Health Canada Santé Canada

Therapeutic Products Directorate
Statistical Report 2007

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

2008-04-22

Health Canada Santé Canada

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Overview

Overview

This document provides a statistical overview relating to the administration of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 as amended (the *PM(NOC) Regulations*).

The *PM(NOC) Regulations* were written by Industry Canada under the *Patent Act*, and were declared in force in March 1993 and amended October 5, 2006. They are administered by the Office of Patented Medicines and Liaison, which is located in the Therapeutic Products Directorate, Health Products and Foods Branch, Health Canada.

In accordance with the Regulatory Impact Analysis Statement ("RIAS") published in *Canada Gazette*, Part II on October 18, 2006,[1] the pharmaceutical patent policy objective is to "balance the effective patent enforcement over new and innovative drugs with the timely entry of their lower priced generic competitors." The early working exception of section 55.2(1) of the *Patent Act* allows a subsequent manufacturer to use a patented invention for the purpose of seeking regulatory approval of that product. The provision, therefore, provides an exception from infringement. The *Patented Medicines (Notice of Compliance) Regulations* [S.O.R./93-133 as amended] ("*PM(NOC) Regulations*") provide the balance through a patent enforcement mechanism to ensure that the early working exception is not abused and that copy-cat drugs are not sold before relevant patent expiry.

Under the *PM(NOC) Regulations*, the Minister of Health maintains a Patent Register. The Patent Register consists of patent lists submitted in respect of drugs for which a Notice of Compliance has been issued. Patent lists filed for inclusion on the Patent Register are subject to the eligibility requirements under the *PM(NOC) Regulations*. In this respect, the Minister may refuse to add or may delete information from the Patent Register. Each patent list is audited by the Office of Patented Medicines and Liaison prior to inclusion on the Patent Register. A web-accessible version of the Patent Register is found at http://www.patentregister.ca/.

Content

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, and litigation resulting from the acceptance or rejection of patents for listing on the Patent Register.

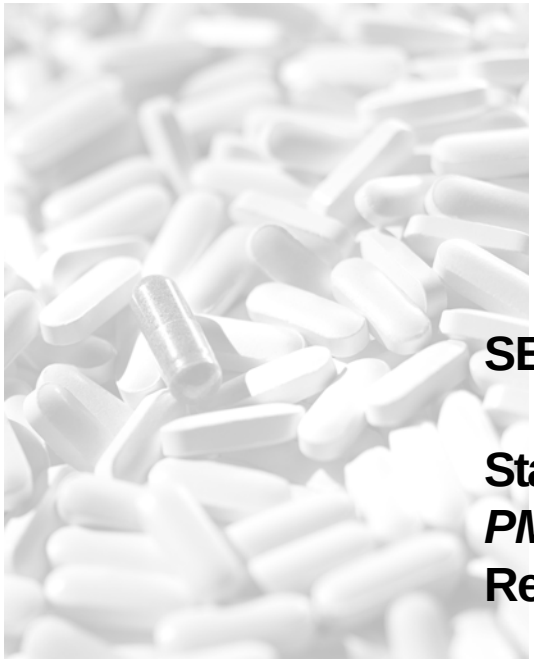
SECTION III of this report outlines statistics relating to the requirements for second persons to address patents listed on the Patent Register. A second person must address patents where it makes a comparison or reference to a drug for which a patent is listed, or where the second person's drug contains the same medicine, in the same route of administration and with a comparable strength and dosage form as another drug for which a patent is listed. A second person addresses patents by filing a Form V Patent Declaration with the Minister, and by serving a Notice of Allegation on the first person. Upon receipt of a Notice of Allegation, the first person has 45 days in which to initiate an application in the Federal Court of Canada, seeking an order to prohibit the Minister from issuing a Notice of Compliance to the second person until expiry of the patent.

Where such a court application is initiated, the Minister is prevented from issuing a Notice of Compliance to the second person for a period of 24 months, or upon resolution of the court application if that is sooner.

The information in SECTION III includes statistics relating to the number of Notices of Allegation served, the resulting initiation of prohibition applications and the respective outcomes of the applications, and the number of prohibition applications initiated per drug. Information on judicial review applications challenging the requirement to address particular patents has also been included.

For ease of reference, listings of acronyms and definitions have been appended to this report as Appendix "A" and "B" respectively.

[1] C. Gaz. 2006.II.1510.



SECTION II

Statistics: Patent Register and *PM(NOC) Regulations* Section 4 Related Information

Number of Patent Lists Submitted for Listing on the Patent Register

1) Number of patents added to the Patent Register:

This information is generated from the electronic Patent Register database. This chart provides the total number of patent lists added to the Patent Register in each year. This does not mean that all listings represent new patents being added to the Patent Register for the first time. Some represent patents already listed on the Patent Register - for previously approved drug submissions - which have now been added again in connection with a different supplemental drug submission. Also, patent lists could have been received in one calendar year but not added to the Patent Register until the following calendar year. The number of rejected patent lists includes all patents rejected for all submissions, not only the number of distinct patents rejected.

	2001	2002	2003	2004	2005	2006	2007
Number of patent lists received (during the calendar year)			510	593	940	962	633
Number of patent lists added to the Patent Register (during the calendar year)	204	197	139	200	449	447	417
Number of patent lists rejected (during the calendar year)	123	48	122	170	252	273	141
Brand New Patents Added (NDS)			22	28	58	49	83
Brand New Patents Added (SNDS)			9	15	46	41	52

2) Number of patent lists rejected:

The information for years 2001 and 2002 is generated from outgoing correspondence from the Office of Patented Medicines and Liaison. The information starting at year 2003 is generated from a database of information populated by the Office of Patented Medicines and Liaison. Rejections included process patents, medical device patents, name change submissions which do not provide an opportunity to file patent lists, and all other patent lists which did not meet the timing requirements set out in the *PM(NOC) Regulations*. The rejection of a patent list for a particular drug submission does not preclude the patent list being on the Patent Register for another drug submission for which it is eligible.

Reason for Rejection	**2001**	**2002**	**2003**	**2004**	**2005**	**Jan 1, 2006 to Jun 15, 2006**
Inappropriate Claims:						
no claim to the medicine or the use of the medicine	24	29	89	85	162	32
devices, eg. patches, inhalers	19	6	2	21	27	21
intermediate	1	0	0	2	0	9
process patents	6	2	0	14	2	2
Submissions for company or product name changes	49	5	5	5	7	12
Timeline related, i.e. does not meet 4(3)[1] or 4(4)[1]	22	6	7	12	18	8
Patent not yet granted	2	0	3	6	17	10

[1] As this section reads prior to the October 5, 2006 amendments to the *PM(NOC) Regulations*

Reason for Rejection	2001	2002	2003	2004	2005	Jan 1, 2006 to Jun 15, 2006
Patent expired	0	0	1	0	0	
Submission related (incorrect strength)	0	0	1	16	8	9
Wrong dosage form (4(7)b)[1]	0	0	14	7	11	
Withdrawn by company	0	0	0	2	0	1
Total	**123**	**48**	**122**	**170**	**252**	**104**

The *PM(NOC) Regulations* were amended on October 5, 2006. These amendments are intended to restore the balanced policy underlying the *PM(NOC) Regulations* by reaffirming the rules for listing patents on the register and clarifying when listed patents must be addressed.

Rejections	Jun 16, 2006 to Dec 31, 2006	2007
New Drug Submission (section *4(1)*)	0	2
Supplemental New Drug Submission (section *4(2)* and *4(3)*)	100	140
Timing (*sections 4(5)* and *4(6)*)	20	6
Total	**120**	**148**

Court Cases Concerning Patent Eligibility

This is a listing of all the judicial review proceedings filed pursuant to Section 18.1 of the *Federal Court Act* concerning decisions respecting the eligibility of patents for listing on the Patent Register pursuant to Sections 3 and 4 of the *Patented Medicines (Notice of Compliance) Regulations*.

FC/FCA	File Name	Ingredient	Start Date	Close Date	Summary
T-304-96 (dismissed)	Merck Frosst – and – the Minister of Health and Apotex & Novopharm	Simvastatin	1996-02-07	1997-06-13	Jurisdiction of the Minister to remove process patents.
T-306-96 (dismissed) A-168-96 (dismissed)	Merck Frosst – and – the Minister of Health and the Attorney General and Apotex and Novopharm	Ivermectin	1996-02-07	1997-06-13	Jurisdiction of the Minister to remove process patents.
T-386-96 (dismissed)	Glaxo Wellcome – and – the Minister of Health and the Attorney General and Apotex and Novopharm	Acyclovir	1996-02-19	1997-06-13	Jurisdiction of the Minister to remove process patents.
T-20-98 (dismissed) A-474-98 (dismissed)	Apotex and Novopharm – and – the Minister of Health and GlaxoBiochem	Lamivudine	1998-01-08	1998-07-29	Applicants sought to require the Minister to remove a patent for an intermediate from the register.
T-1635-98 (dismissed) A-222-99 (dismissed)	Apotex – and – the Minister of Health and SmithKline Beecham	Paroxetine HCl	1998-04-14	1999-04-12	A supplemental new drug submission is a "submission" for purposes of section 4 of the *PM(NOC) Regulations*.
T-1891-98 (dismissed)	Zenith Goldline Pharmaceuticals – and – the Minister of Health and Welfare and Bristol Myers Squibb	Paclitaxel	1998-10-01	1999-09-28	A patent list was added to the Patent Register on the basis of supplemental new drug submissions for a new dosing regimen and new indications. The Applicant sought to have the patent removed.
T-831-99 (discontinued)	Glaxo Group Limited and Glaxo Wellcome Inc. – and – the Minister of Health	Beclomethasone Dipropionate/ Salbutamol/ Zanamivir	1999-05-13	2000-05-30	Patent did not claim the medicine or use of the medicine, but rather claimed a mechanical device.
T-857-99 (dismissed) A-511-00 (dismissed)	Merck Frosst – and – the Minister of Health	Simvastatin	1999-05-14	2000-06-29	Patents for derivatives/metabolites are not eligible for listing on the patent register.
T-1225-99 (discontinued)	Glaxo Group Limited and Glaxo Wellcome Inc. – and – the Minister of Health	Sumatriptan Succinate	1999-06-30	2000-05-30	Patent did not claim the medicine or use of the medicine, but rather claimed a mechanical device.
T-1245-99 (discontinued)	Glaxo Group Limited and Glaxo Wellcome Inc. – and - the Minister of Health	Salmeterol Xinafoate	1999-07-07	2000-05-30	Patent did not claim the medicine or use of the medicine, but rather claimed a mechanical device.
T-50-00 (discontinued)	Glaxo – and – the Minister of Health	Zanamivir	2000-01-13	2000-05-30	The patent is for a device (blister pack) designed for the delivery of, among other medicines, Zanamivir.

FC/FCA	File Name	Ingredient	Start Date	Close Date	Summary
T-994-00 (dismissed)	Warner-Lambert Canada Inc. – and – the Minister of Health	Quinapril HCl and Quinapril HCl / hydrochlorothiazide	2000-06-09	2001-04-24	The patent claims a formulation containing Quinapril; however, the formulation has not received an NOC.
T-1212-00 (dismissed) A-64-02 (granted)	Eli Lilly – and – the Minister of Health	Ceftazidime	2000-07-10	2002-01-10	The patent claims a formulation which has not received an NOC.
T-1524-00 (granted) A-142-03 (granted)	Ferring Inc. – and – the Attorney General, the Minister of Health and Apotex Inc.	Desmopressin Acetate	2000-08-17	2002-03-11 2003-06-19	Ferring's patent was listed on the basis of a drug submission for an additional brand name. Ferring sought to quash the decision to issue an NOC for Apo-desmopressin nasal spray.
T-1768-00 (dismissed) A-44-01 (dismissed)	Bristol-Myers Squibb – and – the Minister of Health	Nefazadone Hydrochloride	2000-09-21	2001-01-19	The patent was removed from the Patent Register on the basis that it was listed for a supplemental new drug submission for a name change to the drug.
T-1830-00 (granted) A-142-03 (granted)	Ferring Inc. – and – the Minister of Health and Apotex Inc.	Desmopressin Acetate	2000-09-21	2003-03-11 2003-06-19	Patent was listed on Patent Register on the basis of a supplemental new drug submission for a name change.
T-1918-00 (dismissed)	Eli Lilly Canada Inc. – and – the Minister of Health	Estradiol	2000-10-18	2002-12-02	The patent contains claims for a patch for administering Estradiol.
T-2216-00 (dismissed) A-171-03 (dismissed)	Janssen-Ortho Inc. – and – the Minister of Health	Fentanyl	2000-11-24	2003-03-07 2004-02-09	The patent contains claims for patch for administering Fentanyl.
T-193-01 (dismissed)	Novartis – and – the Minister of Health	Estradiol-17-B	2001-02-01	2002-10-07	The patent contains claims for a patch for administering the medicine Estradiol-17-B.
T-194-01 (discontinued)	Novartis – and – the Minister of Health	Estradiol-17-B	2001-02-02	2002-04-02	The patent contains claims for a patch for administering Fentanyl.
T-192-01 (discontinued)	Eli Lilly – and – the Minister of Health	Ceftazidime	2001-02-02	2003-10-01	The patent claims a different salt.
T-655-01 (discontinued)	RhoxalPharma Inc. – and – the Minister of Health and AstraZeneca Canada Inc.	Omeprazole/ Omeprazole Magnesium	2001-04-17	2002-11-13	The patent contains claims for Omeprazole combined with another ingredient. Generic wants patent removed; Minister refused on grounds that claims contained a claim to the use of the medicine.
T-1103-01 (dismissed) A-442-02 (dismissed)	Pfizer Canada Inc. - and - the Attorney General of Canada	Azithromycin Dihydrate	2001-06-21	2002-06-24	Definition of ‘filing date’ issue. Does it include ‘priority date’ under Patent Act?

