Federal Court  Cour fédérale

Date: 20160615

Docket: T-1653-15

Citation: 2016 FC 673

Ottawa, Ontario, June 15, 2016

PRESENT: The Honourable Mr. Justice Manson

BETWEEN:

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

Applicants

and

MINISTER OF HEALTH AND ATTORNEY GENERAL OF CANADA

Respondents

JUDGMENT AND REASONS

[1] This is the second judicial review involving a decision of the Minister of Health [the Minister] restricting importation of drugs from two of Apotex Inc.'s drug manufacturing facilities. Specifically, Apotex Inc. [Apotex], Apotex Pharmachem India Pvt Ltd. [APIPL] and Apotex Research Private Limited [ARPL] [collectively "the Applicants"], challenge the

Minister's August 31, 2015 decision that varied the terms and conditions of Apotex's Drug Establishment Licences in respect of its two facilities in India, APIPL and ARPL.

I. Background

A. *Regulatory Regime*

[2] The Respondent Minister is responsible, through her delegates at Health Canada, for administering the *Food and Drugs Act*, RSC 1985, c F-27 [*FD Act*], and the *Food and Drugs Regulations*, CRC, c 870 [*FD Regulations*].

[3] The *FD Act* and *FD Regulations* govern the manufacture, import and sale of all drug products in Canada. To fabricate, distribute or import into Canada for sale any drug, the manufacturer must hold an establishment licence [EL], which is granted when the holder of the EL demonstrates its facilities comply with Good Manufacturing Practices [GMP] and meet the requirements of Part C, Division 2 of the *FD Regulations*. GMP observations are classified by level of risk and depending on the severity and number of observations, may result in the addition of terms and conditions to the ELs, or a non-compliant rating.

B. *The Facts*

[4] On September 30, 2014, following a series of Toronto Star articles highly critical of the Minister's inaction in respect of imported products from ARPL and APIPL, the Minister imposed terms and conditions on Apotex's ELs [the 2014 Terms and Conditions] that prevented the import or sale of drug products from these facilities [the Import Ban].

[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.

[13] On March 14, 2016, the Minister issued a decision removing all terms and conditions on Apotex's ELs for ARPL and APIPL [the March 2016 Decision]. As a consequence, the Respondents brought a motion requesting dismissal of this judicial review for mootness, alleging that the Applicants' sought relief, including that the August 2015 Decision be quashed, is no longer at issue.

C. *Evidence in the Mootness Motion*

[14] The Applicants provided a second Affidavit of Dr. Jeremy Desai [the Desai Affidavit], President and Chief Executive Officer of Apotex, as evidence in the motion which describes the ongoing effect of the August 2015 Decision on Apotex's Regulatory Submissions.

[15] As background, the Desai Affidavit explains that section C.08.004 of the *FD Regulations* provides that a drug manufacturer may obtain a Notice of Compliance [NOC] in respect of a new

drug only after filing a New Drug Submission [NDS] or an Abbreviated New Drug Submission [ANDS].

[16] Upon Health Canada's determination that the submission demonstrates the product is safe and effective under the *FD Regulations*, the product is placed on "patent hold" until the generic manufacturer complies with requirements of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133. Once compliant, the Director General of the Therapeutic Products Directorate [TPD] is required to issue a NOC.

[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.

II. Issues

[21] For the mootness motion, the issue is:

A. Whether this judicial review is moot, and if so, whether the Court should exercise its discretion to hear the application.

[22] For the judicial review application, the issue is:

B. Whether the August 2015 Decision and resulting continuation of the Import Ban through the 2015 Terms and Conditions is unlawful on the basis of its close connection to the decision quashed in the First Judicial Review and on the evidence before the Minister at the time of its implementation.

III. Analysis

[23] The relevant provisions of the *FD Regulations* are attached as Annex A.

