Federal Court  Cour fédérale

Date: 20201106

Docket: T-827-20

Citation: 2020 FC 1040

Ottawa, Ontario, November 6, 2020

PRESENT: The Honourable Mr. Justice Manson

BETWEEN:

VIIV HEALTHCARE COMPANY, SHIONOGI & CO., LTD. AND VIIV HEALTHCARE ULC

Plaintiffs

and

SANDOZ CANADA INC.

Defendant

ORDER AND REASONS

I. Introduction

[1] Sandoz Canada Inc.'s [the "Defendant"] motion is for summary judgment or, in the alternative, to strike the Plaintiffs' Statement of Claim in its entirety (or in part) without leave to amend, pursuant to Rules 215 and 221(1) of the *Federal Courts Rules*, SOR/98-106 [*Federal Courts Rules*], as well as under section 6.08 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [the "*NOC Regulations*"].

II. Background

[2] The core issue involves whether, by virtue of having failed to comply with the time frame mandated to commence an action within 45 days of service of a Notice of Allegation [NOA], under subsection 6(1) of the *NOC Regulations*, the Plaintiffs are now statute-barred from bringing this proceeding. At play in determining the 45 day period is the *Time Limits and Other Periods Act (COVID-19)*, SC 2020, c 11, s 11 [the "*TLOPA*"] and whether it effectively serves to extend the time frame to commence this action.

[3] The parties agree to the pertinent facts as set out in an Agreed Statement of Facts, relevant portions of which are set out below.

[4] The Plaintiff, ViiV Healthcare Company [ViiV USA], is a private limited company incorporated under the laws of the United States.

[5] The Plaintiff, Shionogi & Co., Ltd., also known as Shionogi Seiyaku Kabushiki Kaisha [Shionogi], is a public limited company incorporated under the laws of Japan.

[6] The Plaintiff, ViiV Healthcare ULC [ViiV Canada], is a corporation organized and existing under the laws of the province of Alberta. ViiV Canada markets, sells and distributes various drugs in Canada, including dolutegravir, which is sold in the form of dolutegravir sodium, as a single medication under the brand name TIVICAY® [TIVICAY], and as a

component of the medications TRIUMEQ® dolutegravir/abacavir/lamivudine, JULUCA® dolutegravir/rilpivirine, and DOVATO® dolutegravir/lamivudine.

[7] The Defendant is a corporation organized and existing under the laws of Canada.

[8] The patent in issue, Canadian patent 2,606,282 [the "282 Patent"], entitled "Polycyclic Carbamoylpyridone Derivatives Having HIV Integrase Inhibitory Activity", was granted to ViiV USA and Shionogi on April 26, 2016. ViiV USA and Shionogi are the "owners" of the 282 Patent under subsection 6(2) of the *NOC Regulations*.

[9] ViiV USA and Shionogi have permitted ViiV Canada to list the 282 Patent on the Patent Register maintained by the Minister of Health in respect of TIVICAY.

[10] The Minister of Health has issued notices of compliance to ViiV Canada, enabling it to market and sell TIVICAY products in Canada in various dosage forms, including dolutegravir sodium tablets in strengths of 50 mg per unit for oral administration. ViiV Canada is identified on the 50 mg per unit Form IV and in Health Canada's Drug Product Database as such. The representative for service is listed as "Legal Counsel" at GlaxoSmithKline Inc. [GSK Canada] in Mississauga, Ontario. ViiV Canada is the "first person" under subsection 6(1) of the *NOC Regulations*.

[11] The Form IV declaration filed with Health Canada in respect of the 282 Patent and TIVICAY's 50 mg dosage listed GSK Canada, 7333 Mississauga Road, Mississauga, Ontario as the address for service of an NOA.

[12] The Defendant, on or about November 6, 2019, filed an Abbreviated New Drug Submission [ANDS] with Health Canada for the issuance of a Notice of Compliance [NOC] for the medicinal ingredient dolutegravir sodium in film-coated tablets in a 50 mg strength for oral administration [the "Sandoz Product"].

[13] The ANDS compares the Sandoz Product to ViiV Canada's 50 mg strength of TIVICAY (DIN 02414945; "TIVICAY") for oral administration.

[14] TIVICAY is currently listed on the Register of Innovative Drugs established under section C.08.004.1 of the *Food and Drug Regulations*, CRC, c 870 [*Food and Drug Regulations*] and maintained by Health Canada. The entry for dolutegravir on this Register indicates that May 1, 2022 is the date on which data protection ends. The Defendant cannot obtain its NOC for the Sandoz Product until May 1, 2022 as a consequence of this listing.

[15] On March 15, 2020, Canada Post posted a "COVID-19 Public update" notice [the "COVID-19 notice"] advising that it will no longer be requesting signatures for any deliveries made to the door to help minimize points of close contact. For registered mail, the COVID-19 notice advised that: "To receive the following items only: Registered… please know that we cannot release these items unless a signature is provided. You will receive a notice card

indicating the post office where you can pick up your items by showing proof of identity and signing".

[16] GSK Canada does not operate the mailroom at its Mississauga office. The mailroom is operated by a third party, CBRE Limited [CBRE], who subcontracted with Jetrex Mail Services [Jetrex] to handle, pick up and receive all registered and regular mail. CBRE subcontracted the performance of mailroom services to Xerox Corporation [Xerox]. Registered mail is picked up and signed for by Jetrex, who delivers the registered mail to Xerox at the GSK Canada Mississauga office. Xerox distributes registered mail, along with regular mail, to the internal department mailboxes within GSK Canada.

