Federal Court  Cour fédérale

Date: 20170510

Docket: T-1653-16

Citation: 2017 FC 487

Ottawa, Ontario, May 10, 2017

PRESENT: The Honourable Mr. Justice Manson

BETWEEN:

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

Plaintiffs

and

RONA AMBROSE, JULIE VAUX, CLARK OLSEN, NICK SWITALSKI, CAILIN RODGERS, GEORGE DA PONT, PAUL GLOVER, ANIL ARORA, ANNE LAMAR, SUPRIYA SHARMA, ROBIN CHIPONSKI, MARY MORGAN, STEVEN SCHWENDT, SHARON MULLIN, BARBARA SABOURIN, KAREN REYNOLDS, CRAIG SIMON, MICHELLE KOVACEVIC, JOHN DOE, JANE DOE, HER MAJESTY THE QUEEN AND THE ATTORNEY GENERAL OF CANADA

Defendants

JUDGMENT AND REASONS

I. Background

[1] This is a motion to strike pursuant to Rule 221(1)(a) of the *Federal Courts Rules*, SOR/98-106, in which the Defendants seek an order dismissing the action against all Defendants except Her Majesty the Queen.

A. *The Parties*

[2] The Plaintiffs in the underlying action (respondents in this motion) are Apotex Inc. ("Apotex"), and its two affiliate companies, which are located in India: Apotex Pharmachem India Pvt Ltd. ("APIPL"), and Apotex Research Private Limited ("ARPL") (collectively, the "Plaintiffs"). Apotex is a generic manufacturer and seller of pharmaceutical products in Canada. In addition to manufacturing pharmaceuticals, Apotex imports and sells drugs manufactured by its affiliates.

[3] The Defendants in the underlying action (applicants in this motion) are Rona Ambrose, Julie Vaux, Clark Olsen, Nick Switalski, Cailin Rodgers, George Da Pont, Paul Glover, Anil Arora, Anne Lamar, Supriya Sharma, Robin Chiponski, Mary Morgan, Steven Schwendt, Sharon Mullin, Barbara Sabourin, Karen Reynolds, Craig Simon, Michelle Kovacevic, John Doe, Jane Doe (together, the "Individual Defendants"), Her Majesty the Queen (the "Crown"), and the Attorney General of Canada (collectively, "the Defendants").

[4] Ms. Ambrose was the Minister of Health (the "Minister") between July 2013 and November 2015. Ms. Vaux was, at all relevant times, the Minister's Chief of Staff and most senior political advisor. Mr. Olsen and Ms. Rodgers were, at all relevant times, the Minister's Directors of Communications. Mr. Switalski was, at all relevant times, the Minister's senior special assistant. Mr. Da Pont was the federal Deputy Minister of Health, between August 2013 and January 2015. Mr. Glover is, and was at all relevant times, the federal Associate Deputy Minister of Health.

[5] Health Canada is the federal department that oversees the regulation of drug products in Canada. It consists of various branches, bureaus, and offices, including: (1) the Regions and Programs Bureau ("RAPB"), which is responsible for inspecting facilities that manufacture pharmaceutical products; and (2) the Health Products and Food Branch ("HPFB"), a branch that oversees a number of directorates. The directorates under the authority of the HPFB include (1) the Health Products and Food Branch Inspectorate (the "Inspectorate"), which is responsible for compliance and enforcement activities, and oversight of establishment licencing for facilities that manufacture pharmaceutical products; and (2) the Therapeutic Products Directorate ("TPD"), which is responsible for the federal regulation of pharmaceutical drugs and medical devices.

[6] Mr. Arora was the federal Assistant Deputy Minister of Health of the HPFB, between September 2014 and September 2016. Ms. Lamar is, and was at all relevant times, the federal Associate Assistant Deputy Minister of Health of the HPFB. Ms. Sharma was, at all relevant times until August 2015, the Senior Medical Advisor to the assistant Deputy Minister of Health

of the HPFB; in August 2015, she was appointed as the Senior Medical Advisor to the Deputy Minister of Health.

[7] Ms. Chiponski is, and was at all relevant times, the Director General of the Inspectorate. Mr. Schwendt was, at all relevant times, an employee of the Inspectorate and, for a period of time from 2015 to 2016, the Acting Director General of the Inspectorate. Ms. Mullin is, and was at all relevant times, an employee of the Inspectorate. Ms. Sabourin was, at all relevant times until January 2016, the Director General of the TPD. Ms. Reynolds is, and was at all relevant times, the Director of the TPD's Bureau of Pharmaceutical Sciences. Mr. Simon is, and was at all relevant times, the Associate Director of the TDP's Bureau of Pharmaceutical Sciences. Ms. Kovacevic is, and was at all relevant times, the Assistant Deputy Minister of Health of the Communications and Public Affairs Branch of Health Canada ("CPAB").

[8] Apotex has reserved the right to implead such further individuals who were also personally responsible for, or involved, in the decision and actions taken in this case, who are currently unknown to Apotex and identified herein as John Doe and Jane Doe.

B. *The Regulatory Regime*

[9] In Canada, the sale of drugs is highly regulated and depends upon compliance with federal legislation, which is designed to balance two competing interests—encouraging continued innovation in new drugs and promoting timely access to generic equivalents: (1) the *Patented Medicines (Notice of Compliance) Regulations* [*PM(NOC) Regs*] and (2) the *Food and Drug Act* [*FD Act*] and accompanying regulations [*FD Regs*] (collectively, the "Act and Regs").

These instruments set forth rules and requirements that deal with topics such as the classification of drugs, drug identification numbers ("DINs"), labelling, maintenance of records, conditions for drug manufacturing establishments, good manufacturing practices ("GMP"), and clinical trials.

[10] The Act and Regs are complemented by various policies and guidelines that set out the Minister's interpretation of these pieces of legislation. The Minister is nominally the person responsible for administering the Act and Regs. However, the Minister's power and discretion are, in reality, delegated to various groups and individuals within Health Canada.

(1) Drug Identification Numbers

[11] Every drug sold in Canada in a final dosage form is assigned a DIN by the Assistant Deputy Minister of Health of the HPFB. The assignment of a DIN occurs pursuant to the provisions of Part C, Division 1 of the *FD Regs*, upon application by either the manufacturer of the drug (in Canada), its agent, or by the importer.

[12] In an application for a DIN, the applicant must supply information according to Regulation C.01.014.1(2), which relates to the composition and labelling of the drug. If a manufacturer or importer has provided all of the information prescribed, the Director issues the manufacturer a DIN, unless the Director believes on reasonable grounds that the product is not a drug, that its sale would cause injury to the health of the consumer or purchaser, or that its sale would be a violation of the *FD Act* and the *FD Regs* (Regulation C.01.014.2).

[13] Under Regulation C.01.014.6(2), the Director may cancel the assignment of a DIN for a drug where:

a) the manufacturer of the drug has failed to comply with section C.01.014.5; or	a) si le fabricant de la drogue ne s'est pas conformé à l'article C.01.014.5; ou
b) the manufacturer to whom the number was assigned has been notified pursuant to section C.01.013 that the evidence he submitted in respect of the drug is insufficient.	b) si le fabricant à qui l'identification numérique a été attribuée a été avisé, selon l'article C.01.013, que les preuves présentées au sujet de la drogue sont insuffisantes.

