The Life Sciences Lawyer

Issue 2 2020

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Data as a critical asset in the health sector

Laurie-Anne Ancenys and Juliette Olliveaud of Allen & Overy examine the challenges posed to patients and healthcare providers by an increasing volume of data

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Editor's welcome

Welcome to our second issue of *The Life Sciences Lawyer*. The feedback from our first issue was reassuringly positive, and we look forward to bringing you in-depth analysis of the core issues facing the life sciences over the coming months.

Our focus this issue is the key topic of data. For our Cover Story, Laurie-Anne Ancenys, Counsel, Head of the Paris Tech & Data practice, and Juliette Olliveaud, Associate, at Allen & Overy, look at how the ever-growing volume of data in our digital world presents both challenges and opportunities for patients and healthcare providers.

> **"we look forward to bringing you in-depth analysis of the core issues facing the life sciences"**

Meanwhile, Noel Courage and Ainslie Parsons of Bereskin & Parr LLP discuss the importance of data exclusivity when it comes to defending against generic drug competition.

Elsewhere in this issue, Rajeev Kumar and Pankaj Musyuni of LexOrbis look at AI's potential to strengthen the Indian healthcare system and thus aid it in combatting pandemics, and Sarah Ellson, life sciences regulatory specialist at Fieldfisher, explains why making a novel foods application is still a demanding process, particularly when it comes to CBD products

We also have an article on the role Supplementary Protection Certificates have in protecting innovation, plus much, much more.

I hope you enjoy the issue.

Matt Seex

Matt Seex
Editor

Mission statement

The *Life Sciences Lawyer* educates and informs professionals working in the industry by disseminating and expanding knowledge globally. It features articles written by people at the top of their fields of expertise, which contain not just the facts but analysis and opinion. Important judgments are examined in case studies and topical issues are reviewed in longer feature articles.

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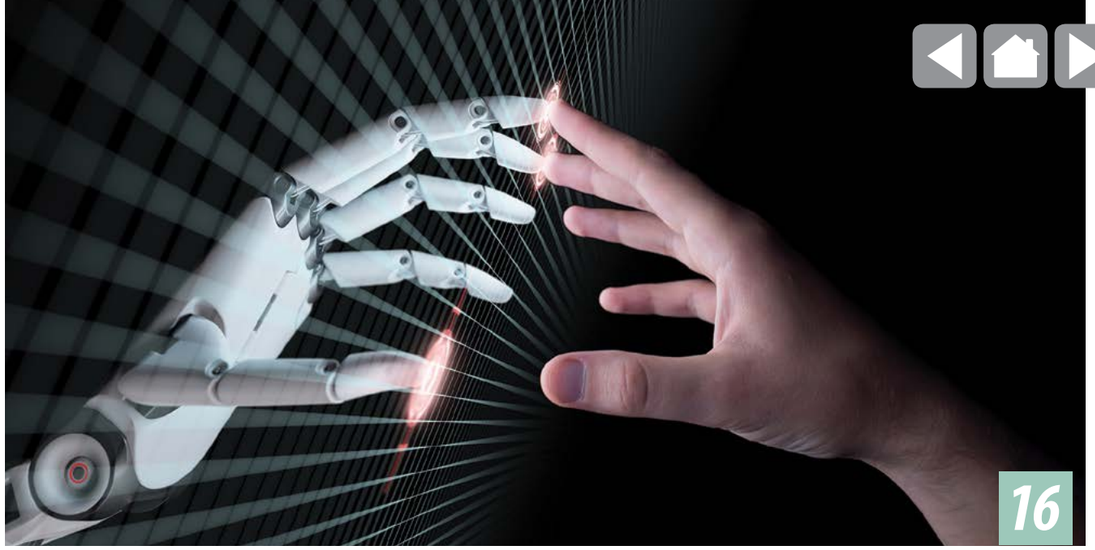

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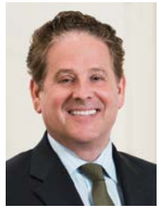

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Bob is a partner at Drinker Biddle & Reath LLP and Co-Chair of the Intellectual Property Group. In October of 2013, he was appointed to a three-year term on the CAFC Advisory Council, was reappointed for another three-year term in 2016, and reappointed in 2019 for an additional three-year term. He is currently serving on the Board of Directors for the American Intellectual Property Law Association.

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Matthew advises on IP aspects of due diligence relating to company and product acquisitions in the medical devices field, IP aspects of company and academic collaborations and manages IP portfolios for R&D units in both the US and UK. He has worked in areas relating to chemistry and biotechnology and and natural products developing strategies to ensure freedom to operate for new product families, clearing the way through oppositions and managing litigation risk.

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Michael handles a wide range of biotechnological subject matter and has particular expertise in the drafting and prosecution of patent applications concerning immunotherapy, protein stability, gene therapy, metabolic profiling, drug delivery, and assay technologies. He has also managed the prosecution of several global patent portfolios, including applications in Australia, Canada, China, India, Japan and the US.

The Life Sciences Lawyer Magazine wishes to take this opportunity to thank the editorial board for their time and support.

News

COVID trademark application is "opportunistic"

AS THE CORONAVIRUS continues its spread across the globe, it comes as no surprise to hear that it has also reached trademark registers. On the same day the World Health Organization (WHO) released the "official" name of the virus, the first "COVID-19" application was filed at the USPTO. According to the USPTO's website, Application Number 88792612 was filed for "COVID-19 VAX" in Class 5 covering "vaccines".

The applicant, AND STILL LLC, a sports clothing company registered in Massachusetts, also filed an application for the mark "CORONAVAX".

According to Robert Reading, Director of Professional Services and Strategy at CompuMark:

"This appears to be an 'opportunistic' trademark application, looking to be first to get onto the record with a new word or phrase while it is in the early stage of acquiring public awareness. This is not uncommon – for example after President Trump mistyped COVERAGE as COVFEVE in a tweet in 2017 over 70 trademark applications were filed at registers around the world for COVFEFE (and for the word with additional elements) for everything from kimonos in Italy to energy drinks in Switzerland.

"What makes this different is that rather than trying to cash in on a well-known term for unrelated business purposes (COVFEFE as used by President Trump had no relevance to energy drinks), this application specifically targets vaccines which makes it directly related to the COVID-19 name. [T]he US Patent and Trademark office … has provisions that prevent the acceptance of applications filed in bad faith, or which are not actually used in the course of business for the product described. Trademarks also cannot be descriptive – COVID-19 VAX is likely to fail that particular test."

After a period of silence, AND STILL LLC's John Barron attempted to rebut claims that his company was simply seeking to profiteer from the pandemic, stating that the purpose of securing the trademarks was to "…provide a service to the vaccine companies and the general public, by making it easy to promote a vaccination with a logical name and a corresponding website domain where consumers could get information on the vaccine".

"There's no way I'm looking to hold anybody hostage for the good name of a vaccination" Barron added.

FSA's CBD novel food deadline

THE UK FOOD Standards Agency (FSA) has given CBD product manufacturers a 31 March 2021 deadline to submit valid novel food authorisation applications. After that date, only those products for which a valid application has been submitted will be authorised for sale. "Novel foods" are defined as foods which have not been widely consumed by people in the EU before May 1997.

The authorisation process is intended to ensure that novel foods meet legal standards, particularly regarding content and safety. Novel food legislation is enforced by local authorities, which have been advised by the FSA that businesses may continue to sell their existing CBD products until the 2021 deadline, provided they are safe to eat, correctly labelled, and do not contain substances prohibited by drugs legislation.

Notwithstanding this advice, the FSA recommends that people who are pregnant, breastfeeding, or taking medication do not use CBD products. Even healthy adults are advised to think carefully before taking CBD, and the FSA recommends an individual take a maximum 70mg of CBD per day (equivalent to approximately 28 drops of 5% CBD) unless otherwise advised by a medical professional. Current FSA advice was drawn up based on recent findings by the British Government's Committee on Toxicity (COT).

Professor Alan Boobis, Chair of COT, said:

"My committee has reviewed the evidence on CBD food products and found evidence there are potential adverse health effects from the consumption of these products. We are particularly concerned about pregnant or breastfeeding women and people on medication.

"We don't know enough to be sure about such a risk but I am pleased with the sensible and pragmatic approach the FSA is taking. The committee will continue to keep these products under review in the months ahead."

The FSA's Chief Executive, Emily Miles, said:

"The actions that we're taking today are a pragmatic and proportionate step in balancing the protection of public health with consumer choice. It's now up to industry to supply this information so that the public can be reassured that CBD is safe and what it says it is."

Pharmaceutical companies are the “big winners” from US-China trade deal

WHETHER THE RECENT US-China trade deal will have the desired effect of ending the acrimonious trade war between the two countries remains to be seen. What is clear, however, is that the deal will have consequences for IP matters such as pharmaceutical patents, and counterfeiting.

Doug Clark, Global Head of Dispute Resolution at Rouse, has over 25 years' IP litigation and commercial law experience in China. He has sat as an arbitrator and acted as an advocate in numerous high technology patent arbitrations, including acting for Qualcomm as lead partner in Asia in global standard essential licensing dispute with Nokia. On the ramifications of the trade deal, Doug comments:

“Most commentary on the recent agreement between the US and China focuses on the provisions for enhanced protection of trade secrets. While this is very important, many of the points had already been addressed by the recent amendments to the PRC Anti-Unfair Competition Law. The nitty-gritty of the agreement reflects real change to many areas that have been of real concern to foreign (and indeed many Chinese) companies.

“Pharmaceutical companies are the big winners from the Agreement. China has agreed to extend the term of patents where the grant has been delayed to allow patentees as well as to take immediate action to prevent infringement while an application for a generic drug is pending. New provisions will be enacted to make it easier to obtain and maintain as valid pharmaceutical patents by allowing patentees to submit post-application test data to show a patent is inventive. While an arcane area of law, this is actually very important. Many foreign pharmaceutical companies have had their patents invalidated in whole or in part because of very strict rules prohibiting post-application test data.

“China has again promised to increase criminal enforcement against counterfeiting by lowering the threshold for transfer of administrative cases to the police for investigation. This must be taken with a grain of salt. China has been promising this reform for years (including in the 1990s introducing a three strikes rule that was quietly shelved) but never really making real changes. China has also promised to increase enforcement on e-commerce platforms where counterfeit and look-alike products are prevalent. The measures include the threat that the platforms may have their licenses revoked if they do not take effective measures. Whether this will really happen remains very much to be seen.”

