Health Canada Santé Canada

Canada

Canada's Patent Register

December 9, 2020

Michelle Ciesielski
Manager, Office of Patented Medicines and Liaison

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Overview

- Background
- What is the Patent Register?
- Adding Patents
- Searching the Patent Register
- Subsequent-Entry Drugs (Generic and Biosimilar)
- Court Challenges
- Removing Patents
- Additional Information
- Questions

Background

- The Minister of Health is designated to maintain a Patent Register under s.3(2) of Canada's "linkage" scheme known as the *Patented Medicines (Notice of Compliance) Regulations* ("*PMNOC Regulations*")
  - Regulatory authority falls under the *Patent Act*

- The Patent Register is the central construct of the linkage scheme

Background

- The early-working exception in the *Patent Act* permits generic/biosimilar drug manufacturers to develop copies of innovative drugs and seek regulatory approval before expiry of the innovator's patents.

- To balance early-working, the *PMNOC Regulations* provide that a generic/biosimilar drug cannot be approved until the patents on the Patent Register have been addressed. This often triggers litigation in the Federal Court.

What is the Patent Register?

- Searchable database of patents associated with drug products, and other information needed to fulfil the requirements of the *PMNOC Regulations*

- Relied on by subsequent-entry (generic and biosimilar) drug manufacturers when filing a comparative drug submission to Health Canada
  - Public-facing database is refreshed nightly

- Relied on by Health Canada when administering the *PMNOC Regulations*
  - Information is available to regulatory officials in real-time

What is the Patent Register?

- Contains entries from March 12, 1993 – present
- Human pharmaceuticals and biologics
- Veterinary pharmaceuticals
- Includes Certificates of Supplementary Protection (CSP) associated with a drug

- Open to public inspection on the Government of Canada website at https://pr-rdb.hc-sc.gc.ca/pr-rdb/index-eng.jsp

Adding Patents

- An innovator may apply to add patents on the Patent Register against an approved drug
- Innovators submit a document called a “Form IV: Patent List”
- Applications are assessed by regulatory officials to ensure that patents meet regulatory requirements (e.g. timing, patent eligibility)
  - Health Canada regulatory officials may consult with officials in the Patent Office
- Eligibility analysis is done parallel to submission review if patent has issued before submission filing date, or after drug approval if patent issues later

