The Life Sciences Lawyer

Issue 2 2021

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# Patent protection of mRNA vaccines and regulatory authorization

Launch interactive document

Janett Lumbreras, Senior Associate, Uhthoff, Gomez Vega & Uhthoff S.C, explains how an mRNA vaccine works, how they are produced, and how compulsory licensing may be required in the face of the COVID-19 pandemic.

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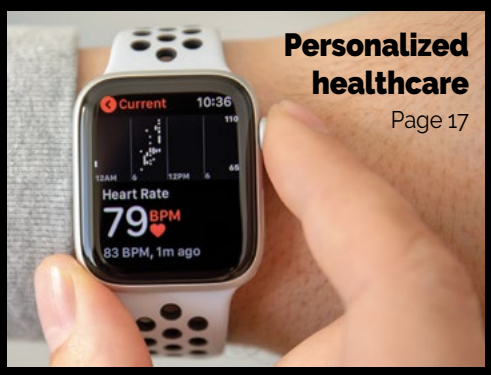


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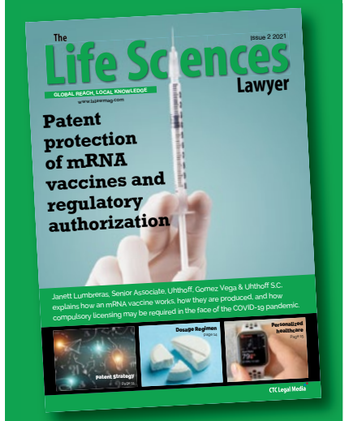



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CTC Legal Media



# Editor's welcome

With COVID-19 continuing to permeate everyday life around the globe it is no surprise that vaccines continue to be a hot topic. So, what is an mRNA vaccine, how does it work, and how could patenting vaccines slow down the recovery from the pandemic? Our cover story, brought to us by Uhthoff, Gómez Vega & Uhthoff, delves into this discussion.

John Weatherspoon, IP Counsel for Open Book Extracts, provides a valuable commentary on patent strategy in the life sciences field – an article that will broaden the mind to alternative and useful techniques to implement in your practise.

> **"Useful techniques to implement in your practise."**

EIP brings us an update on the personalised healthcare boom with an assessment of what it can lend to the life sciences industry. Are we close to a reality where health apps and technologies will be utilized in medical treatment? And how will these new innovations be patented?

Marks & Clerk's thought leaders bring us an update on patenting dosage regimes in Singapore with comparative and influential analysis of both the UK and EU systems. This article calls in to question whether a change in dosage recommendation should be patentable as it is not, as is usually required, novel or non-obvious as the product itself is the same just given in different quantities – but what if the change in dosage changes the effect?

This plus new guidelines on biosimilars, an open letter on UK healthcare data, and an update on life sciences patents in Brasil.

Enjoy the issue

**Faye Waters, 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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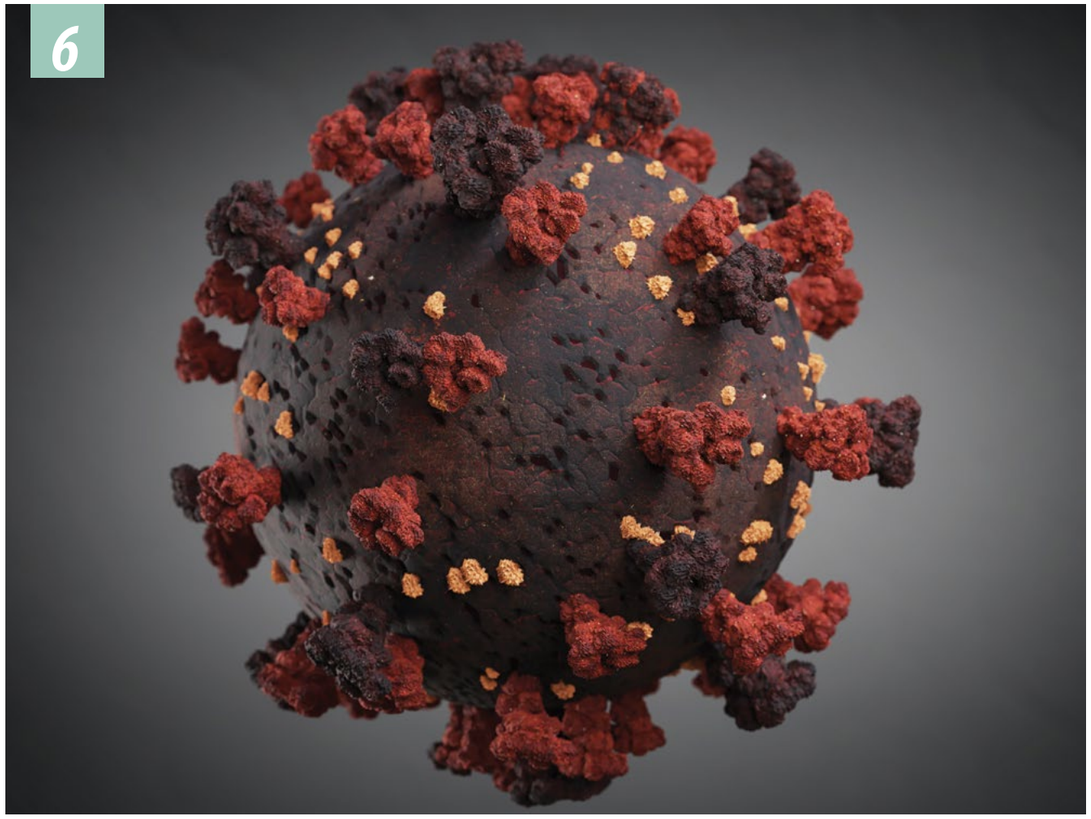






# Patent protection of mRNA vaccines and regulatory authorization

**Janett Lumbreras, Senior Associate, Uhthoff, Gomez Vega & Uhthoff S.C, explains how an mRNA vaccine works, how they are produced, and how compulsory licensing may be required in the face of the COVID-19 pandemic.**

Researchers have been studying and working with mRNA vaccines for decades. Interest in these vaccines has grown since they can be developed in a laboratory using readily available materials for low-cost manufacture and safe administration. This means that the process can be standardized and scaled up, which makes vaccine development faster than traditional methods of making vaccines.

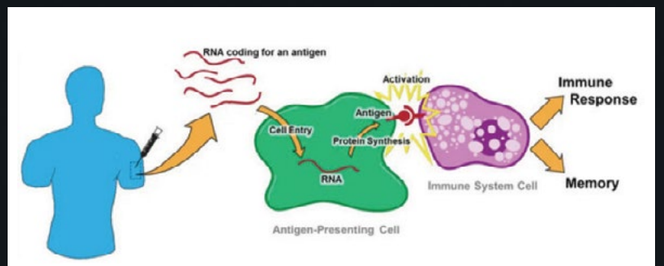
As soon as the necessary information about the virus that causes COVID-19 was available, scientists began designing the mRNA instructions for cells to build the unique spike protein into an mRNA vaccine.

For most emerging virus vaccines, the main obstacle is not the effectiveness of conventional approaches but the need for more rapid development and large-scale deployment.

Janett Lumbreras

## How mRNA vaccines work

Messenger ribonucleic acid (mRNA) vaccines are a novel technology that stimulates the body's own immune response. These vaccines contain information from mRNA, including the "blueprint" or code of a specific virus trait (virus antigen). The information enables the body to produce this antigen on its own: mRNA transfers the information for the production of the antigen to our cell machinery that makes proteins. Cells in our body then present the antigen on their surface and thus trigger the desired specific immune response. When the body comes into contact with the virus, the immune system recognizes the specific antigen and can fight the virus and thus the infection quickly and in a targeted manner.




https://sitn.hms.harvard.edu/flash/2015/rna-vaccines-a-novel-technology-to-prevent-and-treat-disease/A

mRNA vaccines are safe because they are not made with pathogen particles or inactivated pathogens; therefore, they are non-infectious. RNA does not integrate itself into the host genome and the RNA strand in the vaccine is degraded once the protein is made.


## Résumé

**Janett Lumbreras - Senior Associate**

Janett has been Senior Associate at Uhthoff, Gomez Vega & Uhthoff in the Patent Department.

She has a Pharmaceutical Chemistry-Biology Degree, Diplomat in Access to Worldwide Scientific and Technological Information and Industrial and Intellectual Property Law from Universidad Nacional Autonoma de Mexico (UNAM). She is an active member of AMPPI, AIPLA, CNQFBM


Due to the high yields of *in vitro* transcription reactions, mRNA vaccines have the potential for rapid, inexpensive and scalable manufacturing.

mRNA vaccines can be used for infectious diseases, particularly for viruses, that cause both acute (Influenza, Ebola, Zika, etc.) and chronic (HIV-1, herpes simplex virus, etc.) infections.

Cancer vaccines can be designed to target tumor-associated antigens that are preferentially expressed in cancerous cells, for example, blood cancers, melanoma, glioblastoma (brain cancer), renal cell carcinoma, prostate cancer, etc.

Most cancer vaccines are therapeutic, rather than prophylactic, and seek to stimulate cell-mediated responses, such as those from CTLs, that are capable of clearing or reducing tumor burden.

Four of the vaccine candidates currently in clinical trials to prevent COVID-19 are mRNA vaccines: mRNA-1273 (Moderna), BNT-162 (BioNTech), CVnCoV (CureVac), and LNP-nCoVsa-RNA (Imperial College London).

## Types of RNA vaccine

1. Non-replicating mRNA.
2. *In vivo* self-replicating mRNA.
3. *In vitro* dendritic cell non-replicating mRNA vaccine.

## Protection by patent

Patent Rights play an important role in encouraging investment on research of new technologies. The patent system is designed to support innovation and, at the same time, offer a mechanism to ensure that such innovations are accessible to society. Published patents and patent applications are an important source of technical and legal information.

