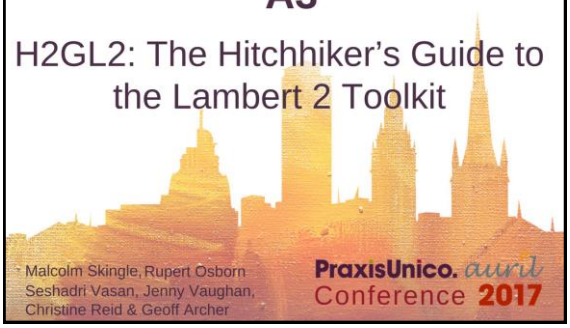
A3

H2GL2: The Hitchhiker's Guide to the Lambert 2 Toolkit



H2GL2: The Hitchhiker's Guide to the Lambert 2 Toolkit – Use in practice

Dr Geoff Archer
Head of Knowledge Exchange
Teesside University
g.archer@tees.ac.uk @GeoffArcher

How we use the Lambert Toolkit

Internally

- Launch coincided with review of collaborative agreements and due diligence process review
- Informed legal services colleagues
- KTP agreement reviewed and options selected for our "default agreement"
- Guide used to inform business team colleagues of rationale for various clauses and the key points of each model

Externally

- Setting the scene
- Heads of Terms used to clarify expectations
- Decision Guide used where initial IP expectations did not match.
- Badge of Good Practice

Outcomes

- Closer working relationship with legal services (less them and us)
- 2 potentially tricky IP negotiations completed in a timely manner
- Implementation of New Lambert KTP Agreement popular amongst business team
- Increased confidence amongst business team re IP
- Contribution to Putting the Customer First Standard evidence
- Raised wider awareness of IP – Thanks to hosting of Toolkit at IPO
- Increased awareness of emerging issues (data protection, bribery & antislavery)

Makeup of Lambert Working Group and IPO hosting significantly overcame "Your Agreement / Our Agreement" arguments.

A few questions

- Q1 - Were you aware of Lambert 2 Toolkit before today?
- Q2 - Have you reviewed collaboration agreement processes since Lambert 2 Launch October 2016
- Q3 - Has Toolkit informed collaboration / consortium agreement or how you develop them?:
  - Significantly
  - Marginally
  - Not at all
- Q4 - Any observations on usage?

HITCHHIKER'S GUIDE TO THE REVISED LAMBERT TOOLKIT
An Overview

Christine Reid

NORTHWOOD REID

Praxis Unico

June 2017

Getting the most out of the Lambert Toolkit

- More than just agreements – a Toolkit
- Guidance – critical to understanding issues for less experienced
- Heads of Terms – use internally and externally
  Reach agreement on the key issues first
  - Respective roles and tasks
  - Financial contribution(s)
  - Provision and use of Background
  - Ownership and Exploitation of Results
  - Confidentiality
  - Academic and Research Use and Academic Publication
  - Warranties and Liability
  - Termination/Expulsion
  - Consequences of Termination/Expulsion

Lambert Toolkit - Principles

- Rights to use IPR are key – minimum for industry is a non-exclusive licence
- One size does not fit all
- Model agreements cannot fit everyone's way of working
- Different approaches/spectrum of solutions
- Starting point/negotiation – can't run on automatic pilot
- Ease/speed the process - not solve every issue
- Not cover every scenario - but cover common scenarios
- Workable and reasonable compromise

Lambert Toolkit - Contents

- Guidance on
  - state aid (new)
  - charitable status of universities (new)
  - data protection (new, but will need updating)
  - anti-bribery (new)
  - issues, e.g. liability, confidentiality, co-ownership of IPR etc., etc.
- 7 Model Collaboration Agreements (One to One)
- Decision Guide
- 4 Model Consortium Agreements (Multi-Party)
- 2 Model Heads of Terms and 2 Model Variation Agreements - prompts