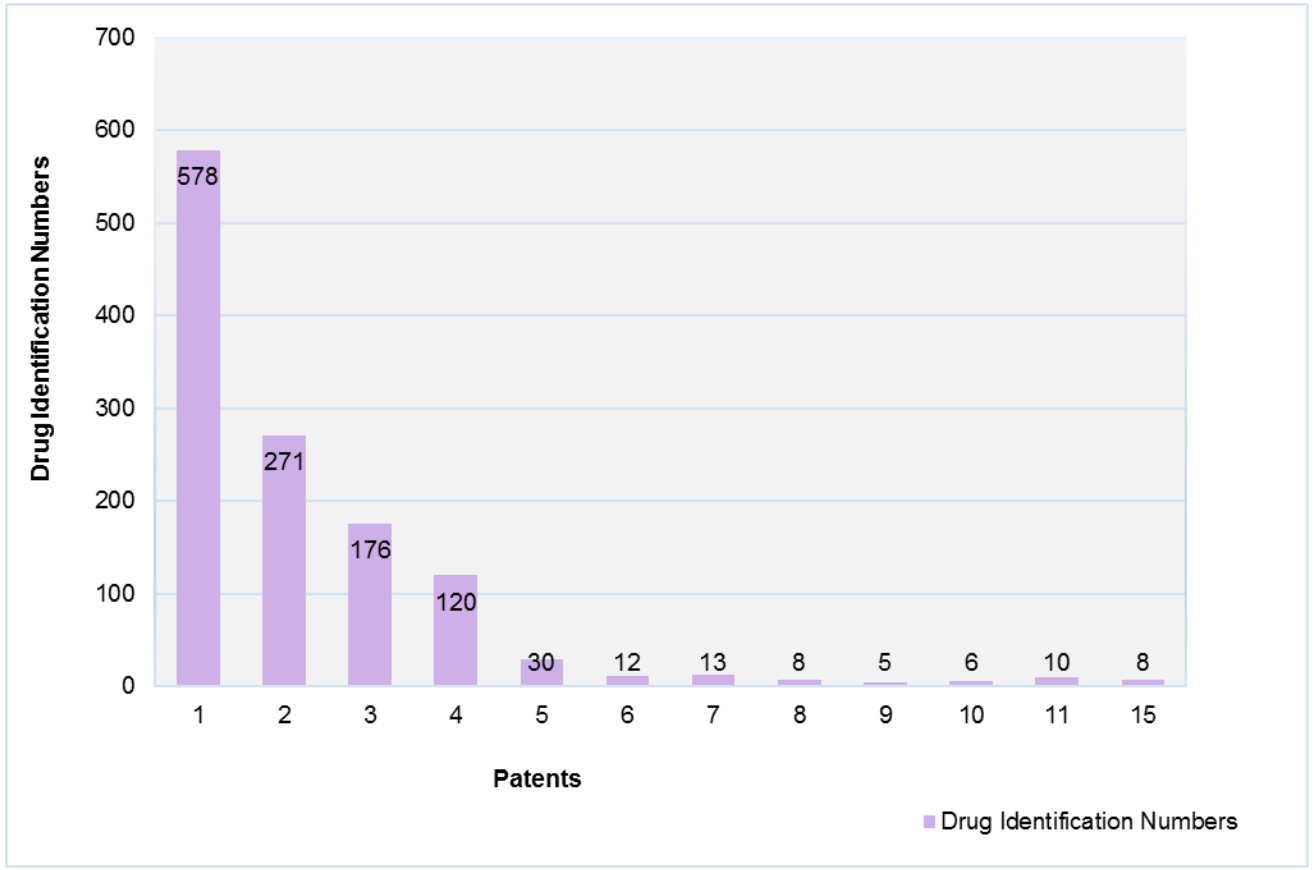
Adding Patents

- Requires a link between the patent and the drug submission approval, also known as product specificity
- Types of eligible patent claims:
  - medicinal ingredient
  - formulation that contains the medicinal ingredient
  - dosage form
  - use of the medicinal ingredient

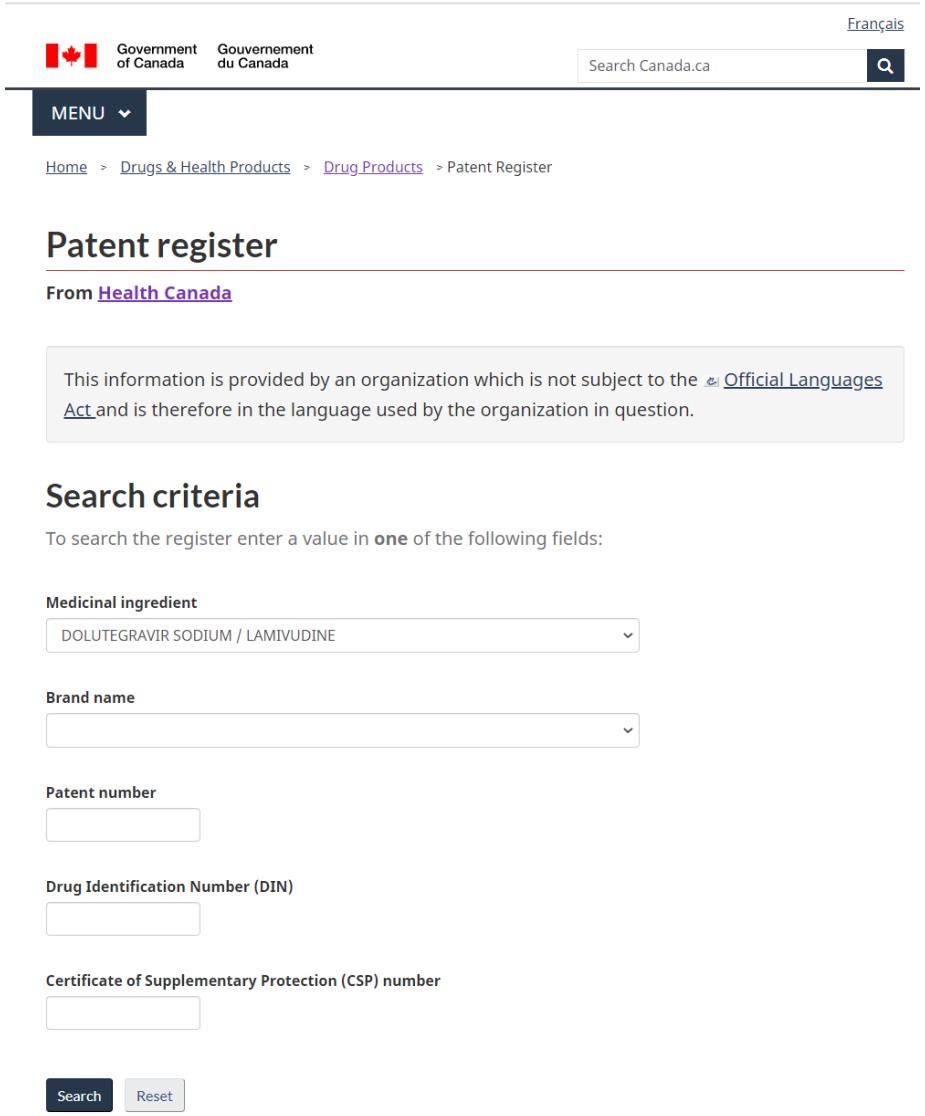
- Not all patents for a drug are submitted/ added
- Patents are added per Drug Identification Number (DIN), therefore lists can be different for different dosage forms or strengths of a drug

