

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

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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

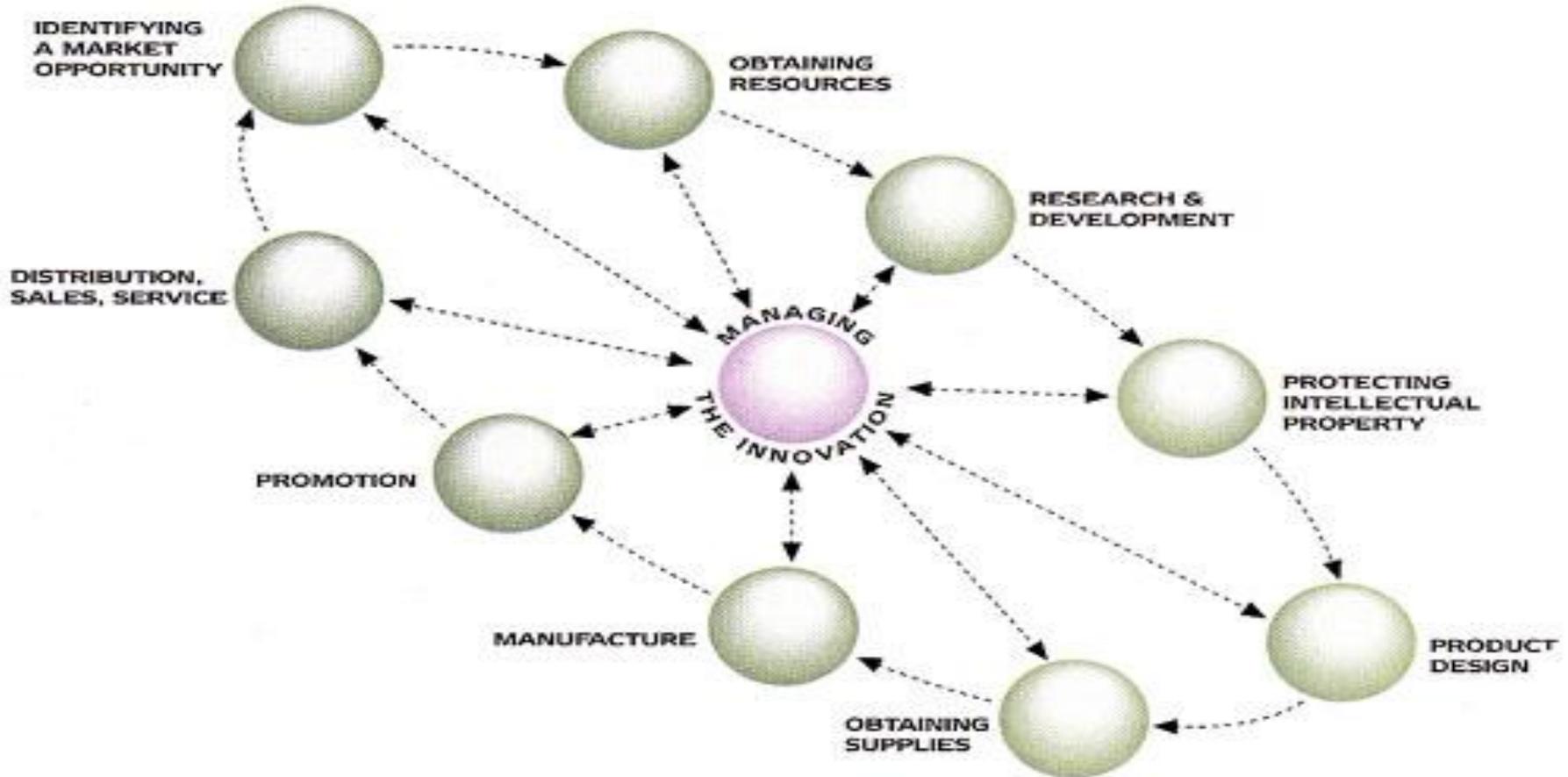
COHRED (Council on Health Research for Development)

