The Patent Lawyer
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Launch interactive document

China's drug Patent Linkage System – is it working?

Dr. Yongqiang Qi, Partner and Patent Attorney at Corner Stone & Partners, evaluates China's drug Patent Linkage System one year on from its implementation to discover some unfortunate failings.

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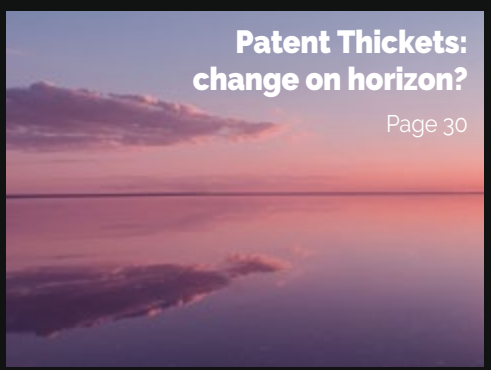

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CTC Legal Media

Editor's welcome

Welcome to *The Patent Lawyer Annual 2023*. With the implementation of the European Unitary Patent Court around the corner, this year has seen speculation as to how the practice may change across the globe. We can expect to see developments unfold throughout '23.

Our cover story this issue explores China's Patent Linkage System, evaluating its efficiency – or lack thereof- and calling into question the protection of innovation over generic drugs.

Our guest interview follows up with Minister Edwin Tong after Singapore Convention Week to gain insight into how IP is evolving in Singapore.

> ***"We can expect to see developments unfold throughout '23."***

Further, find a review of patent thicket concerns that may be stirring change at the US Patent Office; an alternate, positive review of the American Axle case that suggests it was, in fact, a beneficial outcome; an evaluation of how the implications of hindsight are being grossly overlooked by patent examiners; find out how patents are driving sustainability; and an introduction to China's Prioritized Examination program. Plus much, much more!

Our *Women in IP Leadership* segment features Lena Shen of Dakun IP Law. Contact us to find out how you can feature in and support the segment in 2023.

Also find a special feature on disability, authored by Megan Rannard of Marks & Clerk, as part of our ongoing DEI focus.

Thank you to all of our contributors and readers this year, we wish you a very happy and healthy year ahead.

Enjoy the issue.

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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Ken has extensive trial experience as lead counsel in jury and nonjury cases before state and federal courts and before the United States International Trade Commission, as well as *ex parte* and post-grant PTAB experience in the U.S. Patent and Trademark Office.

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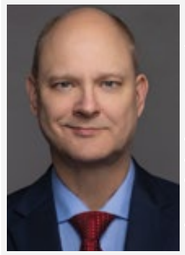
In a career spanning over four decades, Pravin has emerged as an IP trailblazer having strengthened India's IP jurisprudence with a practice encompassing all areas of IP litigation including patents, copyright, design, trademarks, enforcement and dispute resolution.



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

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Osamu is a patent attorney specializing in the fields of biotechnology, pharmaceuticals and diagnostics. Osamu is extensively experienced in all aspect of patent issues in these technical fields.

China's drug Patent Linkage System – is it working?

Dr. Yongqiang Qi, Partner and Patent Attorney at Corner Stone & Partners, evaluates China's drug Patent Linkage System one year on from its implementation to discover some unfortunate failings.

From 4 July 2021, with the 4th amendment to The Patent Law of the PRC, the introduction of a range of implementation measures and regulations concerning drug patents, like The Measures for the Implementation of Early Resolution Mechanism for Drug Patent Disputes, and the launch of the patent information registration platform for marketed drugs in China, began. China's drug patent linkage system, which forms the early resolution mechanism for drug patent disputes, was put into operation.

Dr. Yongqiang Qi

China's drug patent linkage system involves two subjects, viz. the innovative drug manufacturer and the generic drug manufacturer, and three bodies, viz. the court, the National Medical Products Administration (NMPA), and China National Intellectual Property Administration (CNIPA). The two subjects seek to resolve drug patent disputes through administrative adjudication, litigation, or patent invalidation processes. The resolution of drug patent disputes will directly influence the NMPA's approval for the drug to be marketed. Therefore, the three bodies need to coordinate with and restrict each other.

China's drug patent linkage system has been in operation for over a year. Preliminary results suggest that this system does not achieve recognition from generic drug manufacturers or innovative drug manufacturers in terms of drug approval and patent dispute resolution as expected. Many specific regulations or rules in the system need to be further identified and

> **This leads to a wrong situation where an innovative drug has been approved earlier but the generic drug bears a declaration of no patent information about the innovative drug.**

Résumé

Dr. Yongqiang Qi, Partner and Patent Attorney
Focused on patent matters, including drafting applications, replying to OAs, invalidations, prosecution, etc., Yongqiang engaged in research at the Chinese Academy of Sciences for seven years before going to Japan to study and work for eight years. He has practiced as a patent attorney for 15 years and handled a large number of cases for domestic and foreign companies. He studied the European patent system in the UK in 2012, and studied the Japanese patent system in Japan in 2016. He joined Corner Stone & Partners in 2018 and is responsible for the Japanese Department. His rich experience and outstanding skills to look after clients from Japan and other parts of the world have made him one of the core members of our patent team.

some problems occurring during its operation need to be addressed.

A close investigation finds the following two problems with China's drug patent linkage system after its one-year operation:

1. After the patent information registration platform for marketed drugs in China[1] came into use, the information about patent publication and patent declaration is incomplete, the patent declared is inconsistent with that registered in the platform, and the types of declaration are frequently wrong. Even worse, there is no error correction mechanism so the information registered in the platform is confused and thus the platform cannot function properly.

To be specific, the holder of a drug marketing license, usually the manufacturer of the innovative drug, should, within 30 days of receipt of the drug license, register the patent on the drug on the patent information registration platform for marketed drugs. In addition, the information about a patent should be renewed on the platform within 30 days of any change of the patent taking effect, like expiration or invalidation of the patent.

The generic drug applicant, when applying for the license of generic drug marketing, should make a declaration against the patent of the innovative drug registered on the patent information registration platform for marketed drugs. There are four types of declaration:

- Declaration Type 1: There is no relevant patent information on the platform;
- Declaration Type 2: The patent right for the innovative drug has expired or the patent has been invalidated and the license for patent exploitation has been granted;
- Declaration Type 3: The generic drug will not come on the market until the patent expires; and
- Declaration Type 4.1 The relevant patent should be invalidated and Declaration Type 4.2 The generic drug does not fall within the scope of patent protection.

In reality, however, some holders of drug marketing licenses rarely register and publish their patents, and some generic drug applicants submit their applications with declaration types 2-4 but their declarations contain no relevant patent information. Moreover, the patent information in the patent declarations submitted by some generic drug manufacturers is not the information registered and published on the platform, but the information they acquired from other sources.

> **In practice, however, there are no regulations concerning the resolution of disputes over objections.**

In addition, after the patent information registration platform for marketed drugs came into use, the information about newly approved drugs should be registered within 30 days of receipt of the drug license. For the drugs that had been approved before the platform was put to use, however, there is no time limit for the registration of their information. In consequence, some holders of drug marketing licenses are late with registration. Some generic drug manufacturers treat the "transition period" of 30 days as a tactic, submitting their applications with Declaration Type 1 before the related holders of the drug marketing license register. This leads to a wrong situation where an innovative drug has been approved earlier but the generic drug bears a declaration of no patent information about the innovative drug.

Additionally, for Declaration Type 3, "The generic drug will not come on the market until the patent expires", the generic drug manufacturers focus on the risk of infringement as well. Currently, the CNIPA does not impart information transparent enough, especially the information regarding the legal status of a patent concerned and the development of a lawsuit concerned, which influences manufacturers' judgment as to the prospects of a relevant product.

Further, under The Measures for the Implementation of Early Resolution Mechanism for Drug Patent Disputes, the holders of drug marketing licenses are responsible for the truth and completeness of the information they registered and should check and record any objections they received and address them accordingly. In practice, however, there are no regulations concerning the resolution of disputes over objections.

When the legal validity of some patents has changed with patent challenges and patent rights expiring, the information on these patents on the platform is not updated in time. In this regard, we suggest that the CNIPA and the NMPA improve interaction to ensure the timeliness and accuracy of the patent information on the patent information registration platform for marketed drugs. Meanwhile, after a patent is published, generic drug manufacturers are allowed to alter their patent information. A public monitoring mechanism should be established to allow the public to raise objections to the truth and accuracy of the patent information.

2. The nine-month waiting period set in the existing regulations is impractical and is not working as expected.

For the first generic drug manufacturers' applying for a patent challenge, the Measures for the Implementation of Early Resolution Mechanism for Drug Patent Disputes provides

[1] (https://zldj.cde.org.cn/home)

that the drug regulatory and administrative department under the State Council will set a nine-month period for awaiting the approval for marketing of chemical generic drugs starting from the date when the people's court or the administrative department for a patent under the State Council files or accepts the case. The state drug examination agency does not suspend technical examinations during the waiting period.

In fact, given the complexity of some patent disputes and the gradual increase in the number of IP cases in China, few patent infringement cases can be settled within nine months. As a result, the nine-month waiting period fails to work as expected. We suggest that for those patent disputes not settled within the nine-month waiting period, and those core patents probably incurring a high risk of infringement, a communication mechanism be established among the NMPA, the National Healthcare Security Administration (NHSA), and the CNIPA at the key stages of healthcare negotiations and bulk purchases before the drugs come onto the market, so as to address patent infringement and provide proactive and effective patent protection for innovative drugs.

In terms of procedure, an enterprise files a lawsuit with a court or files an application for adjudication with the CNIPA, and the court or the CNIPA gives notification of acceptance of the case to the enterprise. Under regulations, the enterprise should submit the duplicate of the notification to the state drug examination agency within 15 days of receipt of the notification and inform the generic drug applicant of the situation. However, there are no clear standards as to whether the enterprise should submit it in person or by courier and, in the event of the latter, how to determine the time of delivery. In addition, no formal notification is given for the start of the waiting period, which will also influence the enterprise's subsequent strategies and commercial expectations.

> **Few patent infringement cases can be settled within nine months.**

China's drug patent linkage system is the result of both the urgent need for the reform of the domestic pharmaceutical industry examination and approval system and the international environment, based on the actual development of China's pharmaceutical industry. Since its inception, however, there have been quite a few controversial issues about it. In the meantime, both the drug manufacturers and the legal circle expect that the judicial and administrative departments may use their discretion and subjective initiative in this area to contribute more practical cases to the improvement of China's drug patent linkage system so as to strike a balance between the innovative drug manufacturers and the generic drug manufacturers, make more innovative drug enterprises benefit from the system, and have more patients gain access to effective and affordable drugs

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An interview with Minister for Culture, Community and Youth and Second Minister for Law, Edwin Tong SC

Following on from Singapore Convention Week, *The Patent Lawyer* caught up with Edwin Tong to learn more about developments in the IP field in Singapore.

How has the legal industry evolved over the last few years? What are the challenges and opportunities for Intellectual Property professionals?

Legal service is a derived demand and is closely connected to economic and business developments. Therefore, the way in which the legal industry evolves depends on how businesses work and transact in the current climate.

Over the last few years, businesses have faced many challenges, many of which had a consequential impact on the legal industry.

Due to the COVID-19 pandemic, there has been an acceleration in the adoption of technology within the legal industry. Like their clients, practitioners have had to embrace the increased use of technology. They now engage their clients and potential clients online and participate virtually in Court hearings, arbitration hearings, and mediation sessions.

> **The legal industry has also become more borderless.**

With technology, the legal industry has also become more borderless. Clients are now more used to instructing their service providers over email or virtually, instead of meeting face-to-face, and thus more open to engaging legal services based overseas. This has resulted in more intense competition from professionals based overseas than before.

The pandemic, Russia-Ukraine conflict, and other geopolitical tensions have disrupted global supply chains, and led to slow economic growth and high inflation. As a result, practitioners have had to help their clients manage increased legal risks, even as they grow more prudent in their spending due to business uncertainties. This adds to the cost pressures faced by the traditional law firms, which have already been facing pressure for many years, such as from legal process outsourcing, and commoditization of legal services. They have to find new ways to deliver value for their clients.

While there are many challenges, there are also immense opportunities in novel and niche areas, in particular for IP professionals, due to the rise of the digital economy.

- IP activities have been growing steadily. For example, in 2021, patent and trademark filings reached record highs globally and in Singapore.
- Intangible assets now make up more than 90% of a company's value in S&P 500 companies. Globally, intangible assets alone are now worth US$74 trillion.
- IP professionals are now sought after, not just for their traditional IP protection and prosecution services, but also increasingly advising businesses on how they can extract value out of their IP. Hence, there will be demand in emerging areas, such as IP strategy, valuation, monetization, and financing.

Singapore has long recognized the possibilities of IP. We have continually worked with our partners and stakeholders, both locally and globally, to develop our IP ecosystem.

Through various legislative reforms and initiatives in the past decade or so, we have developed a top-ranked IP regime and capabilities across a wide range of IP activities. Looking ahead, as underlined in the Singapore IP Strategy (SIPS) 2030 launched in April 2021, we aim to establish Singapore as a leader in intangible assets ("IA") and IP expertise and services. We want to help businesses better use their IA and IP as a tool for economic growth, and create and capture value for Singapore. Ultimately, such efforts present a myriad of new opportunities for IP professionals in Singapore.

> **We want to help businesses better use their IA and IP as a tool for economic growth, and create and capture value for Singapore.**

In light of the digital economy, how has dispute resolution changed?

We have seen increased adoption of technology in dispute resolution, accelerated by the pandemic.

The process of dispute resolution, which was once viewed to be a physical, high-touch one in terms of giving evidence, cross-examination and so on, can now be conducted online.

When the pandemic started, our Courts, as well as dispute resolution institutions in Singapore – the Singapore International Arbitration Centre ("SIAC") and the Singapore International Mediation Centre ("SIMC") – quickly made provisions for online arbitrations and mediations so that hearings can continue uninterrupted. Maxwell Chambers, which has always been in the business of providing brick-and-mortar facilities, pivoted very quickly to similarly provide virtual and hybrid hearing services, and have been doing well over the last two years through the pandemic.

Online and hybrid dispute resolution became the norm during the pandemic, and most counsel, judges, arbitrators, and mediators have taken well to it. This modality is likely to stay, at least to some extent, even in the endemic era.

Singapore has always focused on supporting the needs of businesses, and is currently a choice location for international parties for dispute resolution services. We offer physical, hybrid and online dispute resolution services, to cater

Résumé

Mr. Edwin Tong SC was appointed Minister for Culture, Community and Youth and Second Minister for Law on 27 July 2020. Prior to this, he served as the Senior Minister of State at the Ministry of Law and the Ministry of Health from 1 July 2018 to 26 July 2020. At the Ministry of Law, he focuses on the development and promotion of Singapore's legal and dispute resolution sector. He also handles wide-ranging aspects of law reform, including intellectual property, corporate restructuring and insolvency, and legal aid.

"We have seen increased adoption of technology in dispute resolution, accelerated by the pandemic."

to different preferences, just like how we had offered a full suite of dispute resolution services (viz. arbitration, mediation, litigation) for users to choose from depending on their needs, ensuring that our dispute resolution services keep pace with global developments and advancements of the digital economy.

How should IP dispute settlements be approached in this current geopolitical climate?

In the current geopolitical climate, it is all the more important that there is a trusted and neutral place for parties from different jurisdictions to settle disputes, including IP disputes, fairly, quickly, and cost-effectively, and where the outcomes can be enforced cross-border.

Singapore is one such trusted and neutral forum, supported by excellent infrastructure and manpower.

- We have a trusted legal system, with strong rule of law, strong governance, and low corruption. Our judiciary is well-respected.
- We have credible dispute resolution institutions, including SIAC, SIMC and the Singapore