A. *Preliminary motion to file reply evidence*

[24] As a preliminary matter, on May 20, 2016, the Respondents sought to file reply evidence relating to the status of various government websites as of May 13, 2016. I indicated to the parties at the outset of the hearing that I find this evidence to be of limited value to the Court and inconsequential to my decision on mootness or in the context of the judicial review.

[25] As such, I dismissed the Minister's motion to introduce new reply evidence and did not accept new evidence sought be relied upon by the Applicants in reply thereto.

B. *Mootness Motion*

(1) Whether the judicial review is moot, and if so, whether the Court should exercise its discretion to hear the application.

[26] In *Borowski v Canada (Attorney General)*, [1989] 1 SCR 342 at paras 15-17 [*Borowski*], the Supreme Court of Canada determined that the doctrine of mootness applies when the Court's decision on the merits would have no practical effect in solving a live controversy between the parties. In the context of a judicial review, there is no tangible dispute between the parties where a decision has been overtaken by a subsequent decision (*Stewart v Ontario (Director, Office of the Independent Police Review)*, 2013 ONSC 7907 at para 18).

[27] The Court in *Borowski* set out a basic two part analysis: the Court must first determine whether the required tangible and concrete dispute has disappeared and the issues have become academic; and if so, whether it should exercise its discretion to hear the case by considering:

a. the presence of an adversarial context;
b. judicial economy, which encompasses considerations of whether the decision will have a practical effect on the parties, whether the case is of a recurring nature but brief duration or a question that may evade review by the court, or is an issue of public importance for which resolution is in the public interest; and
c. the need for the Court to be sensitive to its role as the adjudicative branch of government.

[28] The Respondents, the moving party in this motion, submit this application is moot, as the March 2016 Decision removed the 2015 Terms and Conditions imposed by the August 2015 Decision and granted the relief sought by the Applicants. In other words, the desired effect of the application has been achieved (*Doucet-Boudreau v Nova Scotia (Department of Education)*, 2003 SCC 62 at para 17).

[29] They claim that any order by this Court granting the remedies sought in the Notice of Application – an order declaring and quashing the August 2015 Decision as unlawful; an order requiring the Minister to rescind the ban; or, an order restraining the Minister from giving effect to the 2015 Decision – would have no practical effect for the litigants in this case.

[30] The Respondent distinguishes this scenario from the First Mootness Motion, where the Court found the application was not moot, given that the 2014 Terms and Conditions had been

brought forward by the August 2015 Decision (*First Mootness Motion*, above, at paras 11-14). By contrast, the March 2016 Decision removed all terms and conditions, and there remain no restrictions on the importation of products from APIPL and ARPL, such that there is no continuing adversarial relationship.

[31] The Applicants allege otherwise. They claim that despite the March 2016 Decision, Health Canada continues to give effect to the 2015 Terms and Conditions as if they were lawful, reasonable and still in effect, and there is very much a live, and not solely academic issue between the parties.

[32] On the first prong of the *Borowski* test, I am satisfied that the judicial review is moot. The August 2015 Decision and the restrictions on import it imposed cease to exist. Accordingly, there is no live controversy between the parties, and the Applicants' requested relief that the August 2015 Decision of the Minister be quashed is *prima facie* moot.

[33] Although the declaratory relief sought by the Applicants remains, the doctrine of mootness may not be avoided merely by seeking declaratory relief (*Rahman v Canada (Minister of Citizenship & Immigration)*, 2002 FCT 137 at para 18; *Fogal v Canada* (1999), 167 FTR 266, aff'd (2000), 184 FTR 160 (note) (FCA), leave to appeal denied [2001] SCC No 84). Since the dispute giving rise to the appeal has dissolved, any such declaratory relief that may be granted in the application does not flow from a live controversy, and thus it is to be considered in the second step of the *Borowski* analysis (*Danada Enterprises Ltd v Canada (Attorney General)*, 2012 FC 403 at para 61).

[34] While the Court will generally decline to hear and decide moot applications, the question remains whether the Court ought to hear this judicial review, even though its principal underpinnings are now moot, upon considering: (a) the presence of an adversarial context; (b) judicial economy; and (c) the need for the Court to be sensitive to its role as the adjudicative branch of government.