(2) Notices of Compliance ("NOCs")

[14] In the case of a "new drug", the application for a DIN must also comply with the requirements of Part C, Division 8 of the *FD Regs*. A new drug is defined as (C.08.001):

(a) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component, that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug;	a) une drogue qui est constituée d'une substance ou renferme une substance, sous forme d'ingrédient actif ou inerte, de véhicule, d'enrobage, d'excipient, de solvant ou de tout autre constituant, laquelle substance n'a pas été vendue comme drogue au Canada pendant assez longtemps et en quantité suffisante pour établir, au Canada, l'innocuité et l'efficacité de ladite substance employée comme drogue;
(b) a drug that is a combination of two or more drugs, with or without other ingredients, and that has not been sold in that combination or in the proportion in which those drugs are combined in that drug, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that combination and proportion for use as a drug; or	b) une drogue qui entre dans une association de deux drogues ou plus, avec ou sans autre ingrédient, qui n'a pas été vendue dans cette association particulière, ou dans les proportions de ladite association pour ces drogues particulières, pendant assez longtemps et en quantité suffisante pour établir, au Canada, l'innocuité et l'efficacité de cette association ou de ces proportions employées comme drogue; ou

(c) a drug, with respect to which the manufacturer prescribes, recommends, proposes or claims a use as a drug, or a condition of use as a drug, including dosage, route of administration, or duration of action and that has not been sold for that use or condition of use in Canada, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that use or condition of use of that drug	c) une drogue pour laquelle le fabricant prescrit, recommande, propose ou déclare un usage comme drogue ou un mode d'emploi comme drogue, y compris la posologie, la voie d'administration et la durée d'action, et qui n'a pas été vendue pour cet usage ou selon ce mode d'emploi au Canada pendant assez longtemps et en quantité suffisante pour établir, au Canada, l'innocuité et l'efficacité de cet usage ou de ce mode d'emploi pour ladite drogue.

[15] To sell a new drug, the manufacturer has to file with the Minister a new drug submission ("NDS"), an extraordinary use new drug submission, an abbreviated new drug submission ("ANDS"), or an abbreviated extraordinary use new drug submission. The Minister must also have issued a NOC in respect of the new drug, which must not have been suspended, and the Minister must have received sufficient information from the manufacturer regarding the labelling of the new drug. The information submitted must be sufficient to enable the Minister to assess the safety and effectiveness of the new drug, and include the information prescribed by Regulation C.08.002(2). Upon request, the manufacturer may have to submit samples of the new drug and additional information or material respecting the safety and effectiveness of the new drug (C.08.002(3)).

[16] Generic pharmaceutical manufacturers, like Apotex, generally submit an ANDS, which does not typically include the results of clinical trials. Instead, an ANDS compares the drug formulation in question to a formulation, in the same dosage form, that is already on the market in Canada. These comparison studies include "comparative bioavailability studies" or "bioequivalence studies", which are used to establish equivalence with the approved drug.

[17] The generic manufacturer must also satisfy the requirements of the *PM(NOC) Regs*, which involve addressing whether the medicament in question is covered by any patents listed on the "Patent Register". The Minister's authority with respect to the review and issuance of NOCs is delegated to the Director General of the TPD.

(3) Establishment Licences ("ELs") and Good Manufacturing Practices ("GMP")

[18] Part C, Division 1A of the *FD Regs* governs the issuance, amendment, and suspension of ELs in Canada. Pursuant to Regulation C.01A.004(1)(a), no person shall fabricate, package/label, or import a drug except in accordance with an EL. The Minister has delegated the authority to oversee the EL regime to the Director General of the Inspectorate. The Inspectorate, with assistance from RAPB inspectors, is responsible for inspecting establishments that hold ELs, both within Canada and abroad.

[19] Inspections conducted by the Inspectorate and RAPB verify that establishments are complying with GMP, the requirements of which are contained in Part C, Division 2 of the *FD Regs*. In addition to the requirements set out in the *FD Regs*, the Minister publishes numerous guidance documents, which explain the compliance mechanisms available to remedy and enforce GMP deficiencies. Information about the Inspectorate, including directives, guidance documents, policies, and checklists can be found on Health Canada's website.

C. *Events underlying this action*

(1) Apotex's regulatory history

[20] Both prior and subsequent to September 30, 2014, Apotex held and continues to hold valid, unsuspended DINs and NOCs for the products from APIPL and ARPL that were the focus of an import ban, which was first announced and implemented on September 30, 2014 (the "Import Ban"). At no time were these DINs and/or NOCs suspended or cancelled.

[21] Both prior and subsequent to September 30, 2014, Apotex held and continues to hold valid ELs in respect to its manufacturing facilities in Canada, which allow Apotex to import products from APIPL and ARPL. Additionally, all of Apotex's facilities, in Canada and abroad, had been physically inspected by Health Canada's inspectors and found to be GMP-compliant.

(2) The Import Ban

[22] The Import Ban prevented the importation into Canada of drug products made at APIPL and/or ARPL. The Import Ban was implemented through two mechanisms: (1) shipments were detained by the Canadian Border Services Agency; and (2) terms and conditions were imposed on Apotex's ELs, prohibiting the import and sale of products from ARPL or APIPL. At the same time, the Defendants released public statements and press statements to justify the Import Ban, allegedly defaming the Plaintiffs (the "Public Statements").

[23] The purported basis for the Import Ban was that APIPL and ARPL were not compliant with GMP. However, none of the DINs or NOCs for any of the banned products were cancelled or suspended, nor were any of Apotex's ELs suspended, in accordance with sections of with the *FD Regs* that deal with GMP compliance. Instead, the Minister's action was taken pursuant to section C.01A.008 of the *FD Regs*.

[24] In October 2014, Apotex commenced an application for judicial review of the decision to implement the Import Ban. By Judgment dated October 14, 2015 (*Apotex Inc v Canada (Health)*, 2015 FC 1161), this Court quashed the Import Ban, finding that the Minister had acted for an improper purpose in implementing the ban (i.e., to ease media and political pressure) and had failed to act in accordance with the principles of natural justice. The Court also ordered the Minster and Health Canada to retract the Public Statements.

(3) The August 2015 Decision

[25] In June 2015, Health Canada conducted inspections of the APIPL and ARPL facilities. These inspections failed to identify any concerns. On August 31, 2015, Ms. Chiponski wrote to Apotex and advised that Heath Canada had decided to amend, in part, the terms and conditions it had imposed through the Import Ban (the "August 2015 Decision"). The amended terms and conditions provided that the Import Ban remain in place for products manufactured prior to June 10, 2015, and that products manufactured after June 10 be subject to further testing in Canada prior to their sale.

[26] In September 2015, Apotex commenced a second application for judicial review seeking to quash the August 2015 Decision. By Judgment dated June 15, 2016 (*Apotex Inc v Canada (Health)*, 2016 FC 673), this Court declared the August 15 Decision unlawful, on the basis that it was "infected" by the improper purpose that had motivated the Import Ban and that there was no evidence to support implementing or maintaining the August 15 Decision.

(4) The data integrity issue

[27] On or about September 23, 2014, the then-Director General of TPD, Ms. Sabourin, received a telephone call from a colleague at the Inspectorate, regarding data integrity at ARPL and APIPL, and an electronic copy of the FDA's Form 483. Shortly after, a draft NOC for Apotex's Apo-Rasagiline was delivered to Ms. Sabourin, indicating that APIPL and ARPL would be responsible for manufacturing and testing the drug product. Because of the GMP and data integrity concerns that had been raised regarding APIPL and ARPL, Ms. Sabourin declined to sign the draft NOC. Ms. Sabourin also informed Apotex that NOCs would not be issued for submissions containing data from APIPL and ARPL until further notice (the "November 2014 Decision"). Although it had already applied for judicial review of the Import Ban, Apotex implemented corrective and preventative action to address these GMP and data integrity concerns.

