Health Canada Santé Canada

Therapeutic Products Directorate

Statistical Report 2002

Patented Medicines (Notice of Compliance) Regulations

by the Office of Patented Medicines and Liaison

Canada

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SECTION 1

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* are written by Industry Canada under the *Patent Act*, and were declared in force in March 1993. 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.

The stated objective of the *PM(NOC) Regulations* is to prohibit the Minister of Health from granting a marketing approval (a Notice of Compliance) for a drug, that relies upon the earlier approval of a related drug until all the relevant product and use patents pertaining to the earlier approved medicine have expired.

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. The electronic copy 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 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 II 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.

Further information on the administration of the *PM(NOC) Regulations* can be found in the *Guidance for Industry* on the *Patented Medicines (Notice Of Compliance) Regulations*, effective May 10th, 2000 or by contacting, through email, Patent_Register@hc-sc.gc.ca.

SECTION II

Statistics: Patent Register
(Section 4 Related Information)

Number of Patents Submitted for Listing on the Patent Register

Year	Number of patents added to the Patent Register[1]	Number of patents rejected[2]
2002	197	48
2001	204	123

Explanation of statistics:

1) Number of patents added to the Patent Register:
This information is generated from the electronic Patent Register database. This statistic is the total number of patents added to the Patent Register in a given 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.

2) Number of patents rejected:
This information is generated from outgoing correspondence from the Office of Patented Medicines and Liaison for the years 2001 and 2002. Rejections included irrelevant patents, 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 timing requirements set out in the *PM(NOC) Regulations*. The rejection of a patent for a particular drug submission does not mean that the patent might not be on the Patent Register for another drug submission for which it was previously eligible.

Patents Rejected for Listing: Breakdown

2002	**2001**
28 - no claim to the medicine 6 - devices, eg. patches, inhalers 5 - submissions for company or product name changes 6 - timeline related, i.e. does not meet 4(3) or 4(4) 1 - complaint 0 - intermediates 0 - patent not yet granted 2 - process patents	23 - no claim to the medicine 19 - devices, eg. patches, inhalers 49 - submissions for company or product name changes 22 - timeline related, i.e. does not meet 4(3) or 4(4) 1 - complaint 1 - intermediate 2 - patent not yet granted 6 - process patents
Total: 48	Total: 123

Note: The “no claim to the medicine” category includes irrevelant formulations, dosage forms, dual actives etc. Due to recent jurisprudence, Health Canada no longer rejects formulation patents on the basis of lack of relevance.

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*.

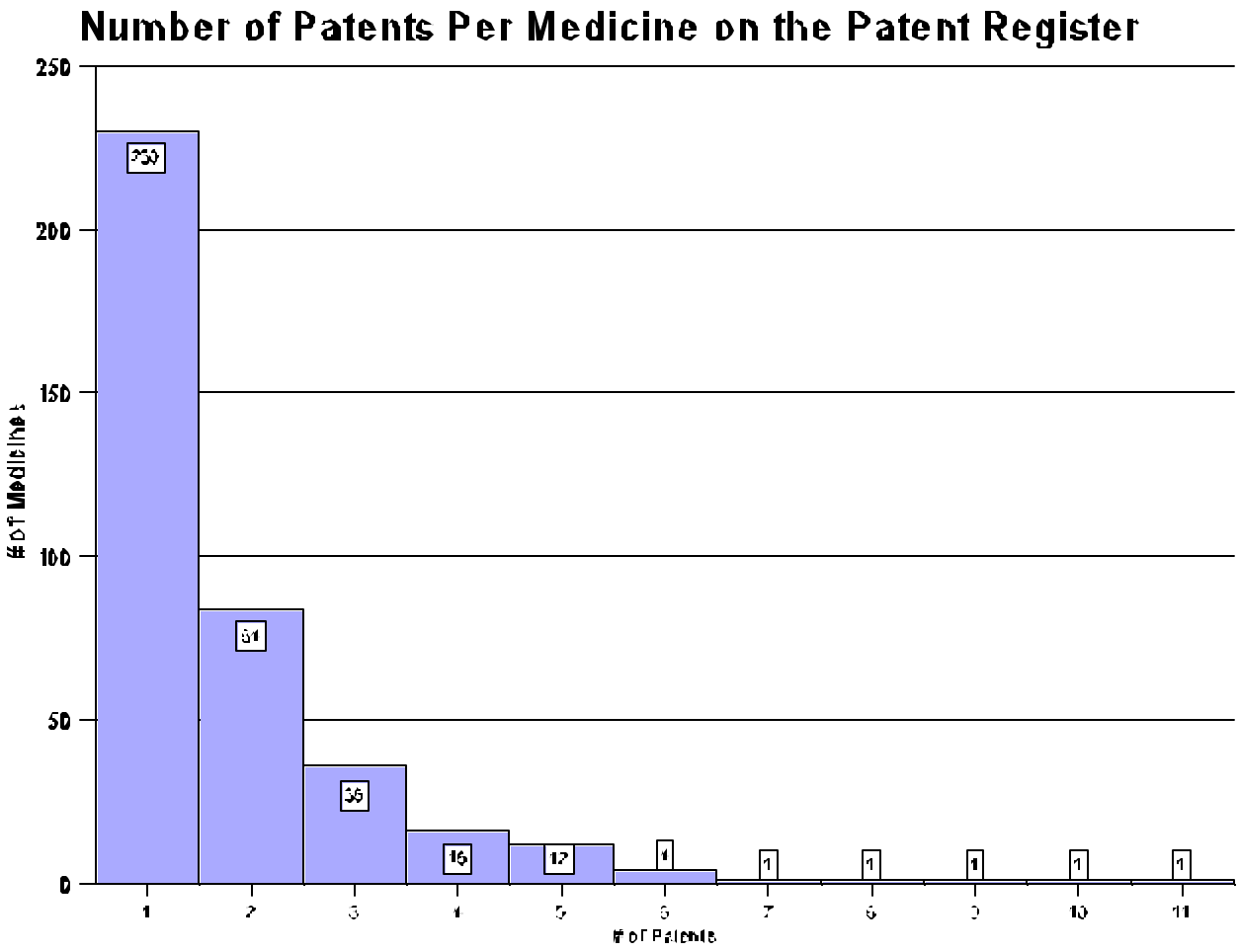
FCTD/FCA	File Name	Ingredient	Start Date	Close Date	Summary
T-304-96 (dismissed)	Merck Frosst v. Minister of Health and Apotex & Novopharm	Simvastatin	1996-02-07	1997-06-13	Jurisdiction of the Minister to remove process patents.
T-306-96 (dismissed) A-168-96 (dismissed)	Merck Frosst v. Minister of Health and 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 v. Minister of Health and 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 v. 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 v. 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 *Patented Medicines (Notice Of Compliance) Regulations*.
T-1891-98 (dismissed)	Zenith Goldline Pharmaceuticals v. 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. v. 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 v. 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. v. 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. v. 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.

FCTD/FCA	File Name	Ingredient	Start Date	Close Date	Summary
T-50-00 (discontinued)	Glaxo v. Minister of Health	Zanamivir	2000-01-13	2000-05-30	The patent is for a device (blister pack/invalid) designed for the delivery of, among other medicines, Zanamivir.
T-994-00 (dismissed)	Warner-Lambert Canada Inc. v. Minister of Health	Quinapril HCl and Quinapril HCl/ hydrochlorothiazid	2000-06-09	2001-04-24	The patent claims a formulation containing Quinapril; however, the formulation has not received a NOC.
T-1212-00 (dismissed) A-64-02 (granted)	Eli Lilly v. Minister of Health	Ceftazidime	2000-07-10	2002-01-10	The patent claims a formulation which has not received a NOC.
T-1524-00 (granted) A-142-03 (ongoing)	Ferring Inc. v. Attorney General, Minister of Health and Apotex Inc.	Desmopressin Acetate	2000-08-17	2002-03-11	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 a NOC for Apo-desmopressin nasal spray.
T-1768-00 (dismissed) A-44-01 (dismissed)	Bristol-Myers Squibb v. 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)	Ferring Inc. v. Minister of Health and Apotex Inc.	Desmopressin Acetate	2000-09-21	2003-03-11	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. v. 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 (ongoing)	Janssen-Ortho Inc. v. Minister of Health	Fentanyl	2000-11-24	2003-03-07	The patent contains claims for patch for administering Fentanyl.
T-193-01 (dismissed)	Novartis v . 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 v. Minister of Health	Estradiol-17-B	2001-02-02	2002-04-02	The patent contains claims for patch for administering Fentanyl.
T-192-01 (ongoing)	Eli Lilly v. Minister of Health	Ceftazidime	2001-02-02		The patent claims a different salt.
T-655-01 (ongoing)	RhoxalPharma Inc. v. Minister of Health and AstraZeneca Canada Inc.	Omeprazole/ Omeprazole Magnesium	2001-04-17		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 - 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?

FCTD/FCA	File Name	Ingredient	Start Date	Close Date	Summary
T-1104-01 (dismissed) A-445-02 (dismissed)	Schering Canada Inc. - and - 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 - 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 (ongoing)	Eli Lilly Canada Inc. - and - The Attorney General of Canada	Sodium monensin	2001-07-20		Patent did not contain a claim to the medicine itself, or the use of the medicine as required under para 4(2)(b) of the *Patented Medicines (Notice Of Compliance) Regulations*.
T-1950-01 (ongoing)	Novartis Pharmaceuticals Canada Inc. -and - The Attorney-General of Canada	Estradiol 17-B	2001-10-30		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 - 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 - 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 - Attorney General of Canada and 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 *Patented Medicines (Notice Of Compliance) Regulations* with respect to supplemental new drug submissions.
T-625-02 (ongoing)	GlaxoSmithKline Inc. v. Attorney General of Canada and The Minister of Health	Lamotrigine	2002-04-18		Formulation patent not eligible for listing on the Patent Register.
T-644-02 (ongoing)	GlaxoSmithKline Inc. v. Attorney General of Canada, Minister of Health and Apotex Inc.	Salbutamol sulphate	2002-04-19		Formulation patent not eligible for listing on the Patent Register.
T-812-02 (ongoing)	Apotex Inc. v. the Minister of Health and AstraZeneca Canada Inc.	Omeprazole	2002-05-23		Minister directed 2nd person to address relevant patent listed on Patent Register. 2nd person alleges that patent is improperly listed and that the product has never been marketed in Canada

FCTD/FCA	File Name	Ingredient	Start Date	Close Date	Summary
T-869-02 (ongoing)	Apotex Inc. v. The Minister of Health and Abbott Laboratories Ltd.	Clarithromycin	2002-06-05		2nd person alleges patent was improperly listed on the Patent Register.

A Snapshot of the Patent Register as of April 1, 2003

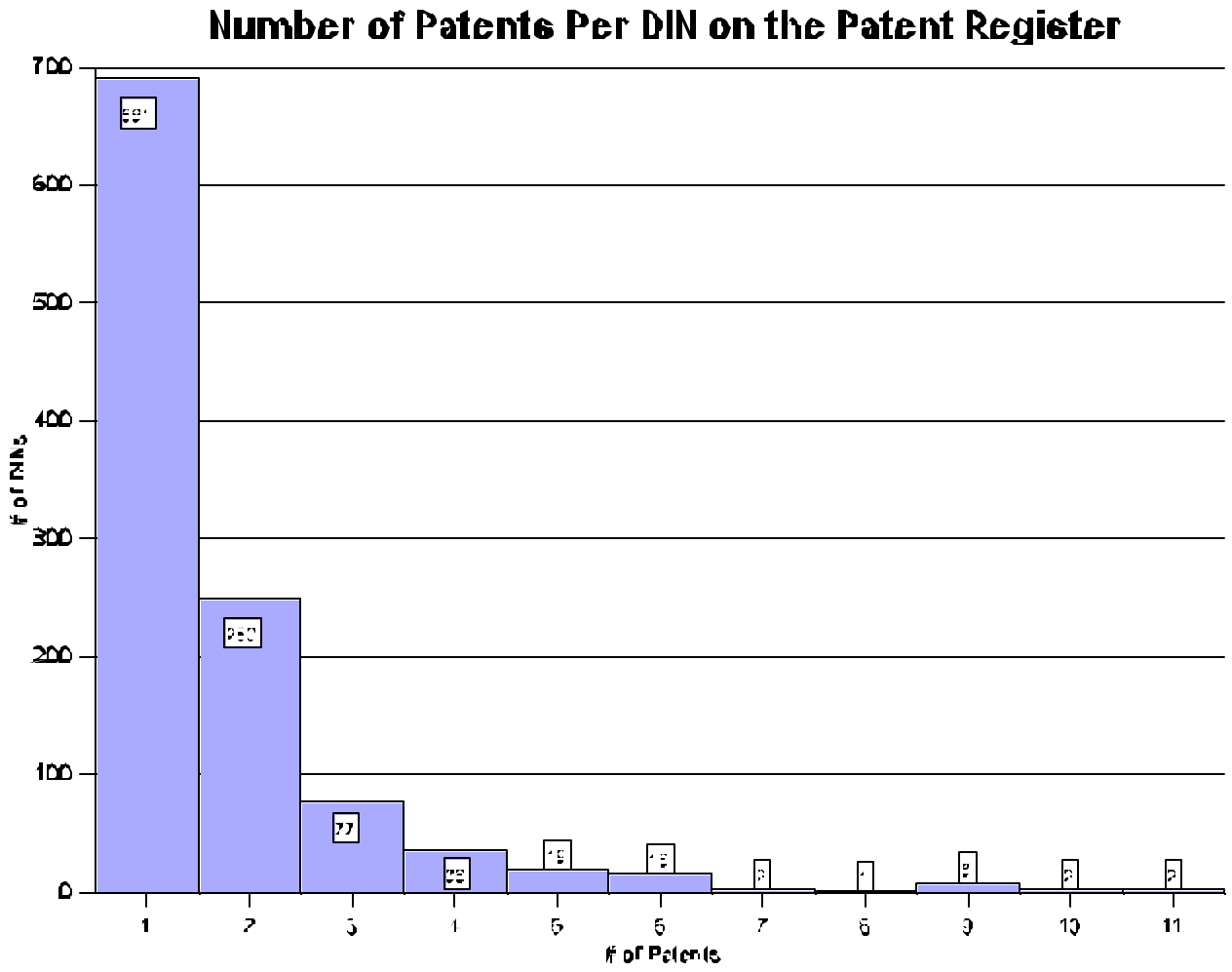


There are presently 390 different medicines listed on the Patent Register. The total number of different patents listed on the Patent Register is 705, and they are distributed per medicine as indicated above. For example, there are 230 medicines which only have one patent listed against them, on the other hand there is 1 medicine which has 11 patents listed against it. The numbers in the above graph do not include patents which have been removed from the Patent Register nor does it 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 takes into account that some products have multiple strength, route, and dosage forms listed on the Patent Register, while others do not.

