Patent Listing and Data Protection:
A Primer for Regulatory Affairs Professionals
CAPRA Dinner Meeting January 14, 2016

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Overview

- Patent Listing
  - PMNOC Regulations
  - Patent Register
  - Patent listing requirements: Forms, eligibility, timing
  - Court proceedings
- Data Protection
  - Eligible drugs
  - Term of protection
  - Pediatric extension
- eCTD Requirements
- Resources

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Overview of Patents

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The nature of a patent

"Patent protection rests on the concept of a bargain between the inventor and the public. In return for disclosure of the invention to the public, the inventor acquires for a limited time the exclusive right to exploit it. It was ever thus."

Justice Binnie, *Free World Trust v. Électro Santé Inc.*, [2000] 2 S.C.R. 1024 at para 13

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The patent specification

“Specification” refers to the two main parts of the patent: disclosure and claims

Disclosure provides public with instructions on how to make and use the invention

Claims define the monopoly enjoyed by the patentee in exchange for disclosure of the invention

Patents can be accessed on CIPO website: http://www.ic.gc.ca/opic-cipo/cpd/eng/introduction.html

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Patent term

If filed on or after October 1, 1989: **20 years from filing**

Patent must issue before it is enforceable

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Patented Medicines (Notice of Compliance) Regulations

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PMNOC Regulations: overview

LINK generic* regulatory approval to status of innovator patents

Authorized by *Patent Act*

Establish Patent Register

Define rules for listing on Register, requirement for a generic/SEB to address patents, court proceedings for order of prohibition

* Generic drug or subsequent entry biologic

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Importance of patent listing

Listing is **CRITICAL**: failure to list may result in loss of rights, possibly opening door to generic entry

There is likely no other effective interlocutory relief in Canada

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Patent Register

List of drugs and their associated patents

Maintained by OPML

Manufacturers submit patents lists for listing against regulatory submissions

OPML determines eligibility of patents submitted for listing

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Search Results for Medicinal Ingredient

Patent Register - Search results for ABACAVIR SULFATE

To view detailed patent and submission information select the link for the record you wish to view.

Medicinal Ingredient Search Results

Medicinal Ingredient	Brand Name	Strength	Dosage	DIN [1]	Patent
abacavir sulfate	ZIAGEN	300 mg	tablet	02240357	1340589 2216634 2289753
abacavir sulfate	ZIAGEN	20 mg / ml	oral solution	02240358	1340589 2216634 2289753

1 Drug Identification Number (DIN)

Patent Listing Requirements

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Patent Listing Requirements

- Forms
- Eligibility
- Timing

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Forms

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Form IVs

Form IV = patent list

Submit forms for listing against NDS and every SNDS, if eligible

If patent is eligible for listing against NDS or SNDS, submit forms for listing against **every** later SNDS

Form IVs: How many?

One form for:

- every patent,
- every submission,
- every DIN

Important: conduct a final check before filing forms to ensure you have the correct # of forms, covering all of the above