- To provide effective solutions in support of LMICs building their research and innovation systems for health and development.
- 20th 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)

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

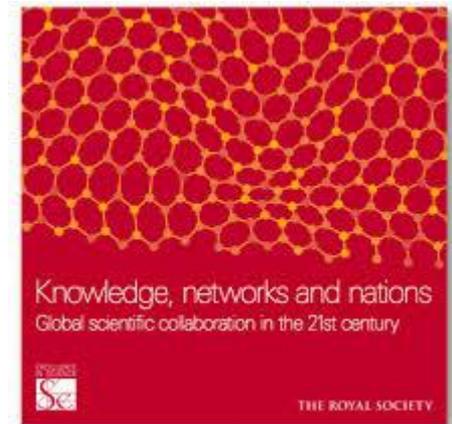
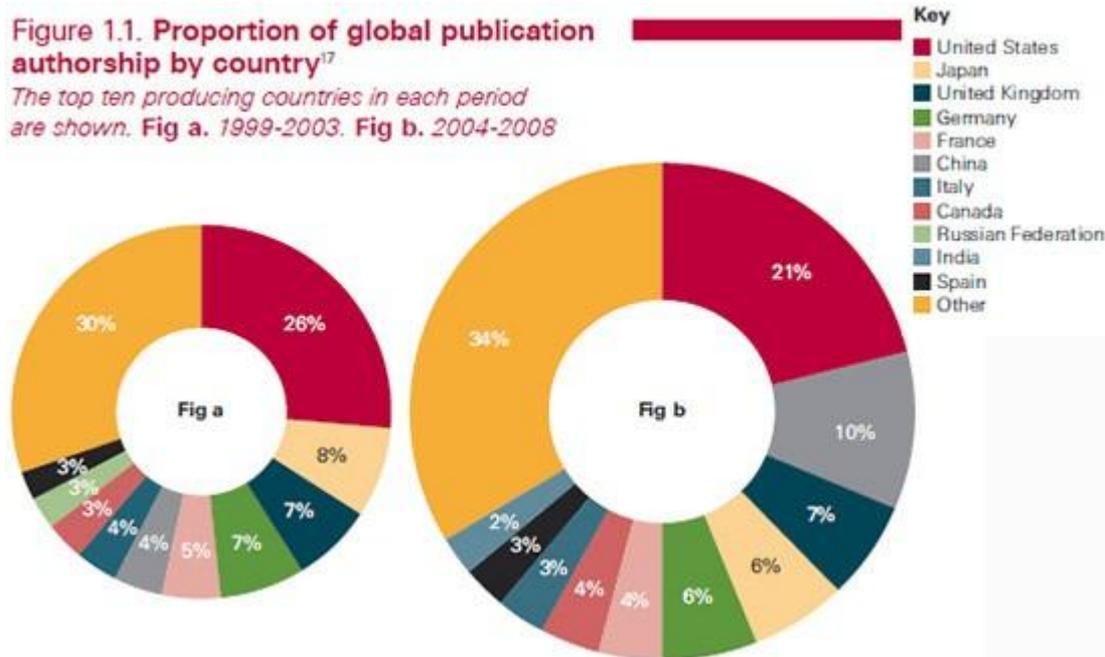
- Exceptions and Limitations:
 - Research exemption
 - Bolar exemption
- Challenges beyond Exceptions and Limitations:
 - Scope of patents – Myriad Genetics Case
 - Risks of “open” and not patenting
 - Patents in a scenario of “no market”
- Creativity in Use
 - approaches from Global Public Health

