Health Canada Santé Canada

July 28, 2011

Notice

Our file number: 11-113626-523

Release of the Therapeutic Products Directorate Statistical Report 2010 for the *Patented Medicines (Notice of Compliance) Regulations* and Data Protection

Health Canada is pleased to announce the release of the Therapeutic Products Directorate Statistical Report 2010 for the *Patented Medicines (Notice of Compliance) Regulations* and Data Protection. This report provides a statistical overview of Health Canada's administration of the *Patented Medicines (Notice of Compliance) Regulations*, and data protection under section C.08.004.1 of the *Food and Drug Regulations*.

As in previous reports, this report includes information regarding trends in the eligibility of patents for listing on the Patent Register, the eligibility of drugs for listing on the Register of Innovative Drugs, and related court activity.

Any concerns or questions regarding the contents of the report should be directed to:

Office of Patented Medicines and Liaison
Therapeutic Products Directorate
Health Canada
101 Tunney's Pasture Driveway
Postal Locator: 0201A1
Ottawa, Ontario
K1A 0K9

Telephone: 613-941-7281
Facsimile: 613-946-5610
E-mail: opml_bmbl@hc-sc.gc.ca

Canada

Therapeutic Products Directorate Statistical Report 2010

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

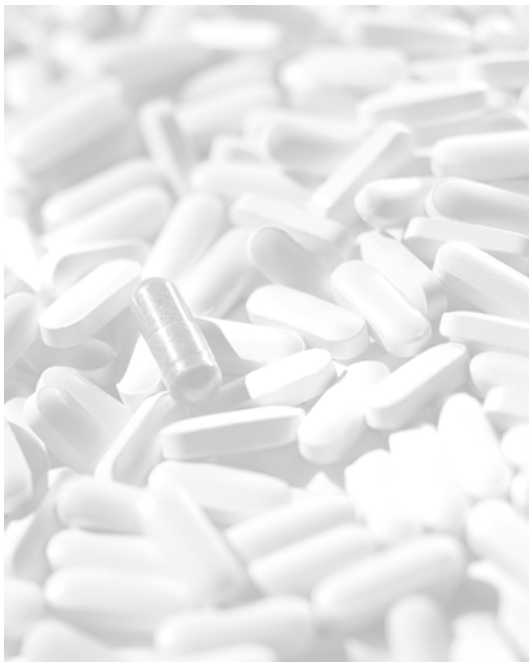
By the Office of Patented Medicines and Liaison




2011-07-06

Canada

Table of Contents



Section I
Overview

Overview

This document provides a statistical overview relating to the administration of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 as amended and the data protection provisions of the *Food and Drug Regulations*, C.R.C., c.870 as amended by S.O.R./2006-241. The two sets of regulations are intended to act as a balanced set of measures, designed to work together to stabilize Canada's intellectual property protection for drugs by ensuring a minimum period of protection and maintaining a reasonable ceiling on the maximum protection available.

A. *Patented Medicines (Notice of Compliance) Regulations*

The *Patented Medicines (Notice of Compliance) Regulations* fall under the authority of the *Patent Act* which is within the mandate of Industry Canada. However, they are administered by the Office of Patented Medicines and Liaison (OPML), Therapeutic Products Directorate, Health Products and Food Branch, Health Canada. The *Patented Medicines (Notice of Compliance) Regulations* came into force in March 1993 and were subsequently amended in 1998, 1999, 2006 and 2008.

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 the effective patent enforcement over new and innovative drugs with the timely entry of their lower priced generic 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 (typically generic) drug manufacturer to use a patented, innovative 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 generic drug to the patent status of the equivalent innovative drug that the generic drug manufacturer seeks to copy. As such, a drug manufacturer that makes a direct or indirect comparison with, or reference to, an innovative drug in respect of which there are patents listed on the Patent Register, must either agree to await patent expiry before obtaining market authorization or make an allegation justifying immediate market entry that is either accepted by the innovator or upheld by the court.

Under the *Patented Medicines (Notice of Compliance) Regulations*, the OPML maintains a Patent Register that consists of patents on patent lists submitted by drug manufacturers in respect of drugs for which market authorization is sought or has issued in the form of a Notice of Compliance. Each patent list is audited by the OPML in order to determine its eligibility under the *Patented Medicines (Notice of Compliance) Regulations*. As such, on behalf of the Minister of Health, the OPML may refuse to add or may delete any patent that does not meet the eligibility requirements. A web-accessible version of the Patent Register is found on the Health Canada website

In addition, the OPML ensures that patents listed on the Patent Register are addressed 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*.

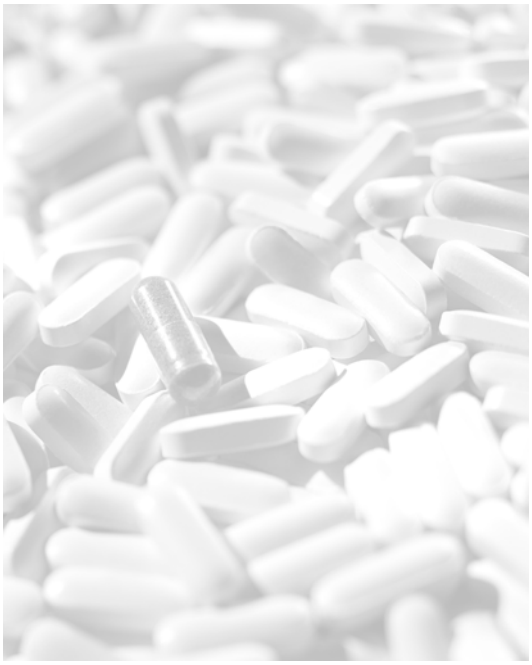
B. Data Protection

Amendments to the data protection provisions in section C.08.004.1 of the *Food and Drug Regulations* were brought into force on October 5, 2006 in order to clarify and effectively implement Canada's obligations under the *North American Free Trade Agreement* and the *Agreement on Trade-Related Aspects of Intellectual Property Rights* with respect to the protection of undisclosed tests or other data necessary to determine the safety and effectiveness 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.