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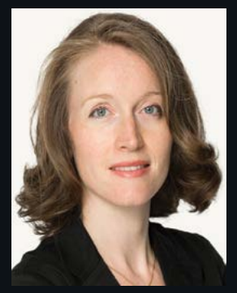
Data as a critical asset in the health sector

Laurie-Anne Ancenys, Counsel, Head of the Paris Tech & Data practice, and Juliette Olliveaud, Associate, at Allen & Overy, look at how the ever-growing volume of data in our digital world presents both challenges and opportunities for patients and healthcare providers.

The collection of vast sets of data and their subsequent valuation and monetization has become a driving force in the global economy. Technologies that can generate, analyze and deploy this growing quantity of information are being adopted increasingly across public and private organizations. Stakeholders from across the value chain are becoming more aware of the opportunities provided when technologies like data analytics and artificial intelligence are applied to the exponential volume of data being created in our digital world.

The EU Commission has indicated that *"Digital solutions for health and care can increase the well-being of millions of citizens and radically change the way health and care services are delivered to patients"*[1]. The variety of healthcare use cases illustrates the great potential value of data exchange in the life sciences sector. Pharmaceutical companies are launching schemes to share research data to help transform diagnosis and develop customized medicine. The use of "real world data" (collected outside formal clinical trials) by healthcare professionals, public authorities and private companies can ensure that healthcare products, innovative technologies and therapies meet patients' needs, leading to favorable health outcomes. In addition, data generated by the Internet of Things (IoT) can help deliver better diagnosis, treatment or personalized care and patients' proactive management of their data through technology can improve outcomes by encouraging better adherence to treatment plans and better management of chronic diseases. Private companies are also developing computer programs to collect and analyze healthcare data from users in order to build better and more tailored products and services.

All these initiatives illustrate the great potential of data and the need to use it to support the rapid advanced delivery of new medical and healthcare products and services.



Laurie-Anne Ancenys

Juliette Olliveaud

[1] Digital Single Market Factsheet, DG Connect, 5 February 2019 https://ec.europa.eu/digitalsingle-market/en/news/transformation-health-and-care-digital-single-market

While data is the key enabler for digital transformation in the life sciences sector, success will depend on the quantity and quality of data obtained as well as how effectively organizations can generate insights and unlock value. In some cases, data held by private companies can be used for a new purpose (e.g. secondary use of patients' data) and be made publicly available (although under specific restrictions), shared with other companies, or processed securely by the public sector, depending on the extent to which sharing the data presents privacy risks or undermines competition.

Stakeholders are increasingly discovering the long-term benefits of accessing and/or exchanging data, thus increasing the trend towards data sharing. Such a data value cycle can only be managed through data sharing agreements governing the access to and exchange of the data.

There are two key elements to successfully working with data that organizations need to have in place before they can think about data monetization. First, organizations need to assess the value of their data by undertaking data audits. Second, they need to have a robust procedure in place for concluding data sharing agreements.

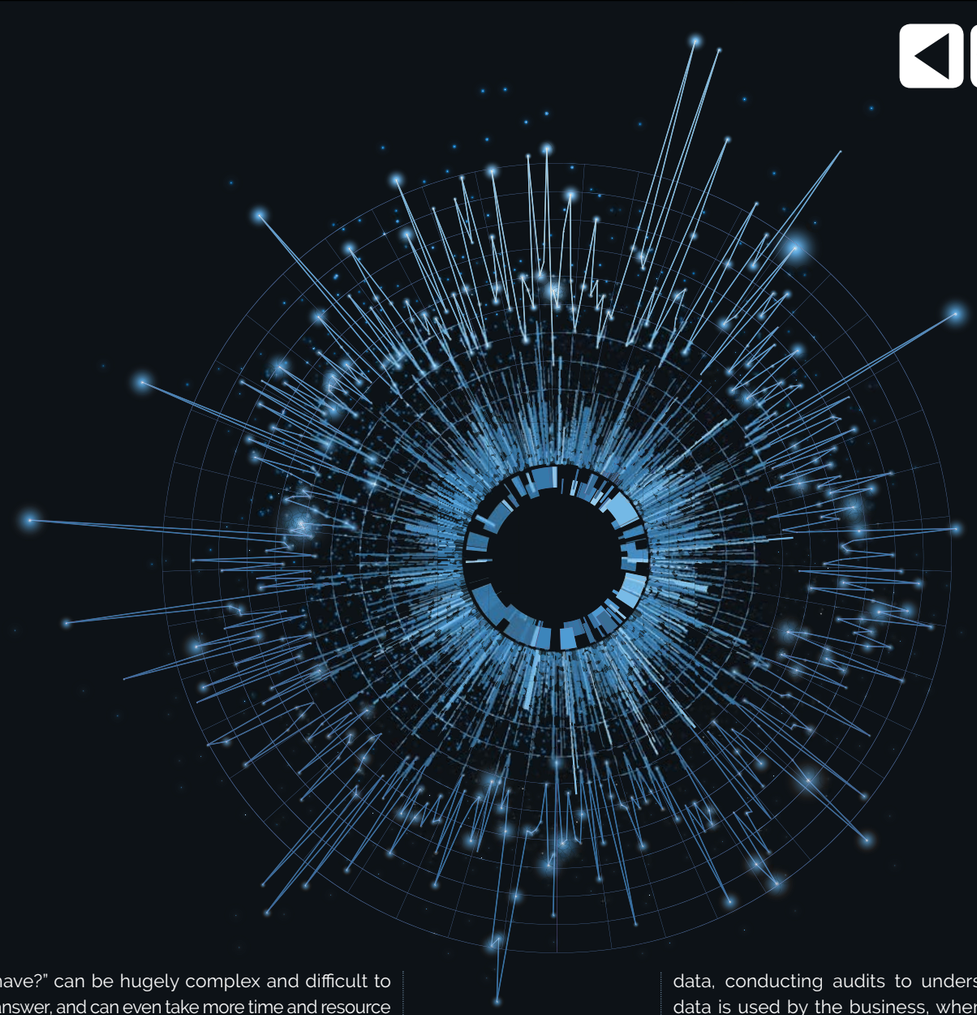
1. Data audits as a first step towards any data monetization strategy

Digitalization has brought Board-level focus to the potential of data found in the business to be "monetized" – ie used to generate efficiencies or economies in the organization or developed into new revenue-attracting opportunities in its own right. But how should organizations approach data monetization? One of the first steps will be to understand what sort of data the business holds, and this process is often described as an internal data audit. However, as volumes and types of data increase exponentially, the very task of answering the question "what data do we have?" can be hugely complex and difficult to answer, and can even take more time and resource to answer than the value to be found in the data deserves.

We would recommend, then, before embarking on a data audit, to take a step back. Rather than trying to "boil the ocean" and document the state and value of all the data in the business, begin by thinking about where you want to get to. Start by focusing on the areas of the business where you believe data can bring the most insight and add the greatest value. In this area or areas, what data do you have or need to acquire to bring you closer to your goals?

The way data can be shared, and its subsequent challenges, will depend on the types and categories of data. Data can be obtained from multiple sources such as publicly available sources, a company's own processes (e.g. sales processes), third-parties' data sets, and/or from the outcome of artificial intelligence machines. Organizations could then find themselves dealing with all sorts of data types, such as open data, derived data, personal data coming directly from individuals, and commercially licensed data. Good data mapping may help to assess the relevant contractual terms to be applied in a data sharing arrangement. Thus, considering the different strategies and business models around data, conducting audits to understand what data is used by the business, where it comes from, how it should be managed and finally how to unlock value and commercialize it, should be considered as an essential preliminary process.

Good data management is also essential for companies to understand how to avoid risks and liabilities arising from misuse of data. The first



Résumés

Laurie-Anne Ancenys

Laurie-Anne is a Counsel in Allen & Overy's Corporate practice and head of the Technology & Data practice in Paris. She assists French and international clients with e-commerce issues, in particular with the digitalization of their activities and often as part of multi-country studies. Laurie-Anne has developed an expertise in data protection compliance projects and, more specifically, in the implementation of GDPR compliance programs, global data protection strategies and international data transfers.

Juliette Olliveaud

Juliette is an Associate in Allen & Overy's Corporate practice in Paris and is part of the Technology and Data practice. She advises on data protection compliance projects, in particular with regards to the General Data Protection Regulation (GDPR). Juliette also drafts and negotiates complex IT agreements and assists international clients with the digitalization of their activities.

thing to establish is who owns the data. This may be difficult due to the absence of a European regulation that specifically regulates ownership of data. Indeed, most jurisdictions do not recognize that data can constitute property by itself but instead confer certain protection on data and data sets when that data meets specific requirements (i.e. copyright, database rights, trade secrets, or patents). What makes the issue even more complicated is the multiplicity of categories of data and the numerous stakeholders involved in the data value cycle. Depending on the ownership, different rights and obligations will apply to stakeholders.

In the health sector, the development of big data has raised complex questions with regard to data ownership, as it is likely to involve the collection and exchange of large amounts of data, including the personal data of patients. Therefore, it may be unclear who will own such data among the different stakeholders involved, such as the healthcare organization, the patient, providers, or any other third party.

The absence of harmonization of approaches to healthcare data in different jurisdictions further complicates the picture. For example, health data is neither managed in the same way in all European Union member states nor within national healthcare systems.

2 Data monetization through contractual agreements

Access and exchange of health data appears to be essential to optimize the efficiency of health services and to promote research, disease prevention and personalized healthcare. To this end, access to and/or exchange of data must be enabled and facilitated.

From a legal perspective, data sharing can be addressed through contractual agreements that create legal certainty in a fragmented and undeveloped regulatory environment. Such contractual arrangements may take different forms, including partnership agreements, data sharing agreements or license agreements.

Although the benefits of data sharing are significant, data sharing agreements raise important challenges. From the possible loss of competitiveness to the potential reputational damage when monetizing sensitive types of data, challenges surrounding partnerships are numerous. It is thus not only essential to implement good contractual solutions to minimize risk and maximize commercial gain, but also to carefully consider how the associated risk can be mitigated when sharing or monetizing data. Contractual rights and obligations will vary depending on the purpose of the transaction (e.g. research or regulatory submission), nature of counterparties (e.g. medical institutions and practitioners, pharmaceutical companies) and data categories (e.g. clinical data, sales data, commercially licensed data etc.). For instance, when sharing clinical data, non-compete clauses and fair revenue sharing should be considered, whereas proper remuneration should be covered when providing patient data to a software editor or artificial intelligence service provider. This explains why, before using analytics to generate revenue and growth from data, it is essential to assess the value of the data asset.