Scientists have studied the use of mRNA as a novel therapeutic since the early 1990s. The first patent family identified was published in 1990. However, it was not until 2005 that a group of researchers from the University of Pennsylvania published findings on mRNA technology that have since been deemed critical to the development of mRNA-based therapies. US Securities and Exchange Commission filings, highlighted by Knowledge Ecology International, reveal a series of sublicenses for mRNA-related patents that stem from the University of Pennsylvania to both Moderna and BioNTech. The 2017 filings indicate that the University of Pennsylvania exclusively licensed their patents to mRNA RiboTherapeutics, which then sublicensed them to its affiliate CellScript. CellScript proceeded to sublicense the patents to Moderna and BioNTech; however, the patent numbers are redacted in all the filings, making it difficult to determine which are relevant to the production of COVID-19 vaccines.

> **"A novel technology that stimulates the body's own immune response."**

Another key aspect of an mRNA vaccine platform is the ability to deliver the mRNA to a cell using a lipid nanoparticle. Some early work on lipid nanoparticles was done jointly by the University of British Columbia and Arbutus Biopharmaceuticals in 1998. US Securities and Exchange Commission filings show that patents relating to this early technology were solely assigned to the University of British Columbia and then licensed back to Arbutus.

Patent-filing activity grew dramatically over the past five years for both infectious disease and cancer indications. The number of applications for infectious disease indications surpassed those for cancer over the past three years, which could reflect increased interest in vaccines following epidemic outbreaks of MERS-CoV, Ebola virus and Zika virus. In August 2019, Moderna received FDA Fast Track Designation for an investigational Zika virus vaccine (mRNA-1893) currently being evaluated in a phase I study.

According to PATENTSCOPE – WIPO, from 2012 to 2021, 1,834 patent applications related with mRNA have been published. The main filing countries are the following:

| Country | |
|---|---|
| **United States of America** | 366 |
| **European Patent Office** | 268 |
| **PCT** | 253 |
| **China** | 245 |
| **Australia** | 149 |
| **Canada** | 122 |
| **Japan** | 89 |
| **Republic of Korea** | 62 |
| **India** | 56 |
| **Mexico** | 33 |

The applicants who have filed the most patent application are listed below:

| Applicant | |
|---|---|
| **CUREVAC AG** | 102 |
| **CUREVAC GMBH** | 68 |
| **MODERNATX INC** | 60 |
| **BIONTECH RNA PHARMACEUTICALS GMBH** | 44 |
| **MEDIMMUNE VACCINES INC** | 36 |
| **VIRONOVATIVE BV** | 35 |
| **INSTITUT PASTEUR** | 28 |
| **HUMAN GENOME SCIENCES INC** | 27 |
| **PASTEUR INSTITUT** | 24 |
| **BIONTECH AG** | 22 |

The present IP landscape includes foundational patents in modified mRNA technologies and delivery technologies that are essential for mRNA therapeutics and vaccines, including their application in specific unmet needs in infectious diseases, cancer (immuno-oncology), and rare and cardiometabolic diseases, among others.

## Compulsory licenses

Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself. It is one of the flexibilities in the field of patent protection included in the WTO's agreement on Intellectual Property —Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

> **The present IP landscape includes foundational patents in modified mRNA technologies and delivery technologies that are essential for mRNA therapeutics and vaccines.**

To explain the public policy objectives for a compulsory licensing mechanism, countries refer to striking a balance between the interest of patentees and that of third parties, public interest, and/or society; preventing abuses that may result from the exercise of exclusive rights; and promoting the public interest at large, such as in situations of public interest and emergency motivated by considerations of public health, nutrition, and national security. Some possible grounds for compulsory licensing are suggested in Article 5A of the Paris Convention (e.g., abuse of patent rights, including failure of the patent holder to work the invention) and in Article 31 of the TRIPS Agreement (e.g., national emergency and public noncommercial use).

Compulsory licenses are thus not limited to public health emergencies or other urgent situations, as is sometimes mistakenly believed. A range of grounds have been set out in national laws, such as:

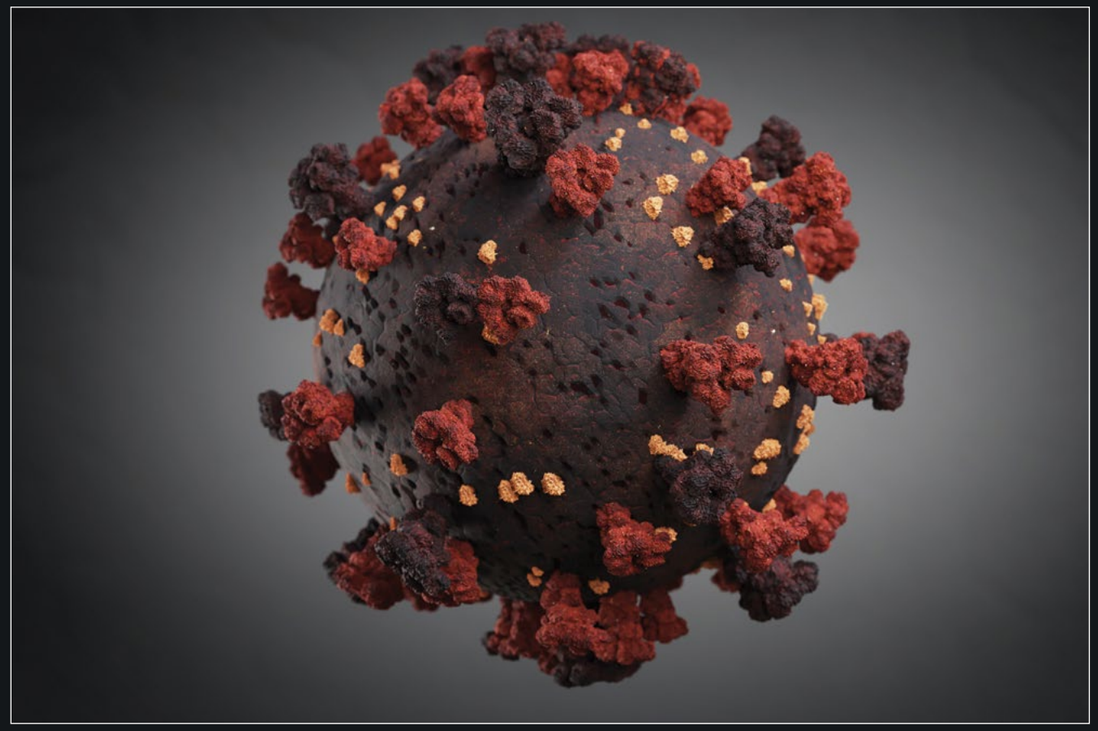
- Non-working or insufficient working;
- Anti-competitive practices;
- Public interest;
- National emergency or circumstances of extreme urgency;
- Dependent and blocking patents.

In Mexico, compulsory licenses can be granted based on articles 146-153 of the Federal Law for the Protection of Industrial Property, which states they can be granted for non-working the patent and national emergency or circumstances of extreme urgency:

> *"…In cases of serious diseases, the General Health Council will declare priority attention, ex officio or at the request of national institutions specialized in said disease that are accredited before it, in which the causes of emergency or national security are justified. Once the declaration issued by the Council has been published in the Official Gazette, pharmaceutical companies may request the granting of a license of public utility to the Institute, which will grant it, after hearing the parties and the opinion of the Council, within a period not exceeding ninety days from the date of submission of the respective application…"*

## Emergency Use Authorization for vaccines

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats including infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies, such as the current COVID 19 pandemic.



Under an Emergency Use Authorization, FDA may allow the use of unapproved medical products -or unapproved uses of approved medical products- in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives. Taking into consideration input from the FDA, manufacturers decide whether and when to submit an Emergency Use Authorization request to FDA. Once submitted, FDA will evaluate the Emergency Use Authorization request and determine whether the relevant statutory criteria are met, taking into account the totality of the scientific evidence about the vaccine that is available to FDA.

There are no specific guidelines from the FDA or European Medicines Agency (EMA) for mRNA vaccine products. However, the increasing number of clinical trials conducted under EMA and FDA oversight indicate that regulators have accepted the approaches proposed by various organizations to demonstrate that products are safe and acceptable for testing in humans.

> **Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner.**

Because mRNA falls into the broad vaccine category of genetic immunogens, many of the guiding principles that have been defined for DNA vaccines and gene therapy vectors can likely be applied to mRNA with some adaptations to reflect the unique features of mRNA.

## Emergency use of vaccines in Mexico

The Federal Commission for the Protection against Sanitary Risks (COFEPRIS) is the health authority responsible for protecting the Mexican population from the risks that may arise from the consumption or use of medicines and medical devices, as well as from those derived from the consumption of food and of other products that we use on a daily basis, while also issuing import and export permits for these products.

The Mexican Government published on March 30, 2020, the agreement declaring a health emergency due to force majeure, the disease epidemic generated by the SARS-CoV2 virus (COVID-19). Furthermore, on November 11, 2020, it published an Agreement instructing the Ministry of Health and the Federal Commission for the Protection against Sanitary Risks to carry out the following actions:

- To resolve the appropriateness of granting applicants the sanitary registration of

health supplies in a period shorter than that mentioned in the equivalence Agreements that have been issued by the former to date, as well as for shorter terms to be established for those that are issued later.
- To analyze, in accordance with the applicable legal framework, the relevance of reducing the documents required in the equivalence Agreements, without implying affecting the quality, safety and efficacy of the drugs and health supplies already indicated.

## Conclusions

Unwarranted restrictions on competition, whether resulting from the abuse of a dominant position resulting from intellectual property rights or other factors, or from anti-competitive agreements, can be addressed through competition law enforcement. Regarding innovation, a key concern is merger control, where competition authorities must ensure that mergers do not threaten R&D pipelines.

