

NEW BUSINESS MODELS OF MEDICINES R&D: A CHANGING ROLE FOR IP?

PANEL: HOW THE IP SYSTEM BENEFITS GLOBAL ISSUES
INTERNATIONAL CONFERENCE ON IP AND DEVELOPMENT
WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO)

GENEVA, 20 MAY 2019

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IP AND ACCESS TO MEDICINES: 2 KEY QUESTIONS

1. IP (TRIPS) impact on medicines prices

- How to ensure affordability with IP monopolies?

2. IP (TRIPS) impact on R&D

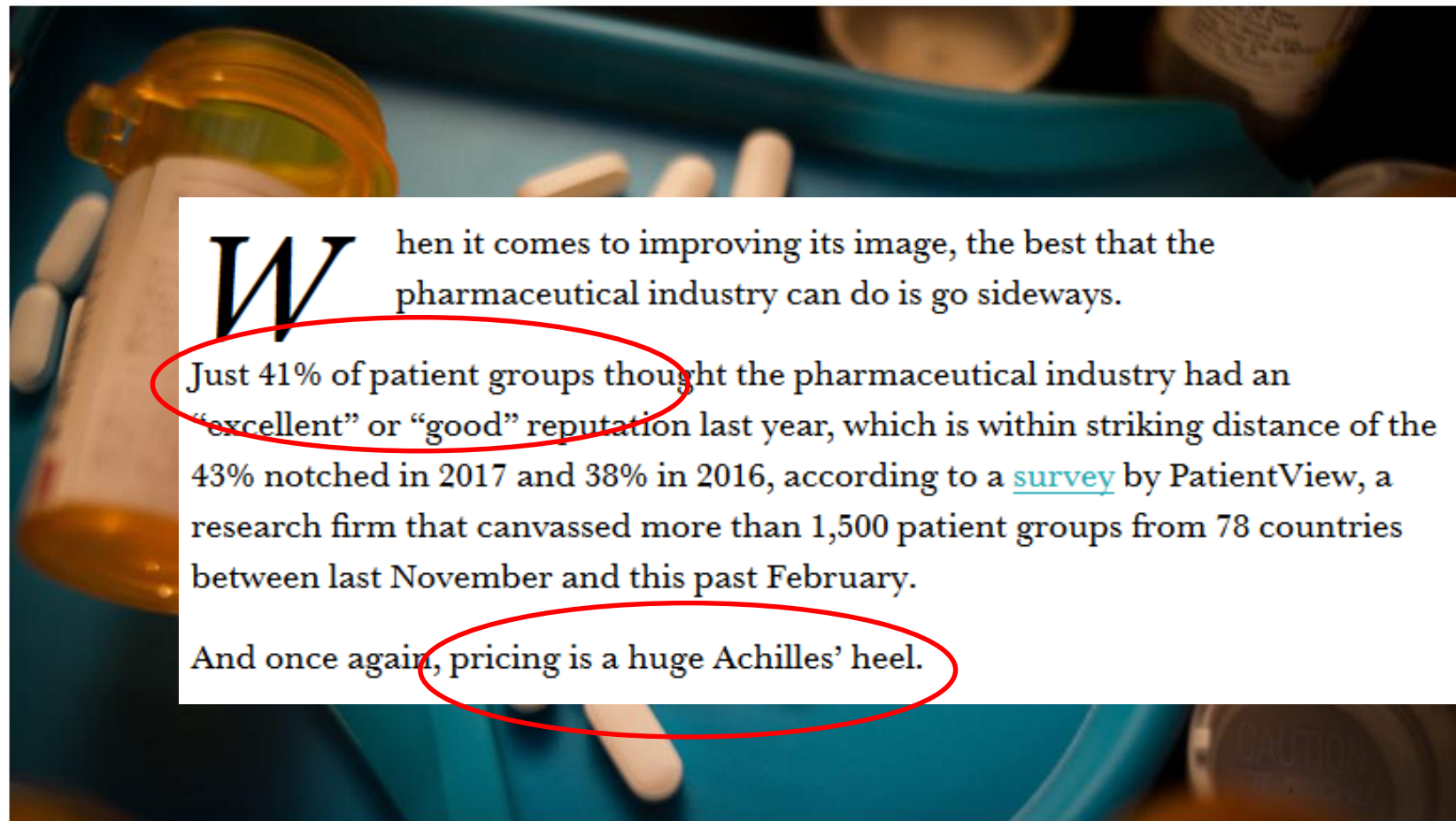
- How to ensure R&D where market fails?
 - Neglected diseases of poverty
 - Antibiotics
 - Outbreak-prone pathogens
 - Pediatric or rare diseases

PHARMALOT

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Pricing is taking a toll on the reputation of the pharmaceutical industry

By ED SILVERMAN @Pharmalot / APRIL 18, 2019



When it comes to improving its image, the best that the pharmaceutical industry can do is go sideways.

