

# Patents: Effectiveness of Exceptions and Limitations in the Context of Development

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31<sup>st</sup> January 2014

# Overview of Presentation

- Introduction and Background
- Patents as tools for Innovation
- Key Exceptions and Limitations in a Development Context
- Beyond Patents - Global Health Perspective
- Conclusions

# Introduction and Background

## COHRED (Council on Health Research for Development)

- To provide effective solutions in support of LMICs building their research and innovation systems for health and development.
- 20<sup>th</sup> Anniversary in 2013: (origins in 1990 Commission on Health Research for Development : the 10/90 Gap).
  - Country level support
  - Support and tools for increased capability
- MIHR ( Centre for Management of Intellectual Property in Health Research and Development) (Rockefeller Foundation)

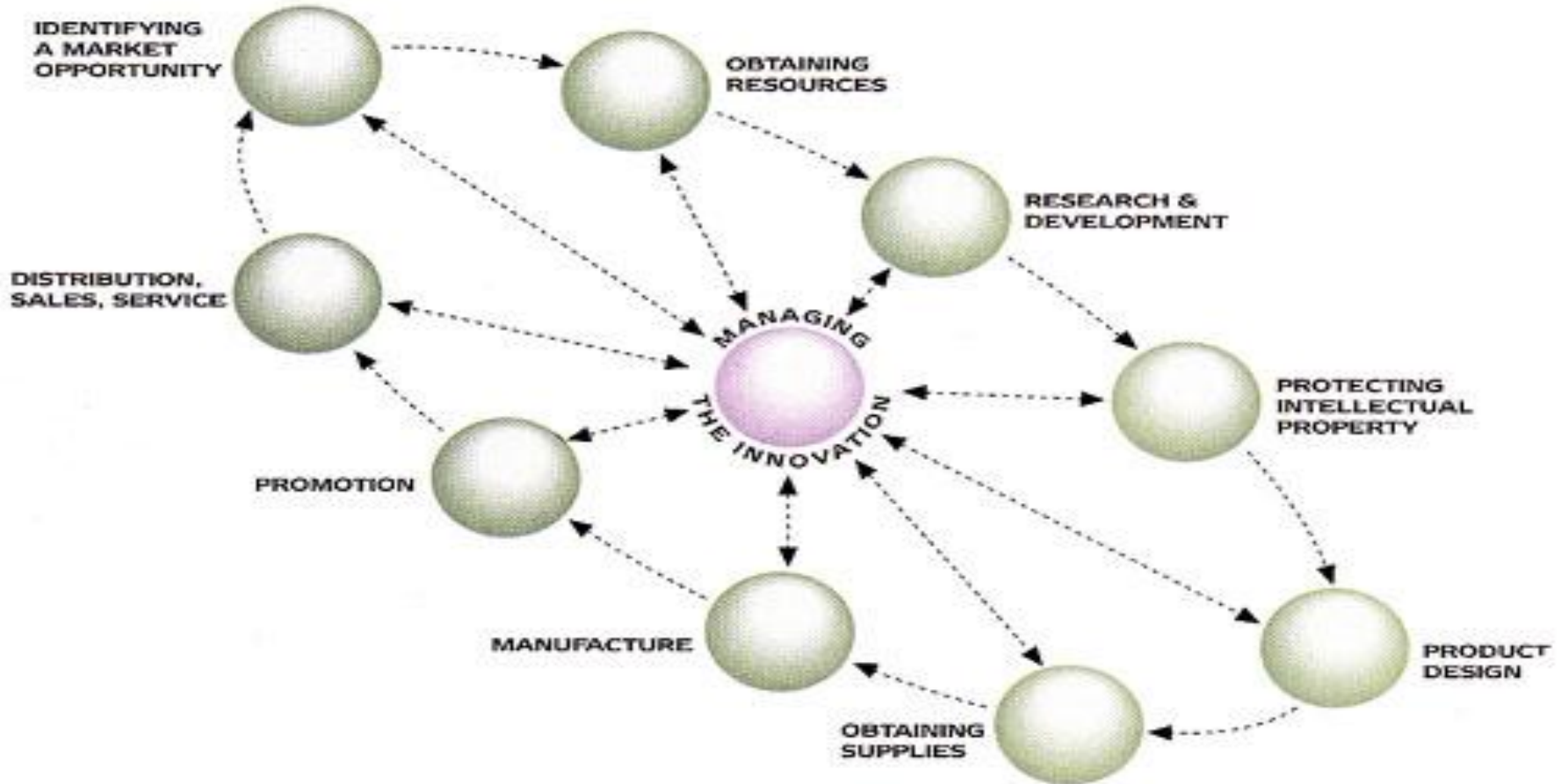


*Research and Innovation for Health...building systems, boosting development.*