Snapshot

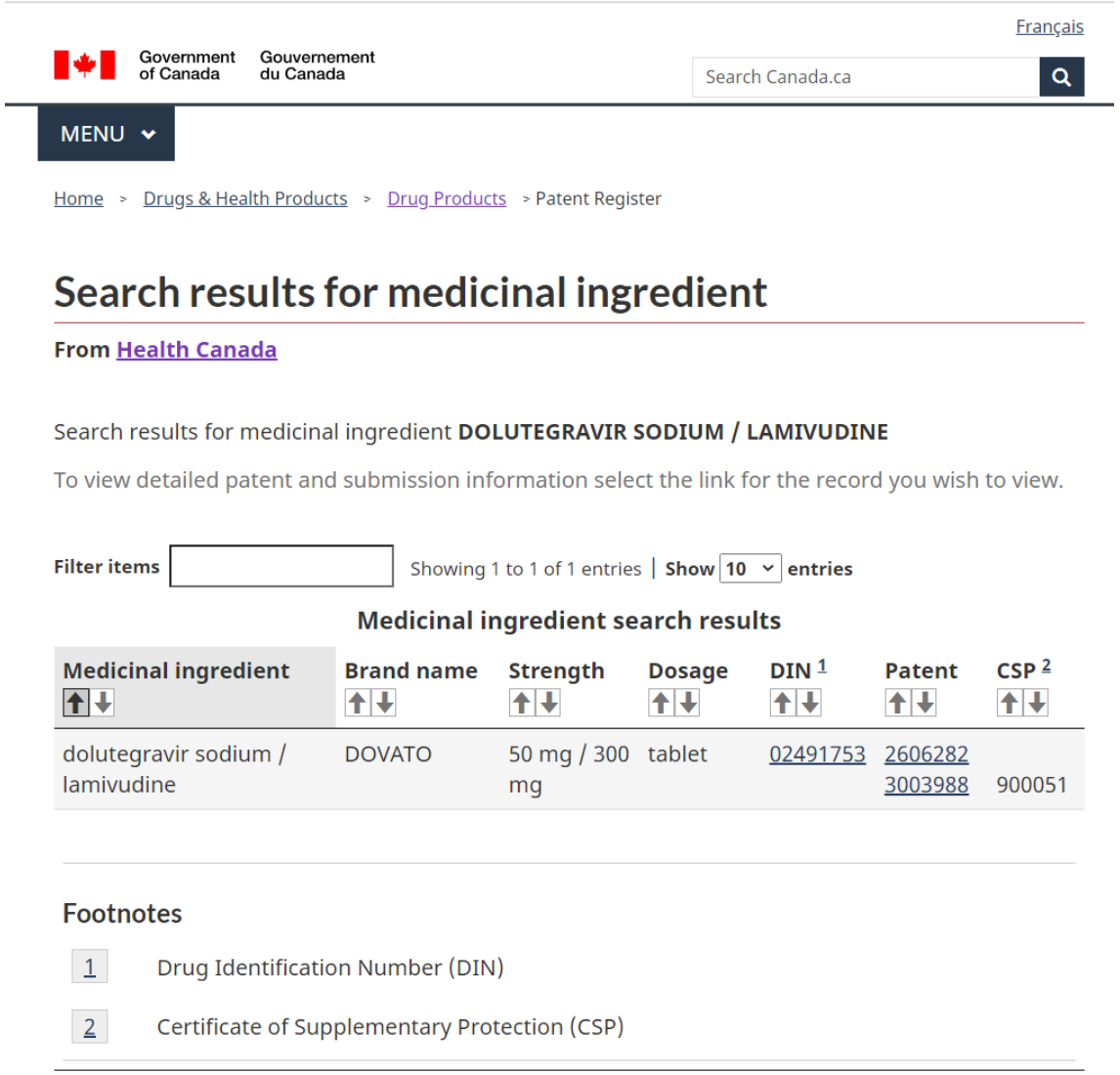
- As of March 31, 2020 there were 1,237 DINs listed on the Patent Register, representing 626 different drugs



