8 NEW SQUARE
INTELLECTUAL PROPERTY

Protecting Public Interest in Patent Law

Withholding injunctions in the public interest

Michael Conway

Barrister, 8 New Square
Lincoln's Inn, London

28 May 2020

When can an injunction be refused in the public interest? – statutory measures

Crown Use

- **ss. 55 – 59 Patents Act 1977**
- See *IPcom v Vodafone* [2020] EWHC 132 (Pat) for a recent overview
- s55(1) – permits use of a patented product or process without consent of the proprietor when authorised by a govt. dept. "for the services of the Crown" – including "for the production or supply of specified drugs and medicines…"

Compulsory Licensing

- **ss.46 – 54 Patents Act**
- s48: "Relevant grounds" for award of a compulsory licence include "*where patented invention is a product and demand for that product is not being met on reasonable terms*"
- Note period of 3 years after grant before compulsory licence can be sought

Discretion to refuse injunctions in the public interest

General

- *Coventry v Lawrence* [2014] UKSC 13
- More flexible approach to awarding damages in lieu of injunction
- *"hard to see how there could be any circumstances in which [the public interest] arose and could not, as a matter of law, be a relevant factor"* per L. Neuberger

Patents

- Consider statutory protections – courts should not be a route to effectively obtain compulsory licence without satisfying the statutory requirements: *Chiron v Organon No 10* [1995] FSR 325
- Enforcement Directive: remedies shall be *"effective, proportionate and dissuasive".*
- Injunctive relief will normally be given unless enforcement would be "*grossly disproportionate*" – *Virgin Atlantic v Premium Aircraft* [2009] EWCA Civ 1512

Exercising the discretion – when/how can public interest be taken into account?

Recent example: *Evalve Inc. & Abbott v Edwards Lifesciences* [2020] EWHC 513 (Pat)

Concerned medical devices for treating a heart valve disorder - Potentially life-saving treatment

Evalve/Abbott's product "MitraClip" already on the market and highly successful: Edwards had developed their own device "PASCAL" which the court had earlier found to infringe Abbott's Patents

Edwards argued that injunctive relief should be refused on the basis that PASCAL was, *in the reasonable judgement of clinicians* better for some patients

Some take-homes from Evalve v Edwards

- UK courts do have a discretion to withhold an injunction on public interest grounds
- But it is to be exercised with caution – Parliament is better equipped to determine the appropriate checks and balances.
- Factors to consider in the clinical setting:
  - The public interest will likely only be engaged for serious medical conditions, perhaps only for life-saving treatments
  - Nature of the competitive product important: generic drugs vs medical devices or biosimilars where tangible differences may exist
  - An injunction may be refused where it is established that patients can only be treated with the infringing product: but clinical preference is unlikely to be enough – there must be objective evidence (see also Arnold J. in *Edwards v Boston* [2018] EWHC 1256 (Pat))

Enforcement of patent rights in the current pandemic

- Treatment or vaccine where there is no alternative:
  - Statutory carve outs provided by crown use or compulsory licensing likely to be engaged (especially in the case of a public health emergency);
  - A court would be very likely to refuse injunctive relief in such circumstances (if it was ever sought: c.f. *Edwards v Boston*; GSK v Wyeth [2017] EWHC 91 (Pat)).
- More of a grey area where an infringing product/process is in an area where demand already being met – e.g. think a new type of ventilator:
- What about supply of generics?

"I doubt a generic version of a life-saving drug would usually engage the public interest in this way at all. I say "usually" because one can think of special cases, such as a novel pandemic disease; but if that happened then the Government could invoke Crown use."

Per Birss J in *Evalve v Edwards* at [77]

International comparisons

Is common law flexibility better suited to accommodate public interest concerns?

Germany:

- Compulsory licence can be awarded on public interest grounds – but no discretion not to award injunction upon finding infringement: *Herzklappen* case 4a O 137/15 LG Düsseldorf

Netherlands

- Again no discretion: statutory protection for public interest through compulsory licensing: *Boehringer v Kirin-Amgen* Supreme Court 21- 04-1995 no. 15623; *Nikon v ASML* Hague District Court 18 July 2018

Switzerland

- Appears to follow Germany: *Evalve, Abbott v Edwards* Federal Patent Court case S2019_002 15 Aug 2019

US: protecting the public interest a core factor (*eBay Inc v MercExchange*)

- *Cordis v Boston* 99 Fed.Appx 928 (2004): strong public interest supports a broad choice (stents)
- But see *Amgen v Sanofi* (2017) 872 F.3d: mere choice is not enough (biosimilars)

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28 May 2020

The Open COVID Pledge: Background and Theory

May 5, 2020

Jorge L. Contreras, University of Utah
Mark Lemley, Stanford Law School

Acknowledgement

Other Members of The Open COVID Coalition:

- Michael Eisen, UC Berkeley
- Ariel Ganz, Stanford
- Jenny Molloy, Cambridge
- Diane Peters, Creative Commons
- Alexander James Phillips, Helpful Engineering
- Mark Radcliffe, DLA Piper
- Eric Steuer, Creative Commons
- Frank Tietze, Cambridge

IPR and Covid-19

Updated: OEM Threatens to Sue Startup that Saved Lives by 3D Printing Medical Valves

by: Norbert Sparrow in Medical, COVID-19, 3D Printing on March 19, 2020

MOTHERBOARD
TECH BY VICE

Hospitals Need to Repair Ventilators. Manufacturers Are Making That Impossible

We are seeing how the monopolistic repair and lobbying practices of medical device companies are making our response to the coronavirus pandemic harder.

By Jason Koebler

Mar 18 2020, 8:15am Share Tweet Snap

$3,000 for Prior Art on Former Panasonic Patent being asserted against ventilator companies by IP Edge, an NPE

future tense

How Patent Abuse Could Hurt the Fight Against the Pandemic

Scientific research that is funded by the public should be available to the public.

By ELLIOT HARMON APRIL 27, 2020 • 1:29 PM

Mechanisms for Opening the IPR Box

- Compulsory Licensing
- Patent Pools/Clearinghouses
- Patent Pledges

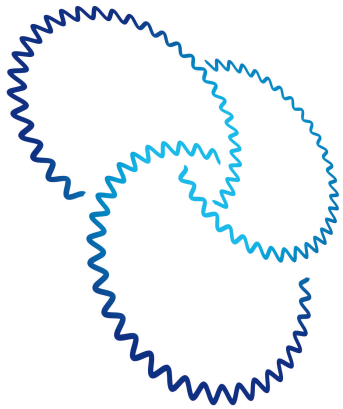
Compulsory Licensing

- Authorized under TRIPS Art. 31
  - Doha Declaration (2001)
- Utilized to compel access to meds in developing countries
  - Brazil, Thailand, India, South Africa
- U.S. mechanisms
  - Bayh-Dole march-in rights
    - Never exercised
  - Governmental use (28 USC 1498)
    - Used regularly -- but requires govt. or contractor use
- Covid-19 compulsory licensing measures
  - Chile, Ecuador, Israel, Germany, Canada

IPR Pools

- Aggregate rights held by diverse holders
  - Eliminates blocking positions
  - Clears thickets
  - Creates efficient licensing (one-stop shopping)
- Complements not Substitutes
  - “essentiality” determinations $$$
- Biopharma attempts
  - SARS (2002-03)
  - H5N1 (2005)
  - H1N1 (2009)
  - CRISPR-Cas9 (2018) - still pending

Clearinghouses



medicines patent pool

Medicines Patent Pool (2010-)

- Organized under WHO/UNITAID
- HIV, TB, Hepatitis-C
- Developing world focus
- Accepts inbound drug licenses
  - AbbVie, Bristol-Myers Squibb, Gilead Sciences, Pfizer, ViiV Healthcare, Johns Hopkins University
- Sublicenses rights to generics manufacturers in LDCs
  - 22 granted
  - Some are royalty-bearing
- 2018 Budget ~$6.5M

Patent Pledges Defined

- Voluntary public commitments
- by patent holders
- to limit the enforcement or utilization of patents
- without direct compensation

Jorge L. Contreras, *Patent Pledges* (Ariz. St. L.J., 2015)

First Covid-19 Pledge Efforts

Medtronic

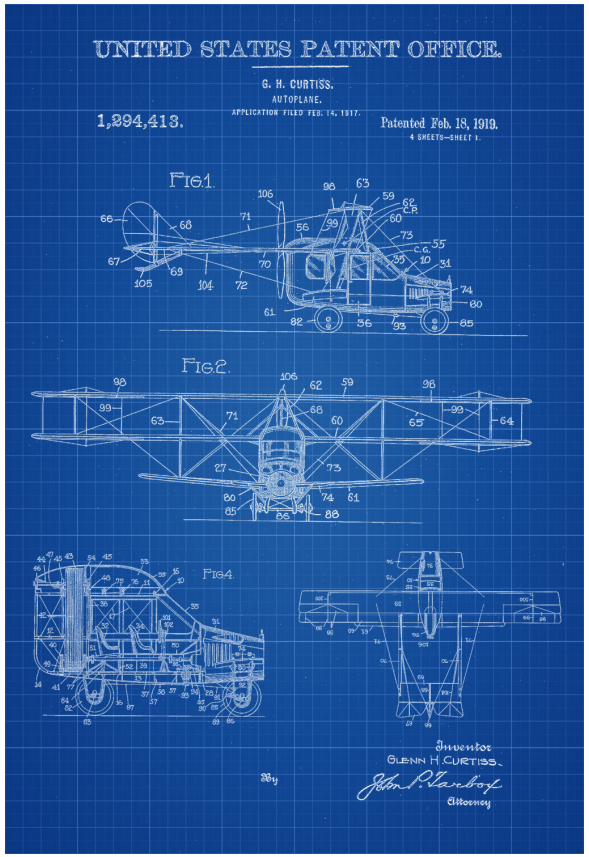
Innovative Genomics Institute

wellcome trust

Designing a Common Pledge for Covid-19

Design principles

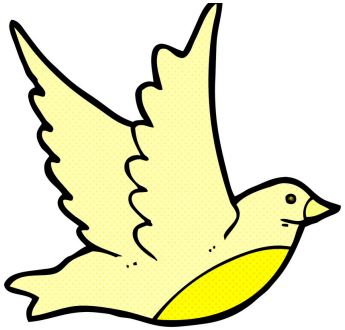
- **Simplicity**
  - Immediate comprehension
  - No resource commitment
- **Uniformity**
  - Engender trust
  - Accelerate adoption
  - Develop community
  - Network effects
- **Self-execution**
  - Public license
  - No signatures
  - No negotiation, admin overhead
- **Limited Scope**
  - Only the pandemic
  - Not a giveaway
- **Free**
  - Free speech and free beer



Why not the public domain?

Retention of IP rights supports:

- **Defensive use**
  - Deter IP attacks
  - Retain some value
- **Limited duration/scope**
  - Potential for monetization outside pledge
- **Enforcement of conditions**
  - Like OSS/GPL (attribution, share-alike)



The Open COVID Pledge

April 7, 2020

Immediate action is required to halt the COVID-19 Pandemic and treat those it has affected. It is a practical and moral imperative that every tool we have at our disposal be applied to develop and deploy technologies on a massive scale without impediment.

We therefore pledge to make our intellectual property available free of charge for use in ending the COVID-19 pandemic and minimizing the impact of the disease.