[28] In January 2015, the TPD 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 given formal notice of this policy on May 22, 2015. In June 2015, the TPD conducted further inspections of the APIPL and ARPL facilities. Overall,

the TPD's findings did not identify any instances of data integrity violations, which had been previously observed by the FDA. However, the TPD determined that, although the new system controls and modified procedures satisfactorily addressed the data integrity concerns, additional supervision was necessary to demonstrate the sustainability and effectiveness of these procedures during times of increased production.

[29] In the fall of 2015, Apotex began proceedings in the Federal Court challenging the November 2014 Decision, and its continuation by the new Director General of the TPD, Marion Law. By Judgment dated March 27, 2017 (*Apotex v Canada*, 2017 FC 315), the Court found that Health Canada's continued refusal to grant NOCs for Apo-Varenicline and Apo-Sitagliptin, the only two products for which the TPD continued to require additional data integrity information as of the date of the hearing before the Federal Court, was neither improper nor unreasonable.

II. The Issues

[30] In their written submissions in support of this motion, the Plaintiffs state that they do not object to the removal of the Attorney General of Canada as a party, provided that the Crown undertakes not to raise any issue, pursuant to section 23 of the *Crown Liability and Proceedings Act*, RSC 1985, c C-50, or otherwise, as to the sufficiency of naming "Her Majesty the Queen" as the proper party in respect to the Plaintiffs' claims against the Crown.

[31] The Defendants do not dispute that the Federal Court has jurisdiction over claims against the Crown. The style of cause, in this action, is hereby ordered to be amended to delete the Attorney General of Canada.

[32] Therefore, the sole issue remaining to be determined in this motion is whether the Federal Court has jurisdiction over the claims made against the Individual Defendants.

[33] Based upon the written material before the Court and the arguments presented at the hearing by the Parties, I dismiss the motion to strike. For the reasons that follow, I find that it is not plain and obvious that the Federal Court lacks jurisdiction over the Individual Defendants.

III. Analysis

A. *The Applicable Test on a Motion to Strike*

[34] Rule 221(1)(a) governs the Defendants' motion to strike as pleaded:

221 (1) On motion, the Court may, at any time, order that a pleading, or anything contained therein, be struck out, with or without leave to amend, on the ground that it	221 (1) À tout moment, la Cour peut, sur requête, ordonner la radiation de tout ou partie d'un acte de procédure, avec ou sans autorisation de le modifier, au motif, selon le cas :
(a) discloses no reasonable cause of action or defence, as the case may be …	a) qu'il ne révèle aucune cause d'action ou de défense valable;
and may order the action be dismissed or judgment entered accordingly.	Elle peut aussi ordonner que l'action soit rejetée ou qu'un jugement soit enregistré en conséquence.

[35] The Supreme Court of Canada, in *R v Imperial Tobacco*, 2011 SCC 42 at paragraph 17, laid out the applicable test on a motion to strike:

> A claim will only be struck if it is plain and obvious, assuming the facts pleaded to be true, that the pleading discloses no reasonable cause of action. Another way of putting the test is that the claim has no reasonable prospect of success. Where a reasonable prospect of success exists, the matter should be allowed to proceed to trial.

> [citations omitted]

[36] The Defendants point out that the *Federal Courts Rules* do not contain a specific provision for striking a claim on the basis that the Federal Court does not have jurisdiction to hear the claim. They argue that the plain and obvious test is ill-suited for issues of Federal Court jurisdiction because, unlike striking a claim for other reasons, the success of a jurisdictional question rarely depends on evidence that will be adduced during discovery. The Defendants also suggest that this difference makes it appropriate to modify the standard on a motion to strike for want of jurisdiction to a balance of probabilities. Further, the Defendants suggest that the double negative situation, which is a possible result under the current test—i.e., a finding that it is not plain and obvious that the Court does not have jurisdiction—can lead to a situation where jurisdiction is not completely determined until trial, which is not ideal.

[37] The Plaintiffs submit that the plain and obvious test is the correct test for challenging Federal Court jurisdiction on a motion to strike under Rule 221(1)(a). They suggest that it is appropriate for the Court to apply a stringent test to the jurisdictional question, because the consequence of finding that the Court does not have jurisdiction deprives the Plaintiffs of their chosen forum. Moreover, they rely on relevant Federal Court of Appeal jurisprudence and the recent Supreme Court of Canada decision *City of Windsor v Canadian Transit Co*, 2016 SCC 54 at paragraph 24 [*City of Windsor*], which endorse the plain and obvious standard:

> The sole issue is whether the Federal Court has jurisdiction under the ITO test to hear the Company's application. If it is plain and obvious that the Federal Court lacks jurisdiction to hear this application, the motion to strike must succeed.

[38] While the Defendants' concern that the jurisdictional question should not be left to be determined at trial may have merit, I disagree that the plain and obvious test is ill-suited or that the standard on a motion to strike for want of jurisdiction should be changed to a balance of probabilities. The history of the test for a motion to strike under Rule 221(1) was canvassed, in 2002, by Prothonotary Hargrave in the decision *Charlie v Vuntut Gwitchin First Nation*, 2002 FCT 344 [*Vuntut*]. In finding that the plain and obvious test, where the standard is beyond a doubt, is appropriate, he stated (*Vuntut* at paras 10, 16 to 18):

> [10] The test for striking out for want of a cause of action, that it be plain, obvious and beyond doubt that a claim or a defence will not succeed, as in the well known trilogy of cases, *Hunt v Carey Canada Inc*, [1990] 2 SCR 959, *Operation Dismantle Inc v The Queen*, [1985] 1 SCR 441 and *Canada v Inuit Tapirisat of Canada*, [1980] 2 SCR 735, is so solidly established that it is no longer usually necessary to dwell on the test. However, in the present instance, the Vuntut Gwitchin Defendants say that the test for striking out for want of jurisdiction is less stringent, submitting that the approach to strike out is really akin to answering a question of law and further, that the burden shifts to the Plaintiff to show, positively, that there is jurisdiction. Here the Vuntut Gwitchin Defendants refer to several examples which they submit support the position that the test for striking out for want of jurisdiction is a preponderance of evidence or a balance of probabilities.
>
> …
>
> [16] Fortunately, this somewhat unproductive discussion of procedure and seeming inconsistent standards on motions to strike out for want of jurisdiction has been laid to rest in *Hodgson v The Queen*. In my reasons of 10 September 1999, in action T-2553-91, I set out at paragraph 28 that I would only find want of jurisdiction where a matter was plain, obvious and beyond doubt, which was not there the case.
>
> [17] On appeal to the Trial Division, Madam Justice Reed was squarely faced with that test as a ground for appeal. In denying the appeal she found that the plain and obvious test applied:
>
> > . . . The "plain and obvious" test applies to the striking out of pleadings for lack of jurisdiction in

> the same manner as it applies to the striking out of any pleading on the ground that it evinces no reasonable cause of action. The lack of jurisdiction must be "plain and obvious" to justify a striking out of pleadings at this preliminary stage.
>
> That finding was not changed when Mr. Justice of Appeal Rothstein denied the appeal. While he noted that counsel for the Defendants conceded the test, it was that test which the Court of Appeal in fact applied in allowing the action to proceed. An application in Hodgson for leave to appeal was dismissed by the Supreme Court of Canada on 6 September 2001.
>
> [18] While some jurisdictional issues ought not to be decided until trial, when all of the facts on the question are before the Court, in other instances jurisdiction may be decided in a summary way. In such an instance it is the usual plain, obvious and beyond doubt test which applies in striking out for want of jurisdiction. Of course, to reach that conclusion, one must initially test jurisdiction on the basis of *Miida Electronics Inc v Mitsui OSK Lines Ltd and ITO-International Terminal Operators Ltd*, [1986] 1 SCR 752.

