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Conflicting applications to claimed designs

John XIA, Partner and Patent Attorney at Corner Stone & Partners, questions whether an invention or utility model patent application can serve as a conflicting application to a claimed design.

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Editor's
welcome



Can invention or utility model patent applications serve as conflicting applications to a claimed design? A question our cover story addresses in the pursuit to assess the current justice and fairness of the law, taking example from a case that compared drawings of a 'joist' in a patent application for use in relation to a ceramic kiln.

Our guest interview this issue is with Emily O'Neill, GC UK at Deminor, who reveals practical advice for trade secret validity, the growing pressures in-house counsel are facing, and key considerations for a strong IP portfolio.

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Key considerations for a strong IP portfolio.
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This issue also provides: in-depth analysis of the complexities surrounding patenting nanotechnology; a review of the advantages and drawbacks of the compulsory licensing system in India; key findings revealed from Clarivate's latest report on patent renewal trends; a look at potential challenges and the welcome benefits of developing technologies for IP; speculation about the dramatic

increase in bioinformatic-related patents; how the foreign filing license system manages cross-border collaborations among inventors from different countries for patent protection in China; and much more!

This issue's *Women in IP Leadership* segment features Dominique Hussey, Vice Chair & Toronto Managing Partner at Bennett Jones LLP, and Natalia Vladymyrova, Managing Partner at Prima Veritas. Contact us to find out how you can support the segment.

Enjoy the issue!

Faye Waterford
Faye Waterford, Editor

Mission statement

The Patent 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. All of this and the top news stories are brought to your desk via the printed magazine or the website www.patentlawyermagazine.com

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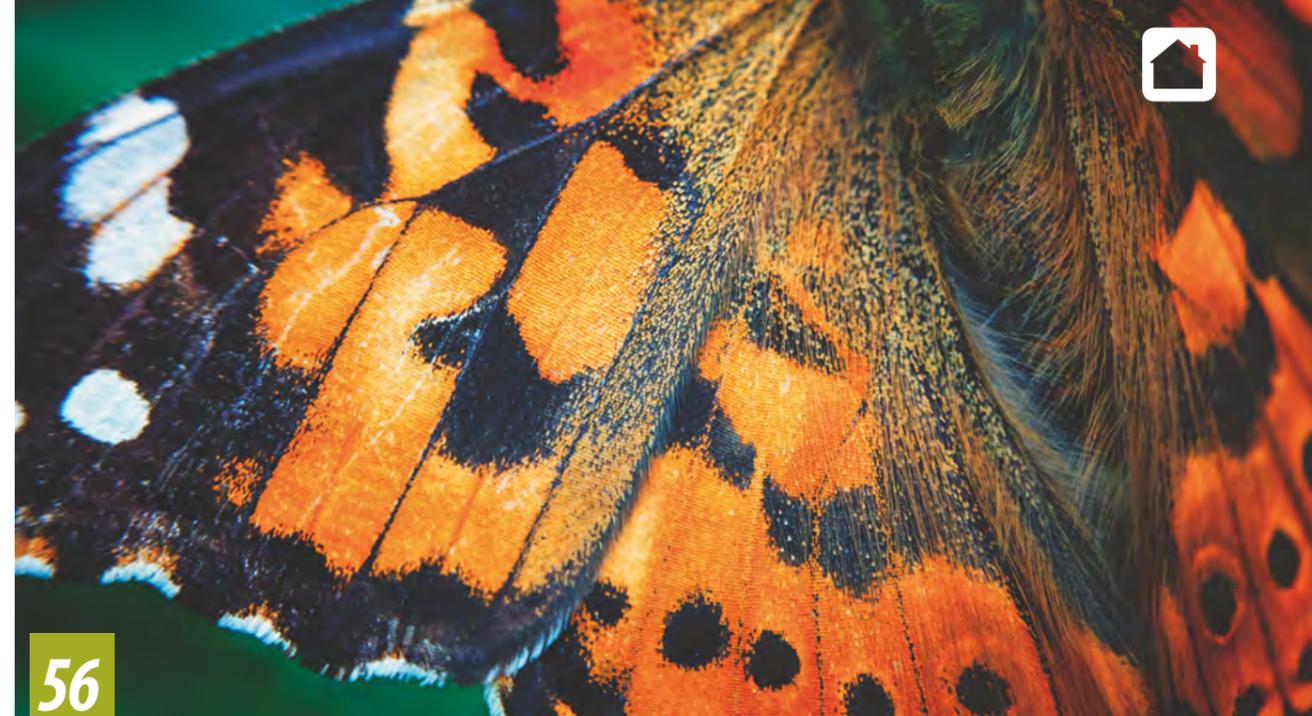
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In a career spanning over four decades, Pravin has emerged as an IP trailblazer having strengthened India's IP jurisprudence with a practice encompassing all areas of IP litigation including patents, copyright, design, trademarks, enforcement and dispute resolution.



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Conflicting applications to claimed designs

John XIA, Partner and Patent Attorney at Corner Stone & Partners, questions whether an invention or utility model patent application can serve as a conflicting application to a claimed design.

Definition of conflicting application

Article 23.1 of the Patent Law of the PRC provides that *"Any design for which a patent right is to be granted shall not be a prior design, and no entity or individual has filed a patent application for the identical design with the patent administration department under the State Council before the filing date and the content of the application is disclosed in patent documents published after the filing date."*

This provision is called conflicting application in practice, which means that an earlier-filed and



John XIA

Résumé

John XIA, Partner and Patent Attorney John spent the first several years of his career in research at the Academy of Science. For the past 20 years John has devoted his attention to the practice of intellectual property law. Certified by All China Patent Attorneys Associations as one of the first patent attorneys in the PRC. John has acquired a deep understanding of integrated circuit layout and design and new plant varieties. His practice includes patent prosecution, appeal, invalidation, and administrative litigation, as well as counseling clients on trademark and copyright matters.



Credit: Wrestock

The Patent Lawyer would like to thank the Editorial Board for their time and support.



later-published application constitutes the conflicting application to the claimed design that is later filed. Meanwhile, under the existing patent law of China, it is a prerequisite that a conflicting application to a claimed design must be an application for an identical design; in other words, an application for an invention or utility model cannot constitute a conflicting application to a claimed design, notwithstanding it is earlier filed and later published.

The Guidelines for Patent Examination (2010) says the following about conflicting application: "In determining the novelty of inventions or utility models, for a patent application for invention or utility model filed on a date, the patent application documents filed by any entity or individual with the patent administration department for the identical invention or utility model before the filing date and the patent documents published after the filing date (including the filing date) are prejudicial to the novelty of the patent application of the filing date. For the sake of simplicity, when determining novelty, the patent application that could be prejudicial to the novelty is called conflicting application." However, the Guidelines fail to specify whether an application for an invention patent or utility model patent can constitute a conflicting application to a claimed design.

A discussion about whether an application for invention or utility model patent can serve as the conflicting application to a claimed design

As to whether published drawings attached to utility models and inventions constitute a conflicting application to a claimed design, both legal precedents and popular opinion agree that pursuant to the provisions of China's patent law, only an application for a design patent can constitute a conflicting application to a claimed design. Unfortunately, however, the existing provisions for conflicting applications may produce unexpected results in some cases and even may affect the justice and fairness of the law.

We have handled a case of a request for invalidation of a design patent in China as follows:

In the No. 6W117740 case of a request for patent invalidation at China National Intellectual Property Administration (CNIPA), the requester put in a request for invalidation of the No. 201530409679.5 design patent ("the patent at issue"), which was filed on October 22, 2015. Evidence 3 cited was used as the conflicting application to the patent at issue. Evidence 3 is the No. 201520809261.8 utility model patent of China which was filed on

“**Both legal precedents and popular opinion agree that pursuant to the provisions of China's patent law, only an application for a design patent can constitute a conflicting application to a claimed design.**”

October 19, 2015, and published on March 9, 2016. Evidence 3 meets the condition that a conflicting application be earlier-filed and later-published. However, Evidence 3 is a patent for a utility model, which does not accord with "the identical design" set forth in Article 23.1 of China's patent law.

In this regard, CNIPA says in the Decision on Examination of Request for Patent Invalidation (No. 50938 Decision): "Evidence 3 is a document of invention patent in China, which was filed before the filing date of the patent at issue and published after the filing date of the patent at issue. Pursuant to Article 23.1 of the Patent Law and Section 4.5.5 of the Guidelines for Patent Examination, a conflicting application set forth in Article 23.1 of the Patent Law should be a patent application for the identical design. A patent for an invention or utility model differs from a patent for the design in type, and thus an application for an invention patent or utility model patent cannot serve as a conflicting application to a claimed design. Therefore, Evidence 3 cannot be used as the document of conflicting application to the patent at issue."

Although the said decision conforms to the provisions of China's patent law and the guidelines for patent examination, as seen from the following drawings, Evidence 3, notwithstanding a patent for utility model, can effectively serve as the conflicting application to the patent at issue.

The name of the design for the patent at issue is "joist". According to the disclosed brief description of the design, this product is used for the kiln equipment or kiln cars for ceramic tunnel kilns and it belongs to the accessories or fittings of kiln equipment for ceramic kilns. Figure 1 is a drawing of the patent at issue, which is the cross section of Design 1 of the design. As the joist is a long profile, its cross section contains the most important features of the design.

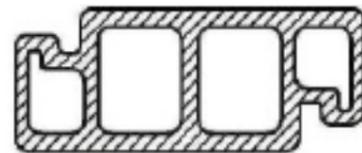


Figure 1

Evidence 3 is the disclosed description of the No. 201520809261.8 utility model patent of China and the name of the patent is an improved kiln equipment or kiln car used for the multifunctional frame structure for firing ceramic washbasins. Figure 10 (Figure 2 below) in the drawing attached to the description also presents the cross section of a joist. It is seen from the description that the joist in Evidence 3 is identical in function and used with the joist in the design for the patent at issue. They both are used for the kiln equipment

or kiln cars for ceramic tunnel kilns to support the ceramics being fired, belonging to the accessories or fittings of kiln equipment for ceramic kilns. Therefore, the joist disclosed in Evidence 3 is identical in type with the joist disclosed in the patent at issue. Moreover, the drawing attached to the description of Evidence 3 shows that the joist disclosed in Evidence 3 is also a long profile and the highlight of its design is also the cross section of the product.

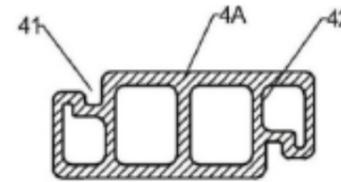


Figure 2

A comparison between Figure 1 and Figure 2 easily points to the conclusion that the joist in Evidence 3 and Design 1 of the design for the patent at issue have identical design; that is, the joist in Evidence 3 had been filed before the filing date of the patent at issue and was disclosed in the patent documents published after the filing date of the patent at issue. Evidence 3 meets the condition for serving as the conflicting application to the patent at issue. Of course, CNIPA has sufficient grounds for not accepting Evidence 3 as the conflicting application pursuant to Article 23.1 of China's patent law, for Evidence 3 is a patent for a utility model while the patent at issue is one for design.

The Higher People's Court of China's Jiangsu Province made a similar decision in its No.786 case in 2020, a case similar to this one, deciding that the application for a utility model patent cannot serve as the conflicting application to a claimed design. The court held that the conflicting application which could be prejudicial to the novelty of the design should be an application for "the identical design". Notwithstanding the drawing attached to the earlier-filed application for the utility model patent may be identical to the drawing in the design which is later filed, the identical drawing in the earlier-filed utility model cannot be sufficient grounds for the conclusion that a patent application for "the identical design" has been filed because the object to be protected for a utility model is the technical solution set forth in the claims, not the design shown in the drawing attached.

We are of the belief that it is worthwhile to discuss the opinion that the application for a utility model patent cannot serve as a conflicting application to a claimed design. What on earth can be called "the identical design"? Just like the aforesaid joist, the drawing in Evidence 3 is

“**Deciding that the application for a utility model patent cannot serve as the conflicting application to a claimed design.**”

identical to the drawing of the patent at issue in use, function and appearance. The only difference between them lies in the types of patent application, viz. utility model and design. However, the difference in types does not necessarily mean that they are not "the identical design". The CNIPA's decision will open up the possibility that when the patentee of Evidence 3 adopts the technical solution as the best way of exploiting their utility model patent, the joist in it will run the risk of infringing the patent at issue. This is blatantly unfair to Evidence 3 which was earlier filed. The circumstances contradict the logic of legal justice; in other words, the existing laws and regulations concerned are loose in some ways.

Our opinion

The analysis of the case above indicates that the existing patent law of China is loose in whether an application for invention or utility model patent can institute the conflicting application to a claimed design and thus needs to be amended properly to obey the logic of justice and fairness of the law. We are of the opinion that an application for an invention or utility model patent can constitute a conflicting application to a claimed design where the drawing attached to the description reveals the highlights of the design.

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An interview with Emily O'Neill, General Counsel UK at Deminor

Emily sits down with *The Patent Lawyer* to discuss practical advice for trade secret validity, the growing pressures in-house counsel are facing, and key considerations for a strong IP portfolio.

Can you introduce yourself, Deminor and your role as General Counsel?

Deminor is a litigation funder. We provide access to justice for companies by funding the costs and legal fees for litigation, whilst taking a share of the damages, enabling companies to go forward to obtain money from their IP without impacting their balance sheet. The company name *Deminor* means *Defense of the Minority* - we are involved in a lot of David and Goliath-type battles for small and medium-sized tech companies that have great IP and whose inventions have been taken by bigger organizations.

I joined Deminor three years ago. Before my time at Deminor, I was the Chief Counsel for IP and Litigation for seven years at an FSTE 110 company which made scientific instruments. It had operations in 32 jurisdictions, for which I managed IP policy and process, as well as litigation above the threshold at the group level. Prior to that, I had spent six years in private practice in the IP team at Bird & Bird, London, following my time as a trainee at Shoosmiths in Reading. During my time as a trainee, I completed a six month secondment at Mercedes UK, where I worked on the high-performance engines business, preparing their contracts for the Formula One season. At that time, they were a supplier of engines for McLaren, so we had some quite exciting projects.

I was the first employee in the UK for Deminor, so going from a big multinational company to being employee number one was really exciting. I set up the infrastructure for the UK office from a business perspective. I set up everything from our benefits to our insurance, and I have been part of the three office moves in three years. I was also responsible for hiring our team. There are nine of us now working to establish our name within the UK. So, there has been a business



Emily O'Neill

aspect, a marketing aspect, and a legal perspective in reviewing the cases we've received for funding, looking at cases and evaluating them. It has been a really exciting three years for me.

What attracted you to the role at Deminor?

I was engaged in my previous role when I saw the Deminor opportunity come up. At the time, I had broad responsibilities across different business units and worked with different companies. I had some responsibility for trade compliance at one stage, and I was a driven divisional General Counsel within that group.



The moral fibre, the ethics of the organization, and what it means to do the role are important to me. Even the meaning behind the name, *Defense of the Minority*, spoke to me.



Credit: LockieCurrie

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but the elements I enjoyed most about my role were litigation and IP.

Litigation for a big multinational is always unwelcome news, so, as Head of Litigation, I was always the least popular person going to any site! The Deminor opportunity offered scope to combine the areas that I enjoyed while keeping a broader perspective and taking on more of a business role. I was excited to start something new, so I began researching the industry. I hadn't had a huge amount of experience with funding, but I saw the exponential growth within the industry and that Deminor was already established with a track record. Although it was going to be a new scale-up environment, I was joining an established organization. Also, the moral fibre, the ethics of the organization, and what it means to do the role are important to me. Even the meaning behind the name, *Defense of the Minority*, spoke to me. I was coming from an organization with a core value of absolute integrity, and it was really important to me to maintain that.

The interactions between teams were much smaller at that time, and joining during lockdown meant that I wasn't meeting people face to face, although I still felt that I had really good connections and relationships with the rest of the Deminor team across the different jurisdictions. We are all working towards that common purpose which makes it a great environment to work in, and that still excites me every day.

What do you define as the practical steps for implementing trade secrets?

I think trade secrets are one of the trickier IP rights to identify and manage. That's because it could be something huge and obvious to the company, like the Coca-Cola formula, or it could be something smaller, like some settings on a piece of equipment which produces something in a specific way.

Implementation begins with having the organization understand what a trade secret is because until you've identified them, you can't protect them. Identification is the first step, while the second step is taking reasonable steps to protect a trade secret. I have a lot of conversations with engineers and in-house personnel who are deciding whether to protect their IP and are considering protection via patent or trade secret. Often the discussion relates to a stretched budget, they say they don't want to invest in a patent, so opt to protect via trade secret. Comments like this tell me that they don't understand or fully appreciate the cost of maintaining a trade secret.

Taking, and being able to demonstrate reasonable steps to keep a trade secret a secret

“ For me, moving from a law firm where I was the one generating the money, to an in-house team where I wasn't and instead had to demonstrate the value of the legal team, created pressure in itself. ”

is what will make that trade secret enforceable. For example, if you've identified something internal to your business that has value and is not publicly available, you need to look at your wider business and identify who *really* needs to have access to it. Then, you need to put in place the physical security – is it a piece of equipment, is it written down in some format, is the data rights management in place to prevent the trade secret being transferred out? Limiting the number of people that have access physically and electronically to the trade secret and demonstrating that in your policy and process are vital steps to proving validity. When looking at a case where a trade secret has been leaked or lost to assess whether we can recover damages, we need to be able to show that the trade secret was there and that reasonable steps were taken to keep that secret.

Maintaining a trade secret is not the responsibility of just one person. It is something that involves different teams at different times: IT for information security, facilities for building security, and HR for employee management. If an employee with access to a trade secret is going to leave, and potentially go to a competitor, it needs to be made known that that's happening. Managers need to know who has access to what. They also need to inform the relevant departments that said person with access to sensitive information is going to a competitor so that the organization can react and take particular steps.

Do you think economic uncertainty increases pressures on in-house counsel? If so, how?

I think it can have a massive impact. For me, moving from a law firm where I was the one generating the money, to an in-house team where I wasn't and instead had to demonstrate the value of the legal team, created pressure in itself. In a time of economic uncertainty, it's important that people understand what legal does and the value you're able to bring.

Additionally, there's not going to be the budget for new shiny tools which could potentially shortcut or make things more streamlined, so being creative with the tools that you do have becomes important. We had a lot of schedules and lists of IP in Excel documents, we used SharePoint, and we used the tools that were already available. We sent out training on the general LMS system which was in place in the company, and we used Forms to send out questionnaires to test people's knowledge.