The data protection provisions are administered by the OPML. Innovative drugs that are eligible for data protection are listed on the Register of Innovative Drugs (RID) after the issuance of the Notice of Compliance.

Detailed 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*.



Section II
Statistics: Patent Register and *Patented Medicines (Notice of Compliance) Regulations*

Number of Patent Lists Submitted for Listing on the Patent Register

Number of patent lists added to the Patent Register:

This information is generated from the electronic Patent Register database. These tables provide the total number of patent lists added to the Patent Register in each year. Note that listings do not necessarily represent new patents being added to the Patent Register for the first time. Some listings represent patents already listed on the Patent Register - for previously approved drug submissions - which have been added again in relation to a different supplement to a new drug submission. Also, patent lists may have been received in one calendar year but not added to the Patent Register until the following calendar year.

Patent Lists	2005	2006	2007	2008	2009	2010
Number of patent lists received (during the calendar year)	940	962	633	629	744	599
Number of patent lists rejected (during the calendar year)	252	273	147	133	141	153

Patent Lists	2005	2006	2007	2008	2009	2010
Number of patent lists added to the Patent Register (during the calendar year)	449	447	417	431	477	373
Patents not previously listed (New Drug Submission)	58	49	83	68	89	77
Patents not previously listed (Supplemental New Drug Submission)	46	41	52	110	121	92

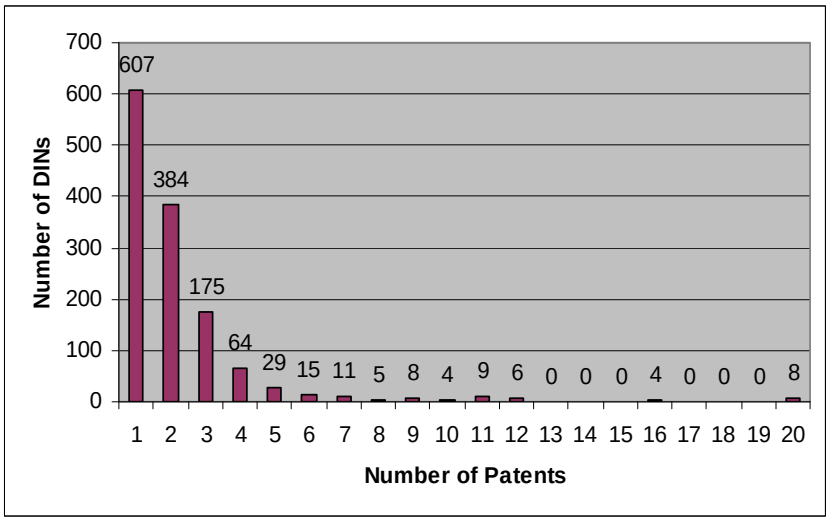
Number of patent lists rejected:

The number of rejected patent lists includes the patent lists rejected for all submissions, and not only the number of distinct patents rejected.

Patent List Rejections	June 16, 2006 to December 31, 2006	2007	2008	2009	2010
New Drug Submission (section 4(2))	16	30	25	39	35
Supplement to a New Drug Submission (section 4(3))	66	101	75	84	46
Timing (sections 4(5) and 4(6))	31	7	8	8	64
Other	20	9	25	10	8
Total	**133**	**147**	**133**	**141**	**153**

A Snapshot of the Patent Register as of December 31, 2010: Number of Patents Per Drug Identification Number (DIN) on the Patent Register

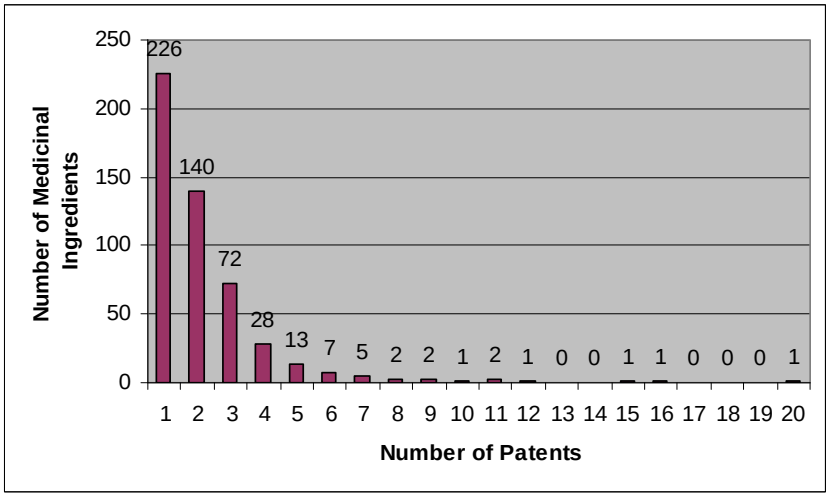
This graph and table represent the number of patents that a second person is required to address when seeking a Notice of Compliance for a patented medicine. As of December 31, 2010 there were 1,329 DINs listed on the Patent Register, representing 502 different medicinal ingredients. The total number of patents listed on the Patent Register is 896 and they are distributed per DIN. For example, there are 607 DINs which only have one patent listed against them; on the other hand, there are eight DINs which have 20 patents listed against them. This data is product-specific, as each DIN is specific to a particular strength, route and dosage form of a medicinal ingredient. Patents may apply to more than one DIN (for example, more than one strength, route and dosage form of a medicinal ingredient). The numbers in the above graph do not include patents which have been removed from the Patent Register nor do they include patents which have expired prior to the generation of this report.