On the following page is another version of this graph, which is product-specific.

A Snapshot of the Patent Register as of April 1, 2003



As previously stated, there are presently 390 different medicines listed on the Patent Register. The total number of patents listed on the Patent Register is 705, and they are distributed per Drug Identification Number (DIN) as indicated above. For example, there are 691 DINs which only have one patent listed against them, on the other hand there are 2 DINs which have 11 patents listed against it. 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 does it include patents which have expired prior to the generation of this report.

SECTION III

Section 5 & 6 Related Information and Miscellaneous Court Cases

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*.

FCTD	File Name	Ingredient	Start Date	Close Date	Summary
T-427-93 (denied) (joined with T-3099-92) A-457-93 (dismissed)	Merck v Attorney General	Enalapril Maleate	1991-09-20	1993-07-16	Is a submission that was "approvable" before the introduction of the *Patented Medicines (Notice Of Compliance) Regulations*, but had not received a NOC prior to their introduction, subject to the provisions of the *Regulations*?
T-2030-96 (dismissed) A-389-97 (dismissed)	Nu-Pharm Inc. v 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 *Patented Medicines (Notice Of Compliance) Regulations*?
T-2845-96 (dismissed)	Apotex Inc. v 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. v 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. v Attorney General and Minister of Health	Enalapril Maleate	1997-11-25	1998-11-19	Can a generic use another generic as a CRP and thus avoid triggering section 5 as regards the brand product.
T-429-98 (discontinued)	Apotex Inc. v Minister of National Health and Welfare	Fluconazole	1998-03-17	1998-07-09	Must submission described in NOA must coincide with submission approved by Minister?
T-1575-98 (discontinued)	Apotex Inc. v Minister of National Health and Welfare	Nabumetone	1998-08-06	1998-09-15	Mandamus to compel Minister to accept ANDS. Minister took position that a ANDS cross-referenced to another ANDS cannot be accepted for review until the review of the referenced ANDS is complete.

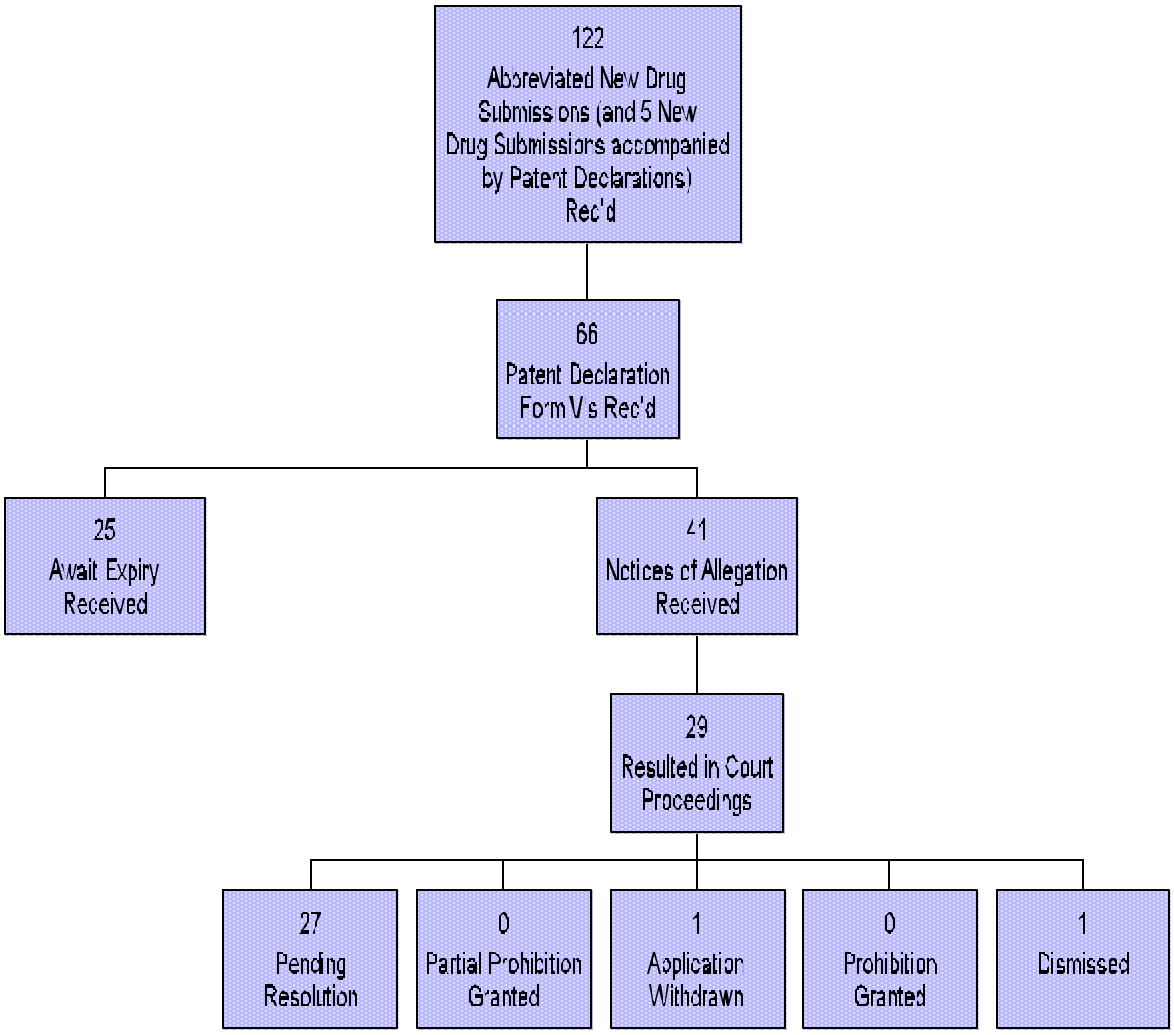
FCTD	File Name	Ingredient	Start Date	Close Date	Summary
T-1574-98 (discontinued)	Apotex Inc. v Minister of National Health and Welfare	Ranitidine	1998-08-06	1999-08-09	Mandamus to compel NOC. Issue is whether the formulation described in the successful prohibition matched the formulation in the submission before Minister.
T-1600-98 (discontinued)	Pfizer Canada Inc. v Minister of Health	Fluconazole	1998-08-07	1998-11-25	Scope of existing prohibition order
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. v the Minister of Health	Pravastatin	1999-11-20	2000-04-10	Can a generic avoid the *Patented Medicines (Notice Of Compliance) Regulations* by seeking approval based on a comparison with a foreign reference product?
T-2063-99 (discontinued)	Apotex Inc. v 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. v 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-493-01 (discontinued)	Apotex Inc. - and - the Attorney General of Canada and the Minister of Health	Apo-X	2001-03-19	2001-09-24	Use of a reference product other than the innovator's product marketed in Canada.
T-838-01 (dismissed)	Bristol-Myers Squibb Canada Inc., GlaxoSmithKline Pharma Inc., Eli Lilly Canada Inc., Merck Frosst Canada & Co. and Pfizer Canada Inc. - and - Apotex	Apo-X	2001-05-17	2003-01-06	Minister deemed submission an ANDS; therefore required a Canadian Reference Product. Applicants sought proof that Apotex was in compliance with Section 5 of *Patented Medicines (Notice Of Compliance) Regulations*.
T-1167-01 (dismissed) A-654-01 (dismissed)	Syntex (USA) LLC, Hoffmann-La Roche Ltd., and Allergan Inc. - and - The Minister of Health and Apotex Inc.	Ketorolac	2001-06-29	2001-11-01	Allegation that NOA was misleading and that 2nd person has not complied with Section 5 of the *Patented Medicines (Notice Of Compliance) Regulations*.
T-1898-01 (granted) A-697-02 (dismissed)	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 *Patented Medicines (Notice Of Compliance) Regulations*.

FCTD	File Name	Ingredient	Start Date	Close Date	Summary
T-2288-01 (ongoing)	Apotex Inc. v the Minister of Health and GlaxoSmithKline Inc.	Paroxetine HCl	2001-12-27		Application for an Order that a generic is not required to address a patent listed on the Register.
T-468-02 (discontinued)	Apotex Inc. v the Minister of Health	Apo-X	2002-03-18	2002-06-03	Motion to compel Minister to identify which patents its Apo-X product must address.
T-644-02 (ongoing)	GlaxoSmithKline Inc. v the Attorney General of Canada, the Minister of Health and Apotex Inc.	Salbutamol sulphate	2002-04-19		Generic cross-referenced a brand product with patents on Register. Is generic required to serve NOA on second brand which also has a patent on the Patent Register for the same ingredient?
T-812-02 (ongoing)	Apotex Inc. v the Minister of Health and AstraZeneca Canada Inc.	Omeprazole	2002-05-23		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. v 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 (ongoing)	Apotex Inc. v the Minister of Health and Abbott Laboratories Ltd.	Clarithromycin	2002-06-05		Application for an Order that a patent is improperly listed on the Patent Register or that generic is not required to address the patent.

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

Of the 122 Abbreviated New Drug Submissions received (and 5 New Drug Submissions which were accompanied by patent declarations) (includes administrative submissions):

- 66 were accompanied by Patent Declarations (61 ANDS, 5 NDS):
  - 41 of the 66 indicated the 2nd person intended to serve a Notice of Allegation (NOA);
  - 25 of the 66 stated that they would await expiry of the patent;
  - 1 of the 66 obtained the consent of the patent owner to market the drug.

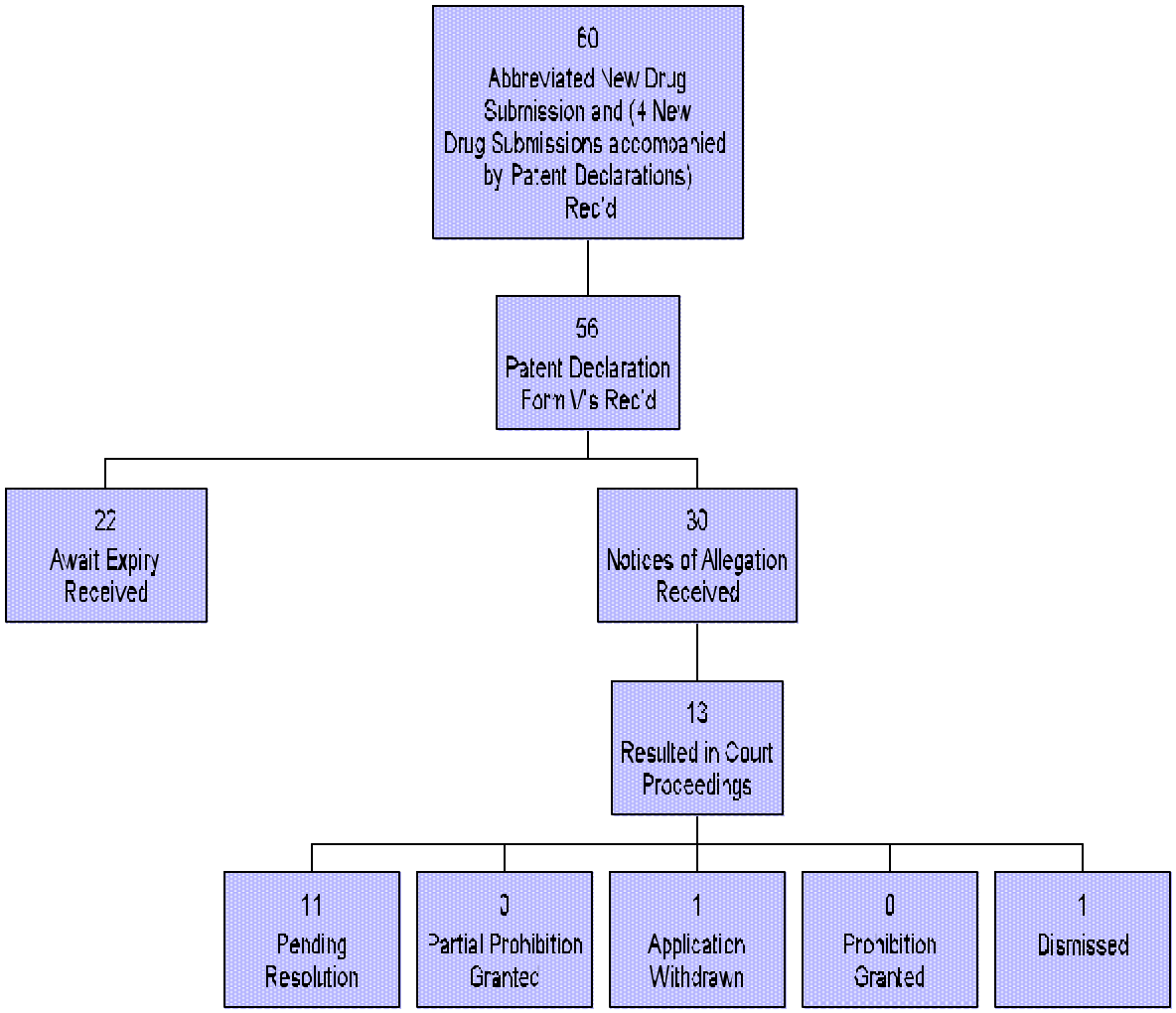


Notes: Appeal applications are not included in these numbers. Court applications may be withdrawn for a number of reasons, including withdrawal of the Notice of Allegation, therefore it should not be assumed that a court application has been withdrawn due to the merits of the case. The 45 day response 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* - 2001

Of the 60 Abbreviated New Drug Submissions received (and 4 New Drug Submissions which were accompanied by patent declarations) (includes administrative submissions):

- 56 were accompanied by Patent Declarations (52 ANDS, 4 NDS):
  - 30 of the 56 indicated the 2nd person intended to serve a Notice of Allegation (NOA);
  - 22 of the 56 stated that they would await expiry of the patent;
  - 4 of the 56 obtained consent of the patent owner to market the drug.

