Therapeutic Products Directorate Statistical Report 2009

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




2010-08-25

Canada

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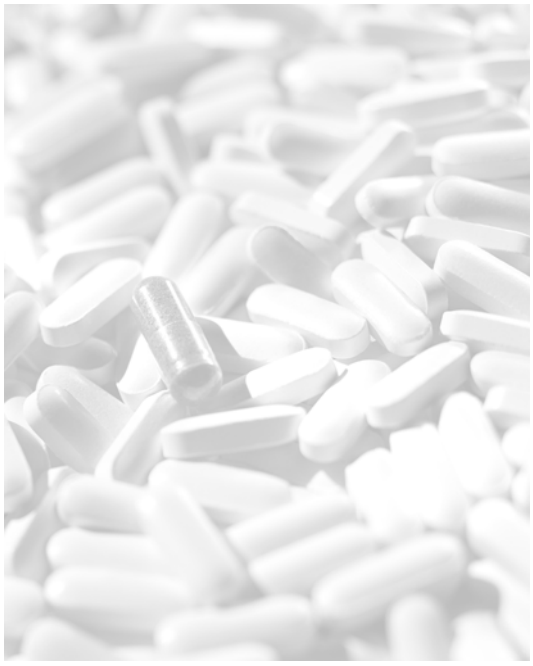


Section I
Overview

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 (*PM(NOC) Regulations*) 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.

Beginning in 2009, the statistics provided will include only the last six years, where feasible, for comparison purposes. Information on judicial review applications is limited to events that occurred during the year.

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

The *PM(NOC) 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 *PM(NOC) 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 *PM(NOC) 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 PM(NOC) 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 *PM(NOC) 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 *PM(NOC) 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 at: http://www.patentregister.ca/.

In addition, the OPML ensures that patents listed on the Patent Register are addressed under the *PM(NOC) Regulations*. Detailed information on the administration of the *PM(NOC) Regulations* can be found in the guidance document: *Patented Medicines (Notice of Compliance) Regulations*, available at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/patmedbrev/ pmreg3_mbreg3-eng.php.

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 behaviour 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") available at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/regist/index-eng.php

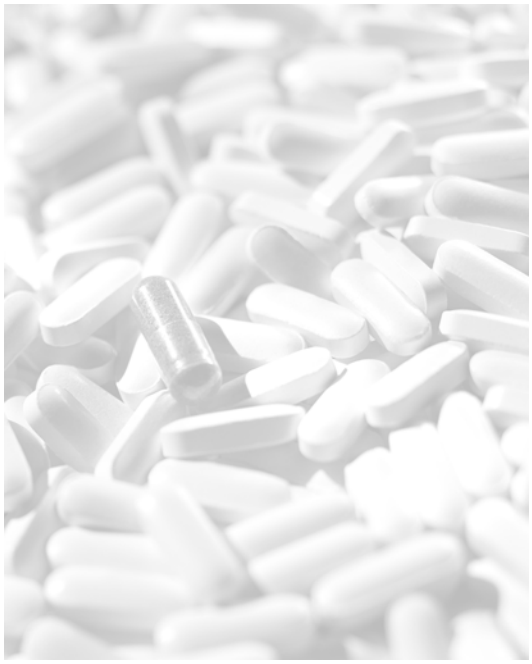
Detailed information on the administration of data protection is available in the guidance document: Data Protection under C.08.004.1 of the Food and Drug Regulations, available at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/data_donnees_protection-eng.php

Contents

Section II of this report outlines statistics relating to the maintenance of the Patent Register, including the number of patent lists filed by first persons, the number of patent lists accepted and rejected by the OPML, and judicial reviews resulting from the acceptance or rejection of patents for listing on the Patent Register.

Section III of this report outlines statistics relating to the requirements for second persons to address patents listed on the Patent Register, from the number of notices of allegation received and the number of applications for orders of prohibition commenced in the Federal Court to the resolutions of appeals by the Federal Court of Appeal. Tables showing the average time to the resolution of prohibition applications and a graph comparing the number of prohibition applications to judicial reviews are also included. Information on judicial review applications has also been included.

Section IV provides information on the administration of the data protection provisions of the *Food and Drug Regulations*. The information includes the number of drugs added to the RID and a breakdown by product type of innovative drugs added to the RID. A list of judicial review applications regarding data protection is also provided.



Section II

Statistics: Patent Register and *Patented Medicines (Notice of Compliance) Regulations:* Section 4

Number of Patent Lists Submitted for Listing on the Patent Register

1) Number of patent lists added to the Patent Register:

This information is generated from the electronic Patent Register database. This table provides 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 now been added again in connection with 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.

	2004	2005	2006	2007	2008	2009
Number of patent lists received (during the calendar year)	593	940	962	633	629	744
Number of patent lists rejected (during the calendar year)	170	252	273	147	133	141

	2004	2005	2006	2007	2008	2009
Number of patent lists added to the Patent Register (during the calendar year)	200	449	447	417	431	477
Patents not previously listed (New Drug Submission)	28	58	49	83	68	89
Patents not previously listed (Supplemental New Drug Submission)	15	46	41	52	110	121

2) Number of patent lists rejected:

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

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

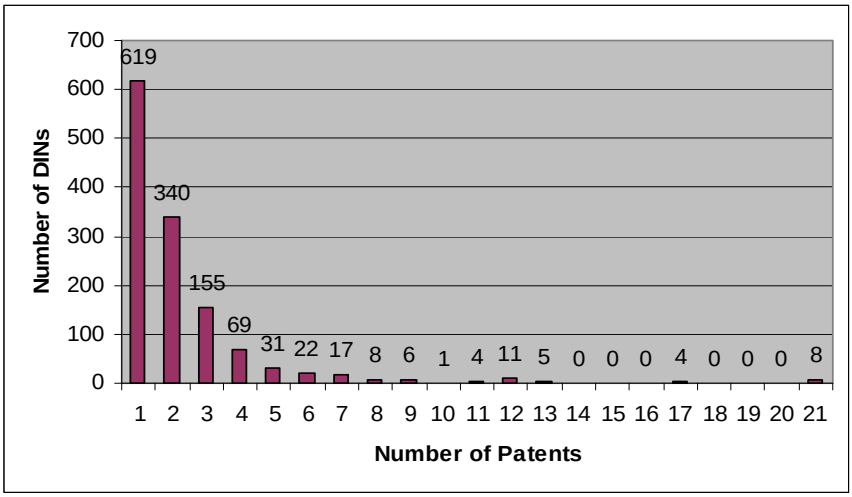
Court Cases Concerning Patent Eligibility: Section 3 and 4 cases

This table lists new cases started in 2009 and changes which took place to ongoing cases during 2009. The proceedings 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 *PM(NOC) 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-884-07 (dismissed) A-208-08 **(dismissed)**	G.D.Searle and Co. and Pfizer Canada Inc. - and -The Minister of Health	celecoxib	2007-05-23 2008-05-05	2008-04-04 **2009-02-09**	Listing eligibility of patent 2,319,201, entitled "Celecoxib Compositions", under s. 4(3)
T-1518-07 (dismissed) A-450-08 **(dismissed)**	Bayer Inc. - and - The Minister of Health and The Attorney General of Canada	estradiol	2007-08-16 2008-09-23	2008-07-10 **2009-04-28**	Listing eligibility of patent 2,167,970, entitled "Transdermal Drug Delivery Device Containing a Desiccant", under s. 4, 4.1
T-1934-07 **(dismissed)**	Solvay Pharma Inc. - and - The Attorney General of Canada and The Minister of Health	testosterone	2007-11-08	**2009-01-30**	**Listing eligibility of patent 2,420,895, entitled "Method for Treating Erectile Dysfunction and Increasing Libido in Men", under s. 4(3)**
T-382-08 **(dismissed)** **A-232-09 (on-going)**	Eli Lilly Canada Inc. - and - The Attorney General of Canada and The Minister of Health - and - Pharmascience Inc.	olanzapine	2008-03-07 **2009-06-05**	**2009-05-08**	**Timing of addition of patent 2,265,712, entitled "Intermediates and Process for Preparing Olanzapine" to the Patent Register**
T-338-09 (discontinued)	**Procter and Gamble Pharmaceuticals Canada Inc. - and - The Minister of Health**	**testosterone**	**2009-03-06**	**2009-04-29**	**Application of timing requirements under s. 4(6) during the submission reconsideration process**
T-582-09 (dismissed) **A-502-09 (on-going)**	**Bayer Inc. - and - The Minister of Health and The Attorney General of Canada**	**drospirenone + ethinyl estradiol**	**2009-04-14** **2009-12-16**	**2009-11-17**	**Listing eligibility of patent 2,194,979, entitled "Solid Drug Forms Containing Clathrates of Steroid Sex Hormones", under s. 4(2)**

A Snapshot of the Patent Register as of December 31, 2009: Number of Patents Per Drug Identification Number (DIN) on the Patent Register

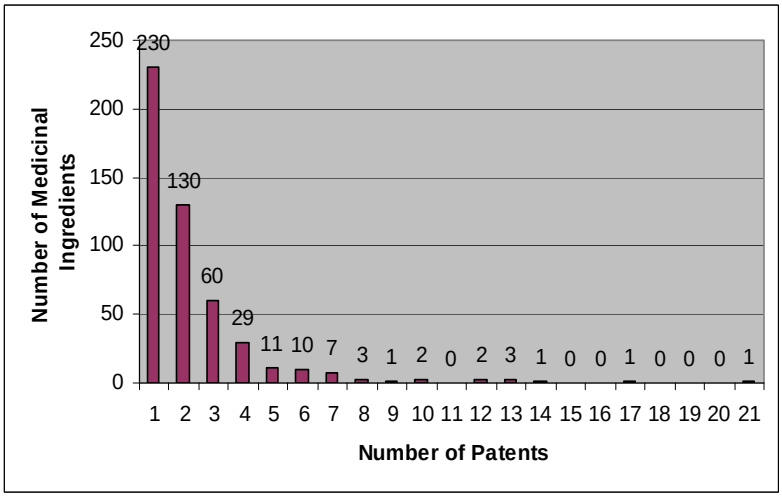
This graph and table represent the number of patents that a second person would have to address when seeking a Notice of Compliance (NOC) for a patented medicine. There are currently 1,302 DINs listed on the Patent Register. There are currently 491 different medicinal ingredients listed on the Patent Register. The total number of patents listed on the Patent Register is 865 and they are distributed per DIN as indicated in the graph. For example, there are 619 DINs which only have one patent listed against them; on the other hand, there are eight DINs which have 21 patents listed against them. Therefore, this graph 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 (i.e. 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	21
Number of DINs	619	340	155	69	31	22	17	8	6	1	4	11	5	0	0	0	4	0	0	0	8

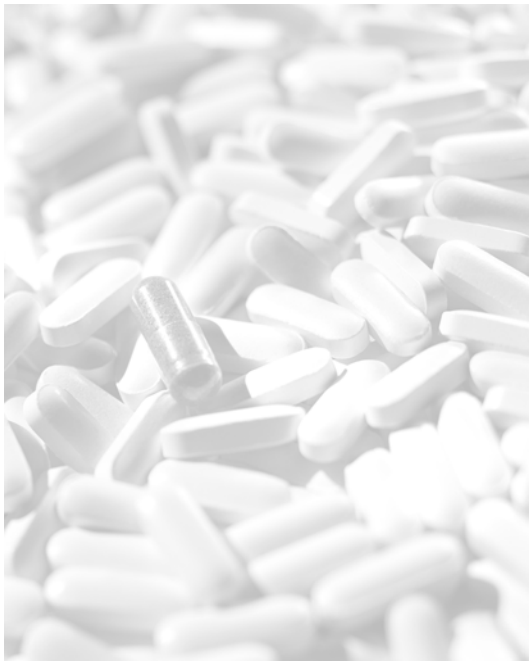
A Snapshot of the Patent Register as of December 31, 2009: Number of Patents Per Medicinal Ingredient on the Patent Register

There are currently 491 different medicinal ingredients listed on the Patent Register. The total number of different patents listed on the Patent Register is 865, and they are distributed per medicinal ingredient as indicated in the graph. For example, there are 230 medicinal ingredients which only have one patent listed against them; on the other hand, there is one which has 21 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. However, this graph is produced by medicinal ingredient. This groups some products that have multiple strengths, routes, and dosage forms listed on the Patent Register with others which do not.

Number of Patents	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Number of Medicinal Ingredients	230	130	60	29	11	10	7	3	1	2	0	2	3	1	0	0	1	0	0	0	1



Section III

Patented Medicines (Notice of Compliance) Regulations: Sections 5 and 6

Applications under section 6 of the *Patented Medicines (Notice of Compliance) Regulations* - Summary as of December 31, 2009

The first table shows the number of submissions received during a specific calendar year and the number of notices of allegation filed as of December 31, 2009.

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.

	2004	2005	2006	2007	2008	2009
Submissions received	101	164	153	157	248	270
Notices of Allegation received	93	101	84	100	158	85

		2004	2005	2006	2007	2008	2009
Prohibition applications commenced		52	51	60	53	73	65*
Prohibition applications discontinued		33	26	37	36	36	24
Prohibition applications granted		6	8	6	7	7	1
	Appeals Filed	4	6	2	4	0	0
	Discontinued	2	1	1	-	-	-
	Granted	-	1	-	-	-	-
	Dismissed	2	4	1	-	-	-
	Pending	0	0	0	4	-	-
Prohibition applications dismissed		13	14	14	9	3	1
	Appeals Filed	11	5	4	3	1	0
	Discontinued	5	-	3	1	1	-
	Granted	2	1	-	-	-	-
	Dismissed	4	4	1	1	-	-
	Pending	0	0	0	1	-	-
Prohibition applications partially granted		0	3	1	1	0	0
	Appeals Filed	0	1	1	1	0	0
	Discontinued	-	-	-	-	-	-
	Granted	-	1	1	-	-	-
	Dismissed	-	-	-	-	-	-
	Pending	-	-	-	1	-	-
Prohibition applications pending resolution		0	0	2	0	27	38

* One application was terminated by the Court.

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

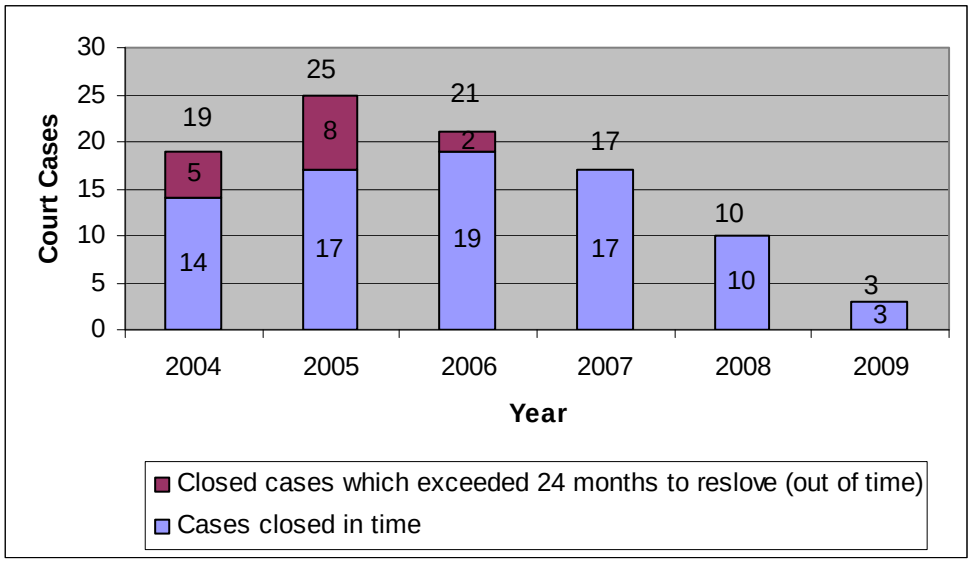
This table represents information regarding applications filed pursuant to Section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, commonly referred to as prohibition applications. The start date of the court case determines the year in which it will be included. Average time to resolution is calculated from the court case start date to the close date of the court case 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)
2004	52	19	22.5	10.8 – 33.8
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	10	10.4	5.0 – 19.5
2009	65	3	3.6	0.9 – 5.1

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

Court Cases Exceeding a 24-Month Resolution Timeframe

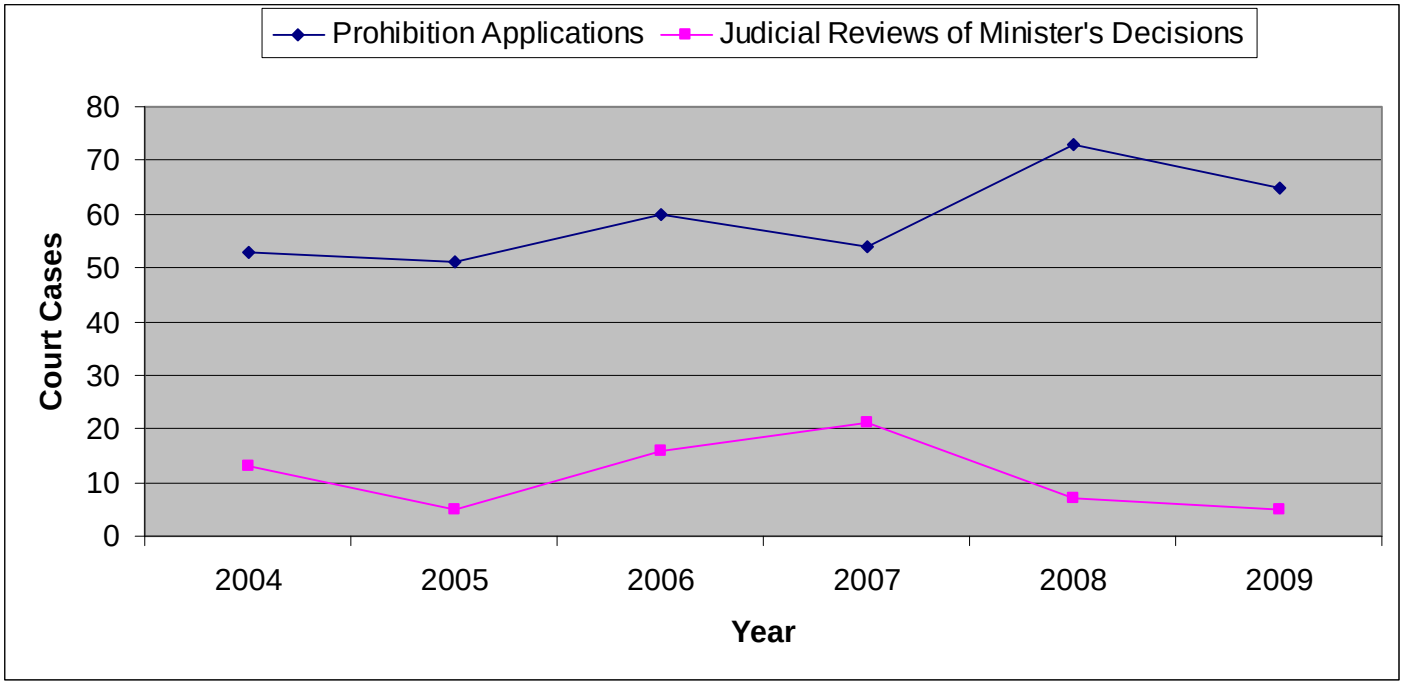
This chart and table represent the number of closed court cases per year which were resolved within 24 months and the number of closed court cases which exceeded 24 months to resolve. The numbers do not include cases which were discontinued.



Year	2004	2005	2006	2007	2008	2009
Cases closed in time	14	17	19	17	10	3
Closed cases which exceeded 24 months to resolve (out of time)	5	8	2	0	0	0
Total number of cases closed	19	25	21	17	10	3

Prohibition and Judicial Review Court Cases Initiated Per Year

This graph and table represent a comparison of the number of applications for judicial review of the Minister's decisions and those for orders of prohibition pertaining to the *Patented Medicines (Notice of Compliance) Regulations.*



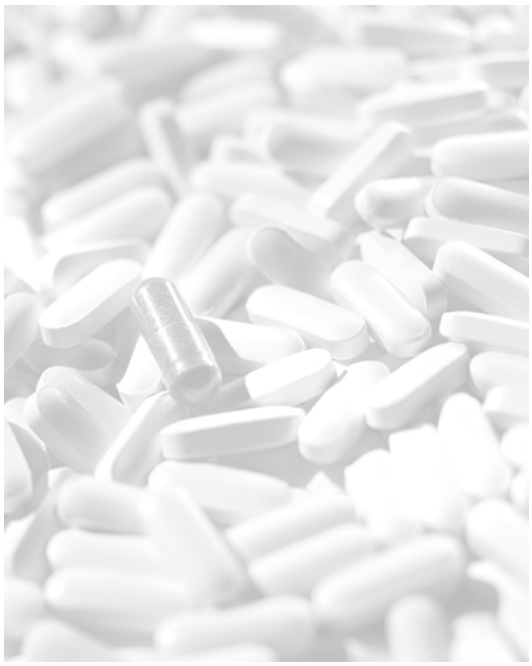
	2004	2005	2006	2007	2008	2009
Prohibition Applications	52	51	60	53	73	65
Judicial Reviews of Minister's Decisions	13	5	16	21	7	5

Court Cases Concerning section 5 of the *Patented Medicines (Notice of Compliance) Regulations*

This is a listing of judicial review proceedings, filed with respect to section 5 of the *PM(NOC) Regulations*, which were new in 2009. Included are changes to cases which were on-going in 2009. 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-750-06 **(discontinued)**	Apotex Inc - and - the Minister of Health	desmopressin	2006-05-02	**2009-03-06**	**Application of section 5; pre-October 5, 2006 version of *PM(NOC) Regulations***
T-837-07 (granted) A-472-08 **(dismissed)**	Pharmascience Inc. - and - The Minister of Health and The Attorney General of Canada	ramipril	2007-05-14	2008-04-04 **2009-06-01**	Application of patent-specific analysis in light of a supplement to an abbreviated new drug submission; pre-October 5, 2006 version of *PM(NOC) Regulations*
T-1351-07 (dismissed) A-470-08 **(dismissed)**	Sanofi-Aventis Canada Inc. - and - The Minister of Health, The Attorney General of Canada and Laboratoire Riva Inc.	ramipril	2007-12-03 2008-09-29	2008-09-22 **2009-05-26**	Application of section 5 in light of a cross-referenced abbreviated new drug submission
T-2100-07 **(allowed and returned to Minister)** **A-397-09/ A-412-09**	Apotex Inc. - and - The Minister of Health	omeprazole	2007-12-03 **2009-09-30** **2009-10-05**	**2009-07-15**	**Application of section 5 in light of a supplement to an abbreviated new drug submission; pre-October 5, 2006 version of *PM(NOC) Regulations***
T-584-08 **(discontinued)**	Sanofi-Aventis Canada Inc. - and - The Minister of Health, The Attorney General of Canada and Laboratoire Riva Inc.	ramipril	2008-04-11	**2009-06-19**	**Application of section 5 in light of a cross-referenced abbreviated new drug submission**

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient	Start Date	Close Date	Summary of Issue
T-1575-09 (on-going)	**AstraZeneca Canada Inc. - and - The Minister of Health, The Attorney General of Canada and Apotex Inc.**	**omeprazole**	**2009-09-21**		**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 *PM(NOC) Regulations***
T-1862-09 and T-1863-09 (on-going)	**Novopharm Limited - and - The Minister of Health and The Attorney General of Canada**	**Drug B Drug A**	**2009-11-13**		**Application of section 5**

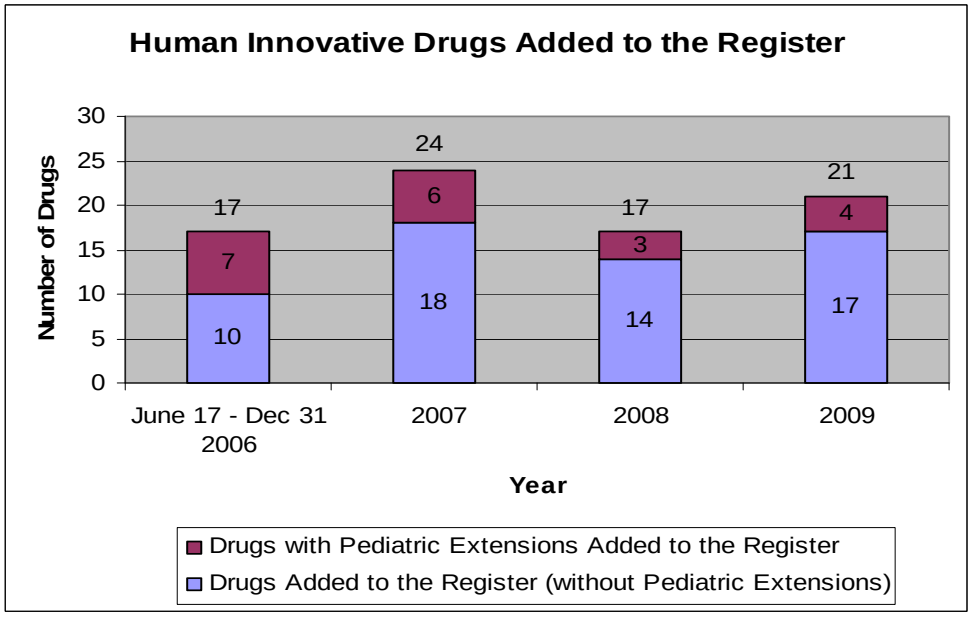


Section IV
Data Protection
(C.08.004.1 of the *Food and Drug Regulations)*

Register of Innovative Drugs (RID)

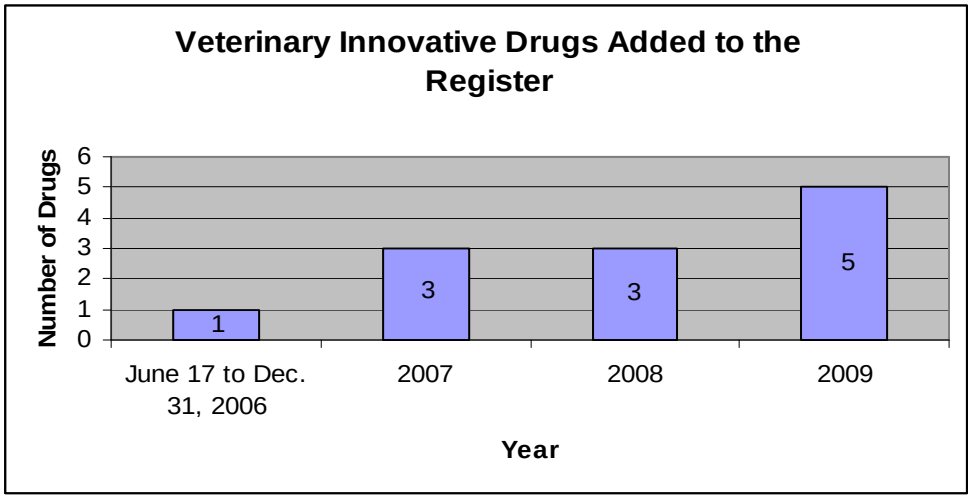
A Register of Innovative Drugs is maintained in accordance with the *Food and Drug Regulations.* Innovative drugs are added to the Register after the issuance of the notice of compliance.

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.



	June 17, 2006 to Dec 31, 2006	2007	2008	2009
Human Innovative Drugs with Pediatric Extensions	7	6	3	4
Human Innovative Drugs (without Pediatric Extensions)	10	18	14	17
Total Human Innovative Drugs	17	24	17	21

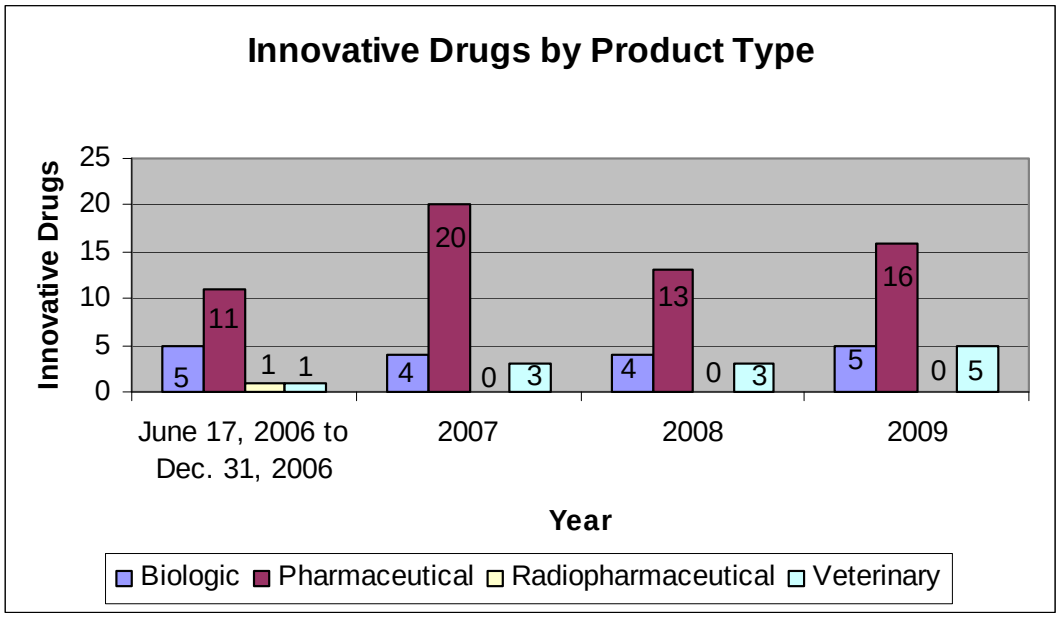
This graph and table display the number of veterinary innovative drugs that were added to the Register of Innovative Drugs by notice of compliance date.



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

Register of Innovative Drugs - Product Type

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



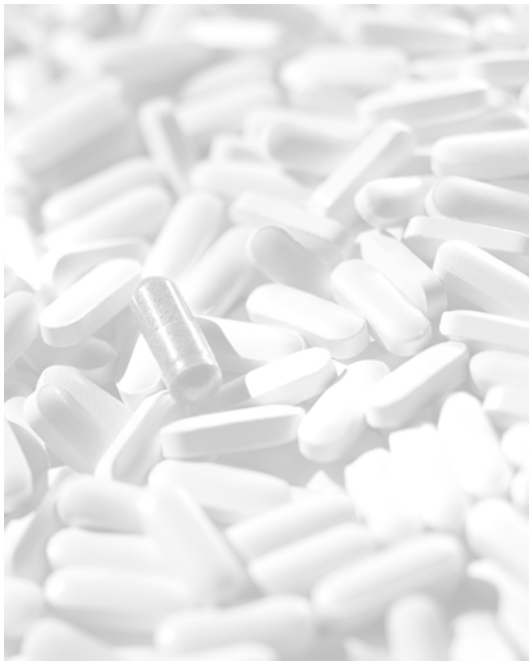
	June 17, 2006 to Dec. 31, 2006	2007	2008	2009
Biologic	5	4	4	5
Pharmaceutical	11	20	13	16
Radiopharmaceutical	1	0	0	0
Veterinary	1	3	3	5

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 proceedings 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-296-08 **A-9-09 (dismissed)**	Lundbeck Canada Inc. - and - The Minister of Health and The Attorney General of Canada and ratiopharm Inc.	memantine hydrochloride	2008-02-25	2008-12-16 **2009-04-29**	Minister of Health's decision to accept and review an abbreviated new drug submission which references a product marketed under Health Canada's notice of compliance with conditions policy
T-1143-08 **A-10-09 (dismissed)**	Lundbeck Canada Inc. - and - The Minister of Heralth (Canada) and Cobalt Pharmaceuticals	memantine hydrochloride	2008-07-23	2008-12-16	Minister of Health's decision to accept and review an abbreviated new drug submission which references a product marketed under Health Canada's notice of compliance with conditions policy
T-1976-06 **(dismissed)** **A-360-09 (on-going)**	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**	**Challenge to the data protection provisions**
T-2047-06 **(dismissed)** **A-352-09 (on-going)**	Apotex Inc. - and - The Minister of Health and The Attorney General of Canada	Not applicable	2006-11-22 **2009-09-11**	**2009-07-17**	**Challenge to the data protection provisions**

Federal Court/ Federal Court of Appeal	Style of Cause	Medicinal Ingredient	Start Date	Close Date	Summary of Issue
T-672-09 (discontinued)	**Lundbeck Canada Inc. - and - The Minister of Health (Canada) and Apotex Inc.**	**memantine hydrochloride**	**2009-04-27**	**2009-05-25**	**Minister of Health's decision to accept and review an abbreviated new drug submission which references a product marketed under Health Canada's notice of compliance with conditions policy**
T-2009-09 (ongoing)	**EpiCept Corporation - and - The Minister of Health**	**histamine dihydrochloride**	**2009-12-01**		**Eligibility for data protection; interpretation of "innovative drug" under section C.08.004.1(1)**



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 Drug Identification Number (DIN) is 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.

Form IV:
Means a Form IV: Patent List filed by a first person under section 4 of the *PM(NOC) Regulations*.

Form V:
Means a Form V: Declaration Re: Patent List filed by a second person under section 5 of the *PM(NOC) Regulations*.

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.

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 (NOA):
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 (NOC):
A notice issued under section C.08.004 of the *Food and Drug Regulations*.

Prohibition Partially Granted:
In the case of more than one patent being addressed in a case, the prohibition will apply to one or more but not to all patents attached to the case.

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

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 maintained by the Minister under section 3 of the *Patented Medicines (Notice of Compliance) Regulations*.

Pending:
The case is 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:
A submission includes a new drug submission (NDS), an abbreviated new drug submission (ANDS), a supplement to a new drug submission (SNDS), and a supplement to an abbreviated new drug submission (SANDS).