[39] I concur. The plain and obvious test is the correct test to use when determining whether a claim should be struck because the Federal Court lacks jurisdiction.

B. *The test for Federal Court jurisdiction*

[40] The Parties agree that the appropriate test to determine whether the Federal Court has jurisdiction over a matter is the test articulated by the Supreme Court in *ITO-International Terminal Operators v Miida Electronics Inc*, [1986] 1 SCR 752 [*ITO*]:

> 1. There must be a statutory grant of jurisdiction by Parliament.
>
> 2. There must be an existing body of federal law which is essential to the disposition of the case and which nourishes the statutory grant of jurisdiction.
>
> 3. The law on which the case is based must be “a law of Canada” as the phrase is used in section 101 of the Constitution Act, 1867.

[41] However, the Parties do not agree as to whether or how *City of Windsor*, above, applies to the proper determination of jurisdiction of this Court.

[42] Further, the Defendants argue that, at the time of the events pleaded, all the Individual Defendants were servants or agents of the Crown and, therefore, the Crown is vicariously liable for their actions pursuant to the *Crown Liability and Proceedings Act.* It is true that the Crown is vicariously liable for torts committed by the Individual Defendants as servants or agents of the Crown. However, this does not preclude the Federal Court from having jurisdiction over the Individual Defendants, should the *ITO*-test be satisfied.

C. *Essential nature of the claim*

(1) Does the essential nature of the claim need to be determined?

[43] The Defendants argue that, subsequent to *City of Windsor*, the first step in determining jurisdiction, before turning to the *ITO*-test, is to characterize the essential nature of the claim. They state that the essential nature of the Plaintiffs' claims against the Individual Defendants is based in tort. The Defendants stress the personal nature of the torts claimed and assert that these private law causes of action, as pleaded by the Plaintiffs, cannot be said to arise from federal law merely because they include, as a component, an allegation of an invalid or unlawful exercise of statutory duty or power.

[44] The Plaintiffs contend that the Supreme Court's direction to characterize the nature of the claim at issue is not applicable to this action because the claims arise under section 17(5)(b) of

the *Federal Courts Act*, RSC 1985, c F-7, not section 23(c) as was the case in *City of Windsor*. They argue that the majority of the Supreme Court was only considering the test to be applied when determining whether the Federal Court has jurisdiction over a claim arising under section 23(c). Further, they submit that, because the language of section 17(5)(b) is very different from section 23(c), it is clear that the Supreme Court in *City of Windsor* intended for this step of determining the essential nature of the claim to be limited in application to section 23.

[45] Section 17(5) of the *Federal Courts Act* states:

Relief in favour of Crown or against officer	**Actions en réparation**
(5) The Federal Court has concurrent original jurisdiction	(5) Elle a compétence concurrente, en première instance, dans les actions en réparation intentées :
(a) in proceedings of a civil nature in which the Crown or the Attorney General of Canada claims relief; and	a) au civil par la Couronne ou le procureur général du Canada;
(b) in proceedings in which relief is sought against any person for anything done or omitted to be done in the performance of the duties of that person as an officer, servant or agent of the Crown.	b) contre un fonctionnaire, préposé ou mandataire de la Couronne pour des faits — actes ou omissions — survenus dans le cadre de ses fonctions.

[46] Section 23 of the *Federal Courts Act* states:

Bills of exchange and promissory notes — aeronautics and interprovincial works and undertakings	**Lettres de change et billets à ordre — Aéronautique et ouvrages interprovinciaux**
23 Except to the extent that jurisdiction has been otherwise specially assigned, the Federal Court has concurrent original jurisdiction, between subject and subject as well as otherwise, in all cases in which a claim for relief is made or a remedy is sought under an Act of Parliament or	**23** Sauf attribution spéciale de cette compétence par ailleurs, la Cour fédérale a compétence concurrente, en première instance, dans tous les cas — opposant notamment des administrés — de demande de réparation ou d'autre recours exercé sous le régime d'une loi fédérale ou d'une

otherwise in relation to any matter coming within any of the following classes of subjects:	autre règle de droit en matière :
(a) bills of exchange and promissory notes, where the Crown is a party to the proceedings;	a) de lettres de change et billets à ordre lorsque la Couronne est partie aux procédures;
(b) aeronautics; and	b) d'aéronautique;
(c) works and undertakings connecting a province with any other province or extending beyond the limits of a province.	c) d'ouvrages reliant une province à une autre ou s'étendant au-delà des limites d'une province.

[47] The Parties both refer the Court to paragraph 25 of *City of Windsor*, wherein Justice Karakatsanis, writing for the majority, stated:

> In order to decide whether the Federal Court has jurisdiction over a claim, it is necessary to determine the essential nature or character of that claim. As discussed in further detail below, s. 23(c) of the *Federal Courts Act* only grants jurisdiction to the Federal Court when a claim for relief has been made, or a remedy has been sought, "under an Act of Parliament or otherwise". The conferral of jurisdiction depends on the nature of the claim or remedy sought. Determining the claim's essential nature allows the court to assess whether it falls within the scope of s. 23(c). Jurisdiction is not assessed in a piecemeal or issue-by-issue fashion.
>
> [citations omitted]

[48] Thus, while the preliminary characterization step is mandated, it is simply identifying the material facts needed to assess whether the claim falls within the statutory grant of jurisdiction identified in the first step of the *ITO*-test.

(2) Does the essential nature of a claim under section 17(5)(b) have to arise from federal law?

[49] The Defendants argue that the essence of the claims against the Individual Defendants is based on alleged breaches of private law duties. They state that *City of Windsor* stands for the principle that in order for the Federal Court to have jurisdiction over these types of claims they must arise under a federal law that is separate from section 17(5)(b). Additionally, the Defendants rely on *Canada (AG) v Telezone Inc*, 2010 SCC 62 at paragraphs 28 to 30 [*Telezone*] to support their assertion that causes of action in tort cannot be said to arise from federal law and, therefore, do not fall within the Federal Court's jurisdiction simply because they include allegations of invalid or unlawful exercises of statutory duty or power.

[50] The jurisdictional question in *City of Windsor* involved section 23, which explicitly states that the Federal Court has jurisdiction in cases where a claim for relief is sought "under an Act of Parliament or otherwise". Justice Karakatsanis interpreted this to mean that the right to seek relief must arise directly from federal law, and not merely in relation to federal law (*City of Windsor* at paras 46 to 48). However, section 17(5)(b) does not have this limitation; rather, it states that the Federal Court has jurisdiction with respect to claims for relief "sought against any person for anything done or omitted to be done in the performance of the duties of that person as an officer, servant or agent of the Crown".