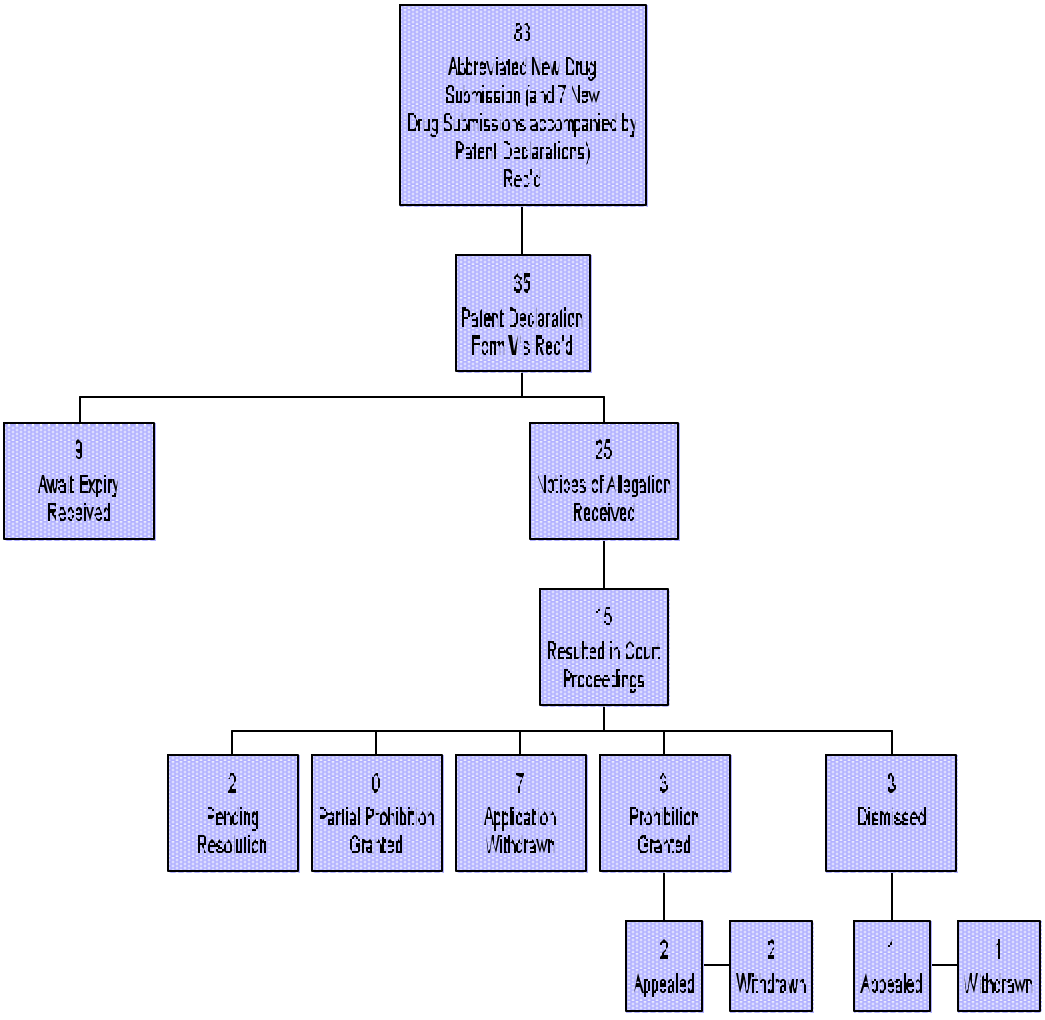


Notes: The number of court applications commenced has decreased from previously released reports, by one due to database accuracy review. Appeal applications are not included in these numbers. Court applications may be withdrawn for a number of reasons, including withdrawal of the Notice of Allegation, 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* - 2000

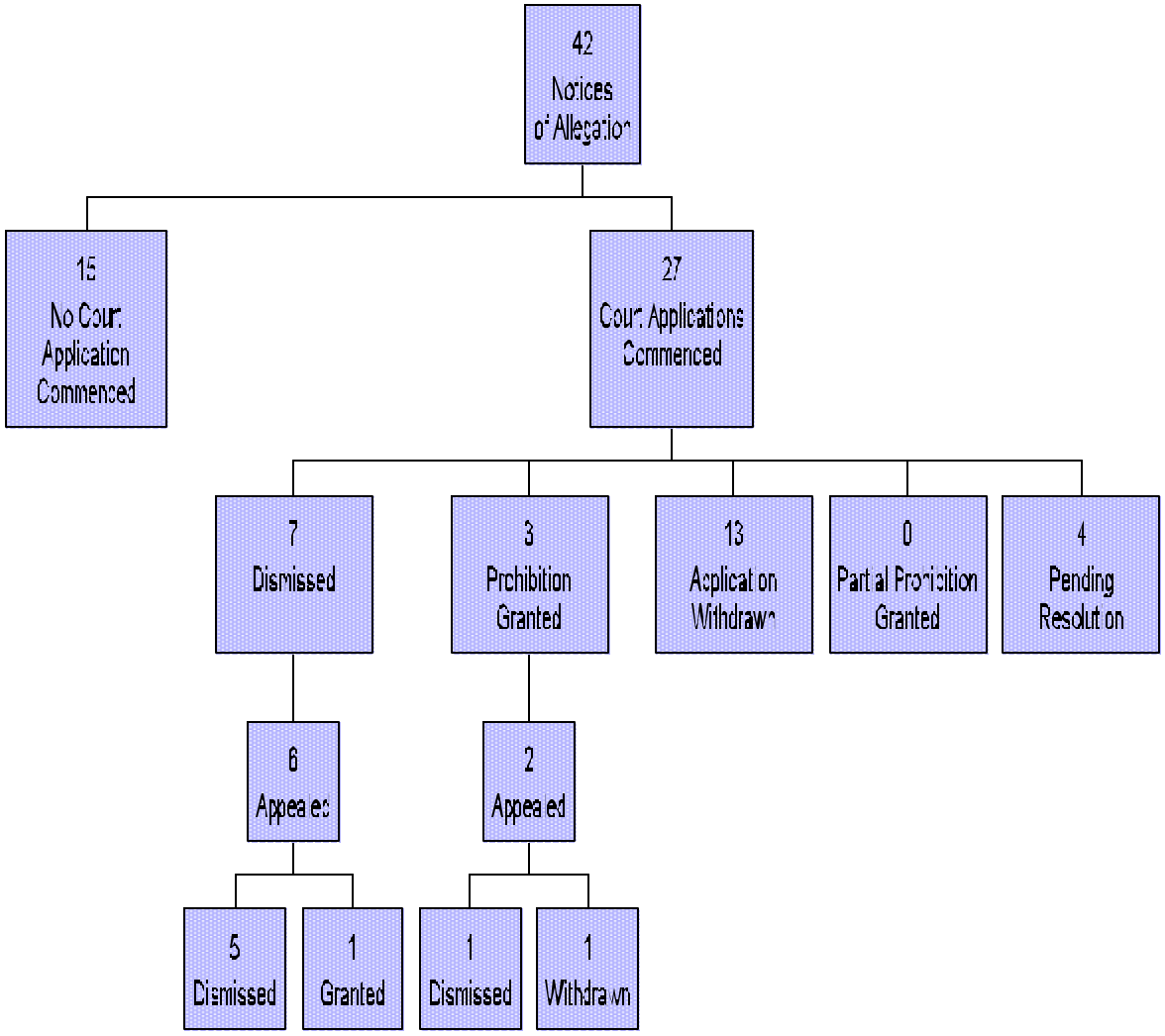
Of the 83 Abbreviated New Drug Submissions received (and 7 New Drug Submissions which were accompanied by patent declarations) (includes administrative submissions):

- ➜ 35 were accompanied by Patent Declarations (38 ANDS and 7 NDS):
  - ➜ 25 of the 35 indicated the 2nd person intended to serve a Notice of Allegation (NOA);
  - ➜ 9 of the 35 stated that they would await expiry of the patent;
  - ➜ 1 of the 356 obtained consent of the patent owner to market the drug.



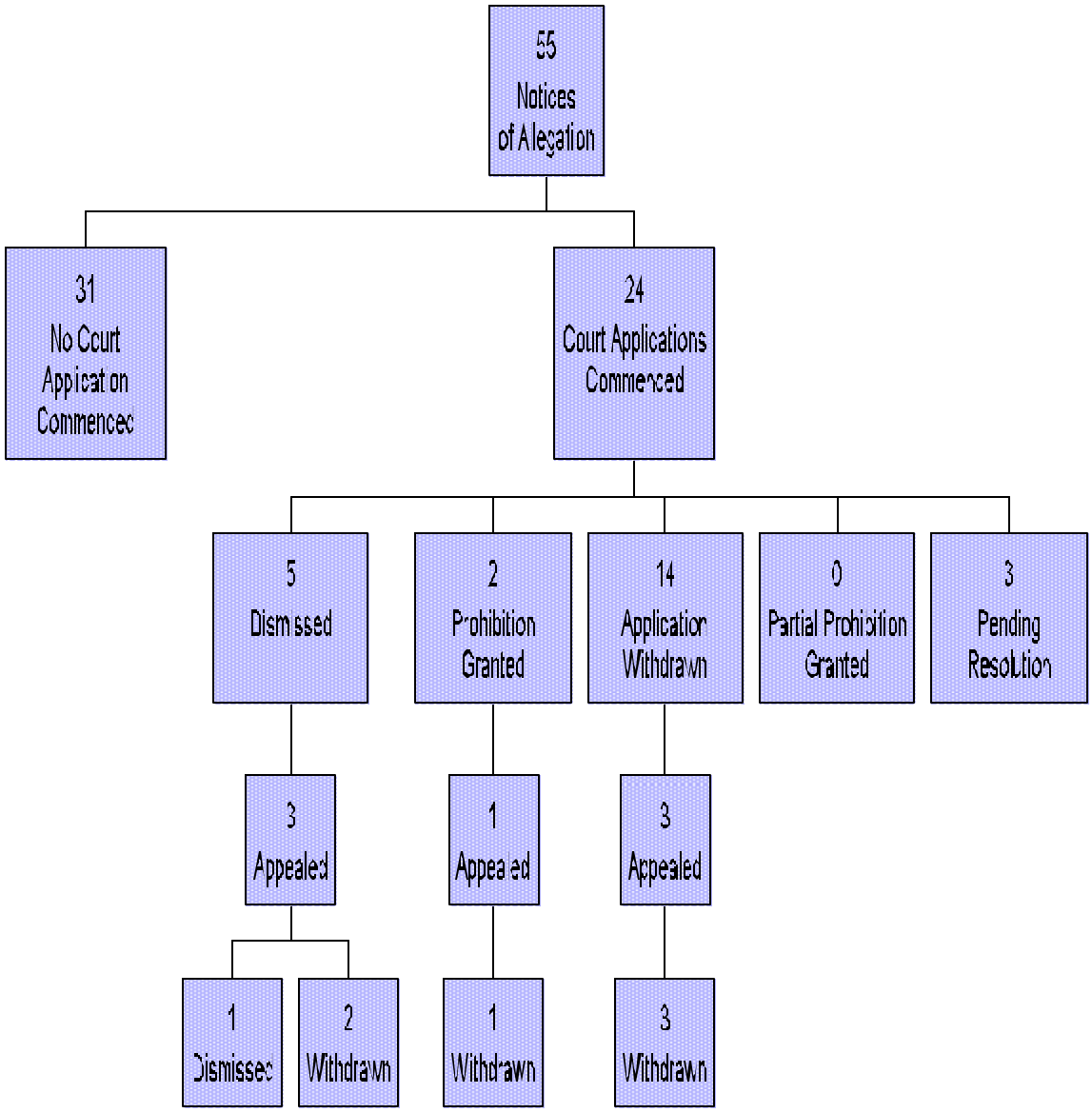
Notes: Appeal applications are not included in these numbers. Court applications may be withdrawn for a number of reasons, including withdrawal of the Notice of Allegation, therefore it should not be assumed that a court application has been withdrawn due to the merits of the case. The 45 day response 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* - 1999



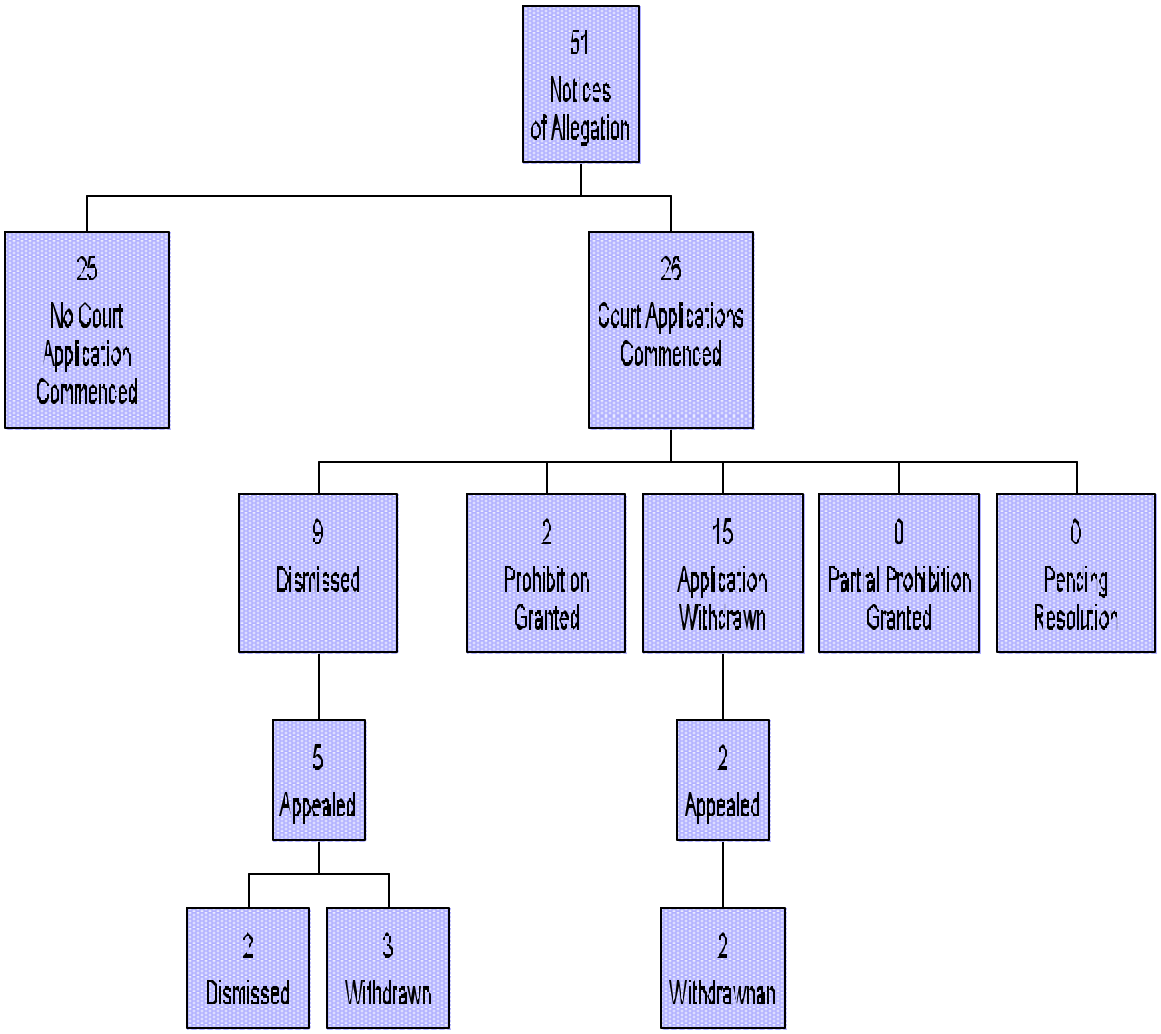
Notes: The number of applications commenced has increased from previously released reports, due to accuracy check of database, 1 case was previously not included in the statistics. Appeal applications are not included in these numbers. Court applications may be withdrawn for a number of reasons, including 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* - 1998