Collaboration Agreements – 7 Scenarios

1. Institution owns the results. Grants Collaborator a non-exclusive licence to use the results for any purpose/limited to a field of use/worldwide/limited geographically
2. As Agreement 1, but Collaborator has the right to call on the Institution to negotiate an exclusive licence – not an option
3. As Agreement 1, but Collaborator has the right to call on the Institution to negotiate an assignment – not an option
4. Collaborator owns the results. Institution has right to use the results for Academic and Research Purposes. Institution's students and staff have Academic Publication Rights

Collaboration Agreements - 7 Scenarios

4A. New Split Ownership Agreement

Each of the two parties has the right to exploit certain results and takes an assignment of those results

Institution has the right to use Collaborator's results for Academic and Research Purposes. Its students and staff have Academic Publication Rights

Collaborator has specific right to use Institution's results for Research Purposes:

any purpose except commercialisation, i.e. licensing for value or sale for value OR

acts done for experimental purposes[or to obtain regulatory approval for any generic or innovative medicinal product (including any clinical trial)]

Collaboration Agreements Scenarios

5. Collaborator owns the results. Institution does NOT have right to use for Academic and Research Purposes and Academic Publication is NOT permitted - more suited to Contract Research perhaps through a subsidiary of the Institution

6. New Knowledge Transfer Partnership (KTP) Agreement.

- Student carries out the project. Company owns the results.
- Institution has the right to use results for Academic and Research Purposes
- Students and staff have Academic Publication Rights.
- Terms similar to Collaboration Agreement 4 with additional terms to reflect KTP programme

Consortium Agreement A Scenario

- Each party owns the results which it creates
- Each party grants each of the other parties a non-exclusive licence to use those results for any purpose
- Any party may exploit any of the results – level playing field
- No exploitation strategy

Consortium Agreement B Scenario

- Envisages a Lead Exploitation Party which is best suited to exploit results.
- Other parties assign IPR in the results to LEP or grant LEP an exclusive licence
- LEP undertakes to exploit and pay other parties a share of the revenues generated from that exploitation/a success payment
- Academic Parties have the right to use the results for Academic and Research Purposes and their students and staff have Academic Publication Rights
- Commercial Parties have the right to use the results for Research Purposes

Consortium Agreement C Scenario

- Two of the four parties are best placed to exploit different results
- Each of the two takes assignment of those results and undertakes to exploit them and to pay other parties a share of the revenues generated from that exploitation/a success payment
- Academic Parties have the right to use the results for Academic and Research Purposes and their students and staff have Academic Publication Rights
- Commercial Parties have the right to use the results for Research Purposes

Consortium Agreement D Scenario

- Each party owns IP in results which it creates
- Each party grants the other parties a non-exclusive licence to use those results for the purposes of the project
- If a party wishes to exploit another party's results or background, it must negotiate a licence or an assignment
- Academic Parties have the right to use the results for Academic and Research Purposes and their students and staff have Academic Publication Rights
- Commercial Parties have the right to use the results for Research Purposes

Lambert Toolkit - Updating the Toolkit

- Lambert Working Group decided to
  - add a model collaboration agreement splitting the ownership of the results – most requested update – now Model 4A
  - add a model agreement for Knowledge Transfer Partnerships now Model 6
  - produce guidance on universities' duties as charities
  - produce guidance on state aid in the context of research collaborations
  - add forms of variation agreement – act as prompts

Lambert Toolkit - Updating the Toolkit

- As well as new agreements and guidance, Lambert Working Group decided to
  - convert the existing Outline into Heads of Terms – and make more prominent
  - add provisions on data protection/ anti-bribery and corruption
  - review the provisions on publication and confidentiality - to take account of results which are not protected by registration
  - review the provisions on liability - differentiate liability for different types of breach
  - add a counterparts clause

Lambert Toolkit - Updating the Toolkit

- Working Group considered, but decided not to
  - prepare a template for a sub-contract
  - prepare model agreements solely for government-funded research
  - prepare model agreements specifically for overseas collaborations – have been converted for Korea and India, work on Brazil and China
  - add provisions relating to stem cells/the use of human tissue
  - adapt the model agreements to meet the requirements of specific sectors: ICT, life sciences, aerospace, defence, nuclear, transport, oil and gas, engineering, creative industries

Thank You

NORTHWOOD REID

Christine.Reid@northwoodreid.com

Public Health England

PraxisUnico. auril Conference 2017

Fast track model agreement for 'One Health' emergencies

S.S. Vasan, DPhil, RTTP, FCMI
Honorary Visiting Professor, University of York
Senior Business Development Manager, Public Health England

Sheffield
15 June 17

Public Health England

PraxisUnico. auril Conference 2017

About PHE

PHE is the national agency for protecting and improving the nation's health and wellbeing and tackling health inequalities so that the poorest and most poorly benefit most.