[51] The Defendants are correct that breaches of statutory power do not automatically lead to related claims in tort being within the jurisdiction of the Federal Court. However, *Telezone* was concerned with the question of whether a claim for compensation could proceed in a Superior

Court without the plaintiff having had the Federal Court, prior to the commencement of the proceedings in the Superior Court, quash the underlying decision on judicial review; not whether the Federal Court had jurisdiction to hear claims for relief arising out of tort, or how the question of jurisdiction over claims in tort should be determined

[52] Further, at paragraph 58 of *Telezone*, Justice Binnie, writing for the unanimous Supreme Court, quoted the following statements made by the Minister of Justice in 1989, when amendments were being made to section 17 of the *Federal Courts Act*:

> For example, a person should be able to sue the Crown in a suitably convenient court for breach of contract to purchase goods or for negligent driving by a Crown employee that causes injuries to another motorist…
>
> …
>
> With this in mind, the government has proposed that both the provincial courts and the Federal Court share jurisdiction with respect to such actions, thereby generally giving a plaintiff a choice of forum.
>
> [citations omitted, emphasis in original]

[53] Justice Binnie concluded that section 17 had to be read in such a manner that gives the Plaintiffs a choice of forum, thereby making available to the Plaintiffs relief in a court that was more "familiar" to them (*Telezone* at para 59). Therefore, contrary to the Defendants' argument, *Telezone* stands for the principle that if an action in tort comes within the scope of section 17, the Plaintiffs should have their choice of forum.

[54] Further, nothing in *City of Windsor* suggests that Justice Karakatsanis was contradicting Justice Binnie's conclusion in *Telezone*: the Plaintiffs have a choice of forum in the cases of a

breach of contract or tort, such as negligence, which properly come before the Federal Court under section 17. In fact, an examination of the trial level decision which led to *City of Windsor, Canadian Transit Company v Windsor (City)*, 2014 FC 461 [*Canadian Transit Company*], shows that the factual situation underlying *City of Windsor* was very different from the factual matrix in this case, and puts the Supreme Court's decision and their comments about section 23(c) into context.

[55] In *City of Windsor*, the underlying claim involved a dispute between the Canadian Transit Company and the City of Windsor over 114 vacant properties that had become a blight on the community, and for which the City of Windsor had issued repair orders. The Canadian Transit Company appealed these orders to the Property Standards Committee, a municipal board that hears appeals of orders made by the City's Property Standards Officer.

[56] At the trial level, the primary relief requested by the Canadian Transit Company was for a declaration that the Ambassador Bridge be considered a "federal undertaking" and, as such, not subject to municipal by-laws (*Canadian Transit Company* at para 6). The City of Windsor, in response, brought an application asking the Court to strike the claim for want of jurisdiction. In assessing the application to strike, Justice Michel Shore commented (*Canadian Transit Company* at paras 12 to 13, and 15):

> [12] Without deciding this matter on the merits, the Court is of the view that it is plain and obvious that the application lacks a reasonable cause of action and that it is bereft of any possibility of success. Even on a generous reading of the Applicant's Notice of Application, it is extremely unclear what exactly the Applicant is asking of the Court. The Applicant does not appear to be challenging any particular decision of the City of Windsor, the Property Standards Committee, or any order of a federal board,

> commission or other tribunal. Rather, the Applicant appears to be simply seeking a legal opinion regarding the applicability of the AICTC from the Court.
>
> [13] The Court does not have the statutory authority to grant such a remedy. A reference to the Court can only be sought by the Attorney General of Canada or a federal board, commission or other tribunal over which the Court otherwise exercises judicial review functions pursuant to paragraphs 18.3 (1) and (2) of the *Federal Courts Act*, RSC 1985, c F-7. It cannot be used by private applicants as a tool to obtain a declaratory judgment from this Court.
>
> …
>
> [15] The Court also finds that it is equally unclear what legal basis the Applicant has relied upon in bringing the application to the Court. The Applicant issued the Notice of Application on the basis of paragraph 23(c) of the *Federal Courts Act*; however, paragraph 23(c) only constitutes a statutory grant of jurisdiction to the Court by the Federal Parliament. The provision does not grant any right of appeal or judicial review to an applicant, nor does it give the Court the authority to grant a declaratory remedy.
>
> [citations omitted]

[57] In this case, unlike City of Windsor, it is clear what the Plaintiffs are requesting: relief against officers of the Crown for anything done or omitted, resulting from activities that are deeply rooted in the framework of the Act and Regs, which harmed the Plaintiffs. As is evident from the discussion in *Telezone*, this Court has the statutory authority to adjudicate claims in tort and contract which properly come before the Court under section 17 of the *Federal Courts Act*. Therefore, the Defendants' statement that the private law causes of action pleaded, in this case, must arise from a separate federal law and cannot be a claim in tort in order for the Federal Court to have jurisdiction, is incorrect.

(3) What is the essential nature of the claims?

[58] Justice Karakatsanis, at paragraphs 26 to 27 of *City of Windsor*, provided the following directions to a court determining the essential nature of a claim:

> The essential nature of the claim must be determined on a "realistic appreciation of the practical result sought by the claimant". The "statement of claim is not to be blindly read at its face meaning". Rather, the court must "look beyond the words used, the facts alleged and the remedy sought to ensure … that the statement of claim is not a disguised attempt to reach before the Federal Court a result otherwise unreachable in that Court".
>
> On the other hand, genuine strategic choices should not be maligned as artful pleading. The question is whether the court has jurisdiction over the particular claim the claimant has chosen to bring, not a similar claim the respondent says the claimant really ought, for one reason or another, to have brought.
>
> [citations omitted]

[59] There is no dispute between the Parties that the action as against the Crown is appropriately before the Federal Court, and that the essential nature of that claim falls within the scope of the Court's jurisdiction.

[60] The issues in the underlying action as pleaded by the Plaintiffs are:

1) Did the Defendants knowingly and in bad faith act unlawfully outside the scope of their authority?
2) Did the Defendants owe the Plaintiffs a duty of care, and fail to exercise reasonable skill, care, and diligence in their interpretation and discharge of their duties and responsibilities under the *FD Act*, the *FD Regulations*, or otherwise at law?
3) Did the Defendants defame the Plaintiffs?
    a. Should the Plaintiffs receive elevated damages by reason of the method of publication of the allegedly defamatory statements and the remaining website content?
4) Did the Defendants conspire to inflict damage upon the Plaintiffs?
5) Should the Plaintiffs receive public law damages or other similar monetary relief?

6) Should the Plaintiffs receive punitive and exemplary damages?

[61] The Plaintiffs seek the following relief against the Defendants, jointly and severally:

1) general, special, aggravated, and punitive damages in the total amount of $500,000,000.00;
2) an interlocutory or a permanent injunction and a mandatory order (or the equivalent declaratory relief) requiring the Defendants to:
    a. cease publication of, and to formally retract and otherwise remove, all remaining defamatory content from their websites, as detailed in the Statement of Claim;
    b. to process Apotex's ANDSs for regulatory approval without any super-added requirement of having to demonstrate "data integrity";
3) an equitable bill of discovery, requiring the Defendants to identify any and all individuals who were involved in and agreed to the decision to implement and sustain the Import Ban, the publication of the defamatory statements, and the data integrity package requirement;
4) pre-judgment and post-judgment interest;
5) the cost of this action; and
6) such further and other relief as this Honourable Court deems just.

[62] The Plaintiffs have alleged multiple wrongdoings, many of which, if proven, could lead the Court to grant all the relief requested. As such, the Court must determine the essential character of each claim made by the Plaintiffs and determine whether each falls within the scope of section 17(5)(b).