FC/FCA	File Name	Ingredient	Start Date	Close Date	Summary
T-1104-01 (dismissed) A-445-02 (dismissed)	Schering Canada Inc. - and – the Attorney General of Canada	Ribavirin	2001-06-21	2002-06-24	Definition of 'filing date' issue. Does it include 'priority date' under Patent Act?
T-1120-01 (dismissed) A-443-02 (dismissed)	Pfizer Canada Inc. - and – the Attorney General of Canada	Atorvastatin	2001-06-22	2002-06-24	Definition of 'filing date' issue. Does it include 'priority date' under Patent Act?
T-1334-01 (dismissed) A-301-03 (discontinued)	Eli Lilly Canada Inc. - and - the Attorney General of Canada	Sodium monensin	2001-07-20 2003-06-26	2003-05-29 2003-12-01	Patent did not contain a claim to the medicine itself, or the use of the medicine as required under paragraph 4(2)(b) of the *PM(NOC) Regulations*.
T-1950-01 (discontinued)	Novartis Pharmaceuticals Canada Inc. -and – the Attorney General of Canada	Estradiol 17-B	2001-10-30	2003-08-28	Patent for a patch containing an active agent in a transdermal carrier does not contain claims to a medicine or the use of a medicine.
T-2272-01 (discontinued)	GlaxoSmithKline Inc. - and – the Attorney General of Canada and the Minister of Health	Cefuroxime Axetil	2001-12-21	2002-04-04	Filing date issue and timing with respect to the submission filing date.
T-2271-01 (discontinued)	GlaxoSmithKline Inc. - and – the Attorney General of Canada and the Minister of Health	Multiple: Hep A Vaccine etc.	2001-12-21	2002-04-04	Filing date issue and timing with respect to the submission filing date.
T-93-02 (dismissed)	Toba Pharma Inc. - and – the Attorney General of Canada and the Minister of Health	Sevoflurane	2002-01-17	2002-09-03	Minister refused to list patents on Patent Register as submission was solely for a manufacturer name change.
T-139-02 (dismissed)	Reference under Subsection 18.3 of the Federal Court Act R.S.C. 1985	Olanzapine	2002-01-28	2002-09-25	Sought interpretation of the requirements of Section 4 of the *PM(NOC) Regulations* with respect to supplemental new drug submissions.
T-625-02 (discontinued)	GlaxoSmithKline Inc. – and – the Attorney General of Canada and the Minister of Health	Lamotrigine	2002-04-18	2003-05-28	Review of decision refusing to list patent on the Patent Register
T-644-02 (dismissed) A-570-04 (discontinued)	GlaxoSmithKline Inc. – and – the Attorney General of Canada, the Minister of Health and Apotex Inc.	Salbutamol sulphate	2002-04-19	2004-09-23	Review of decision to issue NOC without requiring Apotex to address patent.
T-869-02 (discontinued)	Apotex Inc. – and - the Minister of Health and Abbott Laboratories Ltd.	Clarithromycin	2002-06-05	2004-12-03	Second person alleges patent was improperly listed on the Patent Register.
T-2133-03 (dismissed) A-595-04 (dismissed)	Hoffmann-LaRoche Ltd. – and - the Attorney General and the Minister of Health	Trastuzumab	2003-11-14	2004-11-03 2005-05-12	Minister refused to list a patent against a drug submission for a new manufacturing site.

FC/FCA	File Name	Ingredient	Start Date	Close Date	Summary
T-2290-03 (discontinued)	GlaxoSmithKline Inc. – and - the Attorney General and the Minister of Health	Vinorelbine Tartrate	2003-12-04	2004-01-20	Minister refused to add 2 patent lists to the Patent Register as the patents did not contain a claim to the medicine or a claim to the use of the medicine.
T-441-03 (dismissed)	Pfizer Canada Inc. – and - the Attorney General and the Minister of Health	Verapamil Hydrochloride	2003-03-19	2004-03-01	Minister refused to list a patent as the patent did not specify a claim to the medicine or a claim to the use of the medicine.
T-905-03 (discontinued)	GlaxoSmithKline Inc. – and - the Attorney General and the Minister of Health	Zidovudine	2003-06-02	2003-11-06	Minister refused to add a patent list to the Patent Register due to timing and name change issues.
T-1468-04 (dismissed) A-549-05 (dismissed)	Hoffmann-LaRoche Limited - and - the Minister of Health and the Attorney General of Canada	Ibandronate Sodium	2004-08-11	2005-10-17 2006-10-18	An application for an order to quash decision by Minister to refuse to include patent on the Patent Register.
T-1781-04 (ongoing)	Eli Lilly Canada Inc. - and - the Minister of Health and the Attorney General of Canada	Pemetrexed Disodium	2004-10-01		Application for declaration that patent is eligible for listing on the Patent Register.
T-1957-04 (dismissed) A-572-05 (dismissed)	GlaxoSmithKline Inc. - and – the Attorney General of Canada and the Minister of Health	Salmeterol, Fluticasone, Salbutamol	2004-11-25	2005-11-24 2006-10-27	An application for a declaration that the patent is eligible for listing on the Patent Register.
T-1960-04 (ongoing)	Eli Lilly Canada Inc. - and - the Minister of Health and the Attorney General of Canada	Pemetrexed Disodium	2004-11-03		An application for declaration that patent is eligible for listing on the Patent Register.
T-2072-04 (dismissed) A-427-05 (dismissed)	Biovail Corporation (d.b.a. Biovail Pharmaceuticals Canada) - and – the Minister of National Health and Welfare	Buproprion & Diltiazem	2004-11-19	2005-08-22	An application for a declaration that the patent is eligible for listing on the Patent Register.
T-834-04 (dismissed) A-686-04 (dismissed)	GlaxoSmithKline Inc. - and - the Attorney General of Canada and the Minister of Health	Paroxetine Hydrochloride	2004-04-28	2004-12-10	An application for an order quashing Minister's decision rejecting 2 patents for listing on the Patent Register.
T-881-04 (dismissed) A-313-05 (granted)	Janssen-Ortho Inc. - and - the Minister of Health and the Attorney General of Canada	Norelgestromin and Ethinyl Estradiol	2004-05-04	2005-05-30	An application for an order quashing decision of the Minister who refused to add the patent to the Patent Register.
T-114-05 (dismissed) A-152-06 (dismissed)	Procter & Gamble Pharmaceuticals Canada Inc. - and - the Minister of Health and the Attorney General of Canada	Risedronate sodium	2005-01-05	2006-03-30 2007-02-01	An application seeking to quash decision re: refusal to list two patents.
T-283-05 (dismissed) A-100-06 (dismissed)	Pfizer Canada Inc. - and – the Minister of Health and the Attorney General of Canada	Amlodipine besylate / Atorvastatin	2005-02-16	2006-02-16 2006-09-28	An application for judicial review of Minister's decision to refuse to list a patent.

FC/FCA	File Name	Ingredient	Start Date	Close Date	Summary
T-2180-05 (discontinued)	Pfizer Canada Inc. - and – the Minister of Health and the Attorney General of Canada	Tolterodine L-tartare	2005-12-09	2006-02-07	An application for judicial review of the Minister's decision not to list a patent.
T-59-06 (dismissed)	Janssen-Ortho Inc. – and – the Attorney General of Canada and the Minister of Health	Methylphenidate hychloride	2006-01-12	2007-07-09	An application for judicial review of the Minister's decision not to list a patent.
T-108-06 (discontinued)	GlaxoSmithKline Inc. – and – the Attorney General of Canada and the Minister of Health	Lamivudine, abacavir, zidovudine	2006-01-20	2006-05-01	An application for an Order directing the Minister to list a patent.
T-314-06 (discontinued)	Ratiopharm Inc. – and – the Minister of Health	Amlodipine besylate	2006-02-20	2007-12-19	A judicial review to remove a patent from the Patent Register.
T-979-06 (dismissed)	Sanofi-Aventis Canada Inc. – and – the Minister of Health	Cefotaxime sodium	2006-06-15	2007-05-24	An application for judicial review of Minister's decision to remove a patent from the Patent Register.
T-1711-06 (dismissed)	Abbott Laboratories Limited and Abbott Laboratories – and – the Attorney General of Canada	Clarithromycin	2006-09-22	2007-04-26	An application with regards to the Minister's refusal to list a patent on the Patent Register.
T-2011-06 (ongoing)	Abbott Laboratories Limited, TAP Pharmaceuticals Inc. and TAP Pharmaceutical Products Inc. - and – the Attorney General of Canada and the Minister of Health	Lansoprazole	2006-11-16		An application with regards to the Minister's refusal to list a patent on the Patent Register.
T-513-07 (granted) A-383-07 (ongoing)	Abbott Laboratories Limited, TAP Pharmaceuticals Inc. and TAP Phamraceutical Products Inc. - and - Attorney General of Canada and The Minister of Health	Lansoprazole	2007-03-26 2007-08-29	2007-07-31	An application for judicial review of Minister's decision to remove a patent from the Patent Register.
T-487-07 (discontinued)	G.D. Searle & Co. and Pfizer Canada Inc. - and - The Minister of Health	Celecoxib	2007-04-27	2007-11-20	An application for judicial review of Minister's decision to remove a patent from the Patent Register.
T-884-07 (ongoing)	G.D. Searle & Co. and Pfizer Canada Inc. - and - The Minister of Health	Celecoxib	2007-05-23		An application for judicial review of Minister's decision to remove a patent from the Patent Register.
T-894-07 (ongoing)	Novopharm Limited – and – Minister of Health	Celecoxib	2007-05-24		An application with regards to the Minister's refusal to issue a Notice of Compliance.
T-1517-07 (ongoing)	Bayer Inc. – and – The Minister of Health and The Attorney General of	Estradiol-17β	2007-08-17		An application with regards to the Minister's refusal to list a patent on the Patent Register.

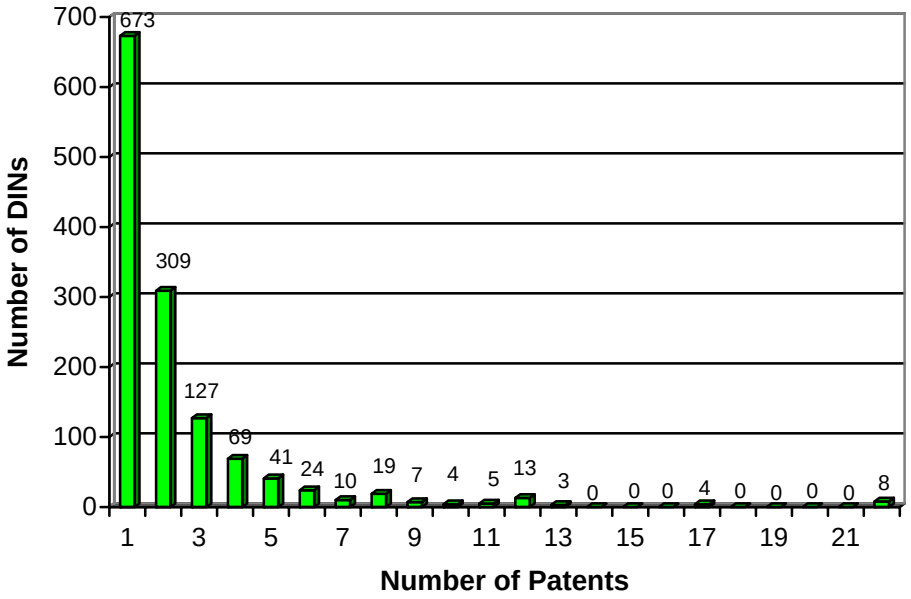
FC/FCA	File Name	Ingredient	Start Date	Close Date	Summary
	Canada				
T-1518-07 (ongoing)	Bayer Inc. – and – The Minister of Health and The Attorney General of Canada	Estradiol-17β	2007-08-16		An application with regards to the Minister's refusal to list a patent on the Patent Register.
T-1522-07 (discontinued)	Astellas Pharma Canada Inc. – and – The Minister of Health	Tacrolimus	2007-08-16	2007-09-05	An application with regards to the Minister's refusal to list a patent on the Patent Register.
T-1564-07 (ongoing)	Abbott Laboratories, Ltd. –and – The Attorney General of Canada and The Minister of Health	Sibutramine HCl monohydrate	2007-08-24		An application with regards to the Minister's refusal to list a patent on the Patent Register.
T-1755-07 (ongoing)	GlaxoSmithKline Inc. – and – The Attorney General of Canada and The Minister of Health	Salmeterol xinafoate / fluticasone proprionate	2007-09-028		An application with regards to the Minister's refusal to list a patent on the Patent Register.
1934-07 (ongoing)	Solvay Pharma Inc. – and – The Attorney General of Canada and The Minister of Health	Testosterone USP	2007-11-08		An application with regards to the Minister's refusal to list a patent on the Patent Register.