> **“What data do you have or need to acquire to bring you closer to your goals?”**

It is also of paramount importance to carefully define data assets and the scope of the right to use this data by providing an exhaustive description of the data to be shared and the permitted actions to be performed on and with the data (e.g. analytics, engineering, translating, decompiling, storing, altering etc.). In addition, covenants, warranties, indemnities and confidentiality should be covered in the data sharing agreements. The parties should also consider covering methods for data delivery, the security measures to be implemented, and data intellectual property rights – including the rights in relation to deliverables generated in the course of their collaboration. Many stakeholders want to obtain explicit recognition of the ownership of the data they hold. It can be extremely complex to define the concept of data ownership through the terms of data sharing agreements. In addition, exclusive ownership of the data is often difficult in practice given the multitude of stakeholders, the complex data flows, and the numerous activities performed on the data. It is therefore often more important to focus on the scope of the license (i.e. on the permitted actions to be performed on and with the data) without preventing the data sharing from achieving its initial purposes. Data sharing is likely to move from standard licensing models to more bespoke, full product and service packages.

When drafting a data sharing agreement, organizations should also consider their own regulatory requirements (i.e. specific statutory prohibitions on data sharing), copyright restrictions, or confidentiality duties that may affect a company's ability to share data.

Finally, planning for what will happen to the data in the event of termination of the agreement is vital to avoid conflict at the end of the contractual relationship.

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Data protection update: ups and downs in the exclusivity term

Noel Courage and Ainslie Parsons of Bereskin & Parr LLP discuss the importance of data exclusivity when it comes to defending against generic drug competition.

It is important for innovative drug companies to take advantage of available exclusivities, to ensure that they can recoup investment from the costly drug development process. The best-known exclusivity is the patent, which is a statutory right to exclude others from exploiting an invention. Patent protection terms vary by jurisdiction, but generally run for 20 years from the filing date of the patent application. In addition to patent protection, an innovative drug may also benefit from data exclusivity, which is a regulatory exclusivity which can run concurrently to the patent term. A recent analysis of a snapshot of the Canadian market showed that both patents and data exclusivity were important as the last line of defense against generic drug competition[1]. It is part of the risk of drug development that there is no guarantee that a company will get either data exclusivity or a patent, or that the exclusivity periods will last long enough to ensure profitability.

Data exclusivity has recently been a focal point in the tug of war between brand name and generic pharma. A main battlefield has been international trade agreements. This article provides an update on data exclusivity in the US, Europe and Canada. This will include an update on the ongoing North American free trade agreement negotiations which included debate on the duration of data exclusivity for biologic drugs.

Noel Courage

Ainslie Parsons

Résumés

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Data exclusivity overview

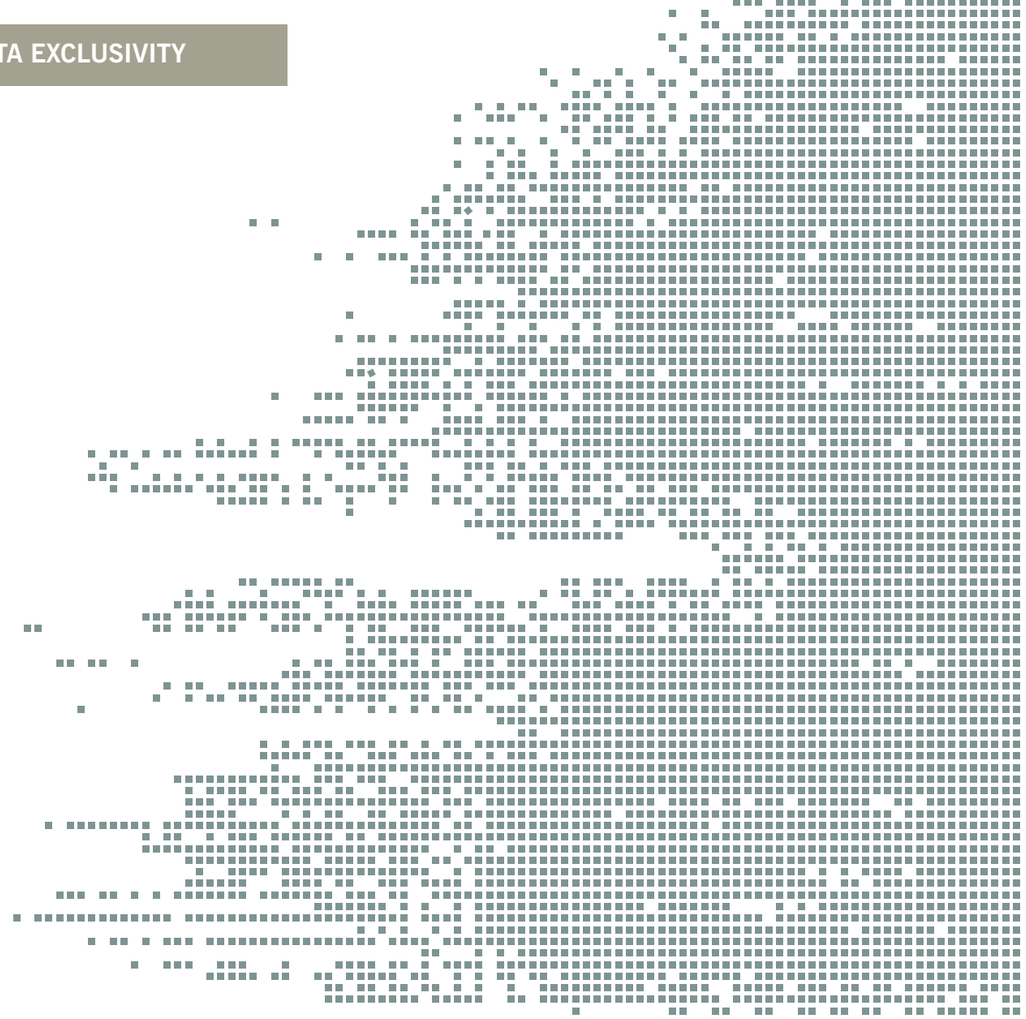
Data exclusivity (also called data protection) protects an innovative company that first developed a drug and invested money and time on clinical trials and regulatory approvals. This exclusivity blocks subsequent drug developers from referencing (comparing to) the innovative drug's data in order to take a shortcut to get marketing authorization. These subsequent drug developers are generic drug manufacturers or biosimilar manufacturers. Without data exclusivity, a subsequent developer could potentially get its marketing approval on the heels of the initial drug approval and undercut on price because it did not have to undergo R&D or significant clinical trial expense[2]. Protecting the innovator company allows it to recoup drug development expenses, and hopefully put part of its profit back into more innovative research. Data exclusivity is time limited and varies between countries. Data exclusivity is also only available for an innovative drug (definition varying by country), not every drug. Data exclusivity is typically not available when small modifications are made to an existing drug.

A biologic drug (also referred to as a "biologic") is a drug which contains an active medicinal ingredient that is derived from a living organism or its products. Biologics are generally larger and more complex than chemically-produced small molecule pharmaceuticals and can be very expensive and time-consuming to develop. Examples of biologics include antibodies, blood products, nucleic acids, vaccines and viruses. Biologics currently account for a significant and expanding portion of the global drug development pipeline.

Canada

Canada presently provides eight years of data protection for an innovator drug[3]. This data exclusivity period applies to both biologics and

1 Noel Courage and Phil Goldbach. "Identifying the Last Line of Defence for Innovative Canadian Drugs." Biotechnology Focus. June/July 2017.
2 Another exclusivity is orphan drug exclusivity, in the U.S. and Europe, for rare diseases, which will not be addressed in this article.



conventional small molecule pharmaceuticals. A manufacturer may not file a drug submission referencing an innovator drug within six years of the initial authorization of the innovator drug. This completely blocks comparisons to the innovator drug. Comparisons may be made in a drug submission after six years. However, there remains an additional two-year period that applies before generic or biosimilar marketing authorization can be granted. Where clinical trials relating to the use of the drug in pediatric populations have been conducted, an additional six months of exclusivity may be added to the eight-year term.

A biosimilar drug or generic drug does not qualify as an "innovator drug" and therefore cannot itself benefit from data protection or other regulatory exclusivity against other subsequent products. There is also no market exclusivity for the first approved generic drug or biologic drug against subsequent drugs.

Europe

Current European regulations provide eight years of data exclusivity for drugs, running from the first marketing authorization date. No biosimilar or generic drug submission for marketing authorization may be submitted during this time. This means that no regulatory review may be conducted during the eight-year data exclusivity period. Data exclusivity is followed by a two-year market exclusivity period[4]. This is similar in principle to the Canadian system, although the terminology and time periods are different. The cumulative ten-year period may be extended for an additional year with respect to certain new indications that have significant clinical benefit over prior indications. Regardless of when the subsequent drug is approvable, it cannot be marketed until after year 10 or 11.

Europe does not provide data protection or other regulatory exclusivity for approved biosimilars or generic drugs to block subsequent drugs.

United States

There is U.S. data exclusivity for the first approved, innovator biologic drug. As in Canada and the EU, a biosimilar or generic drug will typically not be approved on an abbreviated basis unless the FDA can access the innovator's data. For biologics, the exclusivity term provided by the *Biologics Price Competition and Innovation Act* (BPCI Act) is 12 years from the date the reference product was first licensed[5,6]. An additional 6 months of exclusivity may apply to biologics for use in pediatric populations[7]. By comparison, under the *Hatch-Waxman Act*, a five-year data exclusivity period applies to conventional small-molecule generic drugs[8]. The five-year term may be extendable by six months where pediatric studies have been conducted.

The U.S. also has special market exclusivity provisions for the first approved interchangeable biological product[9], to block future subsequent products. This is intended as an incentive for subsequent product manufacturers to try to get their products approved as soon as possible. No data protection is available for a biosimilar or generic drug.

Debating the data protection term for biologics

As noted above, Canada currently provides eight years of data protection for a biologic innovator drug, while the United States provides 12 years of data protection. The term of data protection for biologics has been a matter of debate during negotiations between the United States, Canada and Mexico to modernize the 24-year-old North American Free Trade Agreement (NAFTA).

A draft of the renegotiated NAFTA was published on 1 October 2018 under the new title of the United States-Mexico-Canada Agreement (USMCA; the "Agreement").

Article 20 of the draft agreement related to intellectual property matter and included a data protection period for a new pharmaceutical product containing a biologic of at least ten years (Article 20.49). Also provided was a minimum definition of biologics to include biotechnological products that are or contain a virus, therapeutic serum, toxin, antitoxin, vaccine, blood component or derivative, allergenic product, protein or analogous products.

Innovator companies were happy to see the proposed extension of the Canadian data protection term for biologics from 8 years to 10 years (the United States, which already has 12 years of protection would not be required to change their laws)[10] .