[63] Misfeasance in public office requires the Plaintiffs to show that the Defendants had a "deliberate disregard of official duty, coupled with knowledge that the misconduct was likely to injure the [Plaintiffs]" (*Odhavji Estate v Woodhouse*, 2003 SCC 69 at para 23). Thus, the essential nature of the Plaintiffs' claim in misfeasance in public office, against the Individual Defendants, is whether their actions or omissions conformed to actions that were authorized or required by the Act and Regs. That is, were the Individual Defendants carrying out functions pursuant to federal statute, and in the course of their duties as servants of the Crown, in a manner

where they (1) disregarded the boundaries of their authority or the scope of their duties; and (2) had the means/understanding to know, or a reckless disregard for or a wilful blindness of, the harm would likely come to the Plaintiffs because of their actions?

[64] The principle elements of the tort of negligence are: (1) the existence of a duty of care owed by a defendant to a plaintiff; (2) a breach by the defendant of the duty of care; and (3) damage caused to a plaintiff by the breach (*Donoghue v Stevenson*, [1932] AC 562 at 580 (HL); *Anns v Merton London Borough Council*, [1978] SC 728, at 751 to 752 (HL)). The essential nature of the claim for negligence is whether the operation of the Act and Regs creates a duty of care owed by any of the Individual Defendants to the Plaintiffs. Put another way, did the duties of the Individual Defendants, as governed by the Act and Regs, or the interactions between the Individual Defendants and the Plaintiffs within the context of the regulatory regime governing the manufacture and import of drugs, create a relationship of proximity, such that any of the Individual Defendants owed the Plaintiffs a duty of care?

[65] Additionally, in determining whether any of the Individual Defendants are liable for negligence, the Court will have to ascertain the standard of care owed to the Plaintiffs. This will also require careful consideration of the Act and Regs.

[66] The legal elements of conspiracy are as follows (*Cement Lafarge v BC Lightweight Aggregate*, [1983] 1 SCR 452):

1) two or more persons acting in combination by agreement or with a common design; and
2) (a) the predominant purpose of the conduct is to cause the Plaintiff injury, whether or not the means were lawful; or (b) unlawful conduct directed towards the Plaintiff, in circumstances that the Defendants should know that an injury to the Plaintiff is likely.

[67] In this case, the alleged injury caused to the Plaintiffs is an injury that was effected through conduct that the Individual Defendants were in the position to perform because of their positions as Health Canada employees. Therefore, the essential nature of this claim is whether the Individual Defendants performed their duties in a manner that (1) was by agreement or common design, outside of coordination contemplated by the statutory framework, and (2) for the purpose of causing the Plaintiffs injury, or in circumstances where the Individual Defendants knew, or should have known, that an injury to the Plaintiffs was likely.

[68] In *Colour You World Corp v CBC* (1998), 156 CLR (4th) 27 at 36 (ONCA), Justice Abella (as she then was) defined defamation as follows:

> A defamatory statement is one which has a tendency to injure the reputation of the person to whom it refers; which tends, that is to say, to lower him [or her] in the estimation of right-thinking members of society generally and in particular to cause him [or her] to be regarded with feelings of hatred, contempt, ridicule, fear, dislike, or disesteem. The statement is judged by the standard of an ordinary, right-thinking member of society. Hence the test is an objective one…

[69] The Plaintiffs allege that the Individual Defendants are liable for defamation because of the Public Statements. However, some of the Individual Defendants, namely the Minister and Individual Defendants whose job titles indicate that they are responsible for communications, may have a duty to keep the public informed about the activities of Health Canada, particularly with regards to measures taken to ensure public safety. As such, it is not clear without analysis of the statutory and policy framework of the Act and Regs that the Public Statements were not made in a manner that would provide some of the Individual Defendants with a defense to the claim of defamation: for example qualified privilege, if the tort of defamation is made out.

[70] Therefore, the essential nature of this claim is whether the Individual Defendants were making statements damaging the Plaintiffs' reputation, in a manner for which the statutory framework provides no defense.

[71] Finally, monetary relief in public law is the novel cause of action proposed in *Paradis Honey Ltd v Canada*, 2015 FCA 89 at paragraphs 116 to 118 [*Paradis Honey*], also called abusive administrative action. Although, this novel cause of action has yet to be litigated, liability for the Individual Defendants would seem to be based on whether their actions or omissions in the performance of their duties were administratively acceptable. From this Court's decisions regarding the Import Ban, the August 2015 Decision, and the November 2014 Decision, the essential nature of each action or omission will have to be assessed against the statutory framework created by the Act and Regs to determine whether it was administratively acceptable.

(4) Conclusion on the essential nature of the claims

[72] Based upon the analysis above, I find that the essential nature of the Plaintiffs' claims are as follows:

1) Misfeasance: were the Individual Defendants carrying out functions pursuant to the Act and Regs, in the course of their duties as servants of the Crown, and disregarding the boundaries of their authority with knowledge or reckless disregard of the fact that the Plaintiffs would be harmed?
2) Negligence: did the duties of the Individual Defendants, as servants of the Crown, or the interactions between the Individual Defendants and the Plaintiffs, within the context of the regulatory regime under the Act and Regs governing the manufacture and import of drugs, create a relationship of proximity? If so, was the duty of care breached, causing the Plaintiffs harm?
3) Conspiracy: did the Individual Defendants perform their duties in a manner that was, by agreement or common design, outside of any cooperation contemplated by the statutory

and policy framework of the Act and Regs, to purposefully cause the Plaintiffs injury, or in circumstances where the Individual Defendants knew, or ought to have known, that an injury to the Plaintiffs was likely?

4) Defamation: did the Individual Defendants make statements that would damage the Plaintiffs' reputation in the eyes of an ordinary, right-thinking member of society, in a manner for which the statutory framework of the Act and Regs provides no defense?
5) Monetary relief in public law: were the actions or omissions of the Individual Defendants, in the course of the performance of their duties pursuant to the Act and Regs, administratively acceptable?

[73] Given a contextual and purposive interpretation, the Plaintiffs' claims have the following overarching essential nature: did the Individual Defendants do or omit to do anything, in the performance of their duties as servants of the Crown, under the Act and Regs, and in a manner that was outside of their authority or for an improper purpose, that gives rise to valid claims for relief as pleaded in this proceeding?

D. *ITO-test: Is there a statutory grant of jurisdiction?*

[74] The Parties agree that section 17(5)(b) of the *Federal Courts Act* creates the specific statutory grant of jurisdiction that would be applicable to this action: "in proceedings in which relief is sought against any person for anything done or omitted to be done in the performance of the duties of that person as an officer, servant or agent of the Crown". I find that the overarching essential nature of each of the claims against the Individual Defendants is within the scope of this section, such that there is a specific statutory grant of jurisdiction to the Federal Court.

E. *ITO-test: Is there an existing body of federal law which is essential to the disposition of the case and which nourishes the statutory grant of jurisdiction?*

[75] The Defendants argue that there is a "traditional" line of authority in the Federal Court and Federal Court of Appeal that has maintained that tort claims against individually named Crown servants cannot be pursued in Federal Court. This line of authority purportedly stands for the proposition that both a defendant's liability and a plaintiff's right to damages in tort are provided for by provincial common law, and that it is insufficient that the claims in tort involve alleged misuses of powers or breaches of duties owed under federal statute.

