

# Business Development and Licensing Journal

*For the Pharmaceutical Licensing Groups*

**Maximising value through out-licensing & divestment**

**The future is now: negotiating in post Brexit Europe**

**Actavis vs Eli Lilly: UK Supreme Court introduces Doctrine of Equivalents in Patent Law**

**Introducing the revised Lambert toolkit**



# Welcome



As we move into 2018 there seems to be some small respite from the political instability which was a key feature in the economic landscape during 2017 as the tax reforms progress in the USA. The much anticipated impact of this in terms of deal and acquisition activity is reviewed in the December Deal Watch article from Roger Davies.

With a short pause for the Christmas break, there is hope that Brexit will now not continue its domination of the UK headlines. Although there is still no certainty over what exactly Brexit will bring, our contracts need to be able to adapt to cover new commercial circumstances; Andrew Gottschalk takes a look at the negotiation landscape in the article "The Future is Now".

Also reflecting on the fact that we may in the future need to report on different perspectives from Europe and the UK, Alisa Carter from Gowling WLG has provided insight into the landmark case *Actavis v Lilly* on the doctrine of equivalents explaining the infringement ruling of the UK Supreme Court.

Staying with changes to current practice, updates to the original Lambert agreements are reviewed in our article on the Lambert toolkit. Introduced back in 2004 the Lambert agreements were seen as a means of simplifying negotiations between industry and academia. Finally, focusing on operational aspects, this issue is completed by some insights from AstraZeneca on successful out-licensing and divestments.

I hope that you enjoy reading Issue 26, sending best wishes for a successful and prosperous New Year from all here at the PLG!

Sharon Finch

# Contents

- 3 Editorial**  
*Sharon Finch, Medius Associates*
- 5 Maximising Value Through Out-licensing & Divestments**  
Leveraging the core Alliance Management skill sets to affect a smooth and efficient asset transfer  
*By Steven E. Twait, and Emma Barton, AstraZeneca*
- 13 The Future is now: Negotiating in Post Brexit Europe**  
The UK is consumed by the politics of Brexit. Our attention is locked onto the management of the exit process  
*By Andrew Gottschalk, Group AG*
- 21 Actavis vs. Eli Lilly: UK Supreme Court introduces Doctrine of Equivalents in Patent Law**  
*By Pat Duxbury and Ailsa Carter, Gowling WLG*
- 27 Introducing the Revised Lambert Toolkit**  
Can model agreements help accelerate business development and licensing?  
*By S.S. Vasan, PHE & University of York, Christine Reid, Partner, Northwood Reid, Rupert Osborn, CEO, IP Pragmatics*
- 35 Medius Deal Watch**  
Monthly review of the top deals by value in the healthcare sector  
*By Roger Davies, Medius Associates*

The *Business Development & Licensing Journal* is available free to PLG members.

If you would like to join the PLG please visit the website at [www.plgeurope.com](http://www.plgeurope.com)

## Business Development & Licensing

**Journal** is published by:

The Pharmaceutical Licensing Group (PLG) Ltd  
The Red House  
Kingswood Park  
Bonsor Drive  
Kingswood  
Surrey KT20 6AY

[www.plgeurope.com](http://www.plgeurope.com)

## Editorial Board

**Sharon Finch**  
Editor  
Medius, UK

**Nadine Maalouf**  
Allergan  
Italy

**Jean Guillaume**  
Bioprojet  
France

**Pamela Demain**  
Merck & Co  
USA

**Kim Bill**  
Nestle  
Switzerland

**Jürgen Langhärig**  
Serodus  
Denmark

**Irinia Staatz Granzer**  
Staatz Business  
Development & Strategy,  
Germany

**Enric Turmo**  
Esteve,  
Spain

## Editorial Enquiries

**Sharon Finch**  
T: +44 (0) 20 8654 6040  
E: [admin@plg-uk.com](mailto:admin@plg-uk.com)

## Advertising Enquiries

**Adam Collins**  
T: +44 (0) 1737 356 391  
E: [admin@plg-uk.com](mailto:admin@plg-uk.com)

Publisher's note: The views expressed in the Business Development & Licensing Journal are those of the authors alone and not necessarily those of the PLG. No responsibility for loss occasioned to any person acting or refraining from action as a result of this material in this publication can be accepted by the Publisher. While every effort has been made to ensure that the information, advice and commentary are correct at the time of publication, the Publisher does not accept any responsibility for any errors or omissions. The right of the author of each article to be identified as the author of the work has been asserted by the author in accordance with the Copyright, Designs and Patents Act 1988.

