Court File No. T-1603-18

FEDERAL COURT

BETWEEN:

GLAXOSMITHKLINE BIOLOGICALS S.A.

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: AUG 3 1 2018 Issued by:

Cherlin McColman
Registry Officer
Agent du greffe
(*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 Therapeutic Products Directorate
Office of Submissions and Intellectual Property
Finance Building
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(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
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(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 Therapeutic Products Directorate (**TPD**), on behalf of the Minister of Health (**Minister**). By letter dated August 3, 2018, the TPD advised the Applicant that the Certificate of Supplementary Protection Application No. 900006 (the **CSP Application**) in respect of Canadian Patent No. 2,600,905 (**905 Patent**) and the drug SHINGRIX® is not eligible for a Certificate of Supplementary Protection (**CSP**) in accordance with section 113 of the *Patent Act*, RSC 1985 c P-4 (***Patent Act***) (the **Decision**).

THE APPLICANT MAKES THIS APPLICATION FOR:

2. The Applicant seeks relief as follows:

   (a) A declaration that the CSP Application for SHINGRIX® in respect of the 905 Patent is eligible for a CSP in accordance with section 113 of the *Patent Act*;

   (b) A declaration that the Minister erred in law in interpreting and applying the *Patent Act* and the *Certificate of Supplementary Protection Regulations*, SOR/2017-165 exceeded her jurisdiction or failed to properly exercise her jurisdiction, fettered her discretion and based the Decision on erroneous or unreasonable findings of fact in deciding that the CSP Application for SHINGRIX® in respect of the 905 Patent was not eligible for a CSP;

   (c) A declaration that the Decision is unlawful and/or invalid;

   (d) An order quashing or setting aside the Minister's decision refusing to issue the CSP Application for SHINGRIX® in respect of the 905 Patent;

   (e) An order directing the Minister to issue the CSP Application for SHINGRIX® in respect of the 905 Patent;

(f) In the alternative, an order referring the matter back to the Minister for re-determination as to whether the CSP Application for SHINGRIX® in respect of the 905 Patent should issue;

(g) Costs of this application; and

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

THE GROUNDS FOR THE APPLICATION ARE:

A. <u>SHINGRIX®</u>

3. On November 14, 2016, GlaxoSmithKline Inc. filed a New Drug Submission (**NDS**) (submission No. 200244) with Health Canada seeking market authorization for a new vaccine product: SHINGRIX®.

4. SHINGRIX® is a 50 mcg single-dose suspension containing varicella-zoster virus glycoprotein E (**gE antigen**) adjuvanted with GSK's $AS01_B$ adjuvant system (**$AS01_B$ adjuvant**). The vaccine is described in the NDS as a "two component" vaccine consisting of gE antigen and $AS01_B$ adjuvant and is referred to as "gE/AS01B vaccine".

5. SHINGRIX® is indicated for the prevention of herpes zoster (HZ, or shingles) in adults 50 years of age or older.

6. On October 13, 2017, GlaxoSmithKline Inc. received a Notice of Compliance (**NOC**) in response to the SHINGRIX® NDS to market SHINGRIX® in Canada.

7. SHINGRIX® was classified as an "innovative drug" pursuant to section C.08.004.1 of the *Food and Drug Regulations*, CRC, c 870. As a result, SHINGRIX® was included on Health Canada's Register of Innovative Drugs, which provides at least eight years of market exclusivity from the date on which the NOC for SHINGRIX® was issued.

8. SHINGRIX® has since been awarded "The Best Prophylactic Vaccine (approved or in development)" in the Vaccine Industry Excellence Awards at the 2018 World Vaccine Congress.

9. On October 20, 2017, pursuant to section 4 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, Health Canada listed the 905 Patent on the Patent Register in relation to SHINGRIX®.

B. **905 Patent**

10. The Applicant, GlaxoSmithKline Biologicals S.A. (**GSK**) is the owner of the 905 Patent.

11. The 905 Patent titled "Vaccine" relates to a shingles vaccine containing varicella zoster virus gE antigen and an adjuvant. The 905 Patent was filed on March 1, 2006 and issued on May 5, 2015. The 905 Patent expires on March 1, 2026.

12. The 905 Patent covers the following subject matter, *inter alia*:

    (a) The use of an immunogenic composition to make a vaccine that prevents or ameliorates shingles and post-herpetic neuralgia (pain) in individuals over 50 years of age or in immunocompromised individuals, where the immunogenic composition contains: (i) a gE antigen (truncated to remove the carboxy terminal anchor region), and (ii) a TH-1 adjuvant comprised of QS21, 3D-MPL and cholesterol liposomes (Claim 1); and

    (b) The use of the immunogenic composition containing (i) a gE antigen (truncated to remove the carboxy terminal anchor region, and (ii) a TH-1 adjuvant comprised of QS21, 3D-MPL and cholesterol liposomes where 3D-MPL is contained within a liposome, or where 3D-MPL may be contained within a liposome and the gE antigen is a specific amino acid sequence, SEQ ID NO: 1 (Claims 2 and 3).