Incremental innovation can improve the safety, therapeutic effect or method of delivery of an existing medicine or vaccine. Whether such inventions merit the granting of a patent is judged on a case-by-case basis.

**“Challenges for regulatory systems that impact access include lack of political support and adequate resources.”**

Regulation should promote access to medical technologies of proven quality, safety and efficacy and should not unnecessarily delay the market entry of products.

Challenges for regulatory systems that impact access include lack of political support and adequate resources, a focus on regulating products without effective oversight of the whole supply chain, poorly developed systems for post-marketing surveillance, and different standards for locally produced versus imported products.

In this area, both regulatory and IP tools can be used in a complementary way to combat substandard and falsified products.

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# Considerations for effective patent strategies in the life sciences

**Dr John Weatherspoon, IP Counsel for Open Book Extracts, evaluates his experiences and provides helpful analysis for successful strategies.**

In recent modern times, the life sciences industry has seen absolutely unprecedented changes. With groundbreaking discoveries and technologies from PCR to CRISPR-Cas9, the pace of innovation and change in the global life sciences industry has continued to accelerate. At the same time, the global competitive landscape has continued to evolve. Moreover, advances in computing, big data, artificial intelligence, data mining, etc., are having profound effects on the global life sciences industry, for example in the design and discovery of new therapeutics, new assays, diagnostic tools, etc. With all of these unprecedented changes, the need for planning, building, and designing effective patent strategies is more essential than ever in order to create and monetize valuable patent assets especially in this rapidly evolving global competitive landscape. During the process of developing patent strategies, there are so many important questions that should be taken into consideration. I will discuss several of these considerations in more detail which are important not just in the short term, but for long-term success and for ultimately monetizing valuable patents. Also, these considerations can be useful not only for experienced inventors and established companies, but also for new aspiring entrepreneurs and start-ups.

First of all, what are the goals of all the stakeholders involved? What are the goals and strategies for monetizing a patent or a patent portfolio? A well-thought-out patent strategy, with careful analysis and planning, is essential before investing time, money, energy, resources, etc., in seeking patent protection, in order to achieve the goals and objectives of all the stakeholders involved. There is no “one size fits all” approach for achieving these goals. An effective patent strategy also does not have to be just a one-time endeavor. Instead, it can be a dynamic process that is regularly evaluated, in which the business, financial, commercial, scientific, product development and all other interests of all the stakeholders are carefully considered and discussed, keeping in mind of course the goals of reaching the target clients, consumers or customers if products are being developed based on the patent assets. Also, since the global competitive landscape is dynamic and continues to evolve, and often given the complexities of life science technologies, a team approach can be very useful in developing an effective patent strategy, with careful analysis, evaluation and planning, and with insight and contributions from the company executives, IP counsel, the inventors (for instance, scientists and/or engineers), and all the other team members involved to design a patent strategy in the most effective and efficient manner possible. Moreover, as companies grow, and with additional opportunities for intellectual property protection based on new discoveries, etc., companies that can adapt in a very agile manner can diversify their patent portfolios, pursue multiple goals simultaneously and accordingly build upon, evaluate, and refine their patent strategy to capitalize on these new opportunities. In my

Dr John Weatherspoon

**“The pace of innovation and change in the global life sciences industry has continued to accelerate.”**


## Résumé

**John Weatherspoon, PhD, JD**

Dr Weatherspoon is a registered U.S. patent attorney and is IP Counsel for Open Book Extracts. He has nearly 20 years of experience working with clients, building and managing their patent portfolios, advising on the acquisition, development and monetization of intellectual property portfolios, advising on IP due diligence and providing a wide range of other IP related services. Open Book Extracts (OBX) is a global leader in the cannabinoid industry.

**Designing a patent strategy to effectively navigate the competitive landscape and to meet the goals of the interested parties.**

view, stakeholders that take the time to carefully develop patent strategies, and that also have the ability to very efficiently adapt when needed, can not only differentiate themselves from the competition but come out way ahead.

When a company has identified additional valuable inventions that represent new opportunities for business and monetization, and the company considers patent protection for these new and valuable inventions, how will this impact the overall patent strategy? How many new patent applications should be filed? What is the scope of patent coverage that is desired? What type of claim construction analysis has or will be performed? Also, what about the doctrine of equivalents, enablement, and written description? These are just some of the questions that are important especially when it comes to patent protection in the life sciences industry, and in view of the often complex nature of life science technologies. Asking these important questions up front can really be important and valuable when thinking about patent strategy. Also, having a deep understanding of the patent caselaw and working with experienced IP counsel is really valuable for developing a long-term, effective patent strategy especially in the life sciences. Of course having a global patent strategy involves working with experienced IP counsel in various countries or regions around the world, and this requires careful analysis, planning and a solid infrastructure in place for handling the docketing, deadlines and all the important formalities involved in the patent process, for instance, with national stage patent application filings.

Moreover, good due diligence practices are really valuable when thinking about patent strategy, even before filing for patent protection. What level of IP due diligence has already been performed? IP due diligence is particularly important in the life sciences, especially because the life sciences can often quickly become very "hyper-specialized" in terms of the scientific or technical subject matter. For instance, it is very common for a life science company to have a single molecule, lead candidate or composition of matter as their core IP asset that is the basis and foundation of their patent strategy. Especially in these cases, when a business itself is focused on the development of a single core asset, having a well-planned patent strategy is really essential. More established life science companies may have larger patent portfolios that cover a number of assets, for instance a pipeline of different molecules under development, e.g., from laboratory testing through preclinical studies and eventually clinical trials. Even with more established companies, evaluating patent strategy is a constant process especially given the ever-changing competitive landscape. The patents may also be the subject of a license agreement, or a company may be seeking to acquire new patent assets, and these are also very important considerations in terms of patent strategy. In addition to patent protection, and when thinking about IP strategy in general, it is of course also important to consider whether the stakeholders have other types of intellectual property assets? Trade secrets, for example, are often very valuable especially in the highly competitive life sciences industry. Whatever the case may be, regular analysis, evaluation and planning of patent strategy can be extremely valuable. CRISPR-Cas9 technology is a great example of how a technology can lead to potentially significant advances in science and medicine, and have so much impact across so many disciplines and fields within the life sciences industry. The same technology also presents exciting opportunities and challenges when designing a patent strategy to effectively navigate the competitive landscape and to meet the goals of the interested parties.

"Out of the box" thinking with a team approach is also really powerful, not only when designing patent strategies, but in identifying opportunities for monetizing patent portfolios where potential competitors might miss out. Developing life science technologies, more often than not, requires a team-oriented, multidisciplinary approach, with many areas of expertise and a thorough understanding of the core technology, business insight on the estimated market size, understanding the competitive landscape, product development insight (for instance, with formulations, drug delivery systems, etc.), and so on. All of the team members can have valuable contributions when developing a patent strategy, in terms of specific disclosure, scope of the claims, etc. In terms of patent strategy, team members can also have valuable insight when considering which countries to file in for patent protection (e.g., in the U.S. and/or other countries or regions around the world).

Especially in the life sciences, regulatory considerations can also be another important consideration in the long-term development of patent strategies. For instance, if a company's goal is to seek FDA regulatory approval in the U.S. for a therapeutic product that includes the company's new composition of matter X, and if the company seeks to ultimately have one or more patents listed in FDA's "Orange Book", wherein the patents have claim coverage that covers the new composition of matter X, then this is a great example of regulatory considerations having a direct impact on the design and development of patent strategies.

There are many other considerations that are essential to developing an effective patent strategy. For instance, with the ever-changing global IP landscape in the life sciences industry, what processes and systems are being used to monitor the competitive patent landscape? Stakeholders that can adapt to the changing IP landscape will not only succeed but will have the benefit of being able to strategize in new ways and expand their patent portfolios as new opportunities present themselves. Also, stakeholders that can leverage information technology to their advantage are often in a much better position for monitoring the competitive patent landscape and evaluating their patent strategy accordingly. As mentioned earlier, advances in computing, big data, artificial intelligence, data mining, etc., are having profound effects on the global life sciences industry. However, the impact is much more widespread and has affected the very patent profession itself. Over the past few decades, the overall patent profession has seen a significant increase in the number of companies throughout the world that focus on patent analytics, IP related services, competitive analysis, etc. There is also a vast wealth of publicly available information about the global patent landscape that continues to grow day by day, week by week, month by month, and year by year. Information in the public domain continues to grow, including more peer-reviewed scientific manuscripts, published articles, published reports, etc., all throughout the world. This vast collection of information in the public domain has a direct impact on what is available for prior art searches, which can directly impact patent prosecution and it has an important role as a team thinks about patent strategy. Leveraging information technology and navigating the vast collection of information in the worldwide public domain can often be very useful when thinking about patent strategy. Relevant information about the changing IP landscape can be very useful and such information can help stakeholders when evaluating their own patent strategy, and also help stakeholders better understand potential partners and/or competitors.

In summary, having a well-planned patent strategy is really valuable especially for helping to maximize the value of IP assets. A well-planned strategy is also really important especially in view of the fast pace of innovation and discovery throughout the global life sciences industry. Patent strategies can in many cases be useful for building patent portfolios that can bring in significant revenue streams. The benefits can be very rewarding for all the stakeholders involved.

**"Out of the box" thinking with a team approach is also really powerful.**

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# Dosage regimens: are they patentable in Singapore?

**James Kinnaird and Tim Headley of Marks & Clerk Singapore examine the patentability state of dosage regimens in Singapore in question of the recent UK and EU rulings.**

Are dosage regimens patentable in Singapore? Well, the IP Office of Singapore (IPOS) thinks so, because its Guidelines for Patent Examination clearly states that dosage regimen patents should be considered patentable based on relatively recent case law from the UK. However, Singapore's courts have yet to rule on this issue, so some doubt remains because Singapore's judges have regularly ruled against applying UK law if it is deemed to have been significantly influenced by the European Patent Convention (EPC). That may be the case for dosage regimens and we discuss this further below.