We will implement this pledge through a license that details the terms and conditions under which our intellectual property is made available.

https://opencovidpledge.org

Open COVID License – Patent and Copyright (OCL-PC) 1.1

Open COVID License – Patent and Copyright (OCL-PC) 1.1

Having made the Open COVID Pledge, we (the “Pledgor”), in order to speed the development and dissemination of the technologies needed to end the COVID-19 Pandemic and mitigate the effects of the disease, grant the license described below. Our intent in doing so is to advance the shared cause of ending the COVID-19 Pandemic, and we do so without any expectation of consideration or compensation, and with knowledge of the rights we are licensing.

1. GRANT AND SCOPE

The Pledgor grants to every person and entity that wishes to accept it, a non-exclusive, royalty-free, worldwide, fully paid-up license (without the right to sublicense) under Pledgor’s patents and copyrights that we have the right to license (the “Licensed IP”) to make, have made, use, sell, and import any patented invention, and reproduce, adapt, translate, distribute, perform, display, modify, create derivative works of and otherwise exploit any copyrights, solely for the purpose of diagnosing, preventing, containing, and treating COVID-19.

2. TIME LIMITATION

This license is effective as of December 1, 2019 and lasts until one year after the World Health Organization declares the COVID-19 Pandemic to have ended, but in any event not beyond January 1, 2023, unless otherwise extended by the Pledgor.

3. REGULATORY EXCLUSIVITY

The Pledgor will not assert any regulatory exclusivity against any entity or individual for use of the Licensed IP in accordance with the license granted in Section 1, and we will not seek injunctive or regulatory relief to prevent any entity or individual from doing so.

4. DEFENSIVE SUSPENSION

The license and non-assertion covenant granted above shall automatically be suspended, and the Pledgor shall be free to assert the Licensed IP against the licensee, if the licensee or any entity affiliated with the licensee threatens or initiates a suit or legal proceeding alleging the infringement of any patent or other intellectual property right against the Pledgor or any entity affiliated with the Pledgor.

5. NO WARRANTY

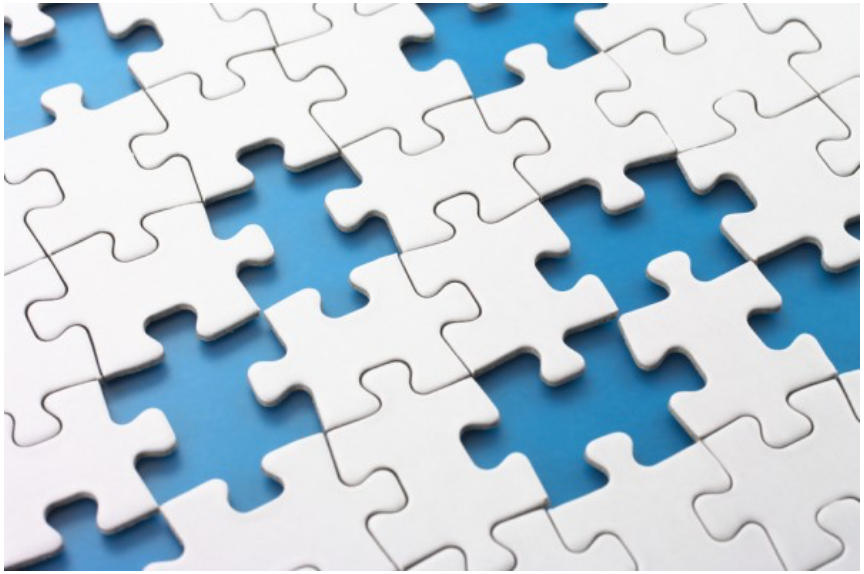
The license granted herein is “AS IS” without any warranties, express or implied.

OCL Principal Terms

- **Licensed Rights**
  - Patent and/or copyright
  - Not TM, trade secret
  - Only within Licensor's power to grant
- **Field**
  - diagnosing, preventing, containing, and treating COVID-19
  - Includes research
- **Term**
  - Duration of WHO-declared COVID-19 pandemic
  - Plus 1-year ramp-down
  - Outside date: 1/1/23
- **Regulatory exclusivity -** waived
- **Defensive suspension**
- Customized licenses can be Compatible or Alternative

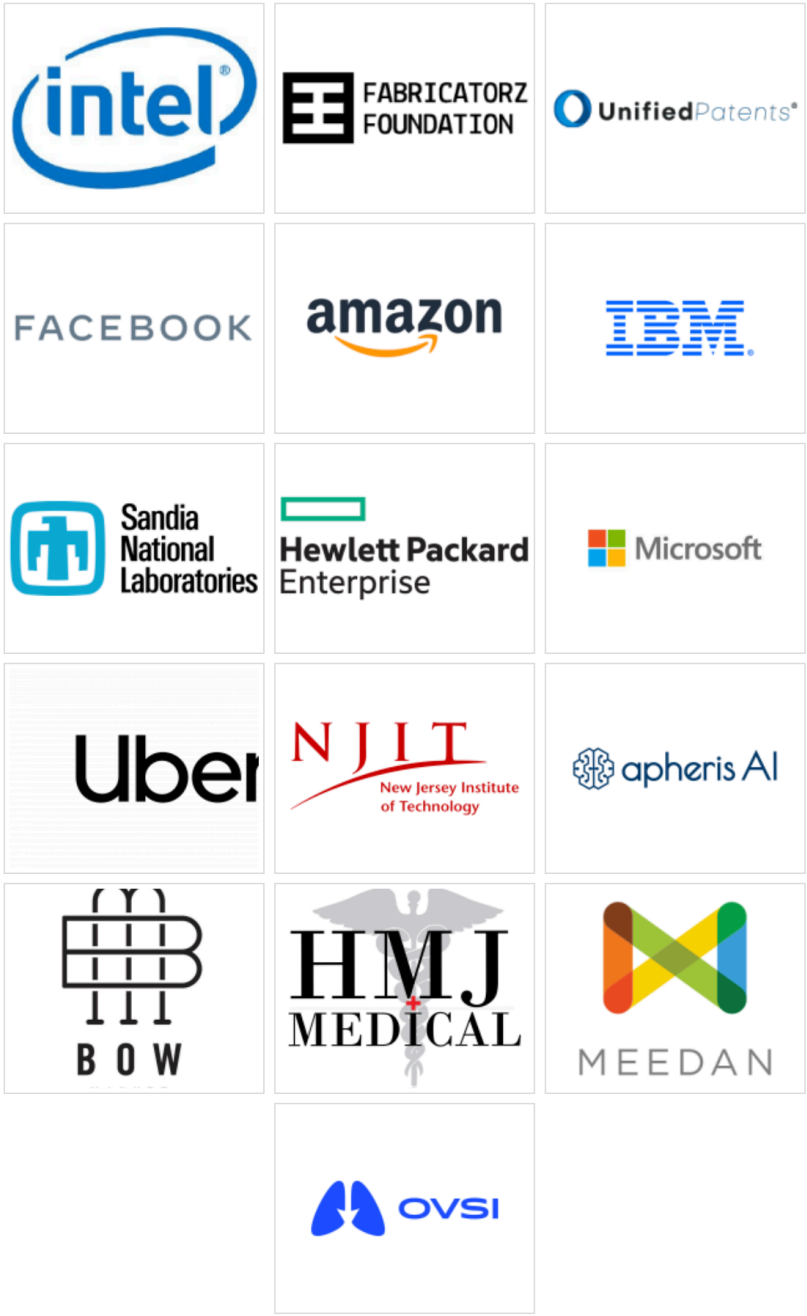
OCL Principal Omissions

- Warranties
- Indemnification
- Choice of law
- Grantbacks
- Sharealike
- Downstream pricing constraints



OCP Adoption

- High tech
  - Huge portfolios
- SMEs
  - Single technologies
- National Lab
  - Selected patents
- University
- Coalition



Next Steps

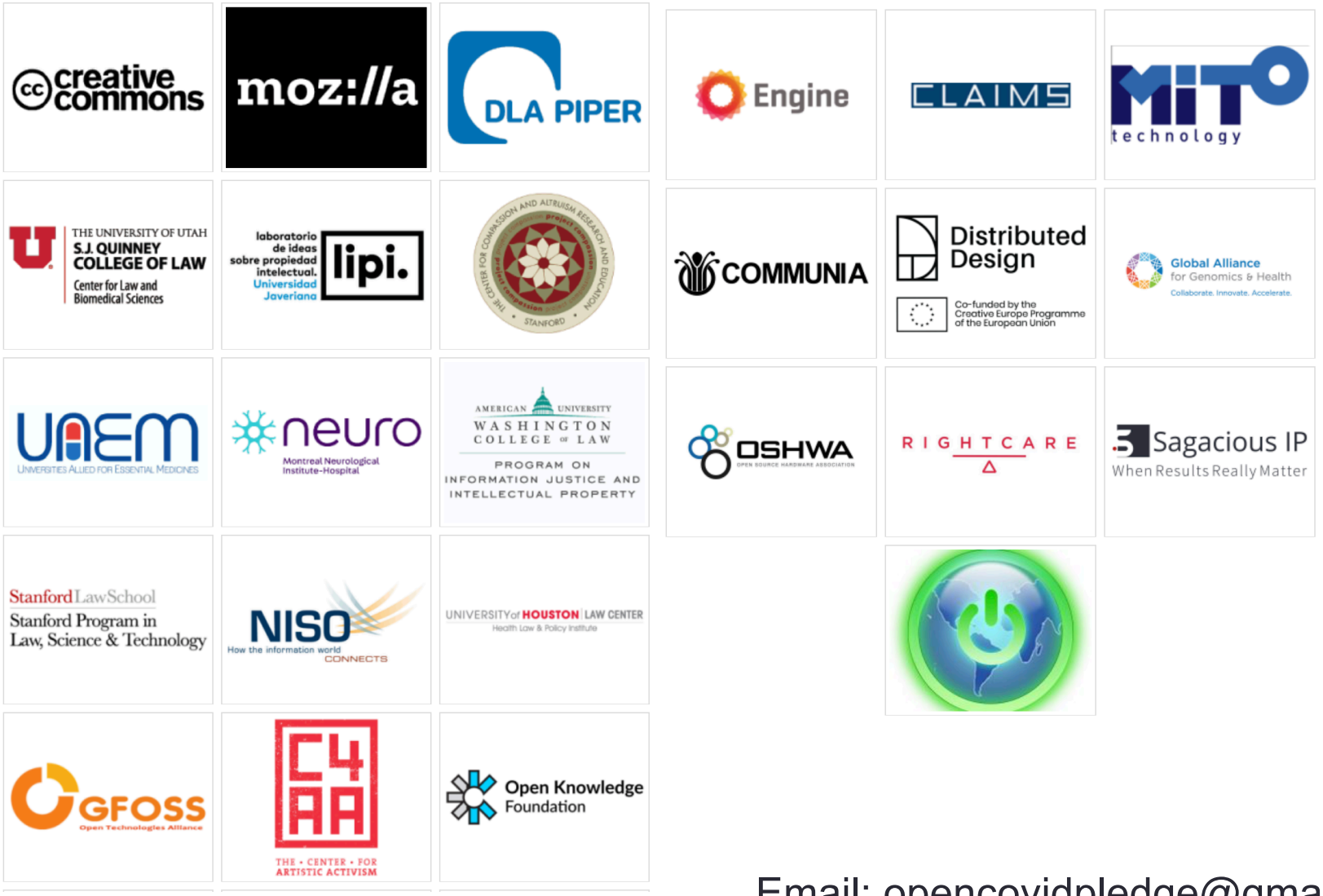
- Stewardship and institutionalization (CC)
- Internationalization
- Linkage/alliance with similar efforts
- Identification and promotion of pledge IPR

Goals

- Meaningful contribution to solving technology bottlenecks in the Covid-19 response
- Developing a usable framework for ongoing and future IPR sharing
  - The next pandemic
  - Climate change

OPEN COVID PLEDGE

How can you Support the Pledge?