A Snapshot of the Patent Register as of December 31, 2007: Number of Patents Per DIN on the Patent Register

This graph is product-specific by DIN. It represents the number of patents a second person would have to address when seeking an NOC for a patented medicine.

There are currently 1317 DINs listed on the Patent Register. There are currently 481 different medicines listed on the Patent Register. The total number of patents listed on the Patent Register is 1092, and they are distributed per Drug Identification Number (DIN) as indicated in the Figure 1. For example, there are 673 DINs which only have one patent listed against them; on the other hand there are eight DINs which have 22 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 medicine, but patents may apply to more than one DIN (i.e. more than one strength, route and dosage form of a medicine). 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.

Figure 1

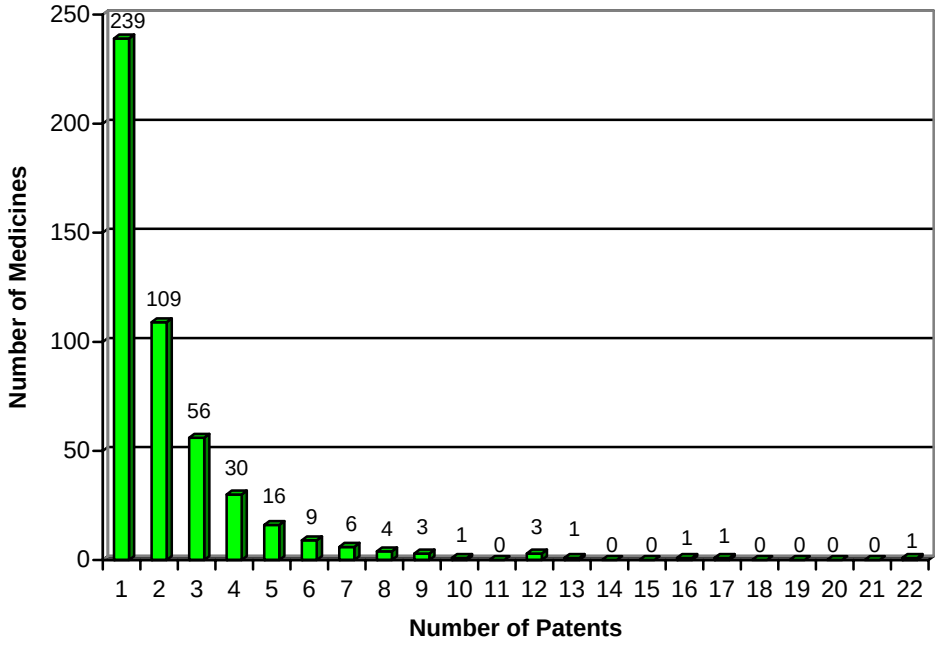


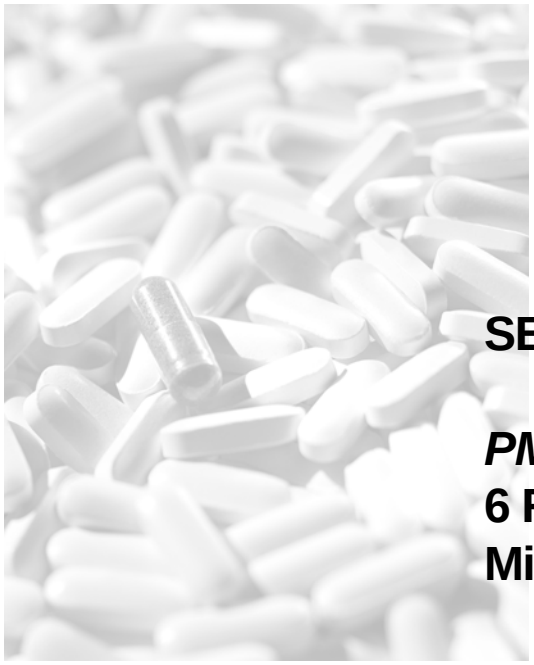
A Snapshot of the Patent Register as of December 31, 2007: Number of Patents Per Medicine on the Patent Register

There are currently 481 different medicines listed on the Patent Register. The total number of different patents listed on the Patent Register is 1092, and they are distributed per medicine as indicated in Figure 2. For example, there are 239 medicines which only have one patent listed against them; on the other hand there is one medicine which has 22 patents listed against it. 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.

The Patent Register is divided according to DIN in a product-specific manner. However, this graph is produced by medicine. This groups some products that have multiple strengths, routes, and dosage forms listed on the Patent Register with others which do not.

Figure 2





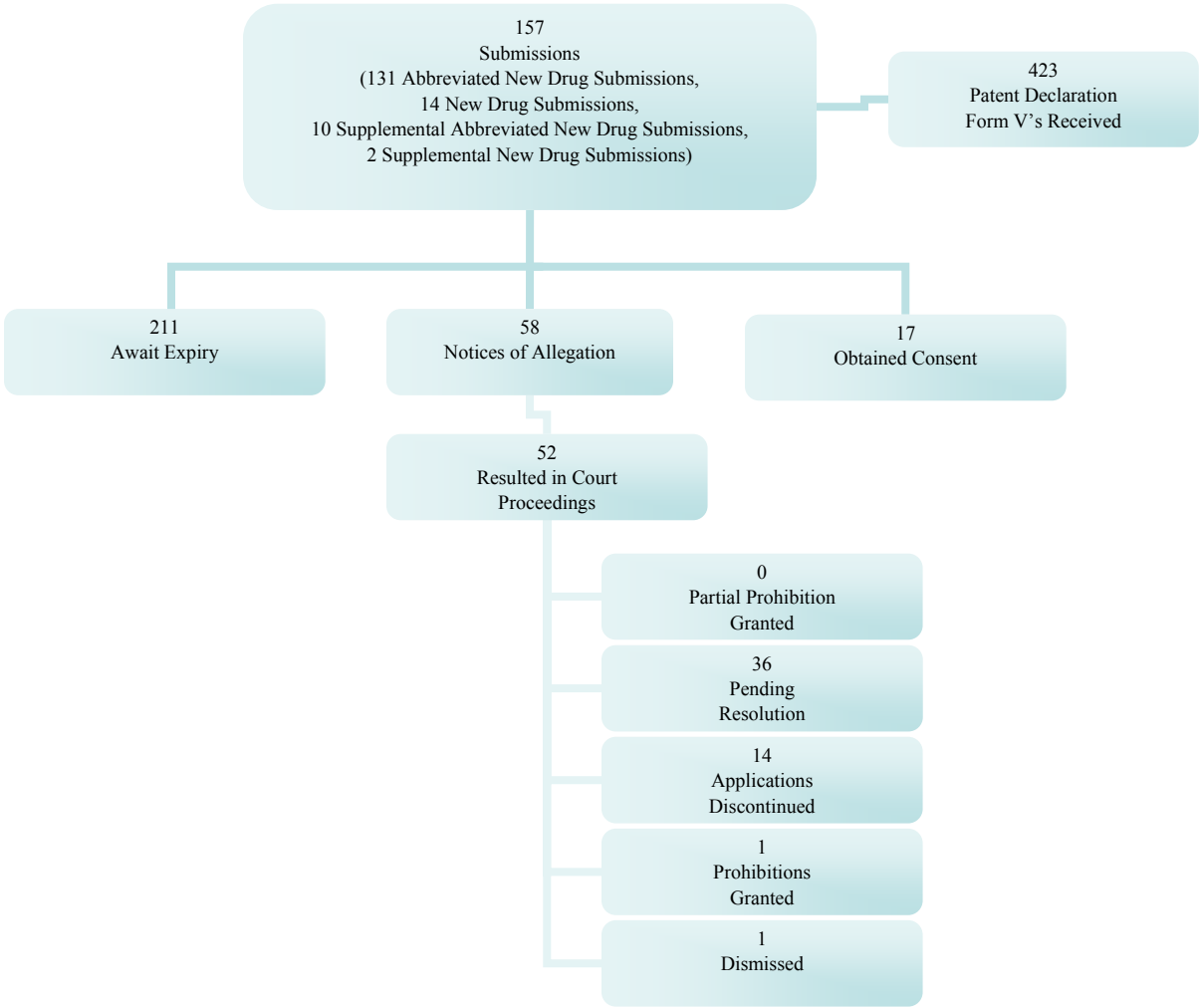
SECTION III

PM(NOC) Regulations Section 5 & 6 Related Information and Miscellaneous Court Cases

Applications under the Patented Medicines (Notice of Compliance) Regulations – 2007

157 Submissions were accompanied by patent declarations, (131 Abbreviated New Drug Submissions, 14 New Drug Submissions, 10 Supplemental Abbreviated New Drugs Submissions and 2 Supplemental New Drug Submissions). These numbers include administrative submissions.

- 157 submissions were accompanied by patent declarations, totaling 423 declarations. (Note: multiple patent declarations can accompany a submission):
  - 195 patent declarations indicated the second person intended to serve a Notice of Allegation (NOA);
  - 211 patent declarations indicated that they would await expiry of the patent;
  - 17 patent declarations indicated consent was obtained of the patent owner to market the drug.