With a highly developed economy and world-class healthcare sector, Singapore punches well above its weight in terms of market size for pharmaceuticals.

Singapore has the highest *per-capita* spending on healthcare among the Association of Southeast Asian Nations (ASEAN). Additionally, the Singapore Government expects healthcare spending to rise significantly faster than GDP due to the aging of its population. These facts, combined with a generally patentee- friendly court system, a robust patent-linkage system (discussed in our previous articles referenced [1] & [2]) and its position as a leading regional shipping and healthcare hub, makes pharmaceutical patent protection in Singapore much more valuable than the city-state's small population would initially suggest.

As Singapore's patent law is modelled closely on the UK's, Singapore's courts tend to look favorably on decisions from the UK courts on issues where there is no local precedent. Therefore, in order to fully appreciate the situation in Singapore, we must first consider the UK's position on dosage regimens.

James Kinnaird

Tim Headley

[1] Previous article: https://www.marks-clerk.com/insights/singapore-s-patent-linkage-scheme-and-its-effects-on-marketing-approval-for-generic-drugs/

[2] Previous article: https://www.marks-clerk.com/insights/singapore-s-patent-linkages-scheme/

## Context: situation in the United Kingdom

A key turning point on the patentability of dosage regimen patents in the UK was the Court of Appeal decision in *Actavis UK Limited v Merck & Co. Inc [2008] EWCA Civ 444 (Actavis v Merck)*. Prior to this decision, it was widely accepted that dosage regimens **were not patentable**. This was based on an earlier Court of Appeal decision in *Bristol-Myers Squibb Company v Baker Norton Pharmaceuticals Inc & Anor [2000] EWCA Civ 169 (BMS)*. This earlier decision held that a claim which differed from the prior art only in how the medication was applied was an attempt at disguising an unallowable method of treatment (methods of treatment are excluded from patentability in the UK and Singapore). It also held that the claims of the relevant patent lacked novelty.

Notably, the European Patent Office (EPO) allowed dosage regimen patents before *BMS* was decided – and continued to do so after the *BMS* decision. This led to a fundamental incompatibility between the UK's position on dosage regimes and that of the EPO, potentially meaning that all EP(UK) patents directed to dosage regimens were effectively invalid and therefore unenforceable. It is notable that the EPO expressly disagreed with (and even criticised) the UK Court of Appeal's decision in BMS – this included the EPO's Opposition Division, who considered the same *BMS* patent (EP 0584001), as well as an EPO Technical Board of Appeal (in T1020/03). The Court of Appeal discussed this criticism from the EPO in *Actavis v Merck*, which led (at least in part) to the Court overturning its original position as expressed in the *BMS* decision and holding that dosage regimen features in second medical use claims are:

- patentable in principle, provided that the dosage regimen is novel and inventive; and
- not necessarily methods of treatment.

The Court of Appeal's new position was binding on lower UK courts and brought the UK's law into line with the EPO's interpretation of the EPC. Indeed, the Court of Appeal explicitly referred to "following" the EPO's position on this issue. However, *Actavis v Merck* did not open the flood-gates to dosage regimen patents in the UK. The judgement noted that dosage regimens resulting from routine optimisation of dosage during clinical trials would not be patentable, and went on to state:

> "[W]e would hold that Swiss form claims are allowable where the novelty is conferred by a new dosage regime or other form of administration of a substance … [however] nearly always such dosage regimes will be obvious — it is standard practice to investigate appropriate dosage regimes. Only in an unusual case such as the present (**where … treatment for the condition with the substance had ceased to be worth investigating with any dosage regime**) could specifying a dosage regime as part of the therapeutic use confer validity on an otherwise invalid claim." [Emphasis added]

The *Actavis* decision was consistent with the EPO approach, where claims drafted in the Swiss-style format, by virtue of being directed at manufacture, avoid any conflict with provisions prohibiting patenting of methods of treatment. This had been the EPO's approach since G05/83, the Board of Appeal in T1020/03 saw no reason to change the EPO's practice even in view of the BMS decision in the UK.

A recent UK Supreme Court decision, *Actavis Group PTC EHF and others v ICOS Corporation and another [2019] UKSC 15*, endorsed the Court of Appeal's approach to dosage regimen patents. In this case, a patent owned by Eli Lilly was directed to the administration of lower doses of tadalafil than were disclosed in the prior art. The patent was held invalid due to a fact-specific dose response curve that would inevitably have been discovered during clinical trials and would lead a skilled team to investigate such lower doses, where they would have found that the lower doses (unexpectedly) worked. Thus, the Supreme Court confirmed that dosage regimen patents have to clear a high bar in order to be novel and inventive, but are patentable in principle.

## Situation in Singapore

The current practice at IPOS is that inventions based on new treatment methods with known drugs are in principle patentable and do not constitute disguised methods of treatment. It does not matter whether the new treatment method is a new route of administration or a new dosage regimen – both are patentable subject-matter in principle. Therefore, provided that a dosage regimen is novel and inventive it should be possible to obtain a granted patent in Singapore. The IPOS Guidelines for Examination refers to *Actavis v Merck* and notes that in most cases, a new dosage regime will generally be presumed to lack inventiveness unless there is a clear technical prejudice pointing away from the claimed dosage regime. This is in line with Singapore's tendency to follow UK patent law.

However, since the issue has not yet been heard by a Singapore court, the validity of dosage

**"Patentable in principle, provided that the dosage regimen is novel and inventive."**

## Résumés

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> **The validity of dosage regimen patents is not yet certain.**

regimen patents is not yet certain. While there may be a presumption that the courts will follow IPOS' practice on the matter, this is not a given. As noted above, Singapore's courts have rejected decisions from the UK courts when it felt that the decision strays from the fundamental principles set out in the Singapore Patents Act. For example, the strict EPO approach to added subject-matter in relation to intermediate generalisations was rejected by Lee Seiu Kin J in *Novartis AG and another v Ranbaxy (Malaysia) Sdn Bhd* [2012] SGHC 253, where the judge noted that while the EPO's approach to added-matter is now firmly entrenched as part of the UK law, "the policy-oriented rules applicable in England by virtue of the European Patent Convention should not be unthinkingly adopted in Singapore without an examination of its compatibility with the local statutory regime". The Singapore courts have also been resistant to other recent changes in UK law, and explicitly rejected the adoption of a doctrine of equivalents introduced by the UK Supreme Court in 2017 as inconsistent with the Singapore Patents Act (*Lee Tat Cheng v Maka GPS Technologies Pte Ltd [2018] SGCA 18).* In part, the reasoning applied by the Singapore courts is that UK law has adapted to conform to the requirements of the EPC as interpreted by the EPO, meaning that the UK courts tend to ignore or reject their own older jurisprudence.

Given the Singapore's courts tendency to follow UK case law that is undiluted by the influence of the EPO/EPC, there appears to be a chance that the Singapore courts could decide that dosage regimen patents are not patentable because they relate to a method of treatment. Even though Singapore is generally seen as being patentee-friendly, this does not fully apply to pharmaceutical patents, where it is virtually impossible to obtain an extension of time for regulatory delays. Given this, there appears to be a reasonable chance that ever-greening patents, such as dosage regimens, may find the Singapore courts a less-favorable environment than might be expected.

Finally, even if dosage regimens are approved by Singapore's courts, decisions on dosage regimen patents are likely to be highly fact-specific. Therefore, decisions may turn on the expert evidence relating to what a skilled person faced with relevant prior art would actually have done during their dosage investigations.

## Are dosage regimen patents worth pursing in Singapore?

Despite the possible issues relating to the validity of dosage regimen patents, they are still worth obtaining in Singapore.

In the first instance, IPOS has indicated that it will grant patents directed to dosage regimens, and so it is possible to obtain a granted patent and such a patent must be presumed to be valid. Singapore has a generally fast and efficient examination procedure with English as the language of proceedings, without onerous formal requirements.

Second, once a patent has been obtained, it will help to dissuade generics companies from entering the market. Singapore's courts are generally patentee friendly and much like the UK, the winner in any dispute is able to seek a cost award. As such, any generic launching at risk is open to losing both an infringement lawsuit and also being responsible for (a portion of) the patentee's costs.

Third, by virtue of Singapore's patents linkage scheme, a dosage regimen patent may even be a hurdle to a generics company seeking to launch a product using a different dosage to that covered by the patent, as explained in our articles mentioned above.

Fourth, litigation in Singapore is relatively expensive. Given this, upon weighing up the costs and benefits of early market entry into Singapore, a generics company may decide that the cost of litigating a dosage regimen patent does not justify the risks associated, considering the relative size of the Singapore market. However, before defending a dosage regimen patent, an innovator company will also need to consider the cost of litigation against the expected market returns in Singapore over the remainder of the patent's life.

Finally, patent term extension is generally very difficult to obtain in Singapore, and most pharmaceutical patents will not be eligible for extension. As a result of the legal framework surrounding patent term extension, later-filed cases that can prolong the monopoly period beyond the expiry date of an initial compound patent are even more important to obtain in Singapore. This is in contrast to other jurisdictions where readily-available patent term extension may result in a stronger patent expiring after any subsequent dosage regimen case.

***Please direct any questions regarding the validity of dosage regimen patents in Singapore to the authors.***


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# Patenting implications of personalized healthcare boom

**Gareth Probert, Partner and Head of the HealthTech practice group at EIP, discusses the exciting changes that the personalized healthcare boom will lend to the healthcare industry and what it means for IP.**

Personalized healthcare is a fairly new term relating to technology that gives individuals effective healthcare based on their own unique attributes.