Email: opencovidpledge@gmail.com

IP and COVID-19: UCL Ventura Continuous Positive Airways Pressure (CPAP) device

Prof David Lomas

Vice Provost (Health) and Head of UCL Medical School
Hon. Consultant Respiratory Physician, UCLH and Royal Free Hospital

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Our team

UCL engineers

- Prof Rebecca Shipley (Director, UCL Institute of Healthcare Engineering)
- Prof Tim Baker (UCL Mechanical Engineering)
- Wider team includes Dr Tom Peach, Mr Tom Rushton, Mr Peter Weston, Mr James Weaver

University College London Hospital clinicians

- Prof Mervyn Singer (UCLH Critical Care)
- Prof David Lomas (UCL Vice Provost Health)
- Dr David Brealey (UCLH Critical Care)

Mercedes AMG HPP (Formula 1)

- Andy Cowell (Managing Director)
- Ben Hodgkinson (Lead Mechanical Engineer)

Other partnerships

- G-TEM (logistics and distribution)
- Oxford Optronix (oxygen analysers)
- LifeRacing (oxygen analysers)
- Avon Protection (breathing circuits)
- Intersurgical (breathing circuits)
- MHRA (UK regulation authority)

Management of COVID infection

2-13th March: oxygen therapy ➜ ventilation

Data from Italy and China: CPAP devices could help patients and keep them off invasive ventilation

i.e. oxygen therapy ➜
Continuous Positive Airways Pressure (CPAP) ➜ ventilation

BUT: (i) there were insufficient devices in the UK
(ii) CPAP wasn't on the NHS care pathway
(iii) CPAP wasn't a priority for HMG's ventilator challenge
(iv) the 'surge' was expected in London 12th April (Easter)

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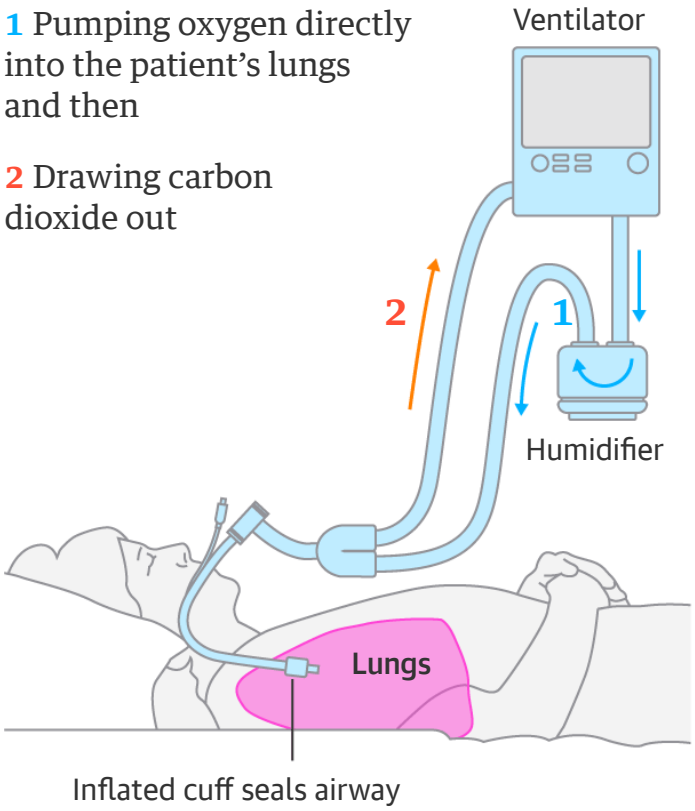
Management of COVID infection

Ventilator

Helps patient breathe by:

1 Pumping oxygen directly into the patient's lungs and then

2 Drawing carbon dioxide out

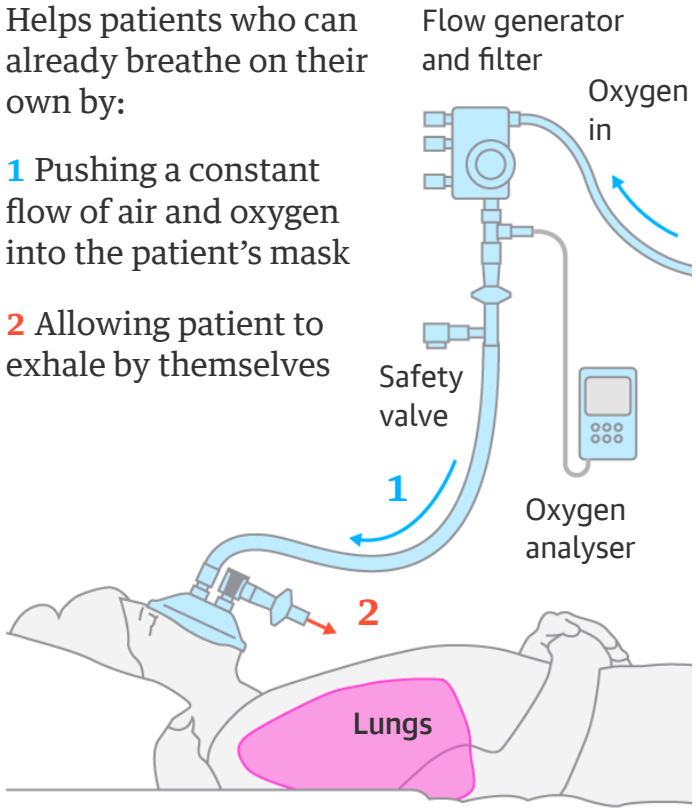


CPAP device

Helps patients who can already breathe on their own by:

1 Pushing a constant flow of air and oxygen into the patient's mask

2 Allowing patient to exhale by themselves



Guardian graphic. Source: UCL, UCLH, Mercedes F1

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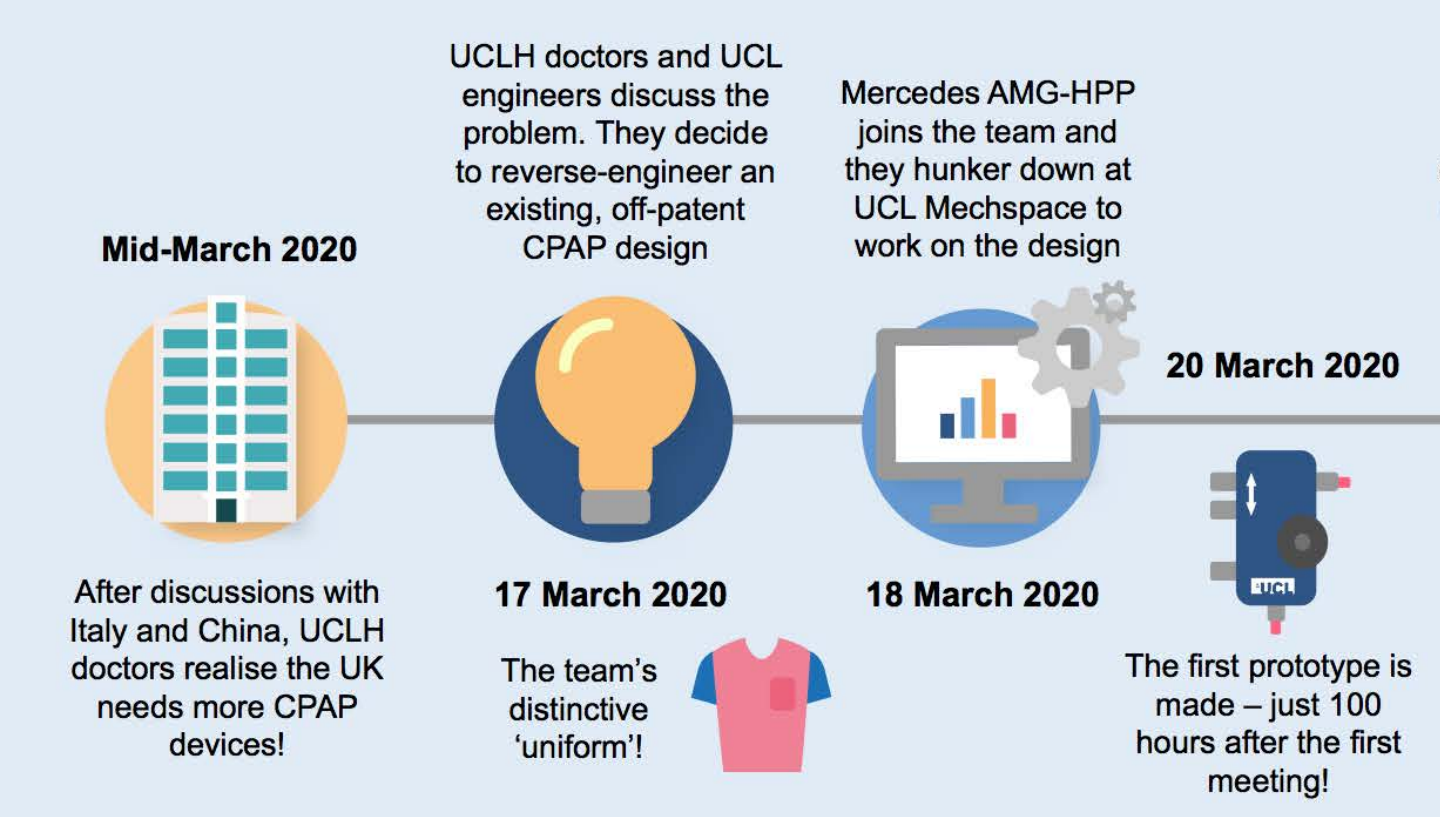
Timeline summary