Research Exemption Background

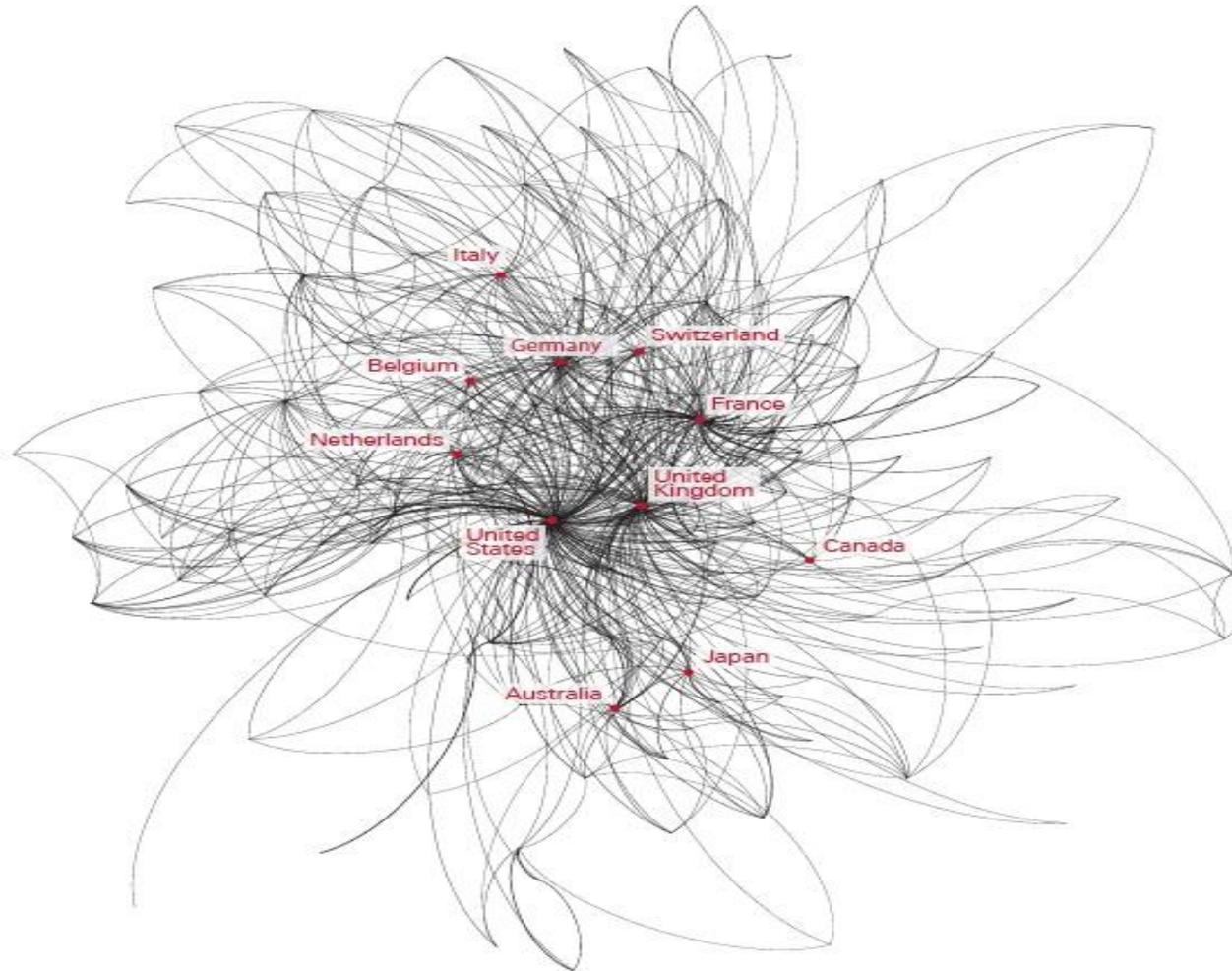
As Louis Pasteur once put it, 'Knowledge belongs to humanity, and thus science knows no country and is the torch that illuminates the world.'