[17] Until mid-March of 2020, when courier packages were received by GSK Canada, an email message was sent to the addressee to advise him or her that a courier package had arrived. An email message was not sent to the addressee of a registered mail package.

[18] On March 16, 2020, GSK Canada began to shut down its Mississauga commercial offices due to the coronavirus (COVID-19) pandemic, and Keith Aguilera, Legal Counsel at GSK Canada [Counsel], and Josée Gravelle, General Counsel at GSK Canada [General Counsel], as part of that shut down, began to work from home.

[19] On or about March 16, 2020, counsel for the Defendant or the Defendant sent a package addressed to "Legal Counsel" at GSK Canada [the "Sandoz Package"] by registered mail. The Sandoz Package included a letter addressed directly to the Counsel and General Counsel at GSK

Canada [the "Sandoz Letter"], a copy of the NOA [the "Sandoz NOA"] and an electronic USB key thumb drive [USB Key] containing password protected subsection 5(3)(c)(iii) documents. With respect to the USB Key, the Sandoz Letter stated:

> In accordance with section 5(3)(c)(iii), a searchable electronic copy of relevant portions of Sandoz's drug submissions are included in the enclosed USB key. This information is confidential and subject to the terms imposed in Appendix 1. The files are password-protected. Please contact me at your earliest convenience for access, which will be provided upon receiving the assurances described in sections 5(3.8) and 5(3.9) of the Regulations.

[20] The Sandoz Package was delivered to the mailroom at GSK Canada's premises on March 17, 2020, but it was not signed for by Counsel or General Counsel at GSK Canada. Canada Post's records indicate that the Sandoz Package was signed for by "S. Turgano". Sergio Turgano is an employee of Jetrex Mail Services, not GSK Canada.

[21] On March 18, 2020, Counsel attended at the Legal Department of GSK Canada solely to pick up documents prepared the previous day by Ms. Niki Kaur, a paralegal at GSK Canada [Paralegal] and to meet the General Manager on a different floor of the GSK Canada offices to sign the documents and for Counsel to notarize them. Counsel then left the GSK Canada office.

[22] At some time between March 17 and March 19, 2020, the Sandoz Package was delivered to the Legal Department's mailbox, however, it was not delivered to, nor was its existence made known to, "Legal Counsel" at GSK Canada.

[23] Effective March 19, 2020, Xerox ceased delivering mail and registered mail to any internal department mailboxes within the Mississauga offices of GSK Canada.

[24] From March 19 to April 6, 2020, the GSK Canada Legal Department did not receive any regular mail, registered mail or courier packages. During that period, the process for handling such material was as follows:

A. For courier packages, an email would be sent to the recipient and the recipient was encouraged to retrieve the items/package from shipping and receiving near security; and/or

B. For regular mail and registered mail, if a name was indicated on the envelope, it was opened, scanned and forwarded to the recipient; if no name was indicated on the envelope, it was opened, scanned and forwarded to the Paralegal for further handling.

[25] On April 3, 2020, the Legal Department at GSK Canada became aware that dolutegravir was listed on Health Canada's Generic Drug Submissions Under Review list. On April 6, 2020, the Paralegal asked Xerox mailroom staff to check whether anything had been received by mail or courier that was addressed to the Legal Department. Xerox advised the Paralegal that nothing was located by the mailroom and that no courier package addressed to the Legal Department was located in the shipping/receiving area. The Paralegal asked Xerox mailroom staff to be on heightened alert for any future correspondence addressed to the Legal Department of GSK Canada. After which, when any courier package for the GSK Canada Legal Department was received, the Paralegal was to receive a phone call from a GSK Canada security person and the courier envelope/package was to be sent by courier to the Paralegal's home address for further handling.

[26] Counsel and General Counsel at GSK Canada are not employed by nor are they legal counsel at ViiV Canada. GSK Canada's Legal Department provides certain legal services for ViiV Canada.

[27] The calendar date five days, for effective service of the NOA by registered mail, after March 16, 2020 was March 21, 2020. The calendar date 45 days after March 21, 2020, for commencement of an action under subsection 6(1) of the *NOC Regulations*, was May 5, 2020. The Plaintiffs did not commence an action under subsection 6(1) of the *NOC Regulations* by May 5, 2020.

[28] On June 11, 2020, Julian Worsley, Senior Consultant Counsel of the Defendant, sent an email to Counsel at GSK Canada alleging service of the Sandoz NOA by registered mail. That letter stated:

> Pursuant to section 9(2) of the *PM(NOC) Regulations*, service by registered mail is deemed to be effected five days after mailing. In this case, the NOA was effectively served on March 21 and GSK had until May 5, 2020 to bring an action against Sandoz. That timeframe has now clearly elapsed, GSK has elected not to pursue a proceeding under the *PM(NOC) Regulations* against Sandoz in respect of the 282 Patent and Sandoz's 50 mg dolutegravir sodium tablets.
>
> By operation of section 6.01 of the *PM(NOC) Regulations*, no infringement action can now be brought against Sandoz as it relates to 50 mg dolutegravir sodium tablets. Sandoz expects its equivalent 50 mg dolutegravir tablets to pass Health Canada's review prior to the expiration of the data protection period on May 1st, 2022, and to receive its NOC immediately thereafter.