# Introducing the revised Lambert Toolkit

## Can model agreements help accelerate business development and licensing?

*By S.S. Vasan - PHE & University of York, Christine Reid - Partner, Northwood Reid, Rupert Osborn - CEO, IP Pragmatics*

The Lambert Toolkit was created to help improve the process of negotiating collaborative research agreements between universities and business through a series of model agreements and guidance. A review by IP Pragmatics in 2013 showed that it would be useful to keep the Toolkit alive by updating the model agreements and guidance. The revised Lambert Toolkit which was launched in October 2016 was meant to address that. Has it?

### About the Authors

**S.S. Vasan** is Public Health England's Senior Business Development Manager and Honorary Visiting Professor at the University of York. A former McKinsey consultant and Rhodes Scholar, he previously worked for Oxford University and as Head of Public Health for its spin-out company Oxitec. He co-authored the fast track model agreement ([www.bit.do/fast-track](http://www.bit.do/fast-track)) and received the Impact Award for Contribution to Society on behalf of his team for knowledge exchange and commercialisation during the Ebola crisis.

**Christine Reid** is founding Partner of the firm Northwood Reid and Legal Adviser to the Lambert Working Group. Her clients include national and multi-national companies, academic institutions, public sector research establishments, Research Councils and a regional development agency.

**Rupert Osborn** is the CEO & Principal Consultant of IP Pragmatics Limited. He has worked in the field of technology commercialisation since 1996. His specific areas of expertise are licensing strategy, negotiation and innovation management. His experience covers the commercialisation of different forms of intellectual property including trademark, copyright and patent licensing.

### The Lambert Toolkit

The Lambert Toolkit was first developed in 2004 to help improve the process of negotiating collaborative research agreements between universities and business through a series of model agreements prepared by a Working Group representing industry and academia. The aim was to produce model agreements which represented a compromise that was fair and balanced, without favouring either party's interests, as well as guidance on their use and the issues commonly encountered in collaborative projects (not least the ownership and licensing of intellectual property rights).

The original Toolkit<sup>1</sup> followed an independent Review of Business-University Collaboration carried out in 2003 by Sir Richard Lambert, later Director-General of the Confederation of British Industry (CBI). He was tasked by HM Treasury to explore the opportunities arising from changes in business R&D and university attitudes to collaboration, and to highlight successful methods of collaboration between universities and industry, including small- and medium-sized enterprises (SMEs). His review made a number of recommendations to help shape policy in this area, and two of these led directly to the development of the eponymous Lambert Toolkit.

## Usage Review

The Intellectual Property Office (IPO) commissioned a review in collaboration with PraxisAuril<sup>ii</sup>, as well as with the CBI and Innovate UK<sup>iii</sup>. This review, conducted by IP Pragmatics Limited in 2013<sup>iv</sup>, relied on evidence from a wide spectrum of public and private organisations collected through an online survey (256 responses), and supplemented by in-depth interviews (48 organisations).

The key findings were as follows:

- Knowledge of the Lambert Toolkit was well established in the research and innovation community, albeit with some differences between SMEs, multi-nationals, and across industry sectors.
- Where the model agreements were used, they were often used in practice not as a first choice, but rather as a compromise position.
- The Toolkit was valued as a good solid foundation for negotiation, a source of clauses that can help resolve negotiation points, and an independent example of a fair and reasonable approach, and its influence therefore extended much more widely than simply to those who used the model agreements.
- The Toolkit can help identify and reach workable solutions to the key issues which arise from different university and industry missions and priorities, and which underlie some of the reasons that the model agreements are not always chosen as a starting point.
- Improvements were suggested to the Toolkit; the most common recommendations being to bring the model agreements up-to-date, to provide additional guidance and to improve awareness and uptake.

## The Updated Lambert Toolkit

It was clear that the Lambert Toolkit had a positive influence on some innovative research partnerships between UK universities and businesses, but the IP Pragmatics' review identified ample scope to develop these foundations through better communication of the best use of the existing tools, targeting them at the organisations that need

them the most with endorsement of their benefit in different situations.