However, following further negotiations in December of 2019, amendments to the Agreement were agreed to by the United States, Canada and Mexico. Among the amendments to the 1 October 2018 draft was a deletion of Article 20.49 (Biologics). The deletion removes any reference to the term of data protection from the Agreement. The December 2019 version of the Agreement has recently been ratified by all three countries. As such, no change to Canada's data protection regime will be required by the Agreement.

While the free trade agreement discussions brought possible extensions of Canada's data protection term for biologics to the forefront, there has been movement in the United States over the last several years to decrease their current 12-year protection term for biologics. Most recently, in June 2019, HR 3379, the *Price Relief, Innovation, and Competition for Essential Drugs (PRICED) Act*, was proposed by legislators seeking to shorten the exclusivity period for biologic drugs from 12 years to 5 years (i.e. consistent with that currently afforded to conventional small molecule drugs in the United States). Whether this bill or other efforts to reduce US data protection will get any traction remains to be seen.

Conclusion

Data protection can be a very important protection for innovator drug manufacturers to maintain market exclusivity. It should be used in conjunction with patents, with a particular focus on which exclusivity can last longest. While the term of data protection for biologic drugs has been debated recently in both Canada and the United States, the status quo is still hanging on.

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3 *Food and Drug Regulations*, section C.08.004.1, C.R.C., c. 870. Drug products authorized prior to June 17, 2006 receive a five-year data exclusivity period (*Food and Drug Regulations*, section C.08.004.1(1), C.R.C. 1978, c. 870).

4 Directive 2001/83/EC, as amended by Directive 2004/27/EC, Art. 10.1. See also, EMEA, EMA procedural advice for users of the centralized procedure for generic/hybrid applications (EMEA/CHMP/225411/2006), Jan. 2011 at page 17. This harmonized regulatory exclusivity applies to reference products applying for marketing authorization since November 2005 and to all member states unless the member state has been granted derogation. Formerly, products approved through the centralized procedure received 10 years of data exclusivity (Directive 2001/83/EC). Products approved at the national level received either 6 or 10 years of data exclusivity, depending on the country.

5 Approval of a biosimilar application is not effective until 12 years after the date on which the reference product was first licensed. In addition, an application under the BPCI Act may not be submitted until 4 years after the date the on which the reference product was first licensed. *Public Health Service Act*, § 351 (k)(7), as added by the BPCI Act.

6 The US 2012 Budget Proposal proposes to reduce the length of exclusivity to facilitate the development of biosimilars (*Fiscal Year 2012 Budget of the U.S. Government* (Feb. 14, 2011) at page 196). Under the Administration proposal, beginning in 2012, innovator brand biologic manufacturers would have 7 years of exclusivity and would be prohibited from receiving additional exclusivity by "evergreening" their products. Fiscal Year 2012 Terminations, Reductions, and Savings – Budget of the U.S. Government, at 119. The rationale for the reduction referred to a 2009 US Federal Trade Commission report that considered a 12 year exclusivity period to be unnecessary to promote innovation by pioneer biologic drug manufacturers (Federal Trade Commission Report, *Emerging Health Care Issues: Follow-on Biologic Drug Competition Federal Trade Commission Report* (June 2009)).

7 *Public Health Service Act*, § 351 (m)(2).

8 *Federal Food, Drug and Cosmetic Act*, 21 USC 355(c)(3)(E)(ii,iii).

9 The length of market exclusivity varies between 12 and 42 months, depending on factors such as whether or not patent litigation is ongoing. *Public Health Service Act*, § 351(k)(6).

10 Mexico does not currently have any data protection for biologics.

AI in the healthcare sector: Indian & pandemic perspective

Rajeev Kumar and Pankaj Musyuni of LexOrbis look at AI's potential to strengthen the Indian healthcare system and thus aid it in combatting pandemics.

Artificial intelligence (AI) is considered a significant factor for emerging researches in the healthcare sector, particularly in the pharma and biopharma industry wherein computing technologies are used to analyze the data. There is no mutually agreed definition of AI; however, processes adopting human intelligence for activities such as reasoning, adoption for learning, understanding and interacting are usually considered key factors for defining AI. The healthcare industry is rapidly growing, with a focus on scientific innovations and transforming rationally. While the innovations related to the field of target drug delivery, drug discovery, preclinical and clinical development are increasing with the technical development, AI has the potential to further strengthen the healthcare system. India, being the fastest growing economy with the second largest population, has a significant stake in the AI revolution.

Usually, developing a new drug or method for therapeutic and diagnostic treatment has been a long and expensive process. Similarly, the development of a biological molecule is even more complex, and includes additional steps during drug development and analysis, even after using high-throughput screening methods for particular targets due to complex biological systems.

It can be understood by a simple example, whereby compounds showing in vitro activity may not become the potential drug when tested in vivo due to adverse effects. The healthcare sector, in general, adopted the approaches of AI techniques such as machine learning wherein the data is analyzed and optimized; deep learning utilizes a logic-based approach to match the biological network. Further, natural language processing technique is used to get the coding to recognize and robotics and Internet of Things (IoT) used for the collection of data and information sharing.

Rajeev Kumar

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Challenges of using AI in healthcare

The primary concern relates to cybersecurity in the healthcare system, since collecting a large amount of information needs to be protected with privacy. Another issue relates to the availability of resources and their understanding regarding access to data and its interpretation. A potential solution to this is to simplify AI models so that users can input data without complication. A social and institutional understanding of AI is also an important factor for consideration. As building in-house experts will be challenging for companies, it is advisable to build a partnership with an organization providing AI technologies. While healthcare companies will benefit from developing AI solutions, the service providers have the opportunity to learn the data interpretation and increase their capabilities. However, it is important to share information between companies with certain regulations and transparency to understand the process and get an optimum AI-powered solution. The role of regulators to build an acceptable regulatory pathway is also an important consideration to the benefit for all. Similarly, the use of patient data with utmost data privacy is also of prime consideration with sensitivity and legal compliance.

AI can be applied to almost every step in the healthcare industry, from the conception of ideas and manufacturing, clinical trials, to generating market and sales analytics. Using a machine learning program can reduce the time spent on examining data significantly and also cost-effective solutions which allow researchers to focus on other issues to get a positive outcome. AI can be applied and used as a useful tool for strategic market analysis and also in decision making to explore the most profitable avenues. The use of digital technologies has the potential to transform the models for drug discovery, and research timelines and partnership with health tech start-ups and academia will be helpful to achieve this. It is also important for healthcare companies to be patient-centric and use the information to design better protocols for clinical trials and also ensure quality and safety. In clinical trials, the use of software techniques can be used to reduce the complexity and cost by remote monitoring or using virtual tools.

Applications in healthcare

AI has the potential to provide substantial incremental value economically and its applications can help in addressing primary issues for access to healthcare facilities, particularly wherein the connectivity and supply to healthcare professionals are limited due to transport and other basic facilities. However, this can be fairly achieved by implementing AI-driven diagnostics tools, personalized treatment techniques, early identification of potential pandemics, and the use of imaging diagnostics. Considering some of the examples where AI can be used includes the use of machine learning by using an algorithm or a computer program and performs without having any explicit programming instruction. This technique is commonly used to streamline the clinical and healthcare process. Further, improvement in diagnosis can be adopted wherein the diagnosis and treatment can be managed by using the past history of patients and maintaining electronic medical records for a ready reference. This will also be helpful to get a clear medical history along with a cost-effective treatment and also saves time. These electronic records can also be used in clinical trial research wherein the data is readily available with the required information. In addition, AI could be helpful for an early stage of drug discovery either during a preliminary screening of new compounds, or prediction of success based on a biological factor, machine learning can be used to get the required information and identify new patterns.

Additionally, machine learning technology is currently being used to monitor and forecast an epidemic, based on information accumulated from the web, social platforms, satellites, and other popular sources. COVID-19 (2019-nCoV) disease, which was identified in December 2019 and has been declared a global pandemic by the WHO can be considered, wherein AI is helpful as a powerful tool by using techniques of machine learning (MI), natural language processing (NLP) and computer vision applications to teach computers to use big data-based models for pattern recognition, explanation, and an early prediction. These functions can be useful in early diagnosis, prediction, and treatment of infections, including fast- spreading infections, and helps to manage socio-economic impacts. Since the outbreak of the pandemic, there has been a scramble to use and explore AI and other data analytic tools, for these purposes.

It has been observed that researchers are increasingly using AI tools such as MI and NLP processing to track and contain coronaviruses which are also helpful in gathering more data to understand the disease. While many counties are tracking individual suspected patients, anonymized data can be collected to study the spread of disease in a more generalized manner. As large amount of data can be collected to gather the relevant information, it is also important to maintain the data privacy to ensure that such data cannot be used for another purpose. The data generated by using AI can be used for knowledge sharing with the utmost transparency.

While this pandemic situation has illustrated several innovative use cases, as well as the urgency to stop the spread of the virus, it is important to not let the consideration of fundamental principles, rights, and respect for the rule of law to be set aside. The positive power and potential of AI is real and helpful in fighting of the spreading of the diseases and eventually saves lives. However, ethical and responsible use of AI must be promised and practiced. It is essential that, even in times of such crisis, we remain conscious of the duality of AI and strive to advance AI for good. An example of using such techniques in India, wherein the Government of India has launched Aarogya Setu, a mobile application aimed to connect health services against 2019-nCoV. The App is helpful in augmenting the initiatives in proactively reaching out to and informing the users regarding the potential risk of infection, best practices and relevant medical advisories

Résumés

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pertaining to the containment of 2019-nCoV pandemic. The App is available in eleven different languages and privacy compliant by its design.

Suggestions

It is possible to make the healthcare system more efficient and automated in various ways such as collaboration with companies specialized in AI-driven medicine discovery to get maximum benefits from expert assistance, advanced tools, and experience. An academia-industry partnership will also be helpful and cost-effective wherein the idea can be tested at a small level. Additionally, developing expertise to adopt AI for new projects can be encouraged. India has an opportunity to leapfrog ahead of the world in healthcare systems by developing unique patient and individual-centric solutions based on AI. The National Digital Health Blueprint circulated by NITI Aayog defines a very compelling roadmap for an innovative and effective healthcare system in India.