13. On January 25, 2018, the GSK Applicant filed a CSP application for SHINGRIX® in relation to the 905 Patent. If granted, a CSP term based on the 905 Patent would expire on March 1, 2028.

C. The CSP Regime in Canada

14. Canada's CSP legislation is set out in sections 104 to 134 of the *Patent Act* and accompanying *Certificate of Supplementary Protection Regulations* (***CSP Regulations***) (collectively, the **CSP Regime**). The CSP Regime came into force on September 21, 2017.

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

16. The CSP Regime provides up to two years of additional market exclusivity beyond patent expiry in the form of patent-like rights for new drugs protected by an eligible patent. This additional period of protection awarded in the form of a CSP is also known as "patent term restoration".

17. The CSP period of protection is intended to compensate, in part, for the period of patent term that is otherwise lost while pharmaceutical products undergo research and development and the governmental regulatory review required in order to obtain market authorization. Prior to Canada's recent implementation of CSP protection in 2017, Canada was the only G7 country that failed to provide patent term restoration for pharmaceutical products.

18. Canada ultimately opted to introduce a cap of two years on CSP in Canada. The two-year cap is the minimum of the possible five year term it could have provided under CETA. In addition to adopting the minimum term extension to comply with its CETA obligations, the CSP Regime adopted by Canada is complex and onerous. In order to be eligible for the maximum two year CSP term, a drug must: (i) be a first approval in Canada; (ii) based on a new drug submission filed in Canada within 24/12 months of the first international filing of an equivalent regulatory submission for the same drug in specified jurisdictions; (iii) contain eligible medicinal ingredients; (iv) pertain to an eligible patent containing eligible patent claims; and (v) have been issued an NOC on or after September 21, 2017.

19. Pursuant to Canada's CSP Regime, the Minister will issue a CSP according to the criteria set out in section 113 of the *Patent Act,* which states:

> 113 The Minister shall issue, to the patentee, a certificate of supplementary protection for the patented invention set out in the patentee's application if, on the day of issuance,
>
> (a) the Minister is satisfied that all requirements set out in section 106 are met;
>
> (b) the applicable period referred to in subsection 106(3) for filing the application has ended;
>
> (c) there is no other pending application that sets out the same authorization for sale and that has priority over, or the same priority as, the application; and
>
> (d) any court proceedings, brought under section 110 with respect to the application or to another pending application that sets out the same authorization for sale and that has priority over, or the same priority as, the application, have been finally disposed of.

20. Section 106 of the *Patent Act* sets out the CSP application criteria, including 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 under s. 106(1)(c):

> 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;
>
> [...]

21. Section 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.

22. Section 104 of the *Patent Act*, under "Interpretation," provides definitions that apply in sections 105 to 134 of the *Patent* Act applicable to the CSP Regime. The following definition is provided for "drug":

> *drug* means a substance or a mixture of substances manufactured, sold or represented for use in
>
> (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; or
>
> (b) restoring, correcting or modifying organic functions in human beings or animals.

23. There is no definition of "medicinal ingredient" in the CSP Regime.

D. Decision under Review – Minister's Refusal to Grant CSP Application No. 900006

24. On April 10, 2018, the Applicant received a letter from the TPD, Office of Patented Medicines and Liaison (**OPML**) communicating a "preliminary decision" to deny CSP eligibility for SHINGRIX® in relation to the 905 Patent (the **OPML Letter**).

25. The CSP application was found ineligible in accordance with section 113 of the *Patent Act*. The OPML Letter deemed that the 905 Patent failed to satisfy section 3(2) of the

CSP Regulations because it did not contain a claim for: (i) the medicinal ingredient, (ii) the medicinal ingredient as obtained by a specified process, or (iii) a use of the medicinal ingredient – contained in a drug for which the authorization for sale set out in the CSP application was issued.

26. The Minister rejected the CSP application on the basis that the 905 Patent did not contain an eligible patent claim. No other grounds were raised by the Minister, and GSK accepts that the CSP application was otherwise deemed eligible on all other grounds.

27. The OPML Letter concluded that the claims of the 905 Patent are directed to a composition comprising medicinal (gE antigen) and non-medicinal ingredients (TH-1 adjuvant or the $AS01_B$ adjuvant), and that a claim to such a composition or the use of same is not eligible under section 3(2) of the *CSP Regulations*.