This is distinct from Personalized medicine, a well-established area whereby patients receive the right drug or dosage regime that works for them.

Under Personalized medicine, a recipient could undergo DNA screening to see what specific form of a disease they have or checks to see whether they have mutations or enzymes that affect whether a drug works for them or not.

Personalized healthcare, on the other hand, typically involves interdisciplinary innovations, such as combinations of engineering, physics, chemistry, and biotech, offering solutions that 20 years ago would have sounded like science fiction.

For example, treatments now available include using a patient's cells to grow them a new blood vessel, organ, or customised implant to replace a part of a jawbone. Researchers at Nottingham Trent University have 3D printed realistic organs from scans of cancer patients so doctors can practice surgery to remove tumours from those individual patients.

A Swiss company has developed a way to take skin cells from a patient and then grow them in the lab to create a Personalized skin graft, which should give better outcomes than conventional skin grafting.

## The quantified self

What also marks out Personalized healthcare as an exciting area is a rapid acclimatisation among consumers of the elements that require it to work: the monitoring and storing of health information, known as the "quantified self".

Gareth Probert

> **Companies operating in this space require legal skills from multiple disciplines.**

Millions of people are already willing users of Personalized tracking of their health via smart-phones and wearables. Fitness watches have maintained their popularity and are becoming more advanced almost with every iteration. The latest Apple device monitors pulse and oxygen saturation and stores it in the cloud. The COVID-19 pandemic has also driven a boom in people buying thermometers and oximeters.

These developments show a direction of travel towards people being comfortable with devices that monitor them personally. It is not hard to see the ready adoption of devices that also, for example, send that information to their doctor.

One of the biggest customers of Personalized healthcare products and services will be health-care providers and insurers. There could be upfront costs, but the long-term benefit is that


## Résumé

**Gareth Probert** is a partner at the patent firm EIP and heads their HealthTech practice group, an interdisciplinary team specializing in protecting innovations in the medtech and healthcare sectors. He also focusses on contentious proceedings before the European Patent Office, often handling multi-party Oppositions for commercially significant patents. During his 20-year career in the profession, Gareth has gained substantial experience in the medtech and healthcare space, along with FMCG, formulations, peptide, food, and chemical sectors. He is also a member of the CIPA Life Sciences Committee and the FICPI-UK Council.

they will be able to monitor their customers to spot when interventions and treatments are needed. This will allow for more cost-effective treatment plans – savings that could pass on to customers.

From an intellectual property (IP) law perspective, this area also presents an exciting challenge. Companies operating in this space require legal skills from multiple disciplines, often with experience of international IP offices, courts, and legal systems.

## Technological blend

Personalized healthcare innovations are blends of different technologies, but many rely on the wireless exchange of information. Currently, this is done mainly via 4G, but the implementation of 5G will change everything.

5G allows the transfer of a massive amount of information at extremely low latency. A medical image file, like an MRI scan, can be exceptionally large. 5G allows the transmission of that file to, for example, an offsite bio-ceramics manufacturer that can make a replacement vertebra to order.

We currently sit at the bottom of a steep adoption curve. It is the equivalent of having a Nokia 3310 with an iPhone 12 on the horizon: the 5G-enabled interconnectedness of what is to come will be a similar leap.

Manufacturers and researchers in the field of Personalized healthcare are often doing exciting things – but separately. Without fast data transfer, a new device that records a patient's health will not partner effectively with a new method of doing something useful with the data. The roll-out of 5G will also help connect these companies, leading to more innovation and the realisation of the long-sought after Internet of Medical Things (IoMT).

## Starting small

Big pharmaceutical companies are great at developing and marketing drug products. Unfortunately, they are not so good at discovering the drug in the first place. Smaller companies in the pharma sector have demonstrated that they are freer to pursue new ideas without the limitations that can beset big companies. Personalized healthcare will follow in a similar vein.

Currently, the market is a mix of small companies doing exciting projects, many of which will fall away due to difficulties in translating the idea into the real world or lack of investment, and big companies working in-house with their own tech. But this is changing as these companies, with their different structures, investors, and risk appetites, do deals to become partners or subsidiaries.

## Protecting a product

It is nearly always possible to find a way to get IP protection for a healthcare or medical innovation. In many cases, it will be possible to protect the product or process directly. However, in other areas, you may need to think laterally, for example by protecting a delivery system for a widget rather than the widget itself.

> **“There may be protectable IP in some of the steps involved in making or using a product rather than the final product itself.”**

In other cases, there may be protectable IP in some of the steps involved in making or using a product rather than the final product itself. Or perhaps you may need to protect the tangible product of a computer-implemented process.

Additive manufacturing is a particularly interesting area for IP protection and thought must be given to protecting all the different aspects, from the materials used, the printing apparatus itself, processing steps, the final product and also the digital files involved.

The key differentiator of this emerging sector is that each innovation may involve combinations of new technologies. Companies operating in this space must be aware of the nuances in protecting those technologies, in terms of both protecting the specific technology and its patentability in different regions of the world. The attitude of patent offices towards patentability varies so international protection strategies must differ also.

## The IP traps

There are two main aspects of IP for companies in this space to be aware of: obtaining protection for an innovation, and the company's freedom to operate in view of third-party IP rights. Both need to be taken seriously in this competitive area. Disputes can occur between companies in this area, and there are many effective ways to try to clear competitors' patent rights out of the way. This can be necessary to avoid potentially costly litigation, paying damages for infringing IP or other damaging legal actions such as injunctions on the sale of a product in a specific market.

An effective and efficient way of clearing patents involves filing an opposition at the European Patent Office (EPO) once a competitor's patent has been granted. Most oppositions result in the limitation or even complete revocation of an opposed patent across the whole of Europe in just one procedure.

## Technical trouble

The position of the EPO concerning computer-implemented inventions is well known and has not changed much over recent years. In Europe, before patent protection can be obtained, there is a need to show a “technical effect” going beyond the mere operation of the computer itself. If a healthcare invention uses computer technology to result in a real-world effect (such as the automated analysis of medical scans to model and then 3D-printing a surgical implant) then this can pave the way to obtaining a patent.

In some cases, where information is analysed to give useful information or advice as the only result, it may be difficult to argue that the required “technical effect” exists. There are differences in other regions, with the US notably being more open to this sort of innovation.

A creative IP attorney can think around the issues to see what aspects of the project can be usefully protected in Europe and elsewhere.

## Looking ahead

In summary, important developments within the Personalized healthcare technology space are happening concurrently with people becoming acclimatised to the monitoring and storing of their health information. As companies in this space look at how to maximise success in this new era for healthcare, it is important for them to implement strategies towards patent protection adapted to their specific products and services.

> **“Both need to be taken seriously in this competitive area.”**

Health insurers and national health providers will be among the largest customers of these revolutionary products, meaning there needs to be a robust long-term approach to both innovation and patenting. The dynamic nature of many smaller companies and start-ups will ensure new approaches can continue to be developed even as the field becomes more mainstream. This is something worth getting excited about and following closely, especially for patent specialists who can look forward to advising on more cases involving Personalized healthcare from now on.

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# Hot topics on Life Sciences Patents in Brazil

**Gabriela Salerno, Partner at Montaury Pimenta, Machado & Vieira de Mello, provides an overview of six topics introduced with the latest Guidelines for Life Sciences patents in Brazil.**

Over the last 5 years, the Brazilian Patent Office has been adopting measures to reduce the backlog in patent examination combined with several improvements in its examination guidelines to perform a high-quality technical examination. In addition, the pandemic scenario has brought other sensitive discussions regarding the Brazilian patent system and its impact on public health issues. This article aims at providing an overview of six topics that directly affects Life Sciences patents in Brazil.

Gabriela Salerno

## I. Updated version of the Guidelines for Examination of Patent Applications in the Biotechnology Field

The first version of the Guidelines for Examination of Patent Applications in the Biotechnology Field issued by the Brazilian PTO was published in 2002 after the Brazilian IP Law was amended to accept the filing of patent applications claiming chemistry- and biotech-related subject matter. This first document looked more like a draft, and it was very limited in terms of scope.

It was only in 2015 that the Brazilian PTO finally published detailed Guidelines to orientate both the Examiners and Applicants as to the rules that should be applied in this specific technological field. The big issue is that every year the biotech industry achieves huge development, so these Guidelines became outdated quite fast.

Therefore, an updated version of the Guidelines was issued in 2020 in an attempt to correct this technological gap of five years. Many improvements were made in this regard, such as the inclusion of several examples of ways to draft antibody claims in accordance with the local practice. It is important to mention that the definition of antibodies in terms of percentage of identity/similarity is still not allowed in Brazil because according to the Guidelines, the characterization of a sequence of interest based on the identity percentage is very broad and generally includes in its scope sequences not supported by the specification or that do not fulfill the patentability requirements. In addition, the Guidelines states that in general, the specification does not provide enough information that would allow the reproduction of all the sequences covered by a definition made in terms of percentage of identity/similarity. On the other hand, a relevant progress was made with the acceptance of Markush formulas to define biological sequences, either for nucleotide or amino acid sequences.

> **"Such as the inclusion of several examples of ways to draft antibody claims in accordance with the local practice."**

The Brazilian PTO itself recognizes that it should not take so much time to update the Biotech Guidelines under the penalty of becoming obsolete and not covering important topics in the biotechnology filed. For example, these Guidelines do not cover specific rules to examine patent applications related to CRISPR technology. Therefore, patent specialists in Brazil defend that these Guidelines be updated at least every year in order to keep up with the developments in the biotech field.

## II. New Guidelines for Examination of Patent Applications in the Chemistry Field

Different from the Guidelines in the biotechnology field addressed in above item I, the first (and only) version of the Guidelines for Examination of Patent Applications in the Chemistry Field was published in 2018. The main reason for this apparent delay is that some topics related to the chemistry field were addressed in the BPTO's general guidelines for examining patent applications belonging to any technological field.

