



LESI Committees:

End of Year Report for the 2023 International Management and Delegates Meeting (IMDM) – April 30, 2023

Submitted: 16 March 2023

Committee Name	Life Sciences Committee
Chairs and Vice Chairs	Joanne van Harmelen and Richa Pandey
LESI Board Liaison	Hayley French

Action Plan

The co-chairs have jointly taken responsibility for arranging the activities for the year to date.

- **Our goals for 2022-2023 were:**

- Maintaining contact with members of the life sciences committee throughout the year with regular virtual and in-person events
- Arranging an in-person event at the Montreal LESI AGM
- Setting dates and presenting regular webinars throughout the year
- Providing content for *Les Nouvelles*
- Providing content for the LESI annual meeting

Other than providing content for *Les Nouvelles*, we are pleased to report that each of these goals have been met.

- **Meetings / Calls**

The Life Sciences Committee co-chairs and LESI Board Liaison have regular meetings to strategize and plan.

Furthermore, a Life Sciences Committee networking meeting was held on **12 July 2022**.

Attendees:

Joanne van Harmelen (jvanharmelen@ENSafrica.com) ; Richa Pandey (richa@krishnaandsaurastri.com); Hayley French (Hayley.French@apitope.com); Anna Gregson (ALGregson@mathys-squire.com); Charlotte Tillett (charlotte.tillett@stevens-bolton.com); Frederic Portal (Frederic.Portal@twobirds.com); Marie Barani (Marie.Barani@allenoverly.com); Julia Barnes-Weise (jbw@ghiaa.org); Ichiro Nakatomi (inakatomi@avida-science.com); Eric Victory (ericvictory71@gmail.com; evictory@auriniapharma.com); Clarissa Ceruti (Clarissa.ceruti@bugnion.eu); David Holt (David.holt@potterclarkson.com); Jake Marshall (Jake.marshall@carpmaels.com).

A copy of the minutes is available through connect.LESI.org.

A further meeting is set for **24 March 2023**.

Joanne van Harmelen visited Delhi in November 2023, and met with Richa Pandey in person for the first time, over a wonderful dinner to discuss and plan some content for the Life Sciences Committee over the next year. Further engagement and networking including other Life Sciences members will occur at our meeting on 24 March 2023 and again at the AGM in Montreal.

- **Key topics for webinars**

The LESI Life Sciences Committee virtual webinar event calendar is set out below.

The following webinars have been held:

- 11 October 2022, 09:00 GMT - **ABS and bioprospecting and licensing challenges / best practices from South Africa, India, Brazil.**
- 17 January 2023, 09:00 GMT – **Exploitation of new technologies in the life sciences industry**

The following webinars are planned:

- 24 March 2023, 16:00 GMT - **Cell and Gene Therapy Partnering and Deal-Making – Where now?**
- Date, to be confirmed - **mRNA therapeutics ‘post’-Covid**
With the demand for Covid vaccines waning, the commercials of vaccine supply are becoming more dominant, as we have seen with the increase in recent Covid-vaccine

related litigation. This has an impact on pharmaceutical originators that are producing vaccines (whether for Covid-19 or other therapeutics) in the mRNA field, on licensees through the WIPO/Medicines Patent Pool who may wish to pivot to other burgeoning developing country diseases, and on voluntary licensees and co-licensees working with pharmaceutical originators to manufacture mRNA vaccines and therapeutics in developing countries. This panel discussion will present the following case-studies:

- WIPO/MPP licensees in South Africa – issues around effective licensing of mRNA vaccine technology, including technology transfer, Covid vaccine demand, and options for the use of licensed mRNA technology for other diseases or infections in developing countries
- Perspectives on the development of new mRNA therapeutics by pharmaceutical originator companies
- Perspectives from voluntary licensees of mRNA technology from pharmaceutical originator companies in developing countries such as India

Moderator: Luca Falciola, Scibilis Consulting Services, Ixelles (Belgium), LFalciola@scibilis.be.

We will be putting out a call for further webinars for 2023 at our networking session on 24 March 2023.

Additional possible topics that may still be included in the open slots:

1. Option agreements have become increasingly popular where the licensor (who is often a small or mid-size biotech company) continues to conduct research and development on the asset, and the licensee (who is often a big-pharma/biotech company) makes a smaller up-front payment for an option to exercise an exclusive license or assignment of the IP at a later stage, on payment of a more significant amount. The agreement may even include an option to acquire the licensee company later on.
2. Remedies outside of the usual remedies for material breach are becoming more common in biotech agreements where the agreement is retained, but claims are provided for damages or a percentage reduction in any future payments related to the agreement. Other issues that influence deal dynamics are also considered, such as the requirement for warranty and indemnity insurance.
3. Far greater emphasis is being placed on IP due diligence and patent landscaping analysis by prospective licensees, particularly those from big pharma/biotech, and relatedly there is an increased inclusion of corresponding warranties in IP transactions. Licensors are therefore also being forced to consider the IP landscape related to their technologies in readiness for any licensing transaction.
4. Complex transactions including public-private collaborations are common, particularly where academic institutes have generated IP relating to technologies that have been licensed to spin-off or small biotech companies, which then are looking to strike deals with big pharma/biotech. These can be challenging, for example, where the academic licensor may have included provisions in the license agreement with the spin-off or small biotech company that would be problematic to big pharma/biotech, such as retaining IP relating to improvements/modifications of the licensed IP, clauses relating to limitations on sub-licensing, clauses providing for cancellation of the license or assignment back to the academic institute if commercialisation does not proceed quickly enough. Therefore it is important, even in the early stage, to consider which clauses may need to be amended in order to facilitate later deals between the spin-off or small biotech company and big pharma/biotech.

