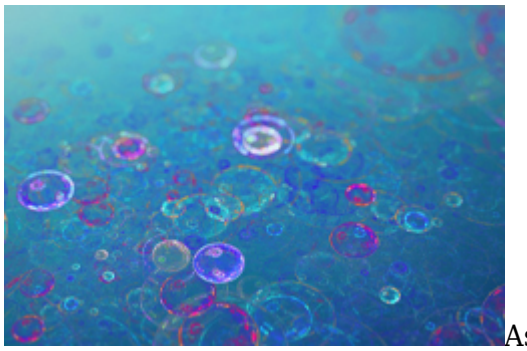
Navigating China-Related Transactions: Legal and Strategic Considerations

 As part of Goodwin's week of exclusive programming during the BIO International Convention in Boston, we're excited to invite you to a session focused on China-based NewCos and the dynamics of cross-border dealmaking. China continues to be a dynamic hub for biotech innovation, and companies operating in this space are navigating new opportunities and evolving challenges.

Join us for a morning of insightful conversations exploring what it takes to launch, grow, and expand China-based NewCos—and how to successfully pursue international transactions in a rapidly changing environment. From legal and regulatory foundations to cross-border growth strategies, our expert panels will share practical perspectives and real-world experience to help guide your next move.

Please RSVP **here** and see below for more details!

Date & Time: Tuesday, June 17 from 8:30 AM – 10:30 AM ET

Location: Goodwin's Boston Office, 100 Northern Avenue. Boston, MA 02210

8:30 AM – 9:00 AM | Registration and Breakfast

9:00 AM – 9:05 AM | Welcome Remarks

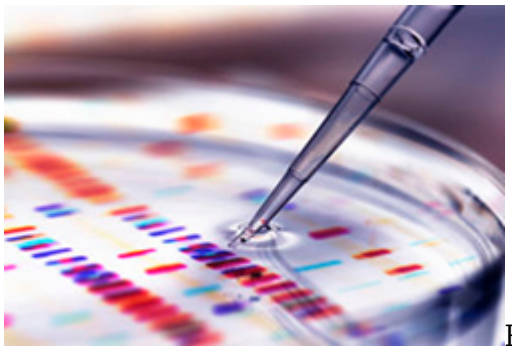
9:05 AM – 9:45 AM | Panel: China NewCos – Strategic and Legal Insights

- Josha Berlin, Head of Corporate Alliances & Business Development, BioCentury Inc. (Moderator)
- David Chen, Partner, Goodwin
- Sue Yao, Executive Director of Licensing and Business Development, Kelun Biotech and Klus Pharma
- Regina Salvat, PhD, Principal, Forbion

9:50 AM – 10:30 AM | Panel: New Challenges and Opportunities in Cross-Border Transactions

- Wendy Pan, Partner, Goodwin (Moderator)
- Alan Wang, Partner, Goodwin
- Jimmy Zhuang, Assistant General Counsel – Business Development, Novo Nordisk
- Tim Opler, Managing Director, Healthcare, Stifel Institutional
- Jon Kiburz, VP Transactions, R&D Business Development, GSK
- Jesús Baena, Director BD&L Oncology, Novartis

2nd BCLT Advanced Life Sciences Institute

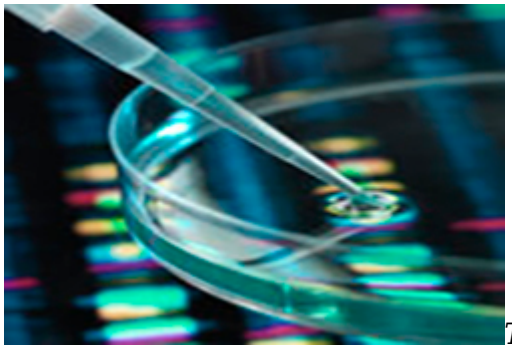
 Rapid advancement in life sciences technologies has made keeping up with the legal implications more important than ever. Join the **Berkeley Center for Law and Technology** for the **2nd BCLT Advanced Life Sciences Institute**, where you will learn from the experts about cutting-edge issues impacting your life sciences practice.

