

Philanthropy and Intellectual Property voluntary licenses: current trends and remaining challenges

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What is a license?

Contract between two parties = outcome of a negotiation process

- **Patent holder allows the contracting party to use the patent (to exercise the patented invention)**
- **Against a payment of royalties or free-of-charge**
- **For a defined period of time**
- **Worldwide or in specific countries (defined territory)**
- **Subject to additional conditions**

Socially responsible licensing

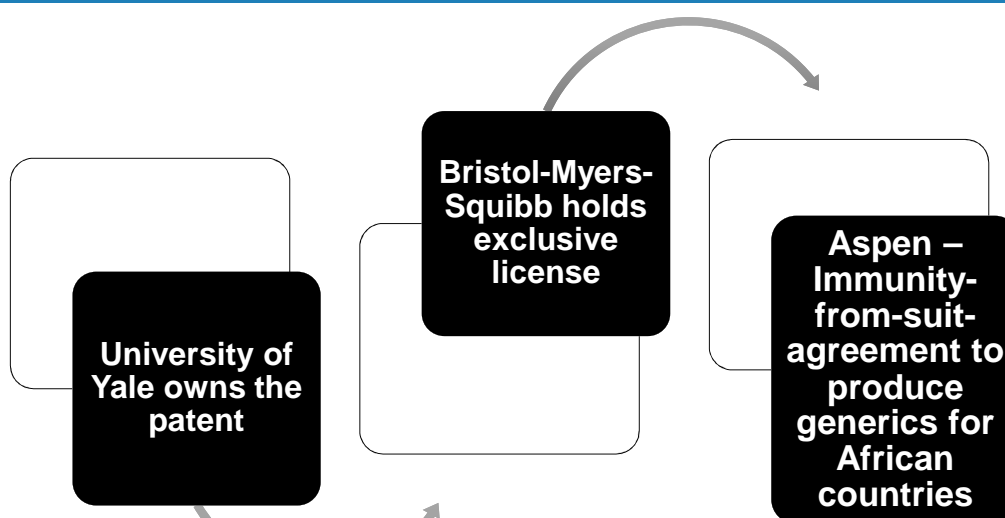
Objective:

- To ensure that licenses are negotiated in a way that facilitates access to the licensed product in countries in need of affordable prices/for patients

Adds a **dimension of social responsibility** to the economic dimension of licensing without necessarily compromising the business (in developed countries)

- When is a license socially responsible?

Civil society pressure: Stavudine in South Africa



Oseltamivir: Pandemic Pressure

Problem:

- Threat of H5N1 (avian flu) pandemic: patent holder faces explosive demand
- Countries threaten to use compulsory licenses to produce locally
- one compulsory license issued but finally not used

Solution:

- Worldwide call to apply for sub-licenses
- Royalty-bearing licenses to granted to four generic companies
- Limited to pandemic preparedness (emergency situation) allowing for governmental stockpiling

2001: Pharma companies sue South African Government over parallel imports - no voluntary license agreements

2001: WTO-Doha Declaration; stavudine case in South Africa (Yale - BMS - Aspen)

2002: Creation of Global Fund to Fight AIDS, Tuberculosis & Malaria

2003: Decision of South African Competition Authority with respect to ARVs: settlement involving license agreements with generic manufacturers

2003 - 2012: Compulsory licenses in Brazil, Ecuador, Ghana, India, Indonesia, Malaysia, Mozambique, Thailand, Zambia, Zimbabwe

2008: Adoption WHO Global Strategy & Action Plan on PH, innovation and IP

2010: Creation of the Medicines Patent Pool

2013: all originator companies with HIV products in the market have license/immunity-from-suit agreements

2014: first agreements on new hepatitis C treatments

What about Universities?

PubNo: WO/2014/045254 / PCT/IB2013/058772

Applicants: ERASMUS UNIVERSITY MEDICAL CENTER ROTTERDAM

Inventors: HAAGMANS, Bartholomeus, Leonardus; [...] ZAKI, Ali, Moh

HUMAN BETACORONAVIRUS LINEAGE C AND IDENTIFICATION OF N-TERMINAL DIPEPTIDYL PEPTIDASE AS ITS VIRUS RECEPTOR

"The invention provides a new previously undescribed Coronavirus isolated from cases of unexplained disease in September 2012 and identified herein as belonging to a newly recognized and previously undescribed species of human Corona Virus (HCoV), herein identified as HCoV-SAI or HCoV EMC or Middle East Respiratory Syndrome-Coronavirus (MERS-CoV)."

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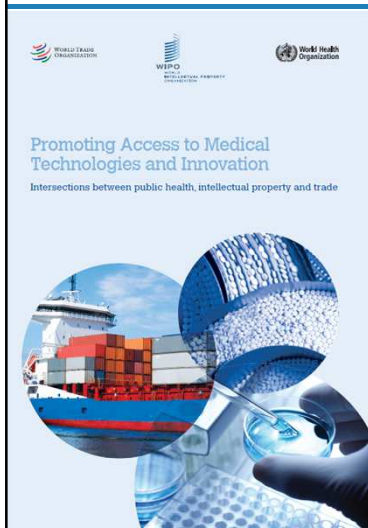
Concluding Remarks

- **Medicines Patent Pool & Access to Medicines Index motivate right holders to review and expand non-exclusive license agreements**
- **Challenges:**
 - upper-middle income countries
 - limited agreements on second & third line ARVs
 - other disease areas
- **Limited data as license agreements in general are not published; restrictive clauses in certain agreements**
- **Reduced prices through increased competition if licenses allow for robust competition**
- **Important that Universities adhere to socially responsible licensing policies!**

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Promoting Access to Medical Technologies and Innovation



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