex's ELs [the 2015 Terms and Conditions] pursuant to section C.01A.012 of the *FD Regulations* – the provision governing amendments to existing terms and conditions [the August 2015 Decision].

[9] The 2015 Terms and Conditions distinguished between drugs made before June 10, 2015 [Pre-June 10, 2015 Products] and those made after [Post-June 10, 2015 Products]. The conditions imposed on the Pre-June 10, 2015 Products are the exact same as the 2014 Terms and Conditions. Post-June 10, 2015 Products, although not banned completely, were subject to various additional testing and reporting requirements.

[10] Just prior to the First Judicial Review hearing, the Respondents brought a motion for mootness arguing that the August 2015 Decision was a "new" decision, unrelated to the Import Ban, and that the 2015 Terms and Conditions allegedly superseded those implemented in 2014 [First Mootness Motion]. The Court dismissed the motion on the basis that the 2014 Terms and Conditions had been brought forth into the 2015 Terms and Conditions, with the result that the Pre-June 10, 2015 Products from APIPL and ARPL remained subject to the Import Ban (*Apotex Inc v Canada (Health)*, 2015 FC 1157 at paras 11-13 [*First Mootness Motion*]).

[11] On October 14, 2015, following the hearing of the First Judicial Review, the Court quashed the Minister's decision to impose the Import Ban, including the 2014 Terms and Conditions. The Court found that the Import Ban was motivated by the Minister's improper purpose of quelling criticism in the media and in the House of Commons, rather than due to a legitimate concern for protecting Canadians' health and safety, and that it was imposed without affording the procedural fairness required in the circumstances (*Apotex Inc v Canada (Minister of Health)*, 2015 FC 1161 at paras 95-121 [*Apotex v Canada*]).

[12] In the present judicial review, the Applicants seek, inter alia, an order declaring that the August 2015 Decision of the Minister is unlawful, and an order prohibiting or restraining the Minister from further carrying into effect the 2015 Import Ban, in particular, by attempting to vary, amend, suspend or otherwise

> alter Apotex's ELs with respect to APIPL and ARPL so as to prohibit the importation of drug products from those facilities.
>
> …
>
> [17] The Desai Affidavit explains that following Health Canada's implementation of the September 2014 Import Ban, TPD refused to complete review of submissions for any products manufactured at APIPL or ARPL, including for products TPD had already found satisfactory. Apotex was informed the affected submissions would not be approved until Apotex provided additional information related to data integrity.
>
> [18] After the Court quashed the Import Ban, Apotex requested that TPD withdraw its requirements for additional data integrity information, and restore patent hold status and/or complete processing of regulatory submissions delayed due to the Import Ban.
>
> [19] TPD will not complete processing Apotex's ANDS where the ANDS includes data generated at ARPL or APIPL prior to June 10, 2015, unless Apotex supplies additional confirmatory data. Apotex claims this distinction flows from the August 2015 Decision under review in this case. Consequently, on November 12, 2015, Apotex commenced another judicial review bearing file number T-1915-15, in which it seeks an order compelling the Minister to issue NOCs in respect of all submissions affected by the Import Ban where no statutory impediments exist; return to patent hold all submissions removed on the basis of data integrity concerns; and review the affected submissions without requiring additional data integrity evidence from Apotex.
>
> [20] Apotex has been supplying the requested data integrity information and the Minister has issued NOCs or placed on patent hold some of the affected submissions. However, TPD continues to require additional data integrity evidence in respect of four regulatory submissions, notwithstanding the March 2016 Decision removing all terms and conditions from Apotex's ELs in respect of ARPL and APIPL.

[130] I have already referred to portions of Justice Manson's analysis in determining the issue that is presently before me, but I will highlight a few portions of that analysis again for convenience:

[57] The question before the Court here is not whether the Minister had the jurisdiction to amend terms and conditions to a drug manufacturer's Els, or of the Minister improperly specifying the source of her jurisdiction. In fact, it is quite evident that the power to amend or impose terms and conditions falls squarely within the Minister's mandate. Instead, the issue is whether the August 2015 Decision was unlawful on the basis that the amendment, in effect, sustained a decision quashed by this Court by maintaining in part, the 2014 Terms and Conditions in the 2015 Terms and Conditions.

[58] **In essence, the lawfulness of the August 2015 Decision depends upon (i) whether it is a sufficiently independent decision from the 2014 Import Ban, and (ii) whether it could nonetheless be justified in the evidence, such that the Minister's improper purpose in imposing the Import Ban did not also taint this subsequent and related decision.**

[59] It is evident that the August 2015 Decision was not implemented as, nor intended to be, a new and independent decision from the 2014 Import Ban. I disagree with the Respondents that the characterization of the August 2015 Decision as an amendment is immaterial. **The two decisions are inextricably interconnected, and the facts before me suggest the August 2015 Decision was neither in substance or form a free-standing and uninfluenced decision, such that it was not also infected by the improper purpose that motivated the Import Ban.**

[60] The statutory authority for the August 2015 Decision arose from section C.01A.012 of the *FD Regulations*, which authorizes the Minister to:

> amend the terms and conditions of an establishment licence if the Minister believes on reasonable grounds that an amendment is necessary to prevent injury to the health of the consumer
>
> [Emphasis added]

[61] On a plain and ordinary reading, it is apparent this provision contemplates and was intended for amendment of *prior existing* terms and conditions of an EL, which only existed on the strength of the 2014 Terms and Conditions, quashed in the First Judicial Review. This is particularly so considering the existence of subsection C.01A.008(4), relating to issuance of an EL, the

provision employed by the Minister in imposing the 2014 Terms and Conditions.

[62] Moreover, as the Applicants identify, the August 31, 2015 letter conveys that the Minister arrived at the August 2015 Decision following consideration only of whether the 2014 Terms and Conditions should be "re-examined" and "amended". Quite plainly, the June 2015 inspections were aimed at ascertaining whether the 2014 Terms and Conditions should be modified, and were not undertaken with an open view to addressing the fundamental question of whether any resultant findings warranted imposing or maintaining an Import Ban.