The most relevant aspects of the Guidelines specifically drafted for chemistry-related patent applications are: (1) an entire chapter with the objective of clarifying certain aspects of substantive examination of stereoisomers and different polymorphic forms of a chemical compound; (2) the fact that the Brazilian PTO has unexpectedly changed its strict position regarding what should be accepted when claiming a composition for medical use, and (3) a full chapter detailing key issues of the requirements to obtain protection for a new medical use of a known substance.

More than 3 years have passed since these Guidelines came into effect and the outcome is positive. The Brazilian PTO not only clarified the examination of important aspects that had never been discussed before, but also became more flexible in terms of claim language by accepting new ways of drafting claims related to medical compositions.

> **"Anvisa cannot prevent the granting of patents anymore which is a very positive outcome."**

## III. Ampliation of the Options for Fast-Track Examination

One aspect that had special attention in the Brazilian PTO in the last couple of years was the effort to adopt fast-track examination for various groups of inventions. The BPTO currently has 17 ways to accelerate examination of patent applications with relevant improvements particularly in the ampliation of PPH agreements and new eligible categories, such as startups, and SMEs (small and medium-sized enterprises). A summarized list of the options of fast-track examination in Brazil is provided below:

1. the applicant is 60 years old or more;
2. the applicant is a physically or mentally disabling disease;
3. the applicant bears a severe illness;
4. the applicant is a micro or small company, or an individual microentrepreneur;
5. the applicant is an Institution of Science, Technology and Innovation;
6. the applicant is a Startup;
7. the application covers a "green" technology (environmentally friendly technology);
8. the application covers a technology directed to the diagnosis, prophylaxis and/or treatment of AIDS, cancer, rare or neglected diseases;
9. the object of the application is related to a pharmaceutical product, process, equipment and/or material for use in the diagnosis, prophylaxis and/or treatment of COVID-19;
10. the application covers products, processes or equipment considered strategic by public policies of the Ministry of Health (in this case, only the Ministry of Health can request the fast-track examination);


## Résumé

**Gabriela Salerno** is a partner in Montaury Pimenta, Machado & Vieira de Mello and head of the technical team of Montaury's patent department.

She graduated with a BSc in chemical engineering from the Federal University of Rio de Janeiro and advises her clients on a wide range of technical issues regarding patent prosecution, particularly in the pharmaceutical and biotechnology fields. She is the current chairwoman of the Biotechnology Committee of the Brazilian Association of Intellectual Property (ABPI). She has a background in innovation management, coordinating projects related to competitive intelligence.

Gabriela has been recognized by numerous international ranking agencies and has published extensively in her area of expertise.

11. the application refers to a technology of public interest or national emergency;
12. if a granted patent is a condition for the applicant to receive financial aids;
13. the object of the application is being reproduced in Brazil without applicant's consent;
14. third parties being accused of infringement;
15. third parties formerly using a technology that was later filed as a patent;
16. the application belongs to a patent family which first application was filed in Brazil; and
17. the application was granted in one or more countries that have a PPH agreement with Brazil.

Items 8 and 9 are particularly related to the life sciences field, but in principle all the above-mentioned options can be used to speed up the examination of life sciences-related patent applications provided that they fulfill one of the requirements 1 to 17. According to statistics provided by the Brazilian PTO, almost 5,000 requirements of fast-track examination were filed in the last five years. The average time between the fast-track examination request and the final decision on the merits of the invention is about one year, which corresponds to a very short period if compared to the regular timeframe of approximately six years to grant a patent in Brazil.

## IV. Change in the workflow with the Brazilian Health Agency (Anvisa)

Another relevant decision that directly impacted the life sciences field, more specifically the patent applications related to pharmaceutical products and processes, was the change in the workflow between the Brazilian PTO and the Brazilian Health Agency (Anvisa).

According to the Brazilian IP Law, all patent applications related to pharmaceutical processes and products must be submitted to Anvisa to obtain its prior consent. Before 2017, Anvisa had the right to issue opinions on the patentability of inventions related to substances of interest to SUS (Brazilian Unified Health System). If the Applicant was not able to overcome Anvisa's objections, then the Brazilian PTO could not perform technical examination of the patent application. This procedure resulted in a certain amount of patent applications stuck in the Brazilian PTO without a final decision on the merits of the invention.

After the publication of a Joint Ordinance between the Brazilian PTO and the Brazilian Health Agency (Anvisa) in 2017, the Agency only analyses whether the object of the patent application includes substances of prohibited use in the country and, if so, requests that the applicant remove these substances from the scope of the claimed invention. Anvisa can still issue opinions on the patentability of inventions related to substances of interest to SUS. However, these opinions are taken by the BPTO as third-party observations. Therefore, Anvisa cannot prevent the granting of patents anymore which is a very positive outcome of the change in the examination workflow between the Brazilian PTO and Anvisa.

> **"The final goal is to reduce the number of applications pending decision by 80%."**

## V. Recent Brazilian Supreme Court Decision on Patent Term for Pharmaceutical Products and Processes

On May 6, 2021, the Brazilian Supreme Court decided that the sole paragraph of Section 40 of the Brazilian IP Law is unconstitutional. This legal provision allowed a minimum validity term of 10 years for patents of invention and seven years for utility models, counted from the granting date. After this decision, all patents granted will be valid for 20 years counted from the filing date, regardless of the time spent by the Brazilian PTO to examine the applications. In addition, the decision applies retroactively to already granted patents related to pharmaceutical products and processes, as well as equipment and materials for use in healthcare. This *ex tunc* effect of the decision also covers patents that were subject to lawsuits challenging the 10-year rule filed by April 07, 2021, irrespective of the technological field.

Since the Supreme Court decision did not provide any information on how to determine whether a patent relates or not to the group of cases defined as "pharmaceutical products and processes, medical equipment and materials for use in healthcare", this classification is being made by the Brazilian PTO based on the following criteria:

(a) Patents that were sent to Anvisa for prior consent;
(b) Patents having the following IPC classifications: A61B, A61C, A61D, A61F, A61G, A61H, A61J, A61L, A61M, A61N; H05G (technologies associated with medicine according to WIPO);
(c) Patents having the following IPC classifications: A61K/6, C12Q/1, G01N/33, G16H;
(d) Patents having a published lawsuit decision; and
(e) Granted Certificates of Addition.

The granted patents affected by the retroactive effect are being reissued with the validity term adjusted in the BPTO Official Bulletin. In case of patents for which the 20-year term counted from the filing date has already elapsed, the extinction of the patent is being subsequently published.

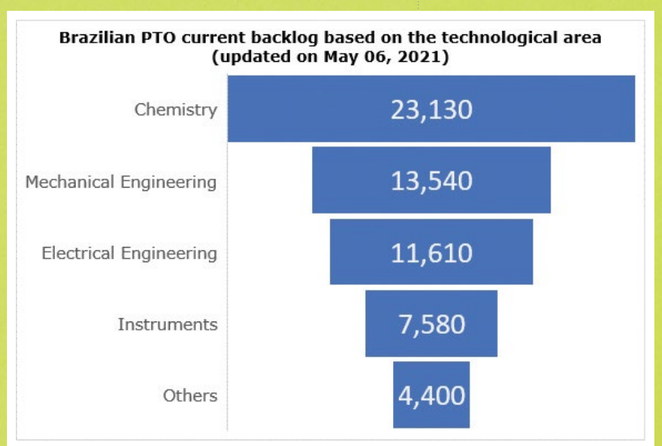
## VI. The Brazilian PTO efforts to tackle the backlog in technical examination

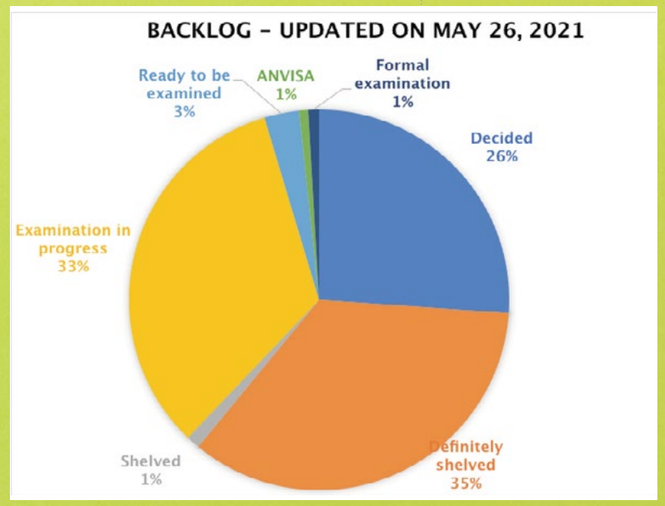
The plan implemented by the Brazilian PTO to tackle the patent backlog reduced 51.2% pending patent applications in 2020. The final goal is to reduce the number of applications pending decision by 80%, in addition to reducing the average grant term to approximately two years.

The strategy used by the BPTO to achieve the proposed goal is relatively simple: use the results of the analysis of patent applications in other countries and regions, such as e.g., the examination performed by the USPTO and EPO.

Currently, the areas most affected by the delay in granting patents in Brazil are chemistry, mechanical engineering and electrical engineering. The chemistry area alone, which includes patent applications of the pharmaceutical and biotechnology fields, is responsible for almost 40% of the current backlog (please see the chart below).

> **"Approx. 89,000 applications were examined in almost two years out of 150,000."**




According to the Brazilian PTO, approximately 89,000 applications were examined in almost two years out of 150,000 applications pending examination, thus reducing the backlog in about 60%. Additionally, according to a recent update provided by the Brazilian PTO, among the pending patent applications, 33% are already under examination (please see the chart below). This means that by keeping this pace, the Brazilian PTO will probably be able to solve the backlog issue in a couple of years.