(a) *Adversarial Context*

[35] The first factor set out in *Borowski* – the existence of an adversarial context – supports the exercise of the Court's discretion. The Applicants have provided evidence that an adjudication on the merits will have collateral and practical significance on the parties' rights, as asserted in a currently pending judicial review application before this Court, and as well in an action for damages the Applicants intend to commence (*Borowski*, above, at para 31; *Apotex v Warner-Lambert Company LLC*, 2012 FCA 323 [*Warner-Lambert*]; *Apotex Inc v Bayer AG*, 2014 FCA at para 9 [*Bayer AG*]).

[36] While the Respondents argue that for the adversarial context to exist, any collateral effects on other proceedings must be dispositive, I disagree. Such a prerequisite to the exercise of discretion is not supported by *Borowski*, or in subsequent case law.

[37] I do note that the Notice of Application in T-1915-15 makes no mention of the August 2015 Decision. Instead, the alleged impropriety of the Minister's actions in refusing to process Apotex's regulatory submissions is because it is based on the 2014 Import Ban that has since been quashed. However, given the close relation between the Import Ban and subsequent August

2015 Decision, including the fact that arguably a continuum exists with respect to the effects of both the 2014 and 2015 Decisions, determinations made on the legality of the August 2015 Decision may collaterally affect T-1915-15.

[38] Further, there is little doubt that the outcome of the judicial review may significantly and collaterally impact any action for damages filed by the Applicants relating to the Import Ban on drug products from APIPL and ARPL.

[39] The issues were vigorously argued by the parties who, given the history of this dispute, clearly have a stake in the outcome: the Applicants, because of the above-described collateral effects, and the Respondents, in that adjudication involves a determination of the lawfulness of Ministerial action.

[40] This factor weighs in favour of the Court exercising its discretion to adjudicate on the dispute, in view of the declaratory relief that remains.

(b) *Concerns for Judicial Economy*

[41] The concern for judicial economy considers whether "the special circumstances of the case make it worthwhile to apply scarce judicial resources to resolve it" (*Borowski,* above, at para 34). Such concerns are answered if the Court's decision will have some practical effect on the rights of the parties (*Borowski*, above, at paras 34, 35). My above finding that a decision on the merits will have a practical, albeit collateral, effect on the parties' rights mitigates concern over wasting scarce judicial resources in hearing and deciding a moot issue.

[42] The Applicants argue that the judicial economy factor weighs in their favour given that (i) considerable time and effort has been expended in this proceeding and (ii) a definitive resolution at this stage, rather than in any collateral proceeding, would save judicial resources. This argument is without merit: the very same proposition was argued and was explicitly rejected in *Borowski*, above, at paragraph 44, where Justice Sopinka, writing for the Court stated: "[t]o give effect to this argument would emasculate the mootness doctrine which by definition applies if at any stage the foundation for the action disappears" (see also *Tamil Co-operative Homes Inc v Arulappah* (2000), 192 DLR (4th) 177 at paras 29-31 (ONCA); *CUPE v Canada (Minister of Transport)*, 2015 FC 1421 at para 11).

(c) *The Court's Law-Making Function*

[43] On the final *Borowski* factor, there is no concern here of the Court encroaching into areas of executive or legislative policy. The issues at play concern the lawfulness of Ministerial action in implementing administrative policies relating to the regulation of drug manufacturers and import of drugs pursuant to the *FD Act* and *FD Regulations*. In adjudicating such issues, the Court would not be departing from its traditional role in supervising those who exercise statutory powers to ensure they do not overstep their legal authority.

[44] In the context of this case, and against these above criteria – in particular, the continued existence of an adversarial context – I am satisfied that the Court should exercise its discretion to hear the matter on its merits, notwithstanding mootness.

C. *Judicial Review*

(1) Whether the August 2015 Decision and resulting continuation of the Import Ban through the 2015 Terms and Conditions is unlawful on the basis of its close connection to the decision quashed in the First Judicial Review and on the evidence before the Minister at the time of its implementation.