# Patents as Tools for Innovation in Market-Based Systems

- Patent origins traced back to Venice in 1450's.
- 2.35M applications filed in 2012: Fastest Growth in 18 years.
- Patents are more important for some industries than others – notably engineering; electronics, chemicals and pharmaceuticals.
- Patents are only one tool in any innovation story.
- Patents are a tool of market-based innovation models.
- They are NOT:
  - in themselves either necessary or sufficient for innovation;
  - they are only effective if can be enforced.
- It is HOW they are used that is ultimately important for innovation and economic development. Our choice.

# Managing Innovation



# Key Exemptions; Limitations and Impact on Development

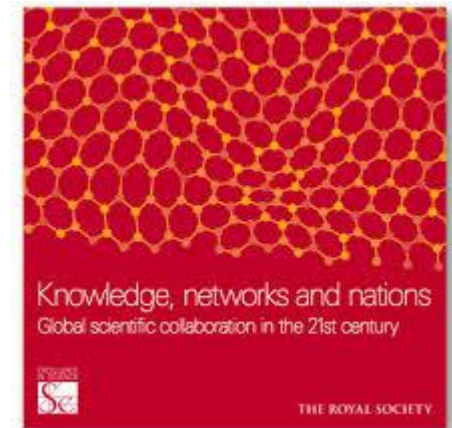
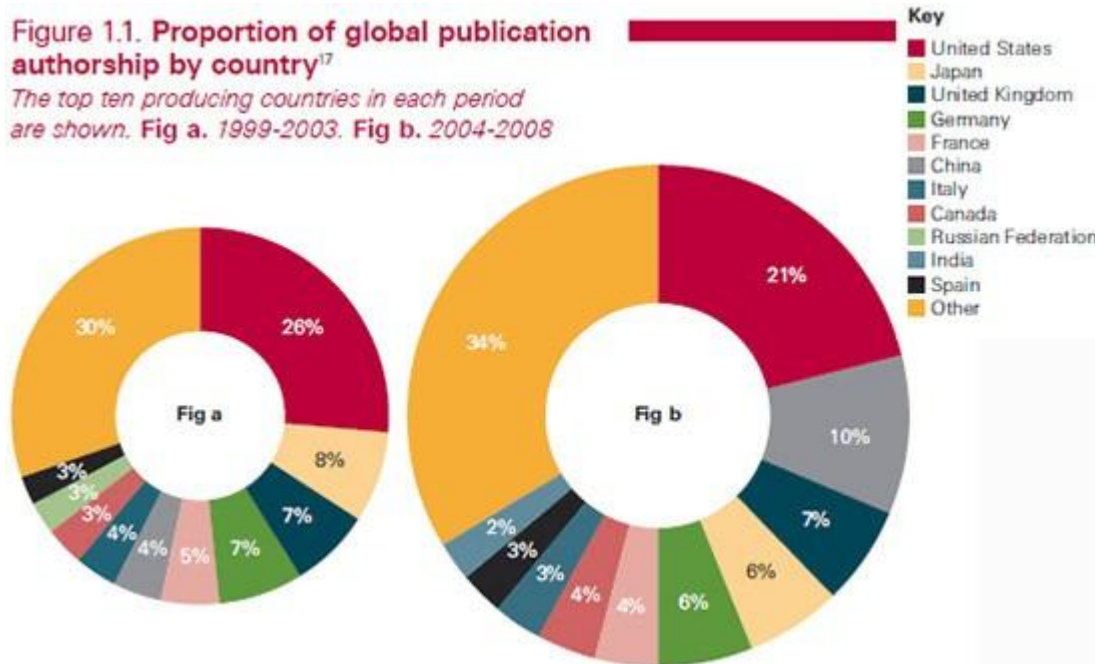
- Exceptions and Limitations:
  - Research exemption
  - Bolar exemption
- Challenges beyond Exceptions and Limitations:
  - Scope of patents – Myriad Genetics Case
  - Risks of “open” and not patenting
  - Patents in a scenario of “no market”
- Creativity in Use
  - approaches from Global Public Health