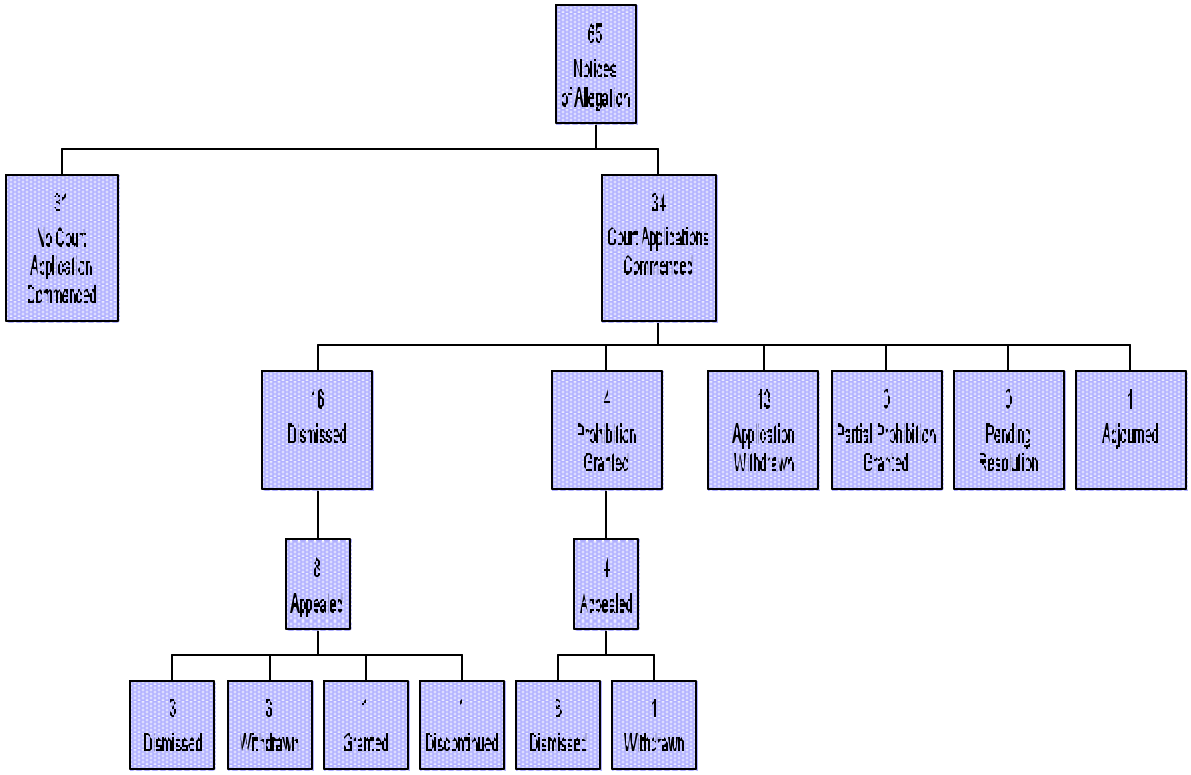
Notes: The number of court applications commenced has increased from previously released reports, due to the addition of the "adjourned" case, which was not previously included in these statistics. Appeal applications are not included in these numbers. Court applications may be withdrawn for a number 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* - 1997



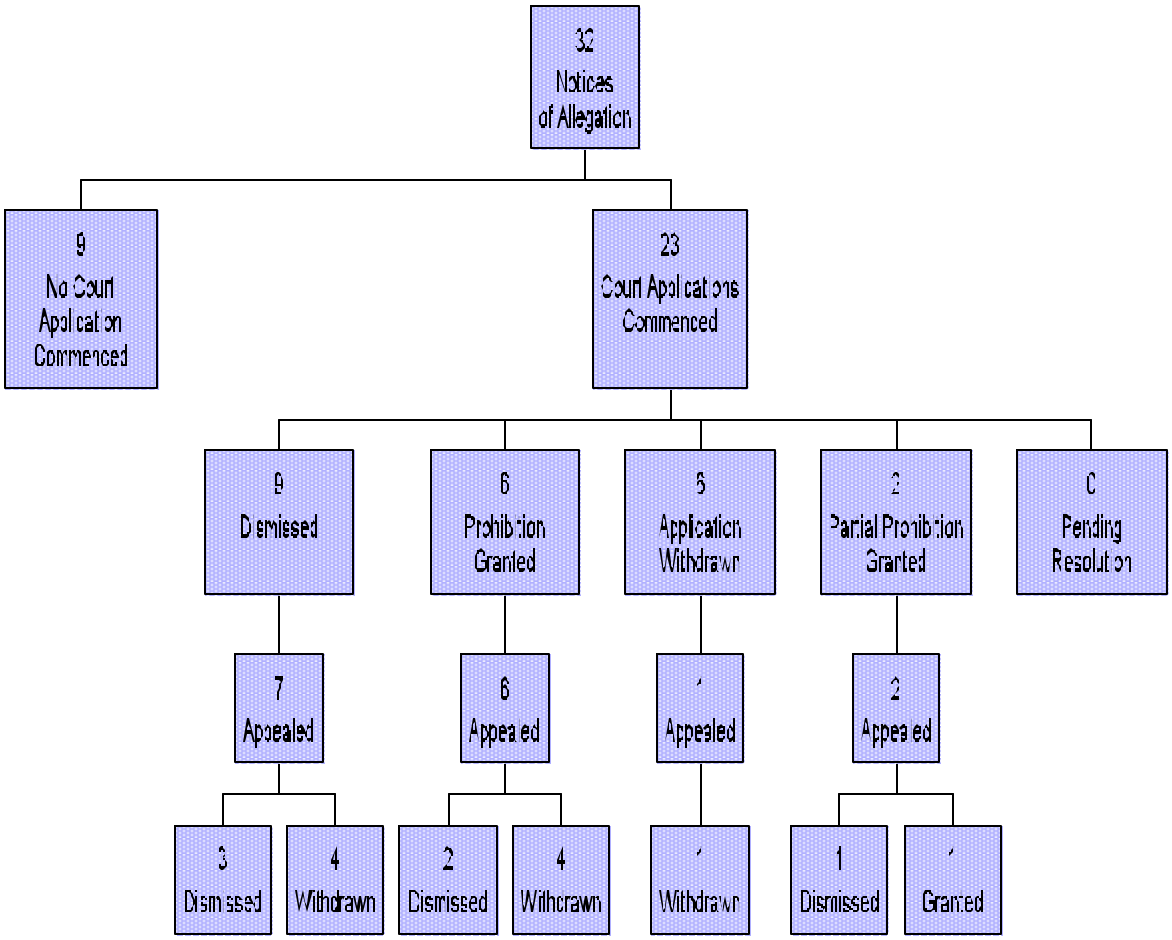
Notes: Appeal applications are not included in these numbers. Court applications may be withdrawn for a number of reasons, including withdrawal of the Notice of Allegation, therefore it should not be assumed that a court application has been withdrawn due to the merits of the case. The 45 day response 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* - 1996



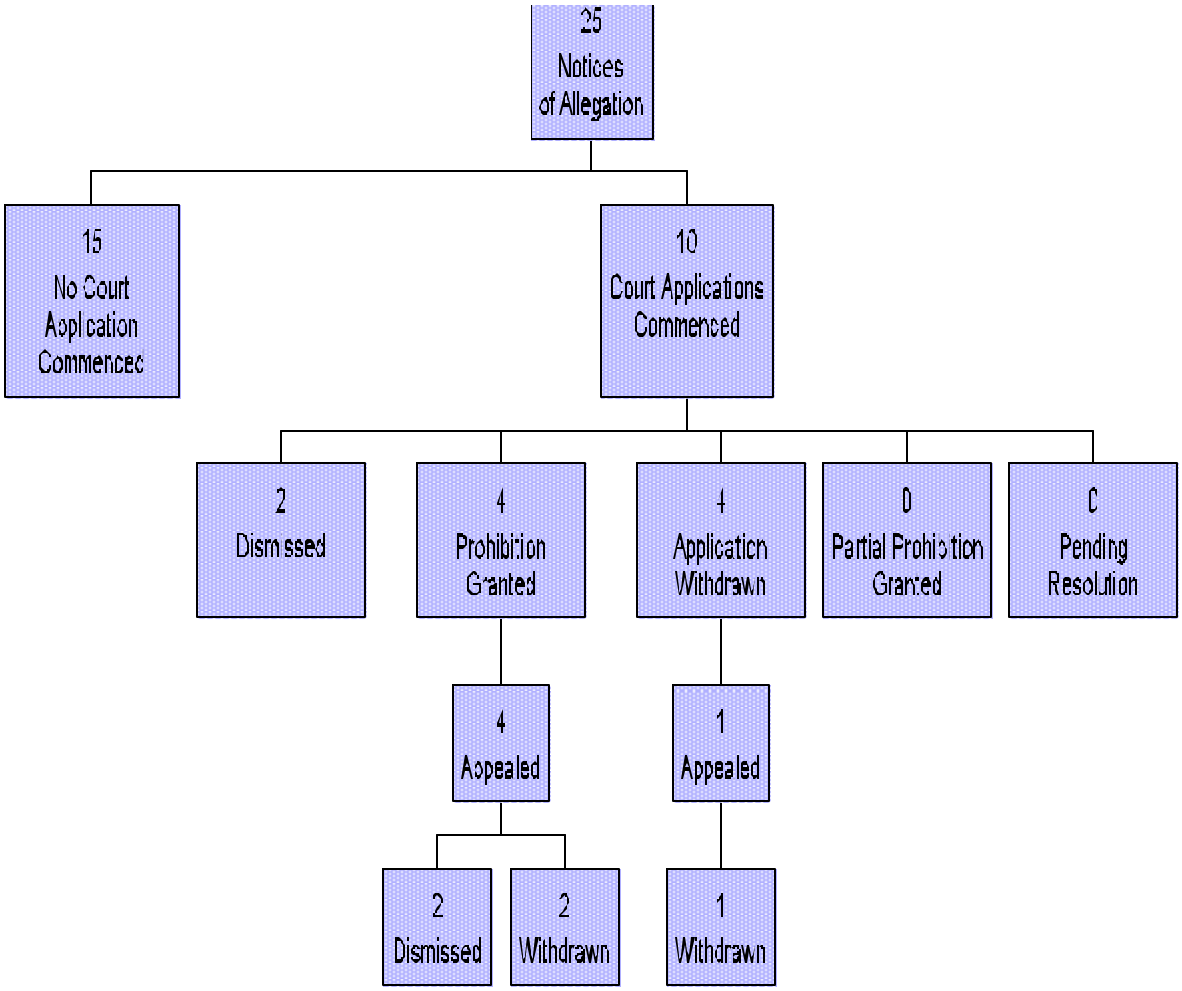
Notes: The number of court applications commenced has increased from previously released reports, due to the addition of the 'adjourned' case which was not previously recorded. Appeal applications are not included in these numbers. Court applications may be withdrawn for a number of reasons, including 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* - 1995



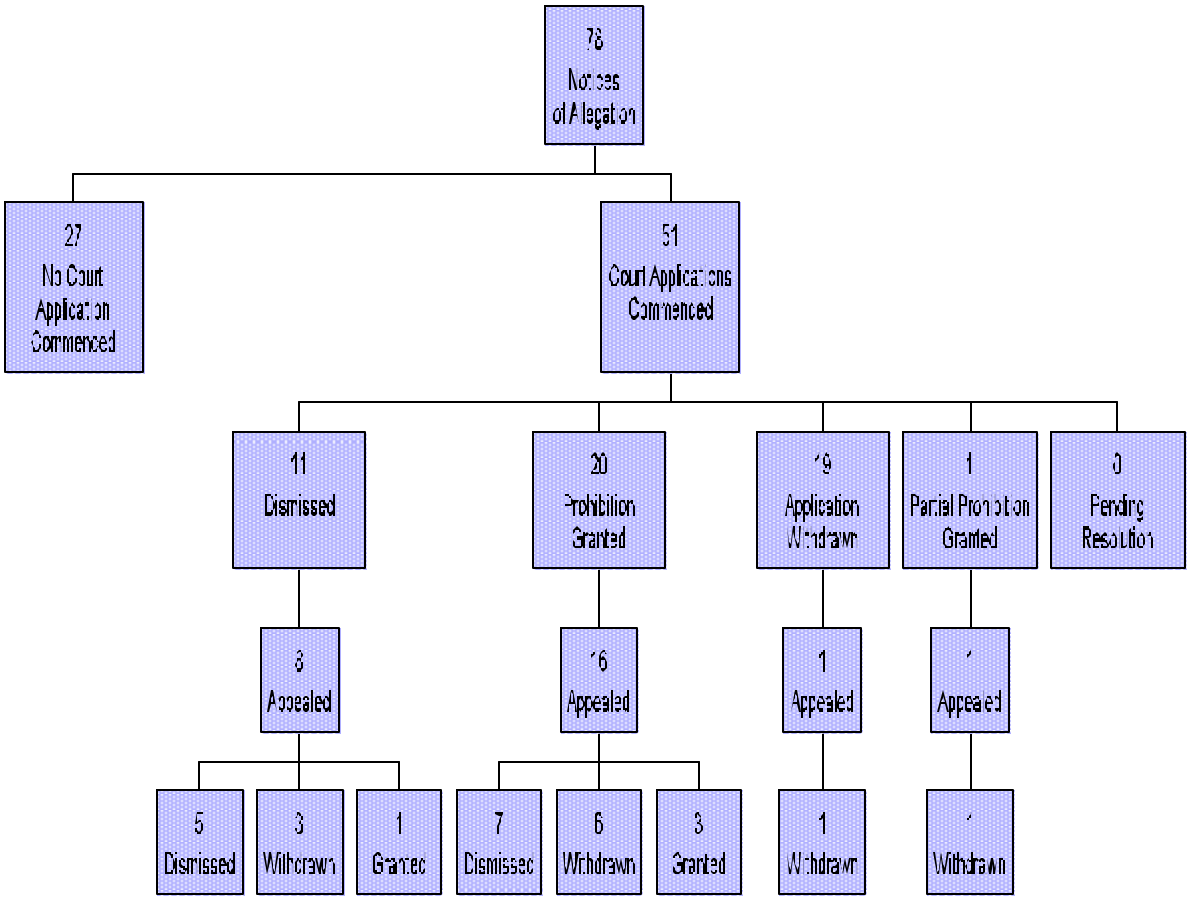
Notes: The number of prohibitions has changed from previously released reports, due to data accuracy check of database. Appeal applications are not included in these numbers. Court applications may be withdrawn for a number of reasons, including withdrawal of the Notice of Allegation, therefore it should 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* - 1994



