Global Challenges Report Patent-based Analysis of the WHO's 2013 Model List of Essential Medicines

Reed Beall and Amir Attaran
Population Health
Faculties of Medicine and of Law

Université d'Ottawa | University of Ottawa

uOttawa
L'Université canadienne
Canada's university

www.uOttawa.ca

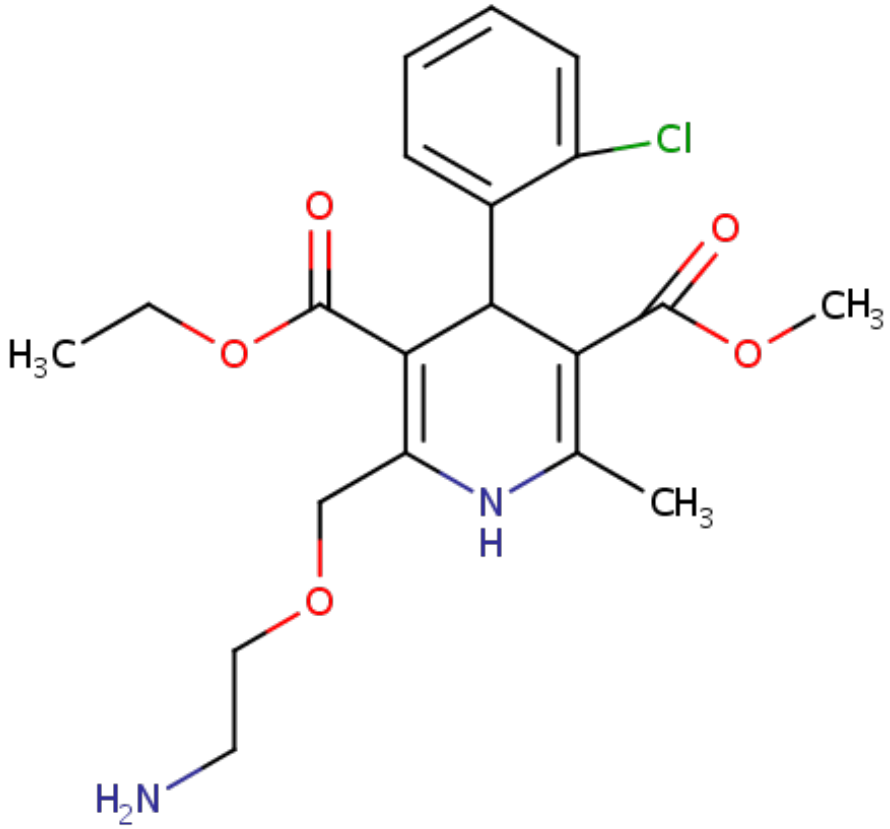
Talking points

- Background information – why int'l med patent info hard to get
- Methodology – our approach and experience
- Results – # of medicines patented and where
- Implications and solutions – for research and for policy

Background information

- WHO's Model List of Essential Medicines
- Why is patent status important?
- Why is medicine patent information so hard to find?