Being agile and adapting to the budget that you do have, and working in creative ways, are important. How can you achieve the objectives? How can you move the majority of the organization



Credit: matejmo

forward with the tools that are available now?

Each year, our budget started at zero, and we had to justify any budget allocation that was required. There wasn't an available budget for new legal software or for a specific trade secret tool for the organization. Often in companies, each business unit has its own budget and its own objectives, and those things don't always overlay with legal priorities. You need to learn to feed into the business in a positive way without causing disruption while maintaining the objective to safeguard and identify the IP and manage litigation in an effective way.

What elements do you believe are integral to a strong IP strategy for protecting assets?

There are three pillars to this. Identification is one – does everybody know what they should be looking for, what can be covered and what the process for reporting that is? Innovation will not be protected if it's within the engineer's head, in their notebook or on the bench, it needs to be reported to the IP manager or the legal counsel. Then, there needs to be a discussion to determine the best way to protect the innovation, linking in with the commercial team, and how it will be used commercially: how and when will it be rolled out? Is it an internal tool, or is it going to be something that's incorporated into products? It's important to align the commercial and marketing strategy with the protection strategy.

Once protected, there need to be consistent reviews to avoid paying renewal fees for particular projects that may be end of life, or for

“ It's important to align the commercial and marketing strategy with the protection strategy. ”

particular technologies that have been superseded for which protection isn't so important anymore. Understanding the value in what you already have protected, and knowing how to manage it is integral to a strong IP strategy. Then, looking more creatively, is there a monetization appetite? Could you extract some value from the IP? Are there other ways that you can protect more broadly so that you can have a licensing regime? This comes back to how value can be added to the business via the legal team.

What aspect of asset protection do you find is often overlooked? And how can companies work to avoid this?

I think confidential information and, to an extent, trade secrets. Obviously, trade secrets are more valuable, but there's a lot of valuable confidential information within businesses and not a huge amount of time and money spent thinking about that. The sensitivity labels within the Microsoft Office Suite are available to everybody, and it's an easy way to keep confidentiality front of mind.

I was part of rolling out document labelling and marking in my previous organization. At Deminor, we have the same process so that the value is really considered in every document that we create, receive, or review. We assess how it should be treated before applying the relevant marking.

I think keeping IP and IP protection at front of mind for people day-to-day by integrating processes into what they're doing, rather than having a separate step, is effective for preventing



oversight. In my previous role, we looked at information holistically: we had GDPR projects, we had market information and sensitive IP information, and then we overlaid that with cybersecurity and information protection measures. From a technical standpoint, this meant that people would have to partition their minds into different ways and be looking at information under four different policies. To simplify this we took a holistic approach to protecting information by preparing a single policy. The policy explains how each of the categories could be protected across the different disciplines so that people would look at a piece of information and easily determine how it should be dealt with.

I think that, generally, patentable inventions and the like are treated with more care and thought than general information. Although, even then, there can be an oversight because technical people may assume protection is obvious, but it may not be for those that aren't experienced. Regular discussions about what is being developed are necessary so that assessments can be made as to whether to seek protection or implement steps to keep internally and treat it as confidential information or a trade secret.

How can the use of outside counsel strengthen a company's IP portfolio? And are there risks when involving outside counsel?

The role of outside counsel is quite different to an in-house counsel within the business. Outside counsel has very specialist expertise in their jurisdiction, which is very valuable when, as an in-house person, you're dealing with a number of jurisdictions and can gain specific information from your outside counsel.

We relied on our law firms for a lot of training. They were happy to come in and deliver training to the businesspeople, which really helped with the bandwidth within our small legal team.

I think in terms of strengthening the portfolio, it's really important to work with counsel that understands the business. We had patent attorneys who were excellent at understanding the products, they had been proactive in understanding the goals, objectives and where the business was going. As a result, they could then add and suggest different things that we needed to think about including inventions within the patent portfolio.

Good counsel can add value in terms of networking and support as well. When going from a big team within a law firm to an in-house team, which is typically smaller, there are fewer brains to pick. Having a strong relationship with your outside counsel, whereby you can pick up the phone and ask a quick question knowing that they're not going to be immediately starting

“**Having a strong relationship with your outside counsel, whereby you can pick up the phone and ask a quick question knowing that they're not going to be immediately starting the clock, is so valuable.**”

the clock, is so valuable. I think it's that relationship which makes you reinstruct those counsel and build long-term relationships.

Is there a case that comes to mind that demonstrates the risks of failing to protect assets correctly?

We had a few examples, some in China and some outside, where we would have employees leave and either go to competitors or set up in competition. There was one example where an employee left and set up literally across the road producing what we said is our product. The difficulty was that there was no patent protection, so we were down to trade secrets. We knew that the product had been produced by the method because it had certain attributes which our product had that no other product on the market had. The person who left wasn't a person who should have had access to the information about the production method. This made it difficult to restrain the use because they had access to information that we say is a trade secret, which meant reasonable steps were not in place for it to qualify as a trade secret.

It's very difficult to enforce in these circumstances. This is a particular risk for larger organizations which grow through acquisition as the newly acquired company, which is also often smaller, may not have had the same processes and procedures or legal support in place. Risks can crystallize, particularly if the smaller organization, for example, has unknowingly been using a third party's IP but, until acquisition, the third party may not have been too interested because it was only a small organization, then suddenly they're part of a big group, there are deep pockets, and there's a target.

It's vital to protect assets correctly through education. Having policies and processes. Supporting businesspeople to ask questions about best practices, all before it gets to a situation where you're crossing a street and buying your own product from someone else.

What has been your greatest learning so far at Deminor?

It's been to keep an open mind and have confidence that I can achieve anything. A lot of the things I've had to do at Deminor were not part of my skill set. Initially, there were things that I hadn't really foreseen, but as different challenges arose, having that problem-solving mindset enabled me to approach each challenge knowing where we need to get to. That's also been one of the more rewarding things, seeing the movement in the company and experiencing the growth. Anyone can achieve anything if they put their mind to it and give it enough time.

Revolutionizing IP protection: navigating the convergence of artificial intelligence, interoperability, and blockchain

Matthew R. Carey of Marshall, Gerstein & Borun reviews the potential challenges and the welcome benefits of developing technologies for IP.

In today's rapidly evolving technological landscape, groundbreaking innovations such as artificial intelligence (AI), interoperability and the blockchain are transforming the way we protect intellectual property (IP). As these technologies permeate various industries and reshape the way we approach traditional IP rights and enforcement, it is crucial to understand their impact on, and abilities to improve, our existing legal frameworks.

This article delves into the multifaceted effects of AI, interoperability and the blockchain on IP protection, examining the implications for stakeholders, users and legal practitioners as they navigate the complexities of this emerging digital ecosystem.

AI While AI has revolutionized many industries, it also has the potential to significantly impact the ways

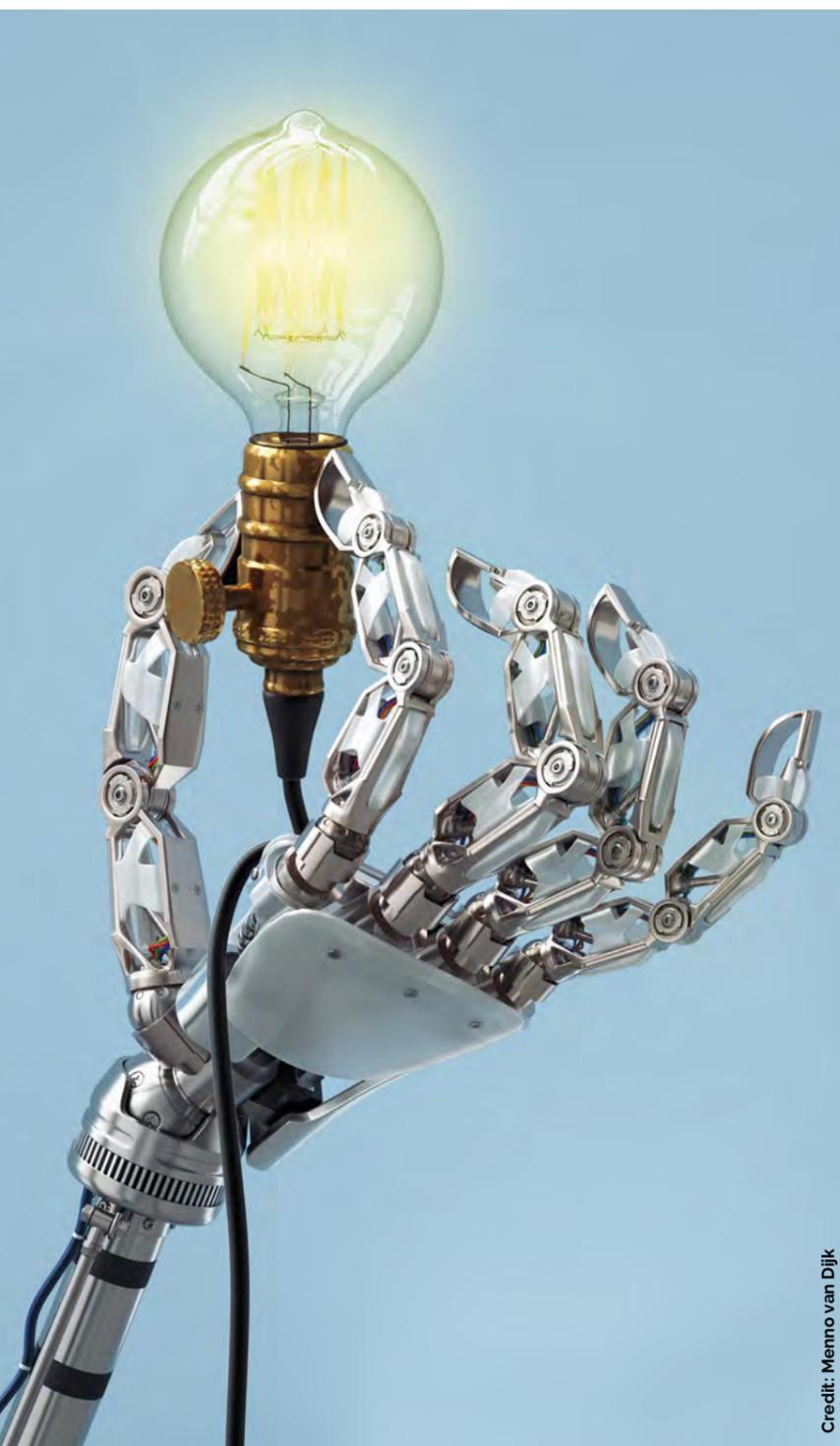


Credit: adventtr



Résumé

Matthew R. Carey is a registered patent attorney at Marshall, Gerstein & Borun who provides strategic intellectual property counsel to a range of clients, from independent inventors and startups to universities and Fortune 500 companies. With a focus on the electrical and software engineering industries, he advises clients at all stages of domestic and foreign patent prosecution, helping them maximize protection across jurisdictions while minimizing costs.



Credit: Menno van Dijk

that IP is protected, enforced and managed.

AI-powered tools may be used to analyze vast amounts of data to detect potential IP infringement (e.g., AI algorithms that scan the internet for websites or platforms using protected images or text without permission or analyze patent databases to identify potential infringers). This can help IP owners take action against potential infringers more quickly and efficiently, while reducing the cost of enforcing IP rights. AI can also be used to accelerate patent search and analysis by reviewing vast amounts of data to identify relevant prior art as well as potentially applicable patents.

The use of AI, however, poses questions associated with the creation of new IP. In particular, as AI systems generate creative works such as music, art and literature, and potentially invent new technologies, policymakers should provide clarity about whether these AI-generated outputs should be eligible for IP protection. They should also identify who should be considered the rightful owner of these rights – the AI, the AI's creator or the user who provided inputs.

Interoperability

Interoperability (i.e., the ability of different systems and technologies to seamlessly work together) can impact existing legal frameworks governing IP rights.

In particular, interoperability encourages innovation and competition through different technologies cooperating, which can lead to the creation of new products and services, but which can also pose challenges for IP protection, especially when it comes to proprietary technologies and companies being hesitant to share these technologies.

Interoperability can also reduce the cost and complexity associated with IP protection. For example, interoperability standards can be established for different patent databases to allow various systems to communicate and share information more efficiently, and thus reduce the time and cost associated with a patent search and analysis. Interoperability can also promote the use of open standards, which can encourage collaboration, lower the barriers to entry for new technologies, promote more transparent and equitable licensing practices, and encourage the formation of patent pools and the participation in non-aggression pacts.

Blockchain

Blockchain is a relatively new technology that incorporates a decentralized, digital ledger that allows secure and transparent transactions without the need for a central authority.

The blockchain is also transforming IP protection by providing a tamper-proof, permanent

record of the ownership and transfer of patents, trademarks and copyrights, thus improving traceability and verification of ownership, and making it easier to enforce IP rights and prevent counterfeiting and piracy.

Additionally, smart contracts (i.e., self-executing contracts with the terms of an agreement between buyer and seller being directly written into lines of code) can not only provide enhanced security and confidentiality for sensitive IP information, but they can also be used to manage the transfer of IP rights and enforce the terms of licensing agreements. This reduces the risk of disputes and ensures IP owners receive fair compensation for the use of their rights.

Further, the blockchain can streamline the process of IP registration and management by supporting a decentralized database of IP rights that anyone with an internet connection can access. Moreover, the blockchain can enable the creation of new markets for IP, with smart contracts being used to manage the licensing and sale of IP rights, enabling individuals and smaller companies to sell or license their IP rights to larger companies without the need for costly intermediaries.

Conclusion

As AI, interoperability and blockchain technologies



Matthew R. Carey

continue to reshape the IP landscape, it is essential for stakeholders and policymakers to adapt and evolve. By fostering collaboration, embracing transparency, and striking a balance between protection and accessibility, we can ensure that our IP frameworks remain efficient, robust, and relevant.

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China: foreign filing licenses for patent applications

Jiuliang Liu, Partner and Senior Patent Attorney at Beijing Sanyou IP Agency Ltd., focuses on how the FFL system manages cross-border collaborations among inventors from different countries for patent protection.

The patent system operates as a “disclosure in exchange for protection” mechanism, which necessitates that inventions (including so called “invention” and “utility model”) granted with patent rights should be made public, enabling free implementation by the public after the expiration of the patent term. However, if a patent application involves an invention that could impact national security or significant interests, the disclosure of such a patent application could potentially jeopardize national security or significant interests. To address this issue, the Chinese Patent Law includes provisions for a confidentiality examination system (i.e., foreign filing license). This article will focus on how this system manages inventions accomplished by cross-border collaborations among inventors from different countries.



Jiuliang Liu

I. Provisions of the Patent Law on foreign filing license (FFL)

1. Relevant legal provisions (Article 20, Paragraph 1 of the Patent Law.)

Any entity or individual who intends to apply for a patent for an invention or utility model completed in China in a foreign country should first submit an FFL request to the administrative patent department under the State Council. The procedures and time limits for the FFL shall be implemented in accordance with the provisions of the State Council.

2. Consequences of not submitting an FFL request and getting its approval

In the 2008 amendment to the Patent Law, the fourth paragraph was added to Article 20, clearly stipulating that for inventions or utility models applying for a patent in a

foreign country in violation of the provisions of the first paragraph of this article, no patent rights will be granted for counterpart patent applications filed in China. In accordance with Article 65 of the 2010 amendment to the Implementing Regulations of the Patent Law, violating the provisions of the first paragraph of Article 20 constitutes grounds for invalidating patent rights.

From the above provisions of the Patent Law and the Implementing Regulations of the Patent Law, it can be seen that if an FFL request should have been submitted and approved in China but was not, the corresponding patent application in China will not be granted in the later stage, and even if it is granted by chance, it runs the risk of being invalidated. Therefore, if the application procedure fails to comply with the relevant provisions of the FFL, it will substantially increase the instability of the patent in China.

II. FFL rules, channels, and time windows

1. According to Article 20 of the Patent Law, the subject of the FFL for applying for a patent in a foreign country should meet three requirements:

- i. the type of application includes an invention or utility model;
- ii. the invention or utility model was completed in China (excluding Hong Kong, Macao, and Taiwan regions);
- iii. the applicant intends to apply for a patent for the invention or utility model in a foreign country.

2. Channels for submitting FFL requests

Submission method	Required documents	Timing	Application method
Filing with a Chinese patent application (associated request)	FFL request	Can be submitted within six months before filing abroad, simultaneously with the Chinese patent application, or afterward	Paper or electronic
Direct submission (standalone request)	FFL request + Chinese description of the technical solution + Power of Attorney (when entrusting an agent)	Submit within six months before filing abroad	Paper only
PCT application (default request)	Qualified PCT application documents acceptable by the CNIPA (submitted by default)		Paper or electronic

3. Time required to receive an FFL decision

According to the provisions of the Implementing Regulations of the Patent Law, if no FFL notice is received within four months from the date of submission of the FFL request, the applicant may apply for a patent for the invention or utility model in a foreign country or submit an international patent application to the relevant foreign agency.

If an FFL notice is received, but no FFL decision was made by CNIPA within six months from the date of submission of the FFL request, the applicant may apply for a patent for the invention or utility model in a foreign country or submit an international patent application to the relevant foreign agency (Article 9 of the Implementing Regulations of the Patent Law).

Résumé

Jiuliang Liu is a Partner and Senior Patent Attorney at Beijing Sanyou IP Agency Ltd., a full-service IP law firm founded in 1986 in Beijing, P.R. China. He has wide-ranging expertise, including patent drafting, patent prosecution, patent search, OA handling, patent reexamination and invalidation, patent administrative and infringement litigation, and patent investigation in the fields of semiconductor, telecommunication, electronics, and computer science, etc.





Credit: alexst

Recommendations on the timing of submitting an FFL request:

Basic facts: Assuming a Chinese applicant files a patent application in China for an invention completed in China (with an application date of January 1, 2023) and then plans to file a US application based on the Chinese application, claiming priority rights under the Paris Convention.

Recommendation: In this case, considering that the priority period is one year from the filing date of the first filed application (China application), and the latest deadline for receiving an FFL decision is six months, the applicant should submit the FFL request no later than July 1, 2023.

III. Case Study

Case 1: A Chinese citizen and a US citizen jointly complete an invention in the United States.