Number of Patents	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Number of DINs	607	384	175	64	29	15	11	5	8	4	9	6	0	0	0	4	0	0	0	8

A Snapshot of the Patent Register as of December 31, 2010: Number of Patents Per Medicinal Ingredient on the Patent Register

There are currently 502 different medicinal ingredients listed on the Patent Register. The total number of different patents listed on the Patent Register is 896, and they are distributed per medicinal ingredient. For example, there are 226 medicinal ingredients which only have one patent listed against them; on the other hand, there is one medicinal ingredient which has 20 patents listed against it. The numbers in the graph do not include patents which have been removed from the Patent Register nor do they include patents which have expired prior to the generation of this report.



The Patent Register is divided according to DIN in a product-specific manner. As this graph is produced by medicinal ingredient, some products have multiple strengths, routes, and dosage forms listed on the Patent Register while others do not.

# of Patents	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
# of Medicinal Ingredients	226	140	72	28	13	7	5	2	2	1	2	1	0	0	1	1	0	0	0	1

Judicial Review Applications Concerning Patent Eligibility: Sections 3 and 4 of the *Patented Medicines (Notice of Compliance) Regulations*

This table lists judicial review applications started in 2010 and changes which took place to ongoing cases during 2010. The applications were filed pursuant to section 18.1 of the *Federal Courts Act* with respect to decisions concerning the eligibility of patents for listing on the Patent Register under sections 3 and 4 of the *Patented Medicines (Notice of Compliance) Regulations*. New cases and changes to open cases which occurred during the year are presented in bold.

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient	Start Date	Close Date	Summary of Issue
T-894-07 **(discontinued)**	Novopharm Limited - and - Minister of Health	celecoxib	2007-05-24	**2010-01-29**	Timing of removal of patent 2,319,201 entitled "Celecoxib Compositions", from the Patent Register
T-382-08 (dismissed)	Eli Lilly Canada Inc. - and - The Attorney General of Canada and The Minister of Health - and - Pharmascience Inc.	olanzapine	2008-03-07	2009-05-08	Timing of addition of patent 2,265,712, entitled "Intermediates and Process for Preparing Olanzapine", to the Patent Register
A-232-09 **(discontinued)**			2009-06-05	**2010-01-18**	
T-582-09 (dismissed)	Bayer Inc. - and -The Minister of Health and The Attorney General of Canada	drospirenone and ethinyl estradiol	2009-04-14	2009-11-1	Listing eligibility of patent 2,194,979, entitled "Solid Drug Forms Containing Clathrates of Steroid Sex Hormones", under section 4(2)
A-502-09 (dismissed)			2009-12-16	**2010-06-15**	
Seeking leave to appeal to Supreme Court of Canada			**2010-09-14**		
T-248-10 (dismissed)	**Purdue Pharma - and - Attorney General of Canada and Minister of Health**	**oxycodone hydrochloride and naloxone hydrochloride**	**2010-02-22**	**2010-07-08**	**Listing eligibility of patent 2,098,738, entitled "Controlled Release Oxycodone Compositions", under section 4(2)**
A-288-10 (on-going)			**2010-08-06**		

Judicial Review Applications Concerning Section 5 of the *Patented Medicines (Notice of Compliance) Regulations*

This is a listing of judicial review applications filed with respect to section 5 of the *Patented Medicines (Notice of Compliance) Regulations*. Included are changes to cases which were on-going in 2010. New cases and changes to open cases which occurred during the year are presented in bold.

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient	Start Date	Close Date	Summary of Issue
T-2100-07 (allowed and returned to Minister) **A-397-09/ A-412-09 (discontinued)**	Apotex Inc. - and - The Minister of Health	omeprazole	2007-12-03 2009-09-30 2009-10-05	2009-07-15 **2010-06-14**	Application of section 5 in light of a supplement to an abbreviated new drug submission; pre-October 5, 2006 version of *Patented Medicines (Notice of Compliance) Regulations*
T-1575-09 **(discontinued)**	AstraZeneca Canada Inc. - and - The Minister of Health, The Attorney General of Canada and Apotex Inc.	omeprazole	2009-09-21	**2010-09-22**	Application of patent-specific analysis in light of a supplement to an abbreviated new drug submission, as ordered in T-2100-07; pre-October 5, 2006 version of *Patented Medicines (Notice of Compliance) Regulations*
T-1862-09 and T-1863-09 **(discontinued)**	Novopharm Limited - and -The Minister of Health and The Attorney General of Canada	Drug B Drug A	2009-11-13	**2010-07-08**	Application of section 5
T-2023-10 (on-going)	**Eli Lilly Canada Inc. - and - The Minister of Health, Sanis Health Inc., MeliaPharm Inc. and Sun Pharma Global FZE**	**olanzapine**	**2010-12-03**		**Application under section 6 regarding the requirement for generic drug manufacturers to address patent 2,041,113, entitled "Thienobenzodiazepine Derivatives and Their Use as Pharmaceuticals"**

Prohibition Applications concerning section 6 of the *Patented Medicines (Notice of Compliance) Regulations* – Summary as of December 31, 2010

The first table shows the number of submissions received during a specific calendar year and the number of Notices of Allegation received as of December 31, 2010.