Background information:
Why medicine patent info hard to find



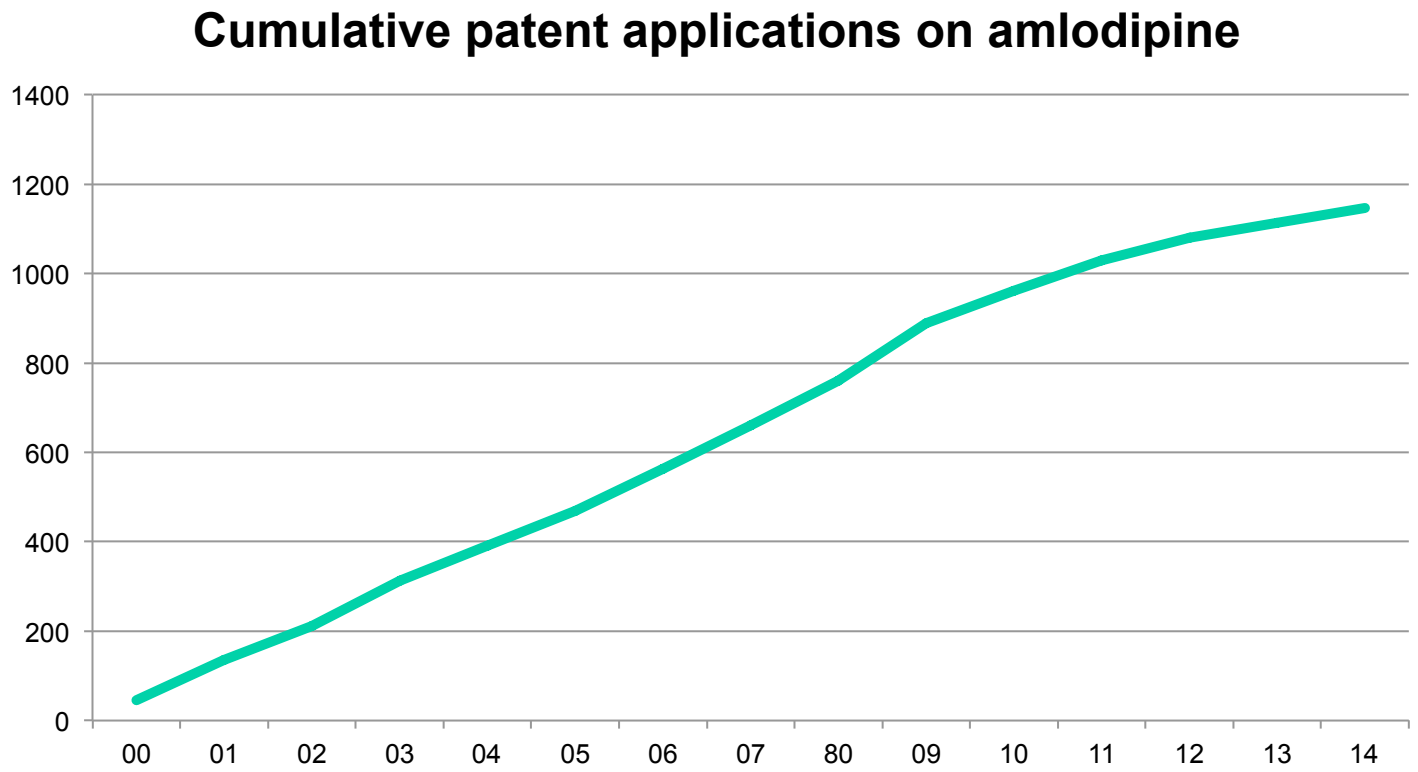
Background information: Why medicine patent info hard to find

- delta.-Amino-.gamma.-hydroxy-.omega.-aryl-alkanoic acid amides of formula I(see formula I)wherein R1 is hydrogen, hydroxy, lower alkoxy, cycloalkoxy, lower alkoxy-lower alkoxyor free or esterified or amidated carboxy-lower alkoxy, R2 is hydrogen, lower alkyl,cycloalkyl, lower alkoxy-lower alkyl, lower alkoxy-lower alkoxy-lower alkyl, cycloalkoxy-lower alkyl, hydroxy, optionally lower alkanoylated, halogenated or sulfonylatedhydroxy-lower alkoxy; amino-lower alkyl that is unsubstituted or substituted by loweralkyl, by lower alkanoyl and/or by lower alkoxycarbonyl; optionally hydrogenatedheteroaryl-lower alkyl; amino-lower alkoxy that is substituted by lower alkyl, by loweralkanoyl and/or by lower alkoxycarbonyl; oxo-lower alkoxy, lower alkoxy, cycloalkoxy,lower alkenyloxy, cycloalkoxy-lower alkoxy, lower alkoxy-lower alkoxy, lower alkoxy-lower alkenyl, lower alkenyloxy-lower alkoxy, lower alkoxy-lower alkenyloxy, loweralkenyloxy-lower alkyl, lower alkanoyl-lower alkoxy, optionally S-oxidised lower alkylthio-lower alkoxy, lower

Background information: Why medicine patent info hard to find

INN: amlodipine

Background information: Why medicine patent info hard to find



Background information

- Medicine patent information is hard to find, for many reasons:
    - Patents are filed before a generic (INN) name exists
    - Compound, (co-)formulation, process, method, device
    - Type of protections varies by country (as does the expirations)

- Difficulties not unique to medicines
    - Not all patents block the entry of competition
    - Many claims in same patent
    - Legal status (application, grant, lapsed)

Methodology – what's a 'patented' medicine?

- US and Canada served as base jurisdictions

- Patents listed in the Orange Book and Health Canada registries
  - Recorded patent numbers in a database
  - But excluded if generic competition existed in US or Canada

- Inherited data from two previous studies that ruled out many medicines (Attaran, 2004 and Kowalski et al in 2009/11)

Methodology (continued) – where is it patented?