Searching the Patent Register



Search Results



Français

Government of Canada / Gouvernement du Canada

Search Canada.ca

MENU

Home > Drugs & Health Products > Drug Products > Patent Register

Search results for medicinal ingredient

From Health Canada

Search results for medicinal ingredient **DOLUTEGRAVIR SODIUM / LAMIVUDINE**

To view detailed patent and submission information select the link for the record you wish to view.

Filter items | Showing 1 to 1 of 1 entries | **Show** 10 **entries**

Medicinal ingredient search results

Medicinal ingredient	Brand name	Strength	Dosage	DIN [1]	Patent	CSP [2]
dolutegravir sodium / lamivudine	DOVATO	50 mg / 300 mg	tablet	02491753	2606282 3003988	900051

Footnotes

1 Drug Identification Number (DIN)

2 Certificate of Supplementary Protection (CSP)

Search Results

Back

Medicinal ingredient(s): dolutegravir sodium / lamivudine

Brand name: DOVATO

Drug Identification Number (DIN): 02491753

Route(s) of administration: ORAL

Strength per unit: 50 mg / 300 mg

Dosage form: TABLET

Human/Vet: Human

Patent number: 3003988

Date granted: 2020-01-07

Expiration date: 2031-01-24

Filing date: 2011-01-24

Code:
C - Applicant has obtained the consent of the owner of the patent for the inclusion of the patent on the above patent list

Name and address for service in Canada :
Keith Aguilera
Legal Counsel
GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga
ONTARIO
L5N 6L4

Certificate of Supplementary Protection

Certificate of Supplementary Protection (CSP) number:
900051
CSP Expiration date: 2033-01-24

Submission 1 of 2

Submission number: 220275

Submission type: NDS

NOC (Notice of Compliance) date: 2019-08-22

Manufacturer: VIIV HEALTHCARE ULC

Address of manufacturer:

Search Results

Submission 1 of 2

Submission number: 220275

Submission type: NDS

NOC (Notice of Compliance) date: 2019-08-22

Manufacturer: VIIV HEALTHCARE ULC

Address of manufacturer:
245 Armand-Frappier Boulevard
Laval
QUEBEC
H7V 4A7

Date added: 2020-01-23

Date amended:

Use of the medicinal ingredient: DOVATO (dolutegravir/lamivudine) is indicated for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents 12 years of age and older and weighing at least 40 kg.