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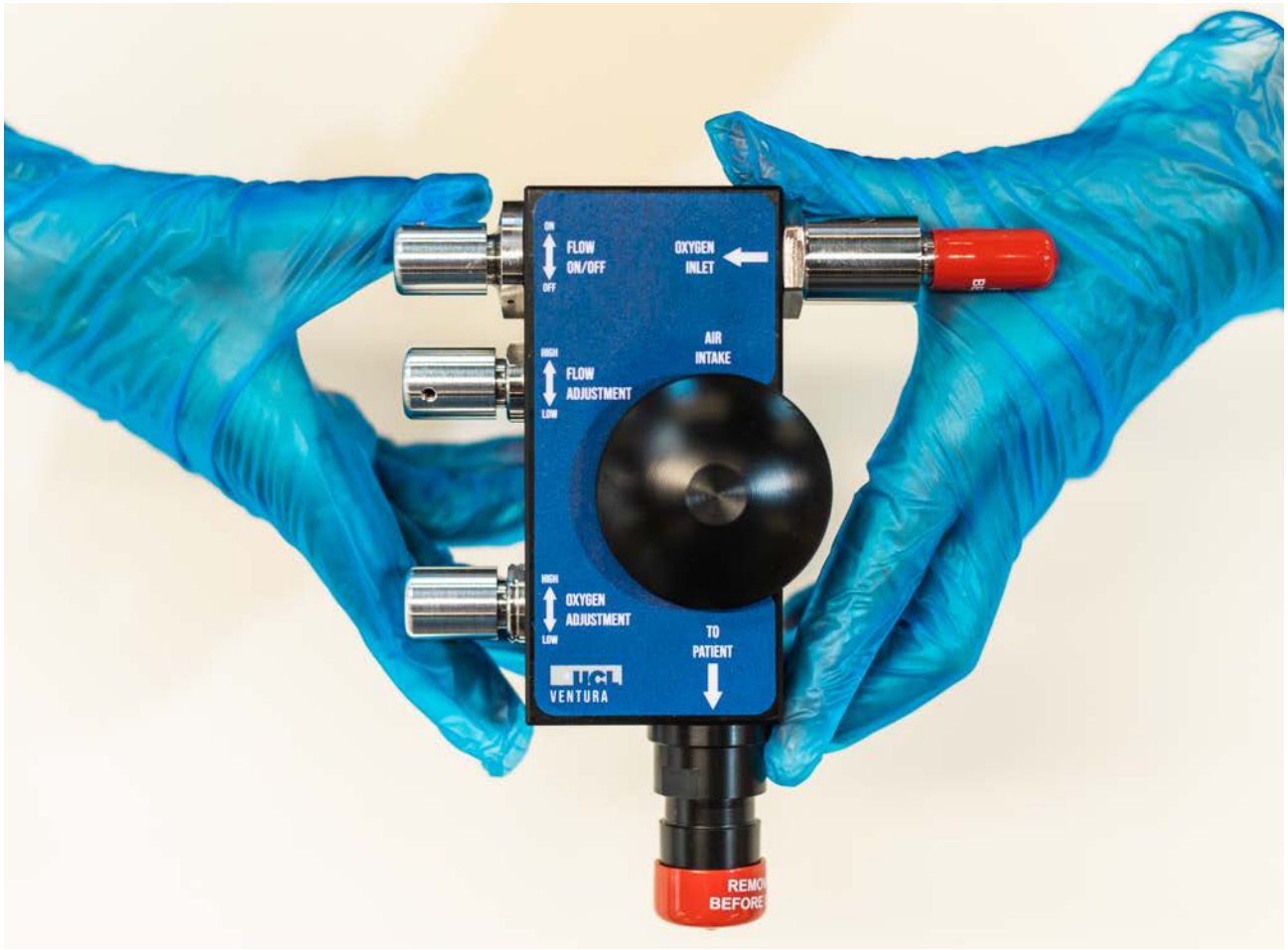
The CPAP Flow Generator Device Mark I and Mark II



- Reverse-engineered an off-patent device, based on the old Philips Respironics Whisperflow CPAP device
- Mark II of our CPAP was developed to reduce oxygen utilisation by up to 70%
- Mark II optimised (a) the air entrainment port, (b) the design of the breathing circuits (valves, filters, mask) for patient comfort and to minimise oxygen utilisation

UCL Ventura – timeline

17th March: team meet at UCL
18th March: contact with Becky Shipley “how can we access the MHRA?”
19th March: contact June Raine Interim Head MHRA (21:46), reply (22:51)
20th March: phone call/e-mail to Andrew Menzies-Gow (Respiratory Clinical Reference Group for Specialist commissioning)
22nd March: prototype delivered to UCL for testing
24th March: NHS issue new guidance including CPAP in care pathway
24th March: NHS honorary contracts issued to Engineering team (UCL + Mercedes HPP) to enable them to continue working/ travelling during lock-down
27th March: MHRA approval for Mark I (10 days after first idea)

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UCL Ventura – timeline

29th March: clinical evaluations at UCLH then sister hospitals commence
Concern about supply chains, financing, and promising that HMG would commit – agree to purchase 100
30th March: press release with worldwide coverage
30th March: DHSC commissioned 10,000 devices for £20m by 15th April
31st March: – *manufactured at less than cost and liability? Mercedes wanted to be protected from claims (as did we!). Agreed £5m liability for UCL*
2nd April: MHRA approval for Mark II CPAP device
3rd April: contract largely agreed, Ministerial approval 8th April
15th April: full order of 10,000 CPAPs delivered, and logistics experts G-TEM packaging and next day delivery, with allocation to NHS hospitals through the NHS England and NHS Improvement Oxygen and Ventilator Programme

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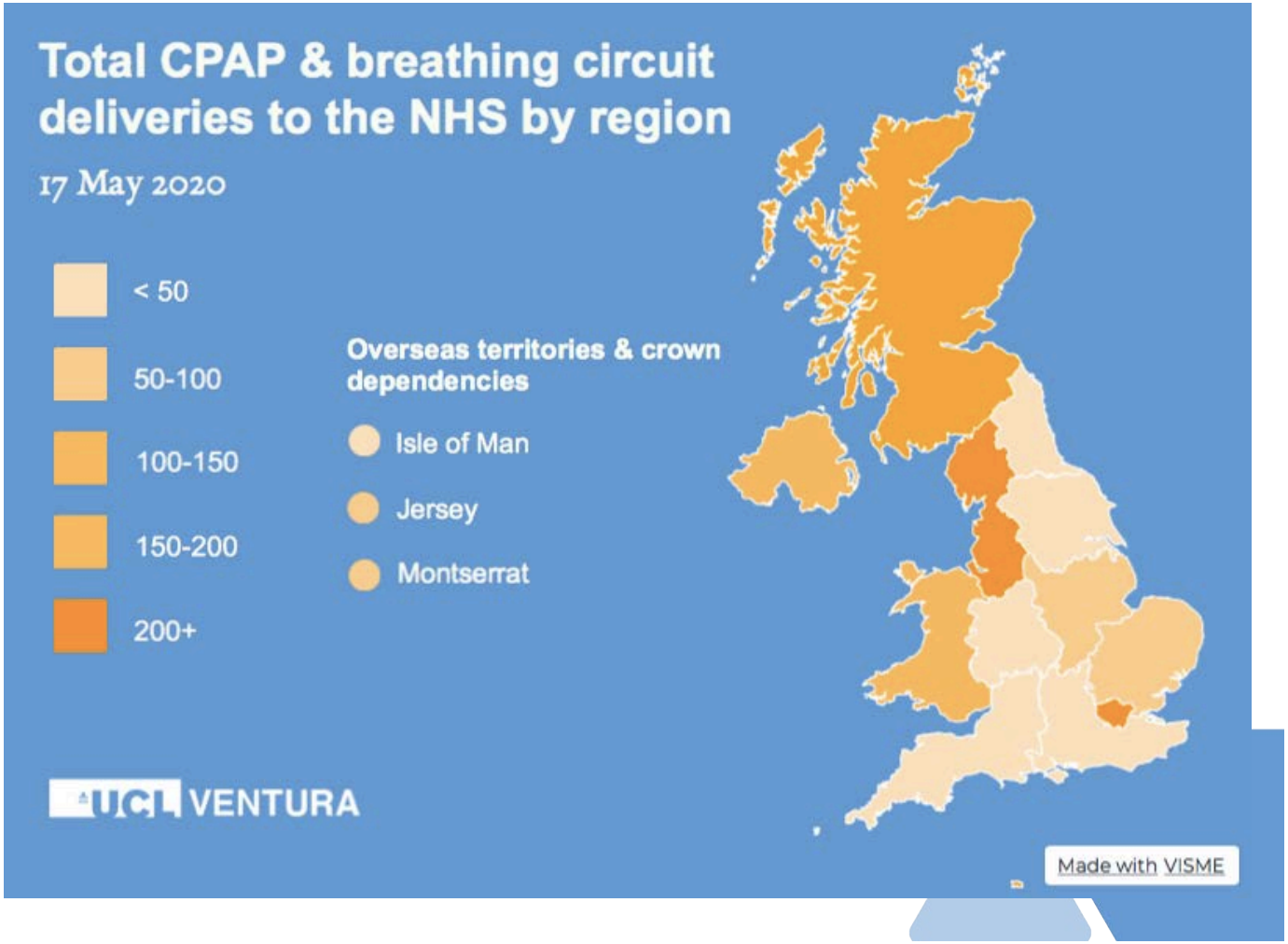
Delivery across UK to NHS hospitals

Approx 1000 CPAPs delivered so far across UK, across 60 NHS hospitals in England, the devolved nations, crown dependencies and overseas territories

Interactive map:

https://my.visme.co/view/kkx8r133-cpap-uk-distribution



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Release of designs and manufacturing instructions at no cost, for humanitarian use

Partnership with UCL Business

We will authorise requests for free licenses from people representing the following organisations:

- Manufacturers
- Research Institutions
- Healthcare providers
- Non-profit sector

Package of designs and manufacturing instructions contains:

1. Manufacturing drawings
2. System schematics and characteristics
3. Bill of materials and type of manufacturing machines used for CPAP production
4. Development tests information
5. Assembly procedures, including build tooling requirements
6. Test procedure and pass-off protocol

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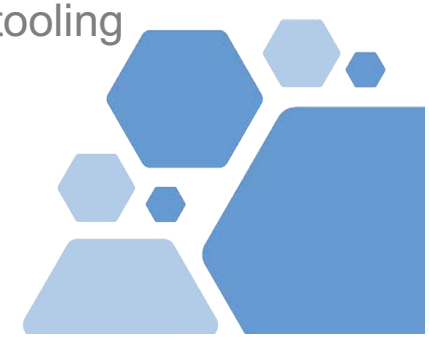

UCL Ventura – the challenges II

(i) No IP despite Mercedes generating a new improved device (a modification to an off-patent device)

(ii) It's hard to give something away!

Approach to licencing:

- limited UCL liability to £10,000
- unable to contract out: death or personal injury from negligence and fraud

Another weekend *pro bono* legal advice started **4th April 2020**

5th April fully signed agreement, and release of a dedicated platform for the licensing process on **6th April**

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1835 downloads of designs across 105 countries (18 May)

International teams are now making progress with local manufacture

20 teams have successfully manufactured prototypes for testing in Brazil, Bulgaria, Canada, Colombia, Germany, India, Iran, Mexico, Russia, South Africa and the US.

Interactive map:

https://my.visme.co/view/4d8xdeq9-cpap-approval-orders

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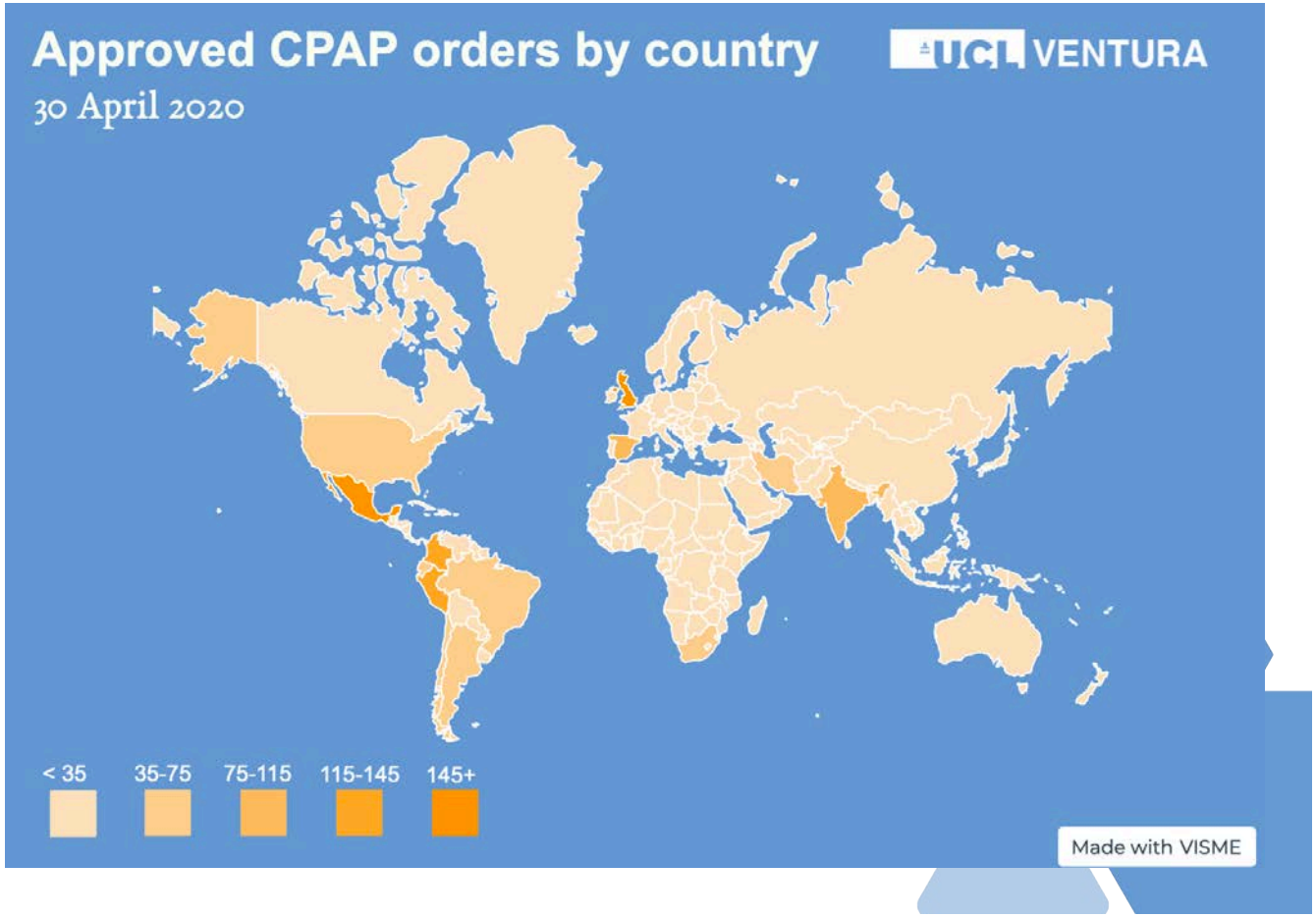

International Support

Support for local manufacturing efforts?

- Working with international groups such as WHO, Just Actions, DFID
- Providing technical and manufacturing support
- Local regulatory approval process (linking to MHRA)
- Ongoing queries around local supply chains, access to materials and financing
- Programme of webinars, online discussion groups

Key considerations:

- Oxygen supply infrastructure and planning (CPAPs need a piped oxygen supply)
- PPE provision
- Resupply of breathing circuits (consumables)
- Training materials

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Summary

Team effort to deliver 10,000 CPAP breathing devices in 15 days

Re-design of NHS pathway for care of COVID-19 patients

Great support from MHRA for Mark I and Mark II devices

Download of designs for international use

No patent, contract with DHSC and licence for international use

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More information

Website:

- www.ucl.ac.uk/covid19CPAP

Email contacts:

- Queries on accessing devices for international use - CPAPcovid19@ucl.ac.uk
- Additional questions and technical support - ihecovid19response@ucl.ac.uk
- Prof Rebecca Shipley, Director of UCL Institute of Healthcare Engineering - rebecca.shipley@ucl.ac.uk
- Prof Tim Baker, Professor of Mechanical Engineering Design – t.baker@ucl.ac.uk
- Prof Mervyn Singer, Professor of Intensive Care Medicine – m.singer@ucl.ac.uk
- Prof David Lomas, Vice Provost (Health) – d.lomas@ucl.ac.uk

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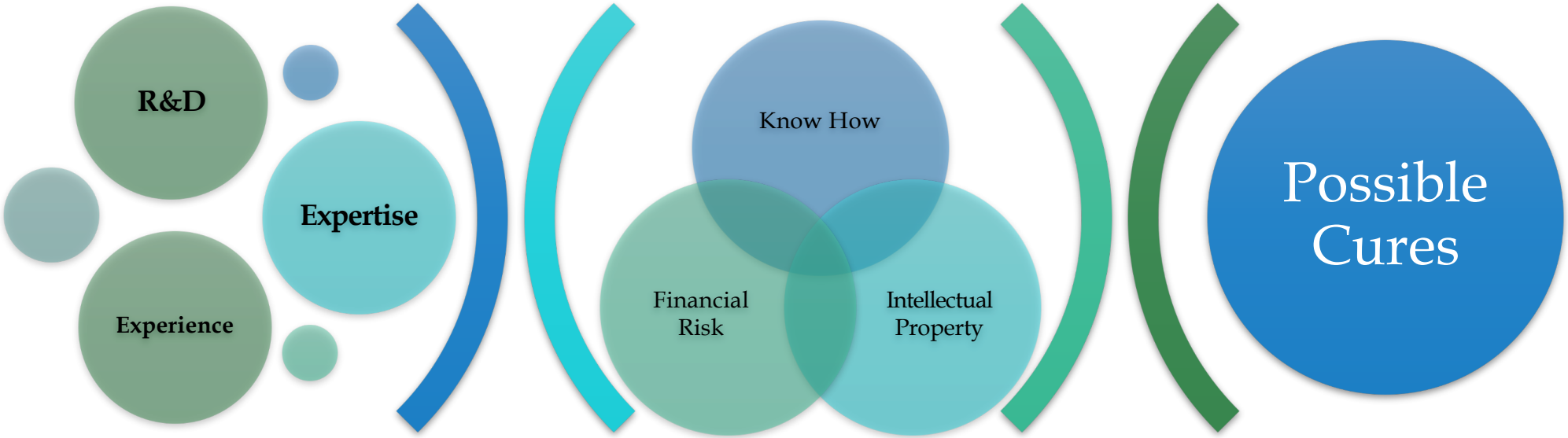
Intellectual Property and COVID 19