[76] The Defendants also state that only claims for breach of contract, in cases where federal statutes govern every aspect of the contractual relationship, are within the Federal Court's jurisdiction. They assert that a similar logic does not apply to claims in tort, and rely on various cases in support of this pronouncement: *Ingle v Canada*, [1984] 2 FC 57 (FCTD); *Stephens*

Estate v R, [1982] FCJ No 114 (FCA); *Leblanc v R*, 2003 FC 776; *Stoney Band v Canada (Minister of Indian and Northern Affairs)*, 2005 FCA 220.

[77] The Plaintiffs contend that the cases presented by the Defendants are distinguishable from this case, and that there is another line of jurisprudence that is more aligned with the facts here, starting with *R v Rhine; R v Prytula*, [1980] 2 SCR 442 [*Rhine/Prytula*], which holds that, where federal legislation provides a detailed statutory framework governing every aspect of the relationship between the parties, a claim in contract or tort can be brought in Federal Court. They rely on the following cases for the principle that the Federal Court has jurisdiction over cases that are in "pith and substance", based on federal law: *Peter G White Management Ltd v Canada (Minister of Canadian Heritage*), 2006 FCA 190 [*Peter G White*]; *Oag v Canada*, [1987] 2 FC 511 (FCA); *Kigowa v Canada*, [1990] 1 FC 804 (FCA); *Gottfriedson v Canada*, 2014 FCA 55; *Maguire v Canada*, [1990] 1 FC 742; *Abdelrazik v Canada*, 2009 FC 580; and *Dickson v Canada*, 2016 FC 836 [*Dickson*].

[78] The Defendants' assertion that tort claims are solely within the jurisdiction of the provincial superior courts because they arise from the common law is not correct. In *Rhine/Prytula* at 447, the Supreme Court articulated the principle that "'contract' or other legal institutions, such as 'tort' cannot be invariably attributed to sole provincial legislative regulation or be deemed to be, as common law, solely matters of provincial law".

[79] Having reviewed the cases relied upon by the Parties, I agree that the cases relied on by the Plaintiffs are more similar to this case than the cases presented by the Defendants. In

particular, the facts in this action are similar to those in *Peter G White*, where the right to operate the gondola was created by a leasing and management regime that was governed by federal legislation. Here, the Plaintiffs' rights to manufacture and import drugs are created by the specific statutory framework of the Act and Regs.

[80] In *Peter G White*, the plaintiff ("PGW") leased Crown land in Banff National Park, where it operated a ski hill. PGW was never able to operate the gondola lift outside of the winter season, having been twice refused a licence by Field Unit Superintendents of Banff National Park, under the *National Parks Businesses Regulations* (the "Park Defendants"). Further, in a management plan for the park, which was tabled in the House of Commons, pursuant to the *National Parks Act*, the summer use of the gondola was prohibited. PGW brought an action for damages in the Federal Court for relief against the Park Defendants, who were Crown servants, alleging that they were liable for breach of a lease and abuse of public office.

[81] The Federal Court of Appeal stated that section 17(5)(b) of the *Federal Courts Act* "expressly contemplates that Crown servants may be sued" and that "in determining the liability of a Crown servant or officer, no distinction should be drawn between the individual's 'official' versus 'unofficial' actions"; therefore, individual Crown servants should not be struck as defendants on the grounds that their allegedly tortious acts occurred in the course of their duties as a servant or officer of the Crown (*Peter G White* at paras 44 to 47). The Federal Court of Appeal further held that the Federal Court has jurisdiction over cases in tort which are in pith and substance based on federal law and when parties' rights arise under and are extensively governed by a detailed statutory framework (*Peter G White* at paras 54 to 60).

[82] The Federal Court of Appeal found that PGW's rights under the lease were created in a legal environment that is heavily regulated by federal legislation because the "federal legislation provides parameters within which leases in national parks may be granted", and PGW's rights are expressly made subject to applicable federal legislation and the need to obtain any necessary licence (*Peter G White* at paras 68, 70). Therefore, the Court of Appeal found that "federal legislation provide[d] a sufficiently detailed framework to nourish and support the grant of federal jurisdiction in this case" (*Peter G White* at para 72).

[83] The Defendants argue *Peter G White* is the "high-water mark" of expansive Federal Court jurisdiction, and that Justice Karakatsanis' comments in *City of Windsor*, at paragraph 69, indicate that cases in which an expanded view of the Federal Court's jurisdiction was taken deviate from the restrictions outlined by the Supreme Court in *ITO*:

> These articulations of the test should not be understood to lower in any way the high threshold articulated in *ITO* itself. The fact that the Federal Court may have to consider federal law as a necessary component is not alone sufficient; federal law must be "essential to the disposition of the case". It must "nourish" the grant of jurisdiction.

[84] However, the cases referred to regarding "these articulations"—*Bensol Customs Brokers Ltd v Air Canada*, [1979] 2 FCR 575 [*Bensol*]; and *The Queen v Montreal Urban Community Transit Commission*, [1980] 2 FC 151 [*Montreal Urban Community*]—are distinguishable on their facts and the standard that these cases articulated provided a lower standard than the standard to be applied in this matter. For example, in *Bensol* at 582 to 583, which is quoted in *Montreal Urban Community*, Justice Le Dain states:

> It should be sufficient in my opinion if the rights and obligations of the parties are to be determined by some material extent by federal

> law. It should not be necessary that the cause of action be one that is created by federal law so long as it is one affected by it.

[85] Moreover, many of the cases relied on by the Plaintiffs were referenced in the Federal Court of Appeal decision *Canadian Transit Co v Windsor (City)*, 2015 FCA 88, and were squarely brought to the attention of the Supreme Court. In my opinion, the cautions of the majority in *City of Windsor* against an expansion of the Federal Court's jurisdiction do not create a new position on the standard laid out in *ITO*. These cautions simply serve to remind the Court of the requirement that the underlying federal statutory framework must be essential to the disposition of the case and must nourish the grant of jurisdiction to the Federal Court. For the reasons that follow, I find that the Act and Regs meet these standards, as articulated in both *ITO* and *City of Windsor*.

[86] The Act and Regs create the rights which the Plaintiffs allege were trammelled. The rights to sell, import, and manufacture drugs are entirely created by federal statute. It is a comprehensive scheme, such that no other common law doctrine informs the scope of these rights. Further, the Act and Regs define the scope of the Minister's and Health Canada's authority and create the metric against which the lawfulness of their actions will be measured. This is particularly true with regards to the allegations of misfeasance in public office and negligence. For example, in addition to the requirements for GMP set out in Part C, Division 2 of the *FD Regs*, the Minister publishes guidelines that explain that any GMP deficiencies noted during an inspection are to be explained unambiguously and directly supported by the *FD Regs*, and also explain the compliance mechanisms available to remedy and enforce GMP deficiencies. Similarly, the issuance, amendment, and suspension of ELs are governed by the *FD Regs.*

[87] In my opinion, the interpretation and application of the Act and the Regs will be essential to the disposition of each of the Plaintiffs' claims due to the nexus that exists between the federal laws and the material facts pleaded against the Individual Defendants. As such, the Act and Regs provide the context required to assess the relevant facts in each claim.

