The Life Sciences Lawyer

Issue 8

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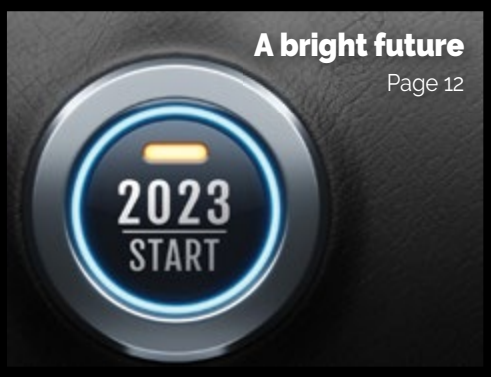
EU pharmaceutical reform

Will this reform put innovation and investment at risk?

A pivotal year of change ahead with increasing administrative complexities



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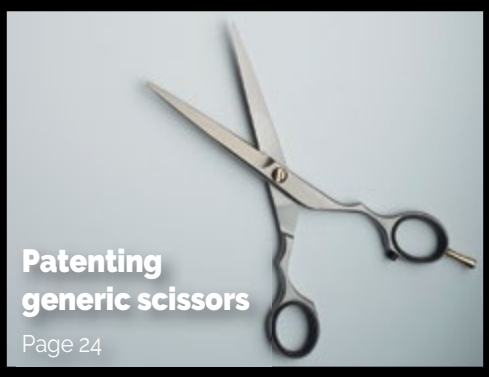

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CTC Legal Media

THE LIFE SCIENCES LAWYER
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CTC Legal Media

Editor's welcome

Change is on the horizon for life sciences: 2023 is set to see EU reform on Pharma Strategy published alongside an IP Action Plan. In this issue, experts foresee what these reforms may mean for innovation in the space, particularly with conditional and regulatory exclusivity being scaled back. Will the implementation of this reform risk future innovation and investment for pharma in the EU?

On the contrary, also find an article on the bright future ahead for life sciences – with AI, connected technologies, and digital innovation continuing to develop and thrive, requiring evolution to a collaborative approach for the protection of such innovation, and the modernization of many laws, the life sciences industry is in a position to make significant headway.

> **"Experts foresee what these reforms may mean for innovation."**

Further, understand key considerations for risk management when it comes to due diligence transactions; understand the use and patentability of genetic scissors, with specific applicability to the CRISPR-Cas system; gain insight into the fast track marketing approval process for health supplies that have been implemented by the Federal Government of Mexico; take a look to see how the 2022 resolutions surrounding information access in Poland is taking shape; obtain insight into post-published evidence and plausibility at the EPO.

This and more. Enjoy the issue.

Faye Waterford

Faye Waterford, Editor

Mission statement

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

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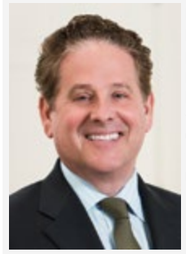

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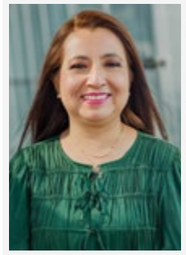

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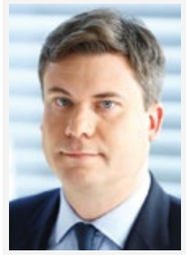

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The Life Sciences Lawyer Magazine wishes to take this opportunity to thank the editorial board for their time and support.

EU reforms in the pharmaceutical sector - a pivotal year of change ahead

Baker McKenzie's experts Fiona Carlin, Brussels, Hiroshi Sheraton, Tanvi Shah & Shira Sasson, London, lay out the momentous changes set to be implemented in the EU's Pharmaceutical Strategy reform which risk the scaling back of established IP and regulatory exclusivities while increasing administrative complexities.

The life sciences sector has long felt the tension between the desire to incentivize and reward medical innovations while enabling equitable access to medicines and containing national healthcare spending. Intellectual property and regulatory exclusivities reward innovation and allow the significant R&D investments required to develop new therapies to be recouped. However, those same rights inhibit the entry of cheaper, generic medicines and do not necessarily promote widespread affordable access to medicines. Forthcoming legislative changes at the EU level look set to alter that delicate balance.

At the beginning of March 2023, the European Commission is expected to publish reform proposals that are the culmination of its EU Pharmaceutical Strategy for Europe[1] (the "**Pharma Strategy**") and IP Action Plan[2], both of which launched in November 2020. The proposals are expected to include a significant realignment of regulatory exclusivities alongside the introduction of an EU-wide compulsory licensing regime. They should be seen in the context of other developments to encourage early generic market entry, including increased scrutiny by competition authorities of alleged abuses of the IP system, most recently in relation to the filing of divisional patents and patent litigation.

> **EU law and policy should encourage the development of those new medicines rather than stem their flow.**

Working documents outlining the Commission's initial thinking on the proposals were leaked in the summer of 2022 after they had been reportedly rejected by the Commission's own Regulatory Scrutiny Board (an internal body charged with quality control over impact assessments and evaluations at early stages of the EU legislative process). The leaked documents proposed to shift the balance away from rewarding innovation as such and towards a system which conditions those rewards on widespread availability of medicines and on addressing unmet patient needs. Having since gone back to the proverbial drawing board, the question is to what extent the Commission will deviate from its original intentions.

There is a lot at stake, not least in terms of Europe's relative global competitiveness in pharmaceutical innovation.

The current EU incentives regime

On top of the patent system, pharmaceutical innovation is incentivized through the availability of Supplementary Protection Certificates ("**SPCs**"), regulatory exclusivities, and orphan and pediatric extensions.

SPCs are a *sui generis* IP right that extend the term of a patent by up to five years in order to compensate for the loss of effective patent protection caused by the lengthy testing and regulatory procedures before a new medicine receives a marketing authorization.

Under the current regulatory exclusivity regime, manufacturers of new medicines benefit from:

- Eight years of regulatory data protection (preventing generic/biosimilar applicants from referencing innovator data in an application for marketing authorization);
- Two further years of market protection (prohibiting the placing on the market of the referencing generic/biosimilar); and
- One further year of market protection if an additional indication that shows significant clinical benefit in comparison with existing therapies is authorized during the initial eight-year period.

In addition, the orphan drug regulatory framework, among other incentives, grants a 10-year market exclusivity period (preventing grant of a marketing authorization for similar medicines for the same indication) for each approved therapeutic indication that has been granted orphan designation. Orphan designation is available for any medicine (1) treating a life-threatening or chronically debilitating disease, with a prevalence in the population of not more than five in 10,000 persons (or where the size of the patient population means that it is unlikely that marketing of the medicine would generate sufficient returns), and (2) where there already is a current method of diagnosis/prevention/treatment, the medicine offers a significant benefit to those affected by the condition.

> **The proposals are expected to include a significant realignment of regulatory exclusivities alongside the introduction of an EU-wide compulsory licensing regime.**

Finally, where manufacturers comply with an agreed pediatric investigation plan ("PIP"), they are rewarded with either a six-month extension to their SPC for non-orphan drugs, or a two-year extension to their market exclusivity for orphan drugs.

EU pharma strategy: scaling back and conditionality of regulatory exclusivities

At the core of the Pharma Strategy is revision of the EU general pharmaceutical legislation and the orphan and pediatric medicines regulations. Legislative proposals are expected to be published by the Commission at the beginning of March, followed by a lengthy[3] legislative process involving the European Parliament and Council.

In its initial Impact Assessments from last summer in relation to the **general pharmaceutical regulation**, the Commission initially proposed a so-called "modulated" (or "carrot and stick") approach. This primarily envisaged the reduction of the period of standard data protection from eight years to six, but allowed for an additional two years (or potentially just one year) to be clawed back provided that the product is placed on all EU markets within two years of receiving

[1] Pharmaceutical Strategy for Europe (Brussels, 25.11.2020 COM(2020) 761 final), available online: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0761&from=EN

[2] Intellectual property action plan implementation, available online: https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/intellectual-property-action-plan-implementation_en

[3] and potentially contentious - given recent news reports of disagreements expressed ---by different groups of MEPs

a marketing authorization. The proposed approach would maintain the existing two years of market protection as well as provide an additional one year of data protection for medicines that address an unmet medical need ("**UMN**"), and an additional six months' data protection for comparative trials. However, the maximum duration of protection would be capped at 11 years in total (the maximum available today).

The reduction of existing rights with the possibility of regaining them being conditional on manufacturers placing their products on all 27 EU markets within two years has been criticized as an unrealistic and political goal. Healthcare spend and pharmaceutical pricing and reimbursement decisions are the exclusive competence of the Member States. There are many administrative reasons outside the manufacturers' control as to why this two-year deadline will be challenging to meet, not to mention multiple commercial and other factors (such as diverse patient populations or disease epidemiology) that may make launch of a product in a particular territory impossible or uneconomical.

The Commission also proposed a change to the definition of UMN as being treatment of a life-threatening or seriously debilitating disease where, in case there is an existing treatment, the new treatment can satisfactorily **cure** the disease. This is a higher bar than the current schemes that reward additional indications with an extra year of market protection and products meeting the definition of orphan diseases with orphan designation, both of which recognize the value of "significant benefit" to patients (rather than requiring a satisfactory cure) where there are existing treatments. This narrow approach effectively limits exclusivity for indications where there is already an existing treatment to the extent that it requires a new treatment to attain what may be an impossible goal. This would likely disincentivize innovation where it is needed most and seems misaligned with the Commission's New Innovation Agenda[4] ambitions for the EU as a world leader in innovation.

In relation to the **orphan regulation**, the Commission's initial preferred approach would fundamentally alter incentives by replacing the fixed 10-year period of market exclusivity with a variable-duration exclusivity period based on the characteristic of the orphan medicine. In the leaked Impact Assessment, the durations proposed were: (i) eight years for products targeting the "highest" unmet medical needs (which has yet to be fully defined); (ii) six years for innovative products (new active substances); and (iii) five years for all other orphan products. An additional two years of market exclusivity would be granted to orphan drugs targeting the highest unmet medical needs or for innovative products, again conditional on the product being made available in all 27 Member States (or additionally based on a lack of return on investment for the developer).

Fiona Carlin

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For the **pediatric regulation**, the preferred proposal would retain the six months SPC extension as the main reward for completion of a PIP, but would add a limit of five years after the adult marketing authorization for deferral of completion of the PIP studies and an obligation, where the adult product is intended for a disease that does not exist in children, to identify if it might also be effective to treat a different condition in children (based for example on the mechanism of action).

The Commission's initial proposals were designed to address accessibility (by threatening to reduce existing rights and thereby allowing earlier generic entry) without costing Member States more money but without due consideration to innovation incentives. It is of scant comfort that the current EU incentives regime is more generous than other jurisdictions[5], not least since the European regulatory approval pathway is significantly longer than in many other places. Policy choices about medicines accessibility are best made at the expert regulatory and payer level in the country-specific context of each Member State. EU law and policy should encourage the development of those new medicines rather than stem their flow.

IP action plan: harmonization - and promotion of generic manufacturing

The stated aim of the IP Action Plan is to promote the harmonization of the EU's IP system, ostensibly in order to drive economic growth and strengthen the EU's economic resilience and recovery. The core pillars are proposals for centralization of the SPC application system (which currently operates on a fragmented national basis), the introduction of a Unitary SPC in conjunction with the Unitary Patent system, and harmonization of the EU's compulsory licensing regime.

SPCs

Harmonization is designed to improve the effectiveness and efficiency of the SPC system by removing red tape and extra costs for business by doing away with national examination and grant procedures. The uniform system will also improve transparency since, under the current regime, it can be difficult to trace what SPC protection exists for which products in which markets. Ultimately this will aid generic entry as well.

At the outset, the Commission was not minded to propose any further erosion of SPC protection after the introduction of the manufacturing waiver provision into the SPC Regulation in 2020. Under this waiver, manufacturing of the SPC-protected ingredient in the EU is permitted during the final six months of SPC protection if carried out either for the purpose of exporting to non-EU markets, or for stockpiling. However, there are concerns that the so-called "modulated" two-year launch conditionality foreseen in the general pharmaceutical legislation review will be carried over into the SPC review in support of the goal of improving patient access across all 27 EU Member States. This would be a further major blow to innovation incentives.

Compulsory licensing

Under the TRIPS Agreement, WTO members are able to authorize the use of patented subject matter without the consent of the patent holders if certain strict conditions are met. Most WTO members have enacted a compulsory license framework. In the case of the EU, this has been done on a Member State level. Following the COVID-19 pandemic, the Commission has prioritized measures to ensure that the EU is better prepared to respond more rapidly and effectively to cross-border threats to public health, including the establishment of the European Health Emergency Preparedness and Response Authority (HERA). In this broader context, the fragmented and uncoordinated national approach to compulsory licensing is seen as a risk.

