Health Canada Santé Canada

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Statistical Report 2020 / 2021

Patented Medicines (Notice of Compliance) Regulations, Data Protection (C.08.004.1 of the *Food and Drug Regulations)* and Certificates of Supplementary Protection

Office of Patented Medicines and Liaison

Date: 2021/11/03

Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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Rapport statistique 2020/2021 pour le *Règlement sur les médicaments brevetés (avis de conformité)*, la protection des données (C.08.004.1 du *Règlement sur les aliments et drogues*) et les certificats de protection supplémentaire.

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Section I - Overview

This document provides a statistical overview of the administration of the *Patented Medicines (Notice of Compliance) Regulations*, data protection under the *Food and Drug Regulations*, and Certificates of Supplementary Protection under the *Patent Act* and the *Certificate of Supplementary Protection Regulations*. These three regimes are administered by the Office of Patented Medicines and Liaison within the Office of Submissions and Intellectual Property, Resource Management and Operations Directorate, Health Products and Food Branch, Health Canada.

Patented Medicines (Notice of Compliance) Regulations

The *Patented Medicines (Notice of Compliance) Regulations* came into force in March 1993 and were last amended in 2017. According to the Regulatory Impact Analysis Statement published in Canada Gazette, Part II on October 18, 2006, the *Patented Medicines (Notice of Compliance) Regulations* help to balance effective patent enforcement over patented drugs with the timely entry of lower priced competitors. On one end of the balance lies subsection 55.2(1) of the *Patent Act*, known as the "early-working" exception. Early-working allows a subsequent-entry (generic or biosimilar) drug manufacturer to use a patented drug for the purpose of seeking regulatory approval to market a competing version of that drug. The *Patented Medicines (Notice of Compliance) Regulations* represent the other half of the balance by linking Health Canada's ability to approve a subsequent-entry drug to the patent status of the drug that is being copied. As such, a drug manufacturer that makes a direct or indirect comparison with, or reference to, another drug in respect of which there are patents listed on the Patent Register, must either agree to await patent expiry before obtaining market authorization, obtain consent from the patent owner, or make an allegation in respect of the patent that is either accepted by the innovator or upheld by the Federal Court.

Under subsection 3(2) of the *Patented Medicines (Notice of Compliance) Regulations*, the Office of Patented Medicines and Liaison maintains a Patent Register (http://pr-rdb.hc-sc.gc.ca/pr-rdb/index-eng.jsp) that consists of patent lists submitted by drug manufacturers in respect of drugs for which market authorization has issued in the form of a Notice of Compliance. Each patent list is evaluated in order to determine its eligibility under the *Patented Medicines (Notice of Compliance) Regulations*.

Detailed information on the administration of the *Patented Medicines (Notice of Compliance) Regulations* can be found in the guidance document: *Patented Medicines (Notice of Compliance) Regulations* (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/patented-medicines/notice-compliance-regulations.html).

Data Protection

The data protection provisions in section C.08.004.1 of the *Food and Drug Regulations* came into force in September 1995 and were last amended in 2021. They implement Canada's trade obligations with respect to the protection of undisclosed test or other data necessary to determine the safety and efficacy of a pharmaceutical product, which utilizes a new chemical entity. In keeping with those obligations, innovative drugs are provided with an internationally competitive, guaranteed minimum period of market exclusivity of eight years. An additional six-month period is available for innovative drugs that have been the subject of clinical trials designed and conducted for the purpose of increasing the knowledge of the use of the drug in pediatric populations.

Innovative drugs are listed on the Register of Innovative Drugs (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/register-innovative-drugs.html) after the issuance of the Notice of Compliance in accordance with subsection C.08.004.1(9) of the *Food and Drug Regulations*.

Additional information on the administration of data protection is available in the guidance document: Data Protection under C.08.004.1 of the *Food and Drug Regulations* (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/guidance-document-data-protection-under-08-004-1-food-drug-regulations.html).

Certificates of Supplementary Protection

The Certificate of Supplementary Protection regime came into force on September 21, 2017 through amendments to the *Patent Act* and the introduction of the Certificate of Supplementary Protection Regulations. A Certificate of Supplementary Protection provides an additional period of protection for drugs containing a new medicinal ingredient, or a new combination of medicinal ingredients, protected by an eligible patent. This implements Canada's trade obligation to provide an additional period of protection for patent-protected pharmaceutical products.

Information regarding applications and Certificates of Supplementary Protection is maintained on the Register of Certificates of Supplementary Protection and Applications (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/register-certificates.html#a1).

Additional information on the administration of Certificates of Supplementary Protection is available in the guidance document: Certificates of Supplementary Protection (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/register-certificates/supplementary-protection-regulations-profile.html).

Intellectual Property Hold

Upon completion of the review of a submission, a final intellectual property 'check' is performed. At this stage, Health Canada has completed the scientific assessment of the safety, efficacy and quality of the drug under the *Food and Drug Regulations*. If the Notice of Compliance would be issuable but for the operation of the *Patented Medicines (Notice of Compliance) Regulations* and/or data protection, the drug manufacturer is so notified, and informed of the date on which the submission would have been eligible to receive a Notice of Compliance. The submission is then placed on an administrative hold called "Intellectual Property Hold" until all the relevant requirements of the *Patented Medicines (Notice of Compliance) Regulations* and/or data protection have been met.

Section II - Statistics: *Patented Medicines (Notice of Compliance) Regulations*

Patent Lists Received

Table 1 displays the number of patent lists received in each fiscal year. Data regarding the actual number of patent lists submitted are available only for the past four fiscal years. While a patent list is required for each Drug Identification Number in a drug submission, decisions with respect to a patent are typically the same for all associated Drug Identification Numbers. As such, the number of patent lists counted by patent per submission is also provided in order to reflect the number of requests for patent listing decisions received.