Accordingly, the Lambert Working Group was refreshed and worked on updating the Toolkit and extending the guidance in areas such as state aid and the charitable status of universities, data protection and anti-bribery. The revised Lambert Toolkit<sup>v</sup> was launched on 6 October 2016 at the AURIL annual conference in Edinburgh by the then Minister of State for Energy and Intellectual Property, Baroness Neville-Rolfe.

Since then, a number of professional bodies have conducted special events across the UK to promote awareness about the Toolkit, with the authors of this article and our colleagues as invited speakers<sup>vi</sup>. Our reflections in this article have been shaped by our interactions with current and potential users of the Toolkit in these fora.

A key and recurring topic of discussion was whether the updated Toolkit is better placed to address the key recommendation of the review, viz. to improve uptake by industry.

The objectives of the Toolkit are to:

- facilitate negotiations between potential collaborators;
- encourage potential collaborators to agree the principal terms before discussing the wording of the collaboration agreement;
- reduce the time, money and effort required to secure agreement;
- inform less experienced collaborators; and
- provide examples of best practice.

The revised Lambert Toolkit consists of:

- heads of terms to help potential collaborators identify and agree the key issues before looking at the wording of any agreements;
- seven 1-to-1 model research collaboration agreements (numbered 1 to 6, plus 4A), details of which have been summarised in this article (**Table 1**);

- a decision guide to help potential collaborators to decide which of the seven collaboration agreements might be most useful to them;
- four multi-party consortium agreements (called A to D), details of which have also been summarised in **Table 1**;
- guidance notes on all the model agreements and on issues such as state aid, charitable status, warranties, liability and data protection;
- model variation agreements for both the collaboration and the consortium agreements; and

- a fast track model agreement (described in detail separately).

The model agreements are starting points and their use is not compulsory. Each model agreement envisages a different set of circumstances, and therefore provides a different approach as to who is to own and have rights to use the intellectual property in the results of the project. None of the Lambert agreements is sector-specific, allowing for flexible use. The Toolkit is provided free of charge for anyone to use.

**Table 1: Summary of the Lambert Model Agreements**

Research Collaboration Agreement	Terms (see <a href="http://bit.do/lambert2">http://bit.do/lambert2</a> )	Owner of the Intellectual Property Rights in the Results
1	The Industrial Collaborator has non-exclusive rights to use the Results, possibly in a specified field/territory for any purpose	Academic/ Research Institution
2	The Industrial Collaborator has non-exclusive rights to use the Results, possibly in a specified field/territory for any purpose and an opportunity to negotiate an exclusive licence of some or all of the Institution IPR	Academic/ Research Institution
3	The Industrial Collaborator has non-exclusive rights to use the Results, possibly in a specified field/territory for any purpose and an opportunity to negotiate an assignment of some or all of the Institution's IPR	Academic/ Research Institution
4	The Academic/Research Institution has right to use the Results for academic and research purposes and there are academic publication rights	Industrial Collaborator
4A	Each party has right to exploit certain Results created during the project and takes assignment of those Results. The Academic/Research Institution has the right to use the Industrial Collaborator's Results for academic and research purposes, there are academic publication rights and the Industrial Collaborator has the right to use the Academic/Research Institution's Results for research purposes	Academic/Research Institution and the Industrial Collaborator
5	Contract research: the Academic/Research Institution has no right to use the Results for academic and research purposes and there is no academic publication without the Industrial Collaborator's permission	Industrial Collaborator
6	Knowledge Transfer Partnership: the Academic/Research Institution has the right to use the Results for academic and research purposes and there are academic publication rights	Industrial Collaborator
Fast track model agreement	Contract research: no publication by the Institution without the Collaborator's permission which cannot be unreasonably withheld The Institution has the right to use Results for academic and research purposes Confidential Information excludes Results The Institution can notify Global Stakeholders that they are carrying out the Work, timeline, details of the Developer, Materials, etc. The Institution has the right to publish the Results (including 'poor' or 'negative' results) and make them available in databases set up by Global Stakeholders Discount if a Product is sold back to the Institution or Commissioning Bodies	Collaborator (or Developer)

Consortium Agreement	Terms
A	Each member of the consortium owns the IPR in the Results that it creates. They grant each of the other parties a non-exclusive licence to use their Results for any purpose.
B	There is a lead exploitation party. The other parties assign their IPR in the Results or grant an exclusive licence to the lead exploitation party. The Lead Exploitation Party undertakes to exploit the Results and share the proceeds with the other parties.
C	Two of the four parties are best placed to exploit different Results. Each of the two takes an assignment of the IPR in specific Results, undertakes to exploit those Results and share the proceeds with the other parties.
D	Each member of the consortium owns the IPR in the Results that it creates. They grant each of the other parties a non-exclusive licence to use those Results for the purposes of the project only. If any member of the consortium wishes to exploit another's Results, it must negotiate a licence or assignment with the owner of those Results.