[63] It is also not contested that insofar as the Pre-June 10, 2015 Products are concerned, the Import Ban was carried forward. This is clear on the face of the 2015 Terms and Conditions and in the Records of Decision following the June 2015 CAPA Inspections, which indicate that products from ARPL and APIPL manufactured before June 10, 2015 "will not be subject to these new recommended Terms and Conditions", "[r]ather, they are subject to the current Terms and Conditions".

[64] The August 2015 Decision's mere continuation of the Import Ban was also confirmed by the Minister's affiant, Mr. Ouimette, who acknowledged on cross-examination that the June 2015 CAPA inspections were carried out with a view to determining whether the 2014 Terms and Conditions could be relaxed.

[65] I find that the August 2015 Decision cannot stand as lawful when the close interconnection between this Decision and the Import Ban is coupled with the lack of evidence before the Minister that supports any reasonable belief an Import Ban was necessary in August of 2015. The Respondents have pointed to no evidence, either of any affiant or circumstantial, to persuade me that even though the August 2015 Decision was an amendment and closely connected to the 2014 Decision, it was nonetheless justified on the facts.

[66] It is apparent that the Minister reviewed new evidence before arriving at the August 2015 Decision. In particular, the investigative reports from the June 2015 CAPA Inspections of ARPL and APIPL found:

a. no instances of data integrity violations of the type observed during the June 2014 FDA inspection;

b. no “high impact observations”, but several medium and low impact observations;

c. deficiencies with respect to documentation and investigation of deviations, indicating that some remaining CAPA elements still needed to be implemented;

d. that despite verification of the system controls and modified procedures, “which satisfactorily addressed data integrity concerns”, additional oversight would be necessary to demonstrate sustainability and CAPA effectiveness upon increased production; and

e. that until Apotex’s retrospective review of data was completed, there remained uncertainty regarding the data that was generated, and thus uncertainty whether regulatory requirements to support the release of these products into the Canadian market had been met.

[67] This information does not support the Respondents’ assertion that an Import Ban was warranted in August of 2015. In fact, these CAPA Inspection Reports verified there were “no instances of data integrity violations” as observed during the June 2014 FDA inspection. As well, though there remained “uncertainty” surrounding some data, as Apotex’s retrospective data review was incomplete at the time of the inspection, a lack or insufficiency of evidence hardly establishes the requisite justification for an Import Ban. This is especially so where following its own inspections, Health Canada had previously issued a Compliant with Terms and Conditions rating to APIPL, and had publicly assured in imposing the Import Ban that there were no health and safety concerns of the banned products. The fact the retrospective data review was not complete also does not establish that the Minister believed on “reasonable grounds that an amendment is necessary to prevent injury to the health of the consumer”, as required by section C.01A.012 of the *FD Regulations*, in light of the other concrete information disclosed by the CAPA Investigation Reports indicating the contrary.

[68] In the First Judicial Review, the Court found that the Import Ban was motivated by the Minister’s desire to silence criticism from the media and in the House of Commons, and thus that it was at the very least instigated under those circumstances by an improper purpose. At paragraphs 102 and 103 of that judgment, I found that:

> [102] … In September of 2014, in the absence of media criticism on the Minister or Health Canada, evidence of the on-going regulatory relationship between Apotex and Health Canada demonstrates that it is unlikely and against past and customary practice that Health Canada would have:
>
> a) suddenly and without explanation withdrawn its own inspectors' Compliant with Terms and Conditions rating for APIPL, which stemmed from an inspection expressly aimed at investigating FDA concerns of the APIPL and ARPL facilities;
>
> b) immediately and without notice ceased the usual pattern of ongoing dialogue for working with regulated parties and taking corrective actions in situations of GMP non-compliance, as outlined by their own policies;
>
> c) banned products from both facilities targeted in the Toronto Star articles, despite the fact that APIPL had just been granted a Compliant with Terms and Conditions rating by Health Canada inspectors and only ARPL had been the subject of the most recent FDA Import Alert; and
>
> d) implemented an Import Ban without first attempting to consult with Apotex regarding the newly learned FDA concerns, or requesting an extension of Apotex's voluntary quarantine.
>
> [103] There is nothing in the evidence to suggest that the events of September were so different from the previous six months such that the Import Ban was needed immediately, without notice or any opportunity to be heard, and for both APIPL and ARPL – facilities expressly mentioned in the critical articles.

[69] Fundamentally, it is not simply the Minister's *reference* to a certain provision of the *FD Regulations* or to a decision subsequently set aside that, in my view, makes the August 2015 Decision unlawful. Rather, it is the perpetuation of a decision found to have been motivated by a purpose falling outside the Minister's delegated authority, and thus a decision not made in

> accordance with, or respecting the supremacy of the rule of law (*Apotex v Canada*, above, at para 107).
>
> **[70] According to the Respondents, it is fundamentally important that the decision in the First Judicial Review did not undermine the legitimate data integrity concerns Health Canada had about the facilities in question. I note that neither the First Judicial Review, nor these reasons suggest that Health Canada did not have data integrity concerns, or that Health Canada is not entitled to consider information from international regulatory counterparts. However, I disagree on these facts that any existing data integrity concerns, which the evidence demonstrates had only improved since September of 2014, justified the continuation of an Import Ban in the August 2015 Decision, without more.**
>
> (emphasis in bold added)

[131] So Justice Manson confirms that, as of the date of his decision "neither the First Judicial Review, nor these reasons suggest that Health Canada did not have data integrity concerns, or that Health Canada is not entitled to consider information from international regulatory counterparts." He simply disagreed that existing data integrity concerns "justified the continuation of an Import Ban in the August 2015 Decision without more."

[132] Justice Manson's conclusion was that the August 15, 2015 decision of the Inspectorate under review was, *on the evidence before him*, nothing more than the continuation of the improper Import Ban by other means that could not be justified by the existence of data integrity concerns at ARPL and APIPL.