“**The key factor in determining whether an FFL is required in China before submitting an application in the United States is where the invention was completed (territorial principle), not who completed the invention.**”

”

Basic facts of the case:

A Chinese citizen (A) and a US citizen (B) jointly complete an invention in the United States. In this situation, is it necessary to submit an FFL request in China before applying for a patent in the United States?

Answer: No.

Analysis:

The key factor in determining whether an FFL is required in China before submitting an application in the United States is where the invention was completed (territorial principle), not who completed the invention. Therefore, if Chinese citizen A participated in completing the invention in China, they should submit an FFL request before filing an application in the United States. However, if both A and B completed the invention in the United States, there is no need to submit an FFL request in China before filing an application in the United States.

Case 2: A Chinese citizen and a US citizen jointly complete an invention in China and the United States, respectively.

Basic facts of the case:

An invention is completed through the cooperation of a US company and a Chinese company. The inventors include a US inventor (A) residing in the United States and a Chinese inventor (B) residing in China. The two jointly complete the invention. A US provisional application has been filed for the invention, but after filing the US provisional application, the applicant realizes that due to the presence of the Chinese inventor, an FFL may be required in China to obtain FFL to apply for a patent outside of China.

For this situation, we raise the following questions based on practical experience:

1. Should a request for FFL be submitted in China?

To answer this question, it is necessary to clarify the true meaning of “the invention or utility model is completed in China” as stated in Article 20 of the Patent Law.

According to Article 8 of the Implementing Regulations of the Patent Law, “an invention or utility model completed in China as referred to in Article 20 of the Patent Law means an invention or utility model with the **substantive content** of the technical solution completed within the territory of China.”

How should we understand the concept of “substantive content of the technical solution”?

This should be defined in conjunction with the definition of “inventor” in the Patent Law. Article 13 of the Implementing Regulations of the Patent Law stipulates that an inventor or designer referred to in the Patent Law is a person who makes a creative contribution to the substantive features of the invention. The “**substantive features**” mentioned above have a similar meaning to the “**substantive content**” in Article 8 of the Implementing Regulations of the Patent Law.

The logic of judging from the perspective of the inventor is that anyone who makes a creative contribution to the substantive features of the invention or utility model should be recorded as an inventor. Therefore, if an invention or utility model includes a person residing in China as an inventor, it means that the Chinese inventor has made a creative contribution to the substantive features of the invention, and thus the invention or utility model should be considered as completed in China.

In this case, the invention is jointly completed by a US person residing in the United States and a Chinese person residing in China. According to Article 20 of the Patent Law and the understanding of “substantive content,” an FFL request should be submitted and approved in China before the US application is filed.

Extended Analysis: If the applicant in this case wishes to file an application in China, they should also consider the US FFL requirement. After obtaining the foreign filing license in the United States, they can submit the application in China. In practice, applicants should submit FFL requests in both the United States and China before filing applications in both countries, and only after approval can they apply for the corresponding invention or utility model in China and the United States.

“**Enterprises should pay full attention to the FFL provisions of the Patent Law when planning global patent strategies.**”

”

2. How to handle the US provisional application that has already been filed?

According to the legal provisions, for inventions jointly completed by inventors from both China and the United States, an FFL should be conducted by the patent administration department of the State Council before applying for a patent outside of China.

However, the applicant has already filed a provisional application in the United States, which appears to violate China’s FFL regulations. In practice, since US provisional applications are not publicly disclosed under US patent law, the applicant should abandon the US provisional application and promptly request an FFL in China.

For this case, if the applicant files a Chinese application or a PCT application, considering that the US provisional application has violated China’s FFL regulations, the Chinese application or PCT application cannot claim priority from the US provisional application.

Conclusion

In the context of deepening economic globalization and international scientific and technological cooperation, enterprises should pay full attention to the FFL provisions of the Patent Law when planning global patent strategies to avoid the risk of losing rights in China or having unstable rights due to the absence of an FFL.

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The rise of bioinformatic-related patents in a data driven world

Rebecca Bennett, Anna Gregson and Andrew White of Mathys & Squire speculate about the dramatic increase in bioinformatic-related patents and detail the industry's largest players.

Bioinformatics is a rapidly growing field that combines biology, computer science, and statistics to analyze biological data. The field has become increasingly important in recent years due to the explosion of data generated by advancements in high-throughput sequencing technologies. The field has played a crucial role in advancing our understanding of genetics, genomics, and personalized medicine. However, there is a common misconception that many of the key aspects of these inventions are unpatentable such as features of genomic pipelines e.g., clustering or aligning. There are of course, challenges to patenting bioinformatics methods but it can and is being done at an increasing rate.

Rise of Bioinformatic-related patents

Patenting in the field of bioinformatics is not new. In fact, the first bioinformatics-related patent was filed in 1988. However, it was not until the

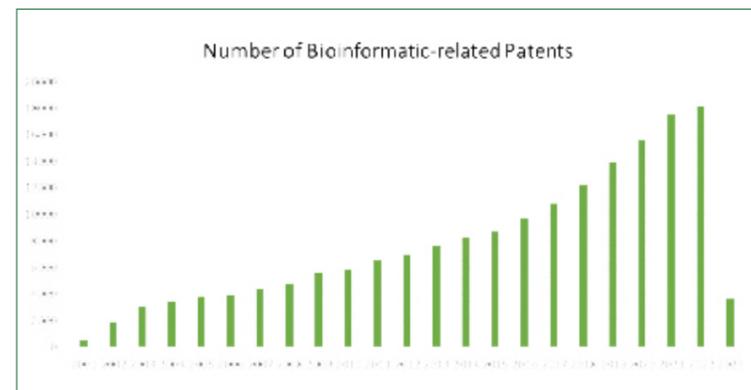


Figure 1: Increasing global trend of bioinformatic-related patents (data acquired from IP Quants)

early 2000s that the number of bioinformatics-related patents began to increase significantly. This initial increase was driven by the rapid advances in DNA sequencing technologies, which enabled researchers to generate vast amounts of genetic data. These advances led to the development of new bioinformatics tools and methods for analyzing and interpreting this data.

In recent years, the number of bioinformatics-related patents has continued to increase. According to a report by the World Intellectual Property Organization (WIPO), the number of bioinformatics-related patent applications increased by an average of 13.2% per year between 2013 and 2018 (Intellectual property protection indicators 2019). From data available since 2001, there has been a year-on-year increase in bioinformatics-related patents with a record-breaking number of patents filed in 2022 at just over 18,000 which is set to be broken again in 2023.

The increase in bioinformatics-related patents can be attributed to several factors.

1. First, the growth of the biotechnology industry has led to increased investment in research and development. This has resulted in the development of new bioinformatics tools and methods for analyzing biological data, which are often patented to protect intellectual property rights.
2. Second, the availability of large datasets, such as those generated by the Human Genome Project, has made it possible to identify new

targets for drug development and personalized medicine. These targets can be patented to protect the commercial rights of the companies that develop them.

3. Finally, the increase in bioinformatics-related patents can also be attributed to advances in artificial intelligence and machine learning. These technologies are being used to analyze biological data and develop new algorithms for predicting disease risk, drug efficacy, and other important factors.

Growth in the bioinformatics market

The bioinformatics market is also a rapidly growing industry commercially, with a wide range of players offering products and services in the field. The global bioinformatics market in terms of revenue was estimated to be worth \$10.1 billion in 2022 and is poised to reach \$18.7 billion by 2027. Some of the major players in the bioinformatics market include:

- **Illumina:** Illumina is a leading provider of DNA sequencing and genotyping technologies. The company's products are used in a variety of applications, including cancer research, infectious disease monitoring, and personalized medicine.
- **Thermo Fisher Scientific:** Thermo Fisher Scientific is a global provider of scientific and laboratory equipment, reagents, and services. The company offers a range of bioinformatics products, including software for genomic analysis, data management, and interpretation.
- **Qiagen:** Qiagen is a provider of sample and assay technologies for molecular diagnostics, applied testing, and academic research. The company offers a range of bioinformatics products, including software for genomic data analysis, interpretation, and visualization.

To give an example, according to data acquired from IP Quants, Illumina Inc has over 470 patents relating to the bioinformatics field ranging from neural network-based pipelines to deep learning-based approaches, highlighting the diversity of technology available to patents within this field.

“According to data acquired from IP Quants, Illumina Inc has over 470 patents relating to the bioinformatics field ranging from neural network-based pipelines to deep learning-based approaches.”



Credit: Kittiphat Abhiratorakul



Résumés

Rebecca Bennett is a Technical Assistant at Mathys & Squire. Her scientific background is within microbial genomics but she also has a great scientific understanding of genetics, bioinformatics, functional microbiology, immunology, disease, and infection. Rebecca achieved a first-class BSc Hons degree in Microbiology and a PhD specializing in microbial genomics from the University of Liverpool.

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Anna Gregson, biotechnology Partner at Mathys & Squire, has experience in a wide range of subject matter in the fields of biotechnology and life sciences, including therapeutic antibodies, plant biotechnology, advanced therapy and stem cells. Anna's expertise comprises drafting and prosecuting applications, coordinating worldwide patent families, as well as representing clients in oppositions and appeals before the European Patent Office

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Andrew White, IT and engineering Partner at Mathys & Squire, is an expert in the MedTech, software, telecoms, and automotive fields, as well as deep tech inventions including bioinformatics. Andrew has experience handling oppositions and appeals at the European Patent Office, as well as managing and prosecuting international IP portfolios for startups, university spinouts, as well as multinational companies.

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Rebecca Bennett



Anna Gregson



Andrew White

These are just a few examples of the major players in the bioinformatics market. However, it is not only in industry where we have observed a rise in bioinformatics-related patents. There is a similar trend in academia. For example, the University of California has filed over 2,000 patent applications between 2002 and 2023, highlighting the academic interest in this field.

As the field continues to grow and evolve, new players are likely to emerge, offering innovative products and services to meet the growing demand for bioinformatics solutions.

Conclusions

The increase in bioinformatics-related patents reflects the growing importance of this field in advancing our understanding of genetics, genomics, and personalized medicine. As the field continues to evolve and expand, we can expect to see even more exciting developments and innovations in the future. It is important for researchers, industry professionals, and patent professionals to stay informed and engaged in this rapidly changing field. In the next few articles, we hope to delve into the different prosecution strategies needed in various jurisdictions, explore key sectors such as AI and highlight some key case studies in this field.

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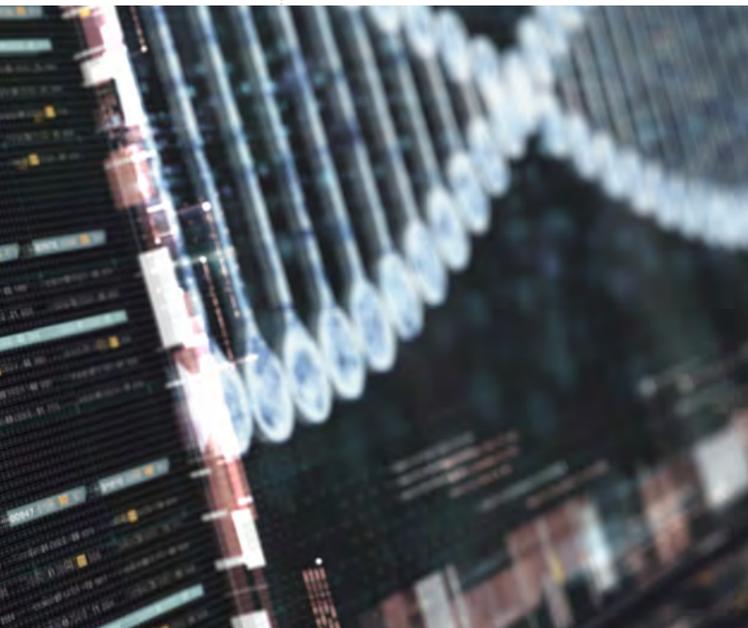
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Established in 1986, Sanyou IP Group started as Beijing Sanyou Patent Agency founded by the former President Ms. Qiang Li. Sanyou is the first private patent agency approved by CNIPA.

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Overarching benefit v overreaching temptations: compulsory licensing of patents in India

Prachi Agarwal and Mishthi Dubey of Anand & Anand review the advantages and drawbacks of the compulsory licensing system in India while reviewing unsuccessful applications that failed to demonstrate the requirements for grant.



In the day-to-day affairs of businesses across the world, licenses are routine and form the backbone of several commercial transactions that help foster ease of operations and render mutual growth. These licenses are also a conventional way of commercializing valuable Intellectual property (IP), wherein a rightsholder conditionally authorizes a third party to utilize its IP in return for an agreed payment, i.e., royalty.

The focus of the present article, however, is based on a different category of licenses in IP, i.e., compulsory licenses, a term widely prevalent but most misconstrued.

Compulsory licensing of IP often takes the center stage in discussions encompassing patents, especially promoting access to medicines, and is often touted as one of the measures of bridging the divide, technological or otherwise, between developed and developing nations.

Meaning of a 'compulsory license'

A compulsory license is a license granted by the Government to produce a patented product or to utilize a patented process without the consent of the patent owner, subject to certain requirements which have to be fulfilled.

While the term was first introduced in 1883 under the Paris Convention¹, compulsory licenses, as they are understood today, find their genesis in Article 31 of the TRIPS Agreement² which provides for 'other use without authorization of the right holder' and includes in its ambit the use of a patented invention by the Government or Government-authorized third parties in addition to a compulsory license.

Need for a 'compulsory license'

By virtue of Article 31, flexibilities were introduced across the world in a system otherwise plagued with the fear of inequities arising from the monopoly (albeit being time-barred) granted to patent owners, especially in case of public health emergencies.

Thus, while Patent law provides a monopoly for a fixed duration, it also provides a mechanism to balance the rights of the patentee and public interest/health through a compulsory license.

It is relevant to mention herein that the aforesaid flexibility is carved out in the statute, in addition to the exceptions to the rights arising from a granted patent, taking account of the legitimate interests of the third parties.³

Compulsory license provisions under the Indian Patents Act, 1970

In India, the provisions relating to compulsory license (and Government use) are concretized in Chapter XVI of the Patents Act, 1970 (hereinafter, also referred to as the Act) and naturally, emulate the guidelines prescribed under the TRIPS Agreement.

Section 84 of the Patents Act, 1970 provides the general considerations for the grant of a compulsory license. The provision extends to any interested person who makes an application to the Controller for grant of a compulsory license on expiry of three years from the grant of a patent.

An application for a compulsory license may be filed on the ground that:

- the reasonable requirements of the public qua the invention have not been satisfied;

¹ Paris Convention for the Protection of Industrial Property, 20 March 1883, Article 5A.

² Agreement on Trade-Related Aspects of Intellectual Property Rights April 15, 1994, Marrakesh Agreement establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S 299, 33 i.Lm. 1197 (1994).

³ *Id.*, Article 30.

⁴ Patents Act, 1970, Section 84.

⁵ *Natco Pharma Limited v. Bayer Corporation*, 2012 (50) PTC 244 (PO, Mum.)

⁶ As per available data on <https://www.ipindia.gov.in/annual-reports-ipo.htm> (accessed on March 16, 2023 at 17:00 IST)



Prachi Agarwal



Mishthi Dubey

- the patented invention is not available to the public at a reasonably affordable price; or
- that the patented invention is not worked in India.⁴

Such an application under S. 84 of the Act may only be filed after three years of the grant of the patent and after efforts to obtain a voluntary license regarding the patent on reasonable terms, have either been rejected or denied within six months.

Grant of a Compulsory license application could also be *Suo motu* pursuant to a notification issued by the Central Government in case of a national emergency or extreme urgency or in case of public non-commercial use under Section 92 of the Act.

Additionally, Section 92A of the Act further recognizes the export of patented pharmaceutical products in exceptional circumstances i.e., to a country with insufficient or no manufacturing capacity for the said product or to address public health problems, etc.

In addition to the above, measures taken by the patentee or their licensee to make full use of the invention along with the ability of the Applicant to work the invention and provide capital are also considered during such a request.

Changing judicial trends pertaining to the grant of compulsory licenses in India

While the first and the only compulsory license was granted in 2012 for Bayer's Sorafenib⁵, applications for compulsory licenses have been filed in India at least since the years 2007-08⁶.

Résumés

Prachi Agarwal is a partner at Anand and Anand since 2018 and is intricately involved in a variety of complex intellectual property litigation including patents, trademarks, copyright and designs. A graduate of National Law University Jodhpur and having done her LLM in Intellectual Property from The George Washington University Law School, Ms Agarwal worked as a patent prosecution assistant at Ditthavong Mori & Steiner, P.C (Virginia) between 2008 and 2011 before starting her journey at Anand and Anand in 2012. Ms Agarwal is a licensed attorney in the Commonwealth of Virginia and is registered with the Bar Council of Delhi.

Mishthi Dubey is an associate at Anand and Anand and has been with the firm since her graduation from Gujarat National Law University in 2019. Ms Dubey has been involved in several disputes relating to Intellectual property, particularly in the field of trademarks, patents, copyright and designs.



The law however has evolved considerably since the grant of Bayer's application, in terms of the weightage given to considerations surrounding the grant of compulsory license applications. A summary of such cases highlighting the changing trends is as below:

1. Natco's applications for Sunitinib and Erlotinib

The first case in India to reach the courts and bring up the issue of compulsory license was in relation to a compulsory license Application filed by Natco Pharma Ltd. (Natco) for Pfizer's drug Sunitinib for export to Nepal under S.92A of the Act.⁷ Similarly, Natco also filed a compulsory license application involving Roche's drug Erlotinib and filed seeking permission to export to Nepal.⁸

While the applications were later withdrawn, the observations made in the aforesaid cases further bolstered the safeguards surrounding the patentees and their rights.

These cases also recognized for the first time in India, the patentee's right to participate and be heard in an application seeking compulsory licensing of their patent, particularly under Section 92A of the Act.

2. Natco's application for Sorafenib

In the year 2012, *Bayer v. Natco* was the first case in the country to not only record the grant of a compulsory license but also to discuss the provisions in greater detail. In fact, the said case went up to the Supreme Court which dismissed Bayer's petition challenging the grant of the compulsory license.

The case involved considerations surrounding the ease of access of the public to the drug Sorafenib; the price of the drug and that the drug was not being manufactured within the country and was instead being imported into India.⁹

It is notable that in the said case, efforts to obtain a voluntary license were deemed to be satisfied despite the lack of response by Natco to the queries raised by the patentee.