The Commission has therefore published a preliminary framework for compulsory licensing with the specific policy objectives of enhancing compulsory licensing efficiency in a crisis, improving consistency with other EU crisis-management initiatives, and ensuring an effective compulsory licensing procedure for exports. In requesting feedback on the framework, the Commission emphasized that compulsory licensing will continue to be a *"solution to be used as a last resort when there is a complete breakdown in voluntary cooperation between right holders, third parties such as manufacturers of products and public authorities."*[6]

This suggests that ultimately, the EU is looking to promote access to medicines in a crisis through voluntary licensing of patents by innovators (to

Résumés

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Fiona is the head of the EU Competition & Regulatory Affairs practice in Brussels. She is the former Chief Executive of much of Baker McKenzie's EMEA Region and the former Chair of the Firm's Global Competition and Antitrust Law Practice comprising more than 320 lawyers in over 40 countries. She has remained an active practitioner throughout her various leadership roles with a particular focus on the pharmaceutical and other regulated industries. Fiona has been listed in "The International Who's Who of Competition Lawyers" every year since 2009. Fiona is recognized as a pre-eminent competition practitioner by Chambers that quotes clients as praising her "legal and pragmatic advice" and describing her as "globally minded".
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4 The New European Innovation Agenda, available online: https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/shaping-eu-research-and-innovation-policy/new-european-innovation-agenda_en

5 For example, market exclusivity for small molecule new chemical entities in the US is granted for five years (though biologics are granted 12 years exclusivity). Canada provides for six years of data protection plus two years market protection. Six years total exclusivity is available in China, eight years in Japan.

6 Call for evidence for an impact assessment, regarding compulsory licensing in the EU, available online: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13357-Intellectual-property-revised-framework-for-compulsory-licensing-of-patents_en

generic manufacturers), backed up by the threat of a more robust system of EU-wide compulsory licensing. The intention is to keep it a "weapon of last resort" but, despite assurances, it is a signal that IP rights are increasingly vulnerable. This is concerning as a strong and predictable IP regulatory framework is a better guarantee of R&D and manufacturing collaboration in the face of a cross-border public health emergency than the threat of what amounts to expropriation.

Competition law: increased scrutiny of patenting practices

As well as being mindful of the upcoming legislative changes outlined above, companies need to be wary of increasing scrutiny from competition authorities when developing R&D, patent enforcement and commercialization strategies based around the available exclusivities.

Competition authorities can readily establish dominance (markets are regularly defined as narrowly as the molecule level (ATC 5) or the mode of action level (ATC 4)) in order to punish any unilateral conduct they see as an unfair drain on public healthcare budgets. Conduct that delays generic entry by as little as a few months is fair game and can result in high fines. The authorities are also adept at opening investigations and wringing settlements from companies as an effective means of putting an early stop to conduct deemed costly to the public purse.

Back in 2005, the Commission broke new ground ruling that AstraZeneca had abused a dominant position by submitting misleading information to national patent offices to acquire SPCs, and by withdrawing marketing authorizations in markets where patents or SPCs were about to expire to delay generic entry. Recognizing that the withdrawals were permitted by regulation at the time, the European Court of Justice ruled that dominant companies have a special responsibility not to use regulatory procedures to hinder market entry in a way that does not constitute "competition on the merits".

The case was one of the factors that triggered the EU pharmaceutical sector inquiry that ran from 2007-2009 during which time, the Commission embarked on a deep-dive investigation into the "toolbox" of tactics patent holders allegedly employ to thwart generic entry. In the decade that followed, enforcement efforts focused largely on so-called reverse (pay-for-delay) patent settlements. The litigation continues but the European Courts have firmly established that patent dispute settlements will be viewed as hardcore violations of the competition rules where they involve any material "value transfer" to generic manufacturers that cannot be plausibly explained other than by the commercial interests of the parties not to compete.

> **This suggests that ultimately, the EU is looking to promote access to medicines in a crisis through voluntary licensing of patents by innovators.**

The European Court of Justice has recognized that whilst a patent grant creates a presumption that the patent is valid, that does not equate to a presumption that the generic challenger's product is infringing. Nor does the subject matter of the patent afford protection against actions challenging its validity, especially in relation to secondary patents where the patent protecting the active ingredient of the originator product has expired.

More recently, there has been a wave of competition investigations into alleged abuses of the patent system and of patent litigation processes to unlawfully deter competing generics. In the current political climate, these various investigations signal a willingness to tighten the IP system and to more aggressively pursue alleged abuses going forward. Companies are on notice that extra caution is required.

Following a recent dawn raid, the Swiss competition authority is reportedly cooperating with the Commission looking into blocking tactics – allegations that Novartis acquired certain patents from Genentech with the intention of enforcing them in multi-jurisdiction litigation to protect its psoriasis product Cosentyx from competition.

The European Commission has recently charged Teva with misuse of the patent system and disparagement of a rival multiple sclerosis medicine to its blockbuster Copaxone in seven EU Member States. Teva is alleged to have artificially extended patent protection after the original active pharmaceutical ingredient patent expired, by systematically filing and withdrawing secondary patents, thereby forcing its generic competitors to file new lengthy legal challenges each time – a tactic the Commission has emotively labelled the "divisionals game".[7] The theory of harm is that by filing for divisional patents, Teva artificially prolonged legal uncertainty for generics to its benefit.

In October 2022, MSD was fined €39m by the Spanish competition authority for having pursued allegedly unjustified patent litigation to delay the entry of a rival generic contraceptive ring. In initiating a pre-trial discovery mechanism designed to help establish the likelihood of infringement, MSD was found to have used the process to artificially create doubt about a patent infringement to create a base for successfully seeking injunctive relief (that halted the rival's sole manufacturing site for two and a half months for the Spanish market).

There appears to have been a number of irregularities in the initial discovery and injunctive relief proceedings and MSD was faulted for failing to engage with the defendant and for a lack of transparency in the information it provided to the court. But the decision is harsh in concluding that MSD had engaged in an "irresponsible" use of patent litigation procedures that amounted to sham litigation. The bar to establish sham litigation has been set high by the European Courts since access to justice is a fundamental human right. The legal test requires that (1) the action could not reasonably be considered as an attempt to establish the patent holder's rights but served only to harass a rival, and (2) the action is conceived in the framework of a plan whose goal is to eliminate competition.

Equally troubling is the finding that MSD's decision to allow the main litigation to lapse some months after the patent expired (at which point the abuse is deemed to have ended) was a separate misuse of the injunctive relief process. The Spanish authority is saying that because injunctive relief is intended to preserve the patent holder's rights so as to ensure the effectiveness of the main proceedings, the fact that the patent holder subsequently halts the main proceedings casts a pall over its intentions in seeking injunctive relief in the first place. There can be many valid reasons to end expensive litigation at any point in the process - as new facts come to light, as management priorities change, as the parties discuss settlement, etc. The risk of any such decision infringing the competition rules because injunctive relief was sought at the outset could have the perverse effect of protracted unnecessary litigation continuing.

Also alarming is the fact that the fine was increased by a "deterrent factor" because the Spanish authority considered that it is "especially costly and problematic for competitors to demonstrate the unjustified nature of the litigation constituting the infraction, given the technical and legal specificity of patent infringement procedures".

The aim is no doubt to create a chilling effect on any patent litigation that may delay generic entry and it may be years before these findings are ultimately challenged on appeal. Left unchecked, the Spanish authority's decision places a considerable burden on companies contemplating patent filing and patent litigation strategies. It will require close monitoring and control of all related internal and external correspondence and exchanges, and solid contemporaneous documentation of the internal decision-making processes to avoid allegations of abuse.

Conclusion

The pending EU legislative changes risk scaling back established IP and regulatory exclusivities unless manufacturers are willing to launch in all Member States within two years. This approach entails greater administrative complexity and cost with no guarantee of being able to maintain current levels of protection, and no guarantee that patient accessibility will materially improve. Pricing and reimbursement approval is the sole competence of Member States some of which do not have the capacity (nor the will from a budgetary perspective) to process many more applications. There can be no quick fix from an EU legislative perspective to what are essentially fundamental macro-economic and policy choices at the Member State level.

The changing legislative environment should be understood against a backdrop of increased scrutiny from the competition authorities focused on ensuring that the patent system is not used to delay generic market entry in pursuit of the overarching policy objective of improving the access and affordability of medicines across the EU.

2023 will see the reshaping of the established incentives landscape for innovators that will impact their R&D and patent strategies alongside their commercialization and enforcement strategies. A multidisciplinary effort will be required from IP, regulatory and competition teams within companies in support of a more cautious and holistic approach to mitigate the associated risks from the new political and legal environment.

> **2023 will see the reshaping of the established incentives landscape for innovators that will impact both their R&D and patent strategies.**

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[7] Divisionals do not extend the period of patent protection - they expire at the same time as the parent patent. There are many scenarios where it is entirely legitimate to file for a divisional patent, for example, where it is not necessarily known at the original filing date which specific inventive embodiments will become a commercial product, or where there is a commercial development opportunity that would benefit from the certainty of grant of a narrower patent for a specific licensed field of use.

A bright future for the life sciences

Gareth Probert, UK and European Patent Attorney at EIP, looks at trends and developments set to affect the life sciences sector in 2023 and beyond.

As another challenging year ends, I look at what the future holds for the life sciences in 2023 and beyond. Spoiler alert – the future is bright!

After the turbulent past couple of years, the life sciences are getting back to "normal" in some ways. In this article, I will highlight some of the changes, challenges, and opportunities coming to the pharmaceutical, biotech, and medtech sectors in 2023.

There are a few noticeable trends permeating across almost all sectors of industry, including the life sciences, notably the drive for sustainability. My practice at EIP encompasses a range of different industries and sectors, including industrial chemistry, pharmaceuticals, biotech, nutrition, and medtech, all of which are under pressure to reduce their environmental impact. This is already generating more innovation, including many interdisciplinary inventions, and so driving more patent filings. For optimal protection, these new cross-technology projects need to be handled by collaborative teams at IP firms, so that people with the best technical expertise can work together. The days of working in siloed technical groups are over – life science innovations deserve a more modern, collaborative approach from their IP firms.

Another unstoppable trend is the rise of AI, connected technologies, and digital innovations, which shows no sign of slowing. Patent offices are trying to keep up with these new types of inventions, which are becoming ubiquitous in the life science sectors. We will see the widespread application of AI to more diverse aspects of pharma, biotech, and medtech businesses as the technologies become more accessible, cheaper, and easier to apply. Again, these developments often need a combination of skills and technical expertise in order for the best patent protection to be obtained. It is no longer the case that a single attorney can draft and prosecute patent applications for a pharmaceutical or biotech case – a more modern, collaborative approach is needed.

There are several significant factors in the pharmaceutical and biotech sectors which will impact 2023 and beyond. Many life science companies are in the fortunate position of being cash-rich, particularly those with vaccine products and nucleic acid platform technology. There have been many predictions that this would lead to increased M&A activity in 2023. Any decision to acquire a company or even just an IP portfolio must include appropriate due diligence. The IP departments of life science companies are becoming increasingly stretched in terms of invention harvesting, portfolio management, life cycle planning and management reporting. This means that commercially important due diligence activities may well be increasingly outsourced to good IP firms in order to support this M&A activity. Not every IP firm is well equipped to handle this critical type of work, and very few have bespoke software tools to allow analysis and collaboration in these projects or in-house commercial IP lawyers. Yet again, IP firms must rise to the challenge of providing a modern, digital, collaborative approach to supporting life science clients engaging in these crucial commercial acquisitions.

Another imminent challenge is the patent cliffs that many established pharmaceutical and biotech companies are facing in the next few years. The need to sustain a patent-protected portfolio of products to generate income is driving both M&A activity and also the internal generation of new products. This ongoing patent life cycle management will require skilled patent attorneys to help both identify and robustly protect the next generation of innovative drugs, platforms, and delivery systems.

In my role as a European patent attorney, I deal directly with the European Patent Office (EPO) both in obtaining patents and also representing life science clients in contentious opposition proceedings. Europe is one of the key markets for pharmaceutical, biotech and medtech companies, and they are some of the most prolific users of the EPO. Any changes in practice at the EPO are therefore extremely relevant to the life science sector.

As part of continuing efforts to modernize the EPO, there will be numerous changes to the law in 2023 which pave the way to allow significant changes in practice in future. Although it will not be introduced immediately, the EPO is making changes this year which will allow patent documents to contain digitally-filed high-quality color figures for the very first time. This should make the inclusion of complex data, for example from biological assays, much easier going forward. Other changes will allow patent examiners at the EPO to digitally provide a wider range of citations during prosecution, including multimedia and internet citations. It will be interesting to see whether these changes result in a wider range of citations being relied on during examination.

My own practice focuses on contentious proceedings, particularly before the EPO, often as part of wider court litigations in Europe and beyond. For obvious reasons, over the past couple of years the EPO has moved away from in-person hearings to the use of a secure Zoom platform for hearings before the Opposition Division and also before the Boards of Appeal. The EPO recently announced that such videoconference proceedings would be the default format for all opposition hearings from now on. There is, of course, a spectrum of views on the merits of videoconference hearings compared to in-person hearings, but videoconference hearings are here to stay.

This change is particularly relevant to life science companies because patents in this area are the most opposed patents across all technical areas, with one exception (foodstuffs). The latest statistics from the EPO show that on average across all technical areas, 2.5% of all granted patents are opposed. However, the opposition rate for biotechnology patents is 5.3% and the rate for pharmaceuticals is 5.7%, both of which are more than double the average.

Similarly, oppositions in biotechnology and pharmaceuticals have the highest average number of opponents compared to other fields. While patents in many other technologies are typically opposed by just one party, life science patents often have multiple opponents. In other words, life science patents are the most opposed technologies at the European Patent Office, and they typically include more opponents than other areas. The move to holding opposition hearings by videoconference is therefore most relevant and most controversial for life science patents. Although parties can request hearings to be held in person, this can only be done for a specific "serious reason". Having several opponents involved does not count as an official "serious reason".