[133] On the evidence before me, I do not see TPD simply continuing the Import Ban by other means. The evidence does not establish that this case falls within Justice Manson's conclusions at para 74 of his decision:

> [74] This case involves a very unique set of circumstances where an underlying decision of the Minister, found to have been made for an improper purpose and carried out unfairly, has been perpetuated in identical form in a subsequent decision without an evidentiary or lawful basis to do so.

[134] The evidence before me shows that data integrity concerns at APIPL and ARPL existed, and continue to exist, as Justice Manson confirmed they did. The evidence before me also shows that, although prompted by the Inspectorate to examine the situation at APIPL and ARPL from the perspective of NOC submissions, TPD undertook its own internal review which eventually led to a general policy for dealing with data integrity concerns, applicable to others besides Apotex. The evidence also shows that in its dealings with Apotex, TPD has focussed upon data integrity concerns and has provided Apotex a full opportunity to understand TPD's concerns and to respond before decisions were made.

[135] Justice Manson made it very clear that his June 15, 2016 decision was dependent upon the evidentiary record before him:

> [72] Though the judgment in the First Judicial Review certainly casts doubt on the propriety of the August 2015 Decision, the fact that the August 2015 Decision relied on a subsequently overturned decision did not, in these circumstances, render it automatically void. In the First Mootness Motion, I found that the addition of the 2015 Terms and Conditions was based on a different platform than that which formed the basis for the 2014 Terms and Conditions, and that the record at that time did not set out a sufficient factual foundation for a determination on the viability of the 2015 Terms and Conditions (*First Mootness Motion*, above, at paras 7, 12). Now, with the benefit of a full factual record, I find that there is simply no evidence supporting any asserted basis for implementing or maintaining the Import Ban so as to support a finding that the 2015 Decision was justified or sufficiently separate from the 2014 Import Ban.

[136] The evidence before me, which I will come to in detail later when I deal with reasonableness, does support TPD's asserted basis for implementing and maintaining the requests for additional data to alleviate the data integrity concerns for Varenicline and Sitagliptin.

[137] In my view, the present situation is very different from the one that confronted Justice Manson in several important respects.

[138] First of all, ever since November 17, 2014 when TPD informed Apotex of its concerns and their impact upon NOC submissions, TPD has continued to approve Apotex's submissions once the additional information is produced. It has, in fact, approved 26 out of 30 submissions and only 2 (Varenicline and Sitagliptin) are waiting for Apotex to produce the requested information. These are not the actions of a Health Canada bureau that is trying to uphold and enforce an improper Import Ban. They are the actions of a bureau that is focussed upon data integrity and which is more than willing to work with Apotex to overcome its concerns. Both sides have worked together to the point that there are only 2 drugs that remain in dispute for which the evidence shows that Apotex has been unable to complete the internal review process that it agreed with the FDA it would complete. Apotex has fully acknowledged the existence of data integrity issues for data that was used in the submissions to TPD for both of these drugs. It may be, in light of the Inspectorate's removing conditions on the Establishment Licenses, that it is unreasonable for TPD to continue its concerns with regard to Varenicline and Sitagliptin, but this will require an examination of the evidence that goes to these two drugs and whether the

Establishment Licence clearances, in fact, remove the grounds of concerns that TPD continues to have. I will come to this later.

[139] Apotex argues that TPD's continuing concerns mean that TPD is now acting completely out-of-step with the Inspectorate. But that does not raise improper conduct, even by inference. It is equally explainable by TPD's having always recognized that it is a separate bureau with a duty and mandate that is different from the Inspectorate's, even though it has habitually acted in step with what the Inspectorate does.

[140] Secondly, the Regulatory provisions that lie behind Justice Manson's June 15, 2016 decision are different from those that govern the actions of TPD in telling ways.

[141] Amendments to the terms and conditions of Establishment Licenses are made in accordance with C.01A.008(1)(4)(b):

Issuance	**Délivrance**
C.01A.008 (1) Subject to section C.01A.010, the Minister shall, on receipt of the information and material required by sections C.01A.005 to C.01A.007, issue or amend an establishment licence.	C.01A.008 (1) Sous réserve de l'article C.01A.010, le ministre délivre ou modifie une licence d'établissement sur réception des renseignements et des matériaux visés aux articles C.01A.005 à C.01A.007.
…	…
(4) The Minister may, in addition to the requirements of subsection (2), set out in an establishment licence terms and conditions respecting	(4) Le ministre peut, outre les exigences visées au paragraphe (2), assortir la licence d'établissement de conditions portant sur :

…	…
(b) any other matters necessary to prevent injury to the health of consumers, including conditions under which drugs are fabricated, packaged/labelled or tested.	b) tout autre élément nécessaire pour prévenir le risque pour la santé des consommateurs, notamment la façon dont la drogue est manufacturée, emballée-étiquetée ou analysée.

[142] Amendments can be made when it is "necessary to prevent injury to the health of consumers."

[143] ANDSs are governed by C.08.002(1)(a) and C.08.002.1(3):

C.08.002 (1) No person shall sell or advertise a new drug unless	C.08.002 (1) Il est interdit de vendre ou d'annoncer une drogue nouvelle, à moins que les conditions suivantes ne soient réunies :
(a) the manufacturer of the new drug has filed 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 relating to the new drug that is satisfactory to the Minister;	a) le fabricant de la drogue nouvelle a, relativement à celle-ci, déposé auprès du ministre une présentation de drogue nouvelle, une présentation de drogue nouvelle pour usage exceptionnel, une présentation abrégée de drogue nouvelle ou une présentation abrégée de drogue nouvelle pour usage exceptionnel que celui-ci juge acceptable;
…	…
C.08.002.1 (3) The manufacturer of a new drug shall, at the request of the Minister, provide the Minister, where for the purposes of an	C.08.002.1 (3) Le fabricant de la drogue nouvelle doit, à la demande du ministre, lui fournir, selon ce que celui-ci estime nécessaire pour évaluer

abbreviated new drug submission or an abbreviated extraordinary use new drug submission the Minister considers it necessary to assess the safety and effectiveness of the new drug, with the following information and material:	l'innocuité et l'efficacité de la drogue dans le cadre de la présentation abrégée de drogue nouvelle ou de la présentation abrégée de drogue nouvelle pour usage exceptionnel, les renseignements et le matériel suivants :
(a) the names and addresses of the manufacturers of each of the ingredients of the new drug and the names and addresses of the manufacturers of the new drug in the dosage form in which it is proposed that the new drug be sold;	a) les nom et adresse des fabricants de chaque ingrédient de la drogue nouvelle et les nom et adresse des fabricants de la drogue nouvelle sous sa forme posologique proposée pour la vente;
(b) samples of the ingredients of the new drug;	b) des échantillons des ingrédients de la drogue nouvelle;
(c) samples of the new drug in the dosage form in which it is proposed that the new drug be sold; and	c) des échantillons de la drogue nouvelle sous sa forme posologique proposée pour la vente;
(d) any additional information or material respecting the safety and effectiveness of the new drug.	d) tout renseignement ou matériel supplémentaire se rapportant à l'innocuité et à l'efficacité de la drogue nouvelle.