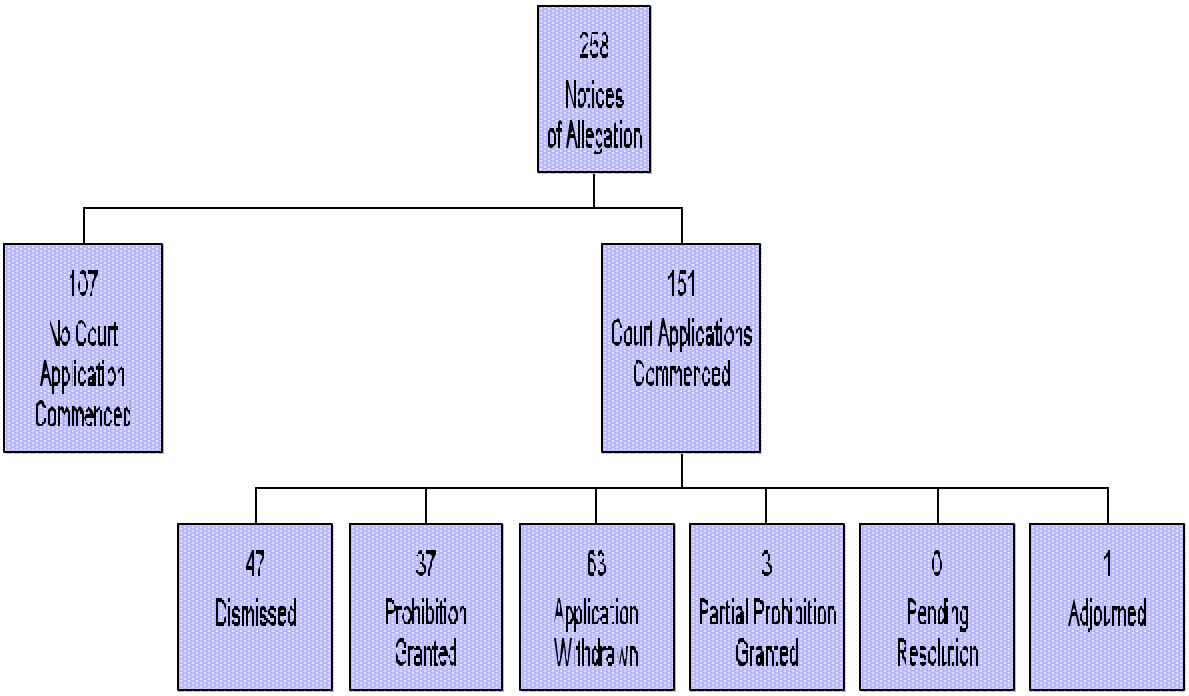
Notes: The number of court applications commenced has decreased from previously released reports, as one 1993 case was previously mistakenly reported as a 1994 case. Appeal applications are not included in these numbers. Court applications may be withdrawn for a number of reasons, including withdrawal 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* - 1993



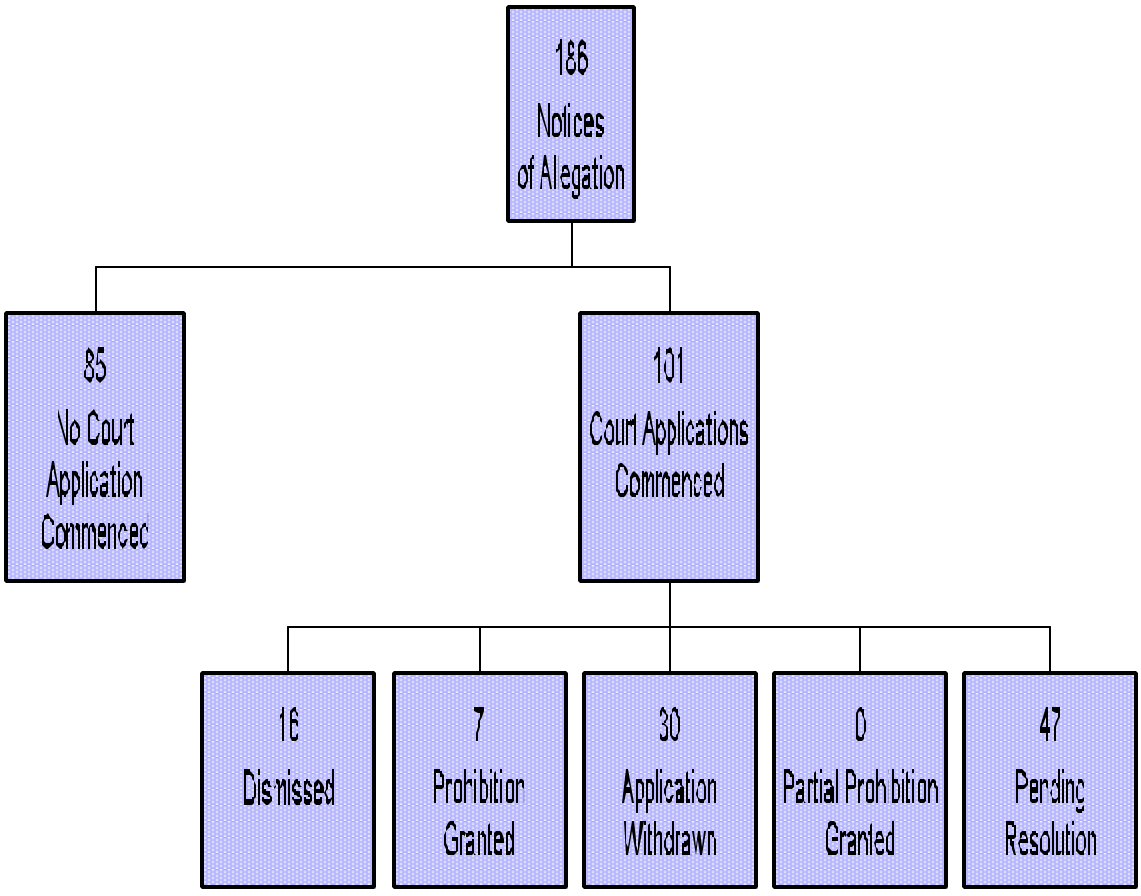
Notes: The number of court applications commenced has increased from previously released reports, due to the fact that one case was mistakenly previously included in the 1994 numbers. Appeal applications are not included in these numbers. Court applications may be withdrawn for a number of reasons, including 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* From 1993 - March 11, 1998



Note: Appeal applications are not included in these numbers. Court applications may be withdrawn 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.

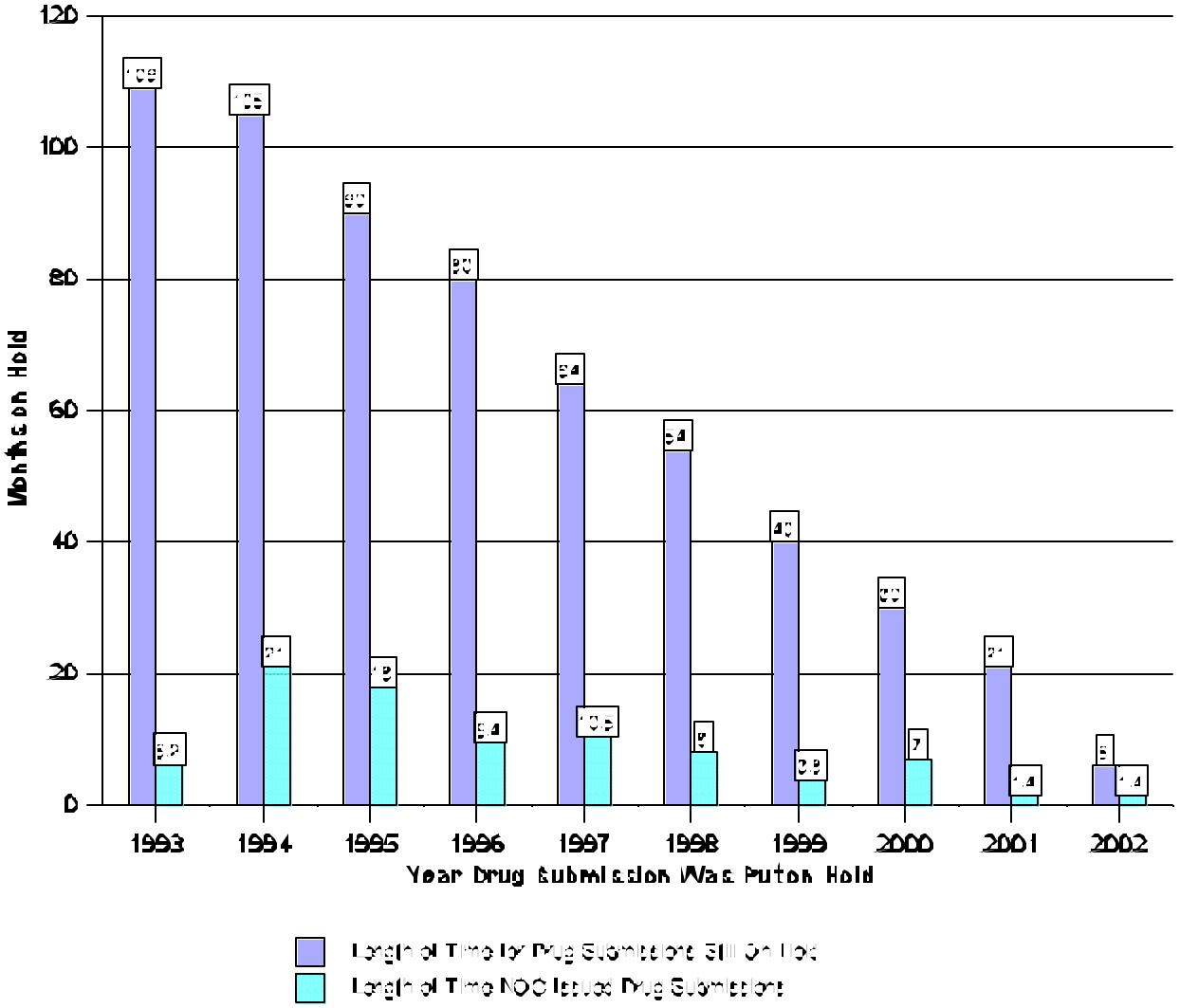
Applications under the *Patented Medicines (Notice of Compliance) Regulations* From March 12, 1998 - December 31, 2002



Note: Appeal applications are not included in these numbers. Court applications may be withdrawn 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.

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

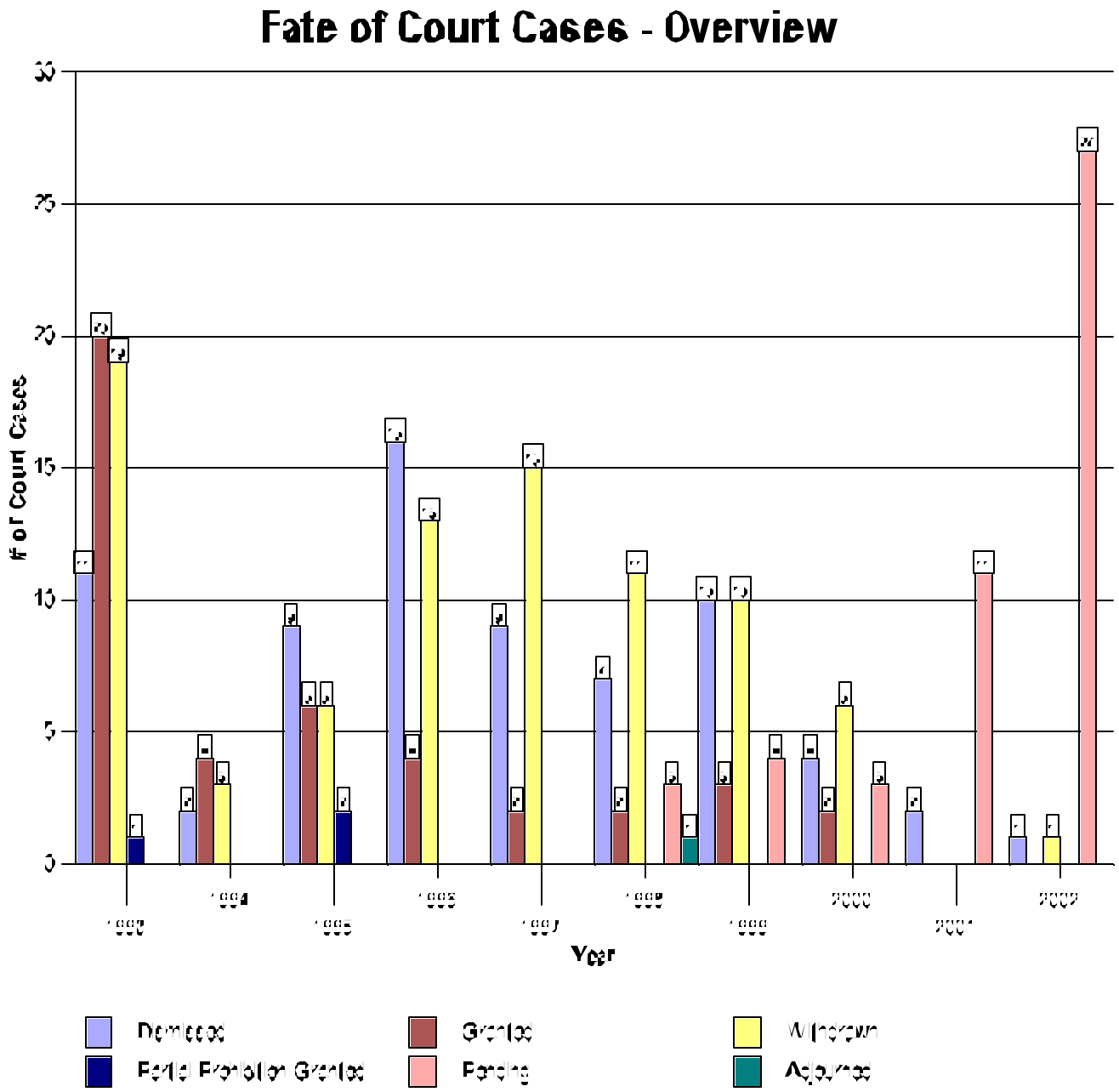
(These numbers include those drug submissions which are awaiting the expiry of the patent.)