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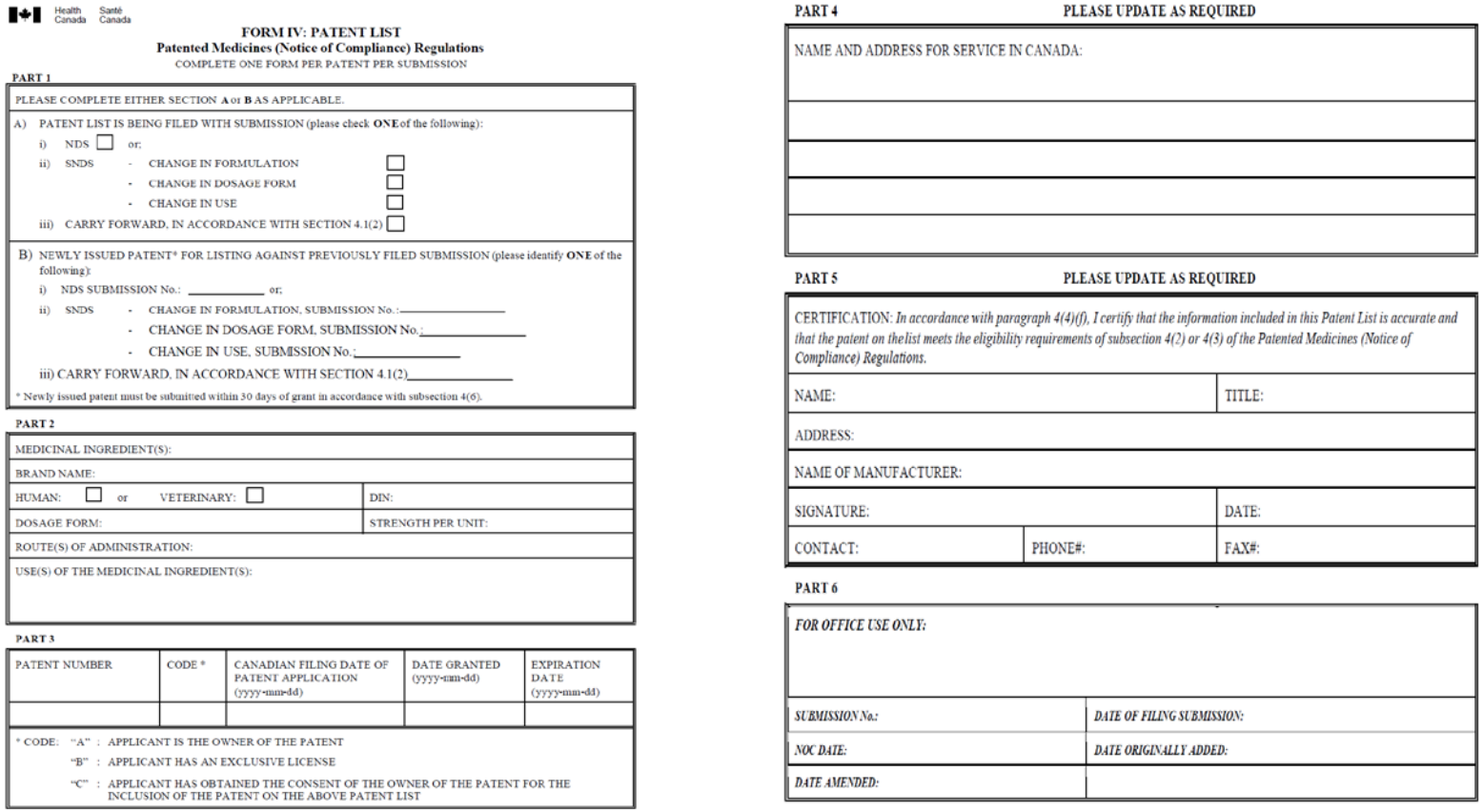
Form IV = patent list



Health Canada / Santé Canada

FORM IV: PATENT LIST
Patented Medicines (Notice of Compliance) Regulations
COMPLETE ONE FORM PER PATENT PER SUBMISSION

PART 1

PLEASE COMPLETE EITHER SECTION **A** or **B** AS APPLICABLE.

A) PATENT LIST IS BEING FILED WITH SUBMISSION (please check **ONE** of the following):
- i) NDS ☐ or;
- ii) SNDS - CHANGE IN FORMULATION ☐
  - CHANGE IN DOSAGE FORM ☐
  - CHANGE IN USE ☐
- iii) CARRY FORWARD, IN ACCORDANCE WITH SECTION 4.1(2) ☐

B) NEWLY ISSUED PATENT* FOR LISTING AGAINST PREVIOUSLY FILED SUBMISSION (please identify **ONE** of the following):
- i) NDS SUBMISSION No.: _____ or;
- ii) SNDS - CHANGE IN FORMULATION, SUBMISSION No.: _____
  - CHANGE IN DOSAGE FORM, SUBMISSION No.: _____
  - CHANGE IN USE, SUBMISSION No.: _____
- iii) CARRY FORWARD, IN ACCORDANCE WITH SECTION 4.1(2)_____

* Newly issued patent must be submitted within 30 days of grant in accordance with subsection 4(6).