Thomas Cueni
Director General

International Federation of Pharmaceutical Manufacturers and Associations

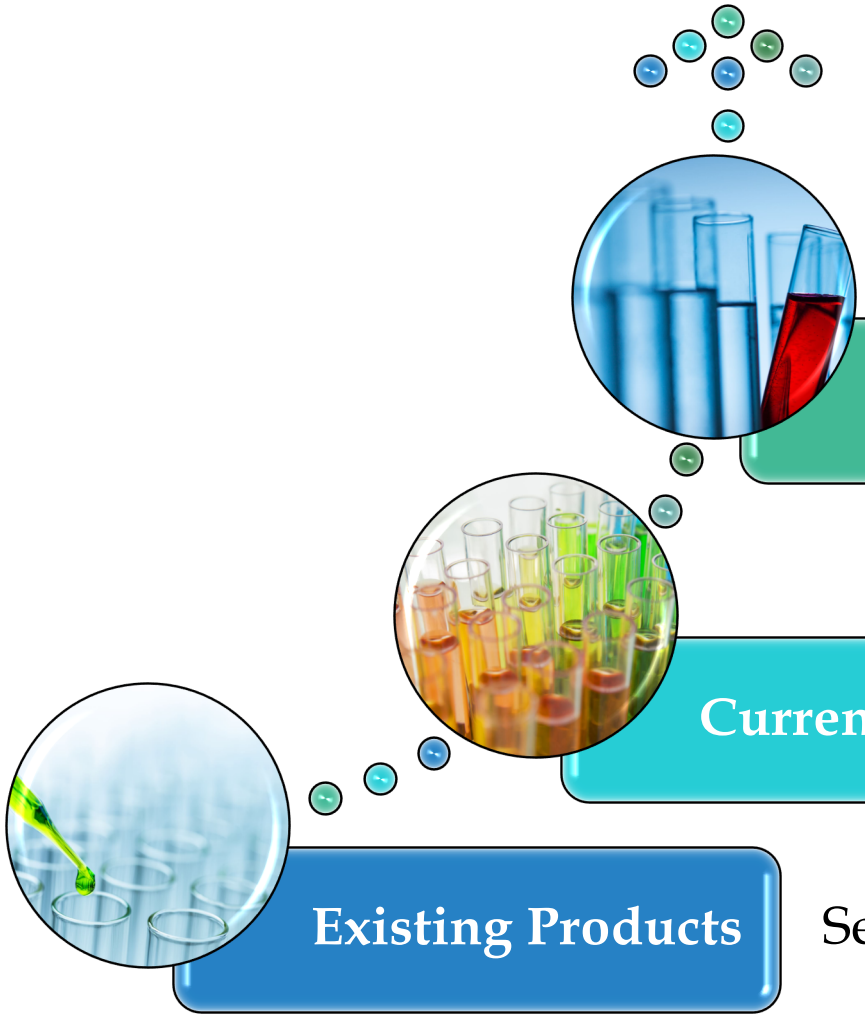
IFPMA

Science Holds The Keys



IFPMA

IP is not an Impediment but a Facilitator



New Treatments

- Know How
- Research

Current Trails

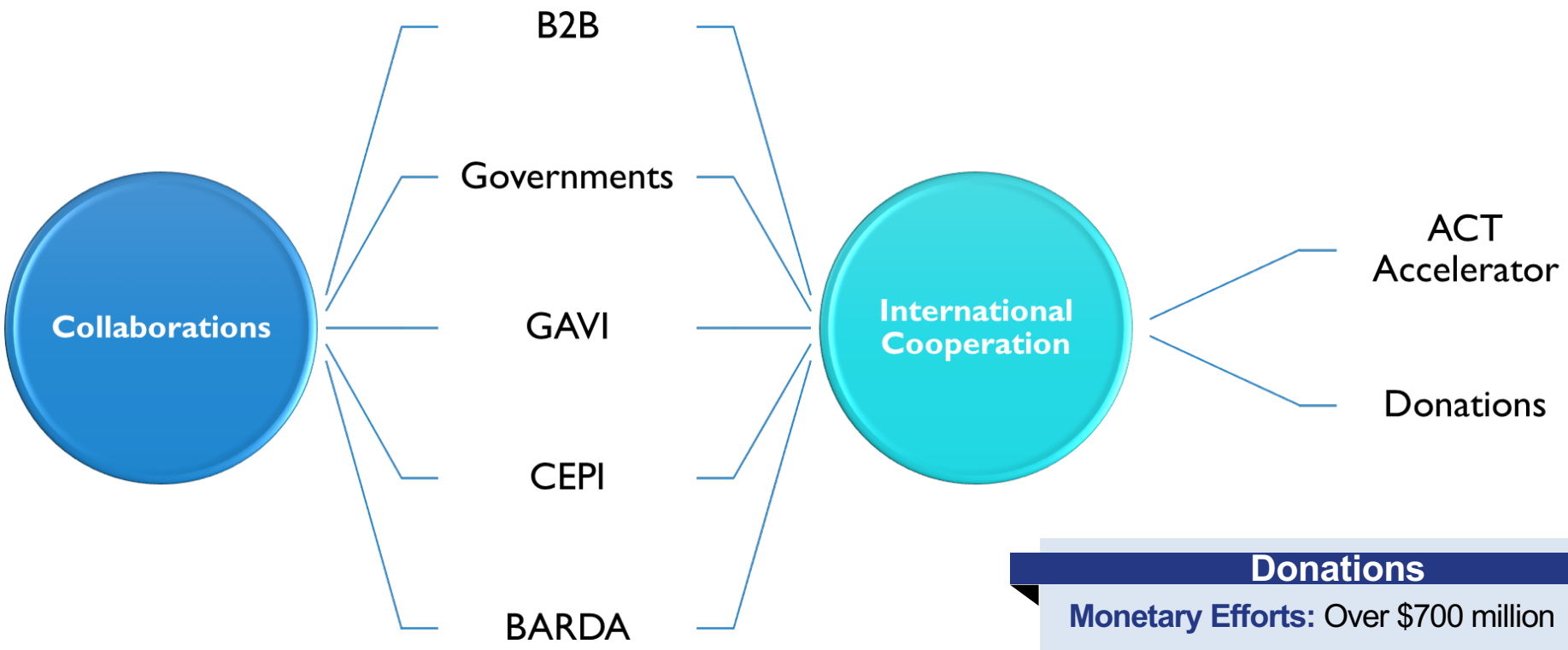
- 140 Treatments
- 120 Vaccines

Existing Products

Secondary Use

IFPMA

Industry Front Foot Forward



Donations

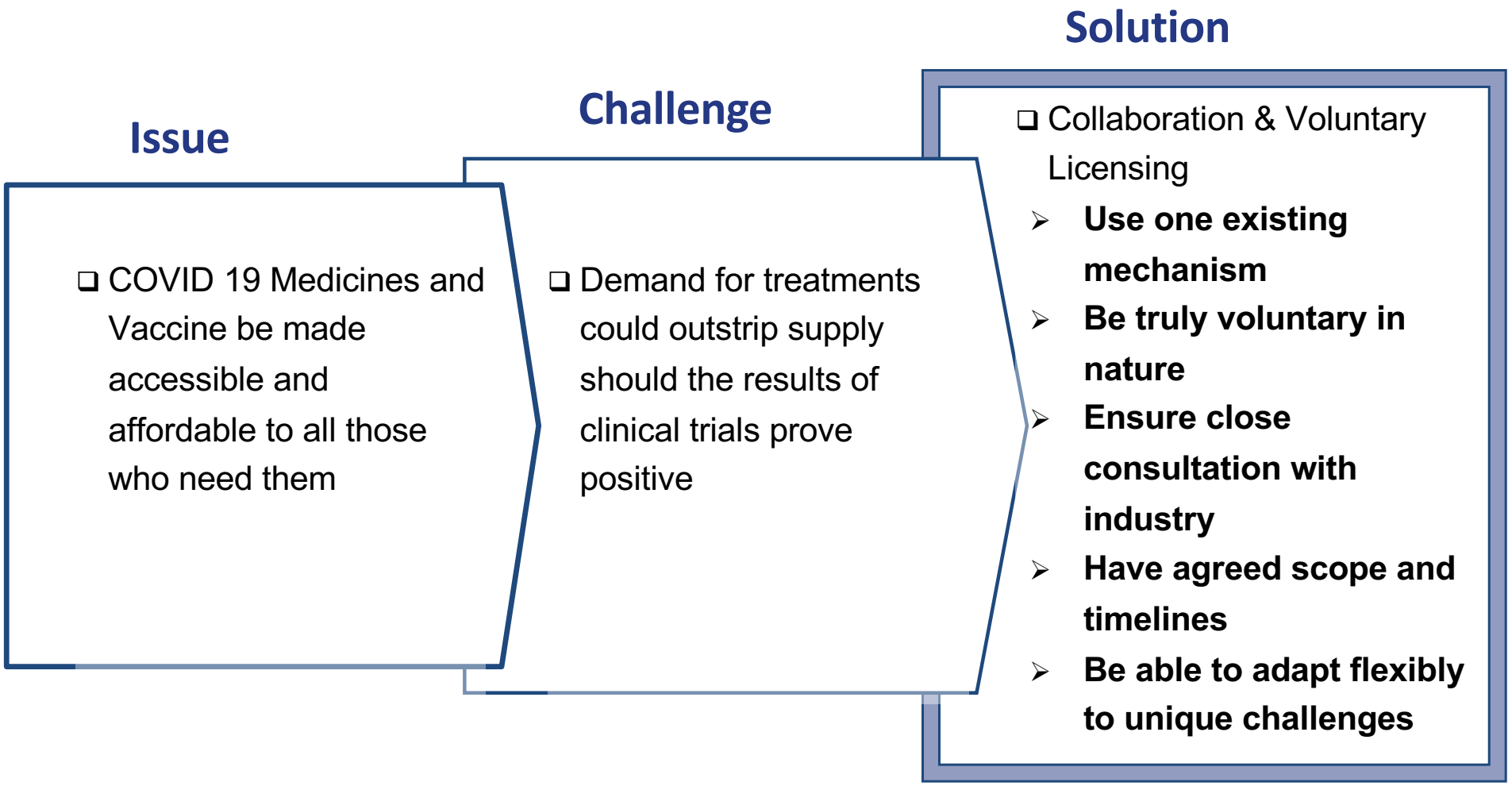
Monetary Efforts: Over $700 million

Non Monetary Efforts: Over $40 million

Medicines and PPE: Over $25 million

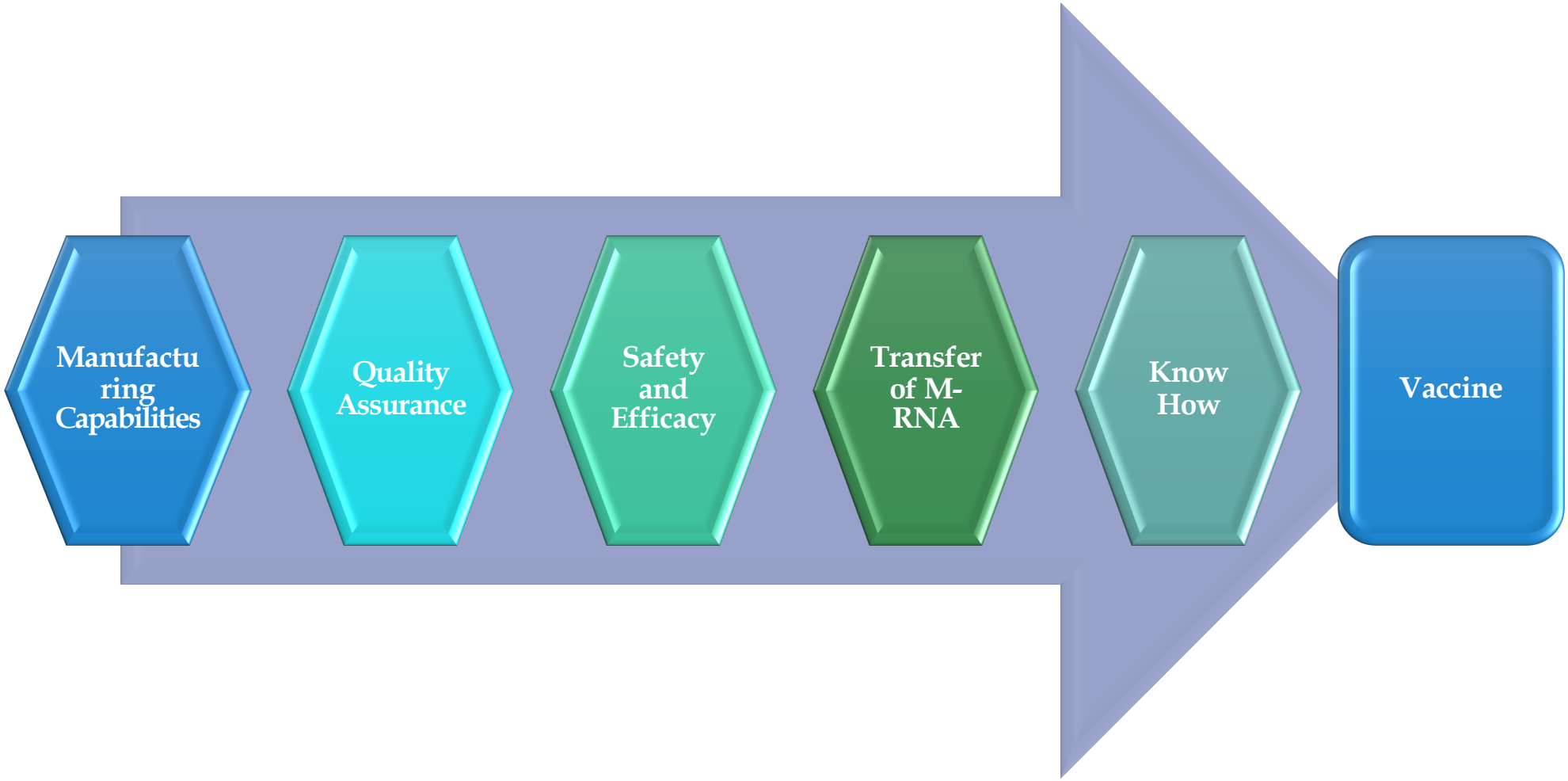
IFPMA

Way Forward



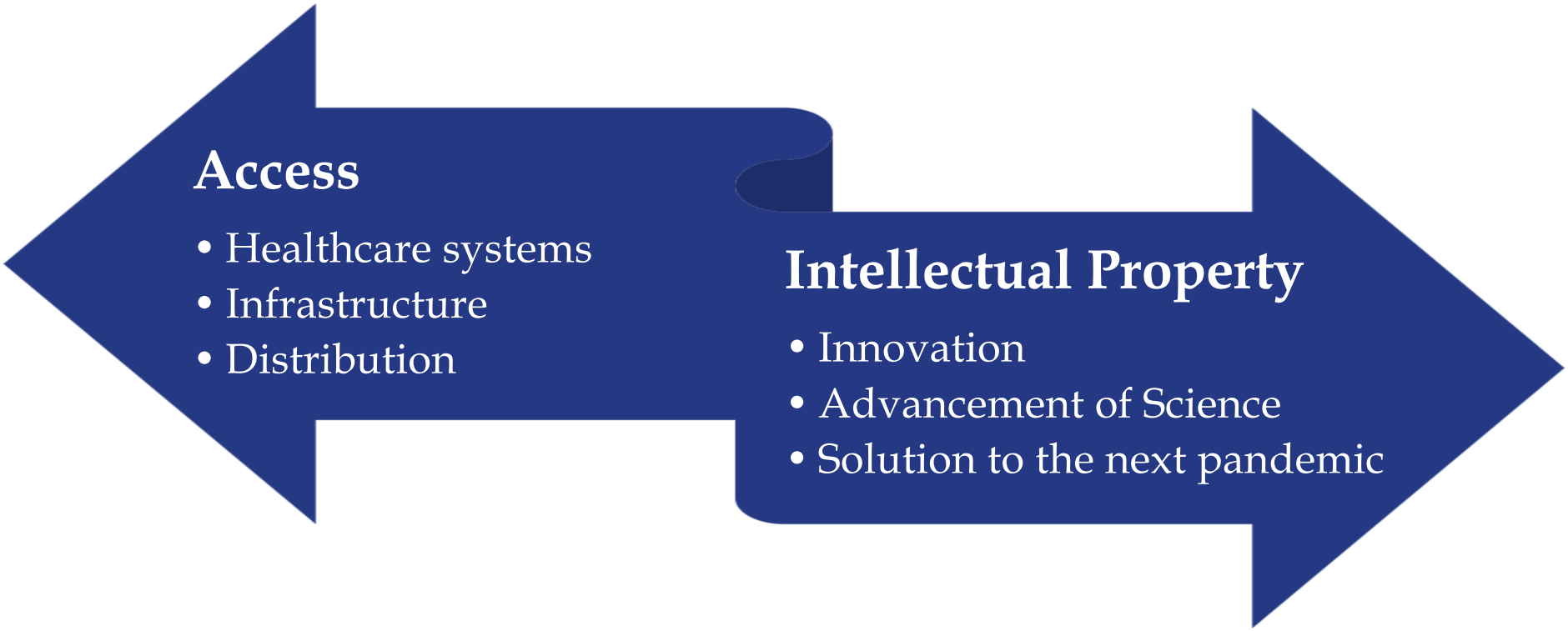
IFPMA

Demystifying Vaccines



IFPMA

Intellectual Property is Not an impediment



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Thank you

PATENTS AND COVID-19 MEDICINES: AN ECONOMIC PERSPECTIVE

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May 28, 2020

Some Basics of Medicine Economics: 1. Rationale for Patents

Ideal of Market-based Economies:

- Competition drives prices to marginal cost (MC)
- Patents grant limited monopoly to innovators, to enable price above MC (P > MC), to recoup fixed costs of R&D
- *Optimal* patent length/breadth: balance *cost to current consumers* from P >MC vs. *benefit of future new products*

Reality: WTO TRIPS 20 year patent + country "flexibilities"

- No evidence 20 yrs. is optimal, even on average
- For medicines in practice: country-level follow-on patent rules + regulatory details determine patent life and incentives

2. Affordability/Access: Insurance and Reimbursement Affect Pricing + Patent Value

- Public +Private Insurance (e.g. NHS) pays for most medicines
- Insured patients are financially protected and price-insensitive => producers raise prices unless payers limit reimbursement
- Payers ex-USA limit *reimbursed* price, usually based on the new drug's incremental benefit or cost-effectiveness
  - e.g.UK NICE: Cost per QALY $\leq$ £30,000 ("Threshold")
- Pricing Issues: In general and especially for COVID
- What Costs and Benefits to include?
- Should Threshold be higher/lower for COVID therapies?
- Should public funding of R&D constrain price?