The second table summarizes the results of applications for prohibition filed in the Federal Court beginning with the number of court applications commenced by first persons and the outcome of the applications. The break-down of subsequent appeals for each possible application conclusion - granted, dismissed, partially granted - is also included. The court applications commenced are the result of the Notices of Allegation made by second persons in respect of first persons' patents.

Documents Received	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**
Submissions received	164	153	157	248	270	301
Notices of Allegation received	101	88	104	172	141	165

Prohibition Applications	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**
Prohibition applications commenced	51	60	53	73	65*	61
Prohibition applications discontinued	26	39	36	43	40	14
Prohibition applications granted	8	6	7	9	2	1
Appeals Filed	6	2	4	1	0	0
Discontinued	1	1	3	-	-	-
Granted	1	-	-	-	-	-
Dismissed	4	1	-	-	-	-
Pending	0	0	1	1	-	-
Prohibition applications dismissed	14	14	9	14	2	0
Appeals Filed	5	4	3	4	1	0
Discontinued	-	3	2	3	-	-
Granted	1	-	-	-	-	-
Dismissed	4	1	1	-	-	-
Pending	0	0	0	1	1	-
Prohibition applications partially granted	3	1	1	0	0	0
Appeals Filed	1	1	1	0	0	0
Discontinued	-	-	-	-	-	-
Granted	1	1	.5	-	-	-
Dismissed	-	-	.5	-	-	-
Pending	0	0	0	-	-	-
Prohibition applications pending resolution	0	0	0	7	20	46

* One application was terminated by the Court.

Average Time to Resolution of Prohibition Applications under the *Patented Medicines (Notice of Compliance) Regulations*

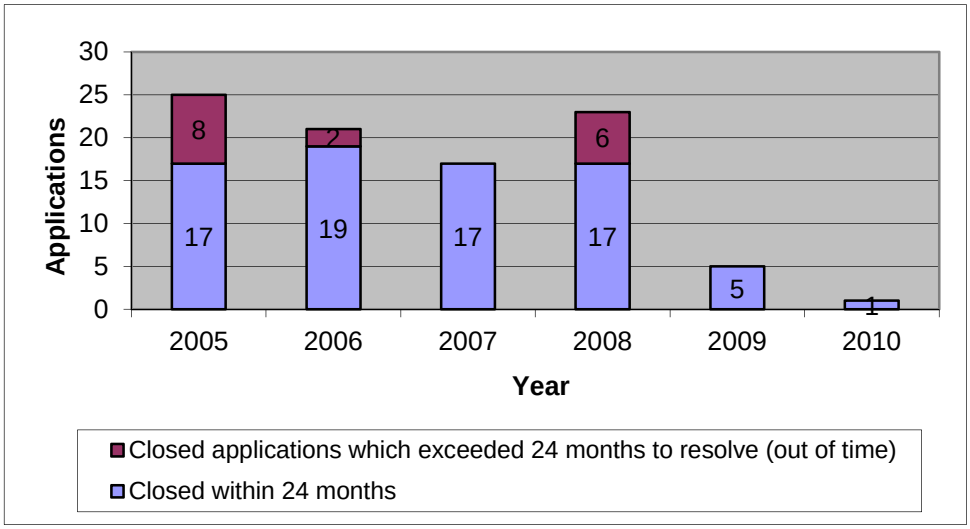
This table represents information regarding court cases filed pursuant to Section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, commonly referred to as prohibition applications. The start date of the application determines the year in which it will be included. Average time to resolution is calculated from the start date to the close date of the application in the Federal Court (appeals not included). The 24-month period is prescribed by paragraph 7(1)(e) of the *Patented Medicines (Notice of Compliance) Regulations.* Pursuant to subsection 7(5), the court may make an order to vary the length of the 24-month stay.

Year	Number of cases per year	Number of cases closed[1]	Average resolution time[1] (months)	Range[1] (months)
2005	51	25	21.5	5.0 – 38.2
2006	60	21	18.2	8.4 – 27.5
2007	53	17	19.1	3.3 – 24.0
2008	73	23	17.9	5.1 – 27.3
2009	65	5	7.6	0.9 – 21.2
2010	61	1	2.2	2.2