PART 2

MEDICINAL INGREDIENT(S):	
BRAND NAME:	
HUMAN: ☐ or VETERINARY: ☐	DIN:
DOSAGE FORM:	STRENGTH PER UNIT:
ROUTE(S) OF ADMINISTRATION:	
USE(S) OF THE MEDICINAL INGREDIENT(S):	

PART 3

PATENT NUMBER	CODE *	CANADIAN FILING DATE OF PATENT APPLICATION (yyyy-mm-dd)	DATE GRANTED (yyyy-mm-dd)	EXPIRATION DATE (yyyy-mm-dd)

* CODE: "A" : APPLICANT IS THE OWNER OF THE PATENT
"B" : APPLICANT HAS AN EXCLUSIVE LICENSE
"C" : APPLICANT HAS OBTAINED THE CONSENT OF THE OWNER OF THE PATENT FOR THE INCLUSION OF THE PATENT ON THE ABOVE PATENT LIST

PART 4 **PLEASE UPDATE AS REQUIRED**

NAME AND ADDRESS FOR SERVICE IN CANADA:

PART 5 **PLEASE UPDATE AS REQUIRED**

CERTIFICATION: *In accordance with paragraph 4(4)(f), I certify that the information included in this Patent List is accurate and that the patent on the list meets the eligibility requirements of subsection 4(2) or 4(3) of the Patented Medicines (Notice of Compliance) Regulations.*

NAME:		TITLE:
ADDRESS:		
NAME OF MANUFACTURER:		
SIGNATURE:		DATE:
CONTACT:	PHONE#:	FAX#:

PART 6

FOR OFFICE USE ONLY:

SUBMISSION No.:	*DATE OF FILING SUBMISSION:*
NOC DATE:	*DATE ORIGINALLY ADDED:*
DATE AMENDED:	

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Eligibility

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Eligibility

Should be determined primarily by Patent Group, in consultation with regulatory

Regulations recently (2015) amended, case-law evolving

Generally, eligibility requires:

- A patent claim for a medicinal ingredient, formulation, dosage form, or use of the medicinal ingredient AND
- The claimed subject-matter was approved/is sought to be approved in the regulatory submission ("relevance")

Again, generally Patent Group needs to identify patents and determine eligibility

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OPML determines eligibility

After forms are submitted, OPML determines eligibility

OPML will advise that a patent is:

(i) preliminarily eligible or

(ii) ineligible, e.g. “relevance” requirement not met

30-day deadline for response, extendable

Generally, Patent Group co-ordinates submissions

Decision may be subject to court challenge (difficult to succeed)

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If patents are eligible

If OPML finds patent eligible:

- Following final check to confirm eligibility, patent will be listed once NOC issues (if submissions pending) or
- If submitted after NOC issues (later-listed patent), will be listed quickly

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Once forms are listed

Double-check listing(s) on Patent Register when advised by OPML of listing

Keep forms up-to-date, including address, uses, lapse of patent

OPML may audit to ensure patent remains eligible on its own (rare) or in response to a generic inquiry

Keep DIN active; patents will be removed from the Register if DIN cancelled under C.01.014.6(1)(a) (sponsor advises that sales discontinued)

Product must be “marketed in Canada”

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Timing

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Timing

TIMING for submission of forms is critical

No extensions of time available

Missed filing opportunity can result in loss of rights, possibly opening door to generic entry

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Timing

For **every** submission (NDS, admin NDS, SNDS, SNDS-C), Form IVs for all eligible patents must be filed together with that submission (even if already listed against prior submission)

Practice tips:

(i) Alert Patent Group of nature of/timing of any planned regulatory submission

(ii) Ensure Form IVs are prepared well before filing any regulatory submissions

(iii) Do **not** file any submission before confirming all required Form IVs are in the submission