Table 1 - Patent Lists Received

Fiscal Year	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Patent Lists - Actual	-	2019	1495	1478	1990
Patent Lists - Patent per Submission	835	898	736	762	934

Additions to Patent Register

Table 2 displays the number of patent lists added to the Patent Register in each fiscal year under the applicable section of the *Patented Medicines (Notice of Compliance) Regulations*. While a patent list is required for each Drug Identification Number in a drug submission, decisions with respect to a patent are typically the same for all associated Drug Identification Numbers. As such, patent lists in this table are counted by patent per submission to reflect the number of decisions underlying the additions to the Patent Register. Note that patent lists may have been received in one fiscal year but not added to the Patent Register until the following fiscal year.

Table 2 - Additions

Fiscal Year	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
New Drug Submission, s. 4(2)	161	121	131	112	121
Supplement to a New Drug Submission, s. 4(3)	22	23	20	10	16
Supplement to a New Drug Submission, s. 4.1(2)	611	521	627	434	605
Total	794	665	778	556	742

Rejections of Patent Lists

Table 3 displays the number of rejections for listing in each fiscal year under the applicable section of the *Patented Medicines (Notice of Compliance) Regulations*. While a patent list is required for each Drug Identification Number in a drug submission, decisions with respect to a patent are typically the same for all associated Drug Identification Numbers. As such, patent lists in this table are counted by patent per submission to reflect the number of decisions underlying the rejections.

Patent lists counted in the "Other" category include those received in respect of submissions that have been withdrawn or cancelled. Note that patent lists may have been received in one fiscal year but rejected the following fiscal year.

Table 3 - Rejections

Fiscal Year	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
New Drug Submission, s. 4(2)	15	46	32	29	19
Supplement to a New Drug Submission, ss. 4(3) and 4.1(2)	45	99	106	54	53
Timing, ss. 4(5) and 4(6)	9	7	3	4	32
Other	5	1	0	1	0
Total	74	153	141	88	104

A Snapshot of the Patent Register as of March 31, 2021: Number of Patents per Drug on the Patent Register

Graph 1 and Table 4 represent the number of patents that a second person is required to address when seeking a Notice of Compliance for a subsequent-entry version of a patented drug. There are currently 639 different drugs listed on the Patent Register. Some drugs have multiple strengths, routes of administration or dosage forms listed on the Patent Register while others do not. The numbers in the graph do not include patents that were removed from the Patent Register nor do they include patents that expired.

Graph 1 - Patents per Drug on the Patent Register

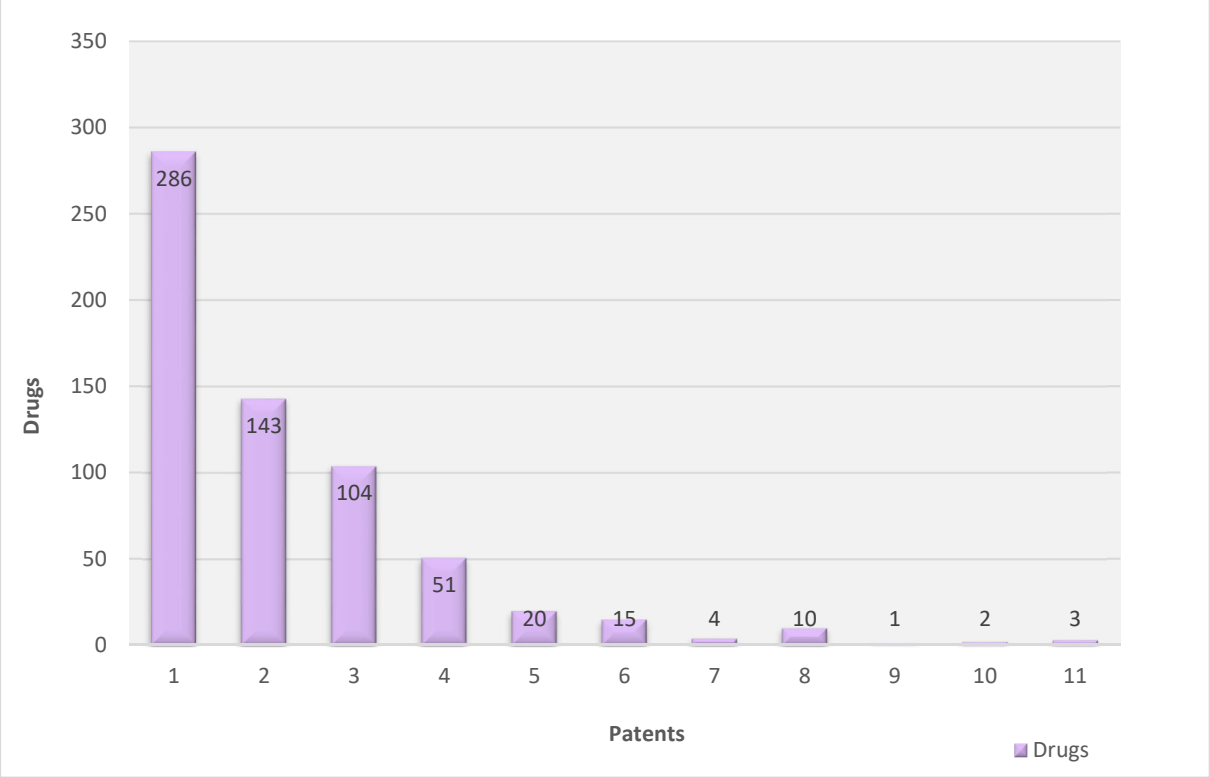

Table 4 - Patents per Drug on the Patent Register

Patents	1	2	3	4	5	6	7	8	9	10	11
Drugs	286	143	104	51	20	15	4	10	1	2	3

A Snapshot of the Patent Register as of March 31, 2021: Drug Identification Number on the Patent Register

Graph 2 and Table 5 represent the number of patents that a second person is required to address when seeking a Notice of Compliance for a subsequent-entry version of a patented drug with a particular Drug Identification Number. As of March 31, 2021 there were 1,144 Drug Identification Numbers listed on the Patent Register, representing 639 different drugs. Patents may apply to more than one Drug Identification Number (e.g., more than one strength, route of administration or dosage form of a medicinal ingredient). The numbers in the below graph do not include patents that were removed from the Patent Register nor do they include patents that expired.

