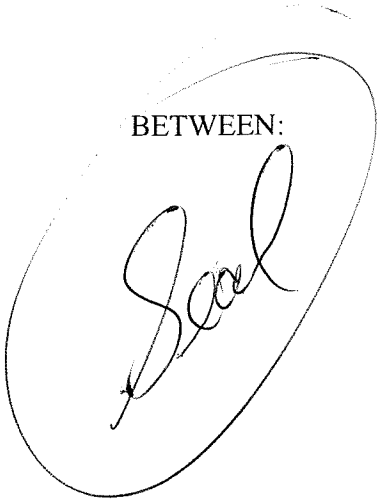
Court File No. T-258-21

FEDERAL COURT

BETWEEN:

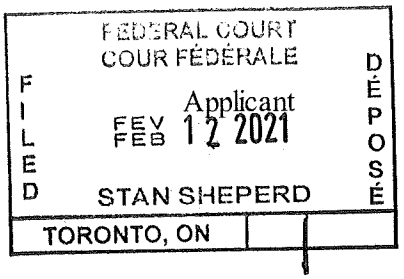


VIIV HEALTHCARE ULC

Applicant

- and -

THE MINISTER OF HEALTH



Respondent

NOTICE OF APPLICATION

TO THE RESPONDENT:

A PROCEEDING HAS BEEN COMMENCED by the Applicant. The relief claimed by the Applicant appears on the following pages.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the Applicant. The Applicant requests that this application be heard at the Federal Court in Toronto, Ontario.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for you must prepare a notice of appearance in Form 305 prescribed by the *Federal Courts Rules* and serve it on the Applicant's solicitor, or if the Applicant is self-represented, on the Applicant, WITHIN 10 DAYS after being served with this notice of application.

Copies of the *Federal Courts Rules,* information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

Date: Issued by:

(*Registry Officer*)

Address of local office: 180 Queen Street West, Suite 200
Toronto, ON M5V 3L6

TO: **THE ADMINISTRATOR**
Federal Court

AND TO: **THE MINISTER OF HEALTH**
c/o Health Products and Food Branch
Resource Management and Operations Directorate
Director General's Office
7th Floor, Room 758
Graham Spry Building
250 Lanark Avenue
Ottawa, Ontario K1A 0

(service to be effected by filing duplicate copies in the Registry pursuant to s. 133 of the *Federal Courts Rules* and s. 48 of the *Federal Courts Act*)

THE ATTORNEY GENERAL OF CANADA
Ontario Regional Office
Department of Justice Canada
120 Adelaide Street West, Suite 400
Toronto, Ontario M5H 1T1

(service to be effected by filing duplicate copies in the Registry pursuant to s. 133 of the *Federal Courts Rules* and s. 48 of the *Federal Courts Act*)

APPLICATION

1. This is an application for judicial review pursuant to sections 18 and 18.1 of the *Federal Courts Act*, RSC 1985, c F-7, as amended, in respect of a decision of the Health Products and Food Branch on behalf of the Minister of Health (**Minister**). By letter dated January 13, 2021, the Minister advised the Applicant that, upon reconsideration further to the Federal Court judgment in *ViiV Healthcare ULC v The Minister of Health*, 2020 FC 726 (the **Judgment**), the Certificate of Supplementary Protection Application No. 900021 (the **CSP Application**) in respect of Canadian Patent No. 2,606,282 (the **282 Patent**), dolutegravir and the drug JULUCA® is refused in accordance with subsections 106(1) and 107(2) of the *Patent Act*, RSC 1985 c P-4 (***Patent Act***) (the **Decision**).

THE APPLICANT MAKES THIS APPLICATION FOR:

2. The Applicant seeks the following relief:

   (a) A Declaration that the CSP Application in respect of the 282 Patent, dolutegravir, and JULUCA® is eligible for a CSP;

   (b) A Declaration that the Minister's interpretation and application of the *Patent Act* and the *Certificate of Supplementary Protection Regulations,* SOR 2017-164 (***CSP Regulations***) in the Decision was unreasonable in finding that the CSP Application in respect of the 282 Patent, dolutegravir and JULUCA® was not eligible for a CSP;

   (c) An Order quashing or setting aside the Minister's Decision refusing to grant a CSP in respect of the 282 Patent, dolutegravir and JULUCA®;

   (d) An Order directing the Minister to grant the CSP in respect of the 282 Patent, dolutegravir and JULUCA®; and

   (e) Such further and other relief as counsel may advise and this Honourable Court permit.