[144] This gives the Minister a much broader discretion to request "additional information" that she "considers…necessary to assess the safety and effectiveness of a new drug."

[145] In her affidavit, Ms. Sabourin says that she did not think that Justice Manson's June 5, 2016 decision required a change in the way that TPD was treating Apotex's submissions and its requests for additional information.

> 69. Contrary to Dr. Desai's assertion (in paragraph 59 of his affidavit) that I and the Minister decided to disregard Justice Manson's decision in T-2223-14, I considered Justice Manson's decision in the days after it was released. However, since Justice Manson did not make any findings in his decision that the data in Apotex's ANDSs which originated from APIPL or ARPL were reliable for the purpose of assessing the quality, safety and effectiveness of new drugs, I did not consider that it required a change in the manner in which TPD was assessing those ANDSs.

[146] Apotex has confirmed that it does not assert that Ms. Sabourin is being dishonest. As for Apotex's request for evidence from Ms. Law, the record shows that, in a motion before Prothonotary Milczynski, Apotex made a request that Ms. Law attend an examination under oath. However, Apotex withdrew this request. So I don't think I can draw any negative inference from Ms. Law's not providing evidence.

[147] Once again, it seems to me that it is possible to argue that TPD acted unreasonably in these circumstances, but I can see no evidence here of an improper motive. Ms. Law's decision to continue the data integrity package requirement appears to be motivated by the same view that TPD has taken since November 2014: that what the Inspectorate does is clearly relevant to NOC submissions but TPD must independently review and assess each situation from the perspective of its own statutory obligations, and in accordance with the criteria applicable under the Act. In this particular instance, that position may have been unreasonable, but I do not think it is evidence of a continuing improper motive that stems from the Import Ban.

J. *Timing Issues*

[148] Apotex also raises timing issues with regard to Ms. Sabourin's reliance upon the FDA's Form 483s:

> 73. Third, Ms. Sabourin's assertion that her decision was based upon the concerns set out in the FDA's Form 483s is belied by the fact that TPD (and, more specifically, Ms. Sabourin's senior-most advisors) knew about the Form 483 for APIPL and yet, for six months, took no regulatory action whatsoever. Not only did two members of Ms. Sabourin's own office -Susan Robertson and Deborah Dinakaran - have full knowledge of the APIPL Form 483, but that knowledge was shared by the Director of BPS, Karen Reynolds, as well as two of her staff.
>
> 74. In fact, it is likely that Ms. Sabourin herself had a copy of the FDA Form 483 for APIPL - or, if not a copy of the document, then knowledge of its contents - many months before she made her November 2014 decision. Although Ms. Sabourin's affidavit states quite emphatically that the September 24, 2014 phone call from Sharon Mullin was "the first time that [she] became aware of concerns about the integrity of data generated at APIPL or ARPL", she resiled from that evidence on cross-examination. She initially said that she could "not be sure" whether she knew about data integrity concerns before the September 24 call. However, when pressed, she admitted that she had in fact been aware of "concerns about marketed products from [APIPL]" before September 24, 2014. This admission is directly contrary to the evidence contained in her affidavit and casts further doubt on Ms. Sabourin's credibility.
>
> 75. In addition, when questioned directly about when she received the Form 483 for APIPL, Ms. Sabourin was unable to answer the question. She said that she had "no idea" when she received the document, and acknowledged that it could have been before the Import Ban was imposed and, presumably, before the September 24 call.
>
> 76. Despite knowing of the data integrity problems at APIPL for months, neither Ms. Sabourin, nor Ms. Reynolds, nor any of the other senior TPD staff believed that those concerns warranted regulatory action. That view changed abruptly with the imposition of the Import Ban.

> 77. Moreover, for well over six months after having learned of the contents of the Form 483 for APIPL, TPD continued to grant NOCs for products manufactured at APIPL. The recommendations in favour of issuance of each of those NOCs would have been approved by Ms. Reynolds and the NOCs were signed by Ms. Sabourin.
>
> 78. If, as Ms. Sabourin now asserts, the information contained in the Form 483s was so serious as to warrant the refusal of NOCs, then:
>
> (a) one would have expected one or more of Ms. Reynolds, Ms. Robertson or Ms. Dinakaran to have discussed the matter with Ms. Sabourin without delay;
>
> (b) one would have expected Ms. Reynolds to recommend against the issuance of the NOCs for Apo-Mycophenolic acid in May 2014103 and for Apo-Linezolid in June 2014 (when the product was placed on patent hold) or in August 2014 (when the NOC was issued) - which did not occur;104 and
>
> (c) one would have expected Ms. Sabourin not to sign the NOCs for Apo-Mycophenolic acid or for Apo-Linezolid.
>
> 79. Given that Ms. Sabourin signed the NOCs, and given that her senior staff continued to recommend the issuance of NOCs for products from APIPL, and given that neither Ms. Sabourin
>
> nor her senior staff had any discussion as to whether the data integrity concerns at APIPL warranted any regulatory action by TPD, one can only conclude that the information in the FDA Form 483s was not, in fact, serious enough to warrant a refusal to issue NOCs.
>
> (footnotes omitted)

[149] It would indeed be strange if the Inspectorate and TPD did not communicate on matters of mutual concern, and/or did not assess and re-assess their own positions in light of developments in either bureau. But the issue before me is not whether TPD responded to positions taken by the Inspectorate, but whether its responses are inextricably entwined with the same improper motive and purpose that caused Justice Manson to quash the Import Ban and

declare the August 31, 2015 decision that varied the terms and conditions of Apotex's Establishment Licences for the APIPL and ARPL facilities to be unlawful.