Artificial Intelligence has a positive impact on the entire healthcare industry, and this can further be streamlined wherein conducting repetitive tasks consumes major time, such as making data entry, analyzing medical test reports, can be done by using AI to get a swifter outcome. As a result, doctors and additional healthcare providers can have more time to focus on other urgent and complex jobs and interact with patients in a better way and with more personnel attention. Similarly, managing data is another important part that includes the test reports and past medical records. With the use of AI, data management in the healthcare sector has become a hassle-free process. All the data can be collected, stored, reformatted and traced in assistance with digital automation in a fast and consistent way. AI can also analyze each step of healthcare systems appropriately and helps in providing solutions for healthcare providers to make correct decisions for organizing the system in a better manner along with the best patient care. The invoice generation process can be digital. The NLP can be utilized which has the capability of a computer program to comprehend human speech. Accordingly, a massive amount of electronic medical records can be analyzed using this technique to evaluate and handle patients with multiple diseases.

Further AI-based apps designed to give medical consultation based on the details of a patient's illness symptoms and past medical records can be effectively used wherein users can add their symptoms in the app, which eventually suggests the recommended action after analyzing the patient's medical history. These apps are minimizing the overall rate of misdiagnosis and making the consultation process more digital. Additionally, AI-based apps can also monitor the usage of drugs by a patient in real-time. These apps use a webcam to autonomously make sure whether the patients are taking medicines according to their prescription or not. It helps patients manage their health conditions. Patients with serious health conditions and those who often fail to follow doctor advice can get maximum benefits from such apps.

> **Machine learning technology is currently being used to monitor and forecast an epidemic.**

Conclusion and way forward

The role of AI and big data in treating global pandemics and other healthcare challenges is only set to grow. Therefore, the demand for professionals with AI skills will be increasing. For professionals working in healthcare technologies, getting educated on the applications of AI in healthcare and building the right skill-sets will prove to be crucial.

The world of artificial intelligence is no longer just science-fiction; in fact, we're well into it. Existing legal frameworks are starting to run into issues when it comes to ownership and intellectual property rights regarding complex AI cases. At the present time, a paradigm change is being observed, with engineering principles and product-process design becoming the main principle guiding development and manufacturing in the healthcare sector.

This implies that adopting a pattern of thinking and using AI for diagnosis, prevention and treatment processes are simultaneously and quantitatively being considered.

AI space exists for the implementation of innovative healthcare operations; further work is definitely required, particularly at the interfaces between the manufacturing, research, regulatory compliance and protecting intellectual property and software engineering, in order to make substantial contributions to the successful operation of the healthcare industries. AI systems are becoming more advanced following which the number of "inventions" created by such systems is bound to increase in the future. This offers a wide scope for the framing of suitable legislation in order to provide adequate legal safeguards. More importantly, there is a need to formulate clear and widely accepted guidelines with respect to the application of regulatory and intellectual property laws to AI. The global healthcare sector, particularly pharma and bio pharma industry, is on the cusp of an exciting era, as rapid developments in AI present the opportunity to make more effective drugs and provide faster and cost-effective healthcare services to patients. Developing an appropriate AI strategy is beset with challenges and will require pharma companies to work in new ways and to collaborate more closely than ever before.

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CBD products face hurdles in every route to market

The stipulation that CBD products making medical claims must be licensed as medicines has turned many manufacturers to food supplement designations, but as Sarah Ellson, life sciences regulatory specialist at Fieldfisher, explains, making a novel foods application is still a demanding process.

In October 2016, the UK's Medicines and Healthcare products Regulatory Agency (MHRA), adopting its usual test for borderline products, stated that products containing cannabidiol (CBD), if advertised for medical purposes, must be licensed. This created a problem for the CBD industry, as many of the products that were already on the market in 2016 claimed to have medical benefits. The MHRA gave manufacturers, whose CBD products were advertised as capable of treating certain conditions, until 31 December 2016 to change their marketing or withdraw their products from sale. Although most complied with these instructions, and the MHRA has taken issue with some companies for not following its rules, in general, the regulator's position has not been strictly policed or enforced. This puts compliant companies at a disadvantage and jeopardizes public trust in both the medical and non-medical sides the CBD industry, as it creates confusion over what is a medicine and what is a food supplement.

According to the results of a YouGov poll on the CBD industry published in October 2019, 47% of people questioned said they would not consider using products that contained CBD, against 28% of respondents who said they would consider it. Of those questioned who said they already used CBD, 61% said they use the products for medicinal purposes, with pain relief the primary use, at 71%, and another 38% using products to treat anxiety and depression. This suggests that assertions about the medicinal benefits of CBD, whether authorized or not, have penetrated public conscience.

To build trust in the sector and avoid criticism from the regulator, it is therefore important for CBD developers to understand the relevant legal parameters before commencing product development.

Résumé

Sarah Ellson
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Sarah Ellson

> **Assertions about the medicinal benefits of CBD, whether authorized or not, have penetrated public conscience.**

Medicinal products

CBD products require a license, referred to as a marketing authorization, before they can be legally sold, supplied or advertised as medicines in the UK. There is an exception for products categorized as "specials", which can only be prescribed and supplied to meet the particular needs of an individual patient and cannot be advertised. To obtain a marketing authorization, a manufacturer must submit clinical trials data to demonstrate the quality, safety and efficacy of their product.

Gathering this data is a long and expensive process. Some medicinal cannabis products, such as Epidiolex, have successfully been authorized by the European Medicines Agency (EMA) about a year after submission of its clinical studies. So far, however, very few other cannabis-based medicines have received marketing authorization for use in the UK. In addition to Epidiolex, Nabilone, a synthetic cannabinoid, is licensed for use with some patients with chemotherapy-induced nausea and Nabiximols (Sativex) is licensed for multiple sclerosis-related muscle spasticity. Once authorized, medicines then face the National Institute for Health and Care Excellence (NICE) appraisal process before they are reimbursed by the NHS.

Novel foods

The time, cost and regulatory scrutiny involved in applying for a marketing authorization has prompted many CBD product manufacturers to abandon or modify claims to their products' medical/health benefits in favor of finding another route to market as a food supplement. While

> **CBD products require a license before they can be legally sold, supplied or advertised as medicines in the UK.**

this initially looked like an easier way to sell CBD, last year saw the erection of new regulatory hurdles for non-medicinal cannabis products.

In January 2019, the European Commission classified all synthetically obtained extracts of hemp and derived products containing cannabinoids (including CBD) as "novel foods". Although not legally binding, authorities can refuse to permit supply of foods and food supplements containing CBD, pending formal approval by the European Food Standards Agency (EFSA) under the Novel Food Regulation ((EU) 2015/2283).

A novel food is one that had not been widely consumed by humans in the EU before May 1997, when the first Regulation on novel food came into force. Hemp seeds, hemp seed oil, and hemp flower oil are not considered novel, as these have a sufficient history of consumption in the EU. The UK Food Standards Agency (FSA) accepted this clarification and has said it will work to achieve compliance in the marketplace in a proportionate manner. In February 2020, the FSA announced that it was giving the CBD industry a deadline of 31 March 2021 to submit valid novel food authorization applications. After this deadline, only products which have submitted a valid application will be allowed to remain on the market. As of February 2020, EFSA had received around 20 novel food applications, two of which have been validated and entered the risk assessment phase, but so far none have been granted the status of approved novel foods.

Obtaining approval

The novelty status of CBD was a blow for the industry, which had hoped that by not making medical claims, manufacturers would be free to sell their products as supplements without significant regulatory constraints. The reality of getting authorization for a novel food from the FSA and EFSA is burdensome and involves a dossier of scientific data that may seem similar to getting a medicine authorized. The FSA website offers detailed guidance on the steps manufacturers need to take to compile the information required to make an application for novel food approval. Where medicines come with calculable dosage information, food manufacturers need to think about the effects of consumption, test for different scenarios, and develop appropriate labelling with recommended intake information.

The FSA has issued guidance, based on recent findings by the UK government's Committee on Toxicity (COT), that those who are pregnant, breastfeeding, or taking any medication not to consume CBD products. They also advise healthy adults to think carefully before taking CBD and recommend taking no more than 70mg a day (about 28 drops of 5% CBD) unless under medical direction.

Because food supplements tend to have much longer consumption periods than medicines, manufacturers need to have data to prove that their product is safe for routine consumption. They also need to consider what happens if someone outside the product's target population consumes the product and include instructions for what to do if this happens. This is especially pertinent to CBD products, many of which are in the form of gummies or chocolates, which are very attractive to children.

All ingredients used in a CBD product need to be clearly labelled with information on allergens and any other active ingredients that could pose a risk to some consumers. Manufacturers also need to think about the stability of a product – i.e., what happens to active ingredients when they exposed to extreme temperatures or pH levels – and provide appropriate storage instructions.

Finally, it is important to demonstrate a controlled production process that will result in the same product every time.

Legal limits

Cannabis remains a controlled Class B drug in the UK, meaning it is illegal to possess without a prescription or license. Tetrahydrocannabinol (THC) is the psychoactive cannabinoid in cannabis that gets recreational users "high" (CBD does not have this effect). CBD manufacturers must therefore comply with the 1971 Misuse of Drugs Act and Home Office stipulations that a product can contain a maximum THC content of 0.2%, and that the THC must not be easily separated from it.

At present, there are no limits on CBD content; in fact, there is more concern about manufacturers overstating CBD percentages than exceeding specified thresholds. However, there are also no standard tests for verifying CBD content and different laboratories have been shown to give different concentration results for the same products. This is a problem when it comes to accurate labelling products and, until it is rectified, manufacturers should ensure they have the highest possible quality control processes in place to deliver consistent products.

Labelling

Clear, compliant labelling is how industry wins the trust of consumers and regulators. When deciding what information to put on labels, CBD manufacturers need to be aware of certain regulations and labelling standards. Any product destined for sale in the EU will need to comply with EU rules on labelling.

Regulation (EU) No 1169/2011 places an obligation on food manufacturers to provide nutrition information to consumers.

EU rules on what nutrition and health claims manufacturers are permitted to make are set out under Regulation (EC) No 1924/2006.

These rules are designed to ensure that any claim made on a food's labelling, presentation or advertising in the EU is clear, accurate and based on scientific evidence. It is unclear how the FSA will proceed in terms of alignment with EFSA processes after the end of the Brexit transition period. As things stand, to avoid the risk of being penalized for failing to adhere to regulatory positions on CBD, manufacturers should be aware of EU rules and continue to adhere to these until the situation is clarified, especially if they have plans to export products in the future.

Common mistakes

Developers of novel food products routinely underestimate the amount of time it takes to gain regulatory approval. How long it takes for dossier preparation and testing will depend on the time and effort put in, but also access to labs and turnaround times. Once the dossier has been submitted to EFSA, the regulator will decide whether or not to accept it. If the dossier is validated, the regulator then has nine months to perform a risk assessment.

