Patents v Open Innovation: Incentivising ‘Medicines for the Many’
Dr Galit Gonen-Cohen
Head of Intellectual Property Law at Novartis, former VP and General Counsel, Europe, Teva
Pharma Patents and Open Innovation

Dr. Galit Gonen-Cohen, Head of Intellectual Property, Novartis Pharma
UCL, Institute of Brand and Innovation Law
27 November 2019
“The biopharma sector interacts within a wider ecosystem which also includes academic institutions and publicly funded research laboratories and institutes. This ecosystem is highly fragmented, however, with each actor working in isolation on a specific part of the process, with strong upstream intellectual property rights, leading to insufficient collaboration.”

“However, aggressive patenting strategies by companies have created closed rather than open innovation, blocking learning, diffusion and dynamic collaborations.”

Medicines for the Many: Public Health before Private Profit, Labour, 2019
The Journal Cell noted that:

“Among the most persuasive evidence for the value to humanity of the synergy between academic biomedical research and industrial product development has been a 50% decrease in deaths from heart attacks and strokes over the past 30 years in the developed world.”
8 of the top 10 best selling medicines in 2017 originated outside of the companies who sell them today.

Source: MTS Health Partners
Why does drug development require open innovation / collaboration?

- Partnerships & external innovation
- Managing IP in collaborations
Why does drug development require open innovation / collaboration?

“Diseases like Alzheimer’s and diabetes are looming tsunamis. Deciphering them could not be done by any single organization … no one company can do it.”

Elias Zerhouni, MD, Sanofi former president of global R&D
Partnerships & external innovation

- Open Source Innovation
- Crowdsourcing
- Other Forms of Collaboration and Partnership
- Public Private Partnerships to improve competitiveness
- Pharma Innovation Centers & Research Alliances to Leverage Synergies from Open Innovation
Gene Therapy for SMA Type 1: Evelyn's Story - click to view the video below or go to https://youtu.be/yRrqbvUv6gQ
Managing IP in collaborations

“IP is fundamental, as it provides the legal framework that allows valuable knowledge to be safely shared.”

The Wall Street Journal
Managing IP in collaborations

Publish vs IP
Novartis #1 for university collaborations

Control of IP can be shared

Clear value enables collaborations
Patents facilitate market-based transactions for converting useful ideas into products and help markets to assign and value the entitlements in a transparent way;

What would the alternative be: imposing forced coordination and non-market-based valuation of inventions? How can this be economically efficient and sustainable?

The Patent System is not perfect but is the best we have.
Thank you
Professor Matthew Todd
Professor of Drug Discovery at UCL
School of Pharmacy
The Cathedral and the Bazaar
Investment in Open Source Software

>$10Bn VC funds
In last 30 yrs

The Open Source Renaissance
Venture Deal Volume and Total Sizes
Things We Might Want to Develop

Can Open Source Research Lead to Investment by People Towards Things Like This?
What I Talk About When I Talk About Open

1st Law: All data are open and all ideas are shared
2nd Law: Anyone can take part at any level
3rd Law: There will be no patents
4th Law: Suggestions are the best form of criticism
5th Law: Public discussion is much more valuable than private email
6th Law: An open project is bigger than, and is not owned by, any given lab


Components

- Laboratory Notebooks
- Public To Do Lists/Discussion
- Open Data
- Community

Contributions

Students → Pharma
Go Big or Go Home!

As Novartis Exits, Who Will Make New Antibiotics?

By Julianna LeMieux - July 25, 2018

Opinion | 23 April 2019

We ignore the disaster in the antibiotics market at our peril

Jeremy Farrar
Director
Wellcome

There is no viable path for new drugs, however valuable they are to society.
We Know There’s Another Way, but
Patents vs. Exclusivities
One Possible Open Source Business Model

For example, one could introduce a new form of data exclusivity, administered by a regulator, that rewards drug development of an open source licensed molecule, pathway or process. In the short term, the data exclusivity would allow the drug developer a certain fixed term of market monopoly, by blocking others from relying on the approval data to file a generic application. This would allow the drug developer a fixed term to recoup some of its investment. The benefit of using data

(https://scholarship.law.umn.edu/mjlst/vol11/iss1/10/)

The Economics of Open Source Pharma – What about data exclusivity?