This was the first notice Counsel at GSK Canada received regarding the Sandoz NOA and accompanying documents.

[29] On June 15, 2020, the Sandoz Package was discovered in the Legal Department's mailbox. Its paper contents were scanned and forwarded to Counsel and General Counsel at GSK Canada, who as of that time continued to work from home.

[30] ViiV USA and Shionogi did not receive the Sandoz Letter and a copy of the Sandoz NOA until June 16, 2020, and were not aware of them before then.

[31] Other than the visits of the Paralegal and Counsel on March 17 and March 18, 2020 described above, no one from the Legal Department at GSK Canada had attended the GSK Canada office at 7333 Mississauga Road, Mississauga, Ontario between March 17 and June 9, 2020, inclusive.

[32] At no time between March 16, 2020 and June 10, 2020 did counsel for the Defendant and/or the Defendant contact Counsel and/or General Counsel, or any other person at GSK Canada, to inquire as to whether the Sandoz Package had been received by them.

[33] The Defendant received no correspondence or other communication from the first person, GSK Canada or the patent owners, in respect of the Sandoz Package, including in particular, the Defendant never received:

A. A request for the password to the password protected subsection 5(3)(c)(iii) documents on the USB Key;

B. An agreement or undertaking from ViiV USA and Shionogi to attorn to the jurisdiction of the Federal Court for confidentiality pursuant to subsection 5(3.9) of the *NOC Regulations*;
C. Confirmation from GSK Canada that it had forwarded the Sandoz NOA and accompanying documents to the patent owners as required by subsection 5(3.4) of the *NOC Regulations*; and
D. Correspondence from GSK Canada, ViiV USA or Shionogi indicating that the owners of the 282 Patent elected to forego their rights under the *NOC Regulations*.

[34] The Defendant's ANDS compared the Sandoz Product to TIVICAY. The NOA alleges that:

A. No claim of the 282 Patent will be infringed through the making, constructing, using or selling of the Sandoz Product;
B. No inducement arises from its proposed labelling;
C. Each claim of the 282 Patent is invalid and void; and
D. The 282 Patent is ineligible for listing on the Patent Register.

[35] The Defendant chose to incorporate by reference subsection 5(3)(c)(iii) documents into the Sandoz NOA, including documents relevant to its allegation that no inducement arises from its proposed labelling.

[36] As the *NOC Regulations* permit, the Defendant chose to impose confidentiality rules "in the portions of its submissions provided to you and referred to herein". Sandoz specifically chose

to password-protect the encrypted electronic USB Key documents it included in the Sandoz Package. In doing so, it thereby rendered the encrypted subsection 5(3)(c)(iii) documents unreadable and not searchable without the password decryption code.

[37] On August 24, 2020, the Defendant served on counsel for the Plaintiffs a searchable electronic copy of its subsection 5(3)(c)(iii) documents.

[38] Having not received the Sandoz NOA, Shionogi and ViiV USA did not attorn to the jurisdiction of the Federal Court before May 5, 2020.

[39] The Plaintiffs filed their Statement of Claim on July 24, 2020, through the e-filing portal maintained by the Federal Court. The Federal Court issued the Statement of Claim on July 28, 2020, and provided a copy of it to counsel for the Defendant that day. Counsel for the Defendant accepted service on July 30, 2020.

[40] Counsel for the Plaintiffs did not provide any documents to counsel for the Defendant on July 28, 2020 with the Statement of Claim, but offered to provide the contact information for the inventors and additional documents if the Defendant undertook and agreed to be bound by the terms of the Federal Court's Model Protective Order. The Defendant's counsel advised on July 28, 2020, that some changes would be needed to the Model Protective Order and asked ViiV/Shionogi's counsel to prepare a draft Protective Order which was provided on August 5, 2020. A draft Protective Order based on the Model Protective Order was tendered to the Court on August 13, 2020. The Protective Order was issued on August 14, 2020.

[41] On August 21, 2020, the Plaintiffs electronically served on counsel for Sandoz 239,698 image files in 7,734 folders. The text files associated with each folder and the native files associated with the Excel files were unintentionally omitted. These native and text files were subsequently provided on September 16, 2020.

[42] The Minister of Health accepted the Defendant's proof of service in March of 2020.

[43] The Defendant was advised by letter from the Minister of Health, dated July 6, 2020, that its application submission No. 232829 for Sandoz Dolutegravir [Dolutegravir (as Dolutegravir Sodium) 50 mg Oral Tablets] had been completed on July 3, 2020. The Defendant has represented that the Minister of Health has determined that the Sandoz NOC will issue once data protection expires on May 1, 2022.

III. Issues

[44] The overarching issue is whether the Plaintiffs' claim, brought under subsection 6(1) of the *NOC Regulations*, is time-barred or statute-barred and therefore should be dismissed as disclosing no genuine issue for trial. In the alternative, should the Statement of Claim be struck? The issues can be distilled as follows:

A. Does the *TLOPA* apply to the "within 45 days" time period for bringing an action under subsection 6(1) of the *NOC Regulations*?
B. Is the Plaintiffs' right of action available by operation section 6.01 of the *NOC Regulations* or because of service of a deficient NOA?

C. Should any of the claims be struck or dismissed, by reason of being statue-barred or otherwise, pursuant to Rules 215 or 221(1) of the *Federal Courts Rules*, or under section 6.08 of the *NOC Regulations*?