# Research Exemption Background

*As Louis Pasteur once put it, 'Knowledge belongs to humanity, and thus science knows no country and is the torch that illuminates the world.'*

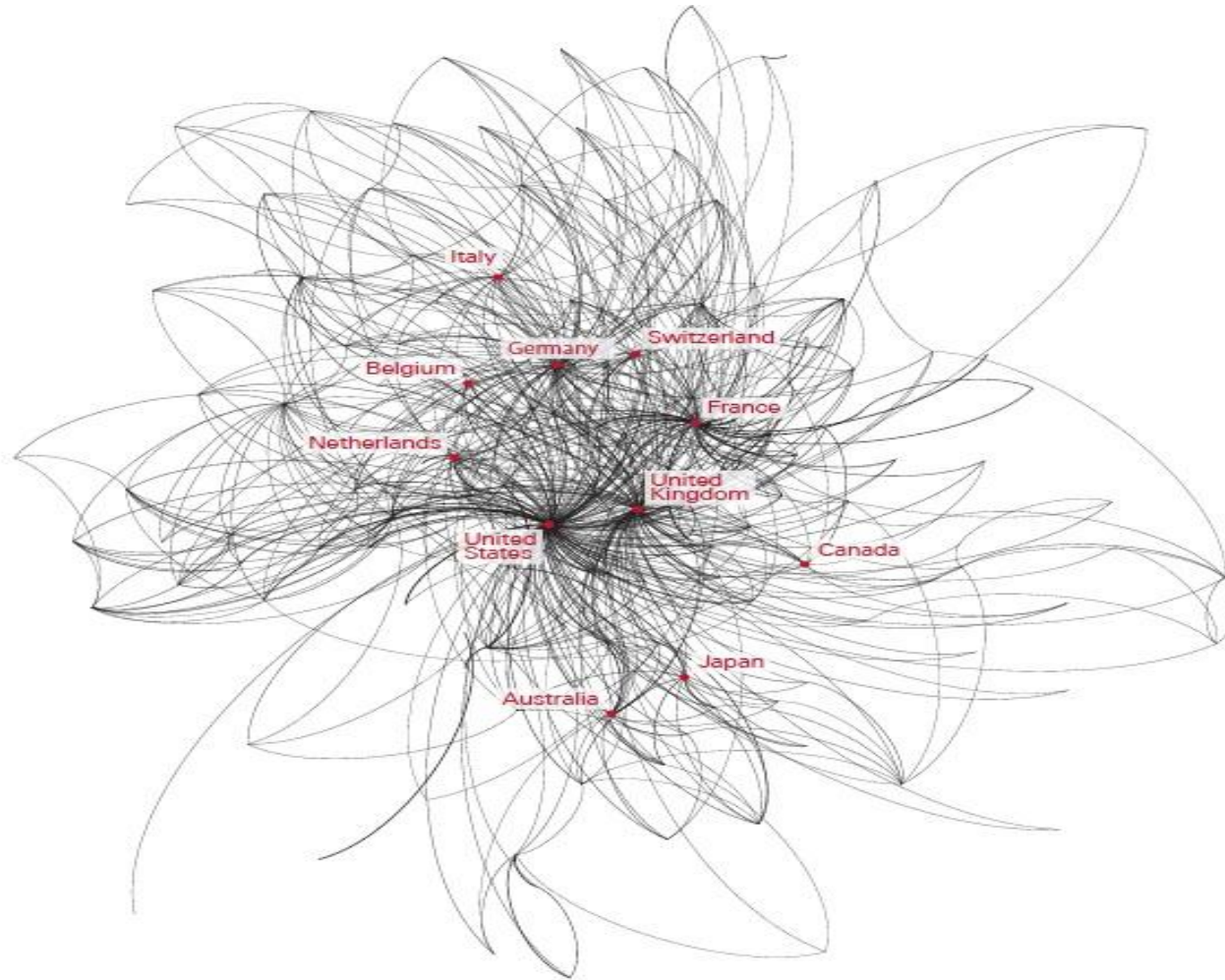
Figure 1.1. Proportion of global publication authorship by country<sup>17</sup>

The top ten producing countries in each period are shown. Fig a. 1999-2003. Fig b. 2004-2008