COVID Medicines:1. Testing Established Drugs: Patents, Regulations and Incentives Matter

- Testing existing drugs requires only Ph. II/III trials
- But financial incentives may be weak *except* for biologics
- Patentability of new attributes, formulations is allowed in US => "evergreening" concerns, esp. for biologics
- E.g. Enbrel patents expire 2028 in US vs. 2015 in EU
- FDA Data Exclusivity is most effective bar to generics entry, but
- US: 5 yrs. for small mols. vs. 12 yrs. for biologics; EU: 10 yrs

=> Weak incentives to adapt older small mol. drugs for COVID

=> Public trials may be needed + outlicense to generic producers

COVID Medicines: 2. New Therapeutics

- R&D costs are relatively modest: Covid-19 pathways known; known compounds can be adapted; Regulatory fast-track
- Volume: potentially large, depends on indication + off-label use
- Price/reimbursement based on standard formulae:
  - Incremental health gain (QALYS) + medical costs averted

=> Modest prices vs. “cures” for chronic, fatal disease e.g. Hep C

- Affordability an issue for payers IFF multiple therapeutics are used in cocktails, especially for early stage/mild disease

COVID-19: 3. Vaccines: HIC vs. LDC Issues

- R&D costs relatively modest: Existing vaccines/techniques adapted quickly to address this virus + regulatory fast-track
- Public funding + private pharma collaborations underway
- Higher Income Countries (HICs): Affordability within current health budgets will be the main challenge => issue for pricing
- Less Developed Countries(LDCs) Huge global volumes => investment in production capacity will require LDC producers
  - Indian, Vietnamese producers are main suppliers of most vaccines and therapeutics for UNICEF
- LDCs will likely require GAVI funding for mass vaccination
  - As for other “essential” vaccines

HICs: Reducing Threshold on Cost-per-QALY for Value-based COVID Vaccine Price

- Assuming annual, universal vaccination: COVID vaccine will pose ongoing new budget challenge for health payers…. But
- Decline in GDP + huge other demands on public budgets =>
- Higher opportunity cost => lower threshold + prices optimal
- R&D incentives for high-volume vaccines will remain
  - Prices are constrained *because* volumes are high
- Also: Public funding for COVID vaccines has been significant
- US: Setting a value-based price, with a reasonable threshold, assures public ROI, while preserving incentives for future R&D
- Such Value-based pricing is preferable to march-in rights that must still determine a fair price + set an uncertain precedent

Less Developed Countries (LDCs): Voluntary Licensing (+ Compulsory License Back-up)

- Voluntary licensing and/or differential pricing (roughly based on GDP per cap.) enabled affordable supply for Hep. C drugs
- LDC vaccine producers may license Covid vaccines …and/or develop their own vaccines
- GAVI funding + UNICEF purchasing provide an established framework for negotiating prices for LDCs
- PAHO negotiates vaccine prices and supply for LATAM
- With time, multiple similar vaccines should provide choice for customers and competitive pressure on supplier prices, also for middle income countries outside purchasing frameworks

COVID-19: IP Law, Policy & Practice
Copyright

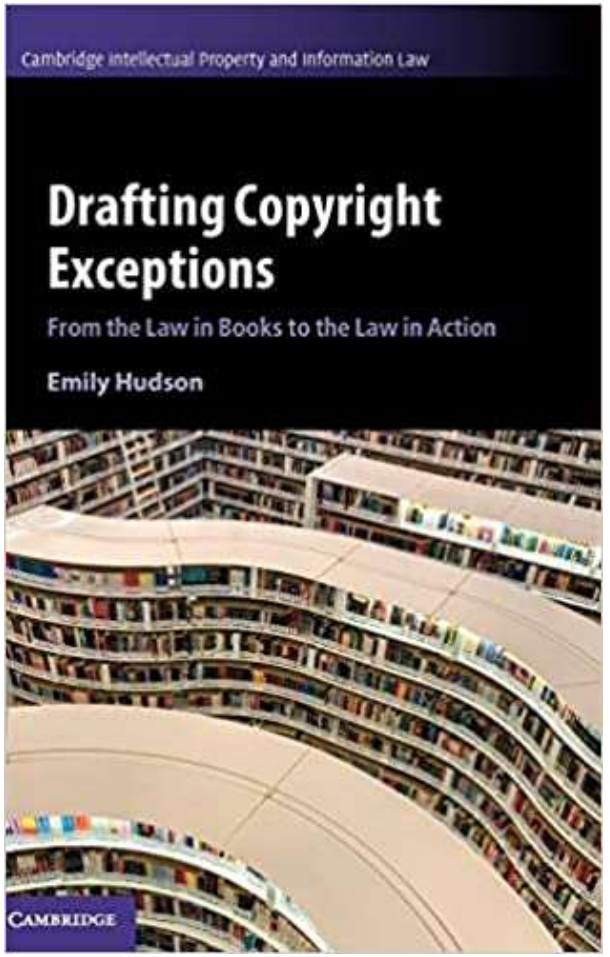
Dr Emily Hudson

Twitter: @DrEmilyHudson

4 June 2020

References

- Emily Hudson & Paul Wragg, 'Proposals for Copyright Law and Education During the COVID-19 Pandemic' (3 June 2020), available on SSRN at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3617720.
- Emily Hudson, *Drafting Copyright Exceptions* (CUP, 2020) (*right*).



What are the issues for higher education?

- Two important changes:
  - Closure of libraries.
  - Movement of assessment and teaching online.
- The pandemic has exacerbated existing issues:
  - Asymmetry in physical and virtual holdings.
    - E-books & other digital content/products (***Paul***)
  - The copyright implications of using third party works in teaching and research.
    - Esp. audiovisual works

Case study: UCL & e-textbooks

- In paper world, UCL passes 20,000 books to catalogue each year
- Using UCL's books budget, the costs of commercial e-textbooks is so great that less than 100 e-books could be procured
- With wildly different licence agreements

The prevailing copyright environment

- Licensing:
  - Blanket licences for educational copying offered by collectives such as CLA and ERA.
    - Note extension of CLA licence (*to 30 June 2020*).
  - Agreements with producers of subscription databases and other digital products.
  - Creative Commons.
- Exceptions (e.g., fair dealing, ss. 32-36A):
  - Hudson & Wragg, p. 5: sector should not concede too much regarding exceptions.

Fair dealing: section 32(1)

- Fair dealing with a work for the sole purpose of illustration for instruction does not infringe copyright in the work provided that the dealing is—
  - (a) for a non-commercial purpose,
  - (b) by a person giving or receiving instruction (or preparing for giving or receiving instruction), and
  - (c) accompanied by a sufficient acknowledgement (unless this would be impossible for reasons of practicality or otherwise).

Controlled digital lending (CDL)

- Could fair use arguments in relation to CDL inform decision-making in the UK under section 32?
  - What are the key tenets of CDL?
  - Warning: CDL is controversial in the US, albeit that some practices seem to have been tolerated.
  - Complaint filed against the Internet Archive on 2nd June.
- In the UK, could CDPA s. 36A (*lending by educational establishments*) help support the rollout of CDL?
  - Applies to digital copies: *Vereniging Openbare Bibliotheken v Stichting Leenrecht* (C-174/15).
- Logistical issues as much an impediment as legal ones.

Public interest

- The existence of a public interest defence to copyright infringement was accepted in *Ashdown v Telegraph Group Ltd* (CA); and note CDPA s. 171(3).
- This defence is unlikely to have survived *Spiegel Online* (C-516/17) and *Funke Medien v Germany* (C-469/17).
- Even if the defence exists, applying it to the pandemic would require a radical reconceptualisation of its function.
- But public interest arguments may be relevant to remedies:
  - Injunction: *Coventry v Lawrence* (UKSC), *Evalve Inc v Edwards Lifesciences Ltd* (Birss J).
  - Damages: a possible relevant consideration, drawing from *General Tire v Firestone* (UKHL).

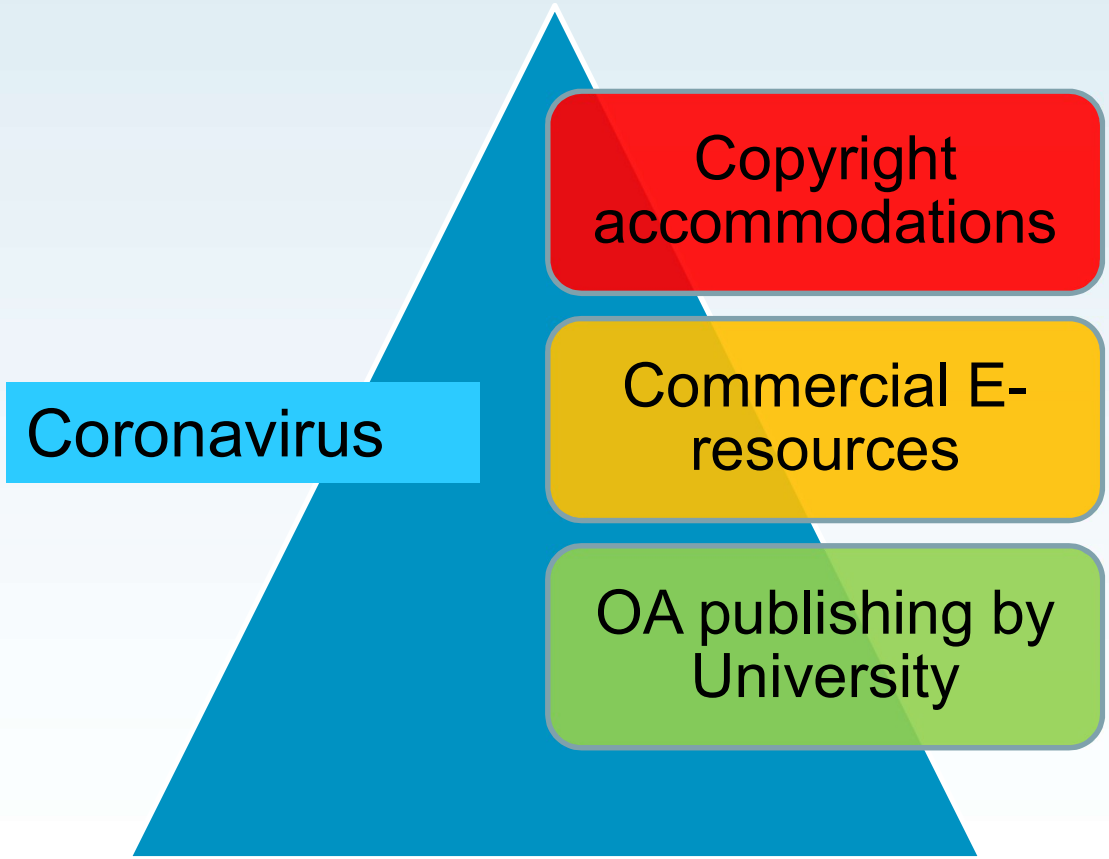
Compulsory licensing

- Rejected by the UK government on the basis that it would 'remove exclusive rights from right holders' and would likely be contrary to international copyright law.
- Legal analysis can be disputed, e.g., by reference to Berne Art. 9(2), state practice in relation to compulsory licensing and the acceptance of remunerated exceptions under the ISD.
- But there are philosophical and practical issues with compulsory licensing.