THE GROUNDS FOR THE APPLICATION ARE:

A. JULUCA®

3. JULUCA® is a fixed dose combination tablet containing 50 mg dolutegravir (as dolutegravir sodium) and 25 mg rilpivirine (as rilpivirine hydrochloride).

4. JULUCA® is indicated as a complete regimen to replace the current antiretroviral regimen for the treatment of human immunodeficiency virus (**HIV-1**) infection in adults who are virologically stable and supressed (HIV-1 RNA less than 50 copies per mL).

5. According to the Regulatory Decision Summary for JULUCA® published by Health Canada, JULUCA® is intended to provide a simplified treatment regimen with improved tolerability and offer continued suppression of HIV-1 in individuals who are already virologically-supressed. The benefits of a two-drug fixed dose combination are stated as improved adherence, tolerability, and quality of life for eligible subjects.

6. JULUCA® is the first drug containing a combination of dolutegravir and rilpivirine to be approved and issued an Notice of Compliance (**NOC**) by Health Canada.

7. The medicinal ingredients contained in JULUCA® (dolutegravir and rilpivirine) are respectively listed on the Register of Innovative Drugs.

B. 282 PATENT

8. JULUCA® was developed by ViiV Healthcare in partnership with Janssen Pharmaceutica NV.

9. The patents to the two individual components of JULUCA® – dolutegravir and rilpivirine – are owned by ViiV Healthcare Company & Shionogi & Co., Ltd., and Janssen Pharmaceutica NV, respectively.

10. The 282 Patent listed in the CSP Application is entitled "polycyclic carbamoylpyridone derivatives having HIV integrase inhibitor activity". The 282 Patent is owned by ViiV Healthcare Company and Shionogi & Co., Ltd.

11. The 282 Patent contains 437 claims, including claims directed to, *inter alia,* the medicinal ingredient dolutegravir, one of the medicinal ingredients contained in JULUCA®.

12. The 282 Patent was filed on April 28, 2006 and was issued in Canada on April 26, 2016. The 282 Patent expires on April 28, 2026.

13. The 282 Patent is listed on the Patent Register in relation to JULUCA®.

C. CERTIFICATES OF SUPPLEMENTARY PROTECTION

14. Canada's CSP legislation is contained in sections 104 to 134 of the *Patent Act* and the accompanying *CSP Regulations* (collectively, the **CSP Regime**).

15. The CSP Regime provides an additional period of patent-like rights for eligible new drugs protected by an eligible patent in the form of a CSP—also known as "patent term restoration". This additional period of protection extends from the date of expiry of the eligible pharmaceutical patent for a period of up to two years.

16. Canada's CSP Regime is intended to implement Canada's commitment to the *Canada-European Union Comprehensive Economic and Trade Agreement* (**CETA**).

17. CSP rights are intended to compensate, in part, for the period of patent term that is otherwise lost while pharmaceutical products undergo research and development and governmental regulatory review required in order to obtain market authorization.

D. CSP REGIME

18. The *Patent Act* contains a framework for the issuance and the administration of CSPs. This framework includes the authority to make the *CSP Regulations*.

19. A patentee must meet several conditions to be eligible for a CSP in Canada, including: (i) there must be a first authorization for sale issued on or after September 21, 2017; (ii) based on a new drug submission filed in Canada within 12 months of the first international filing of an equivalent regulatory submission for the same medicinal ingredient(s) in specified jurisdictions; (iii) eligible medicinal ingredient(s); (iv) an

eligible patent containing eligible patent claims; and (v) no other CSP must have previously issued for the medicinal ingredient(s).

20. This Application addresses the patent eligibility and authorization for sale criteria.

(a) **Patent Eligibility Criteria**

21. Section 106(1)(c) of the *Patent Act* sets out the CSP application criteria on how a patent pertains to a medicinal ingredient or combination of medicinal ingredients contained in a drug for which an authorization for sale was issued:

> 106(1) On the payment of the prescribed fee, a patentee may apply to the Minister for a certificate of supplementary protection for a patented invention if all of the following conditions are met:
>
> [...]
>
> (c) the patent pertains in the prescribed manner to a medicinal ingredient, or combination of medicinal ingredients, contained in a drug for which an authorization for sale of the prescribed kind was issued on or after the day on which this section comes into force;
>
> [...]