Just 41% of patient groups thought the pharmaceutical industry had an “excellent” or “good” reputation last year, which is within striking distance of the 43% notched in 2017 and 38% in 2016, according to a [survey](#) by PatientView, a research firm that canvassed more than 1,500 patient groups from 78 countries between last November and this past February.

And once again, pricing is a huge Achilles’ heel.

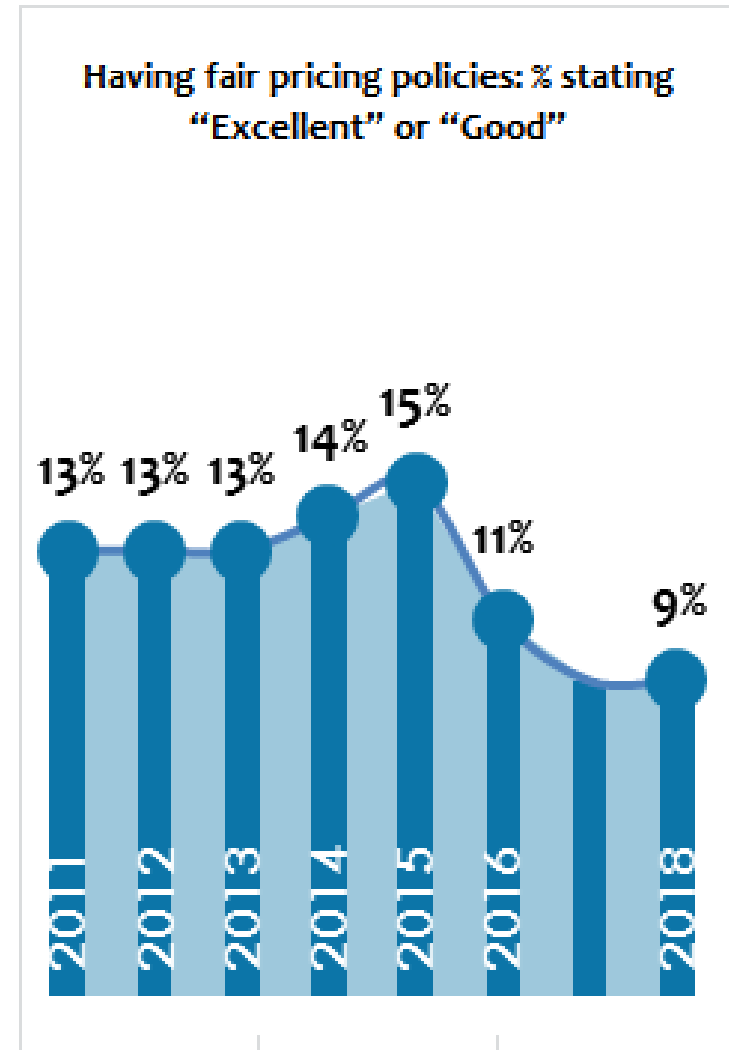
IS ACCESS TO MEDICINES STILL AN ISSUE?

Patient Groups survey:

- April 2019
- 78 countries, 18 languages
- 1,500 respondent patient groups.
- 81% of respondent patient groups worked/partnered with at least one pharma company.
- 46 companies analysed

Results: Drugmakers did excellent or good job of:

- Disclosing or explaining their pricing policies: 12%
- Having fair pricing policies: 9%



OLD

- IP → MONOPOLY RENTS → INNOVATION
- TRADEOFF
- BALANCE
- REWARD FOR INNOVATION = MONOPOLY PRICE PER PATIENT

NEW

- IP → DELINEATE UNITS OF KNOWLEDGE
- JOINTLY ACHIEVE INNOVATION & ACCESS
- REWARD FOR INNOVATION ≠ PRICE PER PATIENT (DELINKAGE)

THINKING OUTSIDE THE BOX: NEW BUSINESS MODELS OF R&D

Traditional pharmaceutical business model



Innovation **“balanced”** against
affordability

New pharmaceutical business model?