28. In reaching this conclusion, the OPML Letter found that:

    (a) the "medicinal ingredient" in SHINGRIX® is limited to one medicinal ingredient, the gE antigen;

    (b) the adjuvant is a carrier which is a non-medicinal ingredient and is considered separate from the vaccine composition; and

    (c) the gE antigen cannot itself be claimed apart from the adjuvant as at least some gE antigens were previously disclosed in the prior art (EP0405867 and EP192902).

29. On May 24, 2018, the Applicant submitted a letter to the OPML seeking reconsideration of the preliminary decision by submitting responding representations and affidavit evidence to the Minister.

30. The Applicant asserted, *inter alia,* that the Minister had incorrectly classified the adjuvant in the 905 Patent and contained in SHINGRIX® as a non-medicinal ingredient. SHINGRIX® is comprised of active ingredients (an antigen and adjuvant) that are responsible for the vaccine's desired effect on the body. As a result, the Minister incorrectly determined that the 905 Patent claims a formulation (*i.e.*, a composition of

medicinal and non-medicinal ingredients) and that such claims are not eligible to support a CSP application.

31. By letter dated August 3, 2018, the Minister issued the Decision under review. The Decision rejected the Applicant's arguments and held that the CSP Application is not eligible in accordance with section 113 of the *Patent Act*. The Minister deemed that the 905 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 medicinal ingredient, (ii) the medicinal ingredient as obtained by a specified process, or (iii) a use of the medicinal ingredient – contained in a drug for which the authorization for sale set out in the CSP application was issued.

32. In denying the Applicant's CSP, the Minister found that:

(a) SHINGRIX® contains a single medicinal ingredient, the gE antigen;

(b) Adjuvants are not medicinal ingredients, and specifically, the $AS01_B$ adjuvant is not a medicinal ingredient in SHINGRIX®;

(c) The patent claims recite "liposomes" and not the lipid making up the liposomes, so the claims require the presence of water, a non-medicinal ingredient, in the compositions in order to form the physical structures that are liposomes;

(d) Components of the $AS01_B$ adjuvant, cholesterol, dioleoyl phosphatidylcholine, QS21 and 3D-MPL, are all non-medicinal ingredients;

(e) There is no provision in section 3(2) of the *CSP Regulations* that permits an eligible patent to pertain to or claim a *composition* comprising a medicinal ingredient and non-medicinal ingredients, or uses of such compositions;

(f) A claim to a formulation does not pertain in the prescribed manner to a medicinal ingredient or combination of medicinal ingredients because a formulation includes non-medicinal ingredients in addition to medicinal ingredients. Such a claim is outside the scope of subsection 3(2) of the *CSP Regulations,* which do not allow for the presence of non-medicinal ingredients.

E. **The Minister's Decision is Contrary to Law**

33. The Minister's Decision that the CSP Application for SHINGRIX® in respect of the 905 Patent is ineligible for a CSP is incorrect, unreasonable, made with fettered discretion, and without jurisdiction. The Decision is furthermore contrary to law and is not entitled to any deference.

34. In reaching the Decision, the Minister erred in fact and law, fettered her discretion and/or acted without jurisdiction by:

(a) Misinterpreting and misapplying the CSP Regime, including sections 106(1)(c) and 113 of the *Patent Act* and section 3(2) of the *CSP Regulations;*

(b) Misinterpreting and misconstruing the 905 Patent, including the claims;

(c) Finding that SHINGRIX® contains a single medicinal ingredient, the gE antigen;

(d) Finding that adjuvants are not medicinal ingredients, and specifically, the $AS01_B$ adjuvant is not a medicinal ingredient in SHINGRIX®;

(e) Finding that the patent claims recite "liposomes," which require water, a non-medicinal ingredient, so the 905 Patent is addressed to formulation claims;

(f) Finding that the 905 Patent claims a formulation, which the Minister defines as a composition of medicinal and non-medicinal ingredients and that such claims are not eligible to support a CSP application;

(g) Misinterpreting and misconstruing the NDS (Submission No. 200244) for SHINGRIX®;

(h) Misinterpreting and misconstruing the Product Monograph for SHINGRIX®; and by

(i) Refusing to issue a CSP for SHINGRIX® in relation to the 905 Patent notwithstanding the object and purpose of the CSP Regime and Canada's obligations under CETA;

(j) Otherwise failing to interpret the laws and facts in the appropriate manner.

35. The Applicant relies on:

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

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

(f) Such further and other grounds as counsel may advise and this Honourable Court may permit.

THIS APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

(a) A certified copy of the 905 Patent;

(b) The affidavits of one or more witnesses;

(c) The record before and the Decision of the Minister dated August 3, 2018; and

(d) 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 31st day of August, 2018.

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