22. Subsection 3(2) of the *CSP Regulations* sets out the prescribed manners in which eligible patents may pertain to medicinal ingredients:

> 3(2) For the purposes of paragraph 106(c) of the Act, the prescribed manners in which a patent may pertain to a medicinal ingredient or combination of medicinal ingredients are the following:
>
> (a) the patent contains a claim for the medicinal ingredient or combination of all the medicinal ingredients contained in a drug for which the authorization for sale set out in the application for a certificate of supplementary protection was issued;
>
> (b) the patent contains a claim for the medicinal ingredient or combination of all the medicinal ingredients as obtained by a specified process and contained in a drug for which the authorization for sale set out in the application for a certificate of supplementary protection was issued; and
>
> (c) the patent contains a claim for a use of the medicinal ingredient or combination of all the medicinal ingredients contained in a drug

for which the authorization for sale set out in the application for a certificate of supplementary protection was issued.

(a) **Authorization for Sale Criteria**

23. Section 106(1)(d) of the *Patent Act* sets out the authorization for sale criteria, including:

> 106(1)(d) the authorization for sale is the first authorization for sale that has been issued with respect to the medicinal ingredient or the combination of medicinal ingredients, as the case may be;

24. Subsection 1(2) and section 4 of the *CSP Regulations* define what constitutes an eligible authorization for sale.

E. CETA

25. Section 3 of the *CETA Implementation Act* requires the *Act* and any federal law that implements a provision of CETA or fulfils an obligation of the Government of Canada under CETA to be interpreted in a manner consistent with CETA.

26. Article 20.27(2) of CETA, which addresses *sui generis* protection for pharmaceuticals, states that:

> Each Party shall provide a period of *sui generis* protection in respect of a product that is protected by a basic patent in force at the request of the holder of the patent or his successor in title, provided the following conditions have been met:
>
> a. an authorisation has been granted to place the product on the market of that Party as a pharmaceutical product (referred to as "marketing authorisation" in this Article);
>
> b. the product has not already been the subject of a period of *sui generis* protection; and
>
> c. the marketing authorisation referred to in subparagraph (a) is the first authorisation to place the product on the market of that Party as a pharmaceutical product.

27. The term "basic patent" is defined in Article 20.27(1) of CETA as:

> a patent which protects a product as such, a process to obtain a product or an application of a product, and which has been designated by the holder of a patent that may serve as a basic

> patent, as the basic patent for the purpose of the granting of *sui generis* protection.

28. The term "product" is defined in Article 20.27(1) of CETA as:

> the active ingredient or combination of active ingredients of a pharmaceutical product.

29. The term "pharmaceutical product" is defined in Article 20.6 as:

> a product including a chemical drug, biologic drug, vaccine or radiopharmaceutical, that is manufactured, sold or represented for use in: (a) making a medical diagnosis, treating, mitigating or preventing disease, disorder, or abnormal physical state, or its symptoms, or (b) restoring, correcting, or modifying physiological functions.

F. THE FIRST DECISION UNDER REVIEW

30. On September 14, 2018, the Applicant filed the CSP Application for the 282 Patent in relation to JULUCA®.

31. The CSP Application lists the medicinal ingredient dolutegravir, which is claimed in the 282 Patent and one of the two medicinal ingredients contained in JULUCA® (dolutegravir and rilpivirine).

32. No CSP has previously issued for dolutegravir alone.

33. By letter dated January 25, 2019, the Minister issued the first Decision under review (**First Decision**). The First Decision determined that the CSP Application was not eligible in accordance with section 113 of the *Patent Act*.

34. The Minister determined that the 282 Patent failed to satisfy paragraph 106(c) of the *Patent Act* and subsection 3(2) of the *CSP Regulations* because it does not contain a claim for: (i) the combination of all the medicinal ingredients, (ii) the combination of all the medicinal ingredients as obtained by a specified process, or (iii) a use of the combination of all the medicinal ingredients – contained in a drug for which the authorization for sale set out in the CSP Application was issued.

35. The Minister rejected the CSP Application on the basis that the 282 Patent did not contain an eligible patent claim because it "*does not pertain to the combination of medicinal ingredients dolutegravir and rilpivirine in the manners prescribed by section 3(2) of the CSP Regulations*."

36. No other grounds were raised by the Minister, and the CSP Application was otherwise deemed eligible on all other grounds.

37. Prior to making the First Decision, the Minister had before it representations (dated December 7, 2018) from the Applicant as to why the CSP Application should be allowed.

38. In its representations the Applicant asserted, *inter alia,* that both paragraph 106(1)(c) of the *Patent Act* and subsection 3(2) of the *CSP Regulations* permit a patent to pertain to (i) a medicinal ingredient contained in the marketed drug product, or (ii) a combination of medicinal ingredients contained in the marketed drug product.