Graph 2 - Patents per Drug Identification Number on the Patent Register

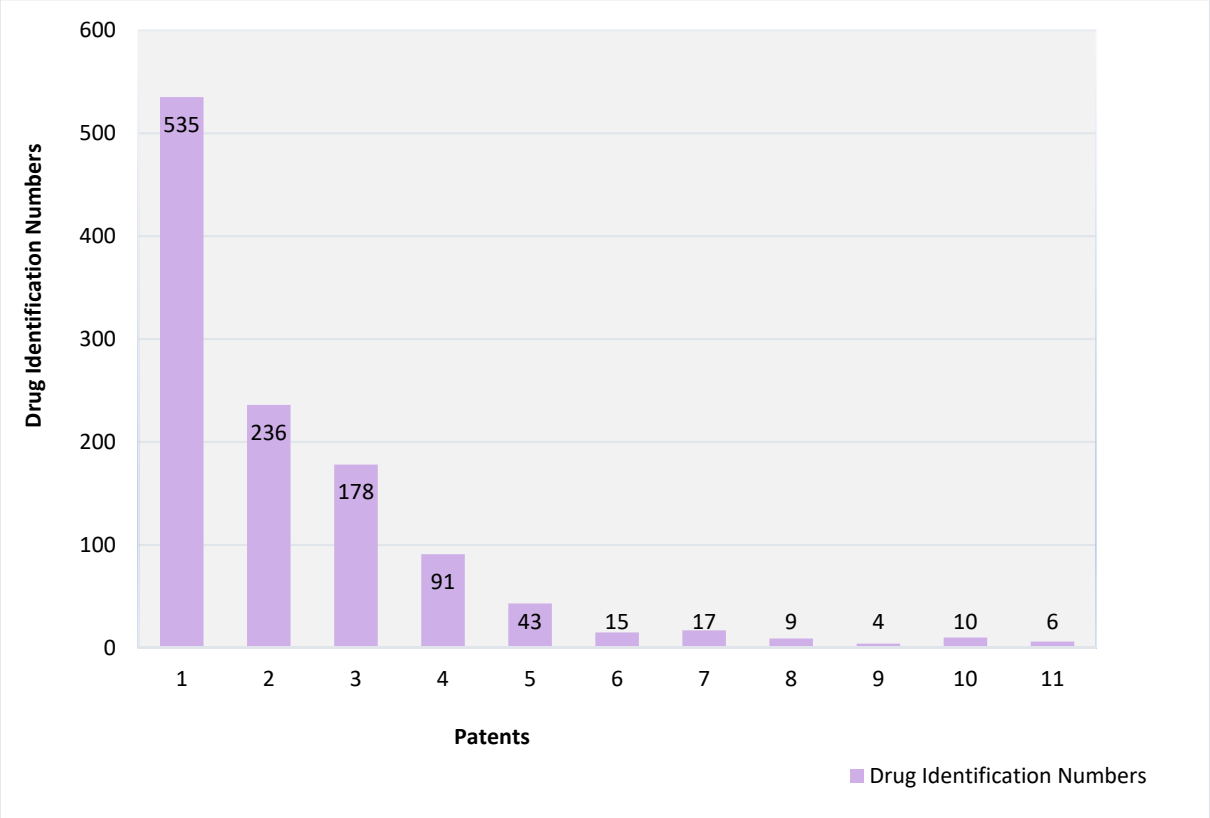

Table 5- Patents per Drug Identification Number on the Patent Register

Patents	1	2	3	4	5	6	7	8	9	10	11
Drug Identification Numbers	535	236	178	91	43	15	17	9	4	10	6

Judicial Review Applications concerning patent eligibility: Section 4 of the *Patented Medicines (Notice of Compliance) Regulations*

Table 6 summarizes judicial review applications with respect to decisions concerning the eligibility of patents for listing on the Patent Register that were active over the past fiscal year. New cases and changes to open cases that occurred during the fiscal year are presented in bold.

Table 6 - Judicial review applications concerning patent eligibility: Section 4 of the *Patented Medicines (Notice of Compliance) Regulations*

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient(s)	Start Date	Close Date	Summary of Issue
T-1476-20 **(Ongoing)**	***Merck Canada Inc v Minister of Health***	**pembrolizumab**	**2020-12-04**		**Rejection on the basis that patent lists did not meet timing requirements**

Judicial Review Applications concerning the administration of Section 7 of the *Patented Medicines (Notice of Compliance) Regulations*

Table 7 summarizes judicial review applications with respect to decisions concerning the administration of section 7 of the *Patented Medicines (Notice of Compliance) Regulations* that were active over the past fiscal year. New cases and changes to open cases that occurred during the fiscal year are presented in bold.

Table 7 - Judicial review applications concerning the administration of Section 7 of the *Patented Medicines (Notice of Compliance) Regulations*

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient(s)	Start Date	Close Date	Summary of Issue
T-870-20/ T-1048-20 **(Allowed)**	***Fresenius Kabi Canada Ltd v Minister of Health***	**adalimumab**	**2020-08-05**	**2020-10-29**	**Effective date of a letter of consent**

Form V: Declaration re: Patent List (Form V)

Table 8 displays the number of submissions containing at least one Form V received during each fiscal year. A drug manufacturer that makes a direct or indirect comparison with, or reference to, a drug in respect of which there are patents listed on the Patent Register, must file a Form V, agreeing to await patent expiry before obtaining market authorization, indicating that consent has been obtained from the patent owner, or making an allegation in respect of the patent.

Table 8 - Submissions containing Form Vs

Fiscal Year	2016/2017	2017/2018	2018/2019	2019/2020	2020/2021
Submissions	126	126	96	153	110

Prohibition Applications concerning section 6 of the pre-September 21, 2017 version of the *Patented Medicines (Notice of Compliance) Regulations*

The *Patented Medicines (Notice of Compliance) Regulations* were amended on September 21, 2017. Under the pre-September 21, 2017 version of the *Patented Medicines (Notice of Compliance) Regulations*, a first person could commence a legal proceeding (commonly referred to as a prohibition application) for an order prohibiting Health Canada from granting a Notice of Compliance for a subsequent-entry version of a patented drug.