	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
Number of NOC Issued **Drug Submissions**	6	7	12	18	6	8	14	7	9	12
Number of Drug Submissions Still on Hold	3	1	3	6	2	4	7	7	1	9

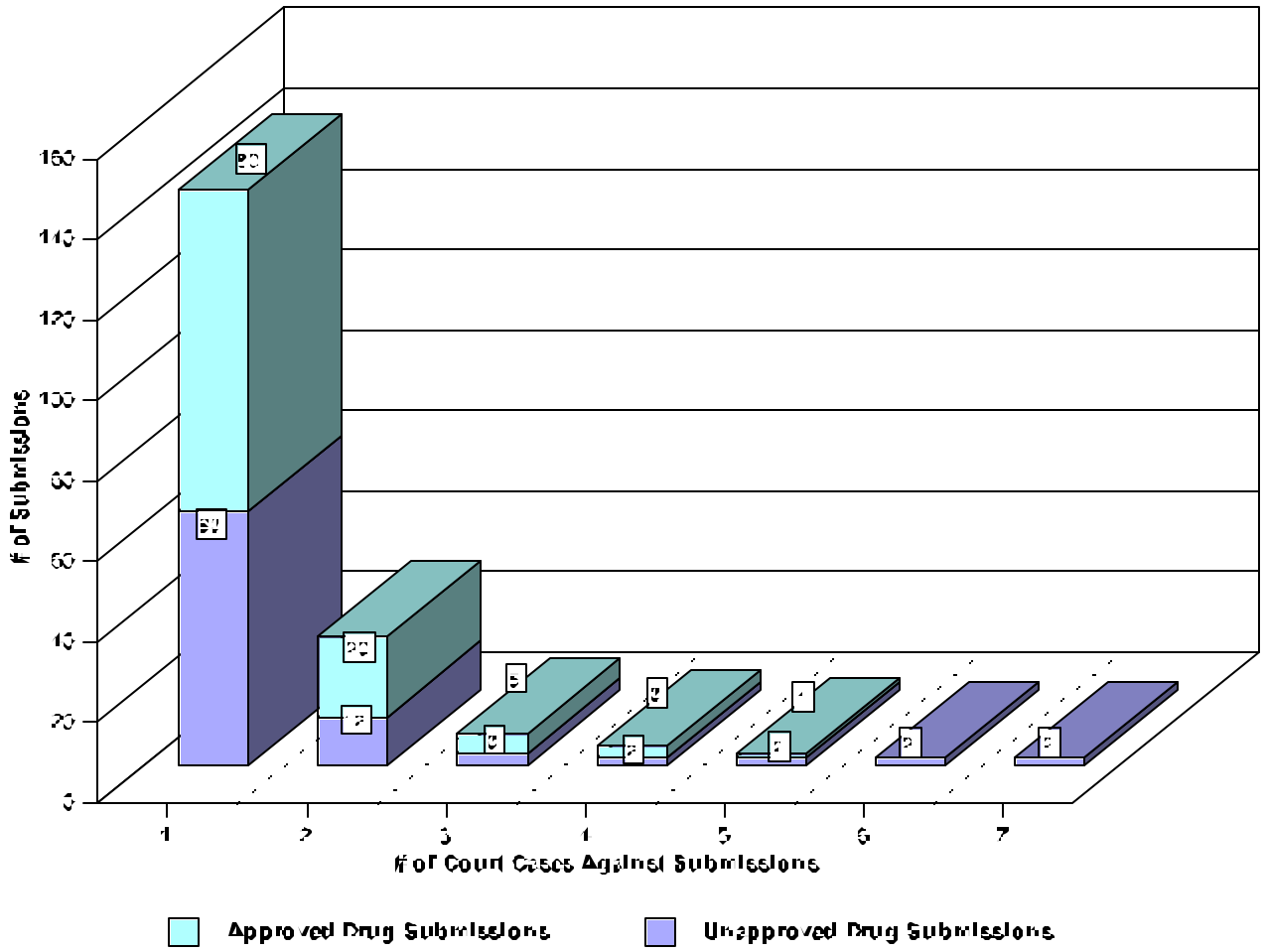
For drug submissions that fall under the *Patented Medicines (Notice Of Compliance) Regulations*, time on patent hold for a cleared drug submission is determined by calculating the difference between the date a drug submission is found approvable and the date the drug submission actually receives a Notice 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 of December 31, 2002.



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



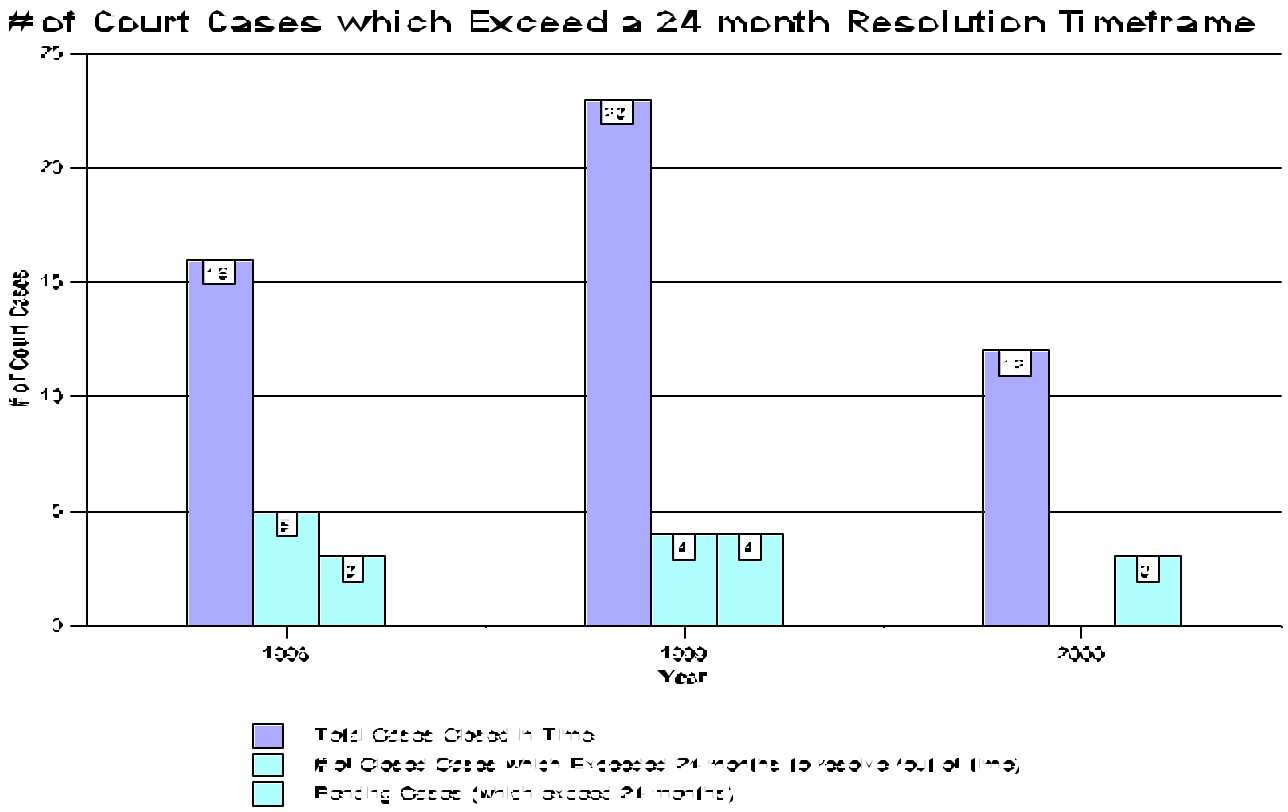
Number of court cases per generic drug submission (ANDS and NDS 1993- 2002). The information is based on individual drug submissions where at least one court case was commenced. You will notice that there are 143 occurrences of a single court case being commenced regarding a particular drug submission, but there are 2 occurrences of 7 court cases being commenced regarding a particular drug submission. The information covers drug submissions filed between 1993 to December 31, 2002. Please note that court applications may apply to more than one drug submissions. 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 page 28 and 29). The above numbers do not include any court applications which involved veterinary medicines.

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

Year	Number of Cases Per Year	Number of Cases Closed	Average Resolution Time (Months)	Range (months)
1993	51	51	24	1 to 58
1994	10	10	24	11 to 66
1995	23	23	22	1 to 46
1996	34	34	18	3 to 43
1997	26	26	15	2 to 42
1998	24	21	14	1 to 44
1999	27	23	17	2 to 38
2000	15	12	11	3 to 23
2001	13	2	16.5	13 to 20
2002	29	2	6	1 - 12

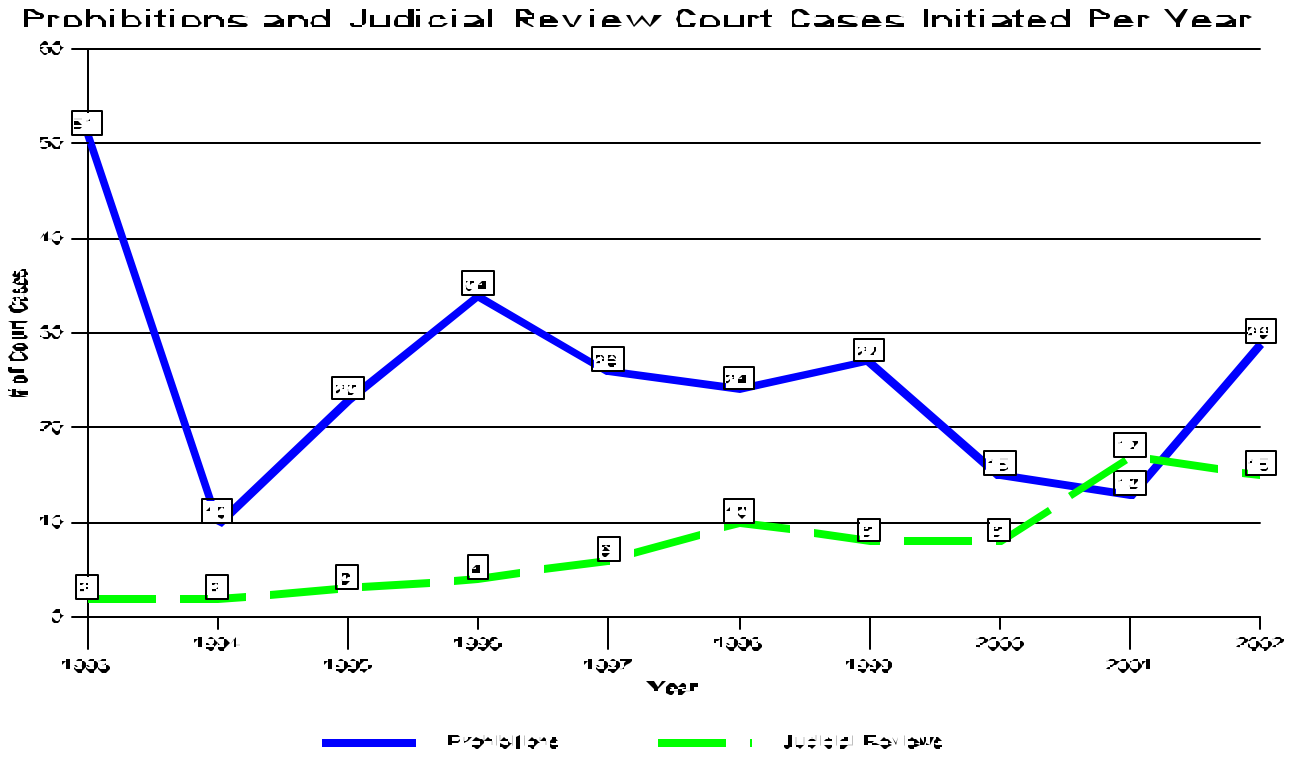
This table represents information regarding proceedings filed pursuant to Section 6 of the *Patented Medicines (Notice Of Compliance) Regulations*, commonly referred to as prohibition applications The start date of the court case determines which year in which it will be included. Average time to resolution 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 *PM(NOC) Regulations.* Pursuant to subsection 7(5) the court may make an order to vary the length of the 24 month stay. Prior to amendments in1998, the stay period was 36 months.



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. Note years 2001 and 2002 do not have cases which have exceed the 24 month resolution period as 24 months have not yet gone by.

Please note 11 cases remain pending for 2001 and 27 cases remain pending for 2002.

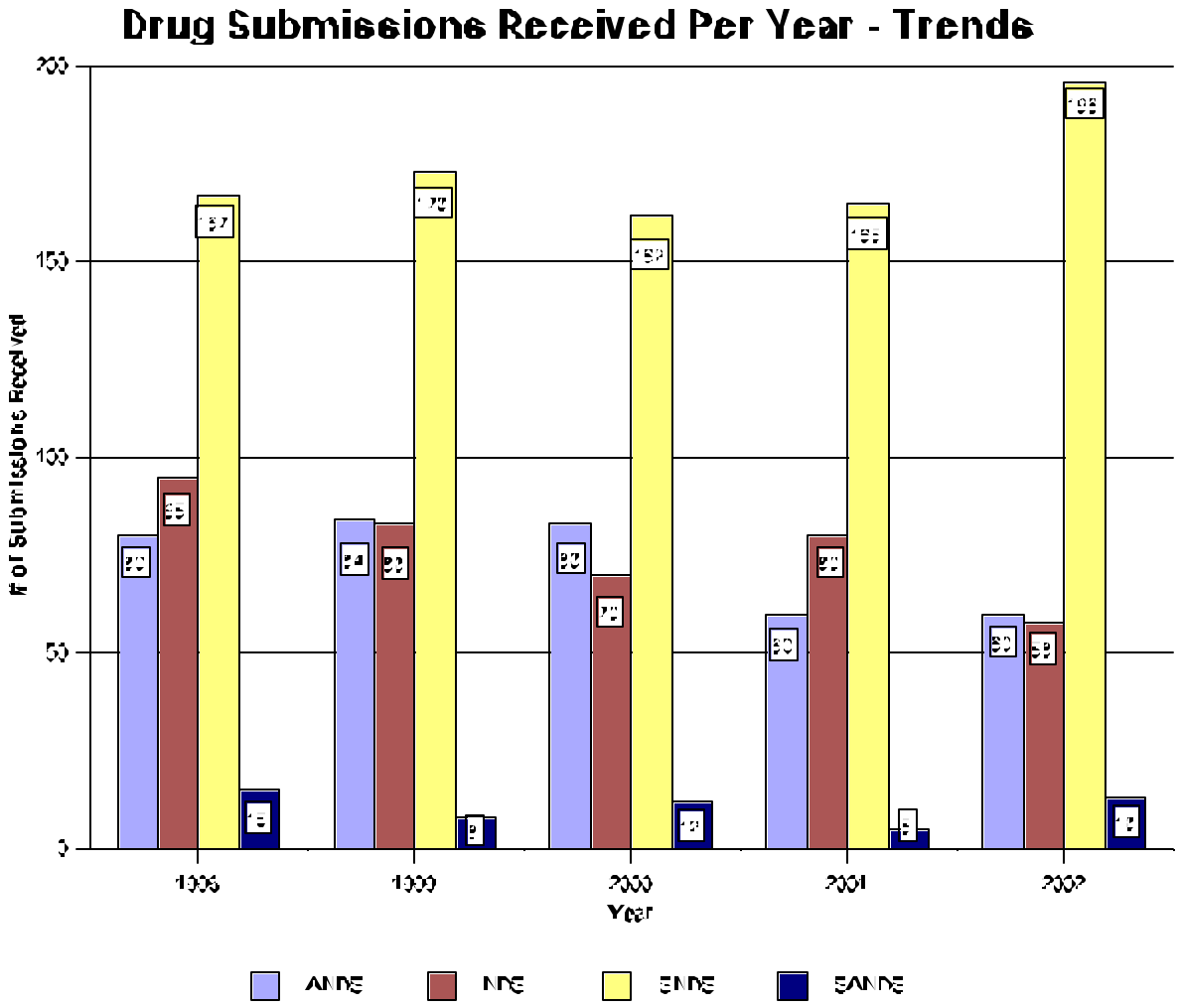


This graph represents how many Prohibition and Judicial Review cases pertaining to the *Patented Medicines (Notice Of Compliance) Regulations* cases were initiated each year.