3. BDR's application for Sprycel

The next case involving a compulsory licensing plea for *Bristol-Myers Squibb Co.'s* Sprycel was however rejected. It was held that the Applicant BDR Pharmaceuticals Pvt. Ltd. made no credible attempt to procure a license from the patent holder and that it had not acquired the capacity to work the patented invention so as to provide any advantage to the public.¹⁰

The said case demonstrated a shift in the trend set by the *Bayer* decision, wherein queries made by the patentee were deemed reasonable and natural and it was noted that the Applicant ought to have responded to the same.

“Plea of an alleged lack of supply in the market or a public health emergency, although does grant an opportunity to a third party to seek a compulsory license, does not necessarily lead to the grant of the same.”

⁷ *In the matter of Patent Application No. IN/PCT/2002/0078/DEL* (Patent No. 209251).

⁸ *In the matter of Patent Application No. 537/DEL/1996* (Patent No. 196774).

⁹ *Natco Pharma Limited v. Bayer Corporation*, 2012 (50) PTC 244 (PO, Mum.)

¹⁰ *M/s BDR Pharmaceuticals Pvt. Ltd. v. M/s Bristol-Myers Squibb Company*, C.L.A. No. 1 of 2013 before the Controller of Patents Office, Mumbai

¹¹ *Lee Pharma Ltd. v. AstraZeneca AB*, C.L.A. No. 1 of 2015 before the Controller of Patents, Patent Office, Mumbai

4. Lee Pharma Ltd.'s application for Saxagliptin

The next decision concerning the application for AstraZeneca AB's Saxagliptin in 2015-16 also followed suit. The compulsory license application was rejected on the ground that the Applicant fell short of demonstrating the reasonable requirement of the public not being met, and the affordability of Saxagliptin vis-à-vis other drugs in the market, including its pricing.¹¹

The order specifically also records that the Applicant failed to demonstrate the exact number of patients who had been unable to obtain the drug on account of non-availability of the same.

Is the term 'compulsory licensing' actually a misnomer?

An analysis of the aforesaid cases clearly demonstrates that there is no straitjacket formula that is generally applicable to the grant of compulsory licenses.

Plea of an alleged lack of supply in the market or a public health emergency, although does grant an opportunity to a third party to seek a compulsory license, does not necessarily lead to the grant of the same.

Thus, while the term may indicate an idea of 'compulsion' surrounding the same, and once granted, a compulsory license application may give effect to the idea of compulsion on part of the patentee, the grant of such licenses appears to be an exception to ordinary circumstances and be given after consideration on a case-to-case basis.

A possible reason behind the above could be the difference in requirements surrounding a particular invention, including the demand in the relevant market, availability of other (even cheaper) substitutes, especially in pharmaceuticals, etc. along with the factors already indicated above.

Further given the demographical divide that is peculiar to the nation, a crucial element to consider is that the demand for a product or the purchasing power of the public may not be uniform across the nation.

Additional considerations necessitating the grant of a compulsory license

1. Collation and comparison of data sets

A good way of ascertaining the demand in the market for any patented product or any product derived directly from a process, especially in the context of India, is through data sets indicating such demand, that may be presented by the applicant and/ or even the patentee opposing such an application.

It is the case of the authors that emphasis on numbers (to show demand, affordability, or the

lack thereof) would lend a sense of objectivity to the decisions of the Controller, which may otherwise be perceived very subjectively and seem unfavorable to the general business atmosphere.

2. Market intelligence

Further, market intelligence may also be given equal consideration in such matters. For instance, if there is evidence indicating diversion of goods to another place/country instead of the place (for which the compulsory license was sought), this will bolster the case against the grant of the compulsory license.

3. Type of product against which compulsory license is being sought

Another key consideration while deciding the grant of such applications, is the nature of the product for which a compulsory license is being sought.

As per the official figures released by the Office of Patent Controller in India, a total of 11 applications for compulsory licenses have been filed to date.

Further, as per the available data, it is believed that a large number of these compulsory licensing applications regarding patents have been filed for pharmaceutical products.

It is often the case involving pharmaceuticals that public health assumes paramount importance. However, the question which remains to be answered is whether the issues relating to public emergencies or fulfilling the requirements of the public can only be met by the grant of a compulsory license.

Conclusion

The tool of compulsory licenses is a powerful measure to alleviate any ill effects or inequities that may arise from the patent system and to enable the Government to meet the demand in the nation.

However, it is the case of the authors that compulsory licensing provisions should be exercised sparingly by the Government, and in a prudent manner so as to ensure that the same is not being utilized to the detriment of the rightsholder or the patentee. It should also not be forgotten that a patent right is granted for a limited term, to incentivize and promote innovation.

In order to strike the right balance between protecting the rights of an inventor and the exploitation of the invention for public welfare, the endeavor should always be to promote collaborative ventures between inventors and market players, including technology transfer agreements, and MOUs.

The aforesaid measures will not only create an amicable environment of knowledge transfer

“The tool of compulsory licenses is a powerful measure to alleviate any ill effects or inequities that may arise from the patent system and to enable the Government to meet the demand in the nation.”

¹² *In Re: Distribution of Essential Supplies and Services during Pandemic*, Suo Motu Writ Petition (Civil) No. 3 of 2021, Para 49.

but will also open avenues for future engagements and partnerships, which will bolster domestic growth.

Moreover, initiatives led by patentees, including Patient Assistance Programmes (PAPs), and donation of products to Government hospitals and NGOs should also be encouraged to provide timely availability and access to medicines by the most underprivileged sections of the society, instead of undertaking the relatively long drawn process of the grant of compulsory licenses.

Government interventions in other forms such as the use of subsidies, and notification under the Essential Commodities Act et al are other methods of ensuring access to technology at affordable costs to the general public, without hampering the rights of a patentee.

The author's assertions hereinabove are further supported by the recent observations made by the Supreme Court.

During the COVID-19 pandemic, while the world at large was grappling with the largest calamity known to mankind in recent times, the Apex Court of India, while dealing with compulsory licenses, indicated other courses of action (as a substitute for compulsory licenses) to tackle the issue of vaccine requirements in an equitable and expedient manner. The same included negotiations with domestic and foreign producers of vaccines.¹²

In conclusion, it is thus stated that while compulsory licenses may always be available as a flexibility in dire circumstances, the need of the hour is to think of collaborative solutions which not only help address the emergency at hand but also leave room for future collaborations and sustainable growth.

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Translation errors: once it is in writing, it is permanent

Dmitry Yakovlev and Maksym Bocharov of Gorodissky and Partners review case examples of incorrect translation which have resulted in the invalidation of filed patents to demonstrate the importance of investing in accurate translation.

Translation is the art of failure - Umberto Eco

Nowadays, to ensure appropriate protection of one's intellectual property, one should often consider going well beyond the borders of one's businesses' country of residence. This often involves a translation from one language into another, and not seldom these languages drastically differ in terms of their linguistic structure and vocabulary. The scope and spirit of a subject matter of intellectual rights is defined by a text. It is the text that strictly outlines the scope of one's intellectual rights, and any given word in this text may have a multi-million price. What happens when this word is wrong can easily be imagined.

Translations are burdensome and costly, sometimes exceeding the other expenses in the course of prosecution of a patent application in a given jurisdiction. High complexity and costs cause clients to search for ways of saving money and time on translations, but this has strings attached. Most importantly, reducing translation costs compromises the quality of translations and, hence, increases the occurrence of translation errors.

In its essence, a translation is not just about placing a word in English instead of a word, say, in Chinese. Word-for-word translations are never adequate. Translating a text means first interpreting it, i.e., extracting its specific meaning to the most subtle detail, and then conveying this meaning in another language in a manner which, on one hand, is grammatically, stylistically, technically and legally correct in terms of the "target" language, and, on the other hand, most precisely reflects the spirit and scope of the "original" text. Translation, whether performed



The scope and spirit of a subject matter of intellectual rights is defined by a text. It is the text that strictly outlines the scope of one's intellectual rights, and any given word in this text may have a multi-million price.



by a human interpreter or an automatic tool, is prone to errors that have consequences. Among the latter, one may name failure to complete the examination procedure and achieve patent grant, invalidation of a granted patent due to mistranslations, denial of efforts at rectification of translation errors discovered after the grant of a patent, and scope of protection under the granted patent being drastically different from the intended scope, making the patent worthless.

Translation errors differ in their nature. Among typical errors, one may name two different basic kinds. The first one is "technical" errors, also known as "typographical errors" or colloquially "typos". The second one is related to semantic contents of the text and linguistic peculiarities of languages involved, in particular to a misinterpretation of the original text or failure to use appropriate technical terminology in the "target" language. Both kinds of errors may adversely affect the scope of legal protection, and they need to be rectified. Apparently, the first type of error is easier to correct, and it is undoubtedly better to rectify errors of both kinds (not to mention preventing them) at the stage of filing or prosecution of a patent application, and not after the patent has already been granted. It should be kept in mind that "typos" may have the same adverse effect on the fate of the patent application or on the scope of the granted patent as the more complicated "linguistic" errors.

Translation errors, especially ones that belong to the second aforementioned kind, can "broaden" or "narrow" the scope of legal protection as compared to what was originally sought. The question is: if the scope that was erroneously broadened by a translation error can be narrowed



by rectifying the error, can the scope that was erroneously narrowed be retroactively broadened? And if so, from what date shall such a change in scope be effective?

Now we will discuss a few examples of the negative effects of translation errors on the fate of patent applications and patents in various jurisdictions.

A European company that specializes in home interior design solutions was granted a Russian patent based upon a PCT application for a fireplace imitation device, where the phrase "a container adapted to contain a body of liquid" was mistranslated as "a container with a body of liquid". Infringement proceedings were initiated against a third-party infringer who was alleged to be marketing in Russia a product manufactured in a third country, in which the patented invention was used. The infringer maintained that the patented invention was not used in their product, since the allegedly infringing product did not include the body of liquid, unlike the patented invention. All patent owner's attempts to rectify the mistranslation at that stage were to no avail.

A patent granted to a European company based on a PCT national phase application was opposed on the grounds of lack of novelty and inventive step. The prior art cited in the opposition recited, *inter alia*, "average particle diameter", and the same was erroneously recited in the opposed claims, whereas "median particle diameter" was originally indicated, and not "average particle



Dmitry Yakovlev



Maksym Bocharov

Résumés

Dmitry Yakovlev, Russian & Eurasian Patent Attorney, Gorodissky & Partners (St.Petersburg)

Dmitry focuses his work on counseling clients on forming patent protection strategy of inventions, utility models and designs in Russia, CIS, Europe, Asia-Pacific region in the sphere of manufacture of heavy engineering, machinery and equipment for agriculture & forestry, electric-powered machines apparatus, computers, TV & radio transmission equipment, medical equipment and apparatus etc. He also has considerable experience of oppositions and appeals before the Russian and Eurasian Patent Offices. Dmitry speaks English, German and Arabian.

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Maksym Bocharov, Ukrainian Patent Attorney, Head of Gorodissky and Partners (Ukraine)

He advises clients on modern patent strategies for the most effective protection of intellectual rights in Ukraine, the CIS and Europe. He has extensive experience in prosecution and enforcement of IP rights and represents the interests of clients before the Ukrainian Patent Office.

His particular professional interest is in the field of chemistry, including production of basic organic and inorganic chemicals, industrial gases, plastic and resins, pharmaceutical preparations and medicines.

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diameter". All patent owner's efforts to rectify the mistranslation by changing "average" for "median" were unsuccessful, and the patent was invalidated in full.

A US patent application was filed claiming priority to an Italian patent application. Instead of filing the Italian patent application with the USPTO, an English translation of the Italian patent application was filed, where an Italian term "semiliquido" was mistranslated as "half-liquid" instead of "semiliquid". In the course of litigation between two parties, the patent granted to the US application was eventually invalidated due to the inaccurate translation of the non-English priority patent application. Notably, as part of the litigation, the patent owner provided a certified translation of the priority Italian patent application that correctly translated the term in question as "semiliquid", but this had no effect.

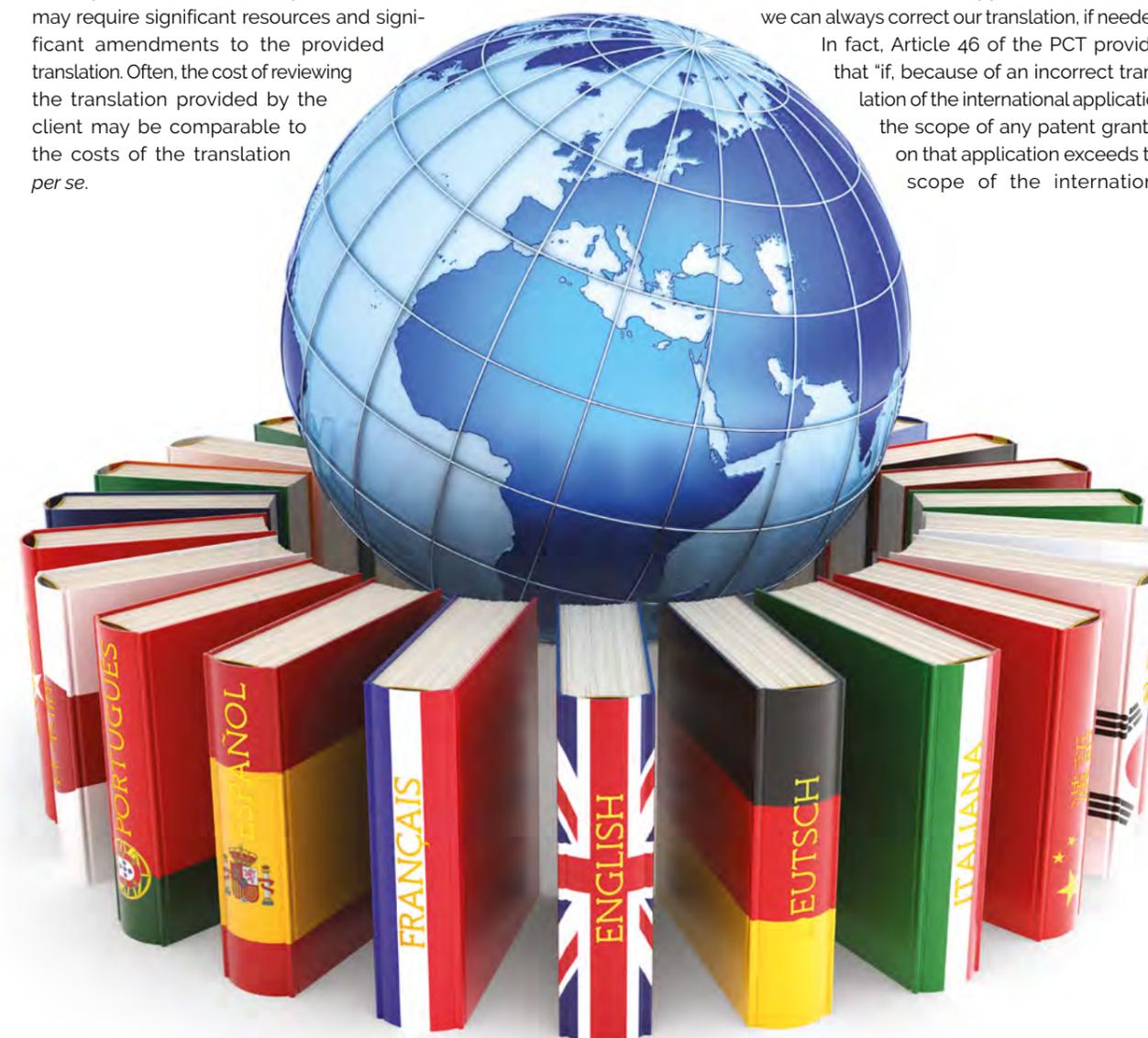
A PCT application originating from China included a phrase in the claims, which was translated from Chinese into English as "a mobile station enters an edge radio frequency unit of a serving cell". At the national phase in Russia, where a Russian translation was prepared in strict accordance with the English language text, the application was rejected since no technically correct translation into Russian of the above-mentioned features was possible, nor was the applicant able to explain how a mobile station can enter a radio frequency unit. In fact, it was meant that the mobile station enters the service range of the radio frequency unit, and not the unit *per se*, but even citing the Chinese priority application did not persuade the examiner.

Rectifying translation errors in the course of prosecution of an application may be facilitated by a Patent Office, if the latter carefully monitors the clarity of features provided in the claims and/or the specification of an application being considered. In such case, an examiner of such Patent Office may raise translation-related issues in the course of substantive examination of the application. In Ukraine, the examiner pointed out an incorrect translation of German language technical terms "Wabenträger" and "-seite", which enabled the applicant to make timely corrections to the translation of respective terms before a patent was granted.

It should be noted that, in particular, the Patent Office of Ukraine generally accepts requests for correcting translation-related errors from an applicant or patent attorney in case the latter notices such errors in the course of prosecution of the application even when a decision on the grant of a patent has already been issued (but grant fees were not yet paid and the patent has not yet been registered with the Official Patent Register!). By way of an example, mistranslation

of term "non-transitory" as "non-transistor" (probably, a misprint) in a Ukrainian patent application was timely noticed by the patent attorney, and the request to correct this error was granted by the Patent Office at the stage of a decision on the grant of a patent. It should be noted, however, that in other jurisdictions correction of such kind of mistranslations may only be possible if the Patent Office points out a mistranslation and suggests an amendment.

These are but a few examples that clearly show that, in patents, it is better to avoid translation errors by making any possible effort to provide a high-quality translation. Some translation errors may be detected when the translation of application materials provided by a client is reviewed by specialists of patent attorney firms. Such checks often reveal mistranslations as well as typographical and other errors in chemical and physical formulas and compounds, which may potentially lead to very serious legal consequences. However, such professional review may require significant resources and significant amendments to the provided translation. Often, the cost of reviewing the translation provided by the client may be comparable to the costs of the translation *per se*.



Preparation of translations of applications by patent attorney firms, as well as performing reviews of translations by qualified patent attorneys makes it possible to prevent mistranslations as well as detect in advance many other potential issues with application materials, such as defects in drawings, mathematical and chemical formulas and expressions etc. This allows the avoidance of problems during examination, in particular objections concerning clarity, consistency of terminology and, ultimately, industrial applicability. Eventually, costs are thus reduced for the client by ensuring quicker and easier prosecution of an application without extra objections and remarks originating from the Patent Office on translation errors and other similar issues.

But what can we do if a translation error did occur? A typical delusion by some of the applicants who are willing to cut translation expenses is: "PCT and almost all patent laws allow making corrections in translated applications. Therefore, we can always correct our translation, if needed".