39. The Applicant asserted that this interpretation was consistent with the CETA text, including the definition of a "basic patent", which refers to a patent that "protects a product as such".

40. The Applicant further asserted that the Minister's interpretation of the phrase "a claim for the medicinal ingredient" in paragraph 3(2)(a) of the *CSP Regulations* should be consistent with the interpretation of the same phrase "a claim for the medicinal ingredient" under paragraphs 4(2)(a) and 4(2.1)(a) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended (***PM(NOC) Regulations***).

41. Under the *PM(NOC) Regulations*, a patent that claims only one or some of the medicinal ingredients contained in the relevant approved drug product is eligible for listing on the Patent Register under paragraphs 4(2)(a) and 4(2.1)(a).

G. THE JUDICIAL REVIEW OF THE FIRST DECISION

42. The Applicant brought a judicial review application before the Federal Court in respect of the First Decision (T-353-19). The application was heard on January 15, 2020 before the Honourable Madam Justice Fuhrer.

43. On July 10, 2020 the Court released its judgment and reasons (**Judgment**), finding the First Decision unreasonable based on the Minister's failure to consider CETA regarding the proper interpretation of the relevant CSP provisions. The Court held that its judgment turned on this consideration. It therefore did not address the other grounds of review advanced by the Applicant on the interpretation of the *Patent Act* and *CSP Regulations*.

44. The Federal Court also held in the Judgment that:

(a) The purpose of the CSP Regime is to "implement the *sui generis* regime of additional 'patent-like' protection for pharmaceuticals described in CETA Article 20.27". CSP term is intended to compensate eligible patentees "for time spent researching and obtaining market authorization for innovative products".

(b) The CSP Regime must be interpreted in a manner consistent with CETA; the CETA text itself must be consulted as part of determining the text, context and purpose of the provisions in question.

(c) CETA affords broad protection for innovative and creative products. The Applicant's interpretation that the 282 Patent protects the product "as such" is not inconsistent with CETA. CETA appears to provide a broader scope of protection than conceived by the Minister.

(d) The Minister's interpretation of the relevant text in the Health Canada CSP Guidance Document (**Guidance Document**) "reads in" "clarifications" that "belie" the Minister's assertion on the grammatical and ordinary sense of the words of paragraph 3(2) of the *CSP Regulations*.

45. The Court remitted the matter back to the Minister for redetermination with the specific direction that the Minister consider CETA.

H. THE MINISTER'S REDETERMINATION

46. By letter dated January 13, 2021, the Minister issued a decision redetermining the CSP Application (the **Decision**). The Minister again refused the CSP Application. The Minister held that where an approved drug contains a combination of medicinal

ingredients (such as JULUCA®), an eligible patent must include a claim for the combination of all the medicinal ingredients, a claim for the combination of all the medicinal ingredients as obtained by a specified process, or a claim for a use of the combination of all the medicinal ingredients, in order to meet the requirements of subsection 3(2) of *the CSP Regulations* and subsection 106(l)(c) of the *Patent Act*.

47. The Minister found that the 282 Patent failed to meet this deemed requirement and therefore was ineligible for a CSP.

48. The Minister asserts that her interpretation of the CSP Regime in the Decision is consistent with Article 20.27 of the CETA text, while the Applicant's interpretation of the relevant CSP provisions is not.

J. THE MINISTER'S DECISION IS UNREASONABLE

49. The Minister's Decision to deny the JULUCA® CSP Application in respect of the 282 Patent and dolutegravir is unreasonable.

50. The Minister reached an unreasonable decision by:

(a) Misinterpreting and misapplying the text, context, and purpose of the *Patent Act*, including subsection 106(1);

(b) Failing to interpret the *Patent Act,* including subsection 106(1), in accordance with its object and purpose with respect to CETA;

(c) Misinterpreting and misapplying the text, context, and purpose of the *CSP Regulations,* including subsection 3(2);

(d) Failing to interpret the *CSP Regulations,* including subsection 3(2), in accordance with their object and purpose with respect to CETA;

(e) Interpreting the *Patent Act* and *CSP Regulations* in a manner that is inconsistent with the object and purpose of the CSP Regime and CETA;

(f) Taking a conflicting position from other CSP eligibility decisions with respect to the scope of CSP protection on dolutegravir as it applies to previously approved drugs, and using that position as a basis to deny the CSP Application;

(g) Arriving at an inconsistent interpretation of the identical phrase "a claim for the medicinal ingredient" in the *CSP Regulations* and the *PM(NOC) Regulations*, which are both promulgated under the *Patent Act*.