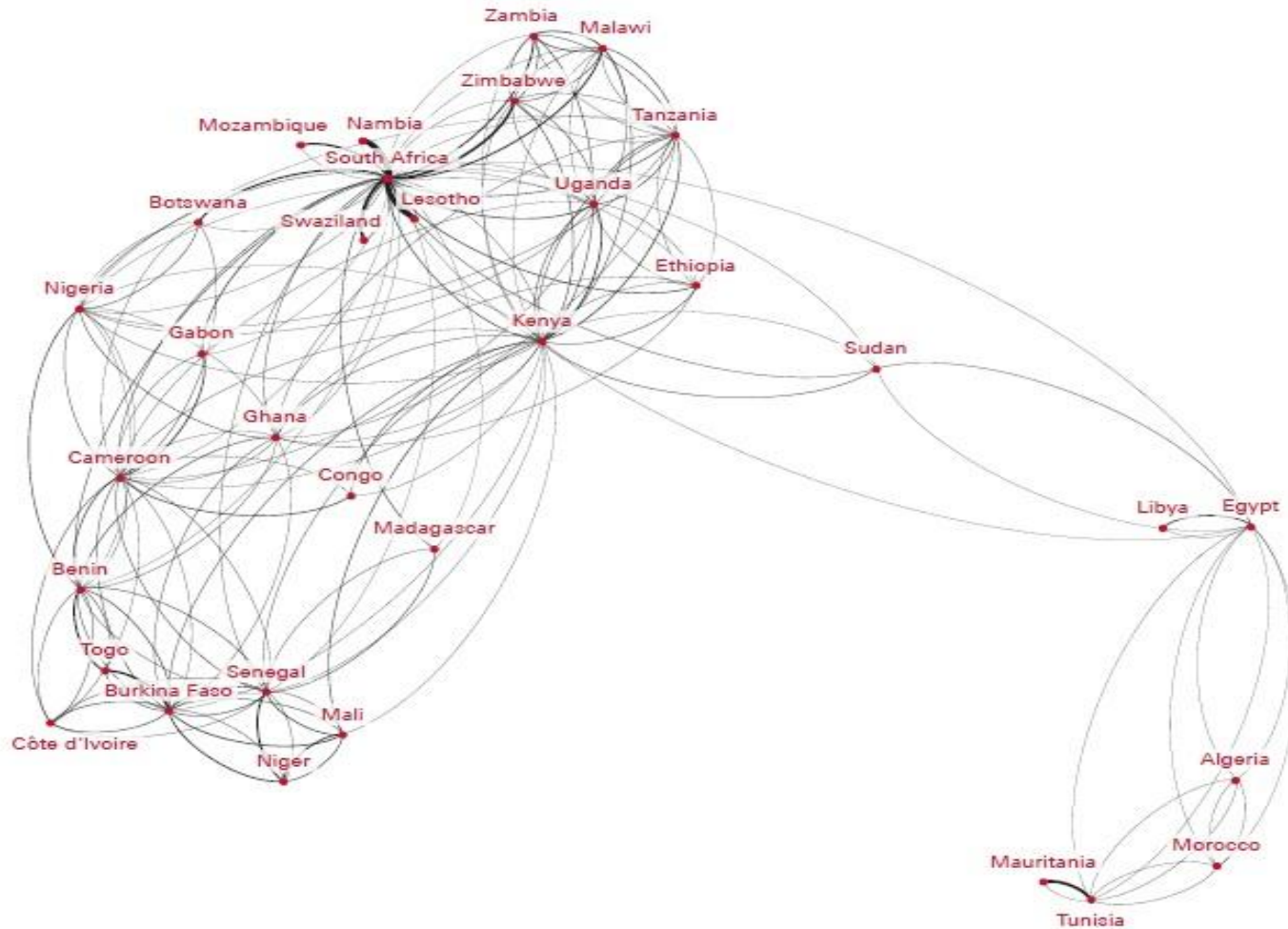


# Science Collaboration is Global





# Science Collaboration Across Africa



# Research Exemption In Global Science Context

- SCP/20/4 lays out the details
  - TRIPS (Article 30)
  - Almost universal acceptance in principle – but ? In practice
  - Not tested in WTO Dispute Settlement yet
  - Many different versions – no “one-size fits all”
  - Key proposal in WHO Global Strategy for Public Health
- Issues regarding private / non- commercial use – SCP/20/3
  - Narrowing of exemption due to blurring of commercial/ non-commercial activity : e.g. Patents in universities for commercialisation
- Examples:
  - Mabey vs Duke University in the USA (2002)
  - Core Valve Inc vs Edwards Life Sciences et.al UK (2009)