## Conclusion

As can be seen from the above discussion, the Brazilian PTO is putting a lot of effort to provide a high standard technical examination while at the same time has made considerable progress in the plan to reduce the backlog in patent examination. These measures have a direct impact in the life sciences field because patent applications in this area could benefit from new examination guidelines addressing relevant topics specifically related to biotechnology and chemistry. These developments bring more legal certainty to applicants that seek patent protection in Brazil.

Regarding the Brazilian Supreme Court decision to abolish the 10-year minimum term of validity for patents of invention, IP specialists are analyzing the options to minimize the damages caused to patentees and one of the goals now is to have the financial autonomy of the Brazilian PTO implemented by the government. Additionally, there are some remedies that can be used in these cases such as filing lawsuits to expedite the examination of pending applications and even filing a petition before the Brazilian PTO in the event the applicant believes that one or more patents should not be affected by this decision because they do not actually refer to pharmaceutical products and processes, or to equipment and materials for use in healthcare.

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# An open letter to UK policymakers: we need to talk about the real issue with health data regulation

**Jaspreet Takhar, Senior Associate at Baker McKenzie, shares her recent open letter which describes the confusion innovators face when it comes to using health data for secondary purposes, and her requests for change.**

As digital health lawyers at Baker McKenzie, we see first-hand the confusion in the life sciences industry around the regulation of health data. We also see how this confusion is stopping innovation in its tracks.

This confusion stems from one fundamental issue: there are **two intersecting regulatory regimes** governing the use of health data that are **inconsistent with one another, but nevertheless overlap**:

- On the one hand, there is the traditional healthcare regulatory framework. This includes the common law duty of confidentiality (which may apply to patient data), clinical trial legislation and the regulation of medical devices and pharmaceuticals.
- Separate to that, there are legal concepts which have been traditionally applied to regulating big data and big tech. These appear in data protection legislation like the GDPR (and now, the GDPR as incorporated into UK domestic law) - the GDPR employs concepts like data controllers and data processors which have been developed and cultivated totally outside the healthcare context, and were originally designed by legislators with quite simple supplier-customer concepts in mind. These 'black-and-white' concepts do not quite work in healthcare, where there are multiple players with nuanced roles, such as healthcare providers, researchers and developers, manufacturers, and distributors.

Jaspreet Takhar

> **We also see how this confusion is stopping innovation in its tracks.**

It's time to talk about the elephant in the room. This dichotomy is at the heart of most, if not all the misunderstandings around the regulation of health data. As a result, we find that many innovators (and even NHS organisations) veer between two extremes:

- being far too risk-averse with their use of health data, sitting on rich datasets which harbour huge possibilities, but perceiving that the regulatory environment is too prohibitive to permit them to use that dataset to its full potential; and
- being far too cavalier, inviting significant risk and regulatory scrutiny.

There is huge potential for regulatory guidance in this space to clarify this intersection between these two regimes. Such guidance would need to involve multiple stakeholders, given the interplay of regulatory regimes, including the National Data Guardian, the Information Commissioner's Office, NHSX, the Medicines and Healthcare products Regulatory Agency, and the Health Research Authority.

The volume of soft guidance is growing exponentially in the health data sphere, but we urge policymakers to focus on streamlining guidance by considering the full depth of regulatory regimes that apply to health data in the UK from the outset. The piecemeal approach of considering confidentiality, data privacy and product regulation in isolation is not working - it is creating a complex web of laws and soft guidance that is impossible for innovators to navigate. This is an opportune moment for regulators to create a harmonised, consistent regime for data-driven innovation in the life sciences industry.

## What should be on the agenda for policymakers?

**1. The different thresholds for anonymisation**

Developers and researchers often request access to 'anonymised' datasets in order to develop (for example) a new AI algorithm with a diagnostic function, or as part of a registry-based study. The problem is that thresholds for anonymisation between the GDPR and the common law duty of confidentiality are very different. We constantly see innovators and NHS organisations get this issue wrong because they conflate the 'confidentiality' standard for anonymisation with the 'GDPR' standard:

- Truly anonymous information falls outside the remit of the GDPR and its compliance obligations, making it an attractive concept for researchers. However, anonymisation under the GDPR is a high bar and difficult to achieve in practice. It involves removing personal identifiers, both direct and indirect, that may lead to an individual being identified.[1] It is often difficult to argue that medical datasets are ever truly 'anonymised' for GDPR purposes.
- The GDPR position is more stringent than under the traditional understanding under the common law duty of confidentiality. Traditionally, researchers in the health space have assumed that removing certain key identifiers (such as name, address, DOB, etc.) will be sufficient to 'anonymise' a dataset for medical confidentiality purposes.
- Often, data considered 'anonymised' for confidentiality purposes are actually 'pseudonymised' data for GDPR purposes. Pseudonymised data may include data where key identifiers have been removed and the data can no longer be attributed to a specific individual without the use of additional information.[2] This additional information must be kept separately and subject to certain technical and organisational measures to ensure non-attribution to any individual. The key takeaway is that pseudonymised data is still personal data subject to the GDPR.

## So what's needed from policymakers?

- We would welcome guidance on the thresholds for anonymisation that takes into account both the GDPR and the common law duty of confidentiality.
- We urge policymakers to consider the status of medical datasets where key identifiers are removed in greater granularity: when are medical datasets truly 'anonymous' and when are they 'pseudonymised'?
- Most importantly, if there is a risk that an innovator is accessing personal data, we need clear guidance on issues such as legal bases for processing and transparency under the GDPR, which leads us to our next point.

> **We urge policymakers to focus on streamlining guidance by considering the full depth of regulatory regimes that apply to health data in the UK.**

## 2. Consent, legal bases, and the messy intersection between the GDPR and the common law duty of confidentiality

In the life sciences industry, we are very familiar with the concept of consent. However, our familiarity with consent is having unintended consequences: innovators conflate consents required for confidentiality purposes or for clinical investigations or interventions, with GDPR consent (often with the result of stifling innovation).

In the healthcare context, when an innovator perceives a requirement for consent, it is always worth stepping back and considering where that requirement for consent is coming from:

- Under the common law duty of confidentiality, healthcare professionals may only disclose confidential patient information outside the direct care setting on the basis of consent or certain other statutory grounds.[3] This 'confidentiality consent' is a relatively low standard of consent (at least when compared to the GDPR); the wording can be quite generic but still be sufficient to permit disclosure of data.
- Separately, there may also be a regulatory requirement for consent. A prime example is the requirement for the 'informed consent' of clinical investigation participants.[4]


## Résumé

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1 Recital 26, GDPR
2 Article 4(5), GDPR
3 For example, section 251 consent under the National Health Service Act 2006
4 Regulation 104, Medical Devices Regulations (SI 2002 No 618, as amended)

- However, this is very different to the GDPR position. Under the GDPR, every processing of personal data requires a legal basis for processing under Article 6. An additional ground is required under Article 9 if processing a special category of data, such as health data or genetic data. It is true that consent appears as a ground under Article 6, and explicit consent is a potential ground under Article 9 of the GDPR.[5] However, the key point is that GDPR consent is one of several grounds which may be available to innovators, even in the life sciences industry. There are a range of other potential grounds, which are far wider than those available in the confidentiality context.

## Alternatives to GDPR consent

These alternative grounds are very useful. Under Article 6, grounds include: legitimate interests;[6] performance of a contract;[7] and compliance with a legal obligation.[8]

Article 9 grounds include processing for:

- scientific research purposes;[9]
- public interest in the area of public health, such as ensuring high standards of quality and safety of health care and of medicinal products or medical devices;[10]
- medical diagnosis and the provision of health or social care or treatment.[11]

At the same time, these grounds ensure data privacy principles are respected, such as requirements to ensure processing is only conducted if 'proportionate' and subject to 'suitable and specific' safeguards.[12] Certain grounds for processing must be on the basis of law, or pursuant to a contract with a health professional, or subject to 'professional secrecy'.[13] The Data Protection Act 2018 sets out further safeguards and hurdles when relying on the above Article 9 grounds.[14] At all times, controllers need to ensure they process only the minimum personal data necessary to fulfil their purpose (the 'data minimisation' principle).[15]

Further, these alternative grounds do not come with the burden of obtaining GDPR consent (which is a very high bar, may not always be practicable, and may be withdrawn by data subjects).

We see that these alternative grounds are under-used, even though they facilitate more 'friction-free' use of data whilst maintaining robust data privacy safeguards. Innovators lean heavily on GDPR consent, conflating the requirement for consent in other contexts (such as under the common law duty of confidentiality) with GDPR legal bases for processing. They mistakenly believe that they require GDPR consent in order to use personal data throughout the product lifecycle, such as for post-market surveillance, clinical follow-up or scientific research. As a result, they are reluctant to maximise the use of their datasets, given that often, GDPR consent has not been obtained. Innovators do not appreciate that alternative (and less onerous) legal bases are already available to them under the GDPR – innovators are just in need of guidance and clarity that they can use these alternative grounds for their selected purposes.

> **GDPR consent is one of several grounds which may be available to innovators, even in the life sciences industry.**

## So what's needed from policymakers?

- We would welcome guidance outlining how GDPR legal bases for processing align with use cases that are fundamental to the development of data-driven innovation in the life sciences.
- We urge policymakers to focus on key areas of the product lifecycle, such as post-market surveillance, clinical follow-up, and scientific research. These should be mapped against the various legal bases described in both Articles 6 and 9 of the GDPR. In the highly complex lifecycle of medicines and medical devices, this is the level of granularity required to foster an innovative ecosystem.

This is why we have contributed to the Goldacre Review[16], a review launched by the government this year to focus on the more efficient and safe use of health data for research and analysis, to complement the forthcoming Data Strategy for Health and Social Care. We urge Dr Ben Goldcare to cut bureaucracy and streamline health data governance in the UK.