IV. Legal Tests

A. *Summary Judgment (Rule 215 of the Federal Courts Rules)*

[45] Rule 215 of the *Federal Courts Rules* provides that the Court shall grant summary judgment where it "is satisfied that there is no genuine issue for trial with respect to a claim or defence". The proper operation of the justice system is served where unmeritorious claims are weeded out at an early stage and claims disclosing real issues that may be successful proceed to trial. There is no genuine issue for trial where a claim is time-barred or statute-barred, such as where a limitation period has expired (*Canada (Attorney General) v Lameman*, 2008 SCC 14 at paras 10-12).

B. *Motion to Strike (Rule 221(1) of the Federal Courts Rules)*

[46] Rule 221 of the *Federal Courts Rules* sets out the grounds upon which the Court may strike out all or part of a pleading, with or without leave to amend. The Court will strike a Statement of Claim under Rule 221(1)(a), where it is plain and obvious that the pleading discloses no reasonable cause of action (*Hunt v Carey Canada Inc*, [1990] 2 SCR 959 at 980; *R v Imperial Tobacco Canada Ltd*, 2011 SCC 42 at para 17 [*Imperial Tobacco*]). The material facts pleaded must be taken as true unless the allegations are based on assumption and speculation

(*Imperial Tobacco*, above at para 22). No evidence is heard on a motion to strike under Rule 221(1)(a) (*Federal Courts Rules*, Rule 221(2)).

[47] A pleading will be struck under Rule 221(1)(c) as being scandalous, frivolous or vexatious or under Rule 221(1)(f) as an abuse of process whereby the claim is so clearly futile that it does not have the slightest chance of succeeding (*Apotex Inc v Syntex Pharmaceuticals International Ltd*, 2005 FC 1310 at para 33).

C. *Dismissing the Action (Section 6.08 of the NOC Regulations)*

[48] On a section 6.08 motion, an action brought under subsection 6(1) of the *NOC Regulations* may be dismissed, "in whole or in part, on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process". The Court will strike a claim commenced under the *NOC Regulations* where the action is clearly futile or it is plain and obvious that the application has no chance of success. The motion judge may consider evidence and make necessary findings of fact in coming to a determination (*Bristol-Myers Squibb Canada v Apotex Inc*, 2017 FC 1061 at paras 21, 23; citing *Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 163 at paras 28, 36).

V. Analysis

[49] The Defendant alleges that the facts admitted by the Plaintiffs signal multiple failures on the part of GSK Canada. The Defendant argues it met the requirements of the second person under the *NOC Regulations*. It is the first person who is required to maintain an address in

Canada for service of the NOA. Therefore, any failures on the part of GSK Canada, listed as the address for service of an NOA, do not negate service of the NOA.

[50] As service by registered mail was effected on March 21, 2020, the Defendant further alleges that the Plaintiffs failed to exercise their right of action "within 45 days", as prescribed by subsection 6(1) of the *NOC Regulations*. As stated above, this 45-day time limit expired on May 5, 2020 and the Plaintiffs' Statement of Claim was issued on July 28, 2020. Further action is barred by section 6.01 of the *NOC Regulations* and the right of action is not saved by service of an allegedly deficient NOA. The relief sought by the Plaintiffs is therefore *quia timet* in nature. Further, the declarations of validity and ownership, as sought by Plaintiffs, are not valid heads of relief. The right of action also is not saved by the *TLOPA*, as subsection 55.2(5) of the *Patent Act*, RSC, 1984, c P-4 [*Patent Act*], prevails over any suspension of time prescribed by the *TLOPA*.

[51] It is the Plaintiffs' position that the *TLOPA* applies to the "within 45 days" time limit established under subsection 6(1) of the *NOC Regulations*, meaning that their Statement of Claim was issued within the suspension period created by the *TLOPA*. In the alternative, this timeline could not start running on the basis of the Defendant's service of an incomplete NOA. The Plaintiffs argue therefore that they are not barred from commencing an action on the basis of section 6.01 of the *NOC Regulations*.

(1) Does the *TLOPA* apply to the "within 45 days" time period for bringing an action under subsection 6(1) of the *NOC Regulations*?

(a) *The TLOPA Suspension Framework*

[52] The *TLOPA* was passed in July of 2020, as part of *An Act respecting further COVID-19 measures*, SC 2020, c 11. It received Royal Assent and came into force on July 27, 2020. The *TLOPA* suspends "any limitation or prescription period for commencing a proceeding before a court" if the time limit is established under an Act of Parliament, whereby time "does not run between March 13, 2020 and September 13, 2020" (the *TLOPA*, s 6(1)(a); *Reference re Section 6 of the Time Limits and Other Periods Act (COVID-19) (CA)*, 2020 FCA 137 at para 12). The purpose of the *TLOPA* is "to temporarily suspend certain time limits… in order to prevent any exceptional circumstances that may be produced by coronavirus disease 2019 (COVID-19) from making it difficult or impossible to meet those time limits" (the *TLOPA*, s 5(1)(a)). Specifically, subsection 6(1) of the *TLOPA* provides:

> **Suspensions**
>
> 6(1) The following time limits are, if established by or under an Act of Parliament, suspended for the period that starts on March 13, 2020 and that ends on September 13, 2020 or on any earlier day fixed by order of the Governor in Council made on the recommendation of the Minister of Justice:
>
> (a) any limitation or prescription period for commencing a proceeding before a court;
>
> (b) any time limit in relation to something that is to be done in a proceeding before a court; and
>
> (c) any time limit within which an application for leave to commence a proceeding or to do something in relation to a proceeding is to be made to a court.