Also, as most life science opposition decisions are subsequently appealed, it is prudent to look at the future of the Boards of Appeal. Although they are an independent body from the rest of the EPO, they have adopted the same secure Zoom platform. So far, the Boards have not

Gareth Probert,

> **"Another unstoppable trend is the rise of AI, connected technologies, and digital innovations, which shows no sign of slowing."**

Résumé

Gareth Probert is a UK and European Patent Attorney at EIP with over 20 years' experience. He is head of the EIP Elements practice group working in the pharmaceutical and chemical sectors. His practice focuses on life science and medtech innovations, and also contentious proceedings. His team handles high value and complex patent matters, often in collaboration with his litigation colleagues at EIP.

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announced videoconference hearings are the default, and currently hold at least 25% of all cases in person. I do not expect this to change, particularly for multi-party opposition appeals.

The infamous backlogs of the Boards of Appeal are being tackled by the implementation of their more draconian Rules of Procedure a few years ago, and by increasing staff numbers. However, the average pendency for an appeal in the life sciences area is still over four years, which seems to me to be unacceptable. This is a fast-moving and commercially significant sector that needs legal certainty within a much faster timescale. Even though the Boards and the management of the EPO are on better terms these days, I do not see the backlog decreasing significantly in 2023.

Another significant IP event in 2023 will be the issuance of the Decision from the EPO Enlarged Board of Appeal (EBA) in the referral G 2/21 addressing the question of plausibility. This is extremely relevant to pharmaceutical and biotech cases and focuses on whether you can use post-filed data (that was not in the application as filed) to overcome inventive step objections. The EBA will decide on how much technical information will need to be included in a patent application as filed to make it plausible that the desired technical effect has been achieved. We will have to wait for the written decision but it is my opinion that the most commonly accepted threshold of accepting post-filed data is if the skilled person had no reason to doubt that there is a desired effect based on the application as filed ("*ab initio* implausibility") will continue. If this is not the case, then the decision could seriously change the timing and content of life science patent applications in the future.

This year will finally see the start of the Unitary Patent and Unified Patent Court (UPC) systems, after many delays and complications (some of which still remain to be resolved!). The UPC promises to provide a completely new forum for enforcing (and also challenging) patents across Europe. There has been plenty of speculation about the best strategy for opting out or keeping in life science patents so I will not add to that discussion here. More importantly, the UPC still needs to decide on the location (or locations?) of the section of Central Division that was planned to be in London. This particular court will handle life science litigation and is therefore a key element in the new UPC system. As the UK is no longer in the EU a new home must be found, with Italy and The Netherlands seen as the most likely candidates. It seems that the decision on the life science court is being pushed back until after the UPC commences in June 2023. The UPC is an opportunity for life science companies to take advantage of, especially in the early days, by helping to develop caselaw to support innovation in Europe. Good IP firms will ensure they have the attorneys, lawyers, support teams, and systems in place so they can represent clients in this new court system.

> **The UPC is an opportunity for life science companies to take advantage, especially in the early days, by helping to develop caselaw to support innovation in Europe.**

I think it is important to remember that the Opposition procedure will remain a fundamental and powerful tool once Unitary Patents begin to be granted by the EPO. The majority of oppositions result in either limitation or complete revocation of a patent in a procedure which is fast (at least for the first instance), inexpensive (compared to litigation in national courts and in the new UPC), and potentially anonymous. Given the uncertainty over how the UPC will decide on cases, the EPO opposition procedure is relatively predictable. Also, filing an EPO opposition does not preclude subsequent UPC proceedings.

So, after a turbulent couple of years, we are facing an interesting and challenging new year with many opportunities. To meet these challenges, IP firms need to embrace digital tools, be creative and collaborative in order to meet the needs of the modern life science sector.

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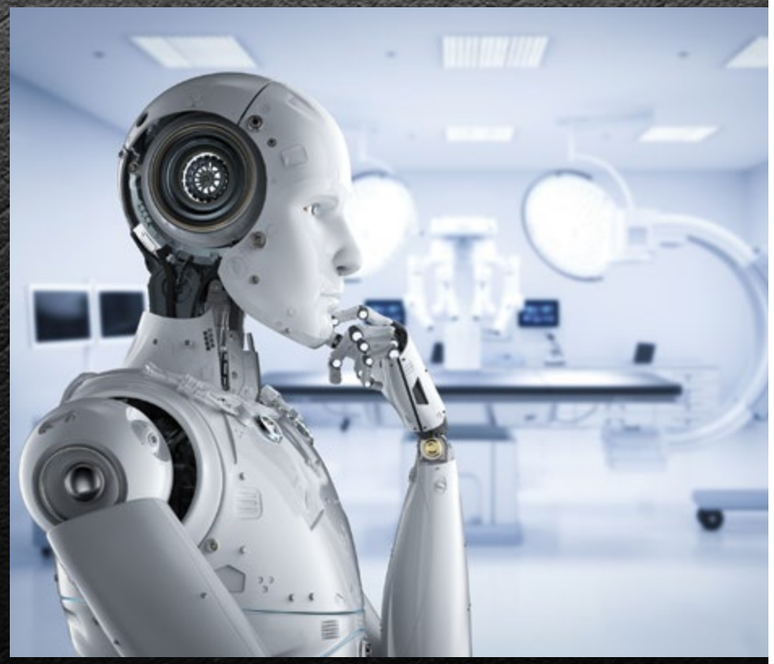
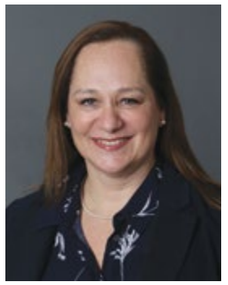


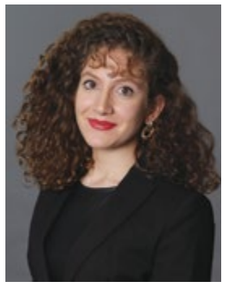
Reshuffle of the EU pharma legislation – reducing IP regulatory rights would bring under question how attractive to innovation and investment the EU will become

Marie Manley and Fjolla Lushta of Sidley Austin LLP analyze the pending review of the EU Pharma Legislation, assessing aspects including potential proposals, regulatory data protection and marketing protection, and orphan market exclusivity.

We are currently faced with the biggest reshuffle of the EU pharmaceutical legal framework in decades. The policy options contemplated by the European Commission ("**Commission**") were leaked at the end of summer by POLITICO, providing the industry with a *taster* of what is to come, although a formal proposal has not been published just yet. As they stand, the preferred policy options *on the table* could significantly affect the pharma industry, raising concerns about whether such changes might trigger a decline in innovation and investments in the European Union ("**EU**") going forwards.



Marie Manley



Fjolla Lushta

What triggered the review?

The review of the EU pharmaceutical legislation (the "**Review**") has been on the political agenda since 2016, after the EU Council ("**Council**") invited the Commission to conduct a review of the current framework, providing evidence-based analysis of the impact of its incentives to promote innovation. In its recommendations on *strengthening the balance in pharmaceutical systems*[1], Council recognized that a strong IP framework is important for promoting access to innovative medicines.

During its Review, the Commission has identified certain deficiencies, including:

- Significant unmet patient medical needs (currently 95% of rare diseases do not have available treatment)
- Unequal access to medicines (namely medicines not being launched in all EU markets),
- Affordability of medicines for health-care systems,
- Supply shortages,
- Insufficient catering for innovation,
- Unnecessary regulatory burdens.

The Commission's contemplated proposals aim to remedy such deficiencies by amending the general pharmaceutical legislation[2], orphan regulation[3], and pediatric regulation[4] (although so far the Commission's preferred option is to maintain the *status quo* with respect to the SPC extension reward in the pediatric regulation). The review of the SPC regulation is also back on the table, amended in 2018 to include a manufacturing export waiver, now calling for evidence on proposals for a single procedure for granting SPCs across the EU. This is likely to be the object of a separative legislative procedure.

Potential commission proposals – what is on the table?

A formal proposal was initially expected by December 2022. However, in August it was reported by POLITICO[5] that the impact assessment reports (the "**Reports**") on the planned changes

Résumés

Marie Manley is a partner and head of the UK Life Sciences at Sidley Austin LLP. Marie advises clients in the pharmaceutical, biotechnology, medical devices, chemicals, cosmetics and food sectors as well as representing them in proceedings before both national and European courts and the regulatory agencies in the UK and across Europe. Marie has particular experience on issues arising during the life cycle of medicinal products, including optimization of IP regulatory rights, advertising, product liability, competition and market access strategy. Marie is recognized as a leader in her field, including a Band 1 ranking in Chambers UK (since 2011) and Chambers Europe 2020 for Life Sciences: Regulatory, as well as recommendations in Who's Who Legal and Best Lawyers (since 2009). She is also ranked as "Leading Individual" for Life Sciences and Healthcare by the Legal 500 UK 2023 and as "Lawyer of the Year" in Life Sciences Law by Best Lawyers 2021.
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Fjolla Lushta is a trainee solicitor in the life sciences regulatory sector. She has experience assisting with client work on the interpretation of the EU and UK applicable legal framework, regulatory compliance, including advertising and promotion, and has a strong interest in the optimization of IP regulatory rights and artificial intelligence. Fjolla is currently working on a high-profile case representing a pharmaceutical company in damages proceedings before the English Courts concerning competition, regulatory, and patent law.

had been rejected by the Regulatory Scrutiny Board ("**RSB**"), which provides "quality control" over EU initiatives before the Commission can trigger the legislative process.

A substantial rewrite of the contents of the policy options contained in the Reports (the "**Proposals**") is not expected. It looks likely that they are here to stay, in one form or another.

The Reports indicate several policy options ranging from making no changes to the baseline position to drastic measures such as scrapping orphan market exclusivity. The Commission then puts forward a "preferred option", which they consider to be on balance the most appropriate solution. The proposed changes to the existing protections and rewards afforded to pharmaceutical products, as they stand, will provide generics *earlier* access to the market and therefore significantly affect the returns on investments of pharmaceutical companies.

Policy Options On the Table

	General Pharma Legislation	Orphan Regulation	Paediatric Regulation
Option 1	8 year RDP + 2 year MP (maintains status quo) ***Special incentives*** • + 1 year RDP → UMN • + 6 months RDP →MAAs include comparative trials • Transferrable exclusivity → AMRs	10 years ME (maintains status quo)	Abolishes rewards (i.e. + 6 months SPC or + 2 year orphan ME)
Option 2	6 years RDP + 2 years MP (for all originators) ***Special incentives*** • +2 years RDP → UMN • Pay or play model → AMRs • R&D transparency → public contribution or funding, including R&D costs	Abolishes 10 years ME	Maintains the current rewards → + 6 months SPC extension still main reward *COMMISSION'S PREFERRED OPTION*
Option 3	6 years RDP + 2 (or 1) RDP if launch in all EU MS + 2 years MP ***Special incentives*** • + 1 year RDP → UMN • + 6 months RDP →MAAs including comparative trials • Transferrable exclusivity → AMRs • R&D transparency → public contribution to R&D costs re clinical trials included in MAA *COMMISSION'S PREFERRED OPTION*	Variable length of ME: • **8 years:** HUMN products • **6 years**: New active substances • **5 years:** Other orphan products • ***Bonus extension:*** + 2 years HUMN products + new active substances → **if** made available in all EU MS or lack of return on investment *COMMISSION'S PREFERRED OPTION*	• + 6 month SPC extension reward → only granted to products addressing UMN + completing PIP • No rewards granted to products not addressing UMN
Option 4	N/A	Variable length ME (as set out in option 3) + new transferrable voucher for orphan medicines addressing a HUMN (can be sold to non-orphan product)	Maintains current awards + extra reward for products addressing UMN: ***Extra rewards:*** • Extra SPC extension (up to 9-12 months) • Priority review voucher → products addressing a children UMN • Transferrable RDP voucher for products addressing children UMN
Option 5	N/A	• Abolishes 10 years ME • Transferrable voucher for HUMN (only HUMN orphan products)	Mirrors option 3 (products not addressing UMN → not entitled to any reward)

Regulatory data protection and marketing protection

Under the current system, medicinal products containing a new active substance benefit from regulatory data protection ("**RDP**") and marketing protection ("**MP**"), the so-called "**8+2+1 formula**". This provides eight years RDP + two years MP + one extra year MP for new therapeutic indications bringing a significant clinical benefit in comparison with existing therapies, provided the new indication is granted within the eight years of RDP. In practice, this means that generic companies have to wait eight years before they can rely on the original innovator's data to support their generic marketing authorisation ("**MA**") applications, and wait until the expiry of MP before launching their product in the EU.

If the Commission's preferred policy option goes forward, this formula will change to create a "standard" and "conditional" period, reducing RDP (not MP) for new medicines by two years, which brings down the total from eight years to six years. *Prima facie*, the contemplated changes may have the effect of stimulating faster generic competition, driving down the cost of the innovator's original drug brand sooner. However, under the new "conditional" element, companies can in fact claw back these two years RDP and return to the baseline eight years, but *only* if they launch their drug in all 27 EU markets within two years of regulatory approval. The proposals suggest that the product must be appropriately and continuously "supplied" in all EU Member States ("**MS**") (with some exemptions).