Office use:

Form IV: patent list

(PDF Version < 500 K)

Submission 2 of 2

Submission number: 233469

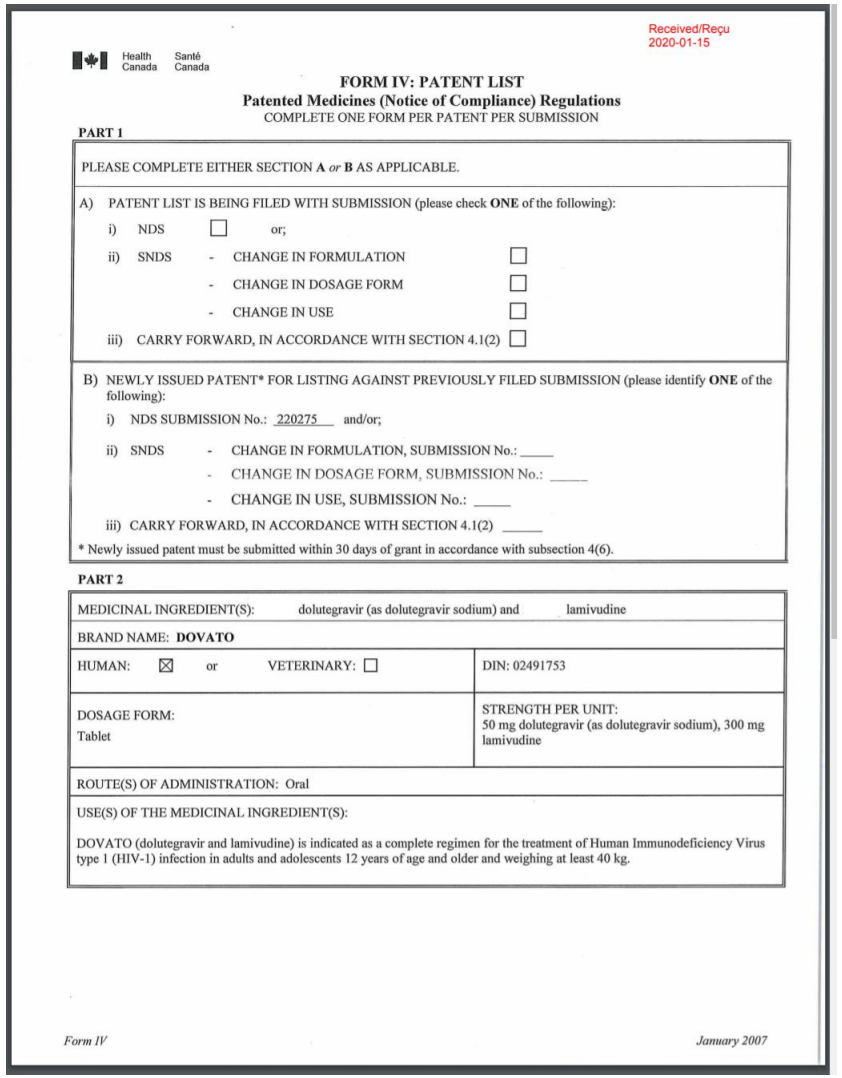
Submission type: carry forward

NOC (Notice of Compliance) date: 2020-09-30

Manufacturer: VIIV HEALTHCARE ULC

Address of manufacturer:
245, Armand-Frappier Boulevard
Laval
QUEBEC

Search Results



Received/Reçu
2020-01-15

Health Canada / Santé Canada

FORM IV: PATENT LIST
Patented Medicines (Notice of Compliance) Regulations
COMPLETE ONE FORM PER PATENT PER SUBMISSION

PART 1

PLEASE COMPLETE EITHER SECTION **A** *or* **B** AS APPLICABLE.