Prohibition Applications

Table 9 summarizes the outcome of prohibition applications filed as a result of Notices of Allegation served on first persons before September 21, 2017. The break-down of subsequent appeals for each possible application conclusion - granted, dismissed, partially granted - is also included. The filing date of the application determines the year in which the outcome is reported.

Table 9 - Prohibition Applications

Fiscal Year	2016/2017	2017/2018
Applications Filed	32	41
Applications Discontinued	23	37
Applications Granted	3	3
Appeals Filed	1	1
Discontinued	0	0
Granted	0	0
Dismissed	1	1
Partial	0	0
Pending	0	0
Applications Dismissed	5	1
Appeals Filed	0	0
Discontinued	0	0
Granted	0	0
Dismissed	0	0
Partial	0	0
Pending	0	0
Applications Partially Granted	1	0
Appeals Filed	0	0
Discontinued	0	0
Granted	0	0
Dismissed	0	0
Partial	0	0
Pending	0	0
Applications Pending Resolution	0	0

Average Time to Resolution

Table 10 displays the average resolution times of closed prohibition applications. The filing date of the application determines the fiscal year in which it is reported. The average time to resolution is calculated from the filing date to the close date of the application in the Federal Court. Appeals and discontinued cases are not included.

The 24-month period was prescribed by the *Patented Medicines (Notice of Compliance) Regulations* and could be varied by the Federal Court under the pre-September 21, 2017 version of the *Patented Medicines (Notice of Compliance) Regulations*.

Table 10 - Average Time to Resolution

Fiscal Year	Applications Filed	Applications Closed	Average Resolution Time (months)	Range (months)
2016/2017	32	9	13.7	1.0 – 23.9
2017/2018	41	4	19.5	9.9 - 23.7

Actions concerning section 6 of the post-September 21, 2017 version of the *Patented Medicines (Notice of Compliance) Regulations*

The September 21, 2017 amendments to the *Patented Medicines (Notice of Compliance) Regulations* replaced prohibition applications with full actions resulting in final determinations of patent infringement and validity.

Notices of Allegation

Table 11 displays the number Notices of Allegation served on or after September 21, 2017 reported in the fiscal year received by the Office of Patented Medicines and Liaison.

Table 11 - Notices of Allegation

Fiscal Year	2017/2018	2018/2019	2019/2020	2020/2021
Notices of Allegation	31	65	78	85

Actions

Table 12 summarizes the outcome of actions for declarations of infringement filed as a result of Notices of Allegation served on the first person on or after September 21, 2017. The break-down of subsequent appeals for each possible action conclusion - granted, dismissed, partially granted - is also included. The filing date of the action determines the year in which the outcome is reported.

Table 12 – Actions

Fiscal Year	September 21, 2017 to March 31, 2018	2018/2019	2019/2020	2020/2021
Actions Filed	10	46	55	60
Actions Discontinued	9	31	36	18
Actions Granted	1	5	0	0
Appeals Filed	1	5	0	0
Discontinued	0	0	0	0
Granted	0	0	0	0
Dismissed	0	0	0	0
Partial	0	0	0	0
Pending	1	5	0	0
Actions Dismissed	0	9*	2	1[#]
Appeals Filed	0	6	2	0
Discontinued	0	0	0	0
Granted	0	0	0	0
Dismissed	0	1	0	0
Partial	0	0	0	0
Pending	0	5	0	0
Actions Partially Granted	0	0	0	0
Appeals Filed	0	0	0	0
Discontinued	0	0	0	0
Granted	0	0	0	0
Dismissed	0	0	0	0
Partial	0	0	0	0
Pending	0	0	0	0
Actions Pending Resolution	0	1	17	41

* 2 of the 9 actions were dismissed on consent [#]The action was dismissed on consent

Average Time to Resolution

Table 13 displays the average resolution times of closed actions. The filing date of the action determines the fiscal year in which it is reported. The average time to resolution is calculated from the filing date to the close date of the action in the Federal Court. Appeals and cases that were discontinued or dismissed on consent are not included.

The Federal Court has varied the 24-month period prescribed by the *Patented Medicines (Notice of Compliance) Regulations* under subsection 7(8) and in other circumstances.

Table 13 - Average Time to Resolution

Fiscal Year	Actions Filed	Actions Closed	Average Resolution Time (months)	Range (months)
2017/2018	10	1	26.4	26.4
2018/2019	46	12	22.8	15.4 – 25.0
2019/2020	55	2	16.2	13.5 – 18.8
2020/2021	60	0	-	-

Prohibition Applications, Actions and Judicial Review Applications concerning the *Patented Medicines (Notice of Compliance) Regulations*

Graph 3 and Table 14 compare the number of applications for judicial review of final decisions under the *Patented Medicines (Notice of Compliance) Regulations* with the number of prohibition applications and actions under section 6 of the *Patented Medicines (Notice of Compliance) Regulations*. The filing date of the application or action determines the fiscal year in which the proceeding is reported.