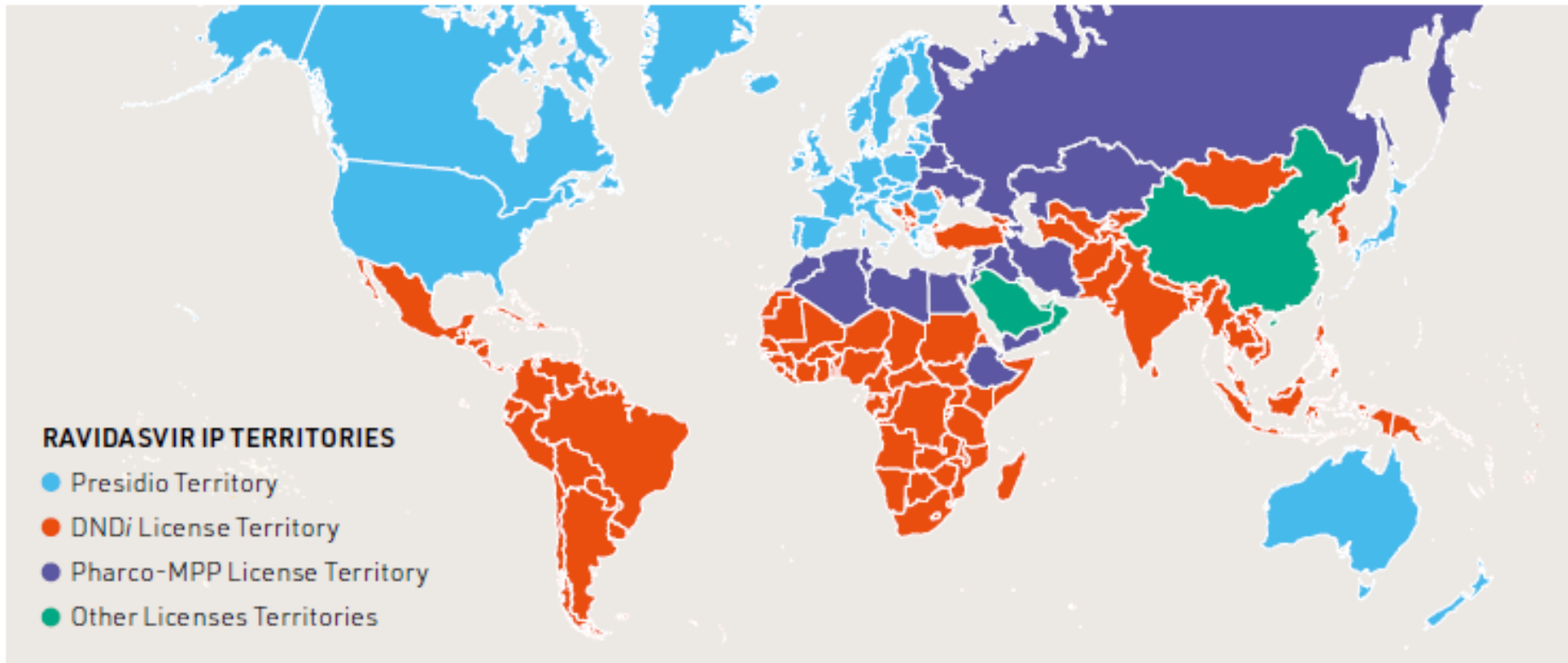
Innovation **with** affordability

DNDI'S HEPATITIS C STRATEGY

- Hepatitis C race: parallel R&D based on public knowledge
 - Gilead, Merck, BMS, J&J, AbbVie, various SMEs
- Gilead: 1st direct-acting antiviral (DAA) to market 2013
 - Sofosbuvir: \$84,000
- DAAs revolutionize treatment: 8-12 week cure
- 2015-17: BMS, Merck, AbbVie enter DAA market
- Slower: SME Presidio Pharmaceuticals: ravidasvir (RAV)

- Drugs for Neglected Diseases initiative (DNDi)
 - 2016 launches ravidasvir+sofosbuvir development
 - Clinical trials in Malaysia & Thailand
 - RAV patents licensed to DNDi, Medicines Patent Pool
 - MPP license royalties: 4% Low-, 7% Middle-, 12% High-Income Countries
 - Especially for MICs excluded from patent-holders' voluntary licenses and tiered-pricing
 - R&D paid by public & philanthropic funds