(1) Misfeasance in public office

[88] The Defendants' official duties with regards to the Plaintiffs were all prescribed by and detailed in the Act and Regs. Additionally, all of the Plaintiffs' rights to import and sell drugs are regulated and arise from the Act and Regs. Further, the Defendants' knowledge of the potential injury to the Plaintiffs would be based upon their understanding of and familiarity with the Act and Regs. For example, the *FD Act*, section 31.2, makes it an offense to sell or import therapeutic products in contravention with the *FD Act* and the *FD Regulations*, with the maximum punishment being a fine not exceeding $5,000,000 or imprisonment for a term not exceeding two years, or both.

[89] As such, determining what constitutes a "deliberate disregard of official duty" involves an interpretation of the Act and Regs, as well as any guidance documents, and the lawfulness of the Defendants' conduct will be decided by reference to these federal laws.

(2) Negligence

[90] Peter Hogg, in *Liability of the Crown*, 4th ed (Toronto: Thomson Reuters Canada Ltd, 2011) at 232 to 244, opines that the Supreme Court has not given clear direction with regards to

how a statutory scheme is to be used to determine the proximity of public servants to plaintiffs in negligence cases. However, he concludes, at 242, that the following principles can be elucidated from a reading of the case law (*Cooper v Hobart*, 2001 SCC 79; *Edwards v Law Society of Upper Canada*, 2001 SCC 80; *The Queen v Saskatchewan Wheat Pool*, [1983] 1 SCR 205; *Hill v Hamilton-Wentworth Regional Police Services Board*, 2007 SCC 41; *Fullowka v Pinkerton's of Canada Ltd*, 2010 SCC 5; *Reference re Broome v Prince Edward Island*, 2010 SCC 11):

1) A public authority will not be open to liability for negligence unless the public authority was in "close and direct" or a proximate relationship with a plaintiff.
2) The relevant statutory scheme is not the exclusive, or even a necessary source of proximity in cases involving public authorities.
3) The statutory scheme will preclude a duty of care, where such duty would conflict with the statute.
4) The statutory scheme may play a positive role in establishing proximity.
5) Factors suggesting proximity include physical and causal closeness, assumed or imposed obligations and expectations, representations, reliance, and the property or other interests involved.

[91] In *Kamloops v Neilsen*, [1984] 2 SCR 2 at 9, the Supreme Court quoted Lord Wilberforce, who opined that "the more operational a power or duty may be, the easier it is to superimpose upon it a common law duty of care". As such, it is possible that the actions or omissions that the Individual Defendants took while performing their duties could attract liability, if a duty of care is proven. Therefore, in order for a court to determine whether the Defendants are liable for negligence, the court will have to engage in an interpretation of the extent of the duties and powers granted by the Act and Regs, and the associated statutory and policy frameworks.

(3) Conspiracy

[92] With regard to the allegedly conspiratorial actions, the injury inflicted upon the Plaintiffs, if any, will have to be assessed based upon the lawful actions that the Defendants could take within their statutory framework. That is, the existence of an injury to the Plaintiffs, and a predominant intent by the Individual Defendants to injury the Plaintiffs, will depend on whether the Individual Defendants' actions were required of them, or allowable, under federal law.

[93] Further, the Plaintiffs claim that the Individual Defendants' conspiratorial conduct was wrongful conduct, outside the boundaries of their statutory authority, despite the fact that it occurred through mechanisms that are inherently tied to the performance of their duties at Heath Canada, for example administration of the EL scheme. However, it is possible that the alleged conspiracy is simply a function of coordination created within Health Canada by the Act and Regs, and the guidelines through which they are made operational. The statutory framework will be essential to determining whether the Individual Defendants acted unfairly, contrary to their own published guidelines, and predominantly to injure the Plaintiffs.

(4) Defamation

[94] As the Plaintiffs point out, if the tort of defamation is made out, there are two defences available to the Individual Defendants: statutory duty and qualified privilege. Deciding whether or not either of these defences is available to the Individual Defendants will be determined by the application of the Act and Regs. In this regard, this case is similar to *Dickson,* where whether the

actions of the individual Canada Revenue Agency defendants (the "CRA Defendants") were justified was dependent on the interpretation of federal laws.

[95] The underlying action in *Dickson*, arose out of a refusal of the Minister of National Revenue to renew the applicants' federal tobacco manufacturing licence because of unpaid taxes. The motions judge, after reviewing the legislation and the jurisprudence relating to jurisdiction, held that the determination of whether the CRA Defendants were liable for wrongfully refusing the tobacco licence would ultimately depend on whether the applicants were exempt from taxation pursuant to section 87 of the *Indian Act*. Therefore, the applicants' claim was "'in pith and substance' based on federal law and [was] governed by a detailed federal statutory framework essential to the outcome of the case" (*Dickson* at para 61).

[96] In this case, whether there is a defense to defamation will have to be addressed against each Individual Defendant's mandate under the Act and Regs, as well as whether they could have believed in good faith that the Public Statements were true, based upon their understanding of the procedures that would be in place under the relevant statutory framework.

(5) Monetary relief in public law

[97] This novel cause of action is based upon a framework of unacceptability, in the administrative law sense, of the public authority's conduct and the court's exercise of remedial discretion (*Paradis Honey* at para 139). An important component to this cause of action is the quality of the public authority's conduct: for example, did the public authority fail to fulfill a

clear and specific duty to act, and is the failure to act unacceptable or indefensible in the administrative law sense (*Paradis Honey* at paras 144 to 145).

[98] As such, interpreting the statutory regime will be determinative in finding liability or not under this novel cause of action. Further, given Justice Russell's findings that Health Canada's continued refusal to grant NOCs, in relation to products that still present data integrity concerns (i.e., Apo-Varenicline and Apo-Sitagliptin), is reasonable and the actions of the TBD not improper, understanding the different aspects of the statutory framework under which each Individual Defendant was operating will be essential to the determination of his or her liability, if any, and whether certain relief should be granted.

[99] Therefore, I find that the Act and the Regs are essential for the trial judge to reach a decision with respect to each of the claims made by the Plaintiffs against the Individual Defendants, and I find that they sufficiently nourish the grant of jurisdiction, meeting the standard set out in *ITO* and reaffirmed in *City of Windsor*. As such, it is not plain and obvious that the rights, obligations, and potential defences arising in this action are not essentially dependent upon and nourished by the federal statutory framework.

F. *ITO-test: Is the law on which the case is based "a law of Canada" as the phrase is used in section 101 of the Constitution Act, 1867?*

[100] The Defendants argue that this stage of the *ITO*-test requires that the private law causes of action arise from federal law, in a manner that is something more than the allegedly tortious

actions being unauthorized by federal law and/or the relationship between the Parties being based on federal law.

[101] The Defendants' understanding of the requirements of the third part of the *ITO*-test is incorrect. The majority in *City of Windsor* is silent on the requirements of this step; however, the minority opinion makes it clear that the third part of the *ITO-test* requires that the federal law, which is essential to the disposition of the case and nourishing of the grant of jurisdiction, be valid federal law: i.e., law that is within the federal legislative competence (*City of Windsor* at para 116; see also *ITO* at 777).

[102] There is no dispute between the Parties that the Act and Regs are within the federal legislative competence.

[103] Based on the above analysis, it is not plain and obvious that the Federal Court does not have jurisdiction to hear the claims against the Individual Defendants.

IV. Costs

[104] Costs are awarded to the Plaintiffs in any event of the cause.

JUDGMENT in T-1653-16

THIS COURT'S JUDGMENT is that

1. The motion is dismissed;

2. The Attorney General of Canada is removed as a party;

3. Costs are awarded to the Plaintiffs in any event of the cause.

"Michael D. Manson"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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