Graph 3 - Prohibition Applications, Actions and Judicial Review Applications

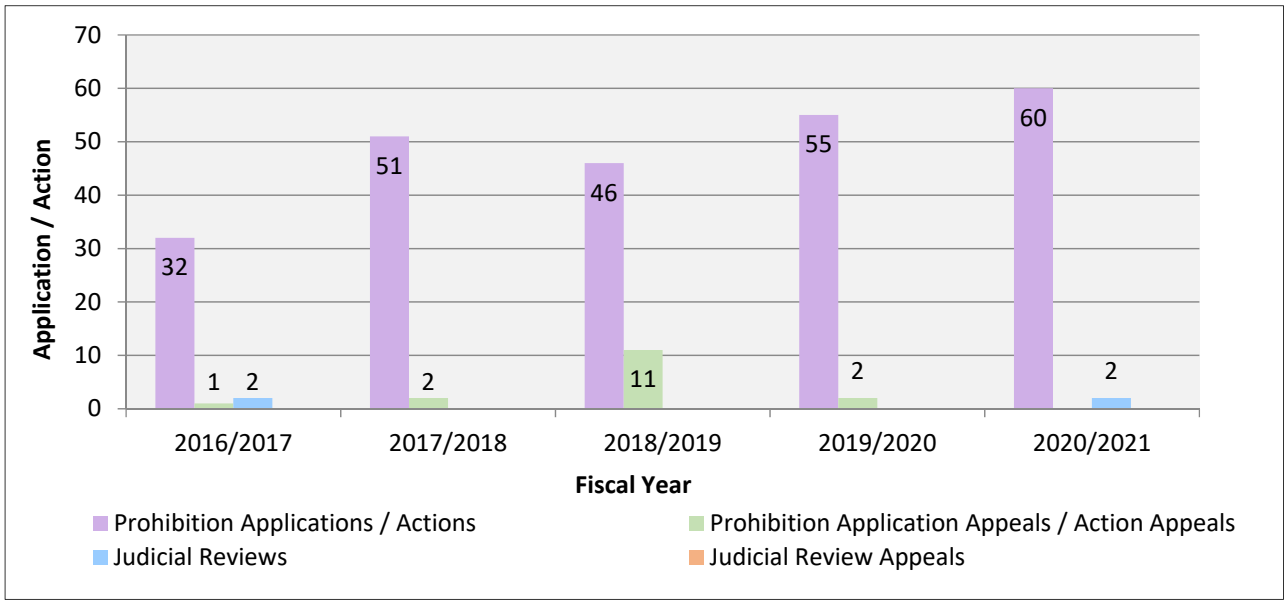

Table 14 - Prohibition Applications, Actions and Judicial Review Applications

Fiscal Year	2016/2017	2017/2018	2018/2019	2019/2020	2020/2021
Prohibition Applications / Actions	32	51	46	55	60
Prohibition Application Appeals / Action Appeals	1	2	11	2	0
Judicial Reviews	2	0	0	0	2
Judicial Review Appeals	0	0	0	0	0

Section III - Statistics: Data Protection (C.08.004.1 of the *Food and Drug Regulations*)

Register of Innovative Drugs

Human Drugs

Graph 4 and Table 15 display the number of human drugs that were added to the Register of Innovative Drugs by fiscal year in which the product received a Notice of Compliance. Pediatric extensions for previously listed drugs may be added up to 6 years after the issuance of the Notice of Compliance. Graph 5 and Table 16 display the number of human drugs added to the Register of Innovative Drugs by product type.

Graph 4 - Human Drugs added to the Register of Innovative Drugs

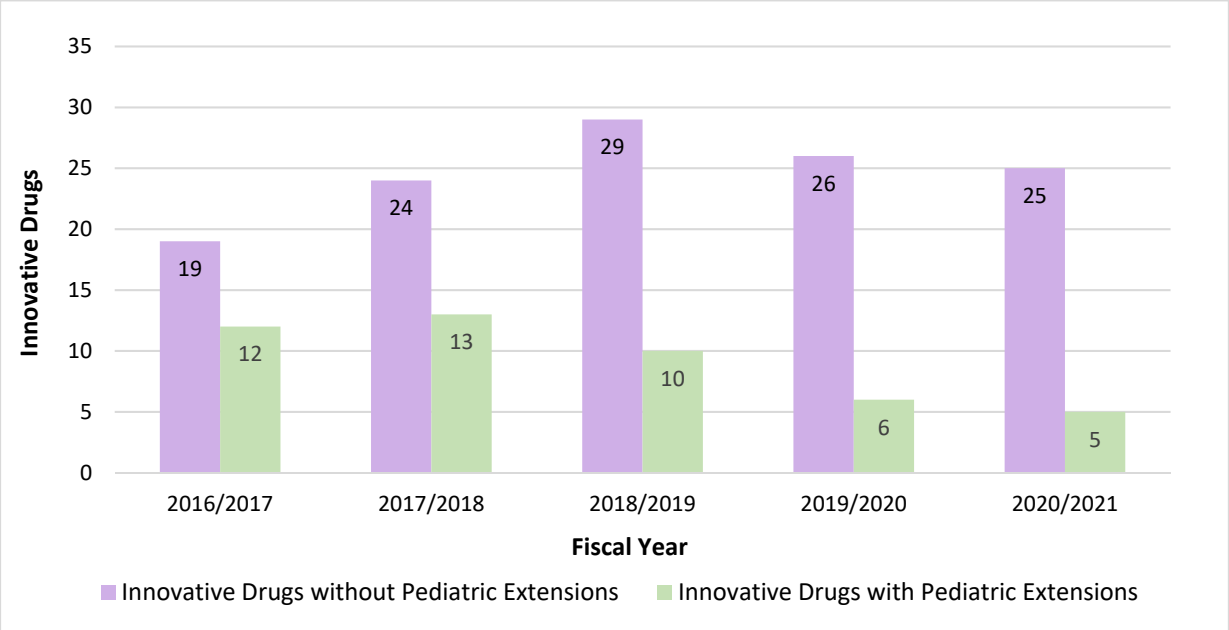

Table 15 - Human Drugs added to the Register of Innovative Drugs

Fiscal Year	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Innovative Drugs with Pediatric Extensions	12	13	10	6	5
Innovative Drugs without Pediatric Extensions	19	24	29	26	25
Total	31	37	39	32	30