[53] Subsection 6(4) of the *TLOPA* states that a suspension may be lifted by order made by the Governor in Council, on the recommendation of the Minister of Justice:

> **Orders in council**
>
> (4) The Governor in Council may, by order made on the recommendation of the Minister of Justice, lift a suspension in circumstances specified in the order.

[54] A July 30, 2020 Order in Council referred to the *NOC Regulations*, lifting the suspension under subsection 6(1) of the *TLOPA* [the "Order in Council"]:

> **Suspension lifted – Patented Medicines (Notice of Compliance) Regulations**
>
> 2(1) The suspension under subsection 6(1) of [the *TLOPA*] of the time limits established by or under an Act of Parliament in relation to proceedings before a court under the *Patented Medicines (Notice of Compliance) Regulations* is lifted.
>
> For greater certainty
>
> (2) For greater certainty, subsection (1) does not affect the application of subsection 55.2(5) of the *Patent Act* with respect to any inconsistency or conflict between [the *TLOPA*] and the *Patented Medicines (Notice of Compliance) Regulations.*
>
> [*Order Lifting Suspensions of Time Limits in Relation to Proceedings Commenced Under Certain Acts for Which the Minister of Industry is Responsible*, C Gaz I, Vol 154, No 32 at 1941].

(b) *The NOC Regulations and NOC Issuance*

[55] The *NOC Regulations* are enabled under subsection 55.2(4) of the *Patent Act*. They bridge the *Patent Act* and the patent rights afforded to the patentee of an innovative drug with the issuance of an NOC by Health Canada, under the *Food and Drug Regulations*, to a subsequent

entry product, a generic drug. Subsection 55.2(4) of the *Patent Act* is directed at preventing infringement by those persons invoking the early-working exception, in relation to a subsequent entry product (*Patent Act*, s 55.2(1); *Bristol-Myers Squibb Co v Canada (Attorney General)*, 2005 SCC 26 at para 53).

[56] Under the *NOC Regulations*, when an NOC submission compares a proposed generic drug to a marketed drug against which patents are listed, as in this case, those patents must be addressed either by awaiting expiry, obtaining consent or otherwise in the NOA (*NOC Regulations*, ss 5(1), (2.1)). Subsection 6(1) of the *NOC Regulations* provides a 45-day period in which the first person or an owner of a patent may bring an action for infringement against the second person, following service of the NOA:

> 6(1) The first person or an owner of a patent who receives a notice of allegation referred to in paragraph 5(3)(a) may, within 45 days after the day on which the first person is served with the notice, bring an action against the second person in Federal Court for a declaration that the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) would infringe any patent or certificate of supplementary protection that is the subject of an allegation set out in that notice.

[57] The importance of the *NOC Regulations* is enshrined in subsection 55.2(5) of the *Patent Act*, which considers inconsistency or conflict between the *NOC Regulations* and any Act of Parliament:

> Inconsistency or conflict
>
> (5) In the event of any inconsistency or conflict between
>
> (a) this section or any regulations made under this section, and
>
> (b) any Act of Parliament or any regulations made thereunder,

> this section or the regulations made under this section shall prevail to the extent of the inconsistency or conflict.

(c) *The Interpretation of the TLOPA and subsection 55.2(5) of the Patent Act*

[58] There is a presumption of coherence between overlapping legislative provisions, whereby a conflict should be avoided if possible. There is an overlap between section 6(1) of the *NOC Regulations* and section 6(1) of the *TLOPA*, whereby both provisions apply to the time limit for bringing an action following service of an NOA.

> It is assumed that the legislature did not intend to make contradictory enactments. The Supreme Court has defined an inconsistency as follows:
>
> …"Inconsistency" in this context refers to a situation where two legislative enactments cannot stand together: see *Daniels v. White*, [1968] S.C.R. 517. The rule in that case was stated in respect of two inconsistent statutes where one was deemed to repeal the other by virtue of the inconsistency. However, the underlying rationale is the same as where subordinate legislation is said to be inconsistent with another Act of Parliament — there is a presumption that the legislature did not intend to make or empower the making of contradictory enactments. There is also some doctrinal similarity to the principle of paramountcy in constitutional division of powers cases where inconsistency has also been defined in terms of contradiction, i.e., "compliance with one law involves breach of the other"; see *Smith v. The Queen*, [1960] S.C.R. 776 at p. 800.
>
> (*Friends of the Oldman River Society v Canada (Minister of Transport)*, [1992] 1 SCR 3 at 38-39)

[59] Subsection 6(1) of the *TLOPA* and subsection 6(1) of the *NOC Regulations* necessarily prescribe two different time periods. Under subsection 6(1) of the *NOC Regulations*, the time to start this action elapsed on May 5, 2020. However, if the suspension period under the *TLOPA* is

engaged, and is not lifted, the time limit would elapse on October 28, 2020 (45 days following September 13, 2020).

[60] These different time limits do not amount to an inconsistency or conflict. I do not find this to be a situation where the two provisions cannot stand together. The purpose of the *TLOPA* was to temporarily suspend certain time limits established by or under an Act of Parliament. In this respect, the two provisions can be reconciled in that they must necessarily be read together. Compliance with the *TLOPA* (i.e. applying the suspension) involves an understanding of the time limit prescribed by the *NOC Regulations*. Further, compliance with the *NOC Regulations* does not produce a breach of the *TLOPA*. As such, the provisions should be read together and it cannot necessarily be implied that following one involves a breach of the other.