A) PATENT LIST IS BEING FILED WITH SUBMISSION (please check **ONE** of the following):

i) NDS ☐ or;

ii) SNDS - CHANGE IN FORMULATION ☐
- CHANGE IN DOSAGE FORM ☐
- CHANGE IN USE ☐

iii) CARRY FORWARD, IN ACCORDANCE WITH SECTION 4.1(2) ☐

B) NEWLY ISSUED PATENT* FOR LISTING AGAINST PREVIOUSLY FILED SUBMISSION (please identify **ONE** of the following):

i) NDS SUBMISSION No.: 220275 and/or;

ii) SNDS - CHANGE IN FORMULATION, SUBMISSION No.: ____
- CHANGE IN DOSAGE FORM, SUBMISSION No.: ____
- CHANGE IN USE, SUBMISSION No.: ____

iii) CARRY FORWARD, IN ACCORDANCE WITH SECTION 4.1(2) ____

* Newly issued patent must be submitted within 30 days of grant in accordance with subsection 4(6).

PART 2

MEDICINAL INGREDIENT(S): dolutegravir (as dolutegravir sodium) and lamivudine

BRAND NAME: **DOVATO**

HUMAN: ☒ or VETERINARY: ☐ | DIN: 02491753

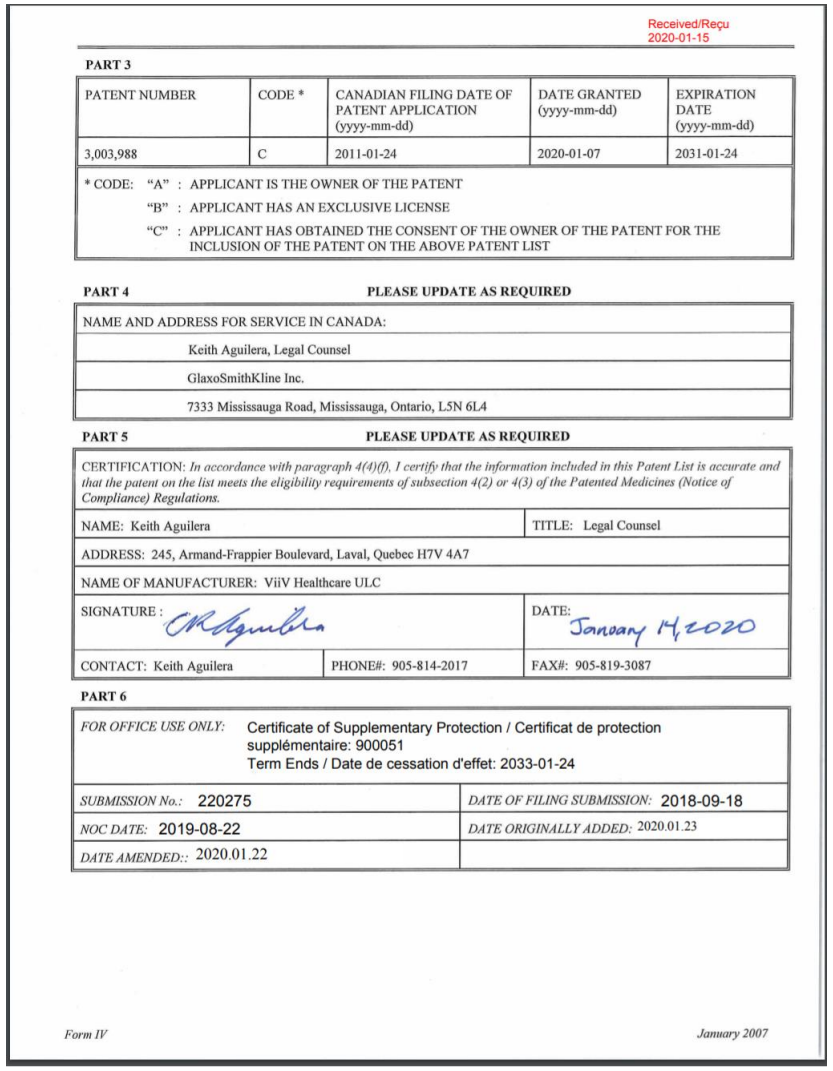
DOSAGE FORM: Tablet | STRENGTH PER UNIT: 50 mg dolutegravir (as dolutegravir sodium), 300 mg lamivudine

ROUTE(S) OF ADMINISTRATION: Oral

USE(S) OF THE MEDICINAL INGREDIENT(S):

DOVATO (dolutegravir and lamivudine) is indicated as a complete regimen for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents 12 years of age and older and weighing at least 40 kg.