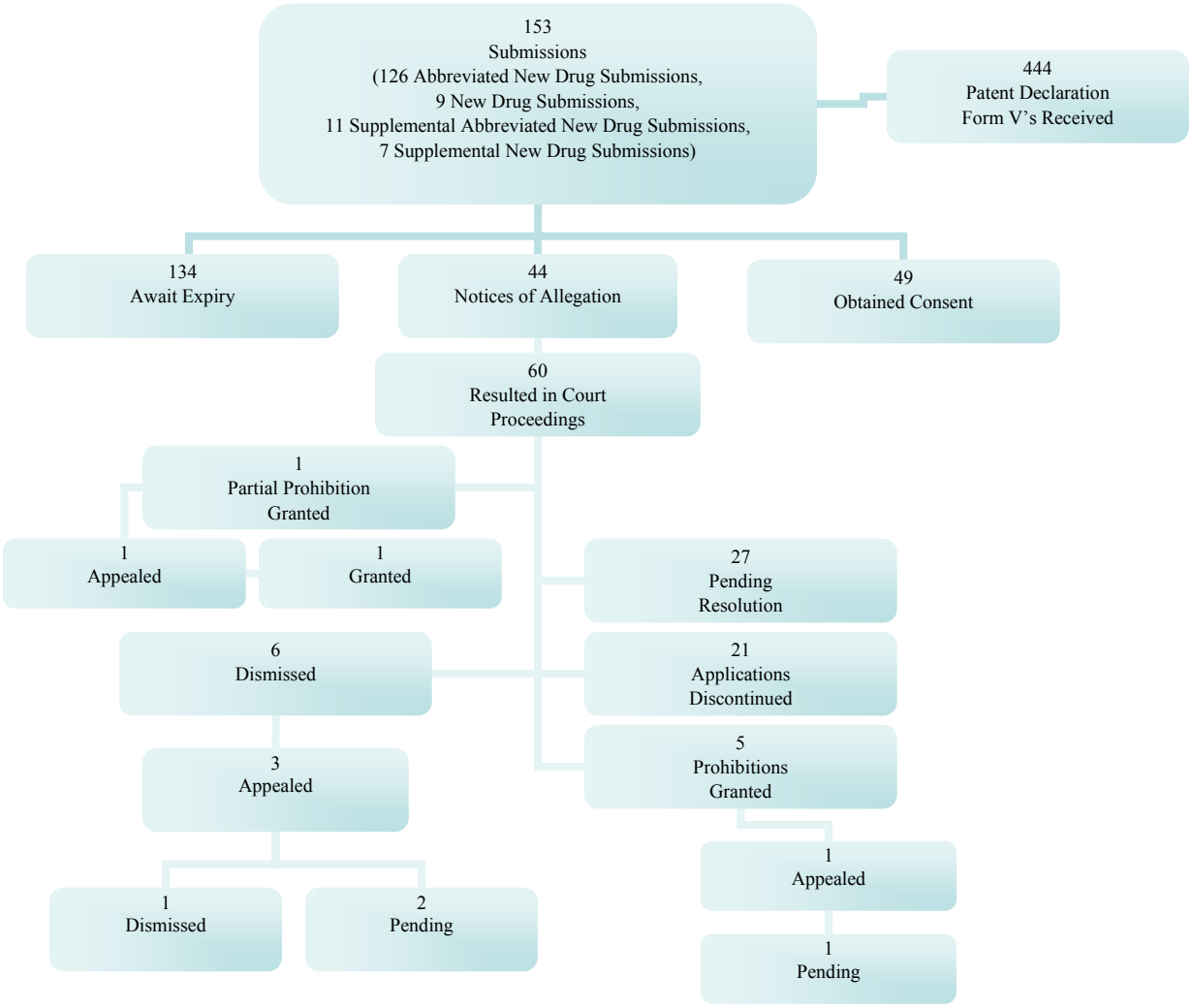


Note: Court applications may be discontinued for a number of reasons, including withdrawal of the Notice of Allegation. Therefore, it should not be assumed that a court application has been withdrawn due to the merits of the case. The 45-day response period after receiving a Notice of Allegation may affect the above numbers at the end of or at the beginning of a calendar year. For example, a Notice of Allegation may be served in November of a year but a court case may not commence until the beginning of the following year.

Applications under the Patented Medicines (Notice of Compliance) Regulations – 2006

153 Submissions were accompanied by patent declarations, (126 Abbreviated New Drug Submissions, 9 New Drug Submissions, 11 Supplemental Abbreviated New Drugs Submissions and 7 Supplemental New Drug Submissions). These numbers include administrative submissions.

- 153 submissions were accompanied by patent declarations, totaling 444 declarations. (Note: multiple patent declarations can accompany a submission):
  - 261 patent declarations indicated the second person intended to serve a Notice of Allegation (NOA);
  - 134 patent declarations indicated that they would await expiry of the patent;
  - 49 patent declarations indicated consent was obtained of the patent owner to market the drug.

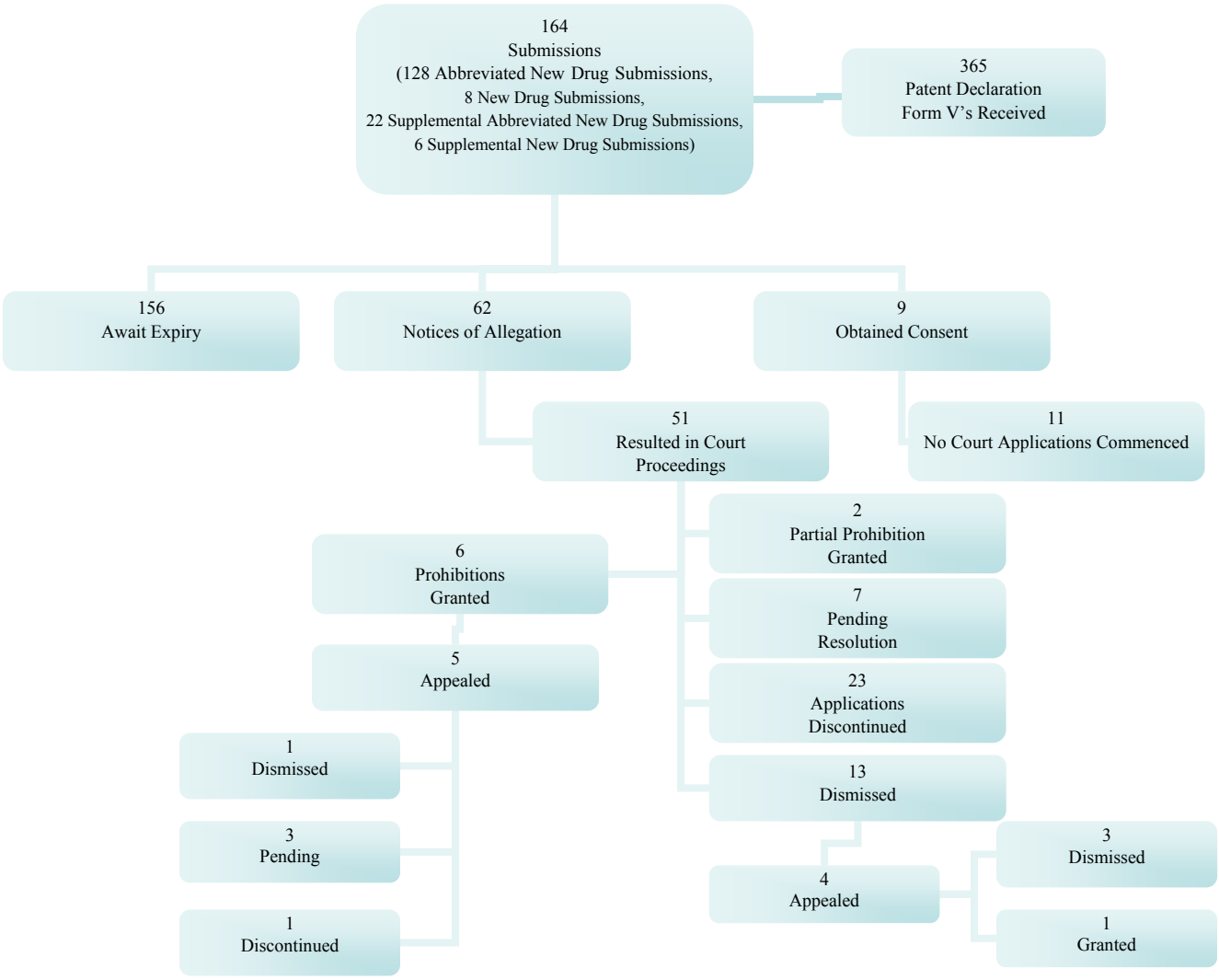


Note: Court applications may be discontinued for a number of reasons, including withdrawal of the Notice of Allegation. Therefore, it should not be assumed that a court application has been withdrawn due to the merits of the case. The 45-day response period after receiving a Notice of Allegation may affect the above numbers at the end of or at the beginning of a calendar year. For example, a Notice of Allegation may be served in November of a year but a court case may not commence until the beginning of the following year.

Applications under the Patented Medicines (Notice of Compliance) Regulations - 2005

164 Submissions were accompanied by patent declarations, (128 Abbreviated New Drug Submissions, 8 New Drug Submissions, 22 Supplemental Abbreviated New Drugs Submissions and 6 Supplemental New Drug Submissions). These numbers include administrative submissions.

- 164 submissions were accompanied by patent declarations, totaling 365 declarations. (Note: multiple patent declarations can accompany a submission):
  - 62 patent declarations indicated the second person intended to serve a Notice of Allegation (NOA);
  - 156 patent declarations indicated that they would await expiry of the patent;
  - 9 patent declarations indicated consent was obtained of the patent owner to market the drug.

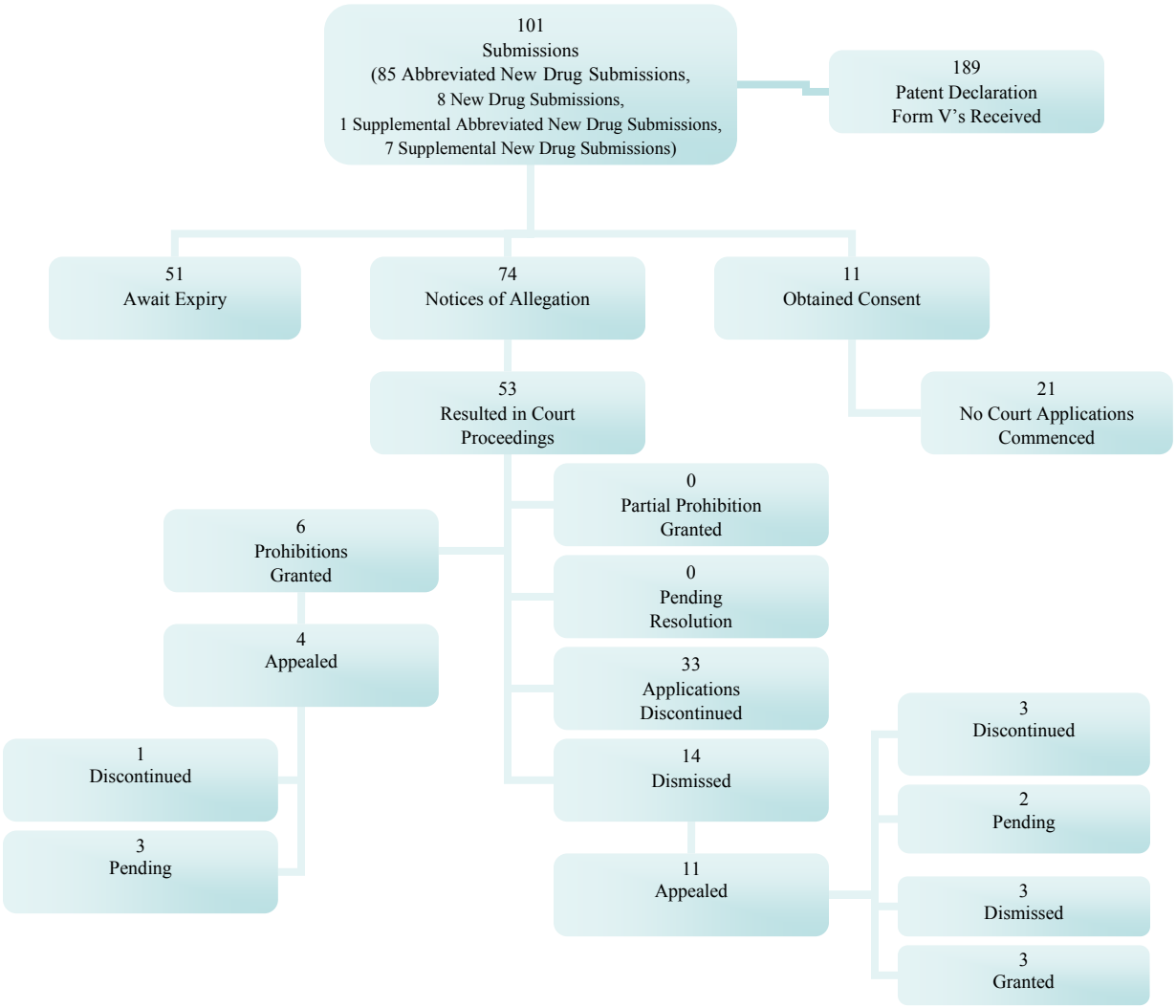


Note: Court applications may be discontinued for a number of reasons, including withdrawal of the Notice of Allegation. Therefore, it should not be assumed that a court application has been withdrawn due to the merits of the case. The 45-day response period after receiving a Notice of Allegation may affect the above numbers at the end of or at the beginning of a calendar year. For example, a Notice of Allegation may be served in November of a year but a court case may not commence until the beginning of the following year.

Applications under the Patented Medicines (Notice of Compliance) Regulations - 2004

101 Submissions were accompanied by patent declarations, (85 Abbreviated New Drug Submissions, 8 New Drug Submissions, 1 Supplemental Abbreviated New Drugs Submissions and 7 Supplemental New Drug Submissions). These numbers include administrative submissions.

- 101 submissions were accompanied by patent declarations, totaling 189 declarations. (Note: multiple patent declarations can accompany a submission):
  - 74 patent declarations indicated the second person intended to serve a Notice of Allegation (NOA);
  - 51 patent declarations indicated that they would await expiry of the patent;
  - 11 patent declarations indicated consent was obtained of the patent owner to market the drug.