- ***Events / Webinars executed***

The LESI Life Sciences Committee held the following virtual workshop on **11 October 2022**.

Bioprospecting, access and benefit sharing in developing countries, 30 years on

The Convention on Biological Diversity (CBD) was signed by 150 government leaders 30 years ago at the 1992 Rio Earth Summit, and recognizes intrinsic value of biodiversity and the importance of conservation and sustainable use of plant genetic resources to fulfil the food, health and other necessities of the growing world population. The CBD is supported in the implementation of its third objective, the fair and equitable sharing of benefits arising out of the utilization of genetic resources by the Nagoya Protocol on Access and Benefit Sharing (ABS) which came into force almost 8 years ago on 12 October 2014. We are still grappling with the question of whether the ABS system that has been implemented through national governments is effective in realising its objectives. The panel consisting of experts from Brazil, India and South Africa will explore some of the challenges in developing countries relating access and the sharing of benefits, and consider how best to achieve tangible results through licensing and bioprospecting agreements.

*Panel: Ana Claudia Mamede Carneiro; Dr. Deepa Tiku; Dr. Joanne van Harmelen
Moderator: Ms. Richa Pandey*

The LESI Life Sciences Committee held the following virtual workshop on **17 January 2023**.

Exploitation of new technologies in the life sciences industry

The successful development of the Covid-19 vaccines has not only demonstrated the importance of collaborations between public and private actors of all sizes to (timely) bring drugs to patients, but has also proven that smaller companies too can benefit from licensing and acquisition deals. This webinar will provide an overview of the different exploitation practices of new pharma and biotechnologies, whether through licensing, partnership or collaboration, and discuss related legal, financial and business challenges.

Come and join us on 17 January for a live discussion with life sciences professionals who will share their own experience and address amongst others:

1. The pros and cons of licensing, acquisition and other collaborations;
2. What to keep and what to license for third party exploitation;
3. What's the value of such new technologies and how do you calculate such value?
4. What if the collaboration does not work?
5. Case study: the pandemic, mRNA and LNP technologies: a diversity of strategies and actors of all sizes from public and private sector.

*Panel: Tine Carmeliet, Professor Petro Terblanche, Mike Rea
Moderator: Marie Barani*

The LESI Life Sciences Committee will hold the following virtual workshop on **24 January 2023**.

The current landscape in ATMP – IP, partnering, funding and more!

This webinar intends to discuss the current market in the advanced therapeutic medicinal product (ATMP) space, with a particular focus on the challenges specific to this sector, and how those impact on aspects such as due diligence, collaboration, funding and deals. These topics will be explored using case studies from two ATMP companies at different growth stages, Quell Therapeutics and NK:IO. Additional insights on access to technology, and issues on manufacturing and supply chain being provided by our speaker from the Cell and Gene Therapy Catapult, which works to support companies in this sector

Panel:

<i>Matthew Garner</i>	<i>Head of IP, Cell and Gene Therapy Catapult</i>
<i>Jodie Albutt</i>	<i>VP of IP, Quell Therapeutics</i>
<i>Michael Hunt</i>	<i>CEO of NK:IO</i>
<i>Kerstin Papenfuss</i>	<i>Director, Pharma, Deep Science Ventures</i>

Moderator:

<i>Anna Gregson</i>	<i>Partner, Mathys & Squire LLP</i>
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- LESI AGM Panel Discussion from the Life Sciences Committee:

Navigating the Deep Tech frontier in life sciences innovation

“Deep tech” refers to the intersection between artificial intelligence (AI), advanced materials and synthetic biology, oftentimes using combinations of these technologies for innovation. Deep tech in the life sciences is one of the most rapidly developing sectors in this field. This space is highly rich in IP and there are unique considerations relating to the protection, management, freedom-to-operate, open source use and commercialisation of intellectual property (IP) as well as relating to regulation that any business operating in this space must navigate. The LESI Life Sciences committee will present a panel discussion covering best practices for IP protection, licensing and regulation in this rapidly developing sector, with particular emphasis on the life sciences industry.

Moderator:

Danie Dohmen, Adams & Adams

Speakers:

Gina Bicknell, Pinsent Masons

David McIntosh, Ropes & Gray

Jude Sullivan, Evozyne, Inc

Madelein Kleyn, Mad K IP Consulting

Richa Pandey, Krishna & Saurastri.

- ***Suggestions for future focus / work to be done by the committee (including any change in scope, updates to the Charter, etc)***

Ichiro Nakatomi has proposed the establishment of an Industry Advisory Board and developed a proposal for this. We will engage further on the implementation of this Board

We will continue to hold quarterly webinars and at least bi-annual virtual/in person meetings for members to attend and network.

LESI Life Sciences Committee members who are attending various international events including INTA, AIPPI, BIO and the like are encourage to reach out to each other, with the aim of facilitating in-person gatherings and networking sessions.

We will continue to engage with the National Chapter Life Sciences LES committees in order to share events and resources.