The programming will share key insights and best practices related to the rapid rise of AI in the life sciences and new trends for licensing, deals, and life sciences funding models. Expert will review key developments in the law (Section 112, obviousness-type double patenting), anti-counterfeiting and patient safety, and the ever-complex interplay of regulatory and IP exclusivities. Finally, don't miss in-depth discussions on future pandemic preparedness and use of trade secrets v. patents for portfolio protection!

The Advanced Life Sciences Institute will be launched virtually through **B-CLE** on May 21 and 22.

Registration is free and available to all, and CLE will be offered.

Major Life Sciences Licensing Deal Trends in China in 2023

 *This is the first of two articles focused on 2023 life sciences deals in China. The second article, which is coming soon, looks at trends in M&A.*

In 2023, there were 240 reported life sciences licensing deals in China, an increase of almost 50% compared to 2021.

That includes 70 out-license deals involving Chinese companies licensing drugs and technologies to foreign companies, with a disclosed aggregate deal value surpassing US$35 billion.

It also includes 170 in-license deals involving Chinese companies licensing drugs and technologies from other Chinese companies or from foreign companies. This represents a 32% increase compared to 2021 — and a 58% increase compared to 2022 (more than making up for the 2022 dip in deals).

Read the full alert **here**.

Spotlight on Life Sciences Collaboration and License Agreements

Goodwin's Intellectual Property team regularly works on the most important deals in the life sciences and biotech sector. Our close relationship with clients ensures that the best intellectual property strategies are in place to foster company and product growth and minimize risk. We take pride in structuring, negotiating, and executing complex license, collaboration and joint development agreements. Recently, our Cambridge team advised Renaissance Pharma Ltd., in its launch and exclusive license agreement with St. Jude Children's Research Hospital for the treatment of newly diagnosed high-risk neuroblastoma patients globally – announced on August 01, 2023.

Manchester, UK-based **Renaissance**, is a rapidly emerging company focused on the development of life changing therapies in paediatric rare disease.

St. Jude Children's Research Hospital is leading the way the world understands, treats and cures childhood cancer, sickle cell disease, and other life-threatening disorders.

Goodwin partner, **Malcolm Bates** said: "We wish Renaissance and St. Jude every success in this very important agreement."

Read the press release **here**.

European Life Sciences Deal Trends

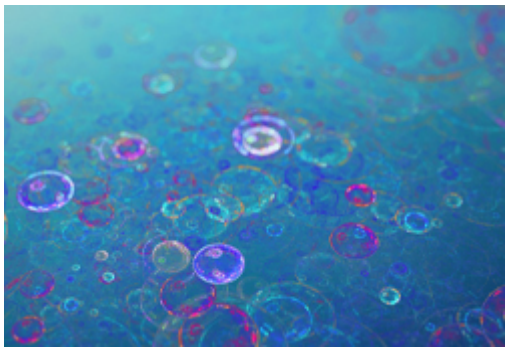
In Europe, life sciences deals increased over the last few years with a strong acceleration in 2021. As a result, the market wonders whether this is just a pick or rather a steady trend which will impact our market in the future as well. Analyzing the reasons of such growth and comparing it with more mature markets such as the U.S. comfort us in thinking that it is just the beginning for continental Europe.

The U.S. life sciences market has been very strong over the past decades and is seen as very mature. The level of venture investments, which are now very much standardized, licensing, M&A and IPOs is very high, both in volume and in number.

For the last ten years or so, the life sciences UK market attracted U.S. investors and an increasing number of growth funds. After a first step of development through venture investments, such companies are now ready for licensing, M&A and IPOs. This is also the trend that we anticipate for the European market even if each country or region still has its own specificities (in particular UK, Germany, France and the Nordic Countries).

Read the **client alert**.

Survival Guide to Structuring Life Sciences Partnering and M+A Agreements



The life sciences space is ever-growing and dynamic as the industry witnesses more companies and, therefore, more collaboration, licensing and M&A agreements, come into the spotlight. While these deals are exciting opportunities for life sciences companies at all stages, they can also be daunting

when it comes to their legal structure.