[150] The fact that TPD took no regulatory action before November 2014 despite knowing about the FDA's concerns does not mean that when action was taken it was improperly influenced by, and inextricably entwined with, the Import Ban and the approach of the Inspectorate. The evidence reveals that such data integrity concerns were a new issue for TPD and it took some time for the bureau to act and develop a response. It was quite proper for TPD to decide on November 2014 that, given the Import Ban and the action of the Inspectorate, it finally had to deal with the data integrity concerns from its owns perspective and in accordance with its own regulatory duties, provided TPD did this in a reasonable and objective way, and its decision was based upon fact and the relevant regulatory scheme, and was not contaminated by the improper motives that brought about the Import Ban or the Inspectorate decision of August 31, 2015. An improper decision from somewhere within the Health Canada system can prompt a legitimate self-examination and response somewhere else in the system, particularly when TPD could not know at the material time that the Court would later find the Import Ban and the Inspectorate decision to be improper.

[151] Ms. Sabourin's evidence to the effect that TPD had data concerns arising from inspections of other Indian drug manufacturing plants besides Apotex in 2014 is not challenged. She says that TPD realised it needed to develop a consistent approach to the problem and was in the process of doing this when Apotex's draft Apo-Rasagiline NOC came before her for signature. See Sabourin Affidavit, at paras 40-54.

[152] After Ms. Sabourin's telephone discussion with Dr. Desai on November 17, 2014, Ms. Sabourin then went on to consult with her own staff with a view to developing a formal plan to deal with data integrity issues and then communicated with Dr. Desai on these matters in a further telephone call on November 24, 2014 and a face-to-face meeting on November 27, 2014. She told Dr. Desai that TPD was developing a consistent approach to deal with data integrity concerns for sites where problems had been identified that could include additional information requests. See Sabourin Affidavit, at paras 48, 50, 51.

[153] TPD then went on to develop a general policy to deal with data integrity concerns that required it to review each submission and determine if additional information was required. TPD's dealings with Apotex followed this approach and Apotex cooperated, even though Apotex did question the need for such information and objected. As matters now stand, only Varenicline and Sitagliptin remain unresolved because Apotex has not, as yet, been able to satisfy TPD on the data integrity concerns arising from these two submissions.

[154] None of this, in my view, suggests that TPD has acted towards Apotex, or continues to act towards Apotex, for an improper motive arising from the Import Ban or the Minister's August 31, 2015 decision on Establishment Licences for APIPL and ARPL.

[155] I think that Apotex is right to point out that whatever data integrity concerns TPD might have had prior to November 2014, those concerns did not prompt any action against Apotex until the Import Ban was imposed and Ms. Mullin made her telephone call to Ms. Sabourin. However, my reading of the evidence is that Ms. Mullin's telephone call precipitated action by TPD, but

the action taken was a legitimate and measured response to concerns that already existed and for which TPD had not yet worked out a consistent approach. Ms. Mullin's telephone call may have pushed TPD to make a decision and take action against Apotex, and eventually against others, but the motive and purpose for that action was not to appease or assuage political and media pressures. It was to ensure that its own mandate to ensure the safety and effectiveness of drugs in ANDSs was being implemented. Given the circumstances of November 2014, and Justice Manson's subsequent rulings on the Import Ban and the August 31, 2015 decision of the Minister, this may be a fine line to draw. But I do think there is a substantive difference between being prompted to take action for legitimate reasons and taking action for an improper purpose. And given what has happened in the interim, I think it has become clearer that TPD did have, and does have, legitimate data integrity concerns, that are not improperly motivated. Any connection between the present status of the Varenicline and Sitagliptin submissions and the Import Ban is extremely tenuous and, in my view, unproven.

K. *Other Concerns*

[156] I also accept some of the concerns behind Apotex's points that Ms. Sabourin, on cross-examination, had memory problems and did not seem to have tried to refresh her memory, and that documentation about any deliberations leading to the November 2014 Decision appears to be non-existent, but I don't think this is enough to establish that Ms. Sabourin was simply "following the Minister's directive to take 'stronger measures' against APIPL and ARPL" as Apotex argues. When these issues are reviewed in the general context of what has occurred in this dispute, I don't think it can be said, to use Justice Manson's words, that TPD's decision and action with regard to Apotex are not "sufficiently independent" from the Import Ban so as to

render them unlawful because of the Import Ban's unlawfulness. And this is particularly the case when it comes to Varenicline and Sitagliptin, which are the only two drugs for which TPD is still requesting additional information in accordance with the policy that evolved out of the November 2014 situation. It seems to me that the real test of whether an improper purpose continues to taint TPD's dealings with Apotex lies in whether or not there are genuine data integrity concerns involving Varenicline and Sitagliptin that justify TPD's continued insistence on additional information. The evidence before me is that there are genuine concerns.

L. *Conclusions on Improper Motive*

[157] Apotex has not convinced me that the Minister's refusal to end her prohibition on granting NOCs for products manufactured at ARPL or having APIs sourced from APIPL is inextricably bound up with, and based upon, the Import Ban. The evidence suggests that Ms. Mullin's call of September 24, 2014 and discussions with others may have alerted Ms. Sabourin to the Import Ban and the Inspectorate's position, but Ms. Sabourin is clear that what she took from the call was that "there were possible implications for submissions," and that what TPD then did was to assess those implications to reach a conclusion that the way to deal with the problem was to request additional information to support Apotex's ANDSs and, eventually, to formulate and implement a policy to deal with similar situations that might arise in the future. The evidence is persuasive that, notwithstanding an improper Import Ban, there have been, and continue to be, legitimate data integrity concerns with ANDSs involving certain drugs from APIPL and ARPL. There is no direct evidence that, in acting as it did in November 2014, TPD was simply falling in line and following "marching orders" from the Minister. And any inference to this effect is not, in my view, established on a balance of probabilities. Data integrity

concerns existed and TPD was legally obliged and duty-bound to assess them in accordance with its own mandate. The evidence suggests to me that this is what, in fact, occurred.