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Timing

For an eligible patent that issues after a regulatory submission is filed, Form IVs must be filed within 30 days after patent issuance

A patent that issues AFTER a regulatory submission (NDS, admin NDS, SNDS, SNDS-C) is filed can be listed only if it is filed in Canada **before** the regulatory submission is filed

Practice tips: (i) Prior to regulatory filings, consult with Patent Group to ensure that all relevant patent applications have been filed for listing

(ii) Prepare and submit Form IVs ASAP after patent issuance is confirmed

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PMNOC Proceedings

Before Minister will issue generic NOC, generic must "address" patents listed on the Register as of its filing date and innovator may commence a court proceeding to challenge any allegations of invalidity, non-infringement

During pendency of court proceeding (up to 24 months), **Minister is prohibited from granting NOC**

If Court not satisfied generic will not infringe valid patent, **will prohibit Minister of Health from granting NOC to generic**

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DATA PROTECTION

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Data protection

Food and Drug Regulations, s. C.08.004.1

Register of Innovative Drugs maintained by OPML lists drugs subject to data protection

No application requirements:

- Submissions are automatically reviewed for data protection;
- Guidance requests sponsors indicate if they believe drug is eligible for data protection;
- Submissions can be made in response to negative eligibility decisions

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Data protection

Independent of patent status

Applies to an "innovative drug":

> "a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph"

Whether other variants protected (e.g. metabolites, prodrugs) is assessed on case-by-case basis

Data protection can be lost if innovator is not marketing in Canada

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Term, relationship to *PMNOC Regulations*

6-year “no-file” period

- Generic/SEB cannot file its submission until 6 years after first NOC for innovative drug

8-year “no-grant” period

- Minister cannot grant NOC to generic until 8 years after first NOC for innovative drug

Because prohibition proceedings take up to 24 months, such proceedings can be completed between the 6 and 8-year data protection periods

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Pediatric extension

Additional 6 months of protection if information regarding pediatric use is provided; pediatric indication not required

OPML must determine “clinical trials were designed and conducted for the purpose of increasing knowledge of the use of the innovative drug … and this knowledge would thereby provide a health benefit to members of those populations”

DEADLINE: SNDS must be filed within **5 years** of first NOC for innovative drug

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eCTD REQUIREMENTS

(PATENT LISTS and DATA PRO)

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eCTD requirements (as of Jan 2016)

Patent lists:

- All patent lists and updates must be filed eCTD
  - Patent lists for later-issued patents discouraged from being faxed first
- Responses to preliminary listing ineligibility letters must be faxed only (will be changed soon)

All **data protection** materials must be filed eCTD

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eCTD requirements (as of Jan 2016)

BUT:

- HPFB implementing fully paperless drug submission filing process by April 2017
- In the future, OPML will require all patent/data protection information electronically
- Guidance doc (non-eCTD electronic-only) will be updated accordingly

Questions regarding electronic filing to OSIP's eReview group: ereview@hc-sc.gc.ca

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RESOURCES

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Guidance documents/databases

Guidance document: PMNOC Regulations http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/patmedbrev/pmreg3_mbreg3-eng.php

Patent Register (with links to forms for patent lists and Form Vs) http://pr-rdb.hc-sc.gc.ca/pr-rdb/index-eng.jsp

Guidance document: Data protection http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/data_donnees_protection-eng.php

Register of Innovative Drugs http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/regist/reg_innov_dr-eng.php

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CAUTION

Guidance documents not necessarily up-to-date, as case-law is evolving

Guidance documents reflect OPML's view of the law

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A FEW TAKE-AWAYS

1. Patent lists: timing requirements are critical, submit later-listed patents ASAP after issue date
2. Patent lists: check the final count (one form for every patent, for every submission, for every DIN)
3. Marketing requirement for *PMNOC Regs* and data pro
4. Consider pediatric extension for data pro: 5-yr deadline
5. Watch for new eCTD requirements

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Thank You

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