This policy option is clearly aimed at addressing the issue of inequitable access of medicines throughout the EU. However, the policy approach does not take into account that the launch of a product depends on various parameters, some of them outside of the Commission's and industry's control. A key factor is that reimbursement decisions and timelines are prerogatives of MS; patients in Romania tend to wait two and a half years before products are granted access to the reimbursement list, compared to an average delay of only four months in Germany, for example[6]. EFPIA, the European Federation of Pharmaceutical Industries and Associations, has proactively issued a public commitment on behalf of its members to voluntarily "file for pricing and reimbursement" within two years of a drug being approved in all 27 EU markets.

The Proposals also provide for an additional year of RDP in instances where the medicine addresses an unmet medical need ("**UMN**") (although total RDP is capped at the maximum baseline of eight years), and a further six months for submitting comparative trials with the MA application.

It is worth noting that the Proposals do not currently plan on making changes to the existing incentive of +one year MP for a new indication.

Orphan market exclusivity

Medicinal products with an orphan designation currently enjoy 10 years of market exclusivity ("**ME**"), meaning that no other product can be assessed or authorised for the same therapeutic indication in respect of a similar medicinal product. Such incentives are crucial to the development of new medicines, and the orphan regulation has worked well in this regard, by stimulating development of medicines to treat rare diseases that without such incentives would not generate sufficient return to attract investment in them.

> **"The contemplated changes may have the effect of stimulating faster generic competition, driving down the cost of the innovator's original drug brand sooner."**

However, the Commission's preferred proposal would drastically halve the current 10 year ME for some products by introducing 'variable' length ME, namely eight years for products addressing "high" unmet medical needs ("**HUMN**"), six years for new active substances and five years for all other orphan products. A further two years is proposed for products addressing HUMN and new active substances, *if* they are made available in all EU MS or there is a lack of return on investment for the company. The latter condition remains rather unclear.

The differentiation in incentives made for HUMN is rather controversial and raises an important ethical consideration, as it results *de facto* in prioritizing certain categories of patients.

A new category of UMN + HUMN

All orphan drugs are, by law, addressing an UMN in order to qualify and obtain the orphan drug status, but only a small number of them will qualify as HUMN (a newly defined and yet unknown classification), which will benefit from longer periods of ME for orphan drugs. This is the Commission's attempt to stimulate R&D and investments in some rare diseases, where less investments have been deployed.

It remains to be seen *exactly* how UMN and HUMN will be defined, although according to EUCOPE, the Commission is considering a more restrictive and criteria-based definition[7]. It is expected that less products will qualify for an orphan designation, and benefit from the special incentives contemplated by the Proposals. This could potentially affect whether companies and stakeholders decide to invest in orphan products, which will be detrimental to the affected patient population.

Transferrable vouchers

The introduction of transferrable vouchers, a new incentive in the general pharmaceutical legislation, is also aimed to incentivize the development of antimicrobial products. Transferrable vouchers are additional periods of exclusivity granted to innovators upon regulatory approval. Subject to certain conditions, these vouchers can extend the protection of other medicines in the innovators' own portfolio or be transferred or sold on to third parties, providing an important source of inter-company funding within the industry. The use of transferrable vouchers is also contemplated in the revision of the orphan and pediatric regulations for medicines addressing UMNs, but they do not feature in the preferred policy option.

R&D transparency

The Commission has suggested that transparency on public contributions to the costs of clinical trials will be mandatory for all medicinal products.

The thought process behind this measure is that greater R&D transparency could strengthen the pricing and reimbursement bodies' bargaining position with MA holders, indirectly contributing to affordability. However, it is questionable how this information will provide a fair basis for determining the reimbursement price of a medicinal product. Costs of developing medicines are more complex than simply assessing the costs of conducting clinical trials. In particular, it should include the expenses of failing attempts to develop the successful treatment.

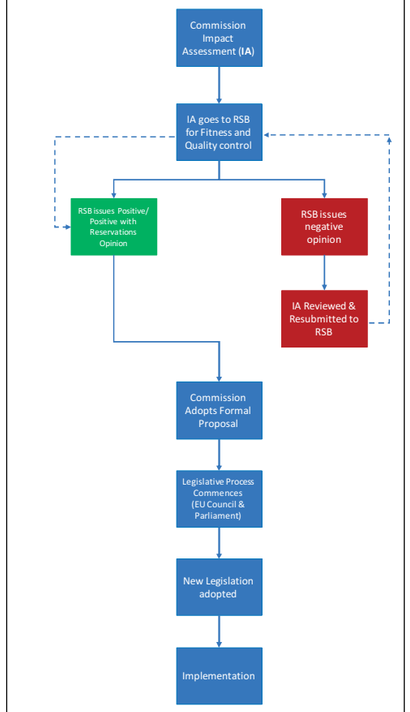
Horizontal measures

Regardless of the policy options which end up being selected, the Commission has proposed 16 common measures, aimed at providing a more flexible and less burdensome regulatory framework. Some examples include simplifying generic MA applications, reducing the instances where notifiable variations are required, setting up a more efficient 'repeat use' procedure and abolishing the 'sunset clause'.

Notably, the proposals suggest an EU-wide centrally coordinated process to provide earlier coordination and dialogue between regulatory authorities, HTA bodies and pricing and reimbursement authorities. The measure appears to be inspired by the new regulatory procedure ILAP (Innovative licensing access pathway) established by the MHRA in the UK, which has proven very popular with the pharmaceutical industry.

This is a rather ambitious proposal from the Commission, as it will require coordination with all 27 MS pricing authorities, which all have their own national agenda.

Role of RSB in the EU legislative process



> **This could potentially affect whether companies and stakeholders decide to invest in orphan products, which will be detrimental to the affected patient population.**

What's next?

Following the RSB's negative opinion, the proposals are unlikely to be published before the end of the first quarter of 2023. The legislative process of the Council and the EU Parliament will then commence, although this could be delayed by the parliamentary elections expected in 2024. Therefore, entry into force of the proposed changes is likely to be several years away.

Conclusion

Despite the current uncertainty and lack of formal proposals, it looks likely that the options we discussed are here to stay. Companies considering launching products or investing in the EU are encouraged to familiarize themselves from now, especially with respect to the conditionality of IP rights for new medicines, as this is likely to affect a company's long-term strategy, product pipelines, and decision-making well before a new law is implemented. Following Brexit, the UK is no longer bound by changes in law made in the EU, and government officials have clearly stated that there is no intention of reducing IP regulatory rights. On the contrary, the UK is eager to ensure that it will remain a world leading platform for the life sciences industry to invest and innovate.

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(1) Council Conclusions on Strengthening the Balance in the Pharmaceutical Systems (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XG0723(03)&from=PT)
(2) Directive 2001/83/EC as amended, and Regulation (EC) No 726/2004).
(3) Regulation (EC) No 141/2000
(4) Regulation (EC) No 1901/2006
(5) POLITICO Article (https://www.politico.eu/article/push-for-fairer-pharma-rules-hits-brick-wall-of-business-interests/)
(6) EFPIA and IQVIA 2022 Survey (https://www.lif.se/globalassets/pdf/rapporter-externa/wait/efpia-patients-w.a.i.t.-indicator-2022.pdf)
(7) EUCOPE Draft White Paper, November 2022 (https://www.eucope.org/wp-content/uploads/2022/11/draft-eucope-umn-white-paper-for-feedback.docx)

Inventive step at the European Patent Office: post-published evidence and plausibility

Dr Roona Deb, Partner at Page White Farrer, reflects on the current process for the assessment of inventive step at the EPO, highlighting important answers from the Board of Appeal that provide clearer guidelines for filing.

The Enlarged Board of Appeal (EBA) of the European Patent Office has been presented with a new referral (G2/21) concerning the admissibility of post-published evidence for the assessment of inventive step in relation to European Patent No. 2 484 209. The outcome of this referral may have important ramifications for how much experimental data is required to be included in a patent application at the time of filing, particularly in the chemical, pharmaceutical, and life sciences sectors.

Assessment of inventive step

The European Patent Office (EPO) assesses the presence of an inventive step in patent claims by applying the long-standing problem-solution approach. The problem-solution approach requires three main steps:

(i) determining the closest prior art,

(ii) establishing the objective technical problem to be solved in view of the closest prior art, and

(iii) considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.

With regard to step (ii), the objective technical problem is formulated on the basis of a technical effect provided by one or more features which distinguish the invention as claimed over the closest prior art. An inventive step may be acknowledged if the claimed invention attains the technical effect and thus solves the objective technical problem across the entire scope of the claim in a non-obvious way. The technical effect typically needs to be supported by experimental data, particularly in the chemistry, pharmaceutical, and life sciences sectors where results may be more unpredictable.

As experimental data may be limited at the early stages of invention development, Applicants in the chemistry, pharmaceutical, and life sciences sectors may have to file patent applications with limited data. Under current practice, if adequate supporting data is not present in the application as filed, data submitted during examination (or opposition) as post-published evidence may be taken into consideration for the assessment of the inventive step. However, the EBA's decision may alter the circumstances under which this practice is allowed.

Background – European patent No. 2 484 209

European patent No. 2 484 209 ("the patent") owned by Sumitomo Chemical Company, Limited was opposed by Syngenta Limited on multiple grounds including lack of inventive step. The Opposition Division rejected the opposition and upheld the patent. The decision was appealed (T0116/18). The Board of Appeal decided that maintenance of the granted patent rests on the admissibility of post-published data relied upon by the proprietor to support a technical effect.

Dr Roona Deb

Claim 1 of the patent as granted is directed to an insecticide composition comprising a combination of two compounds, thiamethoxam and a second generic compound represented by a Markush formula Ia, both of which have known insecticidal activity. The application as filed included data demonstrating a synergistic effect between thiamethoxam and two specific compounds within formula Ia, against two insect species S. litura and P. xylostella.

During opposition proceedings, the opponent was able to demonstrate with data and argumentation that a synergistic effect against these above species was not credibly achieved across the entire scope of the claims. However, in their defense, using post-filed evidence, the proprietor was able to demonstrate a synergistic effect against a different pest species, C. suppressalis.

The Board of Appeal decided that if the proprietor's post-published data were admitted, then an inventive step could be acknowledged. (In this case, the objective technical problem could be reformulated as the provision of synergistic insecticidal activity against the species C. suppressalis, and the solution provided by the combination of compounds of granted claim 1 would be considered non-obvious.) However, if the post-published data were not admissible, then the claimed subject-matter would lack an inventive step on account of being merely an obvious alternative insecticide composition. The admissibility of the post-published evidence is thus pivotal to the outcome of the appeal.

Conflicts in existing case law

The Board of Appeal considered there to be three diverging lines of case law regarding the extent to which post-published evidence can be relied upon by patent proprietors to demonstrate the existence of a technical effect in support of inventive step.

Ab initio plausibility

According to this line of case law, an inventive step may only be acknowledged if the application makes it at least plausible that the claimed subject-matter provides the desired technical effect, and thus solves the objective technical problem. Supplementary post-published evidence typically may not serve as the sole basis to establish that the problem is solved. This standard follows Decision T1329/04 (Factor-9/John Hopkins), and is widely adopted at the European Patent Office (see for example, Decisions T488/16, T415/11, T1791/11 and T895/13). Under this standard, applications based on speculative assertions that are not commensurate with the actual technical contribution to the art would not proceed to grant. In Decisions T1642/07 and T1599/06, the Board of Appeal stipulated that a technical effect could be made plausible by an appropriate theoretical explanation or information.

Ab initio implausibility

Another line of case law provides that post-published evidence may only be disregarded if the skilled person would have legitimate reasons to doubt that a purported technical effect would have been achieved on the filing date of the patent in suit. In other words, according to this line of case law, post-published evidence is taken into account as long as the purported technical effect is not implausible.

This standard of implausibility has been applied in Decision T578/06 (Pancreatic cells/IPSEN), where the Board of Appeal highlighted that the EPC does not require any experimental proof for patentability and considered that the disclosure of experimental data or results in the application as filed and/or post-published evidence is not always required to establish that the claimed subject-matter solves the objective technical problem. The Board further emphasized that the establishment of plausibility is only relevant when examining inventive step if doubts about the suitability of the claimed invention to solve the technical problem addressed were substantiated. Other Decisions applying this standard of implausibility include T536/07 and T1437/07.

No plausibility

There have also been instances where the Boards of Appeal have disregarded the concept of plausibility, and have taken into consideration post-published evidence demonstrating a technical effect of which there was no plausible demonstration in the original application (see T31/18 and T 2371/13). Here, the Boards took the view that the requirement for a plausible demonstration of a technical effect in the original application is incompatible with the problem-solution approach on the basis that the closest prior art in view of which the objective technical problem is formulated, may not be known to the Applicant at the filing date of the application.

Questions referred to the Enlarged Board of Appeal

In view of the divergent case law and the cruciality of the post-published evidence to the outcome of the appeal, the Board of Appeal referred the following questions to the EBA:

"If for acknowledgment of inventive step the patent proprietor relies on a technical effect and has submitted evidence, such as experimental data, to prove such an effect, this evidence not having been public before the filing date of the patent in suit and having been filed after that date (post-published evidence):

1. Should an exception to the principle of free evaluation of evidence (see e.g. G3/97, Reasons 5 and G1/12, Reasons 31) be accepted in that the post-published evidence must be disregarded on the ground that the proof of the effect rests exclusively on such post-published evidence?

2. If the answer is yes (post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration, if based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have considered the effect plausible (ab initio plausibility)?

3. If the answer to the first question is yes (post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can post-published evidence be taken into consideration if, based on the information

"The outcome of this referral may have important ramifications for how much experimental data is required to be included in a patent application at the time of filing."