Me, Intermolecular Blog 2015

Ideation and implementation of an open science drug discovery business model – M4K Pharma [version 1; referees: awaiting peer review]

Al Edwards and team, Wellcome Open Res. 2018, 3:154
## Unpatented but Protected

**Table 1.** Examples of FDA new drug approvals from 1986 to 2014 brought to market with new chemical entity exclusivity but either (i) no patents listed in the FDA Orange Book, or (ii) listed patents expiring prior to new chemical entity exclusivity. The priority review eligibility and orphan drug status of each drug are also indicated. Source: Lietzan, E. The Myths of Data Exclusivity. Lewis Clark Law Rev 20, 91–164 (2016).

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<tr>
<td>1986</td>
<td>Provocholine (methacholine chloride)</td>
<td>Diagnosis of bronchial airway hyper-reactivity in patients who do not have clinically apparent asthma</td>
<td>+</td>
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<tr>
<td>1987</td>
<td>Levatol (penbutolol sulfate)</td>
<td>Mild to moderate arterial hypertension</td>
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<tr>
<td>1989</td>
<td>Anafranil (clomipramine hydrochloride)</td>
<td>Obsessive-compulsive disorder</td>
<td>+</td>
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<tr>
<td>1988</td>
<td>Optipranolol (metipranol hydrochloride)</td>
<td>Open-angle glaucoma and other causes of ocular high pressure</td>
<td>+</td>
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<tr>
<td>1989</td>
<td>Lariam (mefloquine hydrochloride)</td>
<td>Mild to moderate acute malaria</td>
<td>+</td>
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<tr>
<td>1989</td>
<td>Clozaril (clozapine)</td>
<td>Severely ill schizophrenic patients</td>
<td>+</td>
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<tr>
<td>1990</td>
<td>Hexalen (altretamine)</td>
<td>Refractory ovarian cancer</td>
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<tr>
<td>1989</td>
<td>Leustatin (cladribine)</td>
<td>Active hairy cell leukemia</td>
<td>+</td>
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<tr>
<td>1993</td>
<td>Trasylol (aprotinin bovine)</td>
<td>Reduction of bleeding during complex surgery</td>
<td>+</td>
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<tr>
<td>1993</td>
<td>Flumadine (rimantadine hydrochloride)</td>
<td>Influenza type-A infections</td>
<td>+</td>
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<tr>
<td>1995</td>
<td>Revex (naltetolene hydrochloride)</td>
<td>Partial reversal of effects of narcotics</td>
<td>+</td>
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<tr>
<td>1996</td>
<td>Proeamine (midodrine hydrochloride)</td>
<td>Orthostatic hypotension</td>
<td>+</td>
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<tr>
<td>1997</td>
<td>Normiflo (ardeparin sodium)</td>
<td>Prevention of blood clot formation following certain types of surgery</td>
<td>+</td>
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<tr>
<td>1997</td>
<td>Cortolpar (foroldopam mesylate)</td>
<td>Short-term management of hypertension</td>
<td>+</td>
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<td>1998</td>
<td>Inflasurf (callfactant)</td>
<td>Respiratory distress syndrome in premature infants</td>
<td>+</td>
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<tr>
<td>1998</td>
<td>Nilaparot (nilutamide)</td>
<td>Treatment of prostate cancer in men who have undergone surgical</td>
<td>+</td>
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Some Ownership .. Works for Open Drugs!
Professor Adrian Towse
Visiting Professor, LSE and Director Emeritus, Office of Health Economics
Pharmaceutical patents and open innovation

Adrian Towse, Emeritus Director and Senior Research Fellow, Visiting Professor, London School of Economics
My Agenda

- The R&D “machine” of the industry. Is it broken?
- “Open Science” and redefining the role of IP
- Value-Based Differential Pricing: Setting Optimal Prices for Drugs Cross-Nationally
- Sorting out the demand side
  - Health Impact Fund
  - Incentives to tackle AMR
- New drugs for TB
- Concluding thoughts
The R&D “machine” of the industry. Is it broken?

- The science isn’t broken. We are getting innovation – but rather is the cost of delivering it to health systems too high?

- Estimates of $2.6bn - $3bn for the cost of an NCE / NBE / NME (DiMasi et al. 2016). Much disputed (e.g. Prasad and Mailankody, 2017) but …

- A forthcoming paper by DiMasi and Grabowski on R&D cost argues that oncology R&D costs are high, because of (i) low success rates and (ii) the number of indications – lots of trials, and, cumulatively, lots of patients.