- Use US and Canadian data to connect to int'l patent families
- INPADOC and Derwent via Thomson Innovation
  - 2 strategies patent grouping: automated (INPADOC) & non-automated (Derwent)
  - (Did not use TotalPatent because same country coverage)
  - Enhanced INPADOC data
- Note: we call this the 'linkage methodology'
- All countries excluding high income or very high HDI
- After this process, we had our preliminary report for each drug

Methodology – is it accurate?

- Why do we need company validation?
  - Important for (i) legal status, (ii) country coverage
  - Application or patent #s, expiration, legal status
    - Correct these, filled in gaps where countries missing

- Why should we listen to supplier companies?
  - Doing so gives us the “worst case” and therefore most conservative results, because companies may have an incentive to exaggerate patents, but never to conceal them.
  - Because it’s money to them, companies have the greatest possible interest in keeping accurate patent records.

Methodology: Data validation by supplier companies

- WIPO helped liaise contacts
- Some companies were reluctant.
- Only one company, Cipla, outright refused to provide its patent data, after several requests stretching over 6 months.
- Only one company (InSite) remained non-respondent.

- Validation of preliminary data took about 9 months.

Results – which MLEM drugs are patented…

- 95% of the drugs on the 2013 MLEM are off-patent
  - This is now about 92% with 2015 MLEM update
- Most patented meds are still for HIV, but now also hepatitis and cancers
  - With new update, also drugs for TB and reproductive health, including device-medicine combinations (implant, ring)
- See the report for exact list

- Demographic and epidemiological transitions beginning to be reflected in MLEM

Results – where are they patented?

- Developing countries covered by each patent portfolio varies widely from less than 1% to 44% with a median of 15%
- Statistical models included: GDI, HDI, Gini, Rule of Law, population, % healthcare expenditure, life expectancy, edu.
  - Most elegant model (explains 44% of pattern, R^2=0.44):

    (i) Population (best predictor)

    (ii) GDP per capital (half as strong as #1)

    (iii) Proportion of GDP on healthcare (half as strong as #2)
  - Holding the other two factors constant…

    +1 million people = an increase in .07 patents

    +$1000 in GDI per cap = 1.2 patents

    +1% of GDP expenditure on healthcare = 1.14 patents
- Patents filed where there's market and manufacturing prospects

Results – assessed pre-/post-validation

- (In)accuracy of using US/Canadian data to pull int'l patent families for knowing med's patent status….
  - Most common method for quick info on med's patent status
  - 70% of postive country-patent combos correct
    - 30% were incorrect
  - 89% of negative results were correct
    - 11% were incorrect
  - Overall, linkage method was 83% accurate
  - BUT, this method is very **imprecise by individual product**, its error is inconsistent, especially on positive results
    - Results as low as 46% correct by product

Implications – for policy

- Decision-makers may misdirect policy attention where necessary.

- Without trust in data to settle disagreements about how best to manage patents and access to medicines, stakeholders divide along ideological lines and stalemate. The result sadly reinforces the status quo, and inhibits cooperation.

Implications – for companies

- Only supplier companies have most correct and up-to-date records on products' international patent portfolios.

- Voluntary international medicine patent transparency for essential medicines is gaining hold. Examples:
  - GSK's announcement a few weeks ago, joined Merck KGaA
  - At least 6 companies working with Medicines Patent Pool disclosed records for select HIV drugs
  - Consensus should be built to make disclosure the new norm

  BUT not companies agree with transparency. InSite was uncooperative, and Cipla flat out refused.

Solutions - int'l drug patent register

- Central int'l register maintained by neutral entity (WIPO? MPP?)
- Information would ideally include
  - Patent information: application and patent numbers, expiration dates, what is protected (compound, process, formulation, etc), date when information was updated
  - Information on where companies are and are not enforcing patents
  - Portal for companies to exhibit their initiatives in support of affordable access to medicine
- WHO was mandated in 2008 to support such a database. See WHA Resolution 61.21, section 5.1(c).

Correspondence to:
Reed Beall
PhD Candidate
Population Health
Faculty of Medicine
Faculty of Law

Email: Reed.Beall@uottawa.ca
Tel: +1 613.562.5800 ext 2645
Web: reed-beall.squarespace.com

Scheduled degree completion: Dec 2016

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