Résumé

Dr Roona Deb, Partner

Roona has worked in intellectual property since 2008 and is a qualified European Patent Attorney and Chartered Patent Attorney. She holds a first class master's degree and a doctorate in biochemistry from the University of Oxford.

Roona represents academic institutions, SMEs and large multinational companies, and advises on all patent matters in the life sciences and chemistry sectors. She has a wealth of experience in drafting and filing UK, European and international patent applications, prosecuting patent applications at the UK Intellectual Property Office, European Patent Office and worldwide, providing written and oral representation before the European Patent Office in opposition and appeal proceedings, performing competitor surveillance, providing infringement and validity opinions, invention capturing, and advising on due diligence matters. Roona has assisted her clients in developing and managing patent portfolios worldwide.

Roona has particular expertise in diagnostics, digital healthcare, immunology, including antibody technology, molecular enzymology, nutraceuticals and pharmaceuticals, oral care and personal care, polymer chemistry, protein chemistry, and recombinant DNA technology.

in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have seen no reason to consider the effect implausible (ab initio implausibility)?"

The answers to these questions will likely harmonize the approach taken by the European Patent Office in its assessment of inventive step, and provide more certainty for Applicants on the requirements for admitting post-published evidence.

Brief communication of the Enlarged Board of Appeal

On 13th October 2022, the EBA issued a brief communication in advance of the oral hearing that took place on 24 November 2022, highlighting issues of potential significance.

In the present referral, question 1 highlights that imposing rules on when post-published evidence can or cannot be considered would appear to go against the principle of free evaluation of evidence.

The EBA specifically noted: *"....the principle of free evaluation of evidence does not appear to allow disregarding evidence per se insofar as it is submitted and relied upon by a party [...] and is decisive for the final decision. Disregarding such evidence as a matter of principle would deprive the party submitting and relying on such evidence of a basic legal procedural right generally recognized in the contracting states and enshrined in Articles 113(1) and 117(1) EPC."*

From this statement, it appears that the EBA preliminarily considered answering "no" to the first question which may obviate the requirement for plausibility entirely, when relying on post-published data to support inventive step. However, the EBA did subsequently provide guidance on referred questions 2 (*ab initio* plausibility) and 3 (*ab initio* implausibility), and from the EBA's comments, it seemed that it was leaning towards ab initio implausibility:

"It is then on the basis of the application documents and this technical teaching that a purported technical effect relied upon for inventive step is to be assessed as to whether the skilled person, having the common general knowledge in mind, would have had any significant reason to doubt it.

In the absence of any such doubts, the reliance on post-published evidence, such as experimental data, for the purported technical effect would seem to serve as a potential source for a deciding body to conclude whether or not it is convinced of said technical effect when deciding on the inventiveness of the claimed subject-matter."

> **"The answers to these questions will likely harmonize the approach taken by the European Patent Office in its assessment of inventive step, and provide more certainty for Applicants on the requirements for admitting post-published evidence."**

The EBA also pointed out that the technical effect relied upon for inventive step arguments needs to be encompassed by the technical teaching of the claimed invention from the application as filed and "embody the same invention". This is in line with established case law relating to reformulation of the technical problem which stipulates that any effect provided by the invention may be used as a basis for the reformulation of the technical problem, as long as the effect is derivable from the application as filed, or the skilled person would recognize the effect as implied by or related to the technical problem initially suggested.

The final decision of the EBA is eagerly awaited and expected to be issued in Q2-Q3 2023. The EBA is not bound by any opinions expressed in its preliminary communication and its opinions may, of course, have changed following arguments presented by the parties at the hearing.

Concluding remarks

The EBA's decision may alter current practice and filing strategies. In particular, in the life sciences and chemical sectors, there is often a need to strike a balance between filing early to secure the filing date and delaying filing in order to obtain (additional) experimental evidence to demonstrate the technical effect of the invention. If the EBA's decision restricts opportunities to rely upon post-published evidence to support inventive step, then Applicants may want to consider taking more time before filing to increase the amount of evidence/data included in new filings in order to better support the claimed invention. Conversely, if the EBA's decision lowers the threshold for admittance of post-published data, this may give Applicants the chance to file earlier, and to pursue broader and more speculative claims in European patent applications, with the aim of later relying on the use of post-filing data to prove a technical effect, if necessary.

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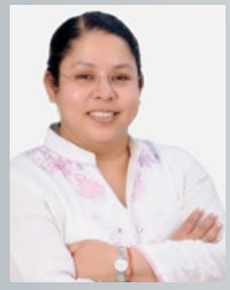
Patenting genetic scissors: the global landscape and an Indian perspective

Manisha Singh, Partner, and Neha Ruhela, Senior Associate, of LexOrbis evaluate the use and patentability of the CRISPR-Cas system in India compared to the global landscape.

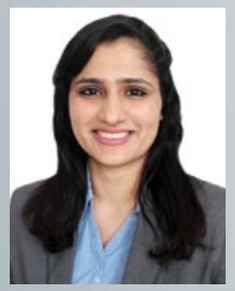
Genome editing is a group of technologies that provide the ability to change an organism's DNA. It allows genetic material to be added, removed, or altered at particular locations in the genome. The 2012 discovery of a new genome-editing method, widely known as CRISPR-Cas system, has triggered a revolutionary wave in the field of biotechnology. The 2020 Nobel Prize in Chemistry was awarded for CRISPR genome-editing. CRISPR technology has enormously higher precision, efficiency, strong specificity and effectiveness when compared to previously known genome-editing methods. In a very short span, CRISPR technology has demonstrated its near-unlimited potential and solution for therapeutics, diagnostics, medicine, and agriculture.

CRISPR-Cas editing

The acronym CRISPR stands for Clustered Regularly Interspaced Short Palindromic Repeats, which are the hallmark of a bacterial defense system that forms the basis for CRISPR-Cas genome-editing technology. The CRISPR-Cas system, often described as 'genetic scissors', makes it possible to search, cut, remove and even replace a mutation in the genome – analogous to 'find-delete-replace' functions in computer word processors. The CRISPR system consists of two parts – a tailor-made guide-RNA and a Cas (CRISPR-associated) protein. Guide-RNA shepherds the Cas protein to a particular region of the genome and then the Cas protein cuts the target DNA. After DNA is cut, the cellular auto-mechanism (an easier process) or alternatively, insertion of a new DNA (a more difficult process) repairs the break in the region of the cut.



Manisha Singh



Neha Ruhela

CRISPR patent map

Using appropriate search string[1], the WIPO database retrieved more than 6,300 patent families for published documents. The trend in worldwide patent numbers has increased from around a dozen filings per month in 2014 to a monthly average ranging from 100 to 150 filings in 2022. With the substantial domination by China and the US over other key players including South Korea, Japan, and European Union, the global CRISPR patent landscape shows strong geographical biases.

Although China outnumbers the US for filings, the foundational patents of the CVC group (University of California, University of Vienna & Nobel co-laureate Emmanuel Charpentier) filed in 2012, as well as the Broad group (Broad Institute, University of Harvard & Massachusetts Institute of Technology) filed a few months later in 2013, have truly revolutionized the whole patent landscape. Globally, the top five positions are predominantly held by the Broad and CVC group and its spinoff. The next five rankings include three agricultural & one medical university of China and another Broad's spinoff. It is interesting to note that all the top 10 applicants/assignees are universities/institutes or their spinoffs. Big Pharma, such as Pfizer and Bayer, are also entering into the gene-editing space through collaboration with successful CRISPR start-ups. Such partnerships could be a point of inflection for the gene-editing industry.

Under Indian jurisdiction, so far more than two hundred CRISPR patent documents have been published which include a lesser number of domestic filers. The evolving patent landscape of CRISPR is yet to be developed fully in India. Considering its promising demographic dividend and huge market, India has immense potential for use of CRISPR-based applications, particularly in affordable healthcare, agriculture & allied sector, and bio-energy. The grant of a few CRISPR-Cas9 patents brings significant advancement for the Indian patent regime and underlines India's ambition for gene-editing.

Crossing the patentability barrier

In February 2022, in *CVC v Broad*[2], the US Patent Trial and Appeal Board (PTAB) decided the long-running, complex, and intriguing IP dispute – 'who first invented the foundational patent for CRISPR-Cas9 editing in eukaryotic cells' in favor of the Broad Institute. PTAB ruling held that the Broad group was the first to prove the CRISPR-Cas9 technology worked in plants and animals including humans. However, CVC's appeal against the PTAB decision is likely on the way. *Per contra*, the game is playing out on a different footing at the European Patent Office (EPO) where the Opposition Division and Boards of Appeal ruled that the CVC group held the first-generation CRISPR-Cas9 patents. These IP wars on various fronts are *per se* sufficient to underscore the commercial prospects of CRISPR.

The major hurdles the CRISPR technology may face in the Indian Patent Office (IPO) are exclusions under clause (b), (i) and (j) of section 3 of the Patents Act, 1970 as below:

1. Ordre public doctrine [section 3(b)]

The public order and moral aspect as well as apprehension over commercial exploitation of germline-editing can be traced into Article 27.2 of the TRIPRS agreement and its statutory doppelganger viz. section 3(b) of the Indian Patents Act which bars patentability of *"an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment"*. However, the application of this provision solely rests at the discretion of the Controller who often raises bald objections of public order or morality leading to the rejection of grant or deletion of certain claims. Hence, this

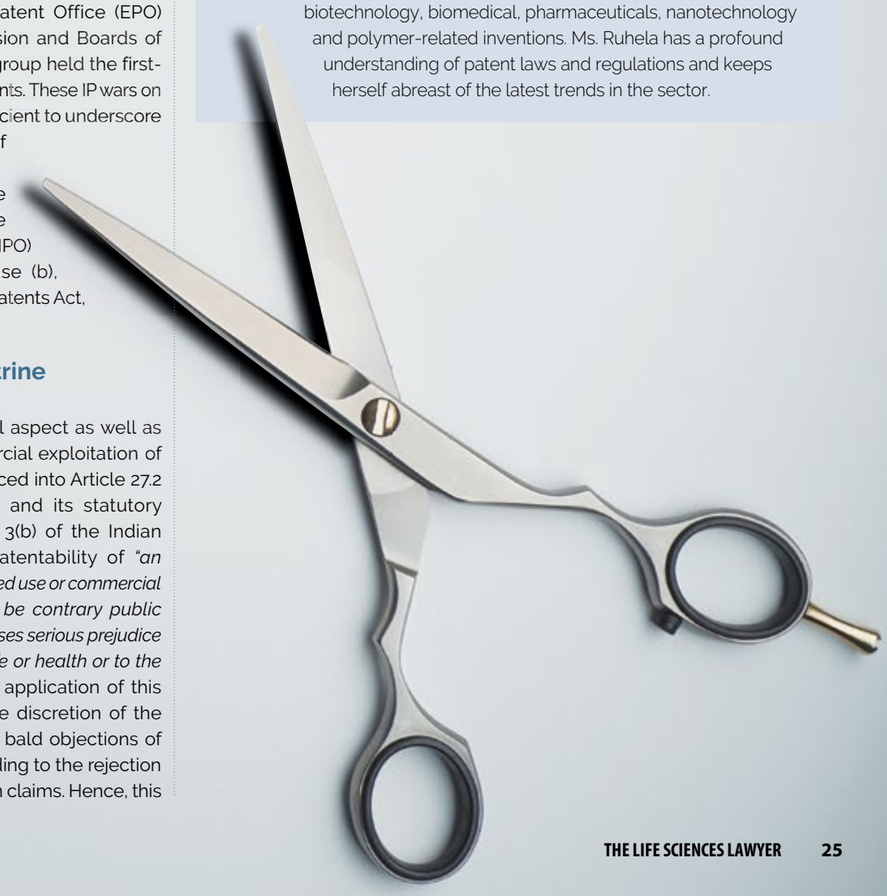
Résumés

Manisha Singh, Partner

Manisha Singh is the Founder Partner of LexOrbis. Manisha is known and respected for her deep expertise in prosecution and enforcement of all forms of IP rights and for strategizing and managing global patents, trademarks, and design portfolios of large global and domestic companies. Her keen interest in using and deploying the latest technology tools and processes has immensely helped the firm develop efficient IP service delivery models and provide best-in-the-class services. She is also known for her sharp litigation and negotiation skills for both IP and non-IP litigations and dispute resolution. She is involved in a large number of intellectual property litigations with a focus on patent litigations covering all technical fields – particularly pharmaceuticals, telecommunications, and mechanics. She has been involved in and successfully resolved various trademarks, copyright, design infringement, and passing off cases in the shortest possible time and the most cost-efficient manner applying out-of-box strategies and thinking. She is an active member of many associations like INTA, APAA, AIPLA, AIPPI, LES, FICPI, and is actively involved in their committee work. She is an active writer and regularly authors articles and commentaries for some of the top IP publications.

Neha Ruhela, Senior Associate

Neha is a registered patent agent and a law graduate. Her proficiency ranges over life sciences, IP practice and law. She holds a master's degree in Biotechnology and earned research experience at the Indian Institute of Technology, Bombay. On the professional front, she deals with drafting, prosecution, opposition and advisory matters, especially in biotechnology, biomedical, pharmaceuticals, nanotechnology and polymer-related inventions. Ms. Ruhela has a profound understanding of patent laws and regulations and keeps herself abreast of the latest trends in the sector.



widely worded provision is without any sufficient guidance or safeguards against the arbitrary exercise of power by the Controller. To provide definiteness, the Indian Parliamentary Committee in its remarkable IPR review recommended that section 3(b) be amended to limit the exclusion to only those inventions which are barred under any law for the time being in force.