**Do these issues impact your organisation? Would you like to discuss any of the above?** If so, don't hesitate to reach out using our contact details.

5 Articles 6(1)(a) and 9(2)(a), GDPR
6 Article 6(1)(f), GDPR
7 Article 6(1)(b), GDPR
8 Article 6(1)(c), GDPR
9 Article 9(2)(j), GDPR
10 Article 9(2)(i), GDPR
11 Article 9(2)(h), GDPR
12 Article 9(2)(j), GDPR
13 Articles 9(2)(h), together with Article 9(2)(3); Articles 9(2)(i) and (j)
14 Sections 10 and 11 of the Data Protection Act 2018; Schedule 1 of the Data Protection Act 2018
15 Article 5(1)(c), GDPR
16 https://www.goldacre review.org/

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# How do the UK MHRA's new guidelines on biosimilar medicines impact your IP strategy?

**The Medicines and Healthcare products Regulatory Agency (MHRA) has published its final guidance on how biosimilars will be regulated in the UK. The guidance introduces some key changes to the European Medicines Agency (EMA) guidelines that previously applied in the UK, with the effect of relaxing the rules to expedite market entry. Michael Pears, Partner at Potter Clarkson LLP, considers the implications of the new guidelines on the intellectual property strategies of both originator and biosimilar manufacturer companies.**

## Biosimilars and new MHRA Guidelines

Biosimilars are generally large, complex molecules such as antibodies, and are highly similar but not identical to another biological medicine already approved (the so-called "reference product"). The development of biosimilars focuses on demonstrating that the differences between the biosimilar and reference product are not clinically meaningful, i.e., no differences are expected in quality, safety, and efficacy.

The new MHRA guidelines[1] encourage a step-wise approach to the development of biosimilars, with an emphasis on comprehensive physio-chemical and biological comparability studies, functional *(in vitro)* analysis and a confirmatory clinical pharmacokinetic study, rather than on comparative efficacy trials. Overall, the guidelines allow for a more streamlined approach to licencing of biosimilars than that under the

1 Guidance on the licensing of biosimilar products - GOV.UK : https://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products/guidance-on-the-licensing-of-biosimilar-products

## Résumé

**Michael Pears**

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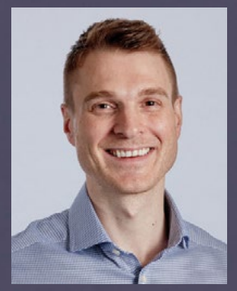

**Michael Pears**

previous EMA rules, with a couple of key differences:

First, the guidelines state **"[n]o *in vivo* studies from animals are requested** as these are not relevant for showing comparability between a biosimilar candidate and its [reference product]". The guidelines go on to state "[w]here investigations in the quality dataset suggest the possibility that a biosimilar candidate may not be highly similar to the [reference product], conduct of *in vivo* studies in animals does not contribute to resolving this and *in vivo* studies should not be done with this intent".

Second, the guidelines state that "in most cases, **a comparative efficacy trial may not be necessary** if sound scientific rationale supports this approach". Justification for comparable efficacy is said to be derived from comparable binding properties and functional characteristics. Justification for comparable safety and immunogenicity is said to be based on the quality attributes, including drug product characteristics (protein aggregates, impurities) and formulation of the biosimilar candidate. There may still be cases requiring a comparative efficacy/safety trial, for example, where it is difficult to predict the impact of analytical differences which have not been resolved by adaptations to the manufacturing process. Exceptionally, additional clinical safety data may be required where safety uncertainties cannot be resolved without patient exposure pre-licensing.

The MHRA has justified these divergences by citing peer-reviewing publications, which contend that an efficacy trial is generally not required to establish biosimilarity once comparability has been demonstrated through the analytical and pharmacokinetic studies.

### IP strategy for originators

Given the prospect for faster biosimilar approvals, originators will need to be prepared for third parties entering the market at an earlier stage. Companies should consider what IP rights they have to maintain exclusivity, and whether anything can be done to prolong exclusivity.

> **"Given the prospect for faster biosimilar approvals, originators will need to be prepared for third parties entering the market at an earlier stage."**

For example, if any patents and supplementary protection certificates are in force, third parties would still not be allowed to market the biosimilar in the UK, despite having the green light from the MHRA to do so. Biologic medicines are complex molecules with the potential for a greater number of patents covering the product itself, and may also be the subject of patents covering new formulations, methods of use and manufacturing, dosage regimes, a new method of administering the medicine, and patient subgroups. Companies should evaluate their patent portfolio to understand their exclusivity position and continually mine clinical trial data to identify new patenting opportunities.

One approach to prolong exclusivity is to patent combination formulations comprising the reference product in combination with one or more other drugs in a single dosage form and marketing it as a new product. Fixed dose combinations often simplify complex treatment regimes for patients, improve compliance, balance adverse effects and can have synergistic benefits.

Should a third party begin preparations for launch before expiry of an originator's patent or SPC, originators should conduct a portfolio review and decide which patent(s) to litigate under in preparation for future IP disputes, as well as considering their arguments for an interim injunction.

Companies should also consider protecting any know-how in their manufacturing processes by way of trade secrets. These processes include precise cell growth conditions, analytical processes, purification methods, and even traits of the cell that produce the drug. Such information is commercially valuable and can give the originator a competitive edge. However, it is not always possible to keep such details secret as regulatory authorities may require the disclosure of manufacturing details for clinical trial data transparency.

As loss of exclusivity nears, efforts should be made to preserve brand equity and patient loyalty. Strategies can be deployed to bolster unit sales for example by building and leveraging brand loyalty, physician and patent outreach initiatives, supporting marketing promotions with repackaged or new trial data, and securing contracts to maintain product access. Consideration may also be given to streamlining manufacturing and distribution costs so as to maintain profitability, and even the launch of an originator's own generic product to compete with other generics.

Finally, to maintain their product pipeline, originators should continue to innovate and develop new medicines and new indications for existing medicines.





### IP strategy for biosimilar manufacturers

For biosimilar manufacturers, companies will still need to check any IP rights that the originator may have before launching a biosimilar.

The patent landscape around the reference product should be reviewed several years before product launch, covering patent filings to the product *per se*, and any secondary patent filings, for example to new formulations, patient subgroups and administration regimes.

An assessment should be made on whether the company's activities will likely infringe the claims of granted patents or current claims of pending applications. For any relevant pending applications, companies should monitor the progress of prosecution and may wish to file third party observations to attack patentability. For patents already granted, companies should consider whether it is possible to design around the claims although care must be taken to ensure that the regulatory requirements to prove biosimilarity are still met. If it is not possible to design around a patent, companies may wish to challenge it, either by filing an opposition at the European Patent Office (if within nine months from the date of grant) or via revocation action(s) before national court(s).

A particularly attractive remedy that manufacturers may seek is a so-called "Arrow declaration", a court declaration that a certain product was known or obvious at a particular date. Such declarations have been granted by courts in the UK and Netherlands, and would enable the manufacturer to cut through the uncertainties of a portfolio of pending applications. The manufacturer could seek a declaration that the biosimilar product/use it proposes to launch cannot be the subject of any valid grant of a patent, either because it is not novel or lacks an inventive step. In this way, the manufacturer would be free to launch without the risk of future infringement proceedings based on currently pending patent applications.

Biosimilar manufacturers should also consider whether it is possible to obtain their own IP around the biosimilar itself. This can be challenging as, by definition, biosimilars should be as close as possible to the reference product. Nevertheless, it may be possible to seek patent protection for inventions relating to a new manufacturing process, new formulations, new combinations or mode of delivery for example, as long as the improvement does not impart clinically significant differences. Thus, manufacturers should check prior to disclosing their product, whether any feature of the product could be protected in its own right. Securing IP rights may prove helpful for biosimilar manufacturers in any licensing negotiations with the originator and/or to generate a valuable income stream through licensing.

> **"Companies will still need to check any IP rights that the originator may have before launching a biosimilar."**

Companies should also reflect on when to approach an originator for a licence, if at all. A licence may enable early launch of the product without the risk of infringement proceedings, although originators may not be willing to grant a licence to a third party competitor. As mentioned above, having their own IP portfolio may assist biosimilar manufacturers in negotiations since they may be in the position to offer a cross-licence as part of any deal, as would the threat of national litigation which could include an "Arrow declaration".

Finally, biosimilar manufacturers may be able to take advantage of exemptions to patent infringement while IP rights are in force, so as to position themselves for prompt market entry upon expiry of the IP right. One exemption is the so-called "Bolar" provisions[2] which enables biosimilar manufacturers to conduct necessary studies and trials to secure marketing authorisations without the risk of patent infringement. Another exemption is the SPC manufacturing waiver which allows biosimilar manufacturers to make SPC-protected medicines in the UK, for export to markets outside the UK and EU, and during the last six months of the SPC term, to stockpile such medicines so that they can be sold in the UK or EU after the SPC has expired.

### Conclusion

The new MHRA guidelines relax the rules for authorizing biosimilars in the UK, creating a faster framework for companies to get their products to market. However, even as biosimilar regulatory approval becomes more streamlined and new market barriers are overcome, originator IP rights can still be an effective block to market entry. Ultimately, patent and regulatory laws are trying to strike a balance between promoting access to treatments on the one hand and incentivising innovation on the other. Originator and biosimilar manufacturers alike will need to devise bespoke strategies to navigate the legal landscape. For example, while originator companies will be looking to secondary patents (e.g. covering new formulations, dosage regimes and manufacture processes) to prolong their monopoly, and possibly trade secrets, biosimilar manufacturers will no doubt welcome fewer barriers to launch but at the same time must be prepared to conduct a thorough review of the patent landscape before product launch.


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[2] Sections 60(5)(i), 60(6D) and 60(6E) of The Patents Act 1977 (as amended) (UK)