Form IV *January 2007*



Received/Reçu
2020-01-15

PART 3

PATENT NUMBER	CODE *	CANADIAN FILING DATE OF PATENT APPLICATION (yyyy-mm-dd)	DATE GRANTED (yyyy-mm-dd)	EXPIRATION DATE (yyyy-mm-dd)
3,003,988	C	2011-01-24	2020-01-07	2031-01-24

* CODE: "A" : APPLICANT IS THE OWNER OF THE PATENT
"B" : APPLICANT HAS AN EXCLUSIVE LICENSE
"C" : APPLICANT HAS OBTAINED THE CONSENT OF THE OWNER OF THE PATENT FOR THE INCLUSION OF THE PATENT ON THE ABOVE PATENT LIST

PART 4 **PLEASE UPDATE AS REQUIRED**

NAME AND ADDRESS FOR SERVICE IN CANADA:
Keith Aguilera, Legal Counsel
GlaxoSmithKline Inc.
7333 Mississauga Road, Mississauga, Ontario, L5N 6L*A*

PART 5 **PLEASE UPDATE AS REQUIRED**

CERTIFICATION: *In accordance with paragraph 4(4)(f), I certify that the information included in this Patent List is accurate and that the patent on the list meets the eligibility requirements of subsection 4(2) or 4(3) of the Patented Medicines (Notice of Compliance) Regulations.*

NAME: Keith Aguilera | TITLE: Legal Counsel

ADDRESS: 245, Armand-Frappier Boulevard, Laval, Quebec H7V 4A7

NAME OF MANUFACTURER: ViiV Healthcare ULC

SIGNATURE : K Aguilera | DATE: January 14, 2020

CONTACT: Keith Aguilera | PHONE#: 905-814-2017 | FAX#: 905-819-3087

PART 6

FOR OFFICE USE ONLY: Certificate of Supplementary Protection / Certificat de protection supplémentaire: 900051
Term Ends / Date de cessation d'effet: 2033-01-24

SUBMISSION No.: 220275	*DATE OF FILING SUBMISSION:* 2018-09-18
NOC DATE: 2019-08-22	*DATE ORIGINALLY ADDED:* 2020.01.23
DATE AMENDED:: 2020.01.22	

Form IV *January 2007*

Subsequent Entry Drugs (Generic & Biosimilar)

- When a manufacturer files a submission that makes a comparison or reference to a drug marketed in Canada, it must address the patents (and CSPs) included on the Patent Register in respect of that drug
- All drug submissions are checked prior to filing
- Patent Register is “frozen” once the submission is filed

- If there are patents/ CSPs, the manufacturer must either:
  - Obtain consent from the patentee,
  - Agree to wait for patent/ CSP expiry, or
  - Challenge the patent(s)/ CSP(s) through the service of a **notice of allegation** on the innovator

Court Challenges

- The innovator has 45 days after receiving a notice of allegation to initiate an **action** in the Federal Court, asking for a declaration that the making, constructing, using or selling of the generic/biosimlar drug would infringe the patent and/or CSP.
- Upon commencing the action, **a statutory stay of 24 months arises**, preventing Health Canada from approving the generic/biosimlar drug until either the stay ends, or the expiry of the patent/CSP if there is a declaration of infringement.