RAVIDASVIR LICENSED TERRITORIES



OUTSIDE THE BOX R&D: DNDI'S HEPATITIS C STRATEGY

April 2018

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Hepatitis C Drugs Can Cost \$84,000. This New One May Be Just As Good—But Cost \$300



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By SY MUKHERJEE April 12, 2018

Striking advances in [hepatitis C drug development](#) over the past five years have made the infectious, liver-wasting viral disease a curable one—if you can afford the drugs.

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THINKING OUTSIDE THE BOX: AUSTRALIA & HEPATITIS C

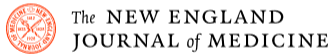


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Perspective

Universal Medicine Access through Lump-Sum Remuneration — Australia’s Approach to Hepatitis C

Suerie Moon, M.P.A., Ph.D., and Elise Erickson, M.A.

☰ Article Figures/Media Metrics

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HIGH PRICES CAN RESTRICT ACCESS TO MEDICINES IN RICH AND POOR countries alike. Australia’s approach to providing direct-acting antivirals (DAAs) for patients with hepatitis C virus (HCV) suggests that, under certain conditions, innovative

February 14, 2019
N Engl J Med 2019; 380:607-610
DOI: 10.1056/NEJMp1813728

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PERSPECTIVE FEB 14, 2019



AUSTRALIA'S “NETFLIX” MODEL HEPATITIS C

- 2014:
 - ~230,000 people with Hepatitis C
 - Hep C drugs: AU\$ 71,400 (\$54,000) per patient
 - Rationing to most severely ill
- 2015:
 - Lump-sum “prize” of ~AU\$ 1 billion (\$766m) over 5 years
 - Unlimited medicines supply → universal access offered
 - Initial government estimate: 61,500 patients
 - Effective per-patient price: AU\$ 16,260 (\$12,460)
- Our estimate 2016-21: 104,000 patients
 - Effective per-patient price: AU\$ 9600 (\$ 7352)
- Savings: AU\$ 6.4 billion or 93,000 patients

AUSTRALIA'S “NETFLIX” MODEL HEPATITIS C

- Public benefit:
 - Lower price and budget certainty
 - Each person = no marginal cost
 - Incentive to treat early
- Seller benefits:
 - Sizeable reward;
 - Revenue certainty;
 - Wide profit margin: Production cost << revenue
 - Production: ~\$50-\$100 per patient
 - Cost ~\$10 M vs ~\$766 M Revenue
- Largest real-world implementation of “delinkage”: reward innovation separately from price
- Similar to patent buyout

AUSTRALIA'S "NETFLIX" MODEL HEPATITIS C

- Broader use? Yes, when:
 - Cost of production is small % of price
 - Payer can reasonably estimate volume needed
 - Supplier willing and able to meet volume of demand
- Other health systems adopt Netflix for Hep C in 2019:
 - Louisiana state (US): \$35 million, 18 months, 10,000 patients
 - Washington state (US): elimination by 2030
 - NHS England (UK): £1 billion over 3 years, 113,000 potential patients
- More out-of-the-box thinking needed:
 - NHS (UK) \$660 M, 5 year offer to Vertex for group of cystic fibrosis drugs – no deal

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U.K. lawmaker challenges the government to issue a compulsory licence for Vertex

By ED SILVERMAN @Pharm



CRAIG F. WALKER/THE BOS



Blog

Global Health Law Groningen

Faced with unreasonable medicines prices, the Netherlands introduces pharmacy exemption in patent law.

Date: 23 February 2019

Author: GHLG Blog

By Ellen 't Hoen LLM, PhD, Medicines Law & Policy www.medicineslawandpolicy.org

3 CONCLUSIONS

1. Growing worldwide concern about innovation and access to medicines → concern about IP-related monopolies
2. New, outside-the-box thinking needed on IP, innovation and access to medicines:
 - Real-world evidence and experience of new business models
 - IP to delineate control over units of knowledge ≠ monopoly
3. Growing willingness worldwide to use flexibilities in IP rules to address access to medicines

Thank you, Merci, Gracias, 谢谢, благодарю вас, شكرا لكم

Comments welcome: Suerie.moon@graduateinstitute.ch