[158] The review undertaken by TPD lends credence to Ms. Sabourin's evidence that what was of real concern to TPD was not the Import Ban, *per se*, but the underlying data integrity concerns "as perceived by inspectors from the US FDA." In other words, the Import Ban aside, there were genuine reasons to be concerned about data from APIPL and ARPL and TPD had to assess those concerns. In neither of his decisions does Justice Manson say that there were no real data integrity concerns, and the evidence before me, which I will come to, makes it clear that there were, and are, data integrity concerns that TPD was required to assess.

[159] The fact that correspondence between TPD and Apotex may reference the Import Ban is not evidence that it was the Import Ban that motivated TPD's assessment of data integrity concerns and its decision to deal with the problems by requesting additional information from Apotex. The same correspondence, in my view, makes it clear that TPD's focus was, and is, the underlying data integrity concerns and not the Import Ban *per se*.

[160] In any event, the real issue before the Court at this stage is whether TPD is acting with a continuing improper intent with regard to Apotex's Varenicline and Sitagliptin submissions, because these are the only two drugs for which TPD is, in terms of the relief requested by Apotex in this application, refusing to end the prohibition on granting NOCs for products manufactured at ARPL or having APIs sourced from APIPL until additional information is provided to overcome data integrity concerns. I can see why Apotex might want to argue that

this is unreasonable in light of the decision by the Inspectorate, but it is not likely that TPD's present position on Varenicline and Sitagliptin is motivated by an improper Import Ban that was imposed in 2014 because of political pressure on the Minister, particularly when it is borne in mind that TPD has worked with Apotex in the interim to overcome data integrity concerns and has dealt with 26 submissions. Whatever the initial influence of the Import Ban, subsequent events have shown that, as far as TPD is concerned, it has not prevented Apotex from having its ANDSs related to APIPL and ARPL dealt with by TPD. It is difficult to see how the Minister's "marching orders" of 2014 could still be impacting the Varenicline and Sitagliptin submissions in 2017 given what has taken place in the interim.

[161] All in all, the evidence suggests to me that the Import Ban was a catalyst for TPD. It prompted and galvanized TPD to put its own house in order with regard to data integrity concerns emanating from APIPL and ARPL, as well as other sites and other drug manufacturers. But those data integrity concerns are, and continue to be, genuine and, what is more, have to be addressed as part of TPD's statutory mandate. TPD went about this task in a rational and cooperative way, and worked with Apotex and others to ensure that their NOC submissions were dealt with and processed while, at the same time, ensuring that the health and safety of Canadians were not compromised. TPD did not, and does not, require data integrity packages in order to perpetuate the motives that lay behind the Import Ban and the Inspectorate's decision. The data integrity concerns at APIPL and ARPL were a real problem and, with regard to Varenicline and Sitagliptin, they continue to be a real problem for reasons I will come to below. The vigorous in-house actions of Apotex in response to the FDA Form 483s make it clear that Apotex thought they were a real problem too, a problem that required a serious assessment and

remedial measures. Apotex's cooperation in providing data integrity packages for most of the drugs at issue confirms Apotex's acknowledgement of the problem. The reasons why this cannot be done for Varenicline and Sitagliptin are not clear on the evidence before me.

M. *Reasonableness*

[162] Just because I have concluded that the evidence does not support an improper purpose in the Minister's refusal to end her prohibition on granting NOCs for products manufactured at ARPL or having APIs sourced from APIPL, does not mean that TPD's present position is reasonable.

[163] Although Apotex is asking the Court to assess reasonableness for "products," I don't think the Court can do this for all "products." Each product, depending upon the nature of the concerns and the time a submission is made, will give rise to different facts and different issues. It seems to me that the Court can only assess reasonableness from the perspective of Varenicline and Sitagliptin, which are the two remaining drugs from Apotex's list of 30 for which TPD continues to require additional information to meet data integrity concerns at APIPL and ARPL.

[164] Apotex makes the following allegations:

> 12. Finally, even if the Minister was reasonable in refusing to rescind the November 2014 decision after the Import Ban was quashed, there is no justification for her to maintain that decision to the present date, given that, in March of this year, she agreed to lift <u>all</u> restrictions on the importation of products from APIPL and ARPL. Indeed, the Minister has not even adduced any evidence on this issue. The witness put forward - Ms. Sabourin - has no knowledge of any events that transpired after the end of February 2016, and the Minister refused a request to produce a witness who

> would have such knowledge (i.e., the current Director General, Ms. Marion Law).
>
> 13. Thus, there is simply no evidence before the Court to justify the November 2014 decision and its continued application.
>
> (emphasis in original)

[165] As I have already indicated, Apotex makes frequent references to TPD's reliance upon the Inspectorate for TPD's own decisions on ANDSs. For convenience, I will repeat some of Apotex's concerns and arguments here:

> 59. At some point later in the fall of 2015, Ms. Sabourin purportedly completed her re- consideration and, acting as the Minister's delegate, concluded that no effect would be given to Justice Manson's quashing of the Import Ban. Accordingly, she decided that TPD would continue to require data integrity packages for products from APIPL and ARPL manufactured or tested prior to June 10, 2015. No reasons for this decision were provided to Apotex.
>
> 60. Then, in late January 2016, the Inspectorate communicated a purportedly new - albeit "preliminary" - decision to Apotex related to the Import Ban. That preliminary decision proposed a relaxation of the terms and conditions related to APIPL and ARPL, such that only two (or perhaps three) terms and conditions would remain in force.
>
> 61. On March 4, 2016, while the Inspectorate was in the process of finalizing its decision, Marion Law, who was the newly-appointed Director General of TPD, wrote to Apotex. In that letter, Ms. Law reconfirmed that TPD's approach to the review of Apotex's submissions was dependent upon the Inspectorate's approach to the importation of products:
>
> > [B]ecause the new decision will replace the 2015 Terms and Conditions, Health Canada will review its requirements for these submissions to confirm whether any changes are required for the requested information once the decision is finalized. We will notify you if there are any modifications to the requested information following the release of the final regulatory decision.