The number of unresolved Judicial Review court cases which were commenced in 2001 is 6, and the number of unresolved Judicial Review court cases which were commenced in 2002 is 13.

SECTION IV

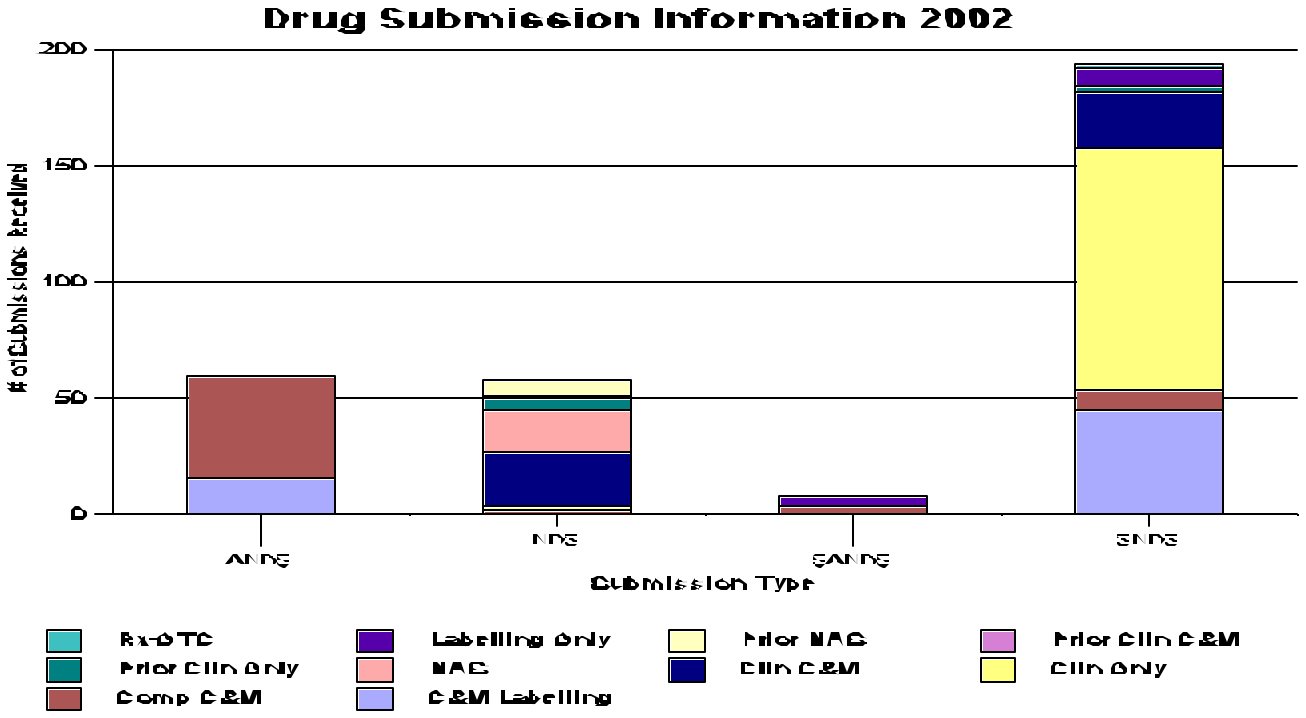
Drug Submission Information



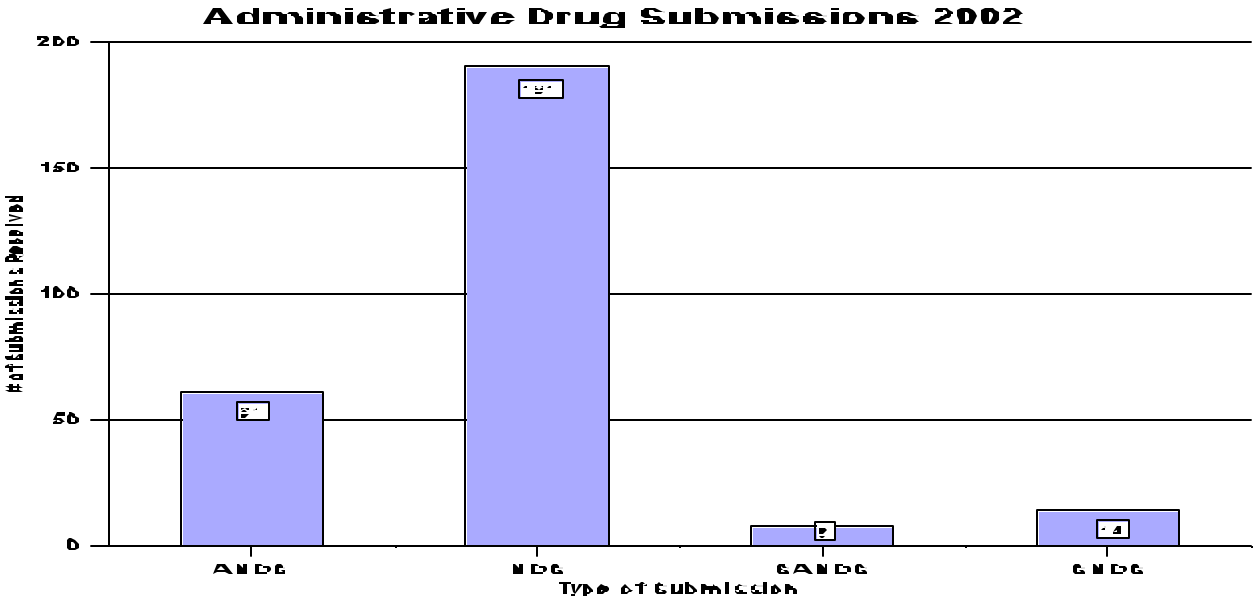
Note: The information above does not include administrative drug submissions. Administrative drug submissions are those processed according to the *Changes to Product Names and/or Manufacturer's Names Policy.* Received date is based on the Central Records (CR) date. The information was taken from the Health Products and Food Branch Annual Reports. Information is only available from 1998 to 2002.

Summary:

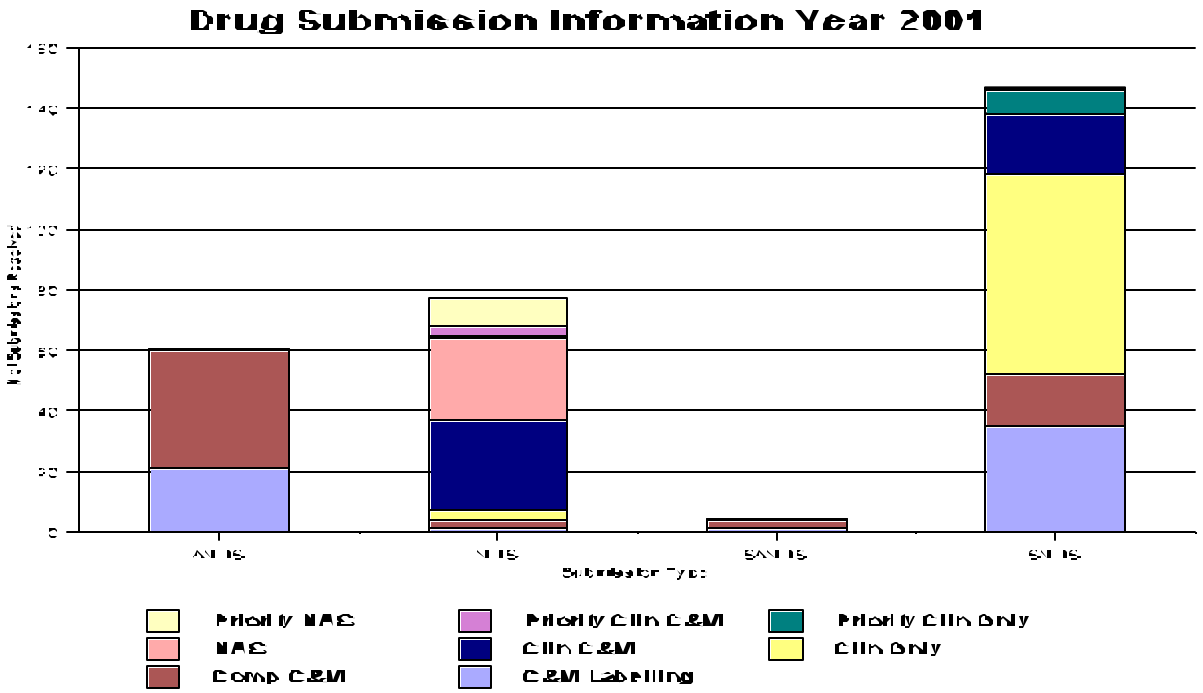
Since the 1998 amendments to the *Patented Medicines (Notice Of Compliance) Regulations*, the number of submissions received in all areas has remained fairly constant. New Drug Submissions (NDS) filed by the brand-name industry have experienced a moderate decrease during this period. The predominantly generic industry-led Abbreviated New Drug Submissions (ANDS) filing has shown an increase in the year 2002 over previous years.



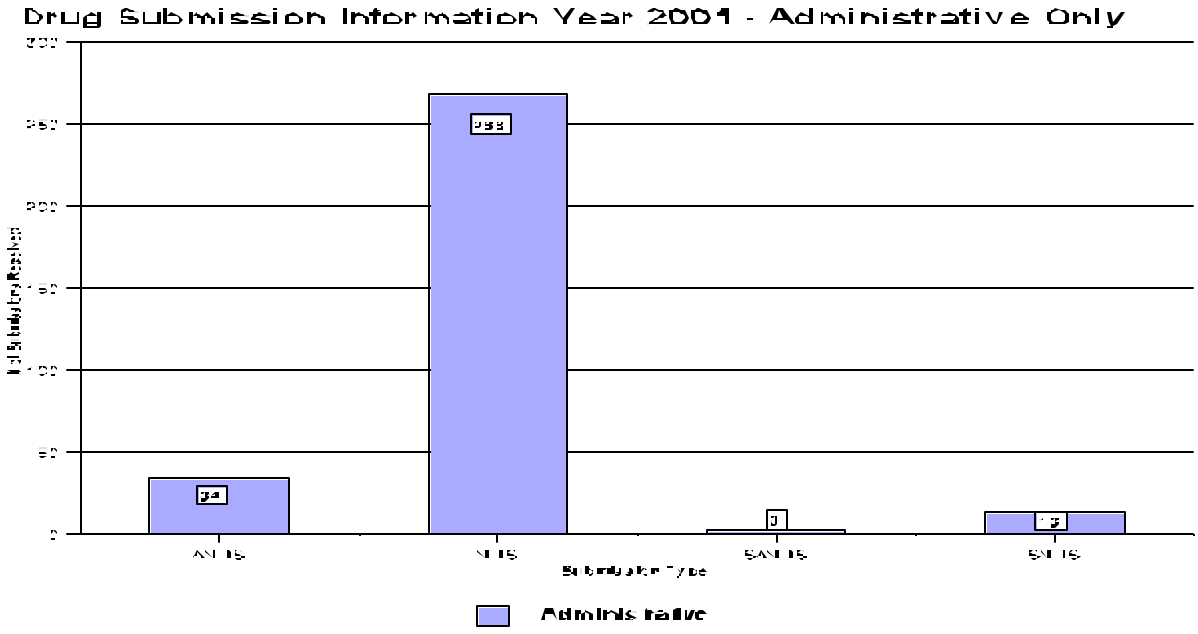
These numbers were taken from the Health Products and Food Branch 2002 Annual Report. These numbers do not include administrative drug submissions, and are based only on those drug submissions received in the calendar year. Administrative drug submissions are located in the diagram below. See acronym list at the end of this document for a definition of the submission types.



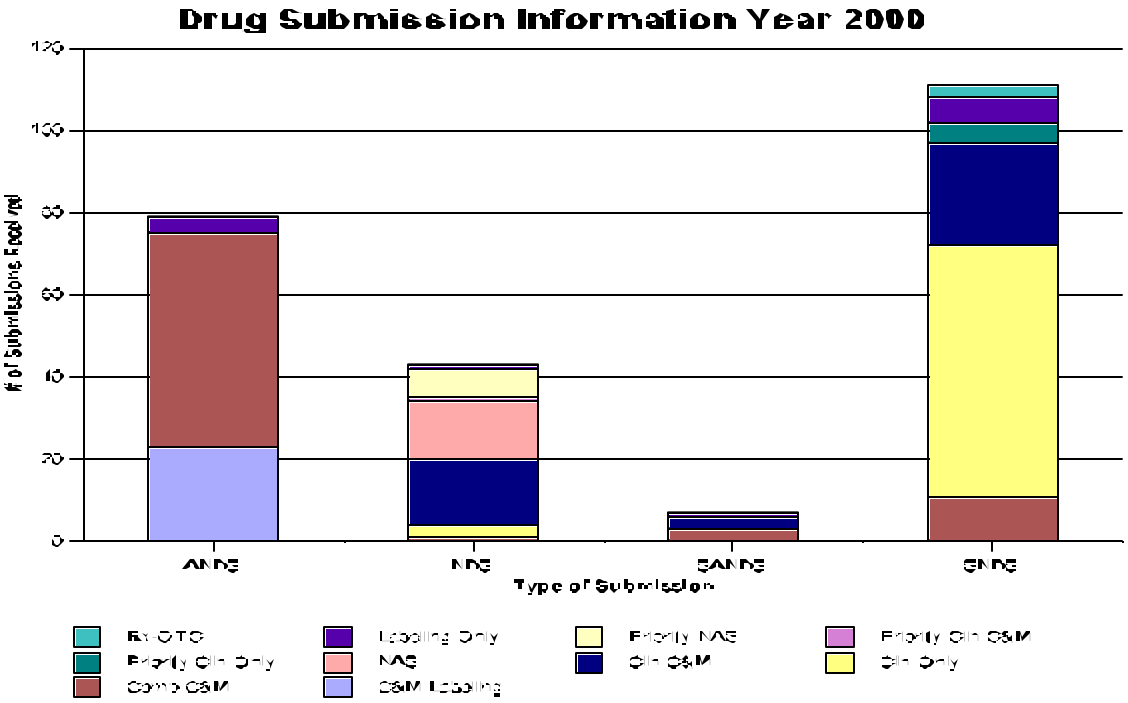
These numbers only represent Administrative type drug submissions, with CR dates in the year 2002. These numbers were taken from the Health Products and Food Branch 2002 Annual Report.