Graph 5 - Human Innovative Drugs by Product Type

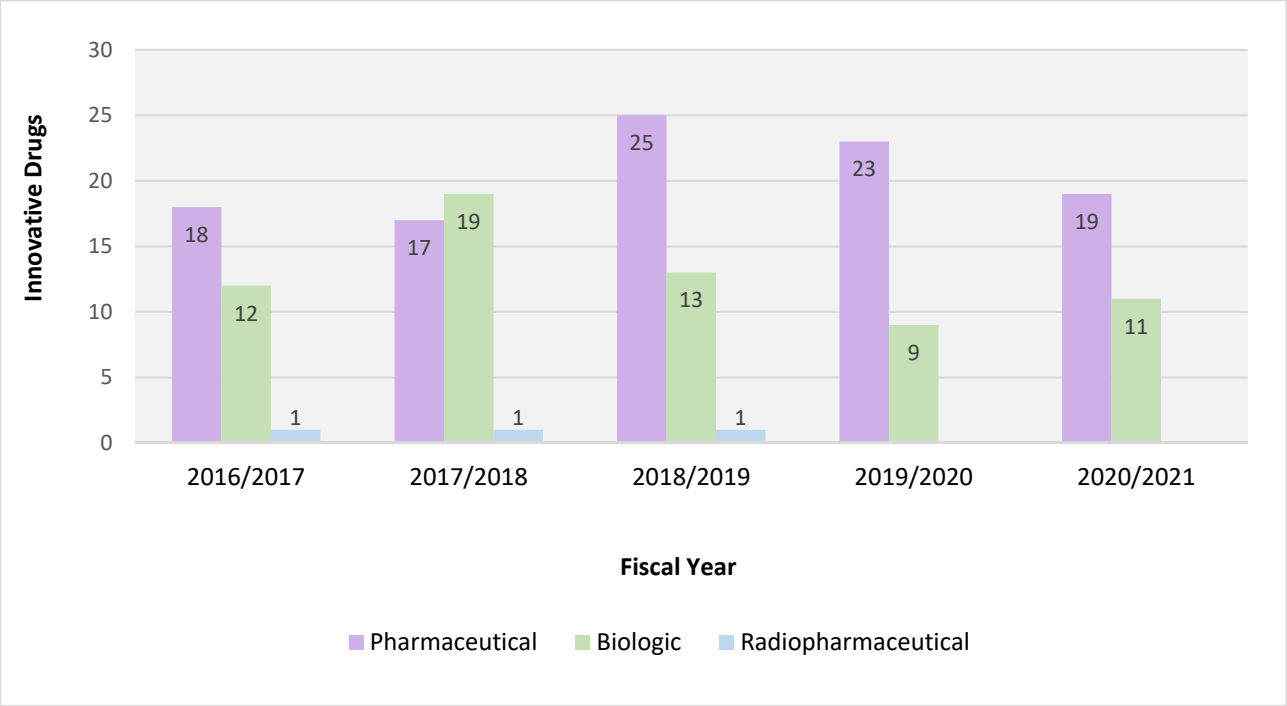

Table 16 - Human Innovative Drugs by Product Type

Fiscal Year	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Pharmaceutical	18	17	25	23	19
Biologic	12	19	13	9	11
Radiopharmaceutical	1	1	1	0	0

Veterinary Drugs

Graph 6 and Table 17 display the number of veterinary drugs that were added to the Register of Innovative Drugs by fiscal year in which the product received a Notice of Compliance. Pediatric extensions are not available for veterinary drugs.

Graph 6 - Veterinary Drugs added to the Register of Innovative Drugs

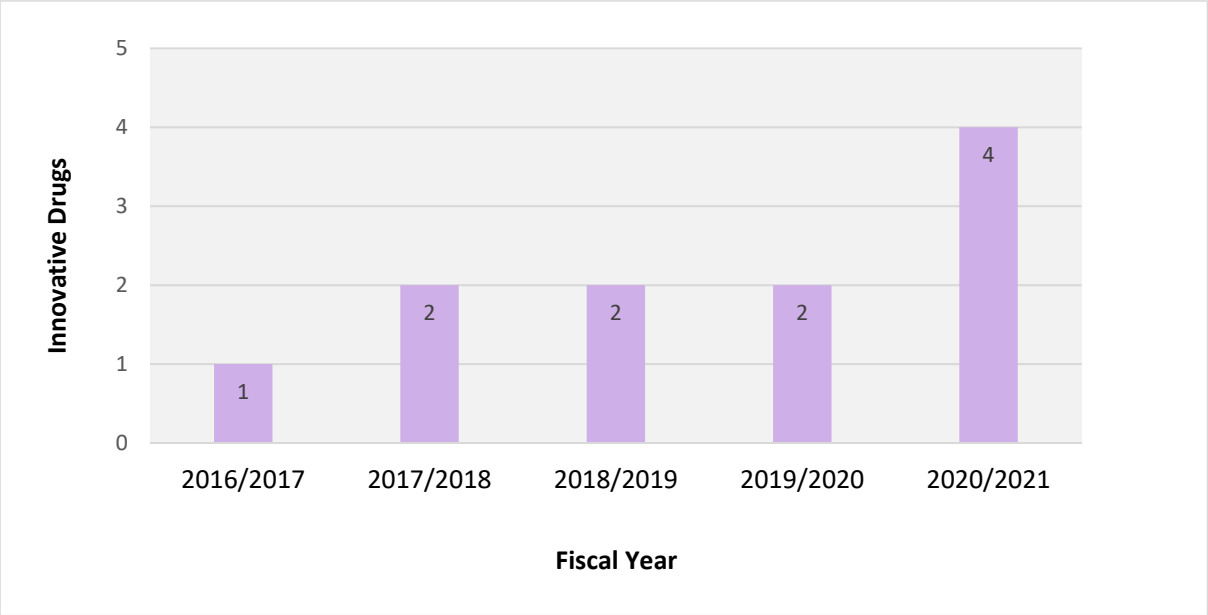

Table 17 - Veterinary Drugs added to the Register of Innovative Drugs

Fiscal Year	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Innovative Drugs	1	2	2	2	4

Judicial Review Applications concerning Data Protection

Table 18 displays the number of judicial review applications and appeals that have been filed over the past five years. The filing date of the application determines the fiscal year in which the proceeding is reported.

Table 18 - Judicial Review Applications and Appeals

Fiscal Year	2016/2017	2017/2018	2018/2019	2019/2020	2020/2021
Judicial Reviews	1	0	1	2	1
Judicial Review Appeals	0	0	0	1	0

Table 19 summarizes judicial review applications with respect to decisions concerning data protection that were active over the past fiscal year. New cases and changes to ongoing cases that occurred during the fiscal year are presented in bold.