[61] The extraordinary nature of the *NOC Regulations* has been affirmed by the Federal Court of Appeal, whereby they "override any other Act or regulation including the *Federal Court Act* and the *Federal Court Rules*" (*Merck Frosst Canada Inc v Apotex Inc*, [1997] 2 FC 561 (FCA) at 7). As discussed above, an inconsistency or conflict between the *NOC Regulations* and any Act of Parliament is addressed in subsection 55.2(5) of the *Patent Act*. This is a clear expression by Parliament to the effect that the *NOC Regulations* are intended to prevail to the extent of the inconsistency or conflict. I find that subsection 55.2(5) of the *Patent Act* does not apply to the current circumstances, in that there is no inconsistency or conflict between the impugned provisions that would engage subsection 55.2(5) of the *Patent Act*. This is not a case of two conflicting time limits, but rather of a suspension that is intended to apply to an existing time limit.

[62] The reconciliation of the two provisions is supported by the language of the July 30, 2020 Order in Council, whereby subsection 2(1) of the Order in Council indicates that the suspension under subsection 6(1) of the *TLOPA* of the time limits established under the *NOC Regulations* "is lifted". Subsection 2(2) of the Order in Council further indicates that subsection 2(1) does not affect the application of subsection 55.2(5) of the *Patent Act*, with respect to any inconsistency or conflict between the *TLOPA* and the *NOC Regulations* (Order in Council, s 2(2)).

[63] An exercise of statutory interpretation requires consideration of the text, context and purpose to ascertain true meaning (*Rizzo & Rizzo Shoes Ltd (Re)*, [1998] 1 SCR 27 at para 21; *Canada Trustco Mortgage Co v Canada*, 2005 SCC 54).

[64] Subsection 6(4) of the *TLOPA* provides a means for ensuring various Acts of Parliament are clearly carved out from the application of the *TLOPA*, whether exempted specifically within the *TLOPA* or not. As the *TLOPA* offers a blanket suspension of time limits, with mechanisms for the suspension to be lifted, I find that the suspension of time limits under the *NOC Regulations* was lifted on the date of the Order in Council, July 30, 2020, meaning that the suspension period applied from March 13, 2020 to July 30, 2020.

[65] I do not find that the interpretive guidance offered by the Office of the Superintendent of Bankruptcy Canada is informative in this respect. The guidance, in relation to the application of section 1 of the Order in Council, suggests that "time limits remain unaffected" in respect of the *Bankruptcy and Insolvency Act* and the *Companies' Creditors Arrangement Act*.

[66] I further disagree with the Plaintiffs that the Order in Council distinguishes subsection 6(1)(b) from subsection 6(1)(a) of the *TLOPA*. Section 2(1) of the Order in Council refers to subsection 6(1) in its entirety in respect of "proceedings before a court". Both subsections 6(1)(a) and 6(1)(b) of the *TLOPA* reference "a proceeding before a court", whether it be in relation to commencing such a proceeding or another step in that proceeding.

[67] As the Plaintiffs' Statement of Claim was issued on July 28, 2020, prior to the lifting of the suspension period, the claim is not statute-barred by reason that the 45-day period to bring a claim under subsection 6(1) of the *NOC Regulations* has elapsed.

(2) Is the Plaintiffs' right of action available by operation of section 6.01 of the *NOC Regulations* or because of service of a deficient NOA?

[68] I have decided that the Plaintiffs may properly bring their claim under subsection 6(1) of the *NOC Regulations*, due to the suspended time period. However, I will nevertheless consider this second issue. In the event *TLOPA* did not apply to suspend the "within 45 days" time limit, the Plaintiffs further sought that their action proceed by way of section 6.01 of the *NOC Regulations*. Section 6.01 prohibits subsequent actions against the second person for infringement, unless the first person did not have a "reasonable basis" for bringing the action within the 45-day period, as prescribed in subsection 6(1) of the *NOC Regulations*:

> 6.01 No action, other than one brought under subsection 6(1), may be brought against the second person for infringement of a patent or a certificate of supplementary protection that is the subject of a notice of allegation served under paragraph 5(3)(a) in relation to the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) unless the first person or the owner of the patent did not, within

> the 45-day period referred to in subsection 6(1), have a reasonable basis for bringing an action under that subsection.
>
> (Emphasis added)

[69] The Plaintiffs allege they lacked a reasonable basis for bringing the action with the 45-day period. They rely on a Regulatory Impact Analysis Statement for what might constitute not having "a reasonable basis":

> Possible situations where the first person or owner of the patent could be found not to have had a reasonable basis for commencing litigation include situations where the information provided by the second person was false, materially misleading, or materially incomplete (including as a result of a subsequent change in the generic product).
>
> (*Regulatory Impact Analysis Statement*, C Gaz I, Vol 151, No 28 at 3322).

[70] This second approach under section 6.01 of the *NOC Regulations* cannot succeed. Service of the NOA was effected on March 21, 2020 and the NOA was not materially incomplete. The bar against subsequent actions has not been circumvented in this case.