One of the reasons why novel food applications fail to make it to the risk assessment stage is that they lack sufficient data on manufacturing controls; or, do not have enough analytical data, or the data they do have is not good enough quality. Typically, there is overreliance on existing literature, in place of data on the manufacturer's own product.

Another common mistake is including data designed to illustrate the efficacy of the product. EFSA is not concerned with whether or not a product "works" and including this information may distract from the key objective, which is to demonstrate safety.

In addition, any attempt introduce health claims into a novel food application will almost certainly result in the application being knocked back straight away.

Finally, applicants should not submit incomplete dossiers and expect the regulator to come back with queries. A far more likely outcome is the application becoming stuck in the system for several months, before being rejected in its entirety without any guidance on what areas require improvement.

What next?

Both medicinal and non-medicinal cannabis CBD products face significant hurdles to obtain regulatory approval. While these may be frustrating, it should be remembered that the rules are set in the interests of public safety, and that attempting to sidestep or antagonize regulators could have serious consequences for individuals, companies and the CBD industry as a whole.

Medicinal CBD products have a fairly well worn, albeit lengthy and expensive, path to approval, however these also have the stigma of cannabis to contend with and still face the need to demonstrate cost effectiveness to ensure reimbursement on the NHS.

The novel foods issue is complicated as it requires many products that are already on the market to seek retrospective approval – something which is proving difficult to enforce.

For new and would-be market entrants to the novel foods arena, there are issues around the lack of available data on CBD, inadequate testing infrastructure and a lack of standardization across the industry.

> **Cannabis remains a controlled Class B drug in the UK.**

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“Please sir, I want some more”

After enduring lengthy regulatory processes to bring their blockbuster drugs and agrichemicals to market, innovator companies can be left with little time remaining on their patents before generics can begin competing. In the EU, and an increasing number of other countries, Supplementary Protection Certificates offer up to five and a half years of additional protection beyond patent expiry for particular authorized products. Joel Beevers and Michael Pears of Potter Clarkson guide us through the twisted history of assessing which products are eligible for SPC protection.

Under EU law, a Supplementary Protection Certificate (SPC) can be granted for a human or veterinary medicinal product (Regulation No 469/2009) or for a plant protection product (Regulation No 1610/96). A key requirement of these twin Regulations is that the product must be *“protected by a basic patent in force”* (Art. 3(a) or Art. 3(1)(a) respectively). In the medicinal context, a *“product”* is defined as the active ingredient or combination of active ingredients in the authorised product.

Although this might seem a straightforward phrase, viewed through the magnifying lenses of the importance and financial worth of SPCs, it has become clear that today’s patents and inventions require something more than was perhaps originally envisaged when the Regulations were written. In this article, we summarise the current interpretation of Art. 3(a) in light of case law from the Court of Justice of the EU (CJEU), and the pending questions before the Court that could bring legal clarity on this challenging issue.

Specified in the wording of the claims

In a *patent* sense, the word “protection” refers to the scope of the patent and its holder’s ability to stop an unauthorised third party from carrying out acts of “infringement”. Provided that a claim uses open language, e.g. “comprising”, its scope would cover anything that includes all of the features of the claim, even if additional features are present. Analysing whether a product falls within the scope of the claim is considered to be the “infringement test”.

In the 2011 *Medeva* (C-322/10) judgment, the CJEU considered a combination product where only two of the active ingredients were mentioned in the claim (to a method of preparing a vaccine), thus the other active ingredients could only fall within the scope of the claim by virtue of its open “comprising” language.

The Court ruled that Art. 3(a) is not satisfied unless each active ingredient being relied on is *“specified in the wording of the claims”*. Thus, a claim to active ingredient [A] can only be the basis for an SPC for active ingredient [A], not the combination of active ingredients [A + B]. For a product to merely “infringe” a claim is not enough for it to be “protected” in the sense of Art. 3(a).

Implicitly, but necessarily and specifically

Two years later, the CJEU was asked by an English court how specific the language of the claim must be for a product to be “specified”. In *Lilly v HGS* (C-493/12), the product was an antibody against Neutrokine-α, defined functionally in the claims as *“An isolated antibody or portion thereof that binds specifically to… the full length Neutrokine-α polypeptide… or… the extracellular domain of the Neutrokine-α polypeptide”*, with no other specific reference to the authorised antibody in the patent.

The Court answered that *“it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula”*, and that a functional formula is not in principle precluded, provided that *“the claims relate, implicitly but necessarily and specifically, to the active ingredient in question”*, taking into account the description in the patent. The English High Court consequently considered the claim language to be suitable, in principle, for supporting an SPC.

Two-part test

The CJEU handed down its leading decision on Art. 3(a) in July 2018 from the UK referral in Teva v Gilead (C-121/17). Gilead’s SPC covered a combination of two active ingredients, tenofovir disoproxil (TD) and emtricitabine, authorised and marketed as the antiretroviral medicinal product TRUVADA®. However, the relevant claim in Gilead’s patent read: *“A pharmaceutical composition comprising a compound according to any one of claims 1-25 [Claim 25 recited TD] together with a pharmaceutically acceptable carrier **and optionally other therapeutic ingredients**”*.

Viewed in light of the *Lilly* judgment, this claim could be argued to relate *implicitly* to the combination of TD and emtricitabine, but it was not clear whether the language of the claim would be enough to relate *“necessarily and specifically”* to that combination. The skilled person, turning to the patent description, would find no disclosure of emtricitabine. Indeed, Teva argued that emtricitabine was not known to work as an anti-retroviral drug at the patent’s priority date and so the claim could not relate necessarily and specifically to its combination with TD.

In answer to the referral, the Court provided a new two-part test:

*“Article 3(a)… must be interpreted as meaning that a product composed of several active ingredients with a combined effect is ‘protected by a patent in force’ within the meaning of that provision where, **even if the combination** of active ingredients of which that product is composed **is not expressly mentioned in the claims** of the basic patent, **those claims relate necessarily and specifically to that combination**” [note the reiteration of the language from Lilly here].*

*“For that purpose, **from the point of view of a person skilled in the art** and **on the basis of the prior art at the filing date or priority date** of the basic patent:*

- *the **combination** of those active ingredients must necessarily, **in the light of the description and drawings** of that patent, **fall under the invention** covered by that patent, and*
- *each of those active ingredients must be **specifically identifiable, in the light of all the information** disclosed by that patent”*

(**emphasis** added).

The first part of the test is explained in paragraph 48 of the judgment as determining whether *“the product to which the claims of the basic patent relate is a specification required for the solution of the technical problem disclosed by that patent”* (emphasis added). Hence, optional features (unless they are themselves inventive) are likely to fail this test.

For the second part of the test, as in *Lilly*, the claims must be interpreted in light of the description and drawings, but also (for Art. 3(a) purposes) on the basis of the prior art at the effective date(s) of the claims. This, for example, may permit a claim to refer to a genus (e.g. a diuretic) and still “protect” a certain species disclosed in the prior art. The judgment appears to rule out any recourse to the result of future research (at least to the extent that the research requires inventive skill), but there remains an issue of whether an SPC application can rely upon the results of *routine* work carried out after the priority date.

Another loose end is whether the two-part test is intended to be applied for all combination products (and perhaps even for all products as a definitive Art. 3(a) test), or whether it only applies *“if the combination of active ingredients… is not **expressly mentioned** in the claims”*. It is possible to envisage scenarios in which, through fortuitous drafting, a specific combination is included in the granted claims (and thus satisfies the second part of the test) but does not satisfy the first part of the test (e.g. because only one of the active ingredients is required to solve the problem in the patent).

While drafting patent applications, innovators would do well to consider what evidence they can include to strengthen the position for the first part of the test by showing that certain combination(s) are independently inventive, and in any event to include basis for commercially relevant combinations that can be explicitly recited in the claims at grant.

Future developments

The CJEU is currently contemplating two joined cases that relate to specifying single active ingredients with alternative claim formats.

In *Royalty Pharma* (C-650/17), the patent claims are defined purely in functional terms (in contrast to the degree of structure from the term “antibody” in *Lilly*), and the active ingredient sitagliptin that is the subject of the SPC application was not mentioned in the patent (and was only developed after the filing date). Nevertheless, the basic patent disclosed the use of a functional class of inhibitors for treating diabetes, which was arguably a necessary innovation without which sitagliptin would not have been developed. Where should the line be drawn between rewarding early-stage basic research and requiring disclosure of a final commercial product?

In *Sandoz v Searle* (C-114/18), the patent claims include a *Markush* formula (a formula representing a structural core shared by a family of compounds, with substitutable part(s)) but the subject of the SPC, darunavir, was not individualised in the patent (and included an unusual substituent). The SPC proprietor argued

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Résumés

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that Art. 3(a) should be satisfied as darunavir fell within the family of structures covered by the claimed formula. Sandoz and Hexal argued that none of the claims relate necessarily and specifically to darunavir, and because the substituent was not common general knowledge the skilled person would not have been able to identify darunavir at the priority date using the patent.

Judgment in these cases is expected in 2020. In the meantime, Advocate General Hogan has issued an opinion, in which he suggests that the two-part test of *Teva v Gilead* should be definitive for Art. 3(a), for single active ingredients too. Regarding the issue of common general knowledge (relevant to the *Markush* substituents), AG Hogan reminds us that the Teva v Gilead test takes into account the prior art as a whole, and thus would be more permissive than the one argued for by Sandoz and Hexal. Further, under the second part of the test, AG Hogan refers to whether the skilled person *"would have been able… to* ***derive*** *the product"*, which suggests that there may still be scope for using routine development work to arrive at the active ingredient(s) in the authorised product.

On a final note, the CJEU declined to take the recent opportunity in *Lilly v Genentech* (C 239/19) to opine on the live issue of whether a patent holder can be granted an SPC on the basis of another party's marketing authorisation without consent. Nevertheless, Art. 3(a) is of some relevance to this point because the more rigorous the requirement for the patent claims to relate necessarily and specifically to the active ingredient(s) of the authorised product, the less likely that a patent based on early-stage research or a platform technology could be used to obtain an SPC based on another party's authorisation.

Thus, the CJEU's imminent judgments on Art. 3(a) could have wide-reaching implications, including either reinforcing or rendering invalid whole families of SPCs. In the high-stakes tussle between innovators and generics manufacturers, clarity on the interpretation of Art. 3(a) may turn into a case of "be careful what you wish for".

Editor's note: The reference in *Sandoz v Searle* (C-114/18) has now been withdrawn by the referring court. A decision is still awaited in the previously-joined case, *Royalty Pharma* (C-650/17).

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COVID-19: The invisible enemy revisited

Alejandro Luna Fandiño of Olivares looks at Mexico's response to the ongoing Coronavirus pandemic.