- Operationally autonomous Executive Agency of the UK Department of Health
- Born 1st April 2013 as a single dedicated service to support local innovation and to provide disease control & protection
- National presence with 129 sender bodies

Public Health England

PraxisUnico. auril Conference 2017

Knowledge transfer in a crisis – WW2

- Penicillin
- Pressurised air transport
- Radio navigation
- Radar
- Synthetic rubber
- Rocket engine
- Jet engine
- Nuclear power
- Computing and encryption

Public Health England

PraxisUnico. auril Conference 2017

Knowledge required on every front

FIELD	KNOWLEDGE NEEDED
Medical	Best clinical practice
Procurement & logistics	How to deploy materials in field
Laboratory	Best diagnostic technology
Sociology	How to deliver health messages
Border security	Appropriate screening at ports
Education	Training practices and materials
Immunisation	Immunology and vaccinology
Drug development	Evaluation of specialist therapeutics
Politics	Information for government & public
Business administration	Resources available in industry

Public Health England

PraxisUnico. auril Conference 2017

The world was faced with the largest ever recorded Ebola outbreak - declared by the WHO as "Public Health Emergency of International Concern"

Country	Cases	Deaths	Ended
Liberia	10675	4809	9 Jun 2016
Sierra Leone	14122	3955	17 Mar 2016
Guinea	3814	2543	1 Jun 2016
Nigeria	20	8	19 Oct 2014
Mali	8	6	18 Jan 2015
USA	4	1	21 Dec 2014
Italy, UK, Senegal, Spain	1 each	0	20 Jul 2015

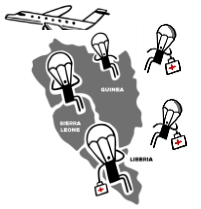
6 Dec 2013 Patient Zero dies in Guinea
8 Aug 2014 WHO declares "PHEIC" 1
28 Jan 2015 Response enters Phase II 2
29 Jul 2015 Lowest number of new cases 3
29 Mar 2016 WHO lifts "PHEIC" 4

KEC

Public Health England

PraxisUnico. auril Conference 2017

Knowledge and trained people had to be mobilised and made available in the affected countries in West Africa



6 Dec 2013 Patient Zero dies in Guinea
8 Aug 2014 WHO declares "PHEIC" 1
28 Jan 2015 Response enters Phase II 2
29 Jul 2015 Lowest number of new cases 3
29 Mar 2016 WHO lifts "PHEIC" 4

Public Health England

PraxisUnico. auril Conference 2017

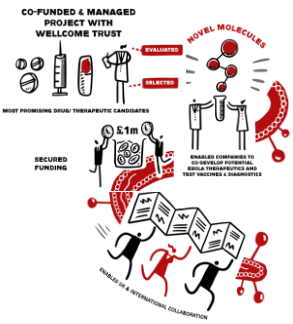
Knowledge was dispersed rapidly across the UK and internationally

6 Dec 2013 Patient Zero dies in Guinea
8 Aug 2014 WHO declares "PHEIC" 1
28 Jan 2015 Response enters Phase II 2
29 Jul 2015 Lowest number of new cases 3
29 Mar 2016 WHO lifts "PHEIC" 4

Public Health England

PraxisUnico. auril Conference 2017

CO-FUNDED & MANAGED PROJECT WITH WELLCOME TRUST



6 Dec 2013 Patient Zero dies in Guinea
8 Aug 2014 WHO declares "PHEIC" 1
28 Jan 2015 Response enters Phase II 2
29 Jul 2015 Lowest number of new cases 3
29 Mar 2016 WHO lifts "PHEIC" 4

Public Health England

PraxisUnico. auril Conference 2017

New emergency preparedness centre

Rajiv Gandhi Institute of Chest Diseases (RGICD) and Public Health England (PHE) have joined hands to set up a collaborative center for emergency preparedness and response at RGICD. The centre was inaugurated in the City on Monday.