# Bolar Exemption

- Bolar Exemption (Regulatory Review)
  - Use of patented inventions in preparation for generic versions to obtain marketing approval – without the consent of the patent holder
  - Based on Roche Products Inc vs Bolar Pharmaceutical Company (1984)
  - EC Directive 2004/27/EC – confirmed this exemption.
- Indian Generic Medicines Industry
  - “Pharmacy of the World” 3<sup>rd</sup> largest producer in world
  - By 2020 Pharmaceutical sales in India estimated to be \$74bn ( 6 x 2010 level)
  - But 70% of population on less than \$2 per day
  - TRIPS compliant since 2006 ( Gable and Kohler, 2014).
- GLIVEC case
  - Comparative cost ( \$5,000 vs \$200 per month)

# GLIVEC (Novartis) Case

- GLIVEC (*imatinib mesylate*) treatment for Chronic Myloid Leukemia
- Section 3(d) Indian Patent Act
  - Bans “evergreening”
  - Confirms the right to implement public health safeguards under TRIPS
  - Challenges “incremental” innovation
- Supreme Court of India – final decision on 1<sup>st</sup> April 2013 – rejecting the appeal of Novartis. First rejected in 2006. (Gabble and Kohler, 2014)

# Other “Limitations” (1)

## Patent Scope:

- Myriad Genetics Case Study
  - BRCA-1 and BRCA-2 links to breast and ovarian cancer
  - Patents on the isolated DNA coding and related screening method ( early 2000).
  - In 2010 - US District Court held that the patents were invalid – not different from what existed in nature
  - In 2012 - US Court of Appeals + Federal Circuit Court - referred to Judicial Review the question of whether human genes are patent- eligible
  - In June 2013 the US Supreme Court ruled against Myriad Genetics patents

# Other “Limitations” (2)

- Is it in “public interest” NOT to patent?
  - Myriad example
  - Neglected Diseases for which there is no market
- Chagas Disease Case Study:
  - “The new HIV/AIDS of the Americas (Hotez et al. PLoS)
  - 8-10 million cases - one of most common for bottom 100m in LAC regions: 2m in Argentina (also now in USA)
  - Chronic disease of poverty – infectious cardiomyopathy
  - Estimated to cost Brazil loss of \$1.3bn in wages and productivity ( DNDi)
  - Two treatments : 40 years old:
  - No Market: No Medicines



*Vinchuca – “kissing bugs”*

# Other “Limitations” (3)

## CHAGAS DISEASE – Creative Approaches using Philanthropic Funding

- One World Health (PATH)
  - Creative licensing from Yale and Uni of Washington (2004) for anti-fungal compounds : creating both a market and non-market opportunity
- Drugs for Neglected Diseases ( DNDi)  
IP Policy to restrict by:
  - Field of Use
  - Territory
  - Markets
  - FTO
  - Preference for public goods....



***“Knowledge always benefits those who have the most – not the communities that need it”***

Ricarda Preve.

<http://www.aljazeera.com/programs/witness>



# Other Creative Use Cases

- Patent Pools ( Medicines Patent Pool)
- BVGH : WIPO Re:search ( 44 agreements: 81 members)
- London Declaration([www.UnitingToCombatNTDs.org](http://www.UnitingToCombatNTDs.org))
- Access to Medicines Index: 20 Pharma Companies.



*Come a long way from the “Battle in Seattle”*

# But Far Enough?...

- Barriers Remain:
  - Understanding the Complexity
    - Not only of patents
    - But also of innovation systems and economic impacts
  - Imbalances in knowledge in LMICs
    - TRIPS and global frameworks
    - Local interest and objectives
    - Neutral agencies needed.
  - Resources
    - To re-balance knowledge and understanding
    - WIPO/ WTO/ WHO trilateral study – a good starting place.



# IP Handbook : Web Resources

Managing Innovation  
for a Better World

ipHandbook of Best Practices

<http://www.iphandbook.org/>



Editor in Chief: Anatole Krattiger (WIPO)





# COHRED TOOLS



[www.cohred.org](http://www.cohred.org)

# Final Reflections

- Turning Theory into Practice is a huge challenge
- Partnerships needed to meet scale of demand for understanding the complexity – WIPO and COHRED?
- The “long view” needed in patenting practice
  - To avoid unnecessarily broad claims that then need exclusions
- Taking the perspective of “What are we ultimately seeking to achieve through the IPR system?”
- How can we use the tools we have to make that happen?
- How can we ensure that **all** have access to the knowledge needed?

Thank You!