Table 19 - Judicial Review Applications concerning Data Protection

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient(s)	Filing Date	Close Date	Summary of Issue
T-827-19 **(Dismissed)** **A-252-20** **(Ongoing)**	*Janssen Inc v Minister of Health*	esketamine hydrochloride	2019-05-22 **2020-10-19**	**2020-09-18**	Ineligibility for data protection on the basis that the medicinal ingredient is a variation (enantiomer) of a previously approved medicinal ingredient
T-1353-19 **(Dismissed)**	*Natco Pharma (Canada) Inc v Minister of Health and Gilead Sciences Canada Inc*	tenofovir alafenamide hemifumarate / emtricitabine	2019-08-21	**2020-07-24**	Submission not accepted for filing
T-984-20 **(Ongoing)**	***Catalyst Pharmaceuticals, Inc and Kye Pharmaceuticals Inc v Minister of Health and Medunik Canada***	**amifampridine**	**2020-08-26**		**Issuance of a Notice of Compliance on the basis that there was no direct or indirect comparison with an innovative drug**

Section IV - Statistics: Certificates of Supplementary Protection

Applications

Table 20 displays information regarding the applications for Certificates of Supplementary Protection that were filed since the coming into force of the regime on September 21, 2017. Applications may be filed before the end of a 120-day period that begins on either the day on which the patent at issue was granted, or the day on which the Notice of Compliance for the underlying submission was issued, as applicable.

Table 20 - Applications

Fiscal Year	September 21, 2017 to March 31, 2018	2018/2019	2019/2020	2020/2021
Total Applications	12	26	15	23
Median Days to File	46	85	63	42
Range of Days to File	1-118	3-119	17-114	4-116

Issuances and Refusals

Table 21 summarizes the outcomes of the applications for Certificate of Supplementary Protection. A Certificate of Supplementary Protection may be issued or refused in a different fiscal year from that in which the application was filed. The refusals counted in this table represent final decisions.

Table 21 - Issuances and Refusals

Fiscal Year	September 21, 2017 to March 31, 2018	2018/2019	2019/2020	2020/2021
Issuances (full term)	0	24	12	21
Issuances (less than 2-year term)	0	2	1	0
Refusals	1	6	1	2
Total Decisions	1	32	14	23

Performance

Health Canada's performance in meeting the service standard is displayed in Table 22. The service standard is 60 calendar days (average) for the first eligibility decision beginning on the day there are no conflicting applications of the highest priority and the time for filing an application having the same or higher priority has ended. According to this standard, Health Canada will inform the applicant either that the Certificate of Supplementary Protection has been issued or that the application has been preliminarily refused with an opportunity to provide representations, within an average of 60 calendar days. If the Certificate of Supplementary Protection is issued, this represents a first and final decision regarding eligibility. If the application is refused, this represents a first decision regarding eligibility.

Table 22 - Performance

Fiscal Year	September 21, 2017 to March 31, 2018	2018/2019	2019/2020	2020/2021
Average Days for First Decision	44	40	22	20

Reasons for Refusal

Table 23 provides a summary of the reasons for refusal of applications between April 1, 2020 and March 31, 2021.

Table 23 - Reasons for Refusal

Application Number	Drug (Medicinal Ingredient(s))	Patent Number	Reasons for Refusal
900052	REBINYN (coagulation factor IX (recombinant), pegylated)	2,665,480	The application did not meet the requirements of paragraph 106(1)(d) of the Patent Act because the authorization for sale was not the first authorization for sale that had been issued with respect to the medicinal ingredient. The medicinal ingredient differed from the coagulation factor IX in previously authorized drugs only with respect to prescribed variations and was considered to be the same medicinal ingredient in accordance with subsection 105(3) of the Patent Act.
900021	JULUCA (dolutegravir sodium / rilpivirine hydrochloride)	2606282	Application was reconsidered following the decision in T-353-19. The patent did not meet the requirements of paragraph 106(1)(c) of the Patent Act and subsection 3(2) of the Certificate of Supplementary Protection Regulations because it did not pertain to the combination of medicinal ingredients.

Judicial Review Applications concerning Certificates of Supplementary Protection

Table 24 summarizes judicial review applications with respect to decisions concerning the eligibility of applications for Certificate of Supplementary Protection that were active over the past fiscal year. New cases and changes to open cases that occurred during the fiscal year are presented in bold.

Table 24 - Judicial Review Applications concerning Certificates of Supplementary Protection

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient(s)	Filing Date	Close Date	Summary of Issue
T-1603-18 (Allowed) **A-138-20 (Ongoing)**	*GlaxoSmithKline Biologicals SA v Minister of Health*	varicella zoster virus glycoprotein E	2018-08-31 **2020-06-08**	2020-03-20	Refusal on the basis that the patent does not pertain to the medicinal ingredient
T-353-19 **(Allowed)**	*ViiV Healthcare ULC v Minister of Health*	dolutegravir sodium / rilpivirine hydrochloride	2019-02-22	**2020-07-10**	Refusal on the basis that the patent does not pertain to the combination of medicinal ingredients
T-1471-19 **(Ongoing)**	*Merck Canada Inc v Minister of Health*	suvorexant	2019-09-06		Refusal on the basis that there was no authorization for sale that met all of the requirements
T-258-21 (Ongoing)	***ViiV Healthcare ULC v Minister of Health***	**dolutegravir sodium / rilpivirine hydrochloride**	**2021-02-12**		**Refusal on the basis that the patent does not pertain to the combination of medicinal ingredients**

Section V - Statistics: Intellectual Property Hold

A Snapshot of Drug Submissions Remaining on Intellectual Property Hold as of March 31, 2021

Graph 7 and Table 25 display the number of drug submissions filed by fiscal year that were still on IP Hold as of March 31, 2021.