In order to best leverage assets, align incentives, allocate risk and draft agreements to position your partnership for success, Goodwin recommends considering the following business, legal and litigation perspectives as you navigate these type of agreements.

Read the **full insight**.

Tensions in University Start-up Life Science Licensing Agreements

University tech transfer offices (TTOs) and venture capital firms (VCs) work closely together to advance certain technologies and discoveries from the lab to the market. However, because there are different motivations and incentives for TTOs and VCs while negotiating licensing agreements, tensions often arise during these negotiations.

At a meeting between certain TTOs and VCs, important deal terms were highlighted as especially sensitive**[1]**, such as equity, royalties, success-based milestones, and windfall success payments. In addition, board seat requests by the university to understand how the company is progressing also creates tension because some VCs see this as a potential conflict-of-interest with respect to adjacent technologies.

Outside of these financial and governance terms, the biggest tensions arise when negotiating intellectual property (IP) encompassing the invention, specifically negotiating points about patent(s), know-how, and development. With regards to patents, tension exists in the management and payment of patent prosecution and who has ultimate control and decision making authority. With regards to know-how, one of the most difficult clauses to negotiate is what is considered an enabled product from which the university would receive royalties and milestone payments. Discussion surrounding the scope of the ongoing collaboration between the university and the company can be complex. A clear understanding of the role of the university's employees at the company, along with ongoing discussions regarding active development projects could aid in understanding the scope and what would be considered enabled products.

Lastly, there are also tensions during the negotiation regarding the economics of sublicensing. Sublicensing of the licensed IP is typically agreed upon by both parties. However, despite this agreement, the specific terms and parameters surrounding the sublicensing can lead to friction, especially around the sharing of non-royalty sublicensing income.

Reflecting upon the perspectives and friction points of both parties can hopefully lead to a more

productive and collaborative drafting and negotiating experience, which hopefully leads to a long-term productive relationship for the specific agreement and other technologies the university may be willing to license.

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[1]
https://techventures.columbia.edu/term-sheet-recommendations-for-launching-university-startups

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Compulsory Patent Licensing in Response to COVID-19: Recent International Developments

Can a government authorize the production of a COVID-19 vaccine without the consent of the patent holder? The answer is likely yes, depending on which country you are in.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides a mechanism for member states to authorize themselves or third parties to produce a patented product without the express consent of the patent holder through the grant of compulsory licenses.

In response to the COVID-19 pandemic, several countries have already taken steps to facilitate compulsory licensing. In March, Canada[1], Germany[2] and France[3] amended their laws to make it easier to issue compulsory licenses, Ecuador[4] and Chile[5] passed resolutions to encourage the use of compulsory licenses, and Israel issued a compulsory license to import from India a generic version of AbbVie's patented product Kaletra for the treatment of coronavirus patients, which has since then been proven to be an ineffective treatment.[6]

More recently, on the basis of national security, Pharmasyntez, a Russian pharmaceutical company, is seeking a compulsory license from the Russian government to manufacture a generic version of Gilead's patented COVID-19 drug remdesivir without Gilead's consent.[7]

A compulsory license, however, may not always be necessary. Following Israel's issuance of the compulsory license for Kaletra, in an official company statement, AbbVie announced its intention to dedicate to the public its intellectual property related to Kaletra[8], and in October 2020, Moderna announced that while "the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic"[9].

Whether reliance on compulsory licenses will be necessary in order to ensure access to COVID-19 vaccines remains to be seen. However, the use of compulsory licenses should be carefully considered, as patent protection is one of the main economic incentives to innovate, particularly in the pharmaceutical field, where the average cost of bringing a drug to market is estimated to be close to 1.3 billion dollars.[10]

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[1] https://laws-lois.justice.gc.ca/eng/AnnualStatutes/2020_5/

[2] https://www.gesetze-im-internet.de/ifsg/index.html?_sm_au_=iVVvns5WHQ11sMDPvMFckK0232C0F

[3] https://www.legifrance.gouv.fr/codes/id/LEGIARTI000042103698/2020-07-11/

[4] https://www.keionline.org/wp-content/uploads/ES-Ecuador-CL-resolution.pdf

[5] https://www.keionline.org/wp-content/uploads/resolucioncoronavirus.pdf

[6] https://www.reuters.com/article/us-health-coronavirus-israel-drug-idUSKBN216237