Concomitantly, the prevailing Indian Guidelines for *'Gene Therapy Product Development and Clinical Trials'* (2019) clearly prohibit germline gene therapy, due to ethical and social considerations. But it also suggests that somatic cell editing may be the more socially acceptable approach because it is not passed on to subsequent generations. Such regulatory flexibilities should also be considered while assessing the non-patentability through the lens of *ordre public*.

2. Method of medical treatment [section 3(i)]

This exclusion is embedded in Article 27.3(a) of the TRIPS agreement which states: *"Members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals"*. Most countries, including members of the European Patent Convention (EPC), Canada, New Zealand, China, Japan, and India exclude or limit the patentability of methods of medical treatment. Under such limitations, beneficial CRISPR-based therapy and diagnosis patents are likely to face challenges.

> **Indian research groups are advancing on gene-editing applications in plants including high-yielding rice, high vitamin-A bananas, and improved mustard and papaya.**

TRIPS flexibility for 'method of treatment' exclusions reflects variations in statutory approaches. For instance, India has taken extra care to prevent exclusivity over the commercial use of medical treatment. Section 3(i) of the Indian Patents Act forbids *"any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products."* Whereas the Article 53 (c) of EPC excludes *"methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body"*. The phraseology of Indian exclusion may seem close to that of EPC in letter, but in spirit and practice the scope of Indian provision is wider than that of the European counterpart.

As an example, IN Application No 201827014776, the Controller applied section 3(i) objected to claims by merely stating that *"said technology is a method of diagnosis which is not allowable as per above mentioned section"*, which resulted in the narrowing of claims to *"an in-vitro non-therapeutic, non-diagnostic method for detecting pyrogens"*.

IPO interprets 'method of medical treatment' exclusion in a broader manner, hence enlarging a lesser protection to such inventions. Most countries do not bar diagnostic methods that can be carried out separately *(in vitro, ex vivo)* from the body. However, IPO refuses these applications by stating that the section 3(i) does not mark any distinction between *in vitro* and *in vivo* methods. Applications No. 201621022807 and 201741015794 have been refused by IPO, wherein the claims recite *"an in vitro multiplex PCR assay"* and *"method for detecting at least one biomarker in a sample"*, respectively.

Also, the exclusory section 3(i) has not yet undergone judicial scrutiny by Indian courts. IPO should update its examination procedures and practices to take this patentability limitation into account and to publish guidance clearly explaining the ambit of exclusion for CRISPR therapeutics and diagnostics.

3. Plant & animal and their variety [section 3(j)]

Section 3(j) of the Patents Act blocks patenting plants and animals in whole or any part thereof including varieties. In particular, genome-edited plants cannot be patented in India. However, India has a *sui generis* system – Protection of Plant Varieties and Farmers Rights Act (PPVFRA) granting IP rights to plant breeders who have developed any new plant varieties. Indian research groups are advancing on gene-editing applications in plants including high-yielding rice, high vitamin-A bananas, and improved mustard and papaya. In 2022, India also exempted genome-edited plants (which are free of exogenous introduced DNA) from stringent biosafety assessment[3]. Thus, the evaluation and release of a genome-edited plant as a new variety shall be governed as per other applicable laws including PPVFRA.

> **The global gene-editing market size was valued at USD 5.2 billion in 2020 and it is expected to reach USD 18.5 billion in 2028.**

Parting comments

The global gene-editing market size was valued at USD 5.2 billion in 2020 and it is expected to reach USD 18.5 billion in 2028 with a forecasted CAGR of 17.2%. CRISPR breakthrough innovations are shaping the future of biotech. It offers unparalleled promises of curing the genetic and complex diseases. Institute of Genomics and Integrated Biology is exploring the possibility of CRISPR-mediated genetic correction of sickle cell disease through a clinical trial. During the pandemic, India launched a CRISPR-based test (FELUDA) for rapid and sensitive Covid-19 diagnostics. India is progressing towards unlocking gene-editing powers which can lead to swelling in patent numbers as well.

Despite few patentability limitations as outlined above, prudent drafting of claims for gene-editing inventions can be achieved with the assistance of a skilled service provider with legal knowledge and sound technical proficiency in the subject matter. Experts having acquaintance with genetic engineering techniques, gene therapy, spectrum of Cas proteins, sectoral regulations, and patent practices can guide the applicants to reap the benefits and obtain maximal possible protection of their inventions under the Indian patent regime. Besides, patent advisors abreast of nuances of patentability across the global gene-editing landscape would facilitate the patenting process more efficiently.

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Accelerated approval for health supplies

Janett Lumbreras Mendoza, Senior Associate at Uhthoff, Gomez Vega & Uhthoff, S.C., reviews the changes implemented by the Federal Government of Mexico in 2020 that aimed to reduce the term required for gaining marketing approval for medical supplies.

Medicines and other health supplies are required, for their sale or supply, to have the corresponding sanitary authorization in its marketing authorization modality, which is issued by COFEPRIS (Federal Commission for the Protection against Sanitary Risks), the authority health in charge of this procedure. Said marketing authorization is valid for five years.

Pursuant to article 194 Bis of the General Health Law, medicines, psychotropic substances, narcotics and raw materials and additives involved in their preparation are considered health supplies; as well as medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical material, healing material and hygienic products, these last ones under the terms of section VI of article 262 of said Law.

The processing of these records should take, in an ideal scenario, 168 business days based on what is established by the Marketing Authorization of Health Supplies. However, the average process takes 358 days, a little more than twice the ideal duration, due to precautions that lengthen the process.

Background

The regulatory system in the pharmaceutical industry in Mexico is governed by government institutions such as the Federal Commission for Protection against Sanitary Risks (COFEPRIS) and the Mexican Institute of Industrial Property (IMPI). These organizations transversally regulate the administrative mechanisms for the operation of the market, as well as grant the registration of new patents, watch over compliance with industrial property rights and allow the entry of innovative and generic medicines.

COFEPRIS has the obligation to regulate the marketing, production, export and advertising of medicines and everything related to toxic substances and environmental impact. Its main objective is to protect the health of the population against health risks caused by biological, chemical, and physical agents.

The IMPI is in charge of registering patents and protecting the different types of industrial property rights.

The coordination between COFEPRIS and IMPI takes place within the framework of a linkage system that must function as a mechanism for consulting information to know the status of patents and thus regulate the entry of new medicines to the market.

To obtain the marketing authorization, the applicant must comply with the provisions of articles 166-170, 172, 174, 177, 177-bis 1 to 177-bis 5, 178 and 179 of the Health Supplies Regulations (RIS) and the following Standards Mexican Officials:

NOM-059-SSA1-2015. Good drug manufacturing practices.
NOM-164-SSA1-2015. Good manufacturing practices for pharmaceuticals.
NOM-073-SSA1-2015. Stability of drugs and medicines.
NOM-220-SSA1-2016. Installation and operation of pharmacovigilance.
NOM-257-SSA1-2014. Regarding biotechnological medicines.
NOM-012-SSA3-2012. That establishes the criteria for the execution of research projects for health in human beings.
NOM-177-SSA1-2013. That establishes the tests and procedures to demonstrate that a medicine is interchangeable.

For our country to be more competitive and guarantee access to quality medicines, it is necessary to implement pharmaceutical policies with a clear vision, which consider the concerns of the different sectors involved.

Fast track approval for health supplies

The fast-track approval process consists of specific interchangeability requirements for generics and biosimilars (including Good Manufacturing Practices), and an additional need for a favorable opinion from the New Molecules Committee to approve new products. All applications must be resolved by COFEPRIS within 60 days after filing.

Article 161 Bis of the Health Supplies Regulation establishes that the Ministry of Health may issue general provisions with the purpose of recognizing that the requirements, tests, evaluation procedures, and other requirements requested by foreign health authorities, to allow in their respective countries the sale, distribution and use of the supplies referred to in said Regulation, are equivalent to those that the General Health Law, the Health Supplies Regulation itself, and other applicable provisions require to guarantee quality, safety, and efficacy of these products. These Regulations must be met to obtain their marketing authorization in the country.

On September 3, 2010, the "Agreement establishing the general provisions that must be complied with in order for the Ministry of Health to issue administrative agreements recognizing that the requirements, tests, evaluation procedures and other requirements requested by foreign health authorities, to allow in their respective countries, the sale, distribution and use of the health supplies referred to in article 194 Bis of the General Health Law, are equivalent to those required by the General Health Law, the Health Supplies Regulation and other legal and technical provisions that are applicable in the matter, to guarantee the quality, safety and efficacy that said supplies must satisfy in order to obtain their marketing authorization in our country, the extension of their registration or any modification to the conditions in which they were registered", which was modified by diverse and published in the official dissemination body itself on March 28, 2019 (General Provisions Agreement).

This agreement recognizes that the requirements of articles 161 Bis, 167, 169 and 170, of the Health Supplies Regulation (RIS), among others, will be automatically recognized when the approval of medicines is requested in Mexico that have been evaluated through the World Health Organization (WHO) Prequalification Program for Medicines and Vaccines. Through this program, WHO

Résumé

Janett Lumbreras Mendoza, Senior Associate at Uhthoff, Gomez Vega & Uhthoff, S.C. in Mexico

Janett joined the firm in 2000, with over 20 years of experience in patent matters, her practice areas are in Chemistry, Pharmacy, and Biotechnology, as well as in the handling of Industrial Designs. She has acted as an expert in different litigation cases related to Life Sciences. Janett holds a Degree in Pharmaceutical Chemistry-Biology, from Universidad Nacional Autonoma de Mexico (UNAM), Mexico City, and has Diplomas in Access to Worldwide Scientific and Technological Information from Universidad Nacional Autonoma de México (UNAM); Industrial and Intellectual Property Law from Universidad Nacional Autonoma de México (UNAM); and Introduction to the UPOV System of Plant Variety Protection under the UPOV Convention from WIPO Worldwide Academy.

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Janett Lumbreras Mendoza

> **Its main objective is to protect the health of the population against health risks caused by biological, chemical, and physical agents.**

prequalifies the safety, quality, and efficacy of medicines in support of health systems in low- and middle-income countries. Thus, once a product is prequalified by the WHO, it may omit various requirements to obtain approval in Mexico.

Derived from the General Provisions Agreement, the Ministry of Health has issued various agreements by which it is recognized that the requirements, tests, evaluation procedures and other requirements requested by foreign health authorities, in their respective countries for the sale, distribution, and use of health supplies are equivalent to those required by the General Health Law, the Health Supplies Regulations and other applicable legal provisions on the matter (Equivalence Agreements).

“The administrative procedures will be streamlined so that the Federal Commission for the Protection against Sanitary Risks resolves the requests for marketing authorization of medicines.”

On the other hand, in accordance with article 84 of the General Law of Regulatory Improvement, the heads of the dependencies of the Federal Public Administration are empowered to simplify the procedures and services provided for in laws, regulations or any other provision that has been issued by the Head of the Federal Executive, by means of general agreements published in the Official Gazette of the Federation, which provide, among other measures, response times shorter than the maximum established, as well as not requiring the presentation of data and documents.

On January 28, 2020, the Agreement was published whereby the requirements established in articles 161 Bis, 167, 169, 170 and 177 of the Health Supplies Regulations and the technical evaluation procedures carried out by the Federal Commission for the Protection against Sanitary Risks for the granting of the marketing authorization of the health supplies referred to in articles 2, sections XIV, XV, subsections b and c and 166, sections I, II and III of the Health Supplies Regulation; in relation to articles 222 and 229 of the General Health Law, the requested requirements and evaluation procedures carried out; as well as the importation of medicines with or without marketing authorization in Mexico, aimed at any disease or condition, which are authorized by the following regulatory authorities: Swiss Agency for Therapeutic Products-Swissmed, European Commission, Food and Drug Administration of the United States of America, Health Canada, Australian Therapeutic Goods Administration, PAHO/WHO Reference Regulatory Agencies; prequalified by the Prequalification Program for Medicines and Vaccines of the World Health Organization or Regulatory Agencies members of the Pharmaceutical Inspection Cooperation Scheme.

This agreement refers to the recognition of safety and efficacy standards, as well as to the importation of medicines with or without marketing authorization in Mexico, for any condition.

The Federal Government, in order for Mexicans to have access to more and better medicines and other health supplies, has undertaken various actions, including signing agreements with international organizations to carry out the acquisition of medicines and medical supplies in abroad, and promote the reform approved by the Congress of the Union to the Law of Acquisitions, Leases and Services of the Public Sector, published in the Official Gazette of the Federation on August 11, 2020, through which it was exempted from the application of said Law, the acquisition of goods or provision of health services contracted by agencies and/or entities with international intergovernmental organizations.

On November 11, 2020, the Agreement by which the Constitutional President of the United Mexican States instructs the Ministry of Health and the Federal Commission for Protection against Sanitary Risks was updated to resolve the admissibility of granting applicants the marketing authorization of health supplies in a shorter-term than that mentioned in the equivalence agreements that have been issued to date, as well as to establish shorter terms in those that are issued later.

Derived from the foregoing, the Agreement establishing administrative measures to fast-track the process of the marketing authorization of medicines and other health supplies that come from abroad is published in the Official Gazette of the Federation.