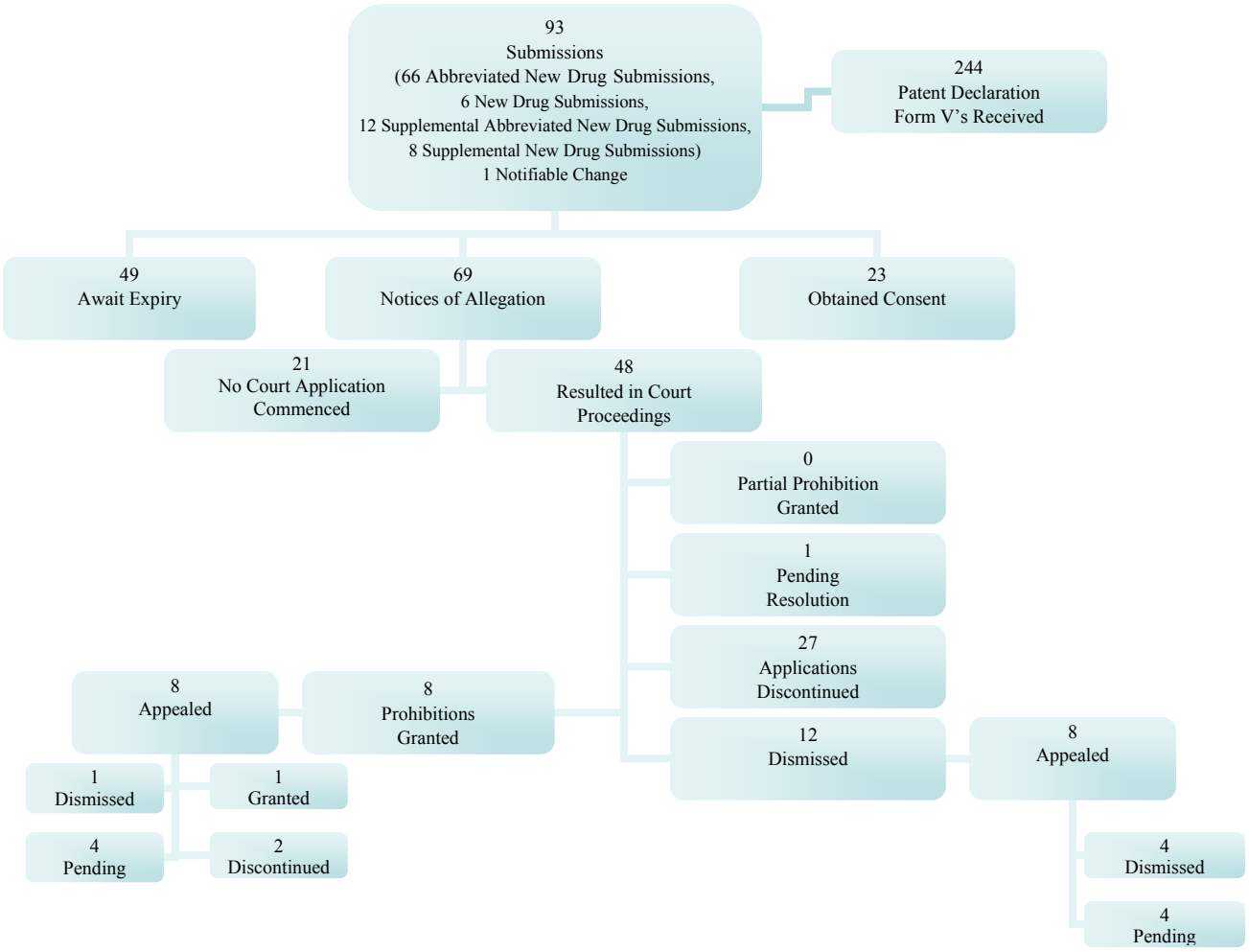


Note: Court applications may be discontinued for a number of reasons, including withdrawal of the Notice of Allegation. Therefore, it should not be assumed that a court application has been withdrawn due to the merits of the case. The 45-day response period after receiving a Notice of Allegation may affect the above numbers at the end of or at the beginning of a calendar year. For example, a Notice of Allegation may be served in November of a year but a court case may not commence until the beginning of the following year.

Applications under the Patented Medicines (Notice of Compliance) Regulations - 2003

93 Submissions were accompanied by patent declarations, (66 Abbreviated New Drug Submissions, 6 New Drug Submissions, 12 Supplemental Abbreviated New Drugs Submissions, 8 Supplemental New Drug Submissions and 1 Notifiable Change). These numbers include administrative submissions.

- 93 submissions were accompanied by patent declarations, totaling 244 declarations. (Note: multiple patent declarations can accompany a submission):
  - 172 patent declarations indicated the second person intended to serve a Notice of Allegation (NOA);
  - 49 patent declarations indicated that they would await expiry of the patent;
  - 23 patent declarations indicated consent was obtained of the patent owner to market the drug.

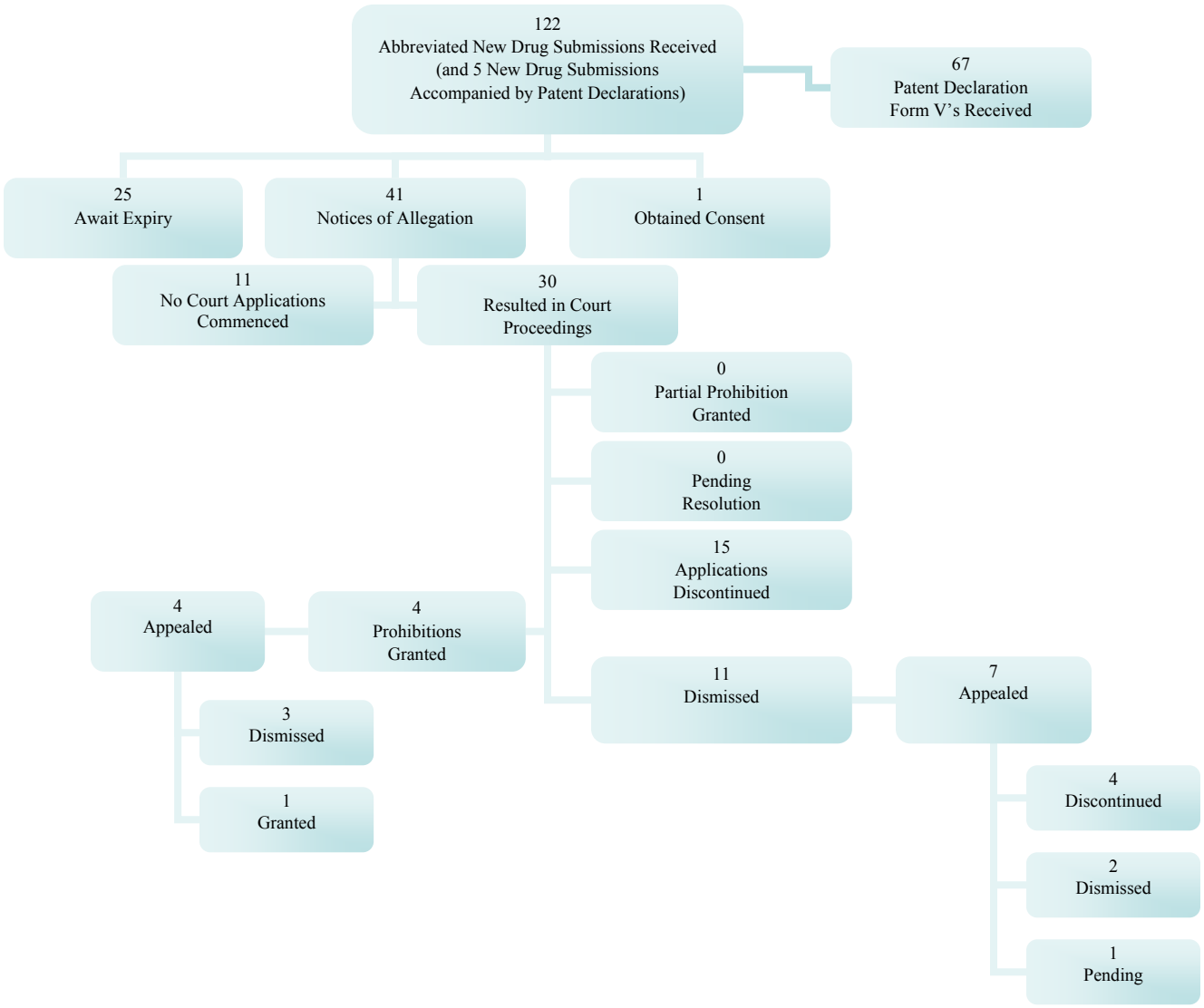


Note: Court applications may be discontinued for a number of reasons, including withdrawal of the Notice of Allegation. Therefore, it should not be assumed that a court application has been withdrawn due to the merits of the case. The 45-day response period after receiving a Notice of Allegation may affect the above numbers at the end of or at the beginning of a calendar year. For example, a Notice of Allegation may be served in November of a year but a court case may not commence until the beginning of the following year.

Applications under the Patented Medicines (Notice of Compliance) Regulations - 2002

67 submissions were accompanied by patent declarations (62 Abbreviated New Drug Submissions, 5 New Drug Submissions)

- 41 patent declarations indicated the 2nd person intended to serve a Notice of Allegation (NOA);
- 25 patent declarations indicated that they would await expiry of the patent;
- 1 patent declaration indicated consent was obtained of the patent owner to market the drug.



Note: Court applications may be discontinued for a number of reasons, including withdrawal of the Notice of Allegation. Therefore, it should not be assumed that a court application has been withdrawn due to the merits of the case. The 45-day response period after receiving a Notice of Allegation may affect the above numbers at the end of or at the beginning of a calendar year. For example, a Notice of Allegation may be served in November of a year but a court case may not commence until the beginning of the following year.

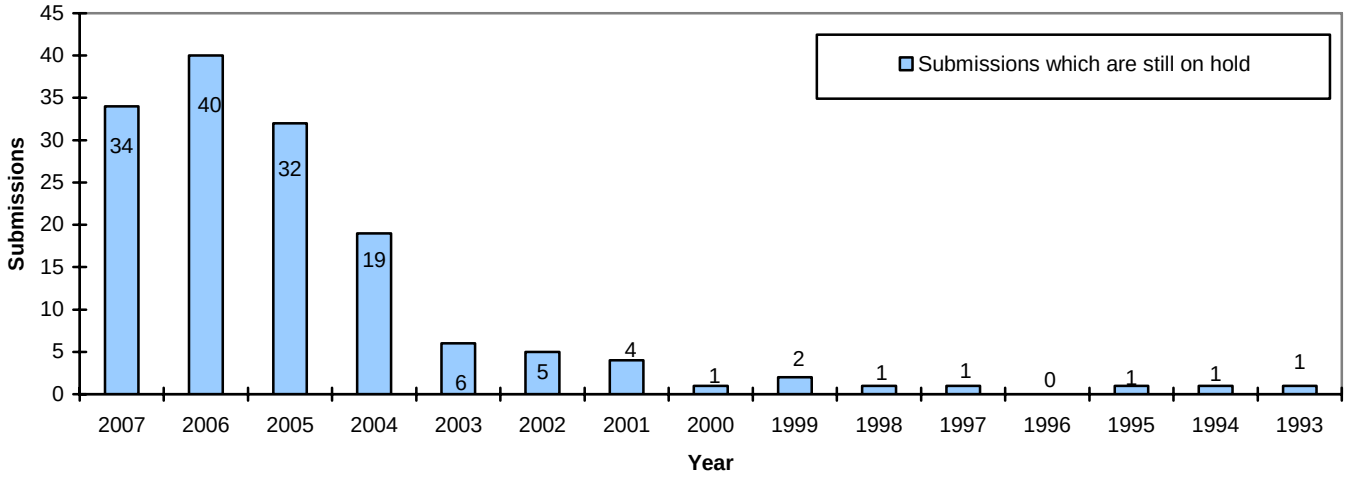
Applications under the Patented Medicines (Notice of Compliance) Regulations - Summary Chart

	2007	2006	2005	2004	2003	2002	2001	2000	1999	1998
Notices of Allegation Received	58	44	62	74	69	41	30	25	42	55
Court Applications Commenced	52	60	51	53	48	30	13	15	27	24
Partial Prohibitions Granted	0	1	2	0	0	0	0	0	0	1
Prohibitions Pending Resolution	36	27	7	0	1	0	0	0	o	0
Prohibitions Discontinued	14	21	23	33	27	15	1	9	12	14
Prohibitions Granted	1	5	6	6	8	4	4	3	4	3
Prohibitions Dismissed	1	6	13	14	12	0	8	3	11	6

Comparison of Average Time on Hold - NOC Issued versus NOC Not Issued

For drug submissions that fall under the *Patented Medicines (Notice of Compliance) Regulations*, time on patent hold for a cleared drug submission is determined by calculating the difference between the date a drug submission is found approvable and the date the drug submission actually receives a Notice of Compliance. This data includes ANDS, NDS, SNDS and SANDS submission types.