[7] https://www.reuters.com/article/us-health-coronavirus-russia-remdesivir/russian-firm-seeks-to-produce-covid-19-drug-remdesivir-without-patent-idUSKBN27I0QH

[8] https://news.bloomberglaw.com/pharma-and-life-sciences/abbvie-to-allow-use-of-intellectual-property-for-coronavirus

[9] https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19

[10] https://www.biospace.com/article/median-cost-of-bringing-a-new-drug-to-market-985-million/

Territorial Licensing in Collaboration Agreements

Life sciences companies often turn to geographical licensing to realise the maximum value from their assets, and to ensure their products reach markets worldwide, particularly where they do not have a global footprint.

In the context of a collaboration agreement, the owner of certain intellectual property rights may

collaborate with a licensee to develop a product, and grant such licensee the exclusive right to further develop and commercialise the product, but only in a specific territory. The licensor may reserve for itself the right to develop and commercialise the product in another territory, usually where that licensor has a presence. In certain cases, usually after much of the development of the product has taken place, the licensor may also grant additional licences limited to *other* specific territories to third parties, further dividing up the territory it had reserved for itself in the initial collaboration agreement.

The above deal structures raise many complex issues of coordination between the parties. Some of these issues in relation to geographical licensing in the context of collaboration agreements are:

1. **Product development**: if multiple parties are conducting activities in their own territories to develop a single product, high levels of coordination between those activities are required. No party will want the activities of another party to damage the value of the product being developed. Sharing results of development activities between the parties could avoid duplication of work, and help to ensure compliance with regulatory obligations. However, development results are costly to produce, and some parties may not be willing to disclose this information freely. The development work may also give rise to intellectual property rights, and the licensor will need to consider the degree of access it will need to those intellectual property rights.

2. **Regulatory authorisation and compliance**:
    a. **Pre-approval submissions:** the collaborating parties will also need to coordinate their submissions to regulatory authorities in relation to the product being developed. Inconsistent statements between such submissions must be avoided in order to protect the value of the product worldwide and ensure timely regulatory approvals can be granted.
    b. **Post-approval submissions:** once the product is on the market, each of the parties involved in its commercialisation will have reporting obligations to the regulatory authorities in their own territory. The parties will likely need to share information relating to safety and regulatory matters. If any additional licensees have been brought into the mix, the licensor will also need to consider whether all regulatory information should flow through the licensor, or whether it should flow directly between these licensees.

3. **Intellectual property management:**
    a. **Patents:** licensees who are taking an exclusive licence under certain intellectual property in a territory – particularly if they are developing improvements to such intellectual property under a collaboration agreement – are likely to want control over the prosecution, maintenance, enforcement and potentially the defence of such intellectual property in their territory. Although this may relieve the licensor of the cost of maintaining the intellectual property in such territory, prosecution of patent applications, and defence of patents, must be coordinated worldwide to avoid inconsistent statements or actions. Such inconsistencies could impede the prosecution of a corresponding patent application, or diminish the validity or enforceability of a granted patent, in another territory.
    b. **Trade marks**: if a licensor licenses rights in a centralised trade mark to various licensees, care also needs to be taken to ensure licensees are restricted in their use of the mark. Licensees should be prevented from acting in ways that could damage the value of such trade mark.

The above issues are tricky to navigate in a collaboration agreement, particularly where significant

development of the product remains to be carried out, and the identity of any future additional licensees remains unknown.

A carefully considered term sheet at the beginning of negotiations can help to ensure that all relevant issues are raised and discussed as part of an overall package, as well as avoiding any key issue being missed which could potentially derail negotiations at a later stage.

"March-In" Rights in the Era of COVID-19: An Unlikely Scenario for Remdesivir

As the total number of COVID-19 deaths in the U.S. is expected to climb to between 180,000 to 200,000 by September 5, 2020[1][2], there currently are no FDA-approved vaccines or drugs to prevent or treat COVID-19. However, the FDA has granted emergency use authorizations to some products for use in certain patients with COVID-19, including to Gilead for its investigational antiviral drug remdesivir[3].