Figure 1.1. Proportion of global publication authorship by country¹⁷

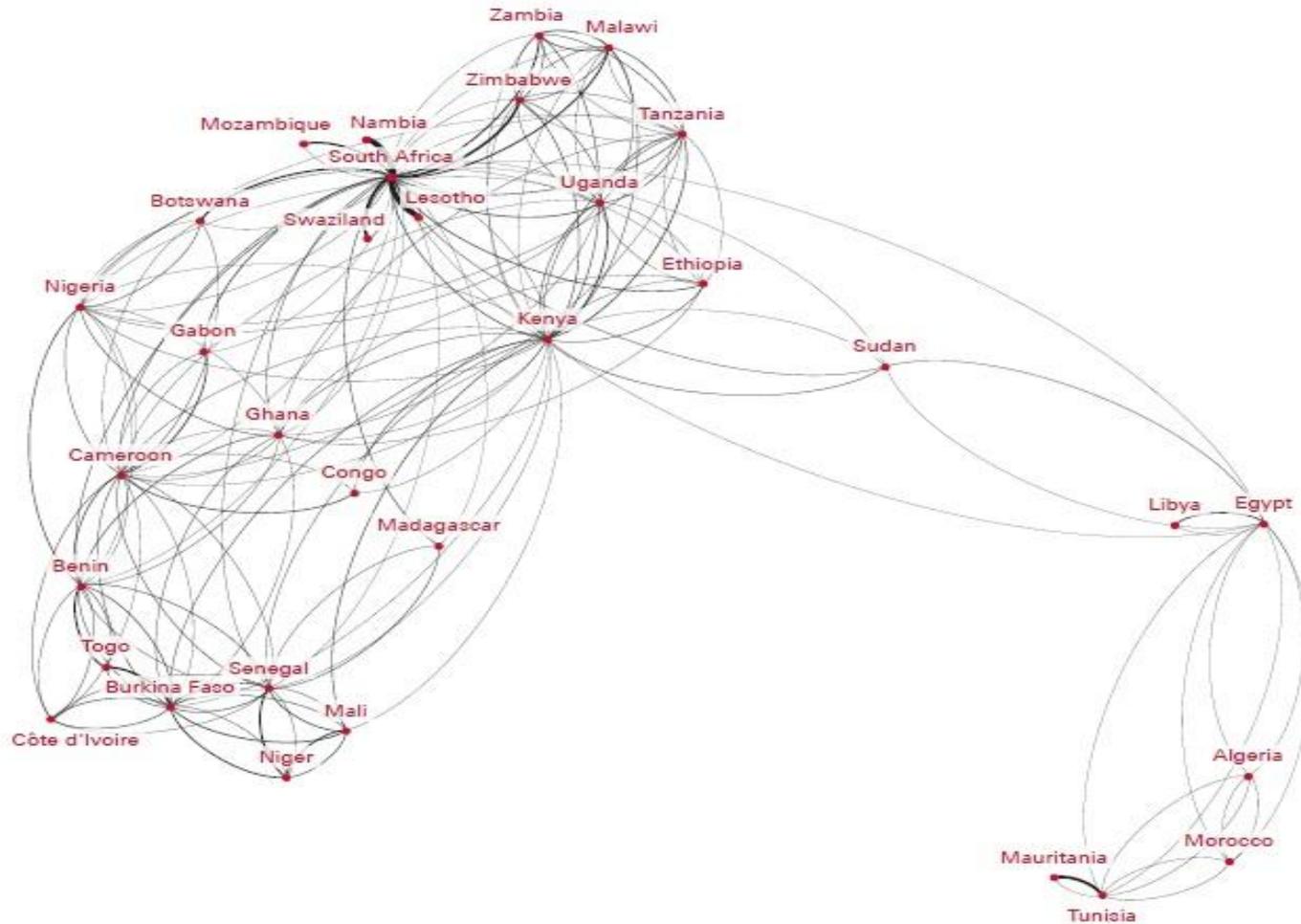
The top ten producing countries in each period are shown. Fig a. 1999-2003. Fig b. 2004-2008



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” 3rd 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 1st 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)
- 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

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!