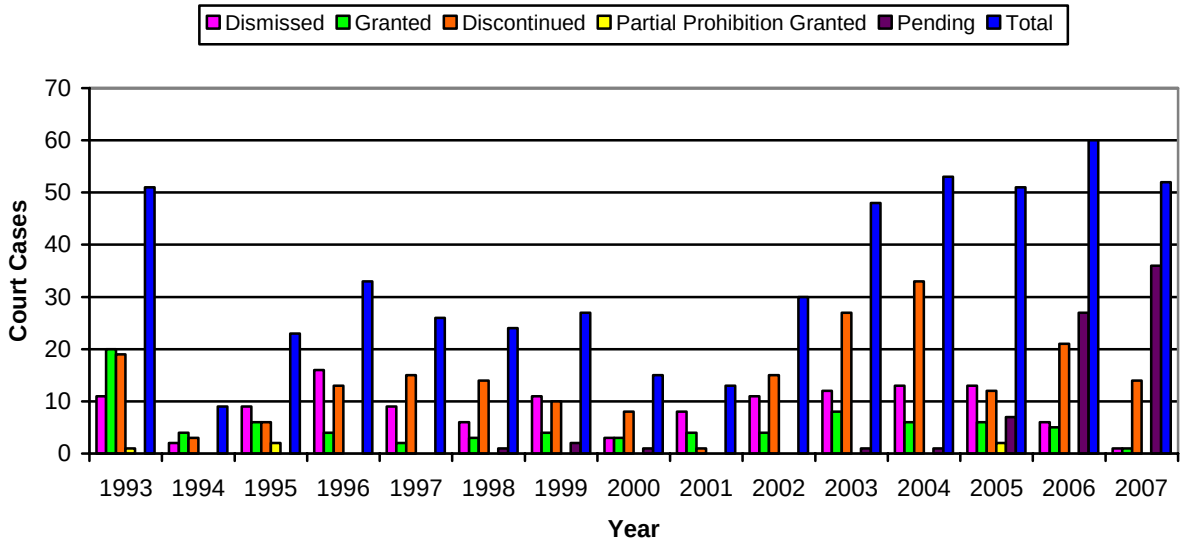
Length of time on hold for drug submissions still on hold is determined by subtracting the date the drug submission was put on hold from the date the report was run.



Year	Submissions which are still on hold	Average number of months before NOC Issued
2007	34	2.3
2006	40	1.7
2005	32	3.7
2004	19	4.9
2003	6	9.1
2002	5	7.3
2001	4	12.9
2000	1	8.3
1999	2	5.4
1998	1	14.6
1997	1	29.8
1996	0	20
1995	1	24
1994	1	21
1993	1	6

(These numbers include those drug submissions which are awaiting the expiry of the patent.)

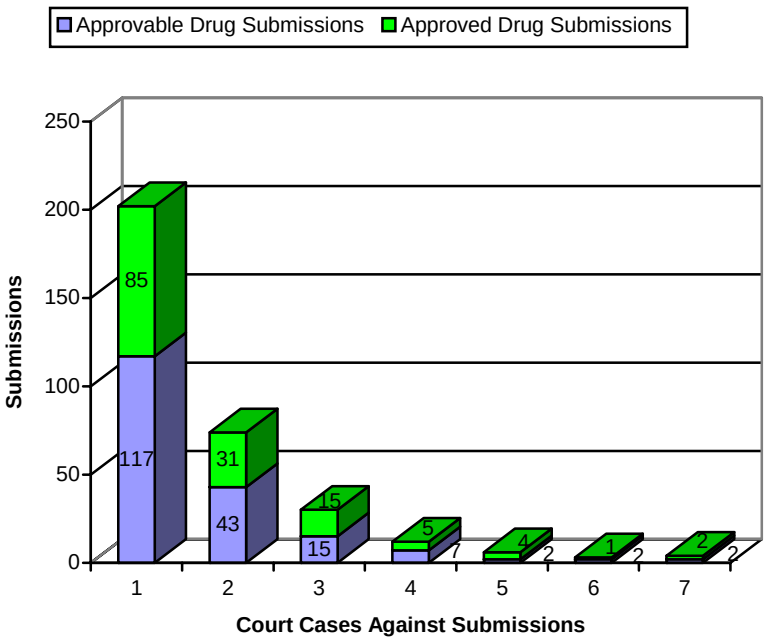
Fate of Prohibition Court Cases - Overview By Year



	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Dismissed	11	2	9	16	9	6	11	3	8	11	12	13	13	6	1
Granted	20	4	6	4	2	3	4	3	4	4	8	6	6	5	1
Discontinued	19	3	6	13	15	14	10	8	1	15	27	33	23	21	14
Partial Prohibition Granted	1	0	2	0	0	0	0	0	0	0	0	0	2	0	0
Pending						1	2	1	0	0	1	1	7	27	36
Total	**51**	**9**	**23**	**33**	**26**	**24**	**27**	**15**	**13**	**30**	**48**	**53**	**51**	**60**	**52**

Total number of Court Applications represented is broken down by the outcome of the Application.

Occurrences of Prohibition Applications in Respect of Second Person Drug Submissions



This graph shows the number of court cases per generic drug submission (for ANDS and NDS 1993- 2007) during the history of the *Patented Medicines (Notice of Compliance) Regulations*. The information is based on individual drug submissions where at least one court case was commenced. It is interesting to note that there are 117 occurrences of single court cases regarding a particular drug submission, but there are two occurrences of seven court cases regarding one particular drug submission. The information covers drug submissions filed between 1993 and December 31, 2007. Please note that court applications may apply to more than one drug submission. Therefore, the above numbers include multiple occurrences of court applications which apply to more than one drug submission. The totals on this page will not match the total of court applications commenced on the charts which follow entitled "Applications under the *Patented Medicines (Notice of Compliance) Regulations* – Summary Chart". The above numbers do not include any court applications which involved veterinary medicines.

Average Time to Resolution of Applications under the *PM (NOC) Regulations*

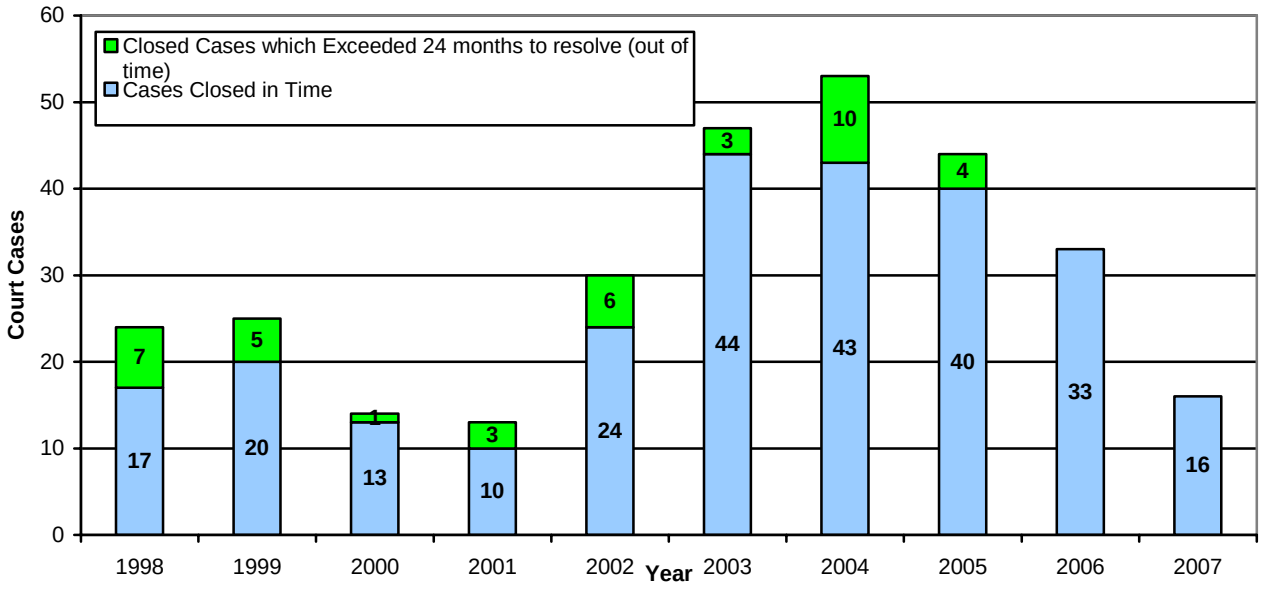
This table represents information regarding applications filed pursuant to Section 6 of the *Patented Medicines (Notice of Compliance) Regulations*, commonly referred to as prohibition applications. The start date of the court case determines the year in which it will be included. Average time to resolution is calculated from the court case start date to the close date of the court case in the Federal Court Trial Division (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. Prior to amendments in 1998, the stay period was 36 months.

Year	Number of cases per year	Number of cases closed	Number of cases which had hearings	Average resolution time[1] (months)	Range[1] (months)
1993	51	51	32	27	7 to 58
1994	10	10	6	26	10 to 66
1995	23	23	17	24	3 to 39
1996	34	34	21	22	8 to 43
1997	26	26	15	15	4 to 31
1998	24	24	11	20.9	.6 – 108
1999	27	25	15	27.9	1.3 – 274
2000	15	14	6	13.8	3.4 – 24.07
2001	13	13	11	21	13 to 24
2002	29	29	14	19.2	1.5 – 38
2003	48	47	17	13.1	.63 – 38
2004	53	53	19	16.54	.1 – 35.4
2005	51	44	21	14.4	1.3 – 26
2006	60	33	12	10.5	1.8 – 23.9
2007	52	16	2	3.4	.6 – 8.6

1. These numbers do not include cases which have been withdrawn by either the Applicant or the Respondent.

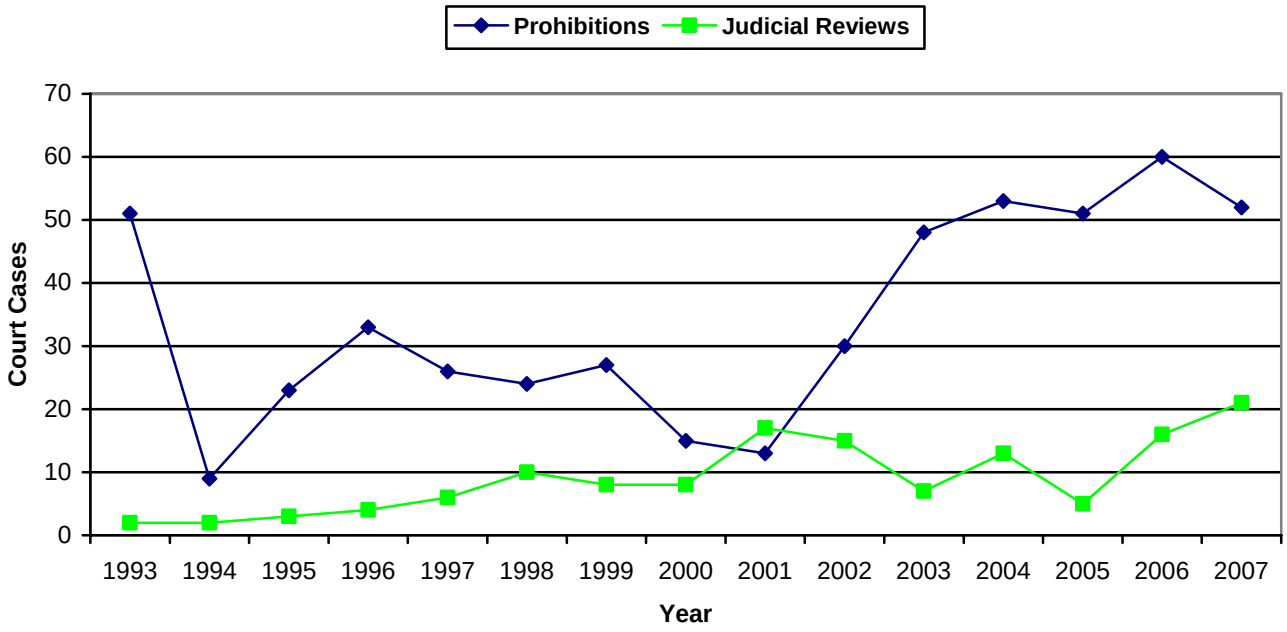
Court Cases which Exceed a 24-Month Resolution Timeframe

This chart represents 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.