62. Approximately one week later, on March 14, 2016, the Inspectorate advised Apotex that it had decided to remove all terms and conditions related to APIPL and ARPL from Apotex's Establishment Licences. Given that all terms and conditions had now been lifted, which meant that the Inspectorate no longer had any concerns with the integrity of data for products produced at APIPL and ARPL, Apotex wrote to Ms. Law and asked her to confirm that TPD would no longer insist upon data integrity packages.

63. Ms. Law wrote back the following morning to "assure" Apotex that "TPD [was] moving ahead to address this issue with minimum delay". Three more days elapsed without a substantive response. So, Apotex sent a follow-up email. Still no response.

64. Finally, on March 21, 2016, Ms. Law provided her response. For reasons that remain opaque, Ms. Law's view of the importance of the Inspectorate's decision had changed markedly since she sent her letter of March 4, 2016. Suddenly and for the first time, she was taking the position that TPD's approach to the review of submissions was entirely independent from, and uninfluenced by, the Inspectorate's approach to the importation of products:

> As you are aware, the objective of the final regulatory decision was to make a new decision with respect to how we treat drugs that were fabricated at APIPL and ARPL before and after June 10, 2015. It did not concern any current or future submissions containing data from these sites.

65. Apotex asked for an explanation as to why TPD was maintaining the data integrity package requirement in the face of the Inspectorate's removal of all terms and conditions related to APIPL and ARPL. However, despite repeated requests, no explanation was ever provided. Instead, Ms. Law stalled for time, advising that she was "continuing to work through this issue" and that she "hoped" to have a response to Apotex "soon".

66. Then, on June 16, 2016, Justice Manson released his decision on the second judicial review that had been commenced by Apotex bearing Court File No. T-1653-15, challenging the Minister's August 31, 2015 decision. In his decision, Justice Manson quashed the 2015 decision just as he had quashed the Import Ban.

> 67. The next day brought yet a further change of course from Ms. Law. On June 17, 2016, she wrote to Apotex and advised that she was embarking on a "fresh review of whether the information in [Apotex's] submissions is sufficient to meet the regulatory requirements or whether additional information is required". This was the first Ms. Law had ever advised of any such "fresh review". More importantly, Ms. Law still refused to provide any explanation as to why data integrity packages would be required in the interim, an explanation that was called for, given that both the 2014 Import Ban and its relaxed 2015 version had been quashed by judgment of this Honourable Court and given that the Inspectorate had determined that that it had no concerns with the integrity of data - whether current or historic - from APIPL or ARPL.
>
> 68. To this date, no explanation has been provided, and no witness has been put forward who is capable of providing one. Moreover, Apotex's request for evidence from Ms. Law herself - who would, presumably, be in a position to provide a justification for the decision, if such a justification existed - was rejected by the Minister.

[166] This account by Apotex gives the impression that there never have been any real data integrity concerns at APIPL and ARPL and that, even if there were, the Inspectorate has now addressed them and given the all-clear. This is not, however, what the evidence reveals.

[167] To begin with, Apotex itself has fully acknowledged that there were data integrity concerns at APIPL and ARPL that required resolution. These concerns were first raised as a result of the January 2014 FDA inspection of APIPL which discovered that staff at APIPL had been conducting drug sample tests that were not reported. In other words, staff were investigating or reporting out-of-specification results. The FDA discovered that staff at APIPL had, at least in some instances, re-tested failing products until a passing result was achieved without addressing why initial test results had failed.

[168] Apotex realized that this gave rise to serious data integrity concerns and informed Health Canada's Inspectorate of the FDA's findings at APIPL in April 2014 and similar observations by the FDA after a June 2014 inspection.

[169] Dr. Desai himself has acknowledged that the FDA's observations of what staff were doing at APIPL and ARPL made it difficult to assess the reliability of data. In cross-examination, Dr. Desai explained the problems as follows:

> 52 Q Would you consider that retesting samples and not reporting the test results, or sort of aggregating them and reporting both suspect and passing without identifying that some had been suspect, would you agree with me that that practice could lead to some concerns about the reliability of the test results?
>
> A It's how it's characterized. I mean, with these types of observations, unless you can get into the -- literally, the devil is in the detail. Until you can characterize the observation with that specific -- and do a specific investigation, it's very hard to make a generalized comment that this is, in fact, concerning or not.
>
> 53 Q Right. And, similarly, it would be hard to make a general statement that it was of no concern at all, it was completely reliable?
>
> A You would have to do the subsequent investigation to fully understand why on that particular test result that approach was taken or not. There's not [*sic*] numerous reasons sometime why data is discarded, and that's okay, provided it's reported. So, until you know the details of this one, it's very hard to make a general statement around the severity of it.
>
> …
>
> 57 Q And, these same types of observations about records missing data and tests being abandoned without any explanation of the out of specification results or any troubleshooting of the problem, these types of observations could potentially impact the reliability of the data; is that correct?
>
> A Well, again, it's the same answer I gave with the previous example you showed that until you go into the specific

> individual investigation and the cause, it's hard to make a determination.