[71] It is clear on the Agreed Statement of Facts that the Sandoz Package was served upon GSK Canada, the appropriate entity. The Sandoz Package was further delivered to the Legal Department at some point between March 17 and March 19, 2020. Additionally, on April 3, 2020, the Legal Department at GSK Canada became aware that dolutegravir was listed on Health Canada's Generic Drug Submissions Under Review list and it implemented procedures at this time, expecting a possible delivery had been or would be made. Failure to locate the Sandoz Package was based on the processes and procedures engaged by the Plaintiffs and GSK Canada.

Understandably, the circumstances created by the COVID-19 pandemic complicated the situation. However, GSK Canada continued to function and there were several opportunities to locate the Sandoz Package upon service.

[72] I do not find that the NOA was materially incomplete due to the password-protected subsection 5(3)(c)(iii) documents that were not searchable and unreadable. Given that two of the Plaintiffs in these proceedings are located outside of Canada, it was not only reasonable, but prudent to encrypt the subsection 5(3)(c)(iii) documents at the outset. The core of the issue is that the Sandoz Package remained undiscovered and the Plaintiffs failed to request the password decryption code, not that the subsection 5(3)(c)(iii) documents where encrypted in the first instance.

[73] The Plaintiffs further raise the concern that the Defendant is benefiting from the exceptional circumstances arising from the pandemic. This result, in their view, is unconscionable. They reference a decision of Justice Knowles of the England and Wales High Court (Queen's Bench Division), where it was unconscionable for the claimant to benefit from unprecedented circumstances when attempting to rely on service by post for default judgment during the pandemic. Her solicitor exercised poor judgment in serving papers on an office he knew or should have known was closed (*Stanley v London Borough of Tower Hamlets*, [2020] EWHC 1622 (QB) at paras 33-34, 36).

[74] The facts of the current case are different. The *NOC Regulations* involve stringent timelines. Data protection expires on May 1, 2022 and the Defendant had sought to serve the

NOA and initiate the time limits under the *NOC Regulations* so that the NOC will be issued at the time data protection expires.

[75] Therefore, the Plaintiffs' action is appropriately brought under subsection 6(1) of the *NOC Regulations*, owing to the operation of the *TLOPA* and the suspended time period. The action is not available by operation of section 6.01 of the *NOC Regulations*.

> (3) Should any of the claims be struck or dismissed, by reason of being statue-barred or otherwise, pursuant to Rules 215 or 221(1) of the *Federal Courts Rules*, or under section 6.08 of the *NOC Regulations*?

[76] As the action was appropriately brought under subsection 6(1) of the *NOC Regulations* in light of the application of the *TLOPA*, this is not an appropriate case to strike or dismiss the claim on the basis that it is statute-barred or on the basis that the remedies sought are *quia timet* in nature.

[77] While the Defendant offers additional arguments to suggest that certain declaratory remedies sought by the Plaintiffs, as it relates to validity and ownership, are inappropriate, I am unconvinced these remedies ought to be struck at this time, as being plain and obvious that they are improperly pleaded. The pleas are properly left for the trial judge to consider on a complete record before the Court.

VI. Conclusion

[78] For the reasons above, I dismiss the motion for summary judgment and to strike the Plaintiffs' Statement of Claim, pursuant to Rules 215 and 221(1) of the *Federal Courts Rules* or under section 6.08 of the *NOC Regulations*.

[79] I would refrain from ordering costs. In these extraordinary times, both parties carried the responsibility of securing expeditious proceedings. The Defendant was aware that the Plaintiffs had not sought the password for the password-protected subsection 5(3)(c)(iii) documents. However, the Sandoz Package had in fact been delivered to the "Legal Department" at GSK Canada, remaining undetected or dealt with for months. While the strict legal requirements of the *NOC Regulations* were adhered to, the actions and inactions of both parties allowed the Sandoz Package to remain undetected and created the unfortunate series of events that led to the result here. In this respect, each party will carry its own costs.

ORDER IN T-827-20

THIS COURT ORDERS that

1. The motion for summary judgment or to strike the Plaintiffs' Statement of Claim is dismissed; and

2. No costs are awarded.

"Michael D. Manson"
Judge

ANNEX

Federal Courts Rules (SOR/98-106)

If no genuine issue for trial

215 (1) If on a motion for summary judgment the Court is satisfied that there is no genuine issue for trial with respect to a claim or defence, the Court shall grant summary judgment accordingly.

Motion to strike

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

(a) discloses no reasonable cause of action or defence, as the case may be,

(b) is immaterial or redundant,

(c) is scandalous, frivolous or vexatious,

(d) may prejudice or delay the fair trial of the action,

(e) constitutes a departure from a previous pleading, or

(f) is otherwise an abuse of the process of the Court,

and may order the action be dismissed or judgment entered accordingly.

Evidence

(2) No evidence shall be heard on a motion for an order under paragraph (1)(a).

Absence de véritable question litigieuse

215 (1) Si, par suite d'une requête en jugement sommaire, la Cour est convaincue qu'il n'existe pas de véritable question litigieuse quant à une déclaration ou à une défense, elle rend un jugement sommaire en conséquence.

Requête en radiation

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) qu'il ne révèle aucune cause d'action ou de défense valable;

b) qu'il n'est pas pertinent ou qu'il est redondant;

c) qu'il est scandaleux, frivole ou vexatoire;

d) qu'il risque de nuire à l'instruction équitable de l'action ou de la retarder;

e) qu'il diverge d'un acte de procédure antérieur;

f) qu'il constitue autrement un abus de procédure.

Elle peut aussi ordonner que l'action soit rejetée ou qu'un jugement soit enregistré en conséquence.