Graph 7 - Drug Submissions Remaining on Intellectual Property Hold

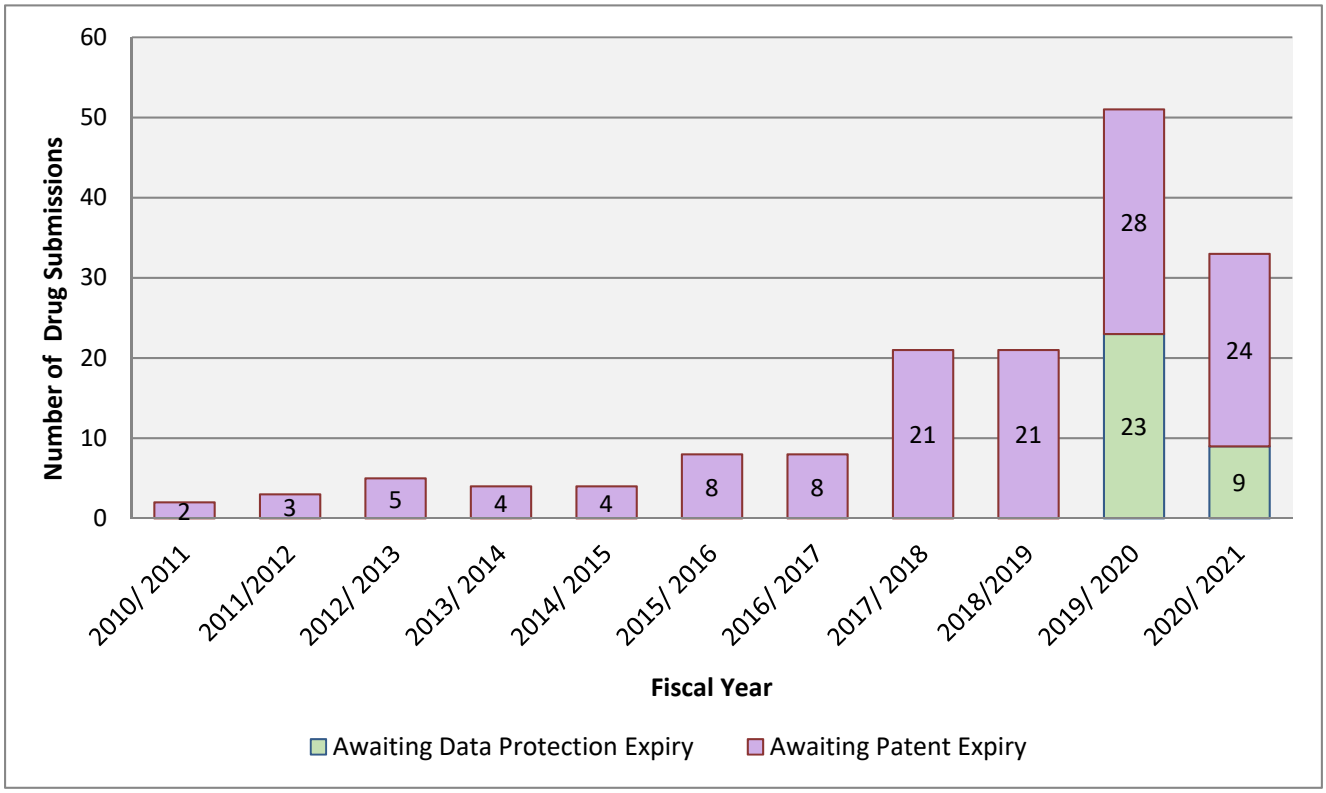

Table 25 - Drug Submissions remaining on Intellectual Property Hold

Fiscal Year	2010/ 2011	2011/ 2012	2012/ 2013	2013/ 2014	2014/ 2015	2015/ 2016	2016/ 2017	2017/ 2018	2018/ 2019	2019/ 2020	2020/ 2021
Awaiting Data Protection Expiry	0	0	0	0	0	0	0	0	0	23	9
Awaiting Patent Expiry	2	3	5	4	4	8	8	21	21	28	24
Total	2	3	5	4	4	8	8	21	21	51	33

Appendix A - Definitions

Action Granted:
The Federal Court granted a declaration that the making, constructing, using or selling of a drug would infringe all patents and certificates of supplementary protection at issue in an action brought under section 6 of the *Patented Medicines (Notice of Compliance) Regulations*.

Action Partially Granted:
The Federal Court granted a declaration that the making, constructing, using or selling of a drug would infringe one or more, but not all, patents and certificates of supplementary protection at issue in an action brought under section 6 of the *Patented Medicines (Notice of Compliance) Regulations*.

Drug Identification Number:
A computer-generated 8-digit number assigned by Health Canada to a drug upon market authorization under subsection C.01.014.2 (1) of the Food and Drug Regulations.

It identifies each drug under the Food and Drug Regulations, sold in a dosage form in Canada, and is located on the package label of prescription and non-prescription drugs that have been evaluated and authorized for sale in Canada.

Fiscal Year:
The period of time beginning on April 1 and ending on March 31 of the following calendar year.

First Person:
The person referred to in subsection 4(1) of the *Patented Medicines (Notice of Compliance) Regulations*, typically a brand name drug manufacturer.

Innovative Drug:
A drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph.

Notice of Allegation:
A notice served under section 5 of the *Patented Medicines (Notice of Compliance) Regulations*. Such notices set out the nature of the second person's challenge to a patent or certificate of supplementary protection listed on the Patent Register or on the Register of Certificates of Supplementary Protection and Applications.

Notice of Compliance:
Market authorization issued under section C.08.004.01 or C.08.004 of the *Food and Drug Regulations*.

Pending:
A court case awaiting judgment.

Prohibition Granted:
The Federal Court granted an order of prohibition that prevents the Minister from issuing a Notice of Compliance until after the expiration of all patents that are the subject of an application under the *Patented Medicines (Notice of Compliance) Regulations*, as they read prior to September 21, 2017.

Prohibition Partially Granted:
The Federal Court granted an order of prohibition that prevents the Minister from issuing a Notice of Compliance until after the expiration of one or more but not to all patents that are the subject of an application under section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, as they read prior to September 21, 2017, where more than one patent is at issue.

Second Person:
The person referred to in section 5 of the *Patented Medicines (Notice of Compliance) Regulations*, typically a subsequent-entry (generic or biosimilar) drug manufacturer.