On August 4, 2020, a bipartisan group of 34 state attorneys general (AGs) asked the U.S. government to exercise its march-in rights under the Bayh-Dole Act and license Gilead's remdesivir to third-party manufacturers in order to scale up production and lower the price of the drug, or allow states to do so.[4] The AGs argued that the U.S. government should exercise its march-in-rights because the price of remdesivir is too high and because Gilead "has benefited from millions of dollars of public funding, including a $30-million NIH-funded clinical trial," and "is unable to assure a supply of remdesivir sufficient to alleviate the health and safety needs of the country."[5]

The AGs' request that the U.S. government exercise its march-in rights under the Bayh-Dole Act, however, does not appear to be tethered to the law.

Under the Bayh-Dole Act, in specific circumstances, the U.S. government has the right to "march-in" and either grant licenses, or require the patent holder/licensee to grant licenses, to third parties under federally funded patents.[6] The U.S. government may exercise its march-in rights if it determines that action is necessary because the patent holder or licensee:

- has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention;
- is not reasonably satisfying health or safety needs;
- is not reasonably satisfying regulatory requirements for public use; or
- has violated the U.S. industry preference provisions of 35 U.S.C § 204.[7]

If the U.S. government decides to exercise its march-in rights, the decision may be appealed to the U.S. Court of Federal Claims, and with respect to items (1) and (3) above, march-in rights may not be exercised until all appeals or petitions are exhausted.[8]

Despite having the authority, the U.S. government has never exercised its march-in rights. In its response to a 1997 petition requesting that the NIH exercise it march-in rights, the NIH noted its unwillingness "to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies,"[9] and, with respect to drug pricing, in response to a 2004 petition, the NIH noted that "because the market dynamics for all products developed pursuant to licensing rights under the Bayh-Dole Act could be altered if prices on such products were directed in any way by NIH, the NIH agrees with the public testimony that suggested that the extraordinary remedy of march-in is not an appropriate means of controlling prices."[10]

Given the fact that: (a) march-in rights are limited to federally funded patented inventions (and it is not clear to what extent federal funds contributed to the development or remdesivir[11]), (b) the Bayh-Dole Act is not triggered by high drug prices, (c) the NIH's unwillingness to exercise its march-in rights, particularly because it does not want to disincentivize innovation and does not believe that the Bayh-Dole Act should be used to control drug prices, and (d) the patent holder/licensee has the ability to appeal the U.S. government's decision to exercise its march-in rights, and some instances march-in rights may not be exercised until all appeals or petitions are exhausted, it seems unlikely that the Bayh-Dole Act will be invoked in response to the AGs' request that the U.S. government exercise its march-in rights.

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[1] According to the Centers for Disease Control and Prevention (CDC) COVID Data Tracker, as of August 21, COVID-19 has claimed 173,490 lives. **https://www.cdc.gov/covid-data-tracker/#cases**

[2] **https://www.cdc.gov/coronavirus/2019-ncov/covid-data/forecasting-us.html#anchor_1587397564229**

[3] **https://www.gilead.com/purpose/advancing-global-health/covid-19**

[4] **https://www.oag.ca.gov/system/files/attachments/press-docs/Remdesivir%20Letter%2020200804.pdf**

[5] **https://www.oag.ca.gov/system/files/attachments/press-docs/Remdesivir%20Letter%2020200804.pdf**

[6] 35 U.S.C. §203(a).

[7] 35 U.S.C. §203(a).

[8] 35 U.S.C. §203(b).

[9] Harold Varmus, Director, NIH, Determination in the Case of Petition of CellPro,Inc.,

August 1, 1997,

http://web.archive.org/web/20070102183356/http:/www.nih.gov/icd/od/foia/cellpro/pdfs/foia_cellpro39.pdf.

[10] Elias A. Zerhouni, Director, NIH, In the Case of Norvir Manufactured by Abbott Laboratories, Inc., July 29, 2004,

http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir.pdf.

[11] https://www.statnews.com/pharmalot/2020/05/08/gilead-remdesivir-covid19-coronavirus-patents/