A team of representatives from PHE, its Chief Executive Duncan Selbie and senior business development manager Professor S S Vasan were present on the occasion. "It is a great move and will help us handle outbreaks," said Dr Shashidhar Baggi, Director, RGICD.

DECCAN HERALD 3

THET

6 Dec 2013 Patient Zero dies in Guinea
8 Aug 2014 WHO declares "PHEIC" 1
28 Jan 2015 Response enters Phase II 2
29 Jul 2015 Lowest number of new cases 3
29 Mar 2016 WHO lifts "PHEIC" 4

Public Health England

PraxisUnico. auril Conference 2017

EBOTAb case study

MicroPharm

Public Health England

Division of Structural Biology, Nuffield Department of Clinical Medicine

Evaluation partners

FONDATION MERIEUX
A family foundation dedicated to fighting infectious diseases

Universitätsstadt Marburg

Public Health England

PraxisUnico. auril Conference 2017

Fast-track approach

- Aug '14 - MicroPharm initiates literature review and contacts PHE, which ropes in Oxford
- Sep '14 - Collaborative venture established
- Nov '14 - First batch of GP produced and immunisation commenced
- Dec '14 - Supply of purified IgG by MicroPharm to PHE for first in vitro study
- Jan '15 - Production of purified IgG by MicroPharm and 1st guinea pig study by PHE completed
- Feb '15 - Patent filed, second guinea pig study by PHE
- Apr '15 - 1st non-human primate ("NHP") study completed
- Jun '15 - 2nd NHP study at completed
- Jul '15 - 3rd guinea pig study by PHE completed
- Jul '15 - Sufficient antisera available to produce a GMP batch of EBOTAb
- Oct' 15 - First journal paper accepted

Public Health England

PraxisUnico. auril Conference 2017

CSFs for rapid knowledge transfer

- A finite window of opportunity
- MicroPharm and PHE had worked together for some time on other collaborative ventures
- Parties prepared to incur costs based on an "agreement in principle"
- Parties had a pragmatic approach to risk/reward sharing
- All three parties needed for success
- PHE's extensive network of collaborators

Public Health England

PraxisUnico. auril Conference 2017

Public Health England

PraxisUnico. auril Conference 2017

From Ebola to Zika

- Public Health Emergency of International Concern (PHEIC) is a formal WHO declaration promulgated by its Emergency Committee under IHR
- 2009 (Swine Flu); 2014 (Polio, Ebola); 2016 (Zika: Microcephaly+GBS)
- But not MERS!
- PHEIC declared (1 Feb 2016) even before the US CDC established the Zika link conclusively (13 Apr 2016). 58 days Ebola overlap. Lifted 18 Nov 2016.
- As of 1 December 2016, of the 28 affected countries/territories, Brazil alone contributed to 91% burden (2189 cases of microcephaly and other CNS malformations), with 200k-1.5m suspected Zika cases
- Biosafety Level 2 sufficient – which has made R&D easier compared to Ebola
- KEC processes and contract templates are reused effectively and negotiations concluded in 24-48 hours (even before the experimental plan being finalised!)

Public Health England

PraxisUnico. auril Conference 2017

Fast track model agreement - Scenario

- The Institution (e.g. PHE) prioritises and evaluates the Developer's Materials against Pathogen of Interest during a 'One Health' crisis facing people, animals and/or the environment, and contributes to the potential development of the Materials as Product.
- Confidential Information excludes Results.
- The Institution has the right to use for academic and research purposes.
- The Institution can notify Global Stakeholders that they are carrying out the Work, timeline, details of the Developer, Materials, etc.
- The Institution has right to publish Results (including 'poor' or 'negative' results) and make them available in databases set up by Global Stakeholders.
- Discount if Product is sold back to the Institution or Commissioning Bodies.