Another option: extend s. 36

- CDPA s. 36 allows educational institutions to copy and communicate not more than 5% of a work for the purposes of instruction, but not where licences are available.
- General idea: incentivisation of licensing.
  - Similar: 'free-for-all' exception proposed by the Whitford Committee.
- Could s. 36 be extended (perhaps temporarily), for instance to allow copying of longer extracts, or even entire works on CDL terms?

3 possible ways forward



UCL LIBRARY SERVICES

Digital Access at a time of crisis

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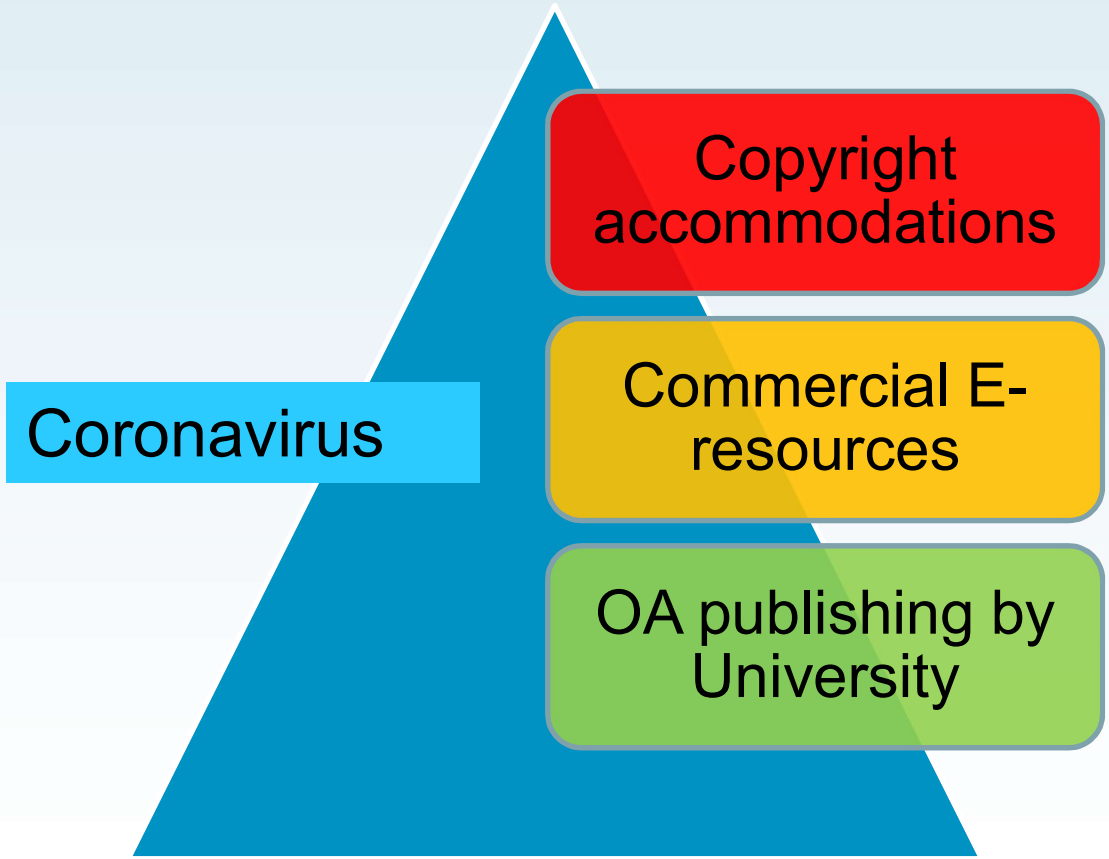
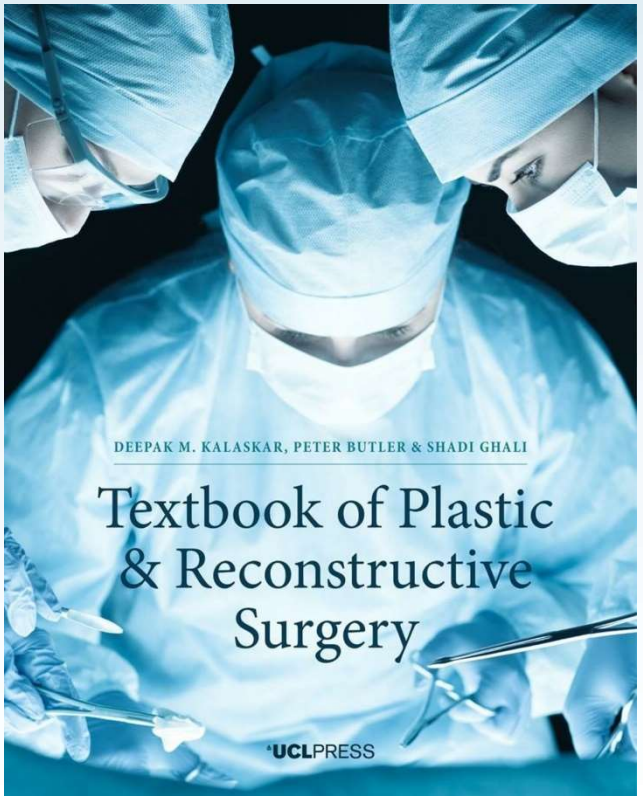
3 possible ways forward



Open Access – the institution as publisher

- *Textbook of Plastic & Reconstructive Surgery*
- Edited by Deepak Kalaskar et al.
- UCL Press, August 2016
- Available as an OA textbook
- 83,759 downloads
- In 192 countries & territories
- 269 sales of paper copy



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UCL PRESS

Downloads by country (April 2020)

243 countries and territories

Culture change required

- Textbooks do not count for the REF
- I am paid royalties for textbooks, OA publishing does not pay royalties
- I will harm my career if I spend time producing textbooks rather than research outputs

- I won't be promoted for writing textbooks
- University policies don't recognized education on a par with research

So…

- University students left between a rock and a hard place
- Copyright restrictions are a barrier
- Commercial e-textbooks are too expensive
- Institutional publishing of OA materials a possible way forward

UCL Student Centre, opened 18/2/19

Let discussion begin…

Christopher Stothers

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How a crisis can change the law

Competition law

Free movement law

State aid law

Overpricing by exploiters

Competition law

Preventing parties collaborating?

23 March 2020 – ECN Joint Statement

- the ECN will not actively intervene against necessary and temporary measures put in place in order to avoid a shortage of supply
- it is of utmost importance to ensure that products considered essential to protect the health of consumers in the current situation (e.g. face masks and sanitising gel) remain available at competitive prices. The ECN will therefore not hesitate to take action…
- …the ECN would like to point out that the existing rules allow manufacturers to set maximum prices for their products. The latter could prove useful to limit unjustified price increase at the distribution level

Competition law

Preventing parties collaborating?

8 April 2020 – Commission Temporary Framework

- The exceptional circumstances of this time and its related challenges may trigger the need for undertakings to cooperate with each other in order to overcome or at least to mitigate the effects of the crisis to the ultimate benefit of citizens.
- The present Communication covers possible forms of cooperation between undertakings in order to ensure the supply and adequate distribution of essential scarce products and services during the COVID-19 outbreak and thus address the shortages of such essential products and services resulting first and foremost from the rapid and exponential growth of demand

Competition law

Preventing parties collaborating?

8 April 2020 – Comfort letter for Medicines for Europe (fka EGA)

- cooperation to model demand for all medicines facing increased demand in the context of COVID-19
- identify production capacity and existing stocks, and to adapt or to reallocate, based on projected or actual demand, production and stocks, and to potentially also address the distribution of COVID-19 medicines
- in the present exceptional circumstances the cooperation practices as set out above do not raise concerns under Article 101
- does not cover any discussion of prices; subject to participating undertakings not unduly increasing prices beyond what is justified by possible increases in costs

Competition law

Preventing parties collaborating?

The Competition Act 1998 (Coronavirus) (Public Policy Exclusion) Orders

- Health Services for Patients in England SI 2020/368 (27 March)
- Health Services for Patients in Wales SI 2020/435 (17 April)
- Groceries SI 2020/369 (27 March)
- Dairy Produce SI 2020/481 (30 April)
- Solent Maritime Crossings SI 2020/370 (27 March)

Free movement law

Protecting national supplies?

13 March 2020 – Commission Communication

- Unilateral national restrictions to the free movement of essential supplies to the healthcare systems create significant barriers and affect dramatically Member States' capacity to manage the COVID-19 outbreak.
- Price regulations may be helpful to avoid soaring and abusive prices

14 March – 16 May 2020 – PPE export authorisations (third countries)

PPE	Masks	Gowns	Glasses
Authorised	13.5m	1m	0.4m
Rejected	4m	0.1m	0.3m

Free movement law

Protecting national supplies?

MHRA guidance – medicines that cannot be exported to EEA or third countries

- **25 February 2020**: 3 medicines added (lopinavir + ritonavir, chloroquine phosphate and azathioprine)
- **13 March 2020**: 1 medicine added (hydroxychloroquine)
- **20 March 2020**: 82 medicines added
- **23 April 2020**: 33 medicines added

State aid law

Preventing governments supporting?

Decisions Mar-May 2019: 64

Decisions Mar-May 2020: 240

Commission Temporary Framework for State Aid, amendment 3 April 2020

- it is also essential to facilitate COVID-19 relevant research and development, to support the construction and upgrade of testing facilities of COVID-19 relevant products, as well as the setting up of additional capacities for the production for products needed to respond to outbreak
- The aid beneficiary shall commit to grant non-exclusive licences under non-discriminatory market conditions to third parties in the EEA

Overpricing by exploiters

What is the answer?

Competition law

- existing rules allow manufacturers to set maximum prices for their products
- subject to participating undertakings not unduly increasing prices
- CMA "lobbied the government for emergency powers to crack down on companies profiteering from the pandemic after finding itself hamstrung by existing laws" (FT, 17 May 2020)

Free movement law

- price regulations may be helpful to avoid soaring and abusive prices

Overpricing by exploiters

What is the answer?

Trade mark law?

3M v Performance Supply

- Defendant alleged to have offered 7m N95 repirators to NY for 500% over list price on 30 March 2020
- Filed SDNY on 10 April 2020
- Temporary restraining order 24 April 2020
- Preliminary injunction 4 May 2020

How a crisis can change the law

Competition law – cooperation means price control

Free movement law – hard to limit within trade area

State aid law – price of aid may be NEND

Overpricing by exploiters – are trade marks the answer?

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