Prohibition and Judicial Review Court Cases Initiated Per Year

This graph represents how many prohibition and judicial review cases pertaining to the *Patented Medicines (Notice Of Compliance) Regulations* cases were initiated each year.



	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Prohibitions	51	9	23	33	26	24	27	15	13	30	48	53	51	60	52
Judicial Reviews	2	2	3	4	6	10	8	8	17	15	7	13	5	16	21

Court Cases Concerning Section 5 of the *Patented Medicines (Notice of Compliance) Regulations* and Miscellaneous Cases

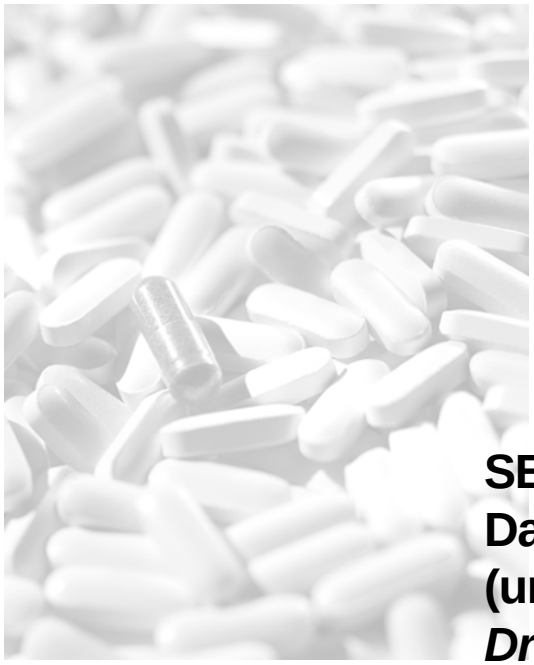
This is a listing of all the judicial review proceedings filed pursuant to Section 5 of the *Patented Medicines (Notice of Compliance) Regulations*.

FC/FCA	File Name	Ingredient	Start Date	Close Date	Summary
T-427-93 (denied) (joined to T-3099-92) A-457-93 (dismissed)	Merck – and – the Attorney General	Enalapril Maleate	1991-09-20	1993-07-16	Is a submission that was 'approvable' before the introduction of the *PM(NOC) Regulations*, but had not received an NOC prior to their introduction, subject to the provisions of the Regulations?
T-2030-96 (dismissed) A-389-97 (dismissed)	Nu-Pharm Inc. – and – the Attorney General of Canada	Drug X and Drug Y	1996-09-03	1997-05-15	Can a generic submission use another previously approved generic drug as a reference product and thus avoid triggering the *PM(NOC) Regulations*?
T-2845-96 (dismissed)	Apotex Inc. – and – the Minister of Health and Janssen et al.	Domperidone	1996-12-23	1998-02-20	Question was whether an existing prohibition extended to prevent Minister from issuing an NOC following a second NOA. Essential similarity of NOAs.
T-2300-97 (dismissed) A-684-99 (granted)	Apotex Inc. – and - the Minister of National Health and Welfare	Ofloxacin	1997-10-24	1999-08-09	To what degree must formulation described in prohibition proceedings coincide with formulation described in drug submission?
T-2552-97 (granted) A-161-99 (dismissed)	Nu-Pharm Inc. – and – the Attorney General and the Minister of Health	Enalapril Maleate	1997-11-25	1998-11-19	Can a generic use another generic as a Canadian reference product and thus avoid triggering section 5 as regards the brand product?
T-429-98 (discontinued)	Apotex Inc. – and – the Minister of National Health and Welfare	Fluconazole	1998-03-17	1998-07-09	Must submission described in NOA coincide with submission approved by Minister?
T-1575-98 (discontinued)	Apotex Inc. – and – the Minister of National Health and Welfare	Nabumetone	1998-08-06	1998-09-15	Mandamus to compel Minister to accept ANDS. Minister took position that an ANDS cross-referenced to another ANDS cannot be accepted for review until the review of the referenced ANDS is complete
T-1574-98 (discontinued)	Apotex Inc. – and – the Minister of National Health and Welfare	Ranitidine	1998-08-06	1999-08-09	Mandamus to compel NOC. Issue is whether the formulation described in the successful prohibition matched the formulation in the submission before Minister.
T-1600-98 (discontinued)	Pfizer Canada Inc. – and – the Minister of Health	Fluconazole	1998-08-07	1998-11-25	Scope of existing prohibition order.

FC/FCA	File Name	Ingredient	Start Date	Close Date	Summary
T-398-99 (granted) A-804-99 (dismissed)	Nu-Pharm Inc. and Merck & Co., Inc. and Merck Frosst Canada & Co. - and - the Minister of Health	Enalapril maleate	1999-03-05	2000-04-20	Seeks order quashing Nu-Pharm's NOC.
T-2074-99 (discontinued)	Apotex Inc. – and - the Minister of Health	Pravastatin	1999-11-20	2000-04-10	Can a generic avoid the *PM(NOC) Regulations* by seeking approval based on a comparison with a foreign reference product?
T-2063-99 (discontinued)	Apotex Inc. – and - the Minister of Health	Paroxetine	1999-11-23	2001-07-19	Does generic have to address patents listed by brand on register subsequent to filing of the generic submission?
T-315-01 (discontinued)	Nu-Pharm Inc. – and - the Attorney General of Canada and the Minister of Health	Enalapril	2001-02-22	2002-06-24	Definition of 'new drug' under Food and Drug Regulations
T-1898-01 (granted) A-697-02 (dismissed) SCC (granted)	Bristol-Myers Squibb Canada Inc. - and - the Attorney General of Canada and Biolyse Pharma Corporation	Paclitaxel	2001-10-23	2002-11-02	Interpretation of section 5(1.1) of the *PM(NOC) Regulations*.
T-2288-01 (discontinued)	Apotex Inc. – and - the Minister of Health and GlaxoSmithKline Inc.	Paroxetine HCl	2001-12-27	2003-12-15	Application for an order that a generic is not required to address a patent listed on the Register.
T-468-02 (discontinued)	Apotex Inc. – and - the Minister of Health	Apo-X	2002-03-18	2002-06-03	Motion to compel Minister to identify which patents Apo-X product must address.
T-644-02 (dismissed) A-570-04 (discontinued)	GlaxoSmithKline Inc. – and - the Attorney General of Canada, the Minister of Health and Apotex Inc.	Salbutamol sulphate	2002-04-19	2004-09-23	Application for an order for Minister's decision to issue NOC to Apotex be quashed.
T-812-02 (dismissed) A-291-04 (dismissed)	Apotex Inc. – and - the Minister of Health and AstraZeneca Canada Inc.	Omeprazole	2002-05-23	2004-04-30	Application for an order that generic is not required to address a patent on the Patent Register.
T-978-02 (dismissed) A-654-01 (dismissed)	Syntex (USA), Hoffmann - La Roche Limited, Allergan Inc. – and - the Minister of Health and Apotex Inc.	Ketorolac Tromethamine	2002-06-28	2002-08-20	Application brought by brand to quash generic NOC. Brand had not started prohibition in response to NOA. Later, claimed allegations in NOA were 'misleading'.
T-869-02 (discontinued)	Apotex Inc. – and - the Minister of Health and Abbott Laboratories Ltd.	Clarithromycin	2002-06-05	2004-12-03	Application for an order that a patent is improperly listed on the Patent Register or that generic is not required to address the patent.
T-2212-03 (discontinued)	Apotex Inc. – and - the Minister of Health	Apo-X	2003-11-25	2004-01-20	Requests the Minister issue NOC.

FC/FCA	File Name	Ingredient	Start Date	Close Date	Summary
T-1122-03 (discontinued)	Procter and Gamble Pharmaceuticals – and - the Minister of Health	Etidronate Disodium	2003-07-03	2005-03-14	Seeking order to quash NOC issued by the Minister to Genpharm.
T-260-04 (dismissed) A-537-04 (dismissed) SCC 30944 (dismissed)	AstraZeneca Canada Inc. - and - the Minister of Health, the Attorney General of Canada and Apotex Inc.	Omeprazole	2004-02-04	2004-09-20	An application for a declaration that Minister erred by not requiring Apotex to address 3 patents.
T-261-04 (dismissed) A-536-04 (granted) SCC 30985 (granted)	AstraZeneca Canada Inc. - and - the Minister of Health, the Attorney General of Canada and Apotex Inc.	Omeprazole	2004-02-04	2004-09-20	If the Canadian reference product is no longer marketed, do the related patents still have to be addressed?
T-262-04 (dismissed) A-535-04 (granted) SCC 30985 (granted)	AstraZeneca Canada Inc. - and - the Minister of Health and the Attorney General of Canada	Omeprazole	2004-02-04	2004-09-20	If the Canadian reference product is no longer marketed, do the related patents still have to be addressed?
T-365-04 (discontinued)	Procter & Gamble Pharmaceuticals Canada Inc. - and - the Minister of Health and Cobalt Pharmaceuticals Inc.	Etidronate Disodium	2004-02-19	2005-03-03	An application for mandamus quashing decision of Minister to issue NOC to generic.
T-1762-04 (discontinued)	Bayer AG, Bayer Healthcare AG and Bayer Inc. - and - Sabex 2002 Inc. and the Minister of Health	Ciprofloxacin	2004-09-28	2004-10-15	Judicial review seeking an Order quashing the notice of compliance issued to generic.
T-586-05 (discontinued)	Aventis Pharma Inc. - and – the Minister of Health, the Attorney General of Canada and Novopharm Inc.	Enoxaparin Sodium	2005-04-01	2006-08-28	Declaration that NOC which was issued is invalid and should be quashed.
T-1438-05 (discontinued)	Apotex Inc. - and - the Minister of Health, the Attorney General of Canada and AstraZeneca	Omeprazole	2005-08-19	2007-05-22	Reissue an NOC.
T-737-06 (ongoing)	Apotex Inc. - and – the Minister of Health and Servier Canada Inc. and Adir	Perindopril	2006-04-27		A judicial review seeking declaration that *PM(NOC) Regulations* do not apply; mandamus to process ANDS without reference to *Regulations* and to prioritize review
T-750-06 (ongoing)	Apotex Inc. - and – the Minister of Health	Desmopressin	2006-05-02		An application for an order of mandamus, compelling Minister to process ANDS for "Product Y" without regard to *PM(NOC) Regulations*.
T-775-06 (dismissed) A-283-07 (ongoing)	Bayer Healthcare AG and Bayer Inc. – and – Sandoz Canada Incorporated and the Minister of Health	Ciprofloxacin	2006-05-05	2007-03-20	An application seeking an order quashing issuance of an NOC.

FC/FCA	File Name	Ingredient	Start Date	Close Date	Summary
T-2188-06 (dismissed) A-163-07 (dismissed)	Sanofi-Aventis Canada Inc. – and – the Minister of Health, the Attorney General of Canada and Novopharm Limited	Ramipril	2006-12-12	2007-03-20	Application seeks an Order quashing decision not requiring Novopharm to address two patents.
T-2189-06 (dismissed) A-162-07 (dismissed)	Sanofi-Aventis Canada Inc. – and – the Minister of Health, the Attorney General of Canada and Apotex Inc.	Ramipril	2006-12-12	2007-03-20	Application seeks an Order quashing decision not requiring Apotex to address two patents
T-2196-06 (dismissed) A-161-07 (dismissed)	Sanofi-Aventis Canada Inc. – and – the Minister of Health, the Attorney General of Canada and Apotex Inc.	Ramipril	2006-12-13	2007-03-20	Application seeks an Order quashing decision not requiring Apotex to address two patents
T-2220-06 (dismissed) A-189-07 (dismissed)	Novopharm Limited – and – the Minister of Health, the Attorney General of Canada	Ramipril	2006-12-15	2007-03-20	An application for judicial review of a decision made by the Minister concerning two patents which, Applicant contends, could not have been the subject of 'early working'.
T-837-07 (ongong)	Pharmascience Inc. – and – The Minister of Health and The Attorney General of Canada	Ramipril	2007-05-14		An application for judicial review of a decision made by the Minister concerning two patents which, Applicant contends, could not have been the subject of 'early working'
T-896-07 (discontinued)	Laboratoire Riva Inc. – and – The Minister of Health and The Attorney General of Canada	Ramipril	2007-05-24	2007-06-28	Application seeks an Order quashing decision not requiring Riva to address two patents.
T-997-07 (discontinued)	Sanofi-Aventis Canada Inc. – and – The Minister of Health, The Attorney General of Canada and Novopharm Limited	Ramipril	2007-06-01	2007-11-14	Application seeks an Order quashing decision not requiring Sanofi-Aventis to address two patents.
T-998-07 (ongoing)	Sanofi-Aventis Canada Inc. – and – The Minister of Health, The Attorney General of Canada and Novopharm Limited	Ramipril	2007-06-01		Application seeks an Order quashing decision not requiring Novopharm to address two patents.
T-2100-07 (ongoing)	Apotex Inc. – and – The Minister of Health	Omeprazole	2007-12-03		A judicial review for an order compeling the Minister to immediately process a submission.