### Fast Track Model

The revised Toolkit also contains the fast track model agreement developed by Public Health England (PHE)<sup>vii</sup>. According to its CEO Duncan Selbie<sup>viii</sup>: “The PHE fast track evaluation agreement was developed during the Ebola crisis to make it easier for public bodies that need to respond to rapidly-evolving situations to work in an agile way, and at short notice, with industry and academia. It provides a framework that protects the interests of the taxpayer but involves a minimum of negotiation and legal drafting, which could otherwise be a barrier during a period of emergency response.”

During an emergency like Ebola or Zika, failure to achieve quick consensus is not an option. Public bodies and global stakeholders must avoid duplication of efforts and promptly share information on which countermeasures are promising and which are dead-ends in order to ensure a coordinated global response.

The ability to use the results for non-commercial purposes will be critical to allow further research and evaluation. If public sector resources are diverted towards fast track evaluation and development of a countermeasure, then it is also reasonable to expect a fair value for the taxpayer if it is sold back to the public in the future.

This way of working yields significant public health benefits, therefore the fast track agreement has gained wider acceptance in US, Canada, Australia, etc<sup>ix</sup>. It has also contributed to PHE winning the PraxisUnico and UK Research Councils Impact Award for Contribution to Society<sup>x</sup>. Efforts are underway to adapt the Toolkit (including the fast track model agreement) in emerging economies like Brazil, China, India and Korea to support knowledge exchange internationally.

“The fast track model agreement is useful in public health emergencies because failure to achieve quick consensus is not an option, for example during the Ebola crisis”



### Perceptions so far

In the PraxisUnico-Auril Annual Conference at Sheffield (15 June 2017 – see photo), we conducted a straw-poll of the 70 delegates who came to our talk. It gave a useful insight on perceptions, even if it is not statistically accurate (**Table 2**). It is too early to assess the true impact of the updated Lambert Toolkit, but most of the professionals we met were aware of the Toolkit and a majority of them are using them. This is our target audience and therefore unsurprising; however, the number of people aware of and using the Toolkit was lower at the Chartered Institute of Patent Attorneys Congress (28 September 2017).

Early data such as click statistics seem to suggest that the 1-to-1 model agreements are more popular than the multi-party consortium agreements<sup>xi</sup>. The guidance and the decision tree are widely praised as useful tools. The Toolkit does not yet cater for business-to-

business collaborations which might especially benefit SMEs. We also heard an interesting application of these model agreements, whereby two parties decided the type of collaboration they should enter into by looking at the type of model agreement they were prepared to sign!

The reconstitution of the Lambert Working Group, and the fact that the revised Toolkit is hosted on a neutral website (of the Intellectual Property Office) have enabled wider acceptance of the model agreements. However, the model agreements cannot cover every situation so the closest one should be used as a starting point for negotiation in order to achieve a reasonable compromise. Academic partners should also remember that the minimum for industry is almost always a non-exclusive licence. We feel that these key points are now better understood, at least by everyone who attended the UK professional events at which we spoke.

“Lambert Agreements cannot fit every situation so the closest model agreement should be used as a starting point for negotiation to achieve a reasonable compromise,”



**Table 2: Straw poll at the Sheffield conference session**

**Q1 - Were you NOT aware of Lambert 2 Toolkit before today?**

Only 9% (6 out of 70) not aware

**Q2 - Have you reviewed collaboration agreement processes since the revised Lambert Toolkit launch in October 2016?**

6% (4 out of 70) did

**Q3 - Has the Toolkit informed collaboration / consortium agreements or how you develop them?**

10% (7 out of 70) said “yes, but marginally”

**Q4 - Are you still using the model agreements?**

Majority (about 67%) said yes

**Q5 - Any observations on usage?**

There were observations on the decision tree, state aid and knowledge transfer partnerships (Lambert 4A Agreement). More details are presented under the section ‘Perceptions so far’ and in our blog.<sup>xi</sup>

We believe that the Lambert Principles (**Table 3**) underlying the original Toolkit and its revision(s) have not changed and will not change. We continue to stress the importance of saving time through the use of “Heads of Terms” and by anticipating the collaboration agreement terms when

applying for Knowledge Transfer Partnerships (Lambert model agreement 4A). The guidance document has a wealth of resources clarifying issues such as state aid, the charitable status of universities, anti-bribery and data protection.