- But R&D cost per patient treated is almost certainly rising,

- Will fast-track access reduce R&D cost? Or shift to the post launch setting? Earlier access means higher expenditure for payers. And payers are asking for more evidence not less.

- Can we revolutionise R&D costs? One way is through IT. If we are able to track patients through EHRs and these capture health status and interactions with the health system, then we can change the costs of pre-launch RCTs and of post-launch RCT /observational studies.

- What about patent pools, open innovation, and open source innovation?
“Open Science” and redefining the role of IP

- Falling drug productivity and lack of understanding of key diseases
  - e.g. high Phase 1 failure rates @90%
- Sharing data and know how at early risky stages reduces duplication and increases knowledge
- IP leads to secrecy
- Recommends “the state ..push the threshold of pre-competitive and open source DD down the development pathway.”

Available at https://www.oxfordmartin.ox.ac.uk/downloads/academic/Transforming_Drug_Discovery.pdf
“Open Science” and redefining the role of IP – my thoughts

● Evidence is that successful companies patent and publish / share
  ● Patents involve the disclose of information

● There are key gains to be had from pre-competitive collaborations
  ● We may need Competition Authorities to look at the boundaries

● We can form innovation clubs in a disease area where the members share their knowledge of trials / studies but retain their IP
  ● This can lead to less duplication (fewer dry holes) and increased knowledge

● Pushing to registration requires a market / uptake. Makes more sense to have effective “pull” incentives
  ● I do not think governments / health systems should pay for effort. They should pay for success, i.e. what they want. Need to separate the demand side failure from R&D efficiency issues.

● There is an argument that much R&D is publicly funded and is not recognised
  ● This should be addressed in tech transfer deals and in e.g. Bayh-Dole type legislation
Value-Based Differential Pricing: Setting Optimal Prices for Drugs Cross-Nationally

- Optimal price levels and differences across markets can be achieved if each payer unilaterally sets an incremental cost effectiveness threshold based on its citizens’ willingness to pay for health and health related gain.
- Manufacturers will price to that threshold.
- Payers should limit reimbursement to patients for whom a drug is cost-effective at that price.
- If there are price differentials between patient subgroups matching value differences, prices will achieve first best static & dynamic efficiency.
- The resulting price levels and use within each country and price differentials across countries should be appropriate for second best static and dynamic efficiency.

Sorting out the demand side – Health Impact Fund

- IGH would have a donor funded pot
- Companies would compete for prizes (health impact awards)
- Each would receive a share of the total reward proportional to the health impact of the project
  - Expert committee assesses impact using IHME analyses
  - Maximum value cap per DALY delivered
- Companies then sell at cost of production
- No IP implications

Available at [https://healthimpactfund.org/en/](https://healthimpactfund.org/en/)
Sorting out the demand side – Incentives to tackle AMR

● More antibiotics needed due to build-up of resistance
  ● But existing treatments are off-patent and we want to restrict use of new treatments. Low revenue.
● Problem 1: an externality that we need to internalise
  ● Reform HTA methods to reflect full value
● Problem 2: we need to delink payment from volume
● New payment mechanisms can include:
  ● market entry rewards
  ● transferable exclusivity vouchers
  ● an “availability” contract

Available at https://www.ohe.org/publications/hta-and-payment-mechanisms-new-drugs-tackle-amr

Funded by the Wellcome Trust
The Center for Global Development and OHE (with a BMGF research grant) have developed a Market-driven Value-based Advance Commitment (MVAC) for TB.

Builds on success of the Advance Market Commitment (AMC) for pneumococcal vaccine.

MVAC differs in three respects:

- the price is based on expected value (DALYs delivered and offsetting health system costs)
- it is funded by the BRICS countries
- Payments guaranteed by an MDB e.g. the World Bank or Asian Development Bank.
Concluding thoughts

● Need to separate the demand side failure from R&D efficiency issues

● Not clear to me that IP is a barrier to tackling either

● We can “push” all of the way, but governments / health systems should not pay for effort. They should pay for success.

● Solving demand side problems with push is not likely to be efficient.

● Danger of mixing the positive and the normative here

● Of course, I may well be guilty of this ….
To enquire about additional information and analyses, please contact:

Adrian Towse
atowse@ohe.org

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Patents v Open Innovation: Incentivising ‘Medicines for the Many’