Public Health England

PraxisUnico. auril Conference 2017

Fast track model agreement – What next?

- Now part of the revised "Lambert 2 Toolkit" hosted by the UK *Intellectual Property Office (www.bit.do/fast-track)*
- Launched by Minister for Intellectual Property Baroness Neville-Rolfe in Oct-16
- Has been incorporated into the milestones of the Australia-Canada-UK-USA *Medical Counter Measures Consortium* (MCMC) Filovirus Task Group
- Has been recommended by the Canada-headquartered *Five Eyes BSL4 Laboratories Network* as good practice for 'One Health' emergencies
- Has been indexed by the *US National Library of Medicine* as a Resource Guide for Disaster Medicine and Public Health

We have requested *InterLab* to be aware of this template for their own use.

We wish to add cross-governmental MTAs, Crown Bodies MoU to this toolkit.

Public Health England

PraxisUnico. auril Conference 2017

Fast track model agreement vs Lamberts

	Terms	IPR
Agreement 1	Collaborator has non-exclusive rights to use in specified field/territory; no sub-licences	Institution
Agreement 2	Collaborator may negotiate further licence to some or all Institution IP	Institution
Agreement 3	Collaborator may negotiate for an assignment of some Institution IP	Institution
Agreement 4	Institution has right to use for non-commercial purposes	Collaborator
Agreement 4A	Each party has right to exploit certain results created during the project and takes assignment of those results. Institution has right to use for academic and research purposed, the Collaborator for research purposes	Institution and Collaborator
Agreement 5	Contract research: no publication by Institution without Collaborator's permission	Collaborator
Agreement 6	Institution has right to use for academic and research purposes	Collaborator

Public Health England

PraxisUnico. auril Conference 2017

Fast track model agreement vs Lamberts

	Terms	IPR
Fast track model agreement	Institution has right to use for academic and research purposes Confidential Information excludes Results Institution can notify Global Stakeholders that they are carrying out the Work, timeline, details of the Developer, Materials, etc. Institution has right to publish Results (including 'poor' or 'negative' results) and make them available in databases set up by Global Stakeholders Discount if Product is sold back to the Institution or Commissioning Bodies	Collaborator (or Developer)

Most important distinction: Fast track was developed for "war time" whereas Lamberts are currently suited for "peace time".

Public Health England

PraxisUnico. auril Conference 2017

Special thanks to colleagues at

MicroPharm

Public Health England

Mr Ian Cameron, Ms Dipti Dashore, Ms Jenny Chan-Pensley and Dr David Rhodes especially.

Next event:

Intellectual Property Office

#learnIP

HG2L2: The Hitchhiker's Guide to the Lambert 2 Toolkit

Jenny Vaughan
Innovation Policy
Intellectual Property Office

Intellectual Property Office is an operating name of the Patent Office

The UK-IPO Goals

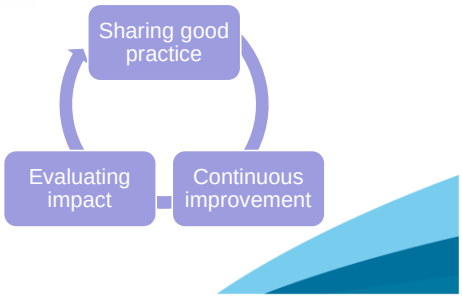
Goals:

- Promoting UK growth through IP policy
- Delivering high quality rights granting services
- Ensuring IP rights are respected and appropriately enforced
- Educating and enabling business to understand, manage and protect their IP
- Improving the skills and capability of our people
- Increasing efficiency and delivering value for money

Our 2017-20 corporate priority

"We will support UK innovation by providing access to tools and resources that improve the ability of the business and research communities to derive value from their IP and to stimulate collaboration."

The IPO's role as secretariat



Thank you

To find out more information visit IP in Education at:
www.gov.uk/ipo

You can email the team at:
innovation@ipo.gov.uk

Visit our exhibition stand today!

follow us on Twitter @The_IPO #learnip