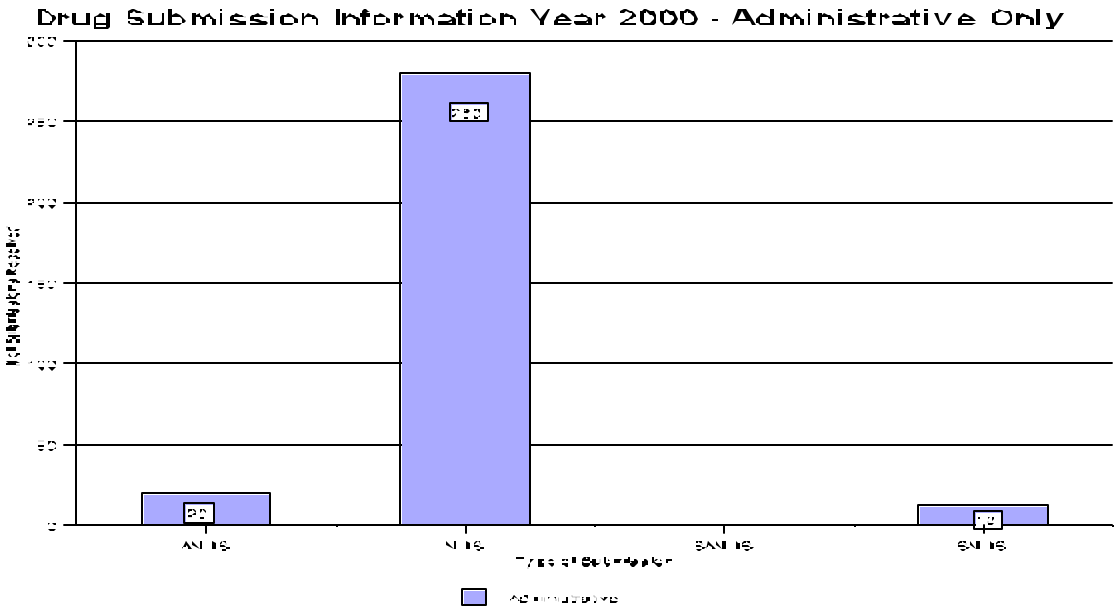
These numbers were taken from the Health Products and Food Branch 2001 Annual Report. These numbers do not include administrative drug submissions, and are based only on those drug submissions received in the calendar year. Administrative drug submissions are located in the diagram below. See acronym list at the end of this document for a definition of the submission types.



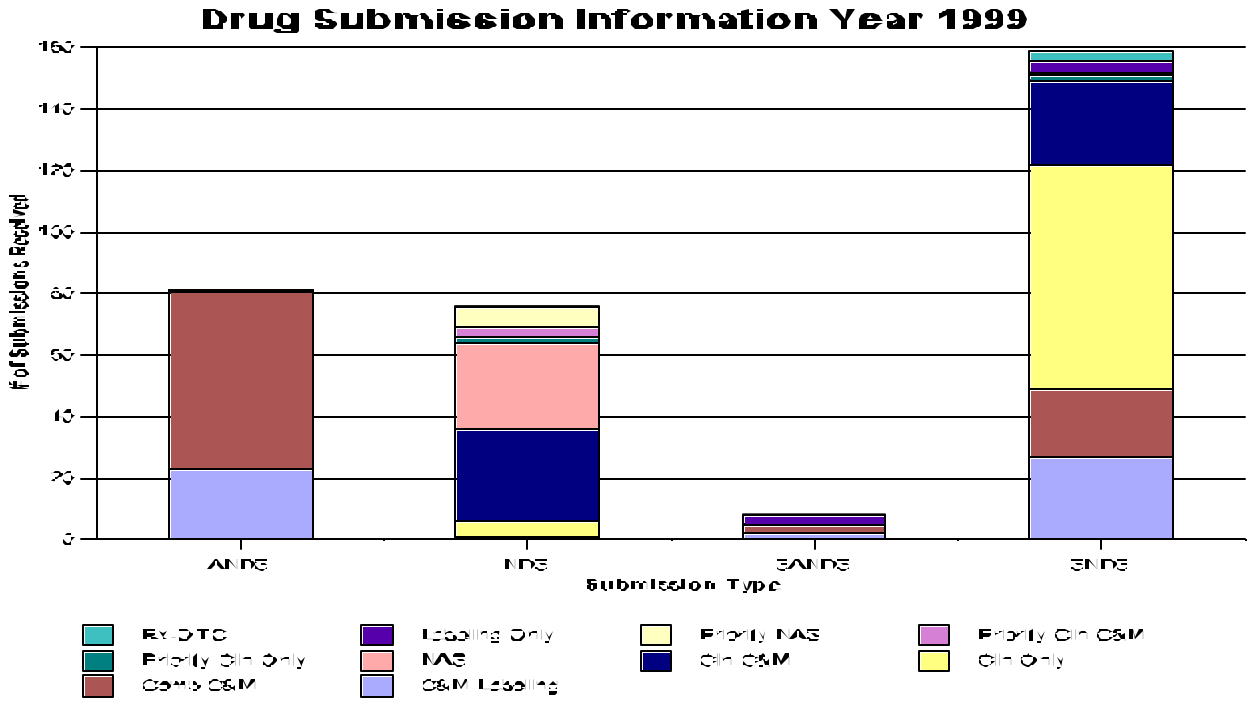
Only administrative drug submissions with a CR date in the year 2001 are represented here. These numbers were taken from the Health Products and Food Branch 2001 Annual Report.



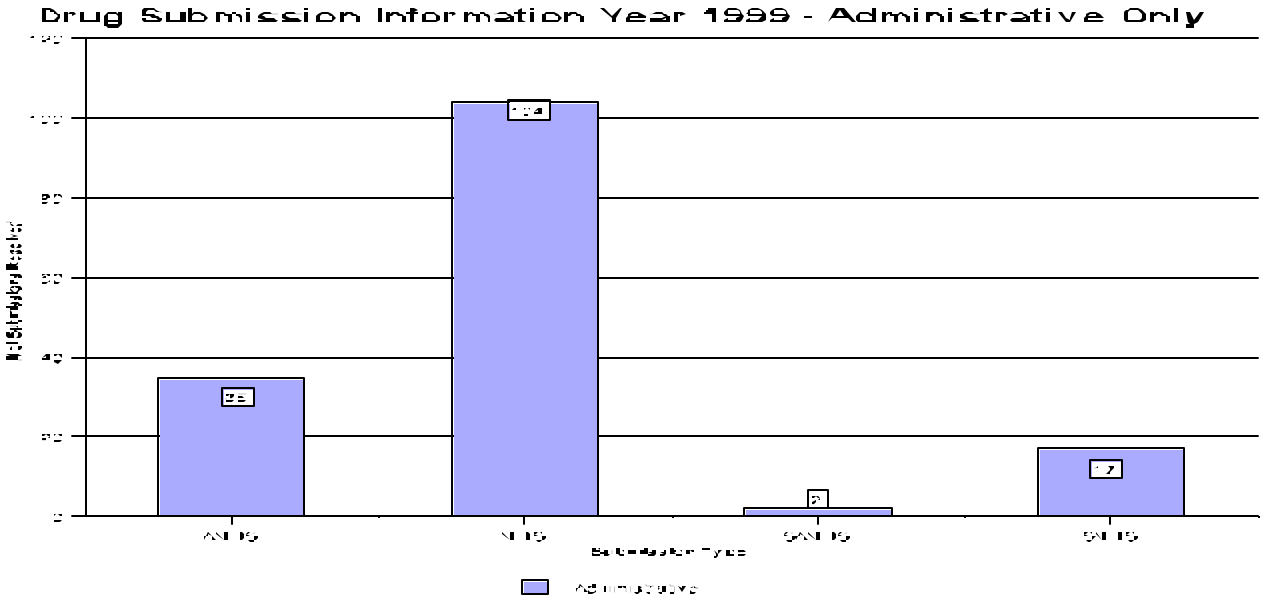
These numbers were taken from the Health Products and Food Branch 2000 Annual Report. These numbers do not include administrative drug submissions, and are based only on those drug submissions received in the calendar year. Administrative drug submissions are located in the diagram below. See acronym list at the end of this document for a definition of the submission types.



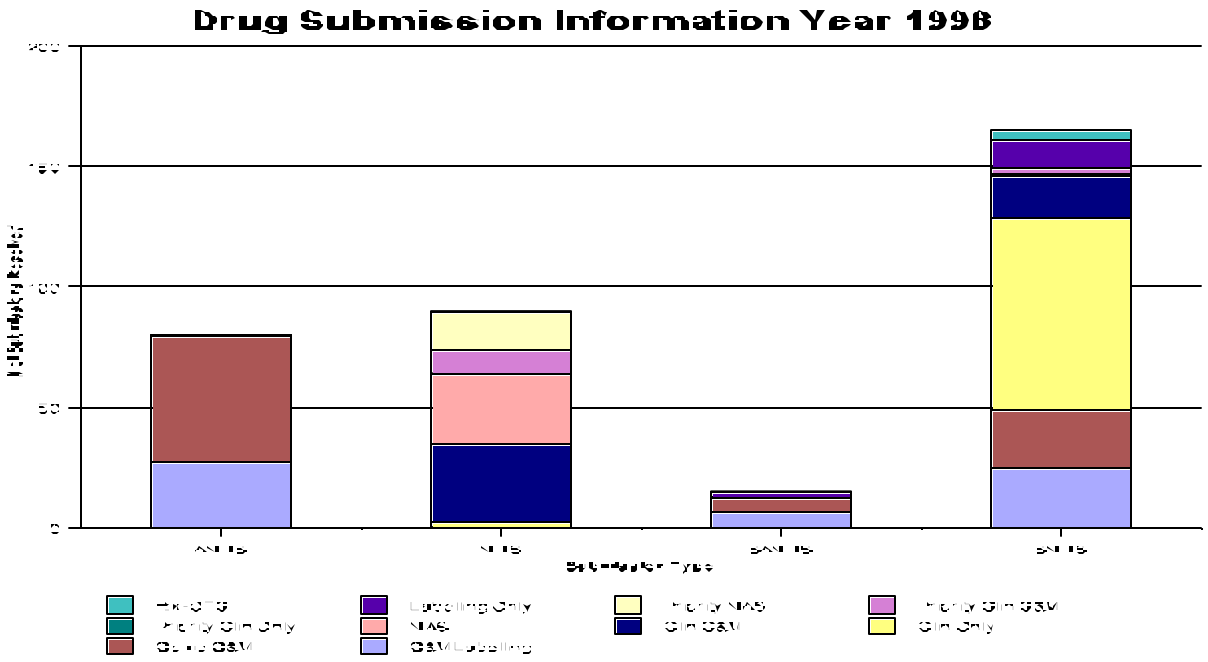
Only administrative drug submissions with a CR date in the year 2000 are represented here. These numbers were taken from the Health Products and Food Branch 2000 Annual Report.



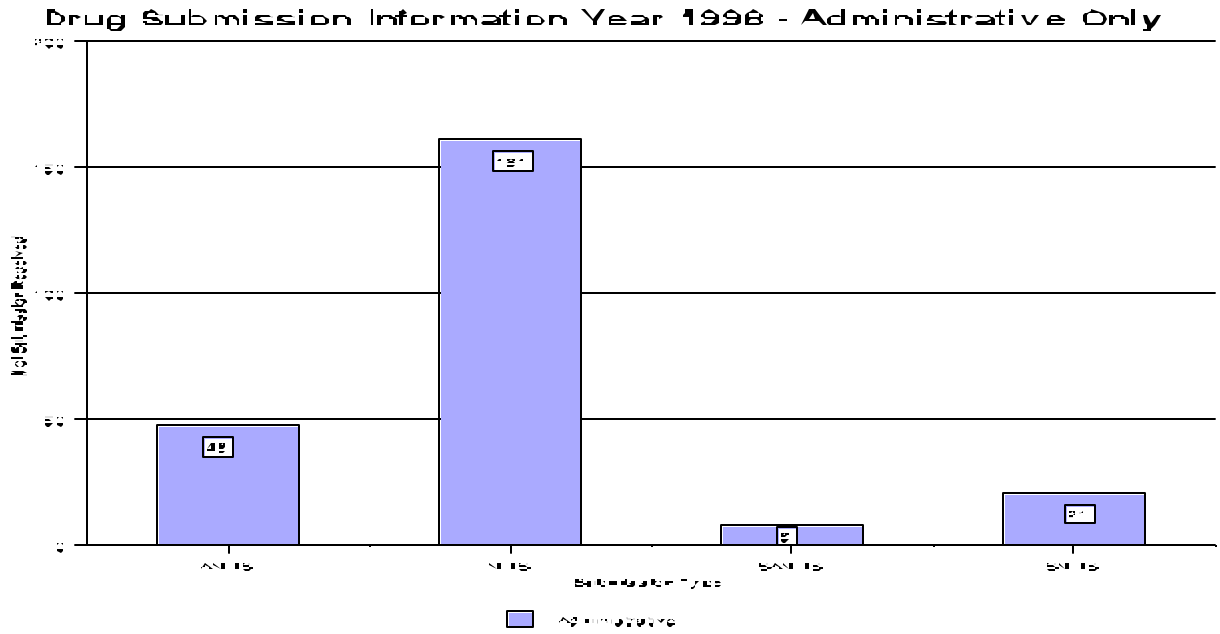
These numbers were taken from the Health Products and Food Branch 1999 Annual Report. These numbers do not include administrative drug submissions, and are based only on those drug submissions received in the calendar year. Administrative drug submissions are located in the diagram below. See acronym list at the end of this document for a definition of the submission types.



Only administrative drug submissions with a CR date in the year 1999 are represented here. These numbers were taken from the Health Products and Food Branch 1999 Annual Report.



These numbers were taken from the Health Products and Food Branch 1998 Annual Report. These numbers do not include administrative drug submissions, and are based only on those drug submissions received in the calendar year. Administrative drug submissions are located in the diagram below. See acronym list at the end of this document for a definition of the submission types.



Only administrative drug submissions with a CR date in the year 1998 are represented here. These numbers were taken from the Health Products and Food Branch 1998Annual Report.

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*	-	Supplemental Abbreviated New Drug Submission
SNDS	-	Supplemental 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. ie.) 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.
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 date of filing 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, to 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).
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 on 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, a 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 a NOC but for the provisions of the *Patented Medicines (Notice of Compliance) Regulations*. In these circumstances, a 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.