1 These numbers do not include cases which have been discontinued by the Applicant.

Prohibition Applications Exceeding a 24-Month Resolution Timeframe

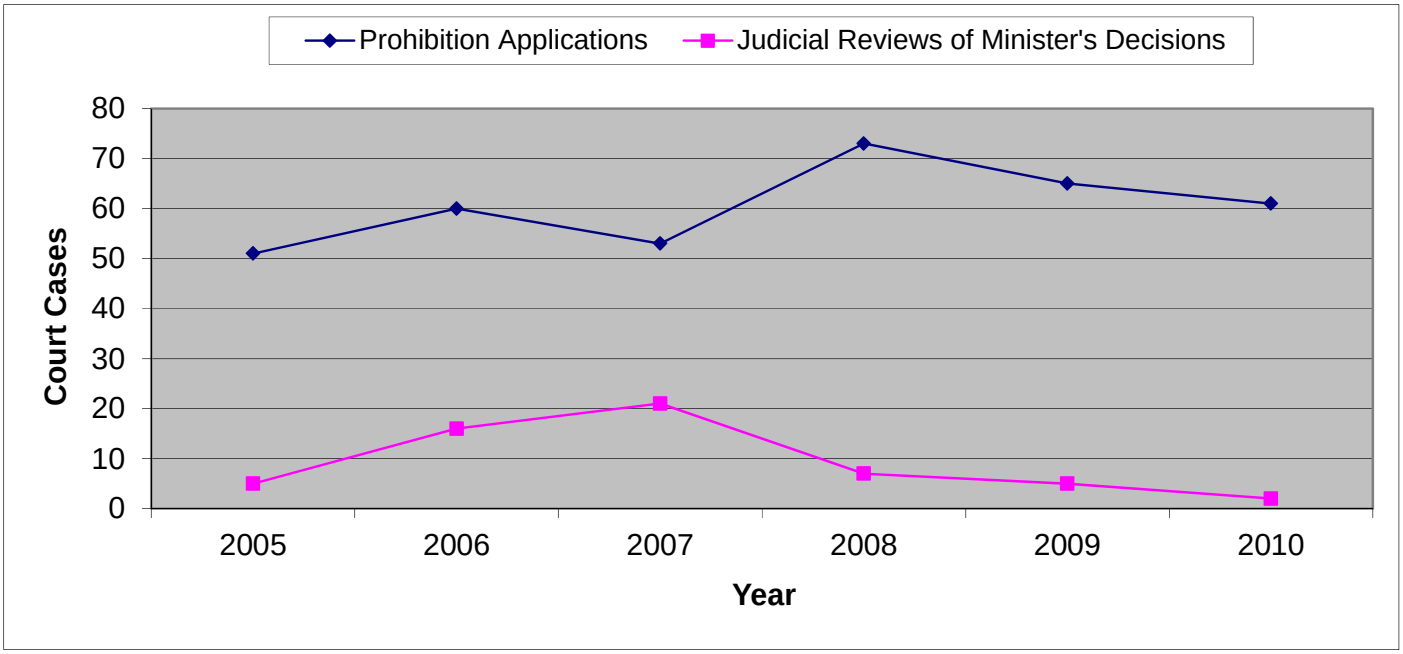
This graph and table represent the number of closed applications per year which were resolved within 24 months and the number of closed applications which exceeded 24 months to resolve. The numbers do not include cases which were discontinued.



Applications	2005	2006	2007	2008	2009	2010
Closed within 24 months	17	19	17	17	5	1
Closed applications which exceeded 24 months to resolve (out of time)	8	2	0	6	0	0
Total number of applications closed	25	21	17	23	5	1

Prohibition and Judicial Review Applications Initiated Per Year

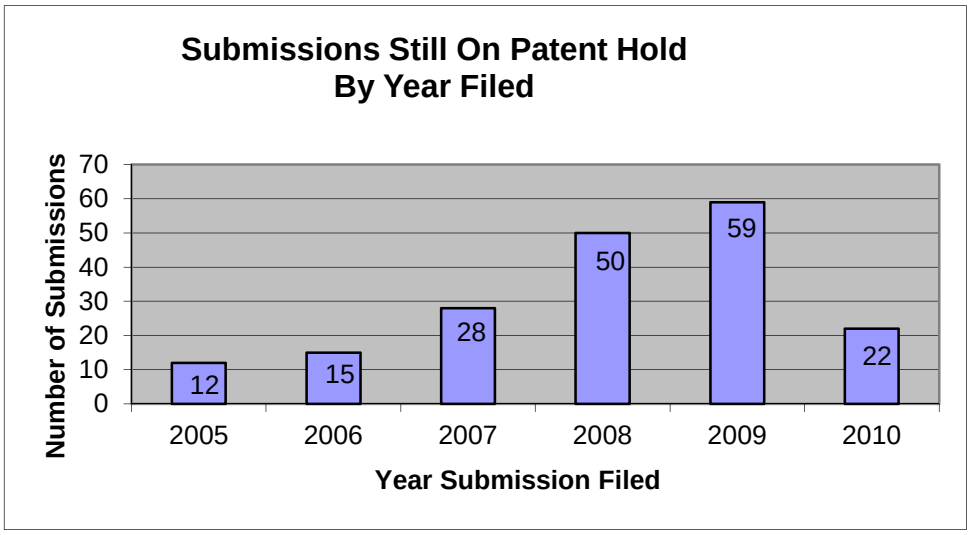
This graph and table compare the number of applications for judicial review of the Minister's decisions concerning sections 3, 4 and 5 with the number of applications for orders of prohibition with respect to section 6 of the *Patented Medicines (Notice of Compliance) Regulations.*