Preuve

(2) Aucune preuve n'est admissible dans le cadre d'une requête invoquant le motif visé à l'alinéa (1)a).

Patented Medicines (Notice of Compliance) Regulations (SOR/93-133)

Right of Action

6 (1) The first person or an owner of a patent who receives a notice of allegation referred to in paragraph 5(3)(a) may, within 45 days after the day on which the first person is served with the notice, bring an action against the second person in the Federal Court for a declaration that the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) would infringe any patent or certificate of supplementary protection that is the subject of an allegation set out in that notice.

6.01 No action, other than one brought under subsection 6(1), may be brought against the second person for infringement of a patent or a certificate of supplementary protection that is the subject of a notice of allegation served under paragraph 5(3)(a) in relation to the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) unless the first person or the owner of the patent did not, within the 45-day period referred to in subsection 6(1), have a reasonable basis for bringing an action under that subsection.

6.08 An action brought under subsection 6(1) may, on the motion of a second person, be dismissed, in whole or in part, on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents or certificates of supplementary protection.

Droits d'action

6 (1) La première personne ou le propriétaire d'un brevet qui reçoit un avis d'allégation en application de l'alinéa 5(3)a) peut, au plus tard quarante-cinq jours après la date à laquelle la première personne a reçu signification de l'avis, intenter une action contre la seconde personne devant la Cour fédérale afin d'obtenir une déclaration portant que la fabrication, la construction, l'exploitation ou la vente d'une drogue, conformément à la présentation ou au supplément visé aux paragraphes 5(1) ou (2), contreferait tout brevet ou tout certificat de protection supplémentaire visé par une allégation faite dans cet avis.

6.01 Aucune autre action qu'une action intentée en vertu du paragraphe 6(1) ne peut être intentée contre la seconde personne pour la contrefaçon d'un brevet ou d'un certificat de protection supplémentaire visé par un avis d'allégation signifié en application de l'alinéa 5(3)a) relativement à la fabrication, à la construction, à l'exploitation ou à la vente d'une drogue conformément à la présentation ou au supplément visé aux paragraphes 5(1) ou (2), sauf si la première personne ou le propriétaire du brevet n'avait pas, dans la période de quarante-cinq jours prévue au paragraphe 6(1), de motifs raisonnables pour intenter une action en vertu de ce paragraphe.

6.08 Toute action intentée en vertu du paragraphe 6(1) peut, sur requête de la seconde personne, être rejetée en tout ou en partie au motif qu'elle est inutile, scandaleuse, frivole ou vexatoire ou qu'elle constitue par ailleurs un abus de procédure à l'égard d'un ou de plusieurs brevets ou certificats de protection supplémentaire.

Patent Act (R.S.C., 1985, c. P-4)

Inconsistency or conflict	**Divergences**
55.2 (5) In the event of any inconsistency or conflict between	(5) Une disposition réglementaire prise sous le régime du présent article prévaut sur toute disposition législative ou réglementaire fédérale divergente.
(a) this section or any regulations made under this section, and	
(b) any Act of Parliament or any regulations made thereunder,	
this section or the regulations made under this section shall prevail to the extent of the inconsistency or conflict.	

Time Limits and Other Periods Act (COVID-19) (S.C. 2020, c. 11, s. 11)

Suspensions	**Suspension**
6 (1) The following time limits are, if established by or under an Act of Parliament, suspended for the period that starts on March 13, 2020 and that ends on September 13, 2020 or on any earlier day fixed by order of the Governor in Council made on the recommendation of the Minister of Justice:	6 (1) Les délais ci-après prévus sous le régime d'une loi fédérale sont suspendus pour la période commençant le 13 mars 2020 et se terminant soit le 13 septembre 2020, soit à la date antérieure fixée par décret pris sur recommandation du ministre de la Justice :
(a) any limitation or prescription period for commencing a proceeding before a court;	a) tout délai de prescription du droit d'introduire une instance devant une cour;
(b) any time limit in relation to something that is to be done in a proceeding before a court; and	b) tout délai relatif à l'accomplissement d'un acte dans le cadre d'une instance devant une cour;
(c) any time limit within which an application for leave to commence a proceeding or to do something in relation to a proceeding is to be made to a court.	c) tout délai dans lequel une demande visant à obtenir l'autorisation d'introduire une instance ou d'accomplir un acte dans le cadre d'une instance doit être présentée à une cour.

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-827-20
STYLE OF CAUSE:	VIIV HEALTHCARE COMPANY, SHIONOGI & CO., LTD. AND VIIV HEALTHCARE ULC v SANDOZ CANADA INC.

HEARING HELD BY VIDEOCONFERENCE ON OCTOBER 19, 2020 FROM TORONTO, ONTARIO (COURT AND PARTIES)

DATE OF HEARING:	OCTOBER 19, 2020
ORDER AND REASONS:	MANSON J.
DATED:	NOVEMBER 6, 2020

APPEARANCES:

Donald M. Cameron R. Scott MacKendrick Melanie Szweras Michael Fenwick Anastassia Trifonoba	FOR THE PLAINTIFFS
Neil Fineberg Kerry Andrusiak K. OMeara	FOR THE DEFENDANT

SOLICITORS OF RECORD:

BERESKIN & PARR LLP Toronto, Ontario	FOR THE PLAINTIFFS
Fineberg Ramamoorthy LLP Toronto, Ontario	FOR THE DEFENDANT