In fact, Article 46 of the PCT provides that "if, because of an incorrect translation of the international application, the scope of any patent granted on that application exceeds the scope of the international



application in its original language, the competent authorities of the Contracting State concerned may accordingly and retroactively limit the scope of the patent, and declare it null and void to the extent that its scope has exceeded the scope of the international application in its original language". In general, the PCT does provide for rectifying an error in translation during the national phase. But, as shown above, actual possibilities of rectifying translation errors in a national phase application, not to mention patent, are limited.

Turning to the European Patent Convention, Rule 139 of the EPC defines three kinds of errors that are amenable to being corrected: (a) linguistic errors; (b) transcription errors; and (c) mistakes. One criterion that must be fulfilled for an error to be allowed to be corrected is that: "the correction must be obvious in the sense that it is immediately evident, that nothing else would have been intended than what is offered as a correction".

Russian patent legislation has adopted an approach that is quite similar to that of the EPC, in that errors that can be corrected are mainly "obvious" and "technical" errors. Until recently, it was common practice to amend the Russian translation in the course of prosecution of a PCT national phase application "on the basis of the PCT application materials", but now the RuPTO does not generally accept such amendments. Amendments to application materials to rectify translation errors may often be accepted only in case the Patent Office points out issues with translation and suggests an amendment. Even worse, amending translation errors when a

patent has already been granted is now generally not allowed.

To avoid problems caused by translation errors, one may name several "countermeasures" against mistranslations which may be generally effective regardless of a particular jurisdiction. Firstly, it is important to ensure stringent quality control of the translation – appropriateness and consistency of technical terminology, linguistic clarity and accuracy of translation in order to accurately reflect the technical and legal intent of the text. Then, routinely reviewing translation quality by internal bilingual or multilingual in-house individuals with expertise in patent prosecution and litigation is highly advisable. Having a high-quality accurate English translation of a priority patent application may best serve the applicant, especially in cases where there is a non-English priority application and English is only an "intermediate" language, the ultimate "target" language also being other than English. This approach is generally used, in particular, in the case of originally Chinese, Japanese, Korean etc., applications, which enter other jurisdictions via the PCT or by claiming convention priority.

One should also keep in mind the procedural difference of filing a translated application in a foreign country and later providing a certified copy of the priority (original language) application and filing an application in the original language and a translation into the required language. In the former case, referring to the original text in an attempt to rectify a translation error may not work, while, in the latter case, the original text, which is considered to be properly filed as of the filing date of the application in question, would provide a basis for amending the translation, if necessary.

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Women in IP Leadership

Celebrating achievements and continuing the empowerment of women





This segment is dedicated to women working in the IP industry, providing a platform to share real accounts from rising women around the globe. In these interviews we will be discussing experiences, celebrating milestones and achievements, and putting forward ideas for advancing equality and diversity.

By providing a platform to share personal experiences we aim to continue the empowerment of women in the world of IP.



If you would like the opportunity to share your experiences with *Women in IP Leadership*, would like to nominate an individual to be involved, or would like to learn more about sponsorship, please contact our Editor.

Dominique Hussey: Vice Chair & Toronto Managing Partner, Bennett Jones LLP

An interview: inspirations, experiences, and ideas for equality.

Dominique is Vice Chair & Toronto Managing Partner at Bennett Jones in Canada. She advises and litigates on behalf of clients as leader of the firm's IP Litigation group and co-head of its Innovation, Technology & Branding group. She was named a 2023 Global Elite Thought Leader – Patent (Life Sciences) by WWL. She received the inaugural *Chambers Canada* Law Firm Leaders Award in 2021, and won the *Managing IP* Outstanding Canadian Practitioner in Patent Law award in 2020. For the last seven years, *Managing IP* has also named Dominique in the Top 250 Women in IP in the world.

What inspired your career?

My career was directly inspired by my upbringing, and conversations around our dinner table. I grew up in a medical and legal family, with parents who were opinionated and who liked a good, heated discussion on topics of science, the arts, politics, policy, and law. It was how we interacted with each other and with friends. For a long time, I could not decide whether I would ultimately pursue medicine or law. My undergraduate degree was a BSc in Biology with a minor in Classics. Midway through my degree, I decided not to choose: I would go to medical school and law school to become a biomedical ethicist – the best of both worlds.

I ended up applying to and attending law school first, frankly because it was easier and faster to prepare to take the LSAT than the MCAT. In Canada, after graduating from law school and before being admitted to the bar, we were required to work at a law





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I would advise others to seek and accept constructive criticism as part of a constant journey of knowledge acquisition.”

firm for an “articling year” to gain practical experience. Physician-side medical malpractice interested me, and the law firm I chose for articling was top-notch in that area. I knew nothing about IP until my final semester of law school, when I took a survey course on Patents, Copyright and Trademark law. It changed everything. IP appealed to every facet of my intellectual curiosity. Copyright appealed to my interest in the arts. Patent law, particularly in the life sciences, spoke to my interest in medicine, and Trademarks are interesting to everyone. It was pure serendipity that the firm where I was articling also had an outstanding IP practice. I was eventually hired as an associate in the IP group with a focus on pharma litigation, and I never looked back. Med school was not to be.

Because I did not end up going to medical school, I felt like my academic career and life experience had been cut short. After the first couple of years of practice, I moved to New York to pursue an LLM at Columbia University Law School. I took courses focused on IP, personal injury, and healthcare, and wrote a paper comparing the US and Canadian regulatory systems that link patent litigation to the approval of prescription drugs.

The rest of my legal career has emphasized life sciences, regulation by health authorities, and patent litigation in particular.

How have you found the pathway to your current position? And can you offer advice from your experience?

I am an active IP advisor and patent litigator, with leadership responsibilities that include heading up the IP litigation group and co-chairing the Innovation, Technology and Branding Group at Bennett Jones LLP in Canada. I am also Vice Chair and Toronto Managing Partner at Bennett Jones, with some national responsibility, and management responsibility over an office of about 450 people. I have benefited immensely from supportive leaders, partners, and colleagues. With their support, the pathway to my current position has really been the result of successively saying yes to opportunities that I have been fortunate to have received, and then working to the best of my ability at each of them.

Based on my experience, I would advise others to seek and accept constructive criticism as part of a constant journey of knowledge acquisition and skills improvement, which is a necessary path to success in patent law. I would advise others to appreciate, respect and listen to all of the people who work around them in all capacities. It makes for a collaborative environment and expands learning opportunities exponentially. Lawyers should learn their clients’ businesses cold – the technical aspects of their

industries, how they make and lose money, their financial health, their risks and their challenges – and view everything they do for the client through the lens of making a positive business impact.

I would advise others to work as hard as they can in their particular circumstances. But I would advise against saying “yes” to every-thing. It worked for me for a time, and I have no regrets, but eventually everyone has to learn how to say no. Some so-called opportunities take precious time from more productive work, necessary rest, and family and friends. It can be difficult to follow through with the “no” but the right answer is usually easy to find. Ask yourself: Do I have to do this? If the answer is yes, do it. If the answer is no, ask yourself, will it advance my career? Will it raise my profile? Will it advance my knowledge? Will it help someone I want to help? Will it give me good experience? If the answer is yes to any of these questions, then ask, will it prevent me from doing any of the above in a better way? Will it mean giving up on something else that is important to me? Would I advise a friend in the same situation not to do it? Will I be saying yes only because I don’t want the discomfort of saying no? If the answer to any of these questions is yes, don’t do it.

What challenges have you faced? And how have you overcome them?

I always find this particular question difficult, as I think the very definition of a legal career is navigating challenges. There can be particularly challenging periods over the course of the career, but I have concluded that the best way to overcome them is to go through them. You accept the challenge and throw yourself at it, like deciding to ski down a terrifyingly steep hill. When I started my litigation career, I was extremely nervous about public speaking, to the point of being sick. I just kept doing it, and working at it, and now it is second nature. I forget to be nervous. It was a challenge to jump into practicing US patent litigation having previously practiced in Canada. I felt I was at a knowledge disadvantage and had to close the gap quickly to be effective. Within a short period I studied and dissected Title 35 and the MPEP, and read essentially every patent opinion that had been issued in the previous decade. I had to do the Canadian version of the same thing when I returned to Canada to practice after four years in New York.

The greatest challenge I faced later in my career was my return to work after I had my second child, 12 years ago. Several months before my due date, I had landed a number of high-stakes patent litigation matters that were going to be handled by the senior partner in our

group in my absence. Just before I was due, that partner decided to join a different firm in a different city. I understood the decision, but the timing was very unfortunate and difficult. As a result, much of that ongoing work moved to other firms. When I returned, I was appointed head of the IP litigation practice. I found the responsibility daunting, but it was an opportunity. We had to rebuild significantly, which was a lot of effort, but ultimately a real success. We have a complex, diverse, vibrant, busy, and exciting practice with a very strong team that continues to grow.

What would you consider to be your greatest achievement in your career so far?

I was extremely honored to have been appointed managing partner of my office, but I know that the achievement is not in the title; it is in the performance, which is ongoing. I am happy that I have been able to commit to my career and have children who understand its demands, are good and decent humans, and know that their parents love them. This too is a work in progress, and to a certain extent the luck of the draw, so it can’t yet be an achievement. I am very proud of the team of lawyers I have helped to build. I take pride in the fact that former associates whom I have trained for the greater part of their careers have become equity partners and excellent practitioners. But ultimately those are their achievements, and not mine. Maybe I will have a better answer to this question in 15 years.

What are your future career aspirations? And how will you work to achieve them?

I aspire to get better and better in each of my roles – as a leader, a manager, a mentor, a trusted advisor and a litigator – and to generate and implement new ideas continuously. I will do this through asking questions, listening, practicing, consulting, coaching, being coached, reading, and intentionally ideating and strategizing. I am trying, highly imperfectly, to approach each of these aspects as a discipline, and accepting that any improvement is good improvement.

What changes would you like to see in the IP industry regarding equality and diversity in the next five years?

I can proudly say that we have a great deal of diversity at our firm and particularly in our IP group at Bennett Jones. And it just so happens that most of the senior people are women. That is not what I see when I look at most other teams – particularly in patent litigation, which historically has been the most male-dominated area of IP law. The landscape has definitely changed, however, and I am hopeful that when

I walk into the courtroom and the board room over the next five years, I will see the profession and the judiciary increasingly reflecting the population.

How do you think the empowerment of women can be continued and expanded in the IP sector?

Women need to keep telling their stories, which can be very empowering. The world over, there are exceptional, leading IP practitioners and group heads who are women and whose very existence is inspiring. In my experience, in IP, women champion, boost, and mentor other women generously, which is extremely empowering. Many of us have large clients who enjoy working with a diverse range of advisors and amplify and recommend women to other clients, which makes a tremendous impact. Honestly, I think women in IP are on the very cusp of having their day in the sun.

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In my experience, in IP, women champion, boost, and mentor other women generously, which is extremely empowering.”





Natalia Vladymyrova: Managing Partner, Prima Veritas

An interview: inspirations, experiences, and ideas for equality.

Natalia is a Ukrainian Patent Attorney with 15 years of experience in intellectual property protection.

After starting her career at an IP law boutique as a patent attorney's assistant, she continued in one of the biggest Ukrainian Alcohol Companies Bayadera Group, and ended with the role of head of intellectual property department in 2012. Later in 2012, Natalia founded her own IP law firm.

Now there are more than 8,000 clients who have already received a trademark for their business with her help.

Natalia is the founder of the patent law firm PRIMA VERITAS in Ukraine, former CEO and co-founder of the legal innovation PatentBot (project was closed in 2022 because of the war). Since 2022, Natalia is a part of Deloitte Netherlands, obtaining the role of manager at Sustainability Tech Hub, which she combines with giving lectures on intellectual property and leading the biggest Instagram blog in Intellectual property.

What inspired your career?

It's a long story. It came from my youth, when I started my own business – I had a shop selling Ukrainian designer outfits and I called it 'Closet' because it was a tiny shop, like a boutique but only two square meters. I have an uncle, a businessman, he commented, 'What a nice name for your shop – have you trademarked it?'. At 18 I didn't know about trademarks. He spoke to his attorney and later presented me with the registration of that trademark.

Later, during my law degree, I was looking for an internship and I found a position at my uncle's attorney's office. Such a coincidence! A year in, I fell in love with intellectual property, I realized how interesting it is and what huge potential it has. I pointed all of my professional aims at the field and 15 years later I'm still here consulting in intellectual property.

How have you found the pathway to your current position? And can you offer advice from your experience?



After my internship I worked in a corporate position at a spirits company, there I started with an initial position as a junior consultant in intellectual property, later becoming the head of the intellectual property department.

Then I gave birth to my first child and I never went back. After the *Suits* series, I was so impressed by the managing partner *Jessica Pearson* – a woman leading a huge law firm with this beautiful office with her name on the door: *Jessica Pearson – Managing Partner*. I wanted to be as successful as her. I opened my own boutique law firm; it was only me, myself and I (laughing) and I became Managing Partner just as I had dreamed. I'm still Managing Partner at Prima Veritas, now we have 10 people in our team and we are one of the most successful firms in our niche in Ukraine.

I also used to be CEO of PatentBot, which is a legal tech start-up helping SMEs to protect their intellectual property. It became one of the best legal innovations but unfortunately, due to the war, I was forced to close it in March 2022. I had to move to Amsterdam, and I've joined Deloitte managing the climate and sustainability tech hub, so it's also connected to solutions, to digital, to technology but it's not connected to intellectual property. I am still running Prima Veritas remotely, with almost 7,000 current clients in Ukraine. I remain the most popular patent attorney for our clients and I apply the largest amount of trademark applications each year. We are doing well despite circumstances especially as registering a trademark is not the number one priority for businesses at this time because of the war. The system has changed and now Ukrainians are registering trademarks in wider jurisdictions, not only in Ukraine but also in Europe and the US to become international brands. I am very proud of it.

My advice would be to regret nothing. Everything that you are doing, you are doing well. I'm always passionate about how women can be so powerful, we are superheroes. In addition to running a law firm I have a 40 hour full-time job here in the Netherlands, I have three children

and I'm a micro-influencer as an Instagram blogger with almost 30K followers. I also run workshop lectures and a course for intellectual property. Passion is like a superpower. If a woman has some concerns about anything she should think about herself – how good is she! How clever is she! How strong she is!

What challenges have you faced? And how have you overcome them?

First, I think the lack of knowledge about myself and a lack of trust from clients' perspective. I was a young woman, 25, when I established my own law firm. It was a real challenge to get new clients. In the beginning, I provided services and took payment afterwards, so no money beforehand, which is not the usual system in Ukraine; people are used to paying for such services beforehand. But I offered this to gain their trust, knowing that I would do the job well and they would be happy to pay after. I knew that clients might not believe in me because I was young and unknown, but I knew I was really good and that I would be paid after the work. This was the most challenging part of starting my firm, but I have worked passed that model now as I have earned trust and reputation.

From a marketing perspective it is all about word of mouth. Ukraine is a big country but, at the same time, everyone knows everyone and knows that's how things work. I knew I had to start with my personal brand and I was good at it. I gained the most popularity with the PatentBot experience: for the last five years I have been the face of PatentBot and I was representing dozens of different pitches, seeing international start-up competitions and all of that. I was constantly making social posts and stories, like an influencer would, saying 'hello, I have this drink today', if I have a drink I will let you know about the brand, the history, how the trademark was registered – I find intellectual property even if it is hidden. This began catching peoples' attention which led to people identifying me as the person to go to for intellectual property. That came through personal branding.

What would you consider to be your greatest achievement in your career so far?

I'm listed in Forbes as one out of 25 women in IT which I achieved in my role as CEO of PatentBot. Also, maybe the most important one, is the love that we have with our clients because love is one of our values at Prima Veritas – we have three values which are love, care, and the best service. I create this atmosphere within a team and with clients so that we do everything with love and it comes back, always. And that's why I'm so popular. I literally spend zero budget on marketing so everything, each of the 7,000 clients,

“
The future of IP is creative, having more women in legal technology would change how IP professionals practice law.
”

came from my creativity with my personal brand and subsequent reputation.

What are your future career aspirations? And how will you work to achieve them?

My closest goal is to gain some new roles here in the Netherlands at Deloitte. I'm already a Managing Partner at my own law firm and I'm happy that I've organized that in such a way that it works without me. I am not an operational manager, I am just a business owner and I can consult my team in some cases or give them a pass to strategy but the main idea is to be the face of it and generate leads and clients just by being myself and I love that.

Here, at Deloitte I hope that I will create some new steps with new challenges.

What changes would you like to see in the IP industry regarding equality and diversity in the next five years?

From what I can see we still don't have a lot of women in C-suite level positions, in management positions, so I think that what the community can give to women in IP is some strong beliefs and support. I truly believe that this is going to change.

I don't have any data or numbers but it's just what I see; that big companies are always managed by men and maybe some partners are women, but managing partners are still a majority men.

It's not only about diversity of sex and nationality, it's also about mental diversity, it's so super that people think about it and I'm so encouraged to have it at Deloitte as well. It is so good that we have started to think about it and the next step is actions and I hope that women will achieve management positions as well, if they want to.

How do you think the empowerment of women can be continued and expanded in the IP sector?

I think it's good to have some communities. As far as I know they do have some Women in IP communities, I've heard about an international one. I have even attended one event organized by those in Ukraine. But I think maybe it could be more, not only in IP but a little bit broader, so women in legal. Having support from a community with similar values always helps you to go further and to move forward.



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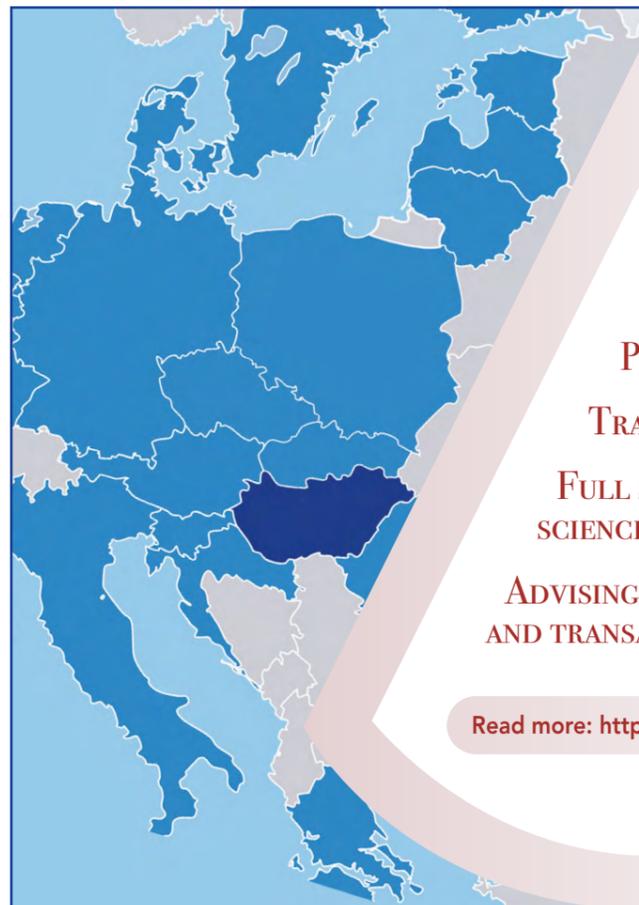


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Industrial property in entrepreneurship and start-ups

Melissa I. Del Busto, Associate at Arias, Fábrega & Fábrega, explains the importance of educating entrepreneurs and start-ups on the topic of IP to assist in protecting future innovation.

In recent years there has been an influx of innovation from entrepreneurs and start-ups globally; Panama is no exception. This growth phenomenon is set to continue with no limits to the creativity of innovation and original concepts with scope for application across different markets.

However, as this desire for entrepreneurship has grown, so too has our awareness of the general lack of familiarity within this developing community of innovators for correctly protecting assets. There are regular procedures for setting up start-ups and new companies, but there is one more extremely important step outside of this routine and that is to determine what industrial property can be protected and commercialized such as patents of invention, industrial models, or designs, among others.

Several questions arise when talking about industrial property in entrepreneurship or start-ups, such as: can I protect my name, my logo, my creations, or inventions? These questions open a door and are the engine for the community to begin to reflect on innovations and inventions that they are considering, have in development, or that are emerging to later protect as valuable assets such as trademarks, patents, utility models, and industrial models, among others.

Industrial property, although sometimes forgotten or unknown, is one of the most valuable assets an organization can have, a value that is sometimes overlooked due to a lack of knowledge about how to identify and/or register assets. The registration of industrial property is extremely important since said protection grants value not only of ownership but of use rights, and the commercialization of the same. Likewise, protected assets facilitate enforcement

against and protection from third-party use.

That is why this developing curiosity around entrepreneurship must go hand in hand with education on the subject of industrial property, and this must be guided by both state institutions dedicated to intellectual/industrial property as well as IP associations and others from the private sector that have the essential tools to bring this knowledge and guidance to the interested public. Education will also be fundamental for continuing the development, protection, and creation of a culture of innovation that will allow growth across different fields, such as science, industry, and technology. Education and training mean empowerment and progress.

We know that sometimes identifying the industrial property to be registered, and more specific tasks such as drafting patents of invention, a utility model, or a model or industrial design, can be challenging since it entails a series of steps and documentation in order to present the creation for its subsequent registration. This highlights the importance of educating on the subject to cultivate and raise general knowledge of the IP field and for creating greater competition between entrepreneurs and start-ups, with the rest of businesses, to encourage innovation.

It should be noted that Panama recognizes the importance of this message and knowledge in the patent field. Through various institutions, such as the General Directorate of the Industrial Property Registry, the Universidad Tecnológica de Panamá, and the National Secretariat of Science, Technology, and Innovation, Panama is imparting this knowledge through workshops to nurture people's understanding. In addition, these educational resources provide a very significant guide for drafting and presenting techniques, either for present or future practices for patents of invention, utility models, or industrial designs/models, to achieve adequate protection, which then allows exclusivity or commercialization of these innovations.

Similarly, we have come across entrepreneurs or small local companies that initially support larger foreign companies with the registration of an invention, and along the way have been able to acquire that patent at the local level. In this instance, there is a need for guidance on the transfer of the same, but also, depending on the stage of the registration at the time of transfer, modifications in specific subjects, in something as precise as the claims of a patent of invention, may be required. At this moment, the entrepreneur or start-up company must receive, as we have provided to our clients, the support and guidance in the *do's and don'ts* at the time of composition and development in order to achieve the main objective: the registration of the industrial

Résumé

Melissa Irene Del Busto has been an associate of the firm since 2016. Ms Del Busto provides comprehensive IP counseling for large international and domestic companies requiring first-class services with an in-depth understanding of Panamanian IP law. She has a wealth of experience representing clients in securing and maintaining patents, trademarks, or copyrights; franchise, licenses of use, and distribution contracts; and related litigation procedures to fully protect their intellectual property assets. She is a member of the Inter-American Association of Intellectual Property (ASIPI) and of the *Asociación Panameña de Derecho de la Propiedad Intelectual* (APADEPI).

Ms Del Busto has a Master of Human Resource and Management Skills from CESTE Business School, Zaragoza, Spain, and a Bachelor of Laws, summa cum laude, from Santa Maria la Antigua University, Panama.

She has been recognized in the 2023 editions of Chambers Global, Chambers Latin America, Legal 500 Latin America, and Leaders League.

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Melissa I. Del Busto

property for its use and commercialization. In other words, there is no exact stage where the entrepreneur or start-up will enter the registration process, but they need to have the tools and knowledge to be able to follow such a path until they obtain the due protection of their innovation.

I would like to conclude that, we find ourselves in such a globalized world where technology allows us to reach all the corners of the globe, and no one escapes the threat of a possible third party who might want to take advantage of, for example, a patent or trademark that has been created, developed, and positioned by the entrepreneur or start-up, in order to profit improperly from these creations. That is why our message conveys the importance of protecting industrial property as a main and valuable asset and ensuring the due protection of inventions, through registration, in order to multiply the value of the industrial property creation and also to prevent third parties from misappropriating assets which were created with so much effort by the entrepreneur or start-up.

At ARIAS, FABREGA & FABREGA we have vast knowledge and expertise in industrial property matters and can support you in the registration process of your precious assets. Whether an entrepreneur, start-up, medium, or large company, we have the tools to support you in the determination of your possible industrial property assets and further protection of your inventions and creations.

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Analyzing the complexities of nanotechnology patents

Manisha Singh and Priya Kush of LexOrbis review the challenges presented in patent protection for nanotechnology and nanomaterials due to their exceptional qualities.

Nanotechnology and nanomaterials are considered emerging and promising fields of science. Although the technology has been here for a few decades, it is still considered an emerging technology because its vast landscape has not been fully explored and demands more research. The most adventurous part of working with nanomaterials is that they have numerous possibilities to play with. Any addition, subtraction, or other manipulation of atoms or molecules in a nanomaterial gives rise to different chemical and physical properties. It is no surprise that certain properties which could occur in nanomaterials are not even possible in their bulk counterparts.

Nanomaterials and nanotechnology

Nanomaterials are materials with dimensions in the range of 1-100 nm where 1nm is 10^{-9} m or simply one billionth of a meter. However, materials constituting particles having a size ≤ 1000 nm are also referred to as nanomaterials. The size is so microscopic that it cannot be observed with the naked eye. But one can be happy to assume that hair and nails grow roughly 1 nm every second. More precisely we can say that the diameter of a DNA molecule is 2 nm, or the size of an influenza virus is 80-120 nm.

The effect of such low dimensions is that the physical and chemical properties in nanomaterials

are decided by surface atoms rather than inner atoms. The importance of nano dimension has already been recognized by nature, be it the conical wax nanostructures over the lotus leaves that impart non-wetting properties to them or the three-dimensional nanostructures in the butterfly wings providing them iridescent color. The high surface area, high surface activity, high reactivity, greater tensile strength, high band gap, superparamagnetism, surface plasmon resonance, etc., are just a few of the effects associated with different nanomaterials.

The technology involving the application of nanomaterials or having component dimensions in the nanoscale regime is termed as nanotechnology. However, nanomaterials and nanotechnology are not confined to any specific field of technology and material. Many state-of-art technological applications have evolved to a new level with the emergence of nanomaterials. Nanomaterials have multiple applications in different fields, such as photoelectrical, photochemical, battery applications, biological applications, sensing, and drug delivery applications. New and novel nanomaterials have been continuously designed and synthesized to meet the changing requirements of the technology.

The broad application of nanomaterials makes nanotechnology multidisciplinary. For example, carbon nanotubes have applications not only in semiconductor technology or high-strength material applications but also in drug delivery and bioengineering. Similarly, the well-known semiconductor nanomaterial "CdSe" has a photo-voltaic and photoelectrochemical application and is also well-utilized in bio-sensing applications.

Undoubtedly, such nanomaterials that are potential candidates for any technical application owing to their unique new properties must be protected. The intellectual property related to the synthesis of such interesting nanomaterial or nanotechnology using nano components can be protected through patents.



Manisha Singh



Priya Kush

Résumés

Manisha Singh, Partner

Manisha is known to be one of the most reputed lawyers in the intellectual property domain, with a decorated career of over 25 years. She has served as a vital advisor to corporations and research organizations in handling intellectual property matters and developing strong IP portfolios. She is ceaselessly engaged in endeavors to strengthen India's IP protection and enforcement system to align it with international standards and work closely with industry associations and the government. Manisha has served as the leading counsel for a client base in over 138 countries in their IP management and litigation matters. She is identified by her clients as a seasoned and reliable counsel for the prosecution and enforcement of all forms of IP rights, and planning and management of global patents, trademarks, and designs portfolios. She has also led numerous negotiation deals on behalf of her clients for both IP and non-IP litigation and dispute resolution.

Dr Priya Kush, Associate

Priya is an Associate in Patents Science at LexOrbis and is working on patent drafting and prosecution. She holds a master's in chemistry and a Ph.D. in nanochemistry from the University of Delhi. She is designated as a National Post Doctoral Fellow at IIT-Delhi under her individual project by the SERB-Department of Science and Technology. With more than 12 years of experience in the field of science, she has expertise in semiconductor nanomaterials and their applications. She further has lectureship experience of over two years at renowned colleges and universities. Her research work is published in eight International journals as the first and corresponding author. She is the recipient of a Ph.D. fellowship from Delhi University, a Junior and Senior research fellowship from the University Grant Commission, best poster presentation award at Bhabha Atomic Research Center, DST-Travel Grant, and National Post-Doctoral Research Fellowship by the SERB-Department of Science and Technology. She is currently pursuing LLB to further enrich her knowledge of the legal aspects of IP. She is also a great enthusiast of Indian Folk Art and pursues various artforms in her spare time.



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Patenting nanotechnology and nanomaterials

Three requisite conditions must be met for the grant of patents - novelty, inventiveness, and industrial application. There may be some variation in the intellectual property law of different countries according to each country's specific requirements and conditions. For patentability under Indian Patents Act 1970, the invention is defined in *Section 2(1)(j)* as a new product or process involving an inventive step and capable of industrial application.

Before establishing industrial applications, the novelty and inventiveness of nanomaterial and related technology must be established. To establish the novelty of a product or a process under *Section 2(1)(l)* of the Indian Patents Act 1970, the invention must not be anticipated by any document or publication in the public domain anywhere in the world. To establish the inventiveness or inventive step, the invention must involve some technical advancement or economic advantage or both over the prior art for it to be non-obvious to a 'person skilled in the art' as defined in *Section 2(1)(ja)* of Indian Patents Act, 1970.

As nanoscience and nanomaterials are emerging fields of science, there is ample opportunity to

design new and novel materials for various applications. Sometimes the new properties could arise by manipulation of size or stoichiometries or even by surface manipulation of nanomaterials. However, *Section 3(d)* of the Indian Patents Act, 1970 which restricts patenting of a new property or new use of a known substance, is a principal hurdle in the way of patents related to nanomaterials and related nanotechnology. It is because the new properties emerging in a material by mere manipulation of size and sometimes, stoichiometries of elements in nanomaterials, may be considered obvious and hence create an obstacle in establishing novelty and inventive step of the invention.

Further, patents relating to nanocomposites which are the physical combination of different nanomaterials could face difficulties from *Section 3(e)* of the Indian Patents Act, 1970 which prohibits patenting of mere admixture of any substance.

Moreover, as the chemistry of nanomaterials is extremely intricate and relatively unexplored, the most limiting aspect in the synthesis and designing of nanomaterials is the reproduction of similar physical and chemical properties in nanomaterials. The dimensions of nanomaterials that account for their distinct properties are complex to control with precision. This limitation



Credit:Rike_

is a considerable hurdle in establishing both the novelty and inventiveness required for the grant of a patent. It is because the inventors, to broaden the scope of claimed process and product, may draft and file overly broad claims (that may sometimes be granted too) and involve a risk of patents overlapping.

It further makes it difficult sometimes to disclose the invention completely in an obligatory manner as provided in *section 10* of the Indian Patents Act 1970, for the want of some sophisticated instrumentation, design or even want of skill. Insufficient disclosure in the complete specification or overly broad claims unsupported by the complete specification are valid grounds to further invite pre- and post-grant opposition under *Sections 25(1)(g)* and *25(2)(g)* respectively.

Due to their beneficial physical and chemical properties, nanomaterials already have different industrial applications. However, most of the nanomaterials and associated nanotechnology are developed at a lab scale in universities and research institutes and may not show the expected results on a large industrial scale. Insufficient prior art and a skeptical view about the actual performance of developed nanomaterial and nanotechnology further hinder their industrial application.

Additionally, the lack of knowledge, awareness, and sufficient prior art from the examination point of view may lead to the rejection of essential patents or may result in the evergreening of patents.

Possible solutions to overcome the issues in nanotechnology patenting

The Indian Patent Laws are designed in such a way that the evergreening of patents can be

avoided effectively. However, certain steps may be taken to handle the patents related to nanotechnology and nanomaterials effectively in the public interest. The first and foremost requirement is creating knowledge and awareness about the intricate multidisciplinary subject. It could help in the better screening of patent applications on relevant solid grounds. Better screening could ultimately help in granting essential patents in the public interest and rejection of patents with frivolous claims.

Further, a different capacity of specialized subject-specific examiners and analysts can be developed to deal with patent applications, specifically those related to nanotechnology and nanomaterials. The challenge is not impossible to overcome as the subject has already been incorporated into academics, and large-scale research is being conducted globally in the multidisciplinary field of nanoscience and nanotechnology.

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- » **Asialaw 2018:** Manisha Singh recognized as Leading Lawyer for IP
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Making it to the finish line: patent renewal trends for portfolio management

Arun Hill and Jack White of Clarivate unpick key findings from a recent report that could help assist companies to manage risk and enter new markets with industry-specific patent renewal insights.

Résumés

Arun Hill has a decade of experience in the field of patent analytics and is an expert in innovation intelligence and ethico-legal issues. He has a background in law and in his spare time, is pursuing a Master of Law degree at the University of Edinburgh, covering innovation and technology areas such as space and robotics. Arun has a track record of working with global technology-focused corporations, governments, and research institutions to deliver actionable intelligence to transform their patent decision-making and strategies.

Jack White joined Clarivate via the CPA Global acquisition in October 2020, and has been with the business since 2014. Prior to IP, Jack started his career in Business Consulting for Deloitte out of London, before moving to Jersey and joining CPA Global. In his time at CPA Global/Clarivate he has held a number of roles across the business including business transformation, change management, M&A integration, and product leadership. In his current role leading the Patent business, Jack is responsible for the strategy, delivery, and performance of all patent-related service lines.



Arun Hill



Jack White

As the stock of patent filings continues to grow at unprecedented rates, so does the size and complexity of the average portfolio. With more assets to manage and greater cost sensitivities, patent holders are under pressure to ensure their portfolios work for (and not against) them. As part of this exercise, patentees must also navigate the terrain of annuities payments spanning multiple jurisdictions, product lifecycles, and shifting organizational priorities. The strategic importance of renewals can often be underplayed. They serve an essential purpose, providing scheduled opportunities to contemplate the utility of patent assets and therefore the continuation of renewal, and deliver wider benefits that promote the patent system's healthy functioning.

Over the last few decades, patent filings have increasingly become utilized as a rich source of commercial, technical, and legal information. Owing to the development of contemporary computing, this has culminated in an entirely new discipline: patent analytics. While invaluable, these types of analysis have focused on 'who is protecting what and where'. Until now, however, patent renewals have been cut out of the frame. Renewals deserve exploration as a dataset of their own. For instance, knowing the typical abandonment rate for a country, industry, or technology could help patentees enter a new market or to manage risk. By combining grant and abandonment rates, we can better understand the chances that a similar patent or application in each field would survive. In doing so,

Knowing the typical abandonment rate for a country, industry, or technology could help patentees enter a new market or to manage risk.

we can see potential renewal dynamics, helping patent holders make contextualized decisions about their exposure to opportunity or risk.

Of course, data is no substitute for expertise. However, at the intersection of data and expertise is better decision-making. If enriched patent data can be combined with knowledge of the IP system, decision-makers are equipped with all the necessary information to anticipate risks within their control and operate more confidently.

In a recent report, we analyzed patent renewals data globally to understand what could be gleaned from annuities data.¹

Key findings from analyzing global patent renewal trends

Analyzing renewals across the worldwide patent system requires a large volume of data. This study drew on legal status information from 70 million patents across five jurisdictions. From a technical standpoint, it is also argued that this analysis is only possible today for two reasons. First, you need the data power to make inferences from

¹ <https://clarivate.com/lp/global-patent-renewal-trends-unpicking-what-survives/>

millions of patents. Second, there needs to be at least 20 years of 'good' data, i.e., in terms of coverage, retrievability, and volume. This study focused primarily on determining what proportion of patents have lapsed due to non-payment of fees. In simpler terms, the objective was to ask, 'What survives?'

In any global analysis, there is a balance to be had between breadth and depth and a trade-off between granularity of insight and providing a holistic overview. This holistic analysis sets the foundations for further use of renewals data. There were several significant findings from the report.

Sectors varied significantly in their abandonment rates. Between the industry with the highest abandonment rate - Luxury, fashion, and sports - and the lowest - medical devices and biotechnology - there was a 12% difference. Even one percentile point represents millions of patents and associated R&D investment. This confirms that there are nuances to renewal activity within technology domains. Chances of



“Of course, data is no substitute for expertise. However, at the intersection of data and expertise is better decision-making.”

survival are likely to be dependent (and informed) by the subject matter of the patent and the technology domain it forms a part of. Although this is not surprising, it does illustrate the potential for renewals data to provide further guidance to patentees on the dynamics of unfamiliar markets. The usefulness of this intelligence is in validation and orientation.

These differences between sectors warrant deeper consideration. Life science verticals, including medical, biotech, and pharmaceuticals, have significantly longer patent lifecycles. On average, almost 35% of patents filed 20 years ago are still enforced today. By contrast, brand-centric sectors move ‘faster’ relative to other industries. Patents were abandoned sooner and exhibited some of the highest abandonment rates. By year 20, only 25% of patents were still in force, 10% less than those in the life science sector. This confirms that differences in R&D lifecycles and the industry’s nature will manifest in patent renewal rates.

A final observation from the report that is worth emphasizing, although widely acknowledged, is the increasing dominance of filing emanating from Mainland China. Considering the footprint of all patent filings over the last two decades, China (Mainland) is overwhelmingly the jurisdiction with the largest volumes of national patent filings, with academic and government institutions being the largest.

Creating new possibilities for portfolio management

At first glance, these findings do little more than confirm observations that are almost intuitive, or even logical, to IP specialists. However, what is unique here is the fact that these findings were derived from data. It represents a first step towards the quantification of patent survival.

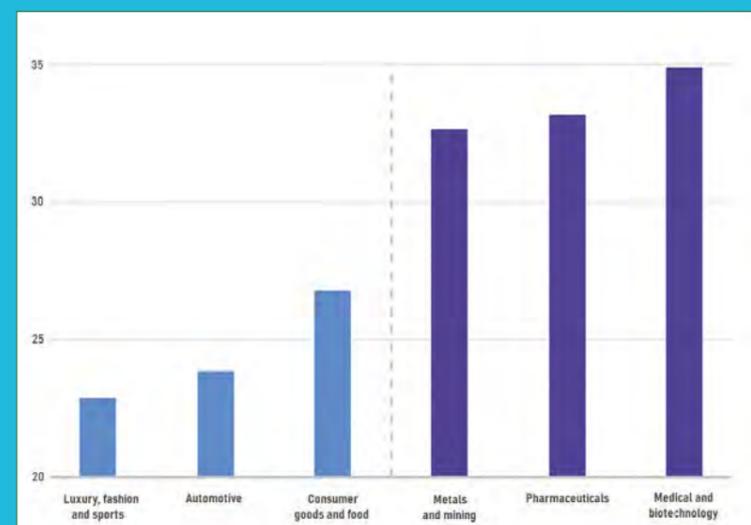


FIG.: Average % of patents maintained by year 20, top three highest and lowest industries. Source: Clarivate

Patents form part of a larger ecosystem shaped not solely by the considerations of the patent owner but the conditions of the patent marketplace. Understanding the dynamics of this marketplace can only further enhance portfolio optimization efforts.

The possibilities for developing ‘renewal intelligence’ are compelling. In the future, more work can be done to understand the relationship between patent strength scoring and abandonment rates, augmenting IP strategy with predictive analytics. Another application emerges as soon as these techniques are applied to smaller, contained datasets through the lens of a particular industry or technology. An example would be, if such an analysis were to focus just on a single sector, like pharmaceuticals. Assuming there was some categorization of the relevant patents, data may indicate whether some therapeutic areas have higher abandonment rates than others. Even more interesting is the possibility of developing models to understand why and when patents should lapse. A much more ambitious endeavour would attempt to combine analysis from patent filings, renewals and litigation to assess risk and opportunity within a defined market.

In an increasingly automated world, the possibility of new technologies and alternative data should be approached with caution. It is often challenging to determine whether something new will be helpful or add an unnecessary layer of complexity, hindering legal practice. When it comes to renewals, the reasons behind a decision to renew or not are unique to the patent rights in question, their owner, and of course, the industry. This article focused on the possibility of using existing patent data that is curated and cleaned to transform the way that practitioners might approach portfolio management. It is not a panacea but something that requires further consideration as a device for decision-making. It gives resource-constrained patent holders (and legal professionals) a means of understanding the landscape and those with larger, more complex portfolios a way to stay lean and deliver all-important cost savings to the organization.

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In focus: border seizure

Dr. Christian Thomas, Attorney at Law and Partner at Kuhnen & Wacker, details how border seizures can be utilized as an effective instrument against imitators and counterfeiters.

Border seizure is a legal instrument that many companies do not even have on their radar, or only to an insufficient extent. Yet border seizure is basically free of charge and can help to clear the European market of counterfeiters and pirated products in an effective and cost-saving way. This can be immensely important, as counterfeit products not only cause economic damage to original manufacturers, but can also sometimes be dangerous to consumers. There are many practical examples, although there is certainly a particular potential danger with regard to counterfeit baby

food, faulty components (such as brakes), or even medicines. The legislator has recognized that it is often very difficult for the original manufacturers to identify the producers of such counterfeits and thus provides the possibility of border seizure by customs authorities as an additional tool.

Ultimately, therefore, with an effectively filed application, the state and European authorities can be “used” to protect one’s own IP portfolio (for example, consisting of trademarks, designs and/or patents) and to prevent the import and export of IP infringing goods already at the external borders of the EU or Germany. German customs authorities in particular have proven effective in this regard in recent years. In 2021, nearly 25,000 cases of goods were seized by German customs, which had a total value of over EUR 310 million. In most cases, the seized goods come from the Far East, especially China, but also from African countries and Turkey (see www.zoll.de). With regard to the goods concerned, it is interesting to note that in addition to clothing, cigarettes, bags, and electronic components, more and more complex imitations from the mechanical engineering and pharmaceutical industries are also being intercepted by customs officials.

The application for border seizure and its requirements

In most cases, the customs authorities only act upon application. In individual cases, however, they may also act *ex officio*. The normal case, however, is action upon



Credit: cogal



application. The application itself is free of charge and is made for one year at a time. It is therefore not necessary to file a separate application for each individual case. If the property rights continue to exist, this can also be extended as often as desired.

In the case of an application for border seizure, a distinction must be made between a national border seizure application and a Union application. The EU-wide border seizure is basically determined by Community law (Regulation (EC) No. 608/2013). This covers all imports and exports of goods from third-party countries into the EU. In addition, the national border seizure procedure is supplemented by national regulations for the intra-European movement of goods. Both approaches (national law and EU law) stand side by side and ultimately allow German customs to take action on imports into Germany, i.e., on intra-European imports, as well as on imports from third countries into the EU as a whole. In border seizure proceedings at EU level, goods suspected of infringing intellectual property rights that claim EU-wide effect can be seized. These include Community trademarks, Community designs, internationally registered trademarks and designs designating the EU, and geographical indications. The border seizure covers goods

If the customs authorities suspect an infringement of property rights during the inspection of cross-border goods traffic, the respective goods are detained.

imported into the EU, goods exported from the EU, or goods declared for re-export.

The application to be submitted electronically must contain, in addition to proof of the IP rights to be covered, proof of the applicant's authorization and information on the possible contact persons. In addition, supplementary information should be provided on the product group concerned and the original products. The customs authorities should also be provided with information on common supply routes and typical characteristics of counterfeits. Ideally, therefore, the customs authorities will be provided with a kind of "guide" that will enable the authorities to distinguish original goods from counterfeits as easily as possible and also to know in advance whether original products are being supplied to the EU at all from a certain region of the world. The prerequisite for border seizure by the customs authorities is the existence of a suspicion of an infringement of property rights. It is not necessary that an infringement of property rights actually exists.

Procedure in the event of action by the authorities

If the customs authorities suspect an infringement of property rights during the inspection of cross-

border goods traffic, the respective goods are detained. At the same time, an information letter is sent to the applicant, informing them of the origin and nature of the goods as well as the parties involved (sender, recipient, forwarder, etc.).

The applicant then has the possibility, within the framework of a Union application, to notify the customs authorities of the infringement of the IP right within 10 days of receiving the notification of the border seizure and to initiate legal proceedings. The court proceedings may be either interim injunction proceedings or "normal" substantive proceedings. In the case of perishable goods, the applicant only has a period of three working days, which cannot be extended.

As an alternative to proof of an initiated procedure, the applicant may file an application for "simplified destruction" of the goods. In this case, the goods will be destroyed by the customs authorities if the declarant or owner of the goods has either positively agreed to the destruction or has not objected to the destruction within the above-mentioned period (10 days). The destruction shall be carried out at the expense and responsibility of the applicant.

If the declarant or owner of the goods objects to the seizure, the goods shall be destroyed only on the basis of a court decision.

Other legal consequences and summary

In addition to the border seizure and destruction described above, the claimant may in principle also demand reimbursement of the costs incurred by them (for example, attorney's fees). In addition, they may be entitled to claims for damages, injunctive relief (e.g., preliminary injunction), and disclosure. In Germany in particular, the possibility of applying for an injunction is a fast and cost-intensive means. However, this can usually only be used to enforce a cease-and-desist order (and not information and/or damages). The German courts issue a temporary injunction within four weeks of becoming aware of the infringement. In most cases, such a preliminary injunction is issued or rejected within a few days of the application being filed, so that as a rights holder you very quickly gain certainty as to whether or not your claims will go through. Since this is a provisional decision, the infringer must then either recognize the preliminary injunction as final, or the rights holder must then file a "normal" lawsuit if necessary.

As far as the assertion of claims for information and damages is concerned, it is generally possible to file an action on the merits. In Germany, proceedings on the merits of a case take between six and 12 months in the first instance (as a general rule). In addition, the losing party generally has the option of filing an appeal. The filing of a main

Résumé

Christian Thomas joined KUHNNEN & WACKER in 2005 and became a partner in 2011.

Having studied law at the Ludwig Maximilian University (LMU) in Munich, Dr Thomas joined the Munich Bar Association in 2005 and obtained a PhD from the University of Salzburg, Austria, in 2009.

As head of the legal department of KUHNNEN & WACKER, he has filed several thousand EU trademark and EU design applications and is deeply committed to obtaining and enforcing IP protection for his international clients.

Before joining KUHNNEN & WACKER in 2005, he worked for a law firm in Australia, which added to his multifaceted background. He is a regular speaker at seminars about trademark and design, frequently writes on IP-related matters, and is a lecturer for commercial law and IP rights at the University of Applied Sciences, Munich. He is proficient in German and English.



Dr. Christian Thomas

action is, of course, only necessary if the opposing party does not meet these claims on a voluntary basis. Practice and our experience have shown that, especially in proceedings in the area of border seizure, further judicial measures are often unnecessary, and the violators often submit without further resistance. This is probably also due to the fact that official authorities are involved and the violators fear having to bear further consequences and are grateful for a quick and uncomplicated settlement.

An increasing number of infringements of industrial property rights can also be expected in the future. The increase in seizure cases in recent years clearly shows the topicality of the problem, but also the increasing effectiveness of the German and European customs authorities. In order to further improve efficiency in this area, in addition to raising the awareness of customs officers, the expansion of cooperation between economic operators and customs authorities is of great importance and desirable. It is therefore to be hoped that in the course of the coming years the number of applications for border seizure will increase and more economic operators will make use of this possibility in order to protect their own economic goods. Ultimately, every successful case of seizure means that jobs are secured and the quality of branded goods is guaranteed.

Contact

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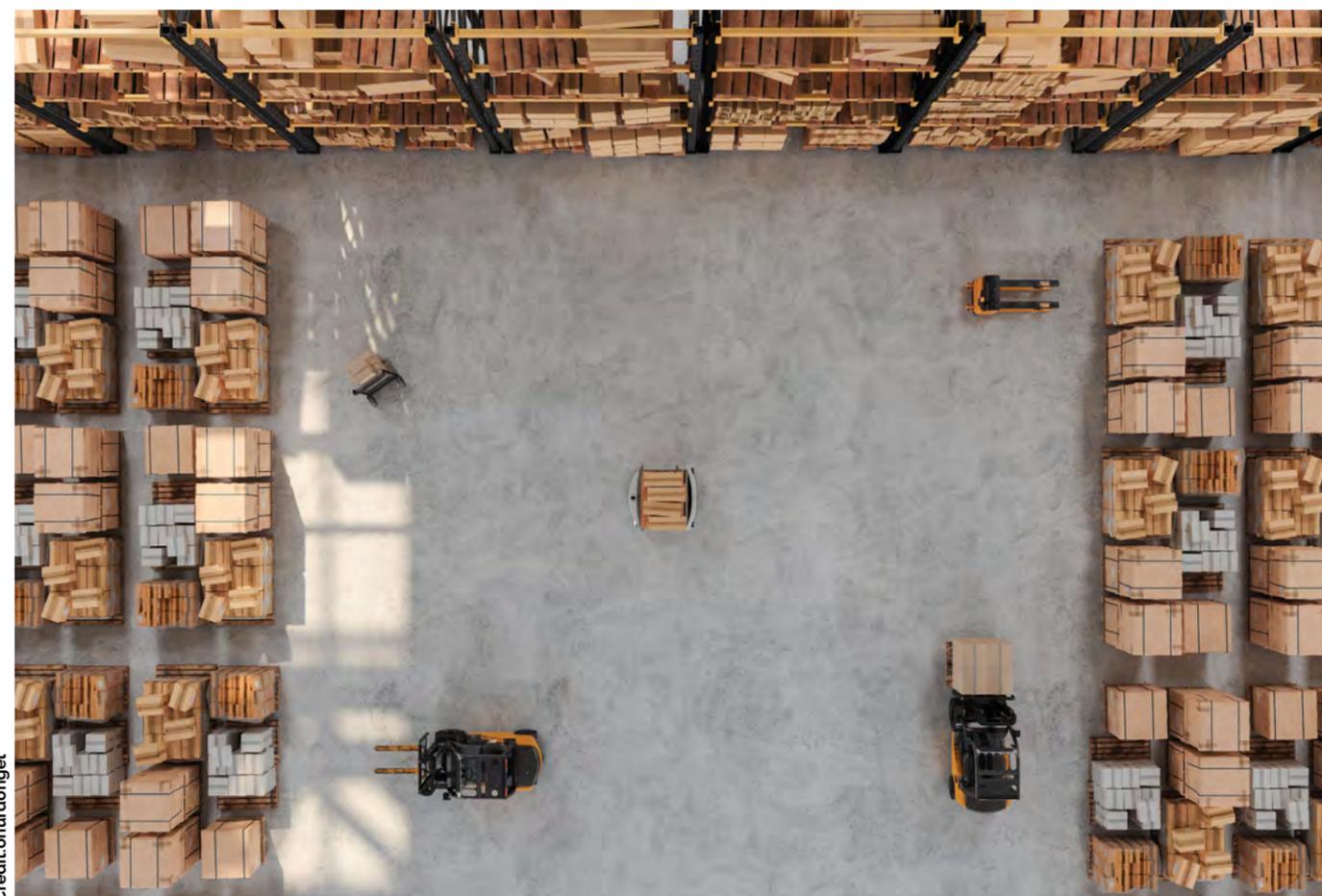
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Delhi High Court examines factors for the patentability of species patents in India

Rachna Bakhru and Suvarna Pandey of RNA, Technology and IP Attorneys review a recent case that investigated species versus genus patent infringement following the availability of linagliptin as a generic medicine in the US as of 2021 in a cross-border conflict with India.

In a landmark decision, the Delhi High Court denied an injunction to the Plaintiff (BOEHRINGER INGELHEIM PHARMA GMBH) for infringement of patent rights in Linagliptin, a drug to treat Type 2 diabetes. While deciding the infringement action, the Court analyzed various vital factors, including species versus genus patent infringement. In this case, the Court also looked at the evergreening of the Patent, public interest, and prior claiming.

Linagliptin is sold under the brand name Trajenta, which acts by inhibiting the enzyme dipeptidyl peptidase-4 (DPP-4). Unlike other DPP-4 inhibitors, linagliptin is excreted chiefly via the enterohepatic system, and safe for patients with renal or hepatic impairment.¹ In 2020, it was the 293rd most prescribed medication in the United States, with more than one million prescriptions. From August 2021, linagliptin became available as a generic medicine in the US.² The company is not manufacturing the drug in India. It has licensed the suit Patent to Lupin Laboratories and Eli Lilly, for which royalties are payable by the said entities to the plaintiffs.

Background and facts

The Plaintiff, BOEHRINGER INGELHEIM PHARMA GMBH, Patentee of two patents- IN'227719 i.e., genus patent (IN '719) and IN'243301 i.e., species patent (IN '301), filed six suits against various Indian pharmaceutical companies seeking an injunction against the manufacturing of Linagliptin. Due to



Rachna Bakhru



Suvarna Pandey

the common issues involved, the Court has given a joint decision in the six suits filed against various defendants.

Genus patents are broad patents covering a group of potential products. Genus claims are written mainly by Markush structure, which claims a large class of chemical compounds. At the same time, the species/selection patent covers a specific compound, which forms a part of the Markush structure claimed in the genus patent. Simply put, the genus patent has a broader coverage, while the species patent has a specific coverage.

The Plaintiff invoked genus patent (IN '719) and species patent (IN '301) in two of the six suits i.e., C.S. (COMM) 239/2019 and C.S. (COMM) 240/2019 against Vee Excel Drugs and Pharmaceuticals Private Ltd.

The genus patent (IN '719) expired on February 21, 2022, while the species patent (IN '301) will expire on August 18, 2023. After the expiry of genus patent (IN '719), the Plaintiff filed four suits i.e., C.S. (COMM) 236/2022, C.S. (COMM) 237/2022, C.S. (COMM) 238/2022 and C.S. (COMM) 296/2022, seeking an injunction against the Defendants (Indian Pharmaceutical companies). The Defendants, in turn, challenged the validity of the species patent (IN '301), on the grounds of section 3(d) and prior claiming as their defense.

According to Section 3(d), the mere discovery of a new form of a known substance that does not result in the enhancement of the known

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3498850/>

² <https://en.wikipedia.org/wiki/Linagliptin>



Credit:Roop_Dey

efficacy of that substance is not patentable. It means that different forms of a known substance must differ significantly in the properties regarding efficacy. Overall, the legislature's intention by including section 3(d) was to disallow evergreening of patents.

The ground of prior claiming is raised where the invention (first application) claimed in a complete specification filed in India has already been claimed in the complete specification of an application (second application) which was filed in India before the priority date of the first application but published on or after the filing of the second application.

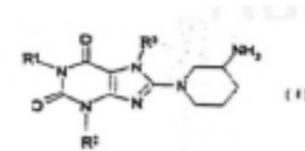
The Court formulated the following main issues for the grant of interim injunction in favor of the plaintiffs:

Prior claiming

- The Court opined that a comparison, in the below table, shows that a substantial part of the chemical structure in Claim 1 of the suit patent and the genus patent are structurally similar. Considering that the plaintiffs have themselves in the proceedings before the Controller admitted that Linagliptin is one of the possible substitutions of IN '719, it would leave no matter of doubt that both the patents are attempting to cover the same subject matter as well. This would not be permissible under the Patents Act.

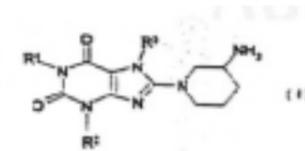
IN '301 (Suit Patent)

Claim 1 of the 301 patent is itself a genus/class of compounds approximately covering 22 alternatives (excluding isomers, tautomers, etc.) of the following structure:



IN '719 (Genus Patent)

Claim 1 of the earlier 719 patent is also a genus/class of compounds but of a much larger size having the following structure.



- The Court also found indications of prior claiming not just in the suit Patent. Still, there were such indications even during the International Phase of prosecuting the suit Patent. The International Search Report (ISR) issued concerning the PCT publication of the species patent by the International Search Authority mentioned the corresponding PCT publication of the genus patent IN'719, i.e., W/O. 02/068420 as a P and X (for determination of novelty and inventive step in regional/national procedures). In India, considering that prior claiming is a ground for revocation under Section 64(1)(a) of the Patents Act, 1970, the P, X reference document highlighted

by the ISA is striking at the novelty and inventive step of the species patent.

- iii) While responding to the examination regarding the genus patent application, Plaintiff submitted a list of 371 compounds, one of which was Linagliptin. The Court noted that the plaintiffs specifically claimed Linagliptin to obtain the grant of the genus patent. However, in the rejoinder filed on behalf of the plaintiffs to I.A. 5806/2022, the plaintiffs made a complete U-turn and stated that Linagliptin had not been claimed in IN '719.

Data in Form 27 / working statement

After perusing the two Form 27s of the same period for genus and the species patent, the Court found that all the pharmaceutical products which the two patents claim to be working in India are the same. In addition, the quantum and value of imports and sales are also the same. Therefore, it is evident that both IN '301 and IN '719 are directed toward the same invention, which is not permissible as per Section 10 of the Act.

“
The plaintiffs have enjoyed a 20-year monopoly of Linagliptin under the genus patent.”

Evergreening

The Court noted that by filing multiple patents for different aspects of the same product, the Plaintiffs are seeking to extend the term of the patent beyond 20 years, granted in respect of the genus patent.

Since, the patent expired on February 21, 2022, it amounts to evergreening or layering of patent protection, which is impermissible under the Indian Patent Law under Section 3(d) of the Patents Act. The Court referred the findings from *Novartis v. Union of India, (2013) 6 SCC 1 (Novartis)* for section 3(d) where the Supreme Court dealt with the issue of whether the therapeutic drug, beta crystalline form of Imatinib Mesylate, qualifies as an invention under Section 2(1)(j) and Section 2(1)(ja) of the Patents Act and whether the Patent can be refused under Section 3(d) of the Patents Act, highlighting that “*Under the scheme of Patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it. To say that the coverage in a patent might go much beyond the disclosure thus seem to negate the fundamental rule underlying the grant of patents.*”

Balance of convenience

The Court addressed the following issues about the balance of convenience and irreparable injury, the fundamental principles which govern the grant of interim injunction:

- i. Whether balance of convenience is in favor of the plaintiffs and against the defendants for the grant of interim injunction?
- ii. Whether the plaintiffs would suffer irreparable injury on account of non-grant of interim injunction?

The Court, while examining the above two questions, noted that the plaintiffs have enjoyed a 20-year monopoly of Linagliptin under the genus patent. Except for the defendants in C.S. (COMM) 239/2019 and C.S. (COMM)240/2019, the other defendants waited for the 20-year term of the genus patent to expire on February 21, 2022, before launching their drugs in the market.

Further, the plaintiffs do not manufacture their drugs in India, but import their drugs into India. Clearly, the intention of the plaintiffs is to monetize the said invention.

Therefore, the present case is one where monetary damage can be calculated and awarded to the plaintiffs in the event the plaintiffs succeed in the present suits. It is a settled position of law that where monetary damages are the adequate compensation for the plaintiffs, an interim injunction should not be granted.

Public interest

The Court thus considered the elements of public interest as the drug Linagliptin is used for the treatment of diabetes, which is a widely prevalent disease in India. Therefore, the public interest also demands that large segments of the population should have easy and affordable access to an anti-diabetes drug. Undeniably, the defendant's products are significantly cheaper than that of the plaintiffs. Considering that Linagliptin is a daily-use drug, affordability plays a major role in its access to wide sections of the public.

Thus, finally taking all the above factors into consideration, the Court concluded that *prima facie* suit patent of the plaintiffs, i.e., IN'301 is vulnerable to revocation on the ground of prior claiming in terms of Section 64(1)(a) of the Patents Act, as the plaintiffs have made an attempt towards evergreening the invention and re-monopolizing the same.

Summary

The order in the present case highlights that the courts also considered the factor of “public interest” equally as to the patentability/technical



Credit: RapidEye

Résumés

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Rachna Bakhru is a Partner with RNA, Technology and IP Attorneys, an IP specialist law firm. She qualified as an Electronics graduate from Delhi University, followed by a diploma in Business Administration and a degree in Law. She is a registered Patent agent and a member of the Bar Council of India.

Rachna currently heads the Dispute Resolution team of the firm, dealing with IP enforcement and advisory. She has over 25 years of extensive experience in managing non-contentious and contentious IP matters, IT, and Technology issues. Her expertise includes risk assessment, IP clearance, regulatory issues, litigation, and alternate dispute resolution. She has worked on portfolios of large international companies and her industry expertise includes Pharmaceuticals and Information technology. She advises her clients on issues related to IP infringement, Information Technology, trade secrets, data protection, and geographical indications.

Suvarna Pandey, Associate Partner

Suvarna is a registered patent agent and a law graduate. Having been in the practice for around 13 years, her specialties include patent searches, patent drafting, and providing patentability and infringement opinions. She is also involved in patent prosecution proceedings at the patent office, opposition and other invalidity proceedings. She is specialized in the development and strategic management of patent portfolios in areas that include Biotechnology, chemical, and pharmaceutical inventions. She has been advising clients on global patent strategy including PCT applications and national phases in designated countries.

Suvarna has also authored various articles and delivered training sessions in the domain of Indian Patent practice.

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parameters, while deciding an injunction/ infringement proceedings at the interim stage, particularly in pharmaceutical matters.

The public interest defense has often been pushed as a "one size fits all" approach in every pharma patent infringement matter and in this case as well it was a strong argument that the injunction will not only affect the interest of the infringer but also the end consumer.

For the species patent to get approval over the teaching/disclosure of genus patent, it is important to show technical advancement or enhancement of the known efficacy to qualify the objection of section 3(d). Ideally, there should not be any overlap between disclosure and claims in the patent specifications for genus and species patents.

The plaintiff has filed an appeal before the Division Bench of the High Court challenging this order. The appeal is yet to be heard on merits. It will be interesting to see the outcome of the appeal bench on the patentability of Linagliptin in the species patent in view of the above-mentioned facts.

The above factors were also discussed in an earlier case *AstraZeneca AB & Anr. v. Intas Pharmaceuticals Ltd.* where the Delhi High Court dealt with Dapagliflozen ('DAPA') which is useful for the treatment of type-II diabetes mellitus. DAPA was claimed in the subject matter of two Patents:

1. IN205147 ('IN 147') discloses Markush structure i.e., a group of compounds that covers 'DAPA' and is a genus Patent.
2. No.235625 ('IN 625') specifically discloses DAPA and is a species Patent. The Patent is valid until May 5 2023.

AstraZeneca, based on these two patents, had sued several Indian pharmaceutical companies for patent infringement. Here, the Court observed that a single formulation as DAPA, is incapable of protection under two separate patents having separate validity periods. When the inventor is the same, the tests regarding "obvious to a person skilled in the art", "anticipation by publication" and "use before the date of filing of patent application with complete specification", cannot be in the context of "person ordinarily skilled in the art" but have to be of the "person in the know". It was also mentioned by the Court that the applicant cannot enjoy two rounds of 20 years of protection, when the legislative policy is to grant protection for a period of one term of 20 years only.

In another recent case, on March 23, the Indian Patent Office also rejected Janssen's secondary (or species) patent application on the fumarate salt form of Bedaquiline, which is a drug for the treatment of multi-drug resistant tuberculosis.

“**Clearly, the intention of the plaintiffs is to monetize the said invention.**”

The Controller refused the patent application on the basis that the pharmaceutical composition of base compound Bedaquiline against M. tuberculosis was already covered under the patents previously granted in favor of the applicant. The controller also mentioned in the order that the applicant had to show data on how an increase in bioavailability results in increased therapeutic efficacy. The combination of fumarate salt of Bedaquiline along with common pharmaceutically acceptable excipient wetting agent is considered a known substance and not patentable u/s 3(d) of the Act. Further, it was also found that the application verbatim copied several portions particularly, the portions related to the use of a wetting agent, from Janssen's own patent application.

Key takeaways

- The genus patent may cover multiple chemical compounds, however, only those compounds will be considered as disclosed which can be obtained by going through the disclosure of the genus patent.
- The species patent application should have enhanced therapeutic efficacy over the compound of the genus patent to overcome section 3(d) requirement.
- Further, as noted from the facts of the above-mentioned cases, the Patentee needs to be cautious of the submissions being made in the response to the examination report, working of the patent information filed in Form 27 and other documents filed during the prosecution of genus and species patents. There should not be overlapping disclosure/s in the complete specification/s and the information in official documents needs to be consistent.

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Get ready for the new patent system in Europe!

Marianne Schaffner and Thierry Lautier of Reed Smith assess reasons to opt-in or out of the new UPC while comparing alternatives with additional guidance for US companies.

In Europe, a revolution in the patent world is underway: it began in January 2023 at the EPO and has already started to take hold. The new system will officially enter into force on 1 June 2023.

The European patent with a unitary effect, Unitary Patent, is an additional type of protection for the entire territory of the EU (Poland, Spain, and Croatia excepted). The classic European patents (which, after grant, split into a bundle of national patents) remain available.

In Europe, innovators will have the choice between national, European patents, and Unitary patents, and combining different types of patents will be possible under certain conditions.

A new court for patent litigation in Europe is created: it is the Unified Patent Court (UPC) having exclusive jurisdiction over Unitary Patents and classic European patents. However, for seven years (renewable once), classic European patents can be opted out from the jurisdiction of the UPC.

Some companies are thrilled about the new system, focusing on its main advantages, namely:

- Opportunity to centrally enforce a European patent, and get a decision covering up to 24 countries, both on injunction and damages (which will include loss and undue profits made by the infringer), with one single court action;
- Ability to obtain orders for collecting evidence prior to litigation (there is no Discovery in the EU, and the burden of proof lies on the plaintiff);
- Super-fast track (decisions to be rendered within 12 months);



Marianne Schaffner



Thierry Lautier

- Very high specialist judges (both legal judges and technical judges);
- Attorney fee savings (only one court action).

While other companies focus on drawbacks, namely:

- Risk of central revocation of a European patent;
- Lack of existing case law (including the risk of multiple procedural motions due to some text uncertainties of the UPCA and the rules of procedure);
- Doubt on the independence of the technically qualified judges as they are part-time judges either as patent attorneys in-hour or in private practice.

New patent strategies in Europe must be contemplated. Here are a few questions to be asked:

- Should I opt-out patents, which one, all of them?
- How and when to decide to go for a Unitary Patent?
- Do my current IP agreements allow me to decide on opting out; on deciding to have, or not, a unitary effect; on how and before which court to commence a patent case?
- How to make my decisions?
- How can I diversify my patent protection, can I file divisionals? Can I cumulate different types of patents for the same inventions?

These questions should have been under consideration for several months now, but nothing is too late.



Credit: Fokusiert

The new European patent system has been awaited for 50 years. There are three major legal texts to know:

- The Agreement on a Unified Patent Court (UPCA) signed on 19 February 2013;
- The Rules of procedure adopted on 8 August 2022;
- EU Regulation No 1257/2012 dated 17 December 2012, creating the Unitary Patent.

Another one to note is the Protocol to the UPCA on provisional application having entered into force on 19 January 2022. This Protocol has been the start of the Provisional Application Phase (recruitment and training of the judges, setting up the case management system).

The system will enter into force on 1 June 2023, with the sunrise period having started on 1 March 2023.

The EPO has allowed patent applicants whose European patents are about to be granted to postpone their grant to be entitled to seek the unitary effect as of June 2023.

In Europe, knowing its geography is key and it will be even more crucial with the new system. In Europe, we have several European zones:

- The EPO zone has 38 member states, namely the EU plus the UK.
- The EU has 27 member states, being recalled that the UK has brexited.

“The system will enter into force on 1 June 2023, with the sunrise period having started on 1 March 2023.”

”

¹ At the start, the 17 UPC members are: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania; Luxembourg, Malta, Netherlands, Portugal, Slovenia, Sweden.

- The “Europe” of the new patent system will have 24 member states i.e., the EU less Spain, Poland, and Croatia.

But... the new system will start with a temporary zone of 17 countries only, i.e., those having signed, ratified the UPCA, and deposited their ratification instrument (the seven remaining countries should join later)¹.

Consequently, the very first Unitary Patents will have effect in 17 countries only.

During the first months or years of the new system, the Europe of the UPC and Unitary patent will have different borders depending on

Résumés

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when unitary effect is requested and when an action will be filed before the UPC.

A brief description of the UPC

The UPC is a new patent court having exclusive jurisdiction over Unitary Patent disputes as well as subject to a transition period over classic European patent disputes.

The UPC judgments will have effect in up to 24 countries (up to 17 at the start) and in the countries where a classic European patent will be in force.

The UPC is composed of a central division with its seat in Paris (and with a branch in Munich). The central division will be competent for revocation actions, declarations of non-infringement, and infringement under certain conditions. It is composed of two legal judges and one technical judge.

There are local divisions in each member state (except Sweden, Estonia, Latvia, and Lithuania, having set up the Nordic-Baltic division) which are competent for infringement actions and counter-claims for revocation (unless they use the bifurcation option). They are composed of two local legal judges and one legal judge from another member state and optionally one technical judge.

The UPC:

- Will allow patent holders to seek central injunction (and even a preliminary injunction), and third parties to seek central patent revocation;
- Will award damages for the entire relevant territory of the UPC;
- Will be super-fast tracked: decision to be reached within 12 months;
- But it will not be any discovery/disclosure.

For US companies, the level of damages due to the geographical scope can be seen as significant progress. Let's consider that France is smaller than California...

What to do if you are eager to use the new patent system and the UPC

How to get a Unitary Patent

The unitary effect must be requested within one month from the grant of the European patent. This request will not be possible until the entry into force of the UPCA.

Thus, the EPO has allowed applicants to request the delay of grant of their soon-to-be-granted European patents as of 1 January, 2023.

Applicants can withdraw the request to delay grant at any time.

It is important to note that a request to delay grant is independent from a request for unitary effect. This means that if an applicant requests

“From a logistic perspective, the Unitary Patent will require fewer formalities and deadlines; all formalities will be performed before the EPO, not before multiple national offices.”

a delayed grant, upon entry into force of the UPCA, a separate normal request for unitary effect will have to be filed within one month from the grant of the European patent.

If a delayed grant has been requested, it is not mandatory to request unitary effect.

Why choose a Unitary Patent?

Depending on the number of states where protection is sought, the Unitary Patent may be less expensive than a classic European patent (e.g., fewer translation requirements, lower annuities, lower administrative expenses).

From a logistic perspective, the Unitary Patent will require fewer formalities and deadlines; all formalities will be performed before the EPO, not before multiple national offices.

In terms of enforcement, the Unitary Patent will from the very beginning fall within the exclusive jurisdiction of the UPC, which will not be the case for a classic European patent during the transitional period.

At the start, the Unitary Patent will cover 17 member states. The seven other member states will never be covered by any Unitary Patents granted before they ratify the UPCA. In the countries not covered by the Unitary Patent, classic European patents will remain.

Unitary Patents can be compared with US patents which are in force for the entire territory of the US and when asserted before one federal court, in any state, the decision has an effect for the entire territory of the US. That's exactly what the Unitary Patent and the UPC will be for Europe.

If cautious, should you opt-out?

In the beginning, the exclusive jurisdiction of the UPC will only be true for Unitary Patents.

During the transitional period of seven years, classic European patent owners can opt-out from the exclusive jurisdiction of the UPC.

As of 1 March 2023, requests for opt-out can be filed with the UPC.

An opted-out European patent will remain within the sole jurisdiction of the relevant national courts

Deciding to opt-out or in can take time as it depends on several factors such as the strength of the patents, and market shares, and involves several levels of decisions within a company.

Further, when co-ownership agreements or licenses are in place, the vast majority do not have provisions on UPC. New provisions need to be agreed upon on how to opt-out and on future patent strategy in Europe.

Opt-outs can be withdrawn at any time during the transitional period only if no national proceedings have been filed. When the opt-out has been withdrawn it is no longer possible to file a new request for opting-out.

Opt-outs will also be available for EP-associated SPCs during these periods.

Some industries, such as the pharma industry, have decided to opt-out patents as they fear a central revocation before the central division of the UPC.

However, as it will be possible to withdraw only once opted-out, it might be advisable to wait and see to keep all options open.

Indeed, the vast majority of patents do not lead to litigation, so there is, for most of them, no legal and business rationale to file a request for opt-out. An opt-out can be seen as an encumbrance which will have to be disclosed in an assignment or license agreement.

Can a more flexible approach be adopted?

While the UPC and Unitary Patent present new opportunities and potential hazards, it may be possible to see for oneself where the grass is greenest.

The decision to obtain a Unitary Patent from a parent application does not prevent from seeking a European patent from a divisional application, and vice versa.

Likewise, the decision not to opt-out a parent European patent does not prevent from opting-

“However, as it will be possible to withdraw only once opted-out, it might be advisable to wait and see to keep all options open.”

out a divisional European patent, and vice versa.

Thus, it is possible to construct patent families that include Unitary Patents, opted-out European patents, and European patents with concurrent jurisdictions between national courts and UPC.

US companies may consider filing a divisional application of their existing European patent applications to keep the options to obtain both a classic European patent and a Unitary Patent.

When extending their US filings, US companies should strategically weigh whether, in addition to a Euro-PCT application, they should designate national European countries in their PCT application, noting that France cannot be designated in the PCT application, but a specific French patent application must be filed.

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