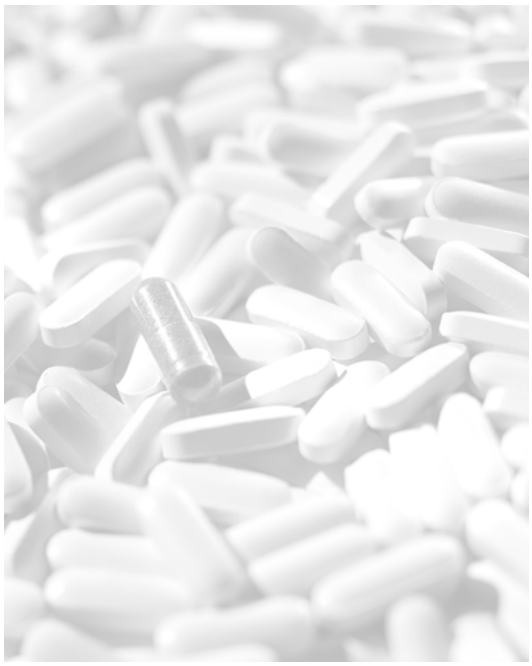
Applications	2005	2006	2007	2008	2009	2010
Prohibition Applications	51	60	53	73	65	61
Judicial Review Application of Minister's Decisions	5	16	21	7	5	2

Submissions Still on Patent Hold

This graph and table show the number of submissions by year filed which were still on patent hold as of December 31, 2010. Note that some submissions may still be in review and are, therefore, not represented in this graph and table.



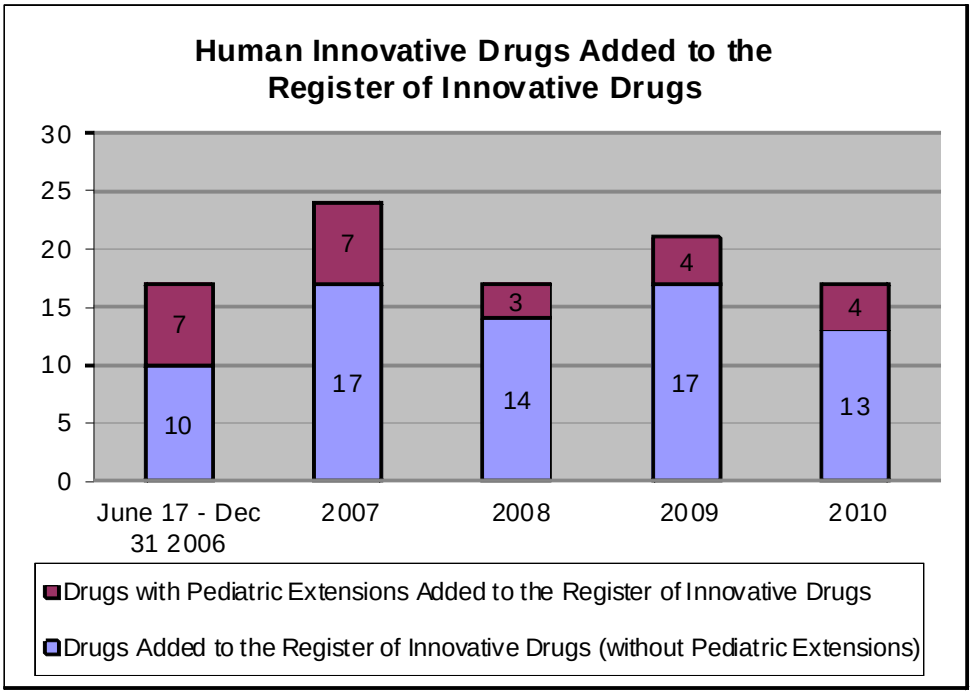
Submissions	2005	2006	2007	2008	2009	2010
Number of Submissions Still on Patent Hold	12	15	28	50	59	22



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

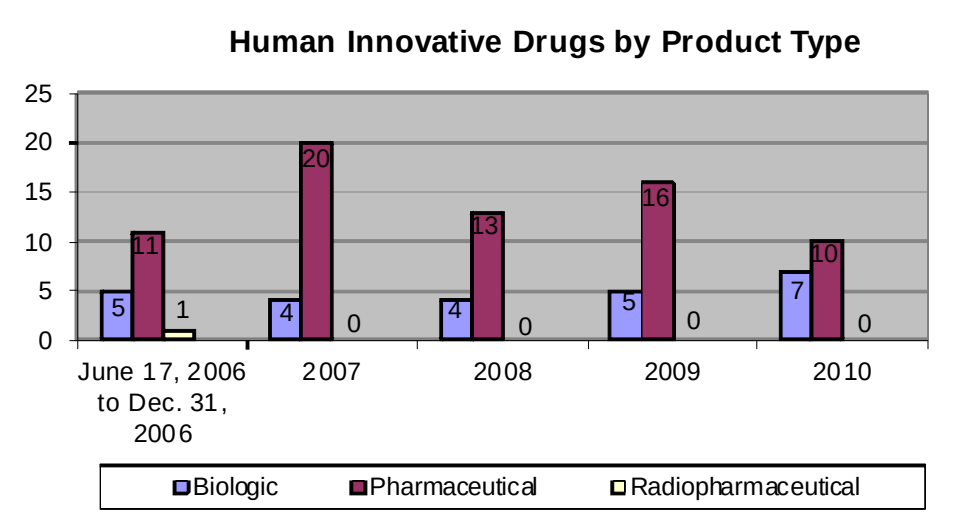
Register of Innovative Drugs - Human Drugs

This graph and table display the number of human innovative drugs that were added to the Register of Innovative Drugs by Notice of Compliance date. Note that pediatric extensions for previously listed drugs may be added at a later date.



