The Face of the Patent is not the ‘Whole Story’: Determining Effective Patent Life in the US

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and Heidi Berven, Ph.D., J.D.
Interface Between Patent Term and Regulatory Exclusivity

Hatch-Waxman Extension

PTO

Patent Term

FDA

Regulatory Exclusivity

Effective Product Exclusivity
Factors Affecting Patent Life and Regulatory Exclusivities

- **Patent Life**
  - GATT
  - Certificates of Correction
  - Terminal Disclaimers
  - Maintenance Fees
  - Patent Term Adjustment
  - Interference
  - Infringement
  - Hatch-Waxman Extensions

- **Regulatory Exclusivities**
  - New Chemical Entities Exclusivity
  - Data Exclusivity
  - Orphan Drug Exclusivity
  - Pediatric Extensions
  - Rx to OTC Switches
  - ANDAs
Patents filed prior to June 8, 1995 receive the greater of 17 years from grant or 20 years from first filing.

- US 5,856,336 expires January 5, 2016
Certificate of Correction

- US 5,565,447
- Expiration date calculated from the face of the patent — March 28, 2014 not October 15, 2013
- There is a Certificate of Correction
Certificate of Correction

Caution: legal status databases will state there is a certificate of correction but will not provide additional information

- Corrected date of first filing
  - Corrected patent expiry date October 15, 2013
  - But a request for extension has been filed so it may change again!!

You must look at the certificate of correction!
Terminal Disclaimers

- All or a portion of a patent term can be disclaimed.
- A patent will have the term of a “reference patent”.
- “Reference patent” is not identified on patent face.
- Start by checking the patent family.
  - US 5,917,007 is a divisional of US 5,679,717
- Strategy not always successful.
Terminal Disclaimers

- US 5,679,717 has a terminal disclaimer and a certificate of correction.
- When does US 5,917,007 expire? Probably on April 29, 2014.
- You need the file-wrapper to confirm the patent term.
Payment of maintenance fees is necessary to prevent patent expiration.

Must be paid on or before due date or within six months grace period.

Can be paid after grace period if unintentional (within 24 months) or unavoidable (any time).
Use caution when stating patents have expired due to failure to pay maintenance fees.

- US 5,104, 361 expired May 14, 2003 for failure to pay maintenance fees.
  - Revival possible
- US 4,875, 623 reinstated due to acceptance of late maintenance fees.
Patent Term Adjustment

Caution: Legal Status Databases Are Incomplete

- American Inventors Protection Act
- Recover term if more than three year pendency
- Complex calculation
- PTA is on the face of the patent and PAIR

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<td>de Haan et al.</td>
<td>Date of Patent: *Jun. 4, 2002</td>
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**Inventors:** Piter de Haan, Oos, Thodoru Antonia Maria Lambréga v.d. Hurk, Vogel, both of (NL); Ryoichi Morita, Naka (JP); Adriano Cornelis Pierre Rovers, Sro; Joostinus Antonitus Maria Zwinkels, Nistelrode, both of (NL)

**References Cited**

**Notice:** This patent issued on a continued protection application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(b) by 18 days.

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 18 days.
Interference

- Two inventors claim the same invention.
  - Who was the first to invent? Determines the patent right.

- Claims can be lost due to an interference

- Caution: not covered by all legal status databases and not on front page of patent
  - Does the patent still claim the item of interest? What patent has those claims?
  - US 6,323,489 lost claims 1-10 due to an adverse judgment in an interference
Infringement

- All or part of patent can be lost in litigation
- Caution: not covered by all legal status databases and not on front page of patent
- US 5,573,780
  - “the patents in the suit are invalid. Judgment is entered in favor of defendant, Merck & Company, and against plaintiff, Apotex Corp.”
Interface Between Patent Term and Regulatory Exclusivity

- Hatch-Waxman Extension
- PTO
- Patent Term
- FDA
- Regulatory Exclusivity

Effective Product Exclusivity
Hatch-Waxman Extensions

- Allows recovery of part of the time spent for FDA approval
  - Up to 5 years extension subject to 14 year cap post approval
- 14 year rule not consistently covered by legal status databases or certificates of extension
- Information is not on the patent front page
- Orange book has errors and omissions
Hatch-Waxman Extensions

- In this case, the patent term expires on February 21, 2006 instead of July 14, 2007 (September 17, 2004 + 1030 days) because of the 14 year rule.

- Caution: Check USPTO website www.uspto.gov for patent term extensions.

**United States Patent**

**Inventors:** Tanno Itoh, Katayamashi, Hideo
Kato, Fukusaki, Nozoe Osamu, Eiichi
Koshibuka, Toshi, Katayamastu,
Tomie Sumii, Katsushikibara,
Noriyuki Yagi, Katayamastu, all of
Japan

**Assignee:** Hokuriku Pharmaceutical Co., Ltd., Katayamastu, Japan

**Patent Number:** 4,528,287

**Date of Patent:** Jul 9, 1985

**FORBIDDEN PATENT DOCUMENTS**

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<tr>
<th>FOREIGN PATENT DOCUMENTS</th>
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<tr>
<td>50-10980 1/1976 Japan 544,363</td>
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<td>56-29483 2/1982 Japan 544,363</td>
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<td>2565275A 5/1975 United Kingdom 544,363</td>
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**Abstract**

The invention is concerned with the novel piperazine-quinoline-3-carboxylic acid represented by formula (I)

**Certificate of Patent Term Extension**

This is to certify that there has been presented to the

COMMISSIONER OF PATENTS AND TRADEMARKS

an application under 35 U.S.C. § 156 for an extension of the patent term. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

1,030 DAYS

with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).
New Chemical Entity (NCE) Exclusivity May Exceed Patent Term

- NCE market exclusivity for five years
- Fondaparinux Sodium
  - Patent expires August 19, 2003
  - NCE market exclusivity expires December 7, 2006
- Caution: Market exclusivity data is not available in patent legal status databases
Data Exclusivity (DE) May Exceed Patent Term

- DE for 3 years
- Caution: not in legal status databases
- Fluoxetine Hydrochloride
  - Product Patent US 4,314,081 expired (it had both Hatch-Waxman and Pediatric exclusivity)
  - New Dosage Form exclusivity until February 26, 2004
Orphan Drug Exclusivity (ODE) May Exceed Patent Term

ODE for 7 years
Anagrelide Hydrochloride
Patent US Re. 31,617 expired on January 13, 1993, ODE until March 12, 2004
Orphan Drug exclusivity information is not available in patent legal status databases.
Pediatric Extensions

- Adds 6 months to each patent listed in the Orange Book.
- Pediatric extensions are not in legal status databases.
- Alendronate Sodium
  - Each patent is extended 6 months by pediatric exclusivity.
  - Including US 4,621,077 that has a 1,371 day extension.

Pediatric Extensions

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If additional clinical trials are required for Rx to OTC switch, three years market exclusivity maybe granted

- Prevents generic OTC versions of product from being launched
- Omeprazole approved for OTC and granted three years market exclusivity

Caution: not in legal status databases
ANDA 180 day exclusivity

- First generic to file paragraph IV certification entitled to 180 day exclusivity
  - Moexipril
  - Teva summary judgement of non-infringement of a US patent (US 4,743,450)
- Caution: not in legal status databases
Conclusion

- You cannot just look at the front page and determine the patent expiration date.
- You should always look at the front page of a patent to cross-check your search results.
- Databases have limitations and omissions.