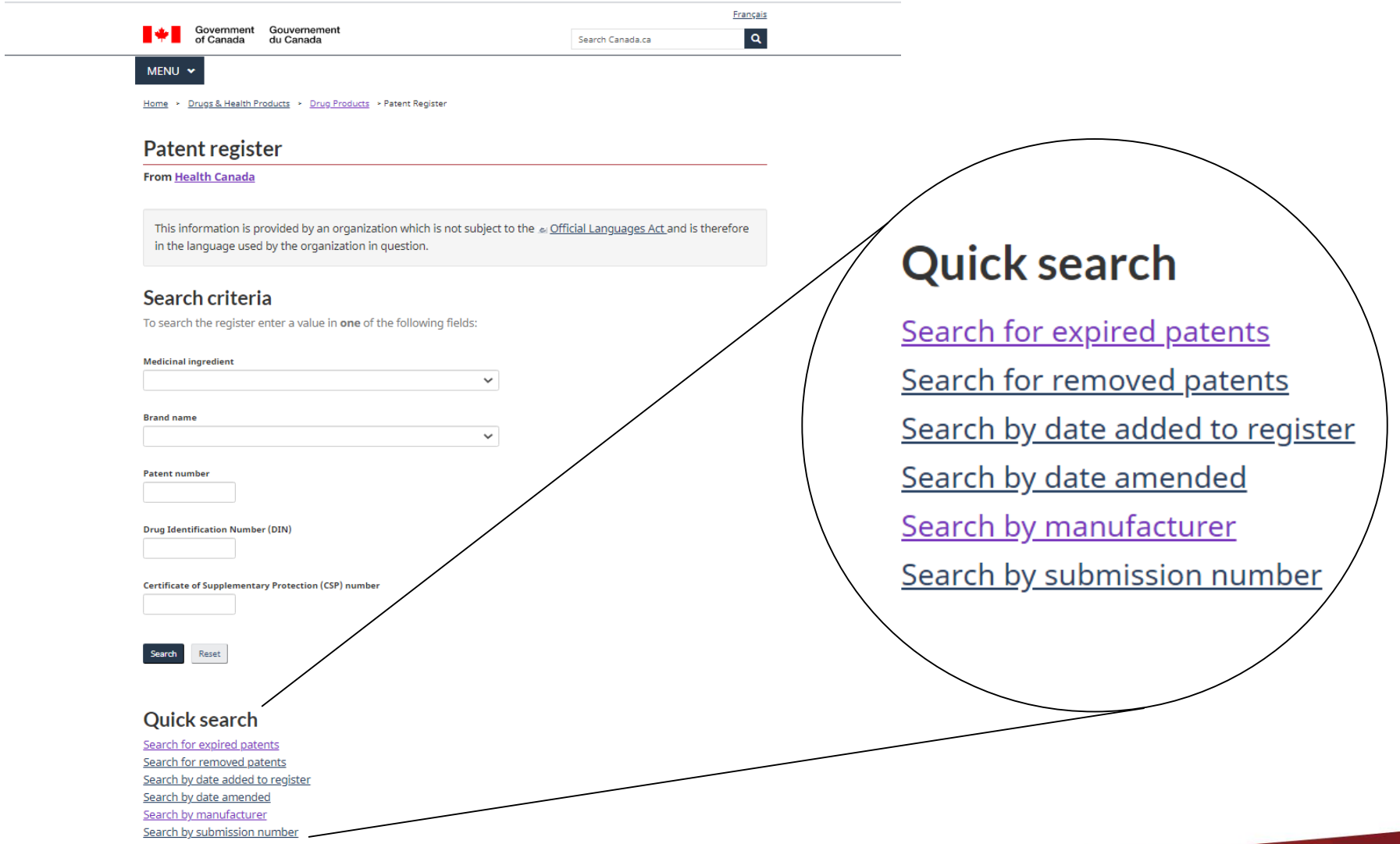
- Approval of subsequent-entry drug depends on outcome of the litigation

Removing Patents

- Prescribed in the *PMNOC Regulations*
  - Administrative error
  - Court declaration that the patent/CSP is invalid or void
  - Court declaration that the patent/CSP is ineligible for inclusion on the Patent Register
  - Request by innovator
  - Expired patent (if no CSP)
  - Expired CSP
  - Cancelled DIN

- Search for expired/removed patents on Patent Register

Patent Register



Additional Information

- Database is available for download as a set of compressed text files to be imported into the user's database of choice
- Statistical Report, published annually and available upon request at https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/drug-products.html
- Guidance Document: *Patented Medicines (Notice of Compliance) Regulations* available at https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/patented-medicines/notice-compliance-regulations.html#a7

Questions ?