**Table 3: Enduring Lambert Principles**

Rights to use IPR are key – the 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 are needed

Only a starting point/negotiation – cannot run on automatic pilot

Ease/speed the process – cannot solve every issue

Cannot cover every scenario – but can cover common scenarios

Aim for a workable and reasonable compromise





It is important to remember that the Toolkit is a means to an end (viz. successful contracts, outcomes and wealth creation). It will need to be updated regularly, for instance, the introduction of the European Data Protection Regulation on 25 May 2018 will necessitate appropriate updates to the data protection provisions of the model agreements and the guidance on data protection. The IPO is also working with key stakeholders to conduct a survey to understand how the Toolkit is being used, by whom (both universities and industry) and what future revisions may be needed.

*The authors would like to acknowledge the Lambert Working Group (especially its chairman Professor Malcolm Skingle CBE of GSK and its member Dr Geoff Archer of Teesside University for their comments); PraxisAuril (which has published blogs and newsletter articles on this topic); and the Intellectual Property Office (especially Jenny Vaughan for her support). Opinions expressed in the article are the authors' own and do not reflect those of our employers. The authors can be contacted at [vasan@phe.gov.uk](mailto:vasan@phe.gov.uk) or [prof.vasan@york.ac.uk](mailto:prof.vasan@york.ac.uk), [christine.reid@northwoodreid.com](mailto:christine.reid@northwoodreid.com) and [rupert.osborn@ip-pragmatics.com](mailto:rupert.osborn@ip-pragmatics.com)*

- i. Lambert Review of Business-University Collaboration, Final Report (ISBN: 0-947819-76-2), HM Treasury: December 2003. Available at <http://bit.do/lambert1>
- ii. AURIL (Association for University Research and Industry Links) and PraxisUnico have merged effective 1 April 2017 to form a single organisation representing the Knowledge Exchange and Commercialisation (KEC) profession in the UK. Their new identity "PraxisAuril" was formally revealed at the AURIL annual conference in Bristol on 5-6 October 2017.
- iii. Innovate UK was then known as the Technology Strategy Board (TSB).
- iv. Collaborative Research between Business and Universities: The Lambert Toolkit 8 Years On (ISBN: 978-1-908908-72-8), Intellectual Property Office: 8 May 2013. Available at <http://bit.do/lambert-usage>
- v. Available at <http://bit.do/lambert2>
- vi. For example, the Licensing Executives Society of Britain & Ireland conducted seminars in London (10 November 2016) and Manchester (20 June 2017). This topic was prominently covered at the Institution of Engineering and Technology's Horizontal Innovation Conference (30 January 2017) and at the Chartered Institute of Patent Attorneys Congress (28 September 2017), both of these in London. The PraxisUnico-Auril Annual Conference in Sheffield (15 June 2017) had an informative session titled "H2GL2: The Hitchhikers Guide to the Lambert 2 Toolkit" attended by 70 delegates.
- vii. Available at <http://bit.do/fast-track>
- viii. Duncan Selbie's Friday Message, Public Health England: 7 October 2016. Available at <http://bit.do/fast-track-duncan>
- ix. See US National Library of Medicine's Disaster Lit, for instance, at <https://disasterlit.nlm.nih.gov/record/13585>. The Toolkit has also been adopted as best practice in government-to-government interactions through the Australia-Canada-UK-US Medical Countermeasures Consortium and the five eyes BSL4Znet between these four countries plus Germany.
- x. Winners of Impact Awards 2015 announced. PraxisUnico & RCUK: 15 September 2015. Available at <http://bit.do/impact-awards-2015>
- xi. See our blog <http://bit.do/praxis-lambert-blog> for caveats on this

# **The Pharmaceutical Licensing Group**

**[www.plg-uk.com](http://www.plg-uk.com)**