Therefore, the administrative procedures will be streamlined so that the Federal Commission for the Protection against Sanitary Risks resolves the requests for marketing authorization of medicines and other health supplies that come from abroad, in the shortest possible time, always guaranteeing their quality, safety and efficacy, in terms of the applicable legal provisions.

The FIRST article of this agreement contains the following provisions regarding terms:

- A period of five business days to decide on the origin of requests for registration of medicines and health supplies that come from abroad,
- A period of three days to request any documentation that has not been exhibited by the holder, and
- The operation of the affirmative ficta in the event that these deadlines are not observed.
- The immediate reactivation of the deadlines in the event that a requirement is issued to the applicant and the latter responds.

Conclusions

Currently, Government Authorities have been generating an accelerated approval mechanism, recognizing an increasing number of approvals issued by foreign authorities, not only existing to date but also recognized in the future by international agencies. It will be important to monitor the impact that these agreements have on the health supplies available in the public and private sectors, in terms of quality, safety, and efficacy standards and in regard to Industrial Property rights.

Import of products without the need for approval can also have impacts, as this mechanism will likely be used to put pressure on companies in price-related discussions.

“It will be important to monitor the impact that these agreements have on the health supplies available in the public and private sectors.”

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- AGREEMENT establishing administrative measures to accelerate the process of marketing authorization of medicines and other health supplies that come from abroad.

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Parallel import of (re)branded generic medicines: CJEU limits the “room for maneuver”

Ricardo Costa Macedo and Rafael Cunha Jóia of Caiado Guerreiro review a recent case that called into question possible trademark infringement on the rebranding of parallel imported pharmaceuticals.

Picture this: company A, a multinational pharmaceutical, owns a registered trademark in territory X. In this territory, one of the divisions of company A markets a pharmaceutical product under the registered sign. In territory Y, another division commercializes an unbranded version of this product at a significantly lower price. Company B smells an opportunity. They purchase the unbranded version of the product in territory X, import it into territory Y, repackage it, rebrand it under the registered sign, and sell it for a price lower than the one charged by company A, but still with a comfortable profit margin. Does this constitute trademark infringement?

The situation above can be described as parallel importing: importation of a product from an EU Member State to another, with its subsequent distribution occurring outside the distribution networks set up by the manufacturer or its authorized distributors.

> **Does this constitute trademark infringement?**

In November 2022, the European Court of Justice (ECJ) issued four different important decisions relating to parallel imports of branded products within the internal market of the European Union (EU). Two of those decisions concern the parallel imports and rebranding/repackaging of generic medicinal products.

In its decision of November 17, 2022, the ECJ has decided that the trademark proprietors of reference and generic medicines may in principle oppose the rebranding of the parallel imported generic version of the reference medicine.

In this decision a pharmaceutical company commercialized branded reference medicines on both the Dutch and Belgian markets. At the same time, the generic´s division of that pharmaceutical company marketed in Netherlands a generic version of the reference medicine, containing the same active pharmaceutical ingredient under the International Nonproprietary Name (INN). This generic version of the medicine was marketed with the name of the generic´s division company.

Given the different price range practice in Netherlands, a Belgium company started to import the generic product from the Netherlands, repackaging and rebranding the generic version of the medicine. Afterwards, the Dutch generic version would be sold as a reference medicine in Belgium.

The parallel importers thought their actions complied with applicable case law. However, the company selling the branded reference medicines disagreed and sought injunctions before the Brussels Commercial Court.

Said pharmaceutical company won both cases in first instance. The case was then appealed, with the Court of Appeal of Brussels referring, under the preliminary reference procedure, several questions to the ECJ.

The ECJ addressed the question of knowing if it is admissible for a third party to sell medicines, imported from another EU Member State, under the original trademark. In solving the question, the court weighed different interests, with the aim of finding out which factors prevail over others in order to find the best solution.

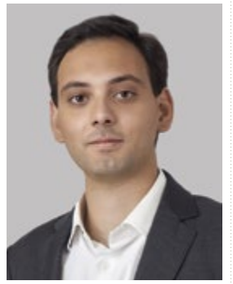
In these types of cases the question always lies in the appropriate balance of interests between the rights of the trademark owner and the principle of unrestricted distribution of pharmaceuticals within the EU.

In this specific case and as a starting point the court remembered that it should be borne in mind that, the registration of a trademark confers on its proprietor exclusive rights which entitle that proprietor to prevent any third party without its consent from using in the course of trade any sign which is identical with that trademark in relation to goods or services which are identical with those for which the trademark was registered. However, EU law does not confer an absolute right on this matter to the trademark proprietor.

It should be considered that a trademark does not entitle the proprietor to prohibit its use in relation to goods that have been put on the market in the European Union under that trademark by the proprietor or if those goods were put on the market with its consent. Certain trademark provisions aim to reconcile the fundamental interest in protecting trademark rights, on the one hand, with the fundamental interest of the free movement of goods within the internal market, on the other hand.

According to settled ECJ case law the *“proprietor of a trademark may legitimately oppose further commercialization in one Member State of a pharmaceutical product bearing its trademark and imported from another Member State, where the importer of that product has repackaged it and reaffixed that trademark to it, unless:”* **(i)** It is established that the use of the trademark rights by the proprietor thereof to oppose the marketing of the relabeled products under that trademark would contribute to the artificial partitioning of the markets between Member States; **(ii)** It is shown that the repackaging cannot affect the original condition of the product inside the packaging; **(iii)** The new packaging states clearly who repackaged the product and the name of the manufacturer; **(iv)** The presentation of the repackaged product is not such as to be liable to damage the reputation of the trademark and of its proprietor; and **(v)** The importer gives notice to the trademark proprietor before the repackaged product is put on sale, and, on demand, supplies it with a specimen of the repackaged product.

Ricardo Costa Macedo



Rafael Cunha Jóia

These five conditions are often called the BMS criteria and if they are not met, then the proprietor trademark may legitimately oppose the commercialization of its pharmaceutical product bearing its trademark in another EU Member State.

In assessing these requirements, one should also consider the meaning of artificial partitioning. According to the ECJ, a pharmaceutical product can contribute to artificial partitioning of the markets if the repackaging is necessary in order to enable the product imported in parallel to be marketed in the importing Member State and the circumstances prevailing at the time of marketing in the importing Member State preclude the medicinal product from being placed on the market in the same packaging as that in which it is marketed in the exporting Member State, thereby making repackaging objectively necessary in order for the medicinal product concerned to be marketed in that Member State by the parallel importer. Finally, artificial partitioning

Résumés

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can be brought if the trademark owner, which markets in different Member States an identical medicinal product under different trademarks, according to the Member State in which the product is marketed, opposes the replacement of the trademark used in the exporting Member State, when that replacement is objectively necessary in order for that medicinal product to be marketed in the importing Member State by the parallel importer (objective necessity criteria).

In the specific case of generic and reference medicines the application of these criteria becomes much more difficult, because in the specific case the medicines involved in parallel trade are generic medicines, whereas the trademarks affixed to the new package corresponds to the reference medicine´s package. Given the similarities between generic and reference medicines, the court focused its decision on knowing if the Generic Products and the Originator Products may be regarded as "identical medicinal products". It noted that "only a medicinal product which is identical in all respects to another medicinal product can be repackaged in new outer packaging bearing the trademark of the other medicinal product". It continued that that "may be the case, in particular, for a reference medicinal product and a generic medicinal product manufactured by the same entity or by economically linked entities and which, in actual fact, constitute one and the same product marketed under two different sets of rules". In this specific case the conditions were all met, given the fact that the generic medicine had been manufactured by economically linked entities and were completely identical in composition, which the ECJ defines with reference to the products' pharmaceutical form and the chemical form of the active substances and their excipients. Given the fact that in this case the generic medicine was manufactured by economically-liked entities, said generic medicine and the reference medicine constitute one and the same product.

However, even considering generic and reference medicine as the same product is not sufficient to allow the rebranding of the generic medicine. The rebranding is only allowed if the aforementioned BMS criteria is met, especially if the objective necessity criteria is not verified, therefore contributing to artificial partitioning Member State markets, thus not allowing the repackaging of a generic medicine.

> **Even considering generic and reference medicine as the same product is not sufficient to allow the rebranding of the generic medicine.**

In this respect, the court turned its analysis to the requirement of the objective necessity saying that parallel imported products can be repackaged provided that repackaging is objectively necessary to market the product in the importing Member State. The court turned to the question of whether it was objectively necessary for a parallel importer to market the generic medicine in Belgium as reference medicine. To answer this question, the court reiterated that parallel traders can, in principle, obtain a parallel import license for generic medicinal products in EU Member States in which these medicines do not have a marketing authorization, but in which their originator counterparts have a marketing authorization. It was therefore considered that where the parallel importer can market the generic medicinal product under its trademark of origin, by adapting the packaging to satisfy the market requirements of the importing country, there is no objective "necessity" to rebrand.

This decision reaffirmed the principle that, proprietors of the trademarks of the reference medicine and of the generic medicine may in principle oppose the rebranding of the parallel imported generic medicine into the reference medicine. However, parallel importers are only allowed to rebrand said generic medicine if the two medicines are identical in all respects and if rebranding is objectively necessary.

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Transparency or ambiguity? Rules for information access in Poland

Dr Maria Jurek, Senior Associate at Bird & Bird, discusses the 2022 resolutions that offers clarification and guidance for accessing documentation relating to medical products.

Despite discussions lasting over a decade and several initiatives taken to increase transparency in the pharmaceutical market's operations, granting appropriate access to information concerning regulated products remains controversial in Poland.

The nature of the problem is one of conflicting interests – some pharmaceutical sector representatives would like to keep all documentation (relating but not limited to the registration dossier, clinical trials or pricing and reimbursement process) confidential, while some entities, the medical community and patients, would welcome greater access to information submitted in connection with marketing medicinal products, foodstuffs for special nutritional purposes or medical devices.

As a result of companies reserving confidentiality of submitted documentation, national regulatory authorities ('NRAs') refuse to provide third parties with information on the data contained in the registration dossier, related to the marketing authorization of a medicinal product, or connected with medical devices' documentation. At the same time, both at the national and EU forums, NRAs advocate for the necessity of increasing access to data to promote greater transparency of information, noting that the current practice of applicants restricting access to data results in more and more information being unavailable to the public. The dualism of the regulators' approach connected with the issue of data transparency raises doubts as to what information, at what stage of proceedings, and on what terms it should be made available.

The year 2022 saw some clarification and guidance on this issue, long awaited by the

INFORMATION ACCESS

“The Council underlined the need to make an active assessment of the legitimacy of making certain information indicated by the applicant confidential.”

Polish market. The Polish Supreme Administrative Court (SAC) issued a judgment[1] stating that access to the register of medicinal products and the documents submitted in authorization proceedings falls under the right of access to public information and should be guaranteed to every entity. Therefore, it is no longer necessary to demonstrate legal interest in accessing the requested documents submitted in the above-mentioned proceedings. Simultaneously, the Transparency Council[2] issued a resolution on improving the transparency of the reimbursement application evaluation process[3]. The Council underlined the need to make an active assessment of the legitimacy of making certain information indicated by the applicant confidential.

The SAC judgment confirmed that the registration dossier (irrespective of the national or centralized procedure) of a medicinal product once it has been authorized for marketing no longer enjoys the presumption of trade secrecy. Moreover, it should be made available as public information. The court also clarified that the national regulator (URPL), as one of the Heads of Medicines Agencies, is bound by EU co-developed acts, including the guidelines adopted by the EMA, which define the information in the registration dossier that may constitute trade secrets. The regulator's refusal to make public information available under the principles set out in the document co-created by the regulator itself violates the principle of loyal cooperation not only towards the European Union, but also towards the other Member States with which the documents in question were adopted jointly. This means that the regulator is violating the principle of loyal cooperation both vertically and horizontally.

According to the commented judgment, the harmonization of pharmaceutical law in the European Union, introduced by Directive 2001/83/EC, makes it necessary to apply all rules concerning the registration of medicinal products uniformly. Therefore the regulator should adhere both to a pro-EU interpretation of the national law and take into account - when considering a request for access to public information – the meaning of the EU regulations directly applicable in Poland, including, for example, Regulation (EU) No. 536/2014 of the European Parliament and of the Council on clinical trials and its provisions stipulating that, e.g., all clinical trials are to be publicly available after a medicinal product has been authorized for marketing.

In turn, the Transparency Council, while justifying the need to provide greater transparency, referred to the principle of openness of public life expressed in the Constitution, also confirmed in the Act on Access to Public Information, according to which every citizen has the right to public information. The Council also pointed out that, according to the Public Finance Act, the management of public funds is public, and undoubtedly, the reimbursement of funds sought by the applicants are such public funds. The NRAs perform public tasks, participating in the implementation of the constitutionally guaranteed citizens' rights to health care, and are therefore entities obliged to provide public information.

In setting out the principles for assessing the secrecy of specific information, the Transparency Council indicated that the decisive element is not the subjective will of the entrepreneur to grant a confidentiality clause to a given piece of information, but the necessity to assess the entrepreneur's secrecy in an objective manner, detached from the will of the entrepreneur in question. Such secrecy cannot be subjectivized only based on statements made by the entrepreneur, who - by its very nature - will not be interested in disclosing any facts from the sphere of its business activity. At the same time, undisclosed, confidential, and secure information must be of a technical, technological, organizational, or other nature having economic value. Also importantly, the restriction on the availability of public information on the grounds of trade secrecy is an exception and therefore cannot be interpreted broadly. The existence of a trade secret must in any case be real and beyond doubt.