In 2009, Mexico battled the first pandemic of the 21st century. An outbreak of a new strain of influenza, the AH1N1 disease emerged, known at the beginning as the "swine flu" or with the xenophobic name of "Mexican flu". The outbreak was believed to have originated in Mexico and was first identified in the country in March. Shortly after its identification, the Mexican government acted quickly to impose tight measures across the country. Millions of face masks were handed out to citizens by the military and police forces. Schools, libraries, museums, concerts, and other public gathering venues were shut down and Mexico City carried out a 15-day quarantine.

Before the pandemic emerged, there were already two available and patented antiviral drugs indicated for influenza, TAMIFLU® (OSELTAMIVIR) and RELENZA® (ZANAMIVIR), which were already on the market. In 2009, these were found to have a significant effect on reducing the severity and duration of the AH1N1 disease symptoms. Many countries agreed that these drugs were useful in the treatment and prevention of the AH1N1 disease. Their immediate availability, together with the Mexican government's quick response, are believed to have helped control the spread of the virus in Mexico.

Eleven years later, the world has found itself in the midst of another global pandemic. COVID-19 has spread across countries rapidly and in a seemingly uncontrolled manner. The majority of nations have responded by ordering some form of lockdown, with varying levels of enforcement.

COVID-19, contrary to AH1N1, is understood to be a coronavirus, rather than a strain of influenza. For this reason, we still know relatively little about the disease and although a vaccine is currently in the early stages of clinical trials; to date, no treatment has been identified and universally agreed-upon.

At the moment of writing this article, compared to other countries, the number of confirmed cases of COVID-19 in Mexico are relatively low. However, trends may suggest that we are at the beginning of an upward curve. There are concerns that Mexico's healthcare infrastructure would not be able to cope with an exponential increase in case numbers and the Mexican Government issued already a declaratory of COVID-19 as a disease of priority attention which is the first step for an eventual or potential declaratory of emergency and then, compulsory licenses.

Alejandro Luna Fandiño

> **"COVID-19 has spread across countries rapidly and in a seemingly uncontrolled manner."**

On 23 March 2020, the Mexican Patent and Trademark Office (IMPI) issued a decree suspending and interrupting procedural terms from 24 March to 19 April 2020. The suspension of activities does not apply to those procedures which are necessary to mitigate the consequences of the pandemic.

On 24 March, the Mexican President announced that Mexico officially entered phase 2 (local transmission) of the outbreak of COVID-19. New and additional measures to contain the spread of COVID-19 and "flatten the curve" of transmission were announced.

These measures were taken gradually by several public and private entities. It is highlighted that most of the private sector acted earlier, faster and in a stricter manner when compared with the public sector.

On 26 March, the Ministry of Health issued a decree suspending the legal terms running during the period of 26 March to 19 April, due to *force majeure*.

The Ministry of Health specified that all of its dependencies would provide everything necessary so that the necessary personnel continue to work to carry out all the procedures that are essential and/or urgent to deal with the contingency, in order to assure the continuity of operations of

Résumé

Alejandro Luna Fandiño

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essential functions related to the control of the COVID-19 virus pandemic.

Sanitary authorizations related to medicines, medical devices and import of supplies, among others, that are strictly related to the attention of the COVID-19 pandemic, will continue to be processed by COFEPRIS during said period.

COFEPRIS announced that their Comprehensive Services Center (CIS) will also remain open to receive and attend to those procedures that are required in order to continue with the supply of medical products to respond to the general health needs of the population (not necessarily related to COVID-19).

At the time of writing this article, it is expected that the Mexican Patent Office (IMPI) will extend the period of inactivity until 5 May, however confirming that new applications for patents, trademarks and designs can be made on-line.

On March 27, the Mexican President published a Decree in the Federal Gazette, implementing extraordinary measures in relation to the outbreak of COVID-19.

This Decree announced the following extraordinary and immediate measures:

- The use of all medical resources available in the public and private sectors in the regions and the surrounding areas.
- The acquisition of all types of goods and services, at national or international level, such as medical equipment, diagnostic agents, surgical and healing materials and hygiene products, as well as any other type of good or service, without any public tender procedure, for the quantities or concepts that are necessary to face the contingency.
- The import and authorization of imports of the above-mentioned goods and services with minimal or no administrative procedure requirements, for the required quantities or concepts.
- Taking the corresponding measures in order to avoid price speculation and stockpiling of the essential products mentioned above.
- Any other measure that is considered necessary by the Ministry of Health.

The Mexican sanitary regulatory agency, COFEPRIS, published an announcement on its official website stating the petitions and proceedings that will remain open during this phase 2 of the pandemic in Mexico. The notice includes applications for "products" that may be used to overcome the health emergency of COVID-19.

Mexico Declares State of Emergency

On 31 March, due to the increase in cases of contagion, the Secretary of Health published a Decree issued by the Health Counsel in the Official Gazette of the Federation, establishing extraordinary actions to address the health emergency due to causes of force majeure, generated by the SARS-CoV2 virus (COVID-19).

There are many doubts and questions regarding the definition or scope of some of the measures and concepts established in this decree, especially the concepts of "emergency due to causes of force majeure", instead of a "contingency or health emergency"; similarly, many questions have arisen about the definition of "essential activities".

Needless to say, the highlighted controversial concepts, as well as all the measures, will have a series of legal impacts on the regulatory, administrative, labor, contractual, and tax fields, among others.

When finalizing this article, it seems that the measures will be extended until June, and the peak of contagious in Mexico will be mid-May.

COVID-19 treatments and patents

Certain pharmaceutical products currently indicated and marketed for other therapeutic indications have shown efficacy in the treatment of the COVID-19 disease. Some of these are already being used as treatments for COVID-19 in other countries. For example, early evidence showed that REMDESIVIR, which was tried on only a few patients in Wuhan, seemed to work well; CLOROQUINE, a treatment for malaria, seemed to be useful for the treatment of serious pneumonias; and LOPINAVIR, a treatment for HIV, and FAVIPIRAVIR had also shown positive results.

The Mexican sanitary regulatory agency, COFEPRIS, has already approved clinical trials for four of the pharmaceutical products that have shown usefulness in the treatment of COVID-19. These are REMDESIVIR, TOCILIZUMAB, HYDROXYCHLOROQUINE and CHLOROQUINE & AZITHROMYCIN. Some of these pharmaceutical products are currently protected by patents and are already being marketed and sold to the general public for other therapeutic indications. Others are in the process of obtaining patent protection.

Patents provide the titleholder with the exclusive right to make, use or sell the product. If a third-party company tries to make, use, or sell a product protected by a patent, the titleholder has the right to commence infringement proceedings before the Mexican Patent Office, IMPI, and later, the courts. During the proceedings, IMPI and/or the courts will decide whether there is actual infringement of the patent. If the court decides that there is actual infringement, a subsequent court procedure will determine the amount of damages the third-party company must pay to the titleholder. This process is very lengthy and expensive for both the titleholder and the third-party company.

During pandemics, patents might seem inequitable and a barrier to public health; this is not necessarily genuine. Once a medicine is approved for the treatment of the COVID-19 disease, it will need to be quickly produced and distributed across the country in an enormous scale. Because only the titleholder (and any commercial licensees) have the right to make and sell the medicine, thus, in case of a global pandemic, third-party pharmaceutical companies would be deterred from meeting an eventual shortage.

Compulsory license regulations in Mexico

The Mexican Industrial Property Law provides for the grant of compulsory licenses in the event of a national emergency, such as a serious disease as declared by the General Health Council. This law helps protect against the risk that patent protection will hinder the production and/or supply of drugs in the event of a health crisis.

The grant of a compulsory license is not automatic. The declaration of serious illness is the first phase of the procedure of the grant of compulsory licenses. According to Article 77 of the Industrial Property Law and Article 51 of its Regulations, the following procedure inter alia must be followed for the grant of a compulsory license:

- There must be a risk that the lack of a compulsory license would prevent, hinder, or increase the price of the supply, distribution, or access to the patented product.
- The General Health Council must issue a declaration of emergency in the Official Gazette, justifying priority attention for the serious disease.
- Once the declaration of emergency is published, third party pharmaceutical companies can request a compulsory license from the Mexican Patent Office (IMPI).
- IMPI will decide whether to grant the compulsory license within a term of no longer than 90 days from the date of the petition.
- Through an agreement with the Secretary of Economy, IMPI may decide to grant the license and, if so, publish a declaration stating that the exploitation of certain patents may be carried out by the grant of a license for the public benefit.
- Within two months after the publication the declaration, the affected patent holders have an opportunity to protest it
- Once the protests have been heard, IMPI will make a definitive resolution, confirming or revoking the declaration.
- Subject to successful challenge by the affected patentee to the grant of license and the declaration being upheld by IMPI, the Ministry of Health will establish the production conditions, quality controls, duration, and scope of application of the license.
- IMPI will determine the appropriate royalties the licensee is to pay the patent holder, upon hearing submissions from both parties.
- The compulsory license is neither exclusive nor transferrable and will be in effect for as long as the public health emergency requires.

AH1N1 in 2009 and COVID-19 now

The 2009 AH1N1 crisis was the first time Mexico came very close to granting compulsory licenses for reasons of national emergency for the public benefit. The disease had spread rapidly to over 200 countries, and the World Health Organization declared a pandemic. At that time, there were already two available treatments for the AH1N1 disease, which were both protected by patents.

However, the requirements for compulsory licenses were not met, which meant that they were not granted. There was no evidence to suggest that the titleholders of the patents for TAMIFLU® and RELENZA® were unable to supply to drugs in a sufficient quantity or that there was a national shortage of supply. There was also no evidence that prices had been set high, on the contrary, it has been said that a pandemic price was agreed between the Mexican government and the titleholders, neither there was evidence that distribution was being blocked.

In any case, the General Health Council had not published a declaration of emergency in the Official Gazette, which is the first phase of the procedure for the grant of compulsory licenses.

In comparison, the COVID-19 pandemic seems much more serious and advanced. When the AH1N1 disease emerged, scientists already knew a lot about influenza through centuries of humans battling mild and severe strains and through decades of research. They comparatively know much less about the new and coronavirus, including its transmission and mortality rate, because it has not been studied as extensively.

Like the AH1N1 virus, the COVID-19 disease has also been declared a pandemic by the World Health Organization and has spread to 185 countries so far. However, the Mexican government's response, at least at the moment of writing this article, appears much more gradual and less strict than it was in 2009, which could be impacting the disease's transmission. It is also impactful that there is currently no universally accepted treatment or cure. Clinical trials are currently underway in Mexico, but it will take time to be approved and then produced and distributed to the general public on a large scale. While a vaccine is currently in development, it would also have to go through rigorous clinical trials to ensure its safety and efficacy, leading some to predict that it could still be a year away from general public use.