[170] In fact, Apotex took these data integrity concerns so seriously that it advised the Inspectorate that it would conduct a complete data review and assessment of laboratory practices at ARPL and that it would test all finished commercial products from ARPL at Apotex's facilities in Toronto before products were released into the Canadian market. Apotex also took extensive corrective measures at APIPL and ARPL, including retrospective reviews of data stored on its Empower system. Apotex implemented a Global Quality Action Plan and proceeded to follow it and work on corrective and preventative plans at both APIPL and ARPL, making progress reports to both the FDA and Health Canada. In fact, in 2015, Apotex committed to the FDA to "perform a 100% Data Integrity review of all pending and approved ANDS prior to the launch of any product in the US market." See Cross-Examination of Dr. Desai in T-2223-14, Exhibit 13. In a May 2015 report, Apotex assured the FDA that it would:

> … continue to work with the Therapeutic Products Directorate (TDP) to address deficiencies for products pending approval (pending ANDs) on a case by case basis. To date we have responded to 5 such deficiencies and are in the process of responding to 6 other deficiencies.
>
> See Sabourin Affidavit, Exhibit V (Apotex Summary of Actions), Applicant's Record, Vol. 3, pp 796-799

[171] Apotex's Empower 3 computer system holds direct data captured for Apotex's chromatography machines going back to September 2013. Data generated prior to that date is held on an earlier system known as Empower 2. It is no coincidence that the submissions for Varenicline and Sitagliptin – the two submissions that remain unresolved – contain data from stability studies conducted at ARPL in 2013. In May 2015, Apotex reported that it had not yet

begun its review of the Empower 2 system and, as of the date of hearing this matter, Apotex had not produced results of its retrospective review of Empower 2 data that is relevant to its Canadian submissions. Dr. Desai on cross-examination said that he was unable to comment on the progress of the Empower 2 review.

[172] So data integrity concerns at APIPL and ARPL have existed since 2014 and have been taken seriously by the FDA and Health Canada, as well as by Apotex itself. As matters now stand, the two remaining unresolved submissions for Varenicline and Sitagliptin continue to have data integrity concerns stemming from data stability studies that were conducted at ARPL in 2013. Apotex has not yet completed the internal review that it committed to, but says that it doesn't matter anymore because the Inspectorate has now given the all-clear. However, unless and until Apotex has completed its review of Empower 2 data, I don't see how TPD can confirm the reliability of data in submissions which have been affected by problematic chromatography testing.

[173] It is true that, as Apotex has continued to work with the FDA and Health Canada, TPD has been willing and able to adjust its data requirements for submissions in response to action taken by the Inspectorate. In June 2015, TPD decided it no longer required additional information to support data generated at APIPL and ARPL after inspections by the Inspectorate in June 2015. This is because TPD was able to conclude that the corrective and preventative measures implemented by Apotex rendered post-June 2015 data reliable. This date was later adjusted to January 2015. Ms. Law explained the situation to Dr. Desai in her letter of July 8, 2016:

> Although Health Canada's on site CAPA verification inspection in June 2015 documented significant progress in the implementation of CAPAs at these sites, the scope of this inspection was limited to previously authorised drug products. As a result, through the course of my review I placed a greater emphasis on Apotex's CAPA submissions and progress reports to the US FDA for APIPL and ARPL and the US FDA responses to these reports as data on submissions were within the scope of these reports. Given that these reports indicate that the majority of the CAPAs and Apotex's own Global Quality Assurance Plan (GQAR) developed to address the observations and associated concerns were implemented at both sites by December 2014, I have concluded that it is reasonable at this time, for TPD to consider data generated at APIPL and ARPL after January 1, 2015 to be reliable. On this basis, the additional information in support of drug submissions where the data in the submission was generated at APIPL or ARPL after January 1, 2015 will not be required at this time.
>
> (emphasis in original)

In my view, however, nothing from the Inspectorate has answered concerns about pre-January 2015 data from APIPL and ARPL.

[174] As matters presently stand, TPD continues to require additional information to confirm the reliability of pre-January 1, 2015 data generated at APIPL and ARPL and, in particular, data generated in 2013 for Varenicline and Sitagliptin. Apotex has not shown how the Inspectorate's March 14, 2016 decision resolves the data integrity concerns over Varenicline and Sitagliptin. Apotex says that the "Inspectorate no longer had any concerns with the integrity of data for products produced at APIPL and ARPL" so that it is not reasonable for TPD to insist upon additional data integrity packages. My review of the Inspectorate's March 14, 2016 decision suggests to me that it removes certain conditions attached to the Establishment Licences because they were found to be no longer necessary, but I don't see how this addresses the problems concerning the reliability of data that was generated at APIPL and ARPL before Apotex

implemented its own corrective and preventive action plan. And it is that data which lies behind TPD's present position with regards to Varenicline and Sitagliptin and that TPD is dealing with in accordance with its present policy.

[175] It seems to me, then, that this decision by the Inspectorate does not remove pre-January 2015 data integrity concerns at APIPL and ARPL, and the 2013 data integrity concerns for Varenicline and Sitagliptin in particular, so that it was not unreasonable for TPD to conduct a fresh review and to request additional information to meet those concerns. Apotex committed itself to a five-year review to satisfy the FDA and Dr. Desai said he did not know the status of that review. This means that TPD cannot make a decision until it is provided with the relevant information.

[176] This position is reasonable because, as the Respondent points out:

(a) the FDA made observations in 2014 of unreported chromatography tests at APIPL and ARPL, as well as failures to investigate out-of-specification results, and re-testing of failing results without reporting or explaining the failing results;

(b) Dr. Desai has acknowledged himself that these matters could potentially impact the reliability of data in drug submissions;

(c) Apotex's own review of Empower 3 data in May 2015 led to an acknowledgment that five of its submissions had been affected by data integrity problems;

(d) on the record before me, Apotex has not completed its review of Empower 2 data, so that TPD has no way of confirming the reliability of data in those submissions which may have been affected by the problematic chromatography testing.

IX. Conclusions

[177] I find that Health Canada's continued refusal to grant NOCs for products manufactured at ARPL or having APIs sourced from APIPL because of continuing integrity concerns over data generated pre-January 2015 is neither improper nor unreasonable.

JUDGMENT

THIS COURT'S JUDGMENT is that

1. The application is dismissed with costs to the Respondent.

"James Russell"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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APPEARANCES:

Harry Radomski Nando De Luca Julie Rosenthal Daniel G. Cohen	FOR THE APPLICANT
Glynis Evans Laura Tausky	FOR THE RESPONDENTS

SOLICITORS OF RECORD:

Goodmans LLP Barristers and Solicitors Toronto, Ontario	FOR THE APPLICANT
William F. Pentney Deputy Attorney General of Canada Toronto, Ontario	FOR THE RESPONDENTS