The Transparency Council stated that there are no grounds for restricting access to the following data:

- Data on the efficacy and/or safety of the medicinal product, including but not limited to data from unpublished clinical trial results. The applicant should decide whether to disclose unpublished data or to wait until the results of the trial are published before submitting the application. The principle of completeness of data publication (no blacking out of selective information) should also apply.
- Indications for which a medicinal product (but also a foodstuff for particular nutritional uses or a medical device) is to be reimbursed. Determining the indication is as important as determining the product itself. It is the medical technology in question, i.e., the medicinal product for a particular indication, that is assessed. Making the indication for use of the medicine secret renders the remaining, non-confidential part of the document incomplete and worthless. The public interest far outweighs the need for secrecy. Similarly, it is unjustified from the point of view of the public interest to try to make secret the content of a proposed drug program, which is in fact aimed at the public, who should have knowledge of the measures proposed under the program. Moreover, drug programs, as publicly funded healthcare benefits, developed in cooperation with the Ministry of Health, become official documents, which prejudges the lack of grounds for excluding the availability of their content.
- Price data, including risk-sharing instruments (RSS). All derived data calculated without taking RSS into account, such as, the Incremental Cost-Effectiveness Ratio (ICER) without RSS or the expenditure of the National Health Service without RSS should be made available. There is no justification for the public not to be able to know whether an applicant has proposed a risk-sharing instrument. The very fact that a risk-sharing instrument has been proposed should have been public.
- Information on the reimbursement of the assessed technology in other countries. This is because such data is publicly available in the country to which they refer. One of the conditions for information to be considered a trade secret is that it must be inaccessible and kept confidential. This condition is not fulfilled in this case.

At the same time, the Transparency Council pointed out that information relating directly to the type of risk-sharing instrument (RSS) and prices, as well as the data on the basis of which the above can be calculated, should be kept confidential.

It is irrelevant that the SAC judgment relates to registration dossiers and the resolution of the Transparency Council refers to improving the transparency of the process of evaluating reimbursement applications. Both should be considered complimentary and are an invaluable source of guidance for entities wishing to reserve the confidentiality of the documents they submit and for entities wishing to gain access to the documentation.

When submitting documentation to the regulator, it is important that the applicant should justify why the information deserves to be protected as a trade secret. When justifying the economic value of the information, it should be indicated that the information has an economic value because, for example, it shows the company's experience or relates to the commercial strategy of the company concerned or its business relationships. It is worth explaining how access to the information or document in question could pose a concrete and real threat to the interest of the business concerned.

Based on this new guidance from the SAC and the Transparency Council, theoretically, obtaining information should now become much easier. But from the practical perspective, a change in the regulators' procedures and mindset is still needed in this respect.

“The restriction on the availability of public information on the grounds of trade secrecy is an exception and therefore cannot be interpreted broadly.”

1 The judgement of 23 February 2022, case No. III OSK 1691/21.

2 The Transparency Council plays a consultative and advisory role to the President of the Agency For Health Technology Assessment and Tariff System (AOTMiT). Its members are appointed by the Minister of Health and it is composed of representatives of the Minister of Health, the President of the National Health Fund, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, the Patient Ombudsman as well as 10 experts with experience, recognised achievements and at least a doctorate in medicine or related sciences or in other fields relevant to the assessment of healthcare services, including ethics.

3 The Transparency Council Resolution No. 8/2022 available at the website: https://www.aotm.gov.pl/aktualnosci/najnowsze/uchwala-rady-przejrzystosci-dot-ograniczenia-liczby-informacji-okreslanych-jako-stanowiacych-tajemnice-przedsiebiorstwa/

Dr Maria Jurek

Résumé

Dr Maria Jurek is a Senior Associate in the Intellectual Property practice based in Warsaw. Her main areas of practice focuses on the enforcement of patents and other IP rights, advertising and promotion of healthcare products and regulatory matters. Combining experience from both private and public sectors, she has a great understanding of the pharmaceutical industry and competition matters.

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Life science due diligence transactions: key considerations to manage risks and reap rewards

Troy Groetken, Intellectual Property Attorney at McAndrews, Held & Malloy, details the importance of carrying out high-value due diligence and highlights key areas to inspect for issues.

In every due diligence involving a life science transaction, the parties (a.k.a. "buyer/licensee/collaborator/partner" and "seller/licensor/collaborator/other partner") need to identify various risks and obstacles that must be addressed. For example, both parties will want to understand key topics such as valuation modeling, valuation timing, intellectual property, the asset transfer process, representations and warranties, recent case law and governmental considerations (e.g., current TRIPS waiver concerns and possible extensions thereto), and more. The due diligence process allows both parties to review each of these topics, among others, and assess potential risks, deal makers and deal breakers, as well as potential alternative approaches that may be needed to overcome obstacles that are uncovered by the due diligence.

Troy Groetken

Résumé

Troy Groetken has more than 25 years of intellectual property (IP) legal experience and more than 25 years of technical experience in the pharmaceutical, biotechnological, and chemical fields. He is recognized in the IAM Patent 1000: The World's Leading Patent Professionals, and has been listed as one of the Best Lawyers in America since 2012. As a registered U.S. patent attorney, Groetken is known globally as a 'go-to' intellectual property attorney for Fortune 500 clients and others on complex and cutting-edge IP matters, and on strategic global patent portfolio development, implementation, and enforcement. He also advises upon and institutes multi-level, front-end and back-end diligence and licensing programs coordinated with a client-focused business modeling approach. In addition, he assists clients with advanced acquisition, divestiture, and platform-positioning transactions designed to generate institutional growth and increased business valuations.

One size due diligence does not fit all

It should be noted that every deal (acquisition, divestiture, license, joint collaboration, joint development, etc.) has its own nuances. Thus, there is no "one-size-fits-all" due diligence. Rather, each deal requires that a potential buyer and seller strategically consider the scale or extent of the due diligence needed.

There are many variables to consider when properly scaling the due diligence team and process:

- The size of the deal
- The type of deal
- The parties involved (e.g., buyer, seller, and other third parties)
- Additional partners (e.g., manufacturing, distribution, commercialization, banking entities, etc.)
- The complexity of the underlying technology involved in the transaction
- The complexity of the transaction itself
- The intellectual property involved
- The business goals of the buyer and seller
- Timing

Who is doing the "due"

Initially, for either party, the due diligence team may be an internal team tasked to assess key variables such as the technology involved, the initial value of that technology, and the key terms the parties may require for the deal to make sense for the transaction to move forward. Thus, each side's due diligence team is typically limited to key members of the C-suite and supportive business, research and development, regulatory, and legal personnel. If a term sheet can be completed by the parties, then the due diligence team will grow to undertake the more advanced steps of the diligence process. The scaling of the diligence team (both internally and externally) is fluid. As various needs arise, additional personnel are brought into the transaction to ensure that their skill sets are utilized at the right time and place.

Go for the goal

The goal of the due diligence review is to allow each party of the transaction to become aware of any risks or challenges of the transaction. For example, in an acquisition-based transaction, the seller of the potential assets will want to consider the key pieces of information that a buyer would want to review. The seller may wish to provide the buyer with key manufacturing, biological deposit, clinical, and regulatory information regarding its life science product/asset. The seller may also wish to provide to the buyer access and review of key ownership and intellectual property information that supports and protects the potential assets to be purchased/transferred. The seller might like to provide the buyer with any prior transactional materials involving the asset(s) to be transferred so that the impact of those transactions can be considered during the diligence process and beyond. In addition, the seller may have already completed various financial modeling that impacts and/or supports its valuation position regarding the potential asset to be acquired. The seller may therefore want to provide a financial support package to the buyer so that the buyer may better understand the seller's valuation assessment. Such information also allows the buyer to compare that valuation with its own.

> **The goal of the due diligence review is to allow each party of the transaction to become aware of any risks or challenges of the transaction.**

The illustrative steps of a hypothetical due diligence for an acquisition, presented above, demonstrate how the due diligence process supports corporate decision-making and ultimately, helps them reach their business goals. This critical review process allows each party, and its corporate teams, to truly communicate better even though they are involved in an arms-length business transaction. It ensures that each party understands and appreciates the goals the other is trying to achieve in the potential transaction, the risks (development, manufacturing, clinical, commercialization, etc.) of the technology to be transferred as an asset, the regulatory climate for that asset, the strengths or weaknesses (short- and long-term) of the intellectual property that supports/protects that asset, and finally the value of the asset (on a domestic or global basis) to be realized should the transaction be completed.

The value of uncovering issues in ownership, IP, valuation, and more

As with any due diligence, a number of issues may come up. Some examples can include confidentiality controls, proper set-up and usage of a "clean room" or "data room," party communication breakdown procedures, valuation position discrepancies or challenges, past transactional encumbrances on the asset(s) in question, agreement language disputes, intellectual property challenges, regulatory challenges, biological deposit difficulties, among many others. For purposes of brevity, a few key pitfall examples to avoid shall be discussed here.

Those key examples include ownership, intellectual property, valuation modeling, and communication breakdowns. Again, these particular topics will be viewed in connection with a hypothetical acquisition-based due diligence process.

• **Ownership**

A seller must consider both an internal and external ownership review of the asset to be offered for purchase. Those reviews can determine if there are any previous transactions that may impact the ownership of the asset or its sale/transfer to another. For example, if the asset to be transferred has patent coverage, have assignments from all of the inventors of that asset been completed and recorded? If not, what is the impact of that outcome? Does that outstanding inventor have an obligation to assign via an employment agreement? A seller's carefully performed due diligence – whether internally or externally – can uncover such a pitfall before a conversation with a buyer ever begins. The diligence process can also assist in potential solutions to the issue to ensure that the ownership challenge is addressed and remedied. Further, no one likes a last-minute "deal breaker" to appear that could have been assessed and addressed by the diligence process. Moreover, it should be appreciated that due diligence also allows the seller to consider future proactive steps. Having learned of an asset ownership challenge during early diligence, the seller will have the opportunity to improve assignment protocols and procedures to prevent future pitfalls.

• **IP**

As for the buyer, as part of its due diligence process they should always consider asking if the seller has any opinions of counsel (e.g., freedom to operate, invalidity, white space analysis, and the like) that it could share in a confidential manner that involves the asset(s) to be potentially purchased. Additionally, the buyer should consider inquiring of the seller as to any current or past assertions of infringement by a third party regarding the potential asset(s) to be purchased that can be shared and reviewed. The same holds true for any past settlement agreements that involve the asset(s). Lastly, the buyer should also consider inquiring with the seller if there are any internal communications or external opinions/assessments of counsel with respect to the patent eligibility of the asset(s) to be purchased. This is especially important to the life science space in light of the current case law climate. Those assessments by a seller may impact whether the deal goes forward, if the valuation picture should change, and the capacity for intellectual property protection (current and in the future) of the asset to be potentially acquired. Such analyses also allow the buyer to consider those positions of the seller and to have its own internal personnel and external counsel consider if any challenges presented can be overcome or mitigated, or if they change the entire dynamics of the deal envisaged.

> **A seller must consider both an internal and external ownership review of the asset to be offered for purchase.**

• **Valuation**

What do the parties do if their valuation models differ greatly? The answer: address this contingency upfront in the parties' term sheet and ensure that term sheet is executed. Typically, the parties can set forth terms and conditions as to the types of models either can use to propose their valuation. The parties can also set forth the terms and conditions as to the "data" that will be used to generate the potentially opposing valuation models for review by each side. The parties can further set forth basic terms and conditions for when the models may have disparity.

• **Document Management**

Tracking extreme levels of detail is obviously critical during the due diligence process. For example, a party may provide a list of documents and other materials that it would like to review to the other party. The second party may provide some, but not all, of the documents or materials requested. A thorough due diligence will carefully catalogue what documents and materials have been reviewed, and which ones have not. This ensures that various potentially critical documents and materials don't "fall through the cracks" as the parties discuss the overall transaction. In any life science transaction, the sheer amount of data, documents, and materials to be reviewed can be voluminous. A carefully planned and set-up due diligence process allows both parties to ensure that physical or digital documents and materials can be properly accounted for, reviewed in a controlled and confidential manner (e.g., the use of a "clean room"), properly returned, and used to provide greater discussion and transparency for the contemplated transaction.

Assessing the scope and magnitude of the subject information allows the requesting party to consider various alternatives, terms, conditions, and approaches, as well as whether it chooses to continue pursuit of the deal. At a minimum, additional representations, warranties, indemnifications, and other provisions should be envisaged by the party requesting the information in order to protect that party's interests should the transaction go forward.

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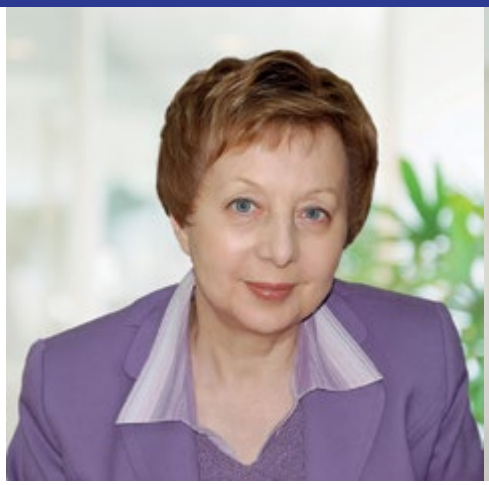

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