51. The Applicant relies on:

(a) *Patent Act*, RSC 1985, c P-4, as amended, including sections 104-134;

(b) *Certificate of Supplementary Protection Regulations*, SOR-2017-165;

(c) *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended;

(d) The text of the Canada-European Union Comprehensive Economic and Trade Agreement;

(e) *Canada–European Union Comprehensive Economic and Trade Agreement Implementation Act*, SC 2017, c 6;

(f) Division 8 of the *Food and Drug Regulations*, CRC, c 870, as amended;

(g) *Federal Courts Act*, RSC 1985, c F-7, as amended, sections 18, 18.1 and 18.2, and the *Federal Courts Rules*, SOR/98-106, as amended; and

(h) Such further and other material as counsel may advise and this Honourable Court permit.

THIS APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

(a) A certified copy of the 282 Patent;

(b) The affidavits of one or more witnesses;

(c) The record before and the Judgment of the Federal Court dated July 10, 2020;

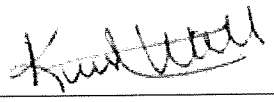
(d) The record before and the Minister's Decision dated January 13, 2021; and

(e) Such further and other material as counsel may advise and this Honourable Court permit.

PURSUANT TO RULE 317 OF THE FEDERAL COURTS RULES, THE APPLICANT REQUESTS THE MINISTER OF HEALTH TO SEND A CERTIFIED COPY OF THE FOLLOWING MATERIAL, THAT IS NOT IN THE POSSESSION OF THE APPLICANT, BUT IS IN THE POSSESSION OF THE MINISTER OF HEALTH, TO THE APPLICANT AND TO THE REGISTRY:

1. All materials considered or created by the Minister of Health, or by any person or entity acting on behalf of the Minister of Health, and including all documentation and communication, pertaining or relevant to the Decision herein.

Dated at Toronto this 12th day of February, 2021.



NORTON ROSE FULBRIGHT CANADA LLP
222 Bay Street, Suite 3000, P.O. Box 53
Toronto, Ontario, M5K 1E7 Canada

Kristin Wall
Morgan Westgate

Tel: 416.216.4000
Fax: 416.216.3930

Solicitors for the Applicant

Court File No. T- -21

FEDERAL COURT

BETWEEN:

VIIV HEALTHCARE ULC

Applicant

- and -

THE MINISTER OF HEALTH

Respondent

NOTICE OF APPLICATION

NORTON ROSE FULBRIGHT CANADA LLP
222 Bay Street, Suite 3000, P.O. Box 53
Toronto, Ontario, M5K 1E7 Canada

Kristin Wall
Morgan Westgate

Tel: 416.216.4000
Fax: 416.216.3930

Solicitors for the Applicant

I HEREBY CERTIFY that the above document is a true copy of the original issued out of / filed in the Court on the
day of FEB 12 2021 A.D. 20
Dated this FEB 12 2021 day of 20

Federal Courts Fees Receipt
Reçu pour frais judiciaires des cours fédérales

NO. A 609025

Federal Court of Appeal / Cour d'appel fédérale ☐

Federal Court / Cour fédérale ☑

Court Martial Appeal Court of Canada / Cour d'appel de la cour martiale ☐

To / À :

Name/Nom : Norton Rose

Organization/Organisation : _____

Address/Adresse : _____

_____

_____

Date : Feb 12, 21

Issuing Office / Bureau émetteur : Toronto

Prepared by / Préparé par : S Shepherd

Court File No./ N° du dossier de la Cour : T-258-21

Style of Cause & Description of Services Provided Intitulé de la cause et description des services rendus	Cost(s) Frais
Notice of Application VIIV Healthcare v Minister of Health **Total =**	$50.00

Method of Payment / Mode de paiement

☐ Account / Compte

Dept# / # Département : _____

Org Code / Code org : _____

Reference Code / Code référence :

_____

☐ Cash / Comptant

☐ Debit Card / Carte de débit

☑ Cheque No. / N° chèque : 723

☐ American Express: _____

☐ MasterCard: _____

☐ Visa: _____

White - Original file - Ottawa
Blanche - Dossier original - Ottawa

Blue - Accounting - Ottawa
Bleue - Comptabilité - Ottawa

Goldenrod - Accounting 2nd copy. Local Office where costs retained by Province (Ottawa Statistics)

Or - Comptabilité 2e copie. Bureau local lorsque les frais sont retenus par la province (Statistiques Ottawa)

Pink - Party
Rose - Partie

Canary - Duplicate - Local office
Jaune - Duplicata - Bureau local

CAS/SATJ-26 (REV 2/11)