Innovative Drugs	June 17, 2006 to Dec 31, 2006	2007	2008	2009	2010
Human Innovative Drugs with Pediatric Extensions	7	7	3	4	4
Human Innovative Drugs (without Pediatric Extensions)	10	17	14	17	13
Total Human Innovative Drugs	17	24	17	21	17

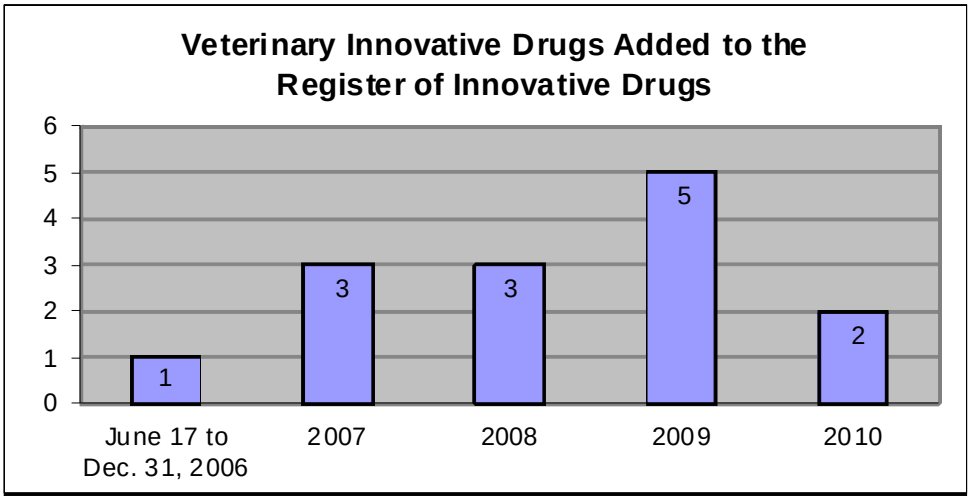
This graph and table display the number of human innovative drugs added to the Register of Innovative Drugs by product type.



Innovative Drugs	June 17, 2006 to Dec. 31, 2006	2007	2008	2009	2010
Biologic	5	4	4	5	7
Pharmaceutical	11	20	13	16	10
Radiopharmaceutical	1	0	0	0	0

Register of Innovative Drugs – Veterinary Drugs

This graph and table display the number of veterinary innovative drugs that were added to the Register of Innovative Drugs by Notice of Compliance date.



Innovative Drugs	June 17, 2006 to Dec 31, 2006	2007	2008	2009	2010
Veterinary Innovative Drugs	1	3	3	5	2

Court Cases Concerning Data Protection Provisions (C.08.004.1) of the *Food and Drug Regulations*

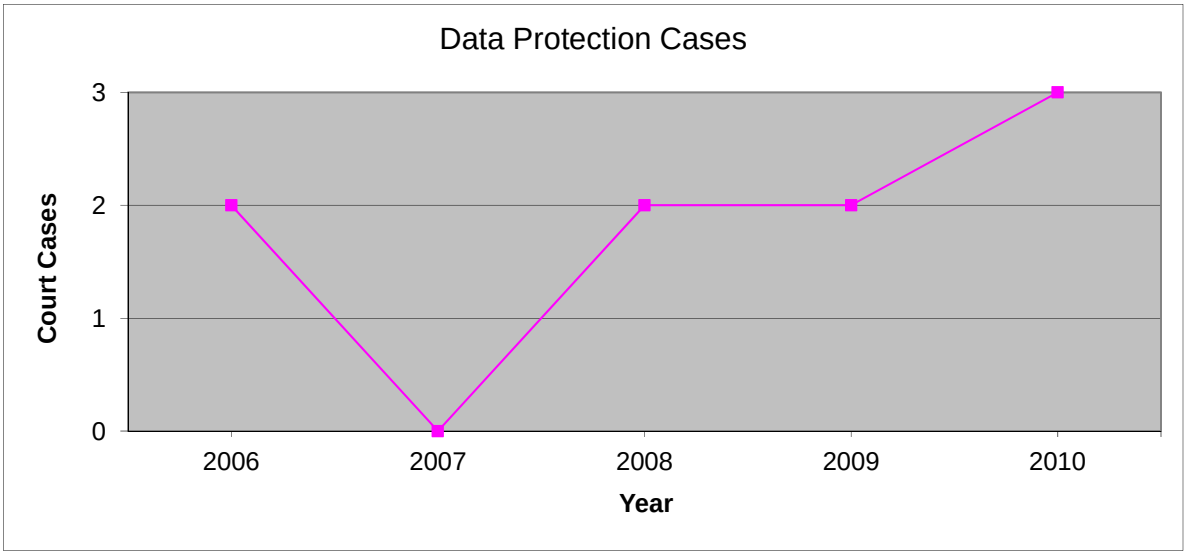
This is a listing of all the judicial review applications in respect of the data protection provisions (C.08.004.1) of the *Food and Drug Regulations.* New cases and changes to open cases which occurred during the year are presented in bold.

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient	Start Date	Close Date	Summary of Issue
T-1976-06 (dismissed) A-360-09 **(dismissed) Seeking leave to appeal to the Supreme Court of Canada**	Canadian Generic Pharmaceutical Association - and - The Governor in Council, The Minister of Health and The Attorney General of Canada	Not applicable	2006-11-14 2009-09-14	2009-07-17 **2010-12-09**	Challenge to the data protection provisions
T-2047-06 (dismissed) A-352-09 **(dismissed)** **Seeking leave to appeal to the Supreme Court of Canada**	Apotex Inc. - and - The Minister of Health and The Attorney General of Canada	Not applicable	2006-11-22 2009-09-11	2009-07-17 **2010-12-09**	Challenge to the data protection provisions
T-2009-09 **(dismissed)** **A-397-10** **(on-going)**	EpiCept Corporation - and - The Minister of Health	histamine dihydrochloride	2009-12-01 **2010-10-22**	**2010-09-24**	Eligibility for data protection; interpretation of "innovative drug" under section C.08.004.1(1)
T-152-10 (on-going)	**Canadian Generic Pharmaceutical Association - and - The Minister of Health and GlaxoSmithKline Inc.**	**fluticasone furoate**	**2010-02-03**		**Eligibility for data protection; interpretation of "innovative drug" under section C.08.004.1(1)**

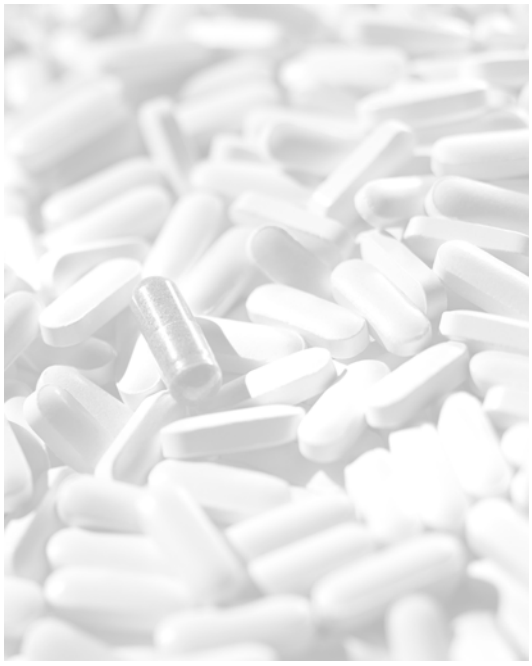
Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient	Start Date	Close Date	Summary of Issue
T-1172-10 (on-going)	**Teva Canada Limited - and - The Minister of Health and sanofi-aventis Canada Inc.**	**oxaliplatin**	**2010-07-21**		**Eligibility for data protection; interpretation of "innovative drug" under section C.08.004.1(1)**
T-2044-10 (on-going)	**Takeda Canada Inc. - and - The Minister of Health, Attorney General of Canada**	**dexlansoprazole**	**2010-12-08**		**Eligibility for data protection; interpretation of "innovative drug" under section C.08.004.1(1)**

Data Protection Court Cases Initiated Per Year

This graph and table represent the number of court proceedings with respect to data protection under (C.08.004.1) of the *Food and Drug Regulations.*



Cases	2006	2007	2008	2009	2010
Court Cases	2	0	2	2	3



Appendix A Definitions

Definitions

Court:
The Federal Court of Canada or any other superior court of competent jurisdiction.

Discontinued:
The cessation of court proceedings where the applicant voluntarily puts an end to the case, with or without leave of the court.

Dismissed:
The removal of a case from court, the termination of a case before trial or before a complete trial. In the case of the *Patented Medicines (Notice of Compliance) Regulations*, however, the dismissal indicates a decision at any point in the matter, either summary, as a result of a motion, or at the end of the proceeding following arguments (hearing).

Drug Identification Number (DIN):
The number located on the label of prescription and over-the-counter drug products that have been evaluated by the Therapeutic Products Directorate (TPD), Biologics and Genetic Therapies Directorate (BGTD) or Veterinary Drugs Directorate (VDD) and approved for sale in Canada. Once a drug has been approved, a DIN is issued which permits the manufacturer to market the drug in Canada.

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.
(C.08.004.1(1), *Food and Drug Regulations*)

Medicinal Ingredient:
A substance intended or capable of being used for the diagnosis, treatment, mitigation, or prevention of a disease, disorder, or abnormal physical state, or the symptoms thereof.

Notice of Allegation:
A notice issued under section 5 of the *Patented Medicines (Notice of Compliance) Regulations*. Such notices set out the nature of the generic manufacturer's challenge to a patent listed on the Patent Register.

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

Prohibition Partially Granted:
An order of prohibition applying to one or more but not to all patents that are subject of a section 6 case where more than one patent is at issue.

Patent Hold:
The period after which a submission has been reviewed and found eligible for a Notice of Compliance but for the *Patented Medicines (Notice of Compliance) Regulations*. Health Canada will ensure that all relevant patents have been addressed before issuing the Notice of Compliance.

Patent List:
Form IVs submitted by the first person pursuant to section 4 of the *Patented Medicines (Notice of Compliance) Regulations*.

Patent Register:
The register of patents and other information maintained by the Minister in accordance with subsection 3(2) of the *Patented Medicines (Notice of Compliance) Regulations*.

Pending:
A court case awaiting judgment.

Prohibition Granted:
The judgment from the court which prevents the Minister from issuing a Notice of Compliance in the case of the administration of the *Patented Medicines (Notice of Compliance) Regulations.*

Register of Innovative Drugs
The register maintained by the Minister in accordance with section C.08.004.1(9) of the *Food and Drug Regulations.*

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

Submission:
Any or all of: a new drug submission (NDS); an abbreviated new drug submission (ANDS); a supplement to a new drug submission (SNDS); a supplement to an abbreviated new drug submission (SANDS); and an extraordinary use new drug (EUNDS).