Conclusion

There has been no precedent for a compulsory license being granted in Mexico, despite coming close during the pandemic of the AH1N1 disease. There were also other mechanisms that were used in 2009 that avoided the need or the legal scenarios for the issuance of compulsory licenses, such as free licenses, cooperation of the authority and titleholders, patents dedicated to the public and pandemic pricing.

In any case, if there is evidence of a shortage of supply or unfair pricing that could limit availability of the medicine and damage the health of the population, compulsory licenses are intended as a safety net to ensure that titleholders are not risking lives for reasons of mere exclusive rights. Provided the conditions in TRIPS and NAFTA and reproduced in the Mexican Industrial Property Law are met, there is no legal reason why they would not be granted but conditions provided and processes contained therein should be observed, otherwise the act would be dictatorial.

If a universal treatment for COVID-19 does become available and if it is patent-protected, the hope is that, similarly, such treatment will not be in short supply and therefore the conditions for compulsory licenses will not be met. This is not only a legal prediction but also a real desire, because if the conditions are not met, this would indicate that the outbreak is not so dangerous and damaging to public health or that we, as human kind, through the health measures and cooperation, defeated the invisible enemy.

Whether the current circumstances will lead to a different result under the provisions of the Mexican compulsory license provisions merits close attention. Nevertheless, whether compulsory licenses are required for this pandemic, history has taught us that a fast-acting government and responsible citizens working in solidarity can help to control the transmission of this invisible enemy.

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Patenting antibodies in Russia

Maria Kuptsova and Tatiana Badaeva of Sojuzpatent discuss the options available in Russia for antibody patent protection.

Biotechnology is one of the most rapidly-growing fields of knowledge. As a result, the practice of patenting biotech inventions is changing very intensively. Antibody inventions represent a significant part of all biotechnological inventions. The development of such inventions requires significant investment, and robust patent protection is crucial.

This article focuses on antibody patent protection in Russia in light of current practice.

Legal framework

There are two ways of obtaining patent protection for inventions in Russia. The first is through filing a national Russian patent application with the Russian Patent Office (RUPTO). The second is through filing a regional Eurasian patent application with the Eurasian Patent Office (EAPO), since once a Eurasian patent is granted, it is valid in all Contracting States, including Russia.

Russian and Eurasian patents are independent. An interesting consequence of this is the possibility of getting both Eurasian and Russian patent protection for the same invention simultaneously.

Both these patents provide protection under similar provisions in Russia.

The scope of rights of Eurasian and Russian patents are each defined by features of independent claims or equivalent features known from a prior art.

Both patent offices devote increasing efforts to counterbalance inventors' demands, on one side, and protection of public interests, on the other. With that, their approaches are not the same.

Although both patent offices apply common general patentability criteria such as novelty, non-obviousness, and industrial applicability, some additional conditions must be met to obtain a patent successfully.

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In particular, both patent offices require that claims must be supported by materials of an application. The analysis of whether this criterion has been met differs between the EAPO and the RUPTO. Presently, the EAPO is more sympathetic, e.g. it does not require that a separate example should be provided for each alternative feature included in a claim.

Furthermore, both patent offices have their own special rules regulating how to state claims, and which features should characterize these, or those subject matters of an invention, and examiners pay much attention to analysis of claims in light of these rules.

When an invention relates to an antibody, the following is considered:

- whether claims contain clear features, which means that a skilled artisan should understand their meaning and/or that the level of generalization of this feature is allowable; and
- whether claims contain a set of essential features of an invention, namely, those features which are important for realization of an intended use of a claimed subject matter and achievement of a technical result/technical effect when practicing this invention.

Further, the RUPTO considers antibodies as proteins and has the following additional requirements:

"In claims that characterize …protein, peptide or polypeptide, isolated from natural source or obtained in another way, having a same or a targetedly altered biological function… should be included: a name of a product, its biological functions (a type of activity, biological property) that determines its intended use in cases when it does not follow obviously from the name, number of corresponding…amino-acid sequence (if it was established) of physicochemical and other features, that allow to differentiate this substance from others".

In turn, the EAPO considers antibodies as inanimate biotech products, so, a claim must satisfy the following rules:

"In claims that characterize a product of inanimate nature whose structure is fully or partly revealed, following is included: structural formula or peculiarities of structure of such products, in particular …amino acid sequence for peptides, polypeptides and proteins.
For products that relate to inanimate objects with unestablished structure, claims contain a set of physicochemical and other features that allow identifying these subjects and distinguishing them from other already known products. Such features can be for instance features of their production method.
In the both above cases function or a type of activity and origin shall be also specified".

As a result, Russian and Eurasian patents relating to the same invention may provide different scopes of protection.

Nowadays, the RUPTO aims to decrease the timeframe of application consideration as much as possible. So, a biotech patent might be granted in two years from the date of filing a national stage application. Another advantage of the RUPTO compared to the EAPO is that patent fees in the RUPTO are quite low. Thus, if a very quick patent is desired, filing a national Russian patent application may be a good way out.

While the prosecution process takes more time in the EAPO, filing a regional Eurasian application is advantageous from the viewpoint that it allows more opportunities for amending materials of an application, and providing arguments supporting the scope of claims and patentability of an invention.

Main approaches for characterization of antibodies in claims for Russian and Eurasian patents

The requirements of Russian and Eurasian patent legislations discussed above outline a specific number of ways to characterize antibodies in claims. For example, it is impossible to characterize an antibody in a claim only by its functional features, such as its capability to bind a certain antigen, or its capability to compete for binding with another antibody.

> **"Russian and Eurasian patents relating to the same invention may provide different scopes of protection."**

Roughly, there are two possible ways: characterizing an antibody by its structural features or characterizing an antibody with "other" distinguishing features along with its physical-chemical properties.

Further, we would like to discuss several common situations in connection with an antibody claim in the RUPTO and in the EAPO.

Characterizing an antibody by its antigen binding region

An antibody may be characterized in claims by reference to its antigen-binding site. However, such features can be stated in claims very differently.

Sometimes an antibody or an antibody-based artificial construct are characterized as "binding to an antigen X and comprising at least one domain responsible for the binding to the antigen" without an indication of domain sequences. In RUPTO practice, in such cases, it is always requested to indicate concrete "essential" sequences of an antigen binding domain, such as complementarity-determining regions ("CDRs"). The same holds true for cases when specification discloses a large pool of antibodies, which are capable of binding a target and have different CDRs. The corresponding claim may relate to all antibodies altogether that are listed as alternatives.

The situation in the EAPO is a little different. According to current practice, when examples disclose amino acid sequences of antibodies, as a rule, it is requested to reflect this information in claims. This is because the above stated provisions of the EAPO relating to antibody characteristics in claims are allowable for equivocation, and it could be concluded that an antibody can be characterized with "other feature" only when its structure is not revealed. However, the EAPO may consider whether a specification proves that many different antibodies to a target antigen were obtained, and whether all of them show the desired effect. Therefore, it is still possible to avoid restricting an antibody claim in the EAPO to

Résumés

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antibodies of concrete amino acid sequences, drawing the Examiner's attention to the amount and nature of supporting information provided in the specification of an application. Nevertheless, it may be requested to restrict the claim further by other features such as features of a production method and/or physical and chemical properties.

As can be judged from the above, both the RUPTO and the EAPO usually accept an antibody claim where a biological function or activity of an antibody is indicated together with its amino acid sequence responsible for this biological function or activity, such as its six CDRs

However, CDRs in claims may be defined not only by reference to their sequences, but by reference to an antibody that "comprises CDRs from a variable chain of a sequence SEQ ID NO: ..." or similar, with or without a reference to any scheme of numbering amino acid residues in antibodies. Usually, but not always, in such a situation it is requested to indicate a numbering scheme in a claim, since CDRs depend on the applied numbering scheme.

The next problematic situation that should be mentioned in connection with CDRs is when not all six CDRs are indicated in a claim, or when a provided characteristic allows some degree of variability in CDRs.

Such a characteristic is usually not allowed in both offices. Only in cases when an application contains a sufficient body of experimental data, confirming that e.g. CDR variability does not change antibody's functionality, can such a claim be accepted.

Characterizing an antibody by Fc region and its modifications

Some inventions relate to modifications of an antibody's fragment crystallizable region ("Fc region") in order to improve an antibody's properties, such as its effector function. In recent RUPTO practice, a claim characterizing an antibody only by an Fc region modification, and the effect of this modification, is not allowed. In articles by RUPTO examiners this position is explained by the fact that Russian patent legislation requires that an antibody claim must state an intended use that can be related only with an antigen binding activity, not with an effect of Fc region modification. Therefore, it is declared that essential features of such objects are antigen binding specificity and features that determine it. As a result, such inventions are usually limited to antibodies from the examples section with specific antigen binding activity and concrete CDRs sequences.

It is worth noting that a method claim may be a good alternative to an antibody claim if an invention relates to modifications of Fc region, since a method claim may offer protection to a product produced by such method i.e. an antibody.

> **The EAPO considers antibodies as inanimate biotech products.**

The EAPO may be more favorable in respect of inventions related to antibodies characterized by modification(s) of Fc region. However, as a rule, EAPO examiners pay much attention to supporting information comprised in the specification of an application, while evaluating whether an invention is generally applicable to antibodies regardless of an antigen binding capability.

Characterizing an antibody by process of production

As we have indicated above, in claims that characterize an antibody or relate to antibodies' "other features" (e.g. a production method) have to be combined with physical and chemical properties, such as a dissociation constant of an antibody and its antigen. Usually, RUPTO or EAPO examiners do not dispute whether given characteristics of physical and chemical properties are justified considering the data provided. However, values of parameters reflecting such properties depend on a measurement method and conditions. Therefore, for evaluation of protection scope, the specification of an application should disclose how exactly this parameter was determined.

Although provisions related to an antibody characteristic in claims are very similar in the RUPTO and the EAPO, the EAPO is more sympathetic to an antibody claim characterizing this product only by features of a method without its physical and chemical properties.

Conclusions

Both the RUPTO and the EAPO have been changing approaches to evaluation of antibody inventions, so we expect that the trend would continue, since interest in antibody patent protection remains high. We cannot predict whether these patent offices will coordinate their efforts in order to improve legislation relating to biotech inventions patenting, or if each of the offices will follow its own path. Nevertheless, it makes sense to use the difference in the EAPO and the RUPTO approaches to obtain optimal protection for an antibody invention, or even to file both Russian and Eurasian patent applications in complex cases.

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