(a) *Standard of Review*

[45] The applicable standard of review in assessing whether the August 2015 Decision is unlawful on the basis of its close connection to the Minister's 2014 Decision is correctness. This is a legal question that involves determining the effect of amending and more importantly, carrying forward and maintaining a decision that was subsequently quashed on the basis it was implemented unfairly and for an improper purpose.

[46] Though the issue before me does not directly involve review of the Minister's interpretation of the governing legislative scheme, I find that the connection of the August 2015 Decision to the 2014 Import Ban, and the Minister's use of certain provisions of the *FD Regulations* to implement the August 2015 Decision, further support correctness review as appropriate. In the First Judicial Review I found that the Minister's interpretation of the *FD Regulations* is a question of law reviewable on a standard of correctness (at paras 74 and 75) – a conclusion that was largely based on Justice Stratas' standard of review analysis of the same Minister applying the same regulations in *Takeda Canada Inc v Canada (Minister of Health)*, 2013 FCA 13 at paras 26, 111, leave to appeal to SCC refused, (2013) 460 NR 399 (note).

[47] Given my below findings, it is unnecessary to adjudicate on other issues raised by the parties, or to analyse the appropriate standards of review to be applied to those issues.

(b) *Analysis*

[48] The Applicants assert that the August 2015 Decision was quashed by the First Judicial Review, as it was premised upon the presumed lawfulness of the 2014 Terms and Conditions, later adjudged by this Court to be unjustified. They emphasize that the June CAPA Inspections were not undertaken with a view to determine whether the imposition of terms and conditions and an Import Ban was actually justified: instead, they were carried out with a view to determine whether the 2014 Terms and Conditions should be modified.

[49] The Applicants argue the August 2015 Decision should be quashed on the basis that the Minister acted unlawfully in:

a. maintaining the Import Ban through the 2015 Terms and Conditions, notwithstanding the Court's judgment on the First Judicial Review;
b. acting in a manner not authorized by the *FD Regulations*;
c. founding her decision upon the (incorrect) assumption that the Import Ban was lawful and justified, thereby tainting the entire decision-making process;
d. failing to act in accordance with the principles of fundamental justice and fairness; and
e. rendering a decision that was substantively unreasonable and contrary to the provisions of the *FD Regulations*.

[50] The Applicants propose that a decision founded upon a decision that is quashed cannot stand (*Thambiturai v Canada (Minister of Citizenship & Immigration)*, 2006 FC 751 at paras 17, 18). They claim that as a matter of law, there were no terms and conditions for the Minister to "amend" in making the August 2015 Decision.

[51] As well, the First Mootness Motion found that the Pre-June 10, 2015 Products manufactured at APIPL and ARPL are still subject to the 2014 Import Ban through the 2015 Terms and Conditions. The Applicants assert that the evidence revealed in the Rule 318 materials, and by the Minister's affiant, Mr. Etienne Ouimette (Executive Director of the Licensing and Inspection Bureau at the Health Products and Food Branch Inspectorate of Health Canada), further supports this conclusion: the Minister's delegates were well aware and, in fact, intended that the Pre-June 10, 2015 Products remain subject to the 2014 Terms and Conditions.

[52] In opposition, the Respondents argue that the characterization of the August 2015 Decision as an "amendment", and reference to section C.01A.012 of the *FD Regulations* does not render it unlawful.

[53] They cite the Supreme Court decision in *British Columbia (Milk Board) v Grisnich*, [1995] 2 SCR 895 [*Milk Board*], as standing for the proposition that the Minister's use of the amending provision is inconsequential, so long as the Minister was acting within her jurisdiction, as "Courts are primarily concerned with whether a statutory power exists, not with whether the delegate knew how to locate it" (*Milk Board,* above, at para 20).

[54] Accordingly, the Respondents submit that the Minister has the authority to impose terms and conditions on an existing EL (*Apotex v Canada*, above, at paras 134-50; *FD Regulations*, section C.01A.008(4)), and regardless of the August 2015 Decision's description as an amendment, it is not nullified merely because it references a decision subsequently set aside.

[55] The Respondents further argue that there was evidence supporting the Minister's August 2015 Decision, including the 2014 FDA reports identifying data integrity issues at the facilities, and information gathered in the course of the June 2015 CAPA Inspections. There is also no evidence to suggest that continuing the terms for the Pre-June 10, 2015 Products was politically motivated or made for any other improper purpose.

[56] I do not find the Respondents' reference to *Milk Board*, above, applicable in this case. *Milk Board* arose in the context of deciding whether an administrative tribunal endowed with powers from both federal and provincial jurisdiction was required to specify which of those powers it was relying upon in making its order. The majority concluded that the only requirement is to possess jurisdiction, and that the source of jurisdiction need not be specified on the face of every order (at para 8).

[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.

[71] Counsel for the Minister cautioned that a finding of presumptive invalidity of the August 2015 Decision based on the outcome of the First Judicial Review could lead to regulatory voids and unintended consequences, particularly in light of the continuing and ongoing regulatory scheme in which this fact pattern took place. I agree.

[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.

[73] I am also wary of the need to avoid undue interference with the discharge of administrative functions in respect of matters delegated to administrative bodies by Parliament. This judgment does not purport to suggest that Health Canada is unable to undertake regulatory

action necessary to protect Canadians' health and safety, either at the time of the August 2015 Decision, or in the future – so long as such exercises of public authority find their source in law.

[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.

[75] It is the interconnectedness of the decisions, coupled with the dearth of evidence justifying an Import Ban in August of 2015, that makes it both legally and logically unsound to now find that the August 2015 Decision was not also tainted by the improper purpose that led to the quashing of the 2014 Terms and Conditions in the First Judicial Review. For this reason, I would grant the judicial review and declare that the August 2015 Decision is unlawful.

[76] Though the Applicants request other relief, a declaration of unlawfulness is the full extent of the relief warranted. The other sought relief essentially invites the Court to make pronouncements and place limitations on Ministerial action where I am confident it would be either redundant or is simply unnecessary.

JUDGMENT

THIS COURT'S JUDGMENT is that

1. The Respondents' motion to introduce reply evidence is dismissed;

2. The Respondents' motion for mootness is dismissed;

3. The August 2015 Decision is declared unlawful;

4. The application is otherwise dismissed;

5. Costs to the Applicants.

"Michael D. Manson"
Judge

ANNEX A

Food and Drugs Regulations, CRC, c 870

Issuance

C.01A.008

(4) The Minister may, in addition to the requirements of subsection (2), set out in an establishment licence terms and conditions respecting

(a) the tests to be performed in respect of a drug, and the equipment to be used, to ensure that the drug is not unsafe for use; and

(b) any other matters necessary to prevent injury to the health of consumers, including conditions under which drugs are fabricated, packaged/labelled or tested.

Conditions

C.01A.012

(1) The Minister may 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.

(2) The Minister shall give at least 15 days notice in writing to the holder of the establishment licence of the proposed amendment, the reasons for the amendment and its effective date.

Délivrance

C.01A.008

(4) Le ministre peut, outre les exigences visées au paragraphe (2), assortir la licence d'établissement de conditions portant sur :

a) les analyses à effectuer à l'égard de la drogue et l'équipement à utiliser afin que la drogue puisse être utilisée sans danger;

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.

Conditions

C.01A.012

(1) Le ministre peut modifier les conditions d'une licence d'établissement s'il a des motifs raisonnables de croire que la modification est nécessaire pour prévenir des risques pour la santé des consommateurs.

(2) Le ministre donne au titulaire de la licence d'établissement un préavis d'au moins 15 jours indiquant les motifs de la modification et sa date d'entrée en vigueur.

FEDERAL COURT

SOLICITORS OF RECORD

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