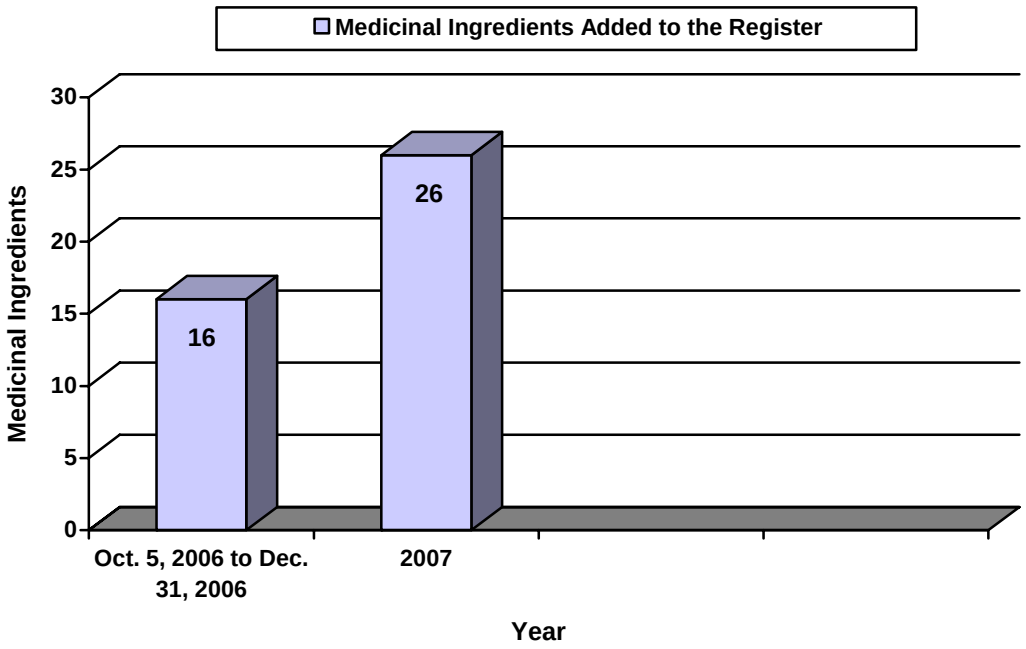
SECTION IV
Data Protection
(under C.08.004.1 of the *Food and Drug Regulations)*

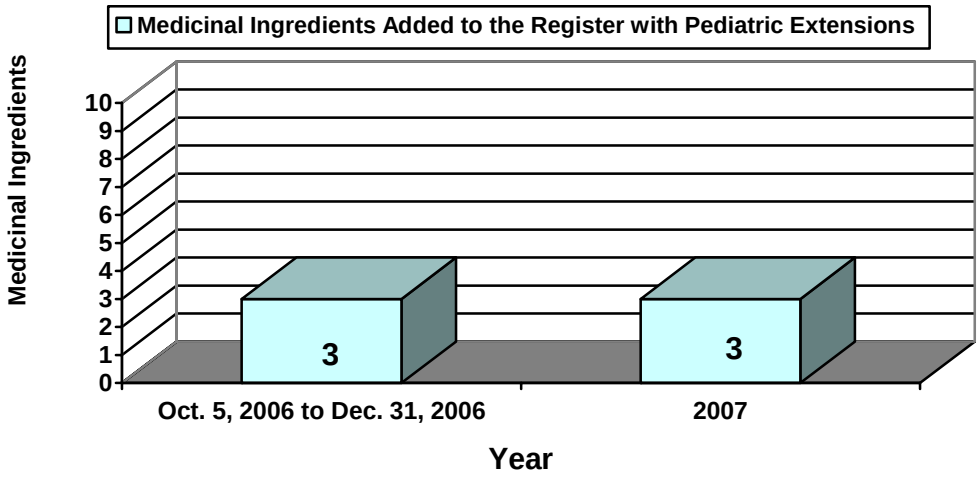
Data Protection (under C.08.004.1 of the *Food and Drug Regulations)*

The objective of this section is to provide information on the administration of the data protection provisions (C.08.004.1) of the *Food and Drug Regulations ("F&D Regulations")* as amended by S.O.R./2006-241 which came into force on October 5, 2006. The provisions were introduced through amendments published in Canada Gazette, Part II on October 18, 2006 with the objective of ensuring that innovative drugs receive a guaranteed minimum period of data protection of eight years where the drug contains a new chemical entity. The intent of this protection is to enable the innovator of the data to protect the investments made in the development of the product by allowing a period of market exclusivity. Innovative drugs are protected for a period of eight years. In the first six years, a subsequent manufacturer is prevented from filing its submission seeking to make a copy of the innovative drug. An extension of six months to the eight-year data protection term is possible if the innovator submits the design and results of clinical trials relating to the use of the drug in relevant pediatric populations. Such a submission must be made within five years after the issuance of the first Notice of Compliance.

Register of Innovative Drugs

A Register of Innovative Drugs has been maintained in accordance with the *F&D Regulations*. Innovative drugs are added to the Register after the issuance of the Notice of Compliance.





Register of Innovative Drugs – Product Type

Product Type	2006	2007
Biologic	5	3
Prescription Pharmaceutical	10	20
Radiopharmaceutical	1	0
Veterinary	0	3

APPENDIX A

Acronyms

Acronyms

SUBMISSION TYPES

ANDS	-	Abbreviated New Drug Submission
DINA	-	Drug Identification Number Application
DIND	-	Drug Identification Number Disinfectants
DINF	-	Drug Identification Number (Category IV)
DINH	-	Drug Identification Number Homeopathics
INDS	-	Investigation New Drug Submission
CTA	-	Clinical Trial Application
CTA-A	-	Clinical Trial Application -Amendment
NDS	-	New Drug Submission
NC	-	Notifiable Change - New Drug
SANDS*	-	Supplement to an Abbreviated New Drug Submission
SNDS	-	Supplement to a New Drug Submission

CLASS

Admin	-	Administrative
Comp/C&M	-	Comparative Bio., Clinical, or Pharmacodynamic/ Chemistry & Manufacturing
C&M/Labelling	-	Chemistry & Manufacturing/ Labelling
Clin/C&M	-	Clinical/Chemistry & Manufacturing
Clin Only	-	Clinical Only
Labelling Only	-	Labelling Only
NAS	-	New Active Substance
Priority -NAS	-	Priority (New Active Substance)
Priority - Clin/C&M	-	Priority-Clinical/Chemistry & Manufacturing
Priority - Clin Only	-	Priority-Clinical Only
Priority - C&M/Labelling	-	Priority-Chemistry & Manufacturing/Labelling
Priority - Comp/C&M	-	Priority-Comparative Bio., Clinical, or Pharmacodynamic/ Chemistry & Manufacturing
Priority-Rx to OTC-No New	-	Priority -Rx to Over the Counter - No New Indication
Rx to OTC-New	-	Rx to Over the Counter - New Indication
Rx to OTC-No New	-	Rx to Over the Counter - No New Indication

DOCUMENTS

DIN	-	Drug Identification Number
NOC	-	Notice of Compliance
NOC - Conditional	-	Notice of Compliance with Conditions
Issuable NOC (Patent)	-	NOC on Hold due to Patent Regulations
Issuable NOC (Rx-OTC)	-	NOC on Hold due to De-Scheduling
NON	-	Notice of Non-Compliance
NOD	-	Notice of Deficiency
NON Withdrawal	-	Notice of Non-Compliance Withdrawal Letter
NOD Withdrawal	-	Notice of Deficiency Withdrawal Letter

APPENDIX B

Definitions

Definitions

Allegation:
Pursuant to paragraph 5(1)(b) of the *Patented Medicines (Notice of Compliance) Regulations*, a claim made by a second person which sets out the nature of a challenge to a patent held by a first person (for example, the patent has expired, the patent is not valid, or the second person's product will not infringe the patent).

Amendments to patent lists:
Pursuant to subsections 4(4) and 4(5) of the *Patented Medicines (Notice of Compliance) Regulations*, the addition or deletion of patents to an existing list.

Amendments to patent status:
These could include court decisions on validity, patent lapse, dedications etc.

Claim for the use of the medicine:
A claim for the use of the medicine for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof.

Claim for the medicine itself:
A claim in the patent for the medicine itself when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents.

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

FC:
Federal Court

FCA:
Federal Court of Appeal

Drug:
Includes any substance or mixture of substances manufactured, sold or represented for use in: a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals; b) restoring, correcting or modifying organic functions in human beings or animals; or c) disinfection in premises in which food is manufactured, prepared or kept. (Refer to section 2 of the *Food and Drug Act*).

Expire:
In relation to a patent: expiry, lapse or termination by operation of law.

Filing Date of Patent:
The Canadian filing date of a Canadian patent application.

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

Medicine:
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.

Minister:
The Minister of Health Canada.

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

Original Patent List:
The first Patent List created for a specific product. In other words, no patents have previously been submitted for listing against the specific product.

Patent:
A granted Canadian patent (not to include a patent application).

Patent Register:
The register maintained by the Minister under section 3 of the *Patented Medicines (Notice of Compliance) Regulations*.

Patent List:
A list of all patents that is submitted pursuant to section 4 of the *Patented Medicines (Notice of Compliance) Regulations*.

Proof of Service:
Proof that the Notice of Allegation was served on the first person; must include a receipt from the courier or registered mail or an affidavit if served by hand.

Second Person:
The person referred to in subsection 5(1) of the *Patented Medicines (Notice of Compliance) Regulations*, typically a generic drug manufacturer.

Submission:
A request for a notice of compliance under section C.08.002, C.08.002.1, or C.08.003 for a drug product as defined in Section C.08.001 of the *Food and Drug Regulations*. Therefore, a submission includes a new drug submission (NDS), abbreviated new drug submission (ANDS), supplemental new drug submission (SNDS), and supplemental abbreviated new drug submission (SANDS).

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).

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

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

Appeal Withdrawn:
An appeal is the application for judicial review by a superior court of an inferior court's decision. The withdrawal of an appeal removes the application from the court, the judicial process ceases to operate and the issue is removed from the consideration of the court. At that point, the decision of the lower court is final.

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

Pending:
The case is awaiting judgment.

Notice of Allegation (NOA):
A notice issued under section 5(1) or 5(1.1) 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.

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) or Biologics and Genetic Therapies Directorate (BGTD) 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. For drugs where there is minimal market history in Canada, there is a more stringent review and the drug is required to have a Notice of Compliance and a DIN in order to be marketed in Canada.

Patent Form V - Declaration Form:
Where a person files or has filed a submission for a notice of compliance in respect of a drug and compares that drug with, or makes reference to, another drug for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics and that other drug has been marketed in Canada pursuant to a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the person shall, in the submission, with respect to each patent on the register in respect of the other drug:

(a) state that the person accepts that the notice of compliance will not issue until the patent expires; or

(b) allege that (i) the statement made by the first person pursuant to paragraph 4(2)(c) of the *Patented Medicines (Notice of Compliance) Regulations* is false, (ii) the patent has expired, (iii) the patent is not valid, or (iv) no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by that person of the drug for which the submission for the notice of compliance is filed. (Refer to the *Patented Medicines (Notice of Compliance) Regulations* for further information.

Patent Hold:
For submissions subject to the provisions of the *Patented Medicines (Notice of Compliance) Regulations*, Health Canada will ensure that all relevant patents have been satisfactorily addressed through the filing of a Form V - Declaration Re: Patent List. Such submissions will not be transmitted to the relevant review Bureau/Centre until such time as all the required Form V documentation has been provided. A CR date will only be assigned when all Form V requirements are met.

When, upon completion of the review of a submission, an NOC would be issuable but for the provisions of the *Patented Medicines (Notice of Compliance) Regulations,* the sponsor will be so notified. The sponsor will also be notified of the date that the submission would have been eligible to receive an NOC but for the provisions of the *Patented Medicines (Notice of Compliance) Regulations*. In these circumstances, an NOC will not be issued until all matters under the *Patented Medicines (Notice of Compliance) Regulations* have been resolved. Until this time, the submission will be placed on "Patent Hold".

Right of Action:
A first person may, within 45 days after being served with a notice of an allegation pursuant to paragraph 5(3)(b) or (c), apply to a court for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of a patent that is the subject of the allegation.

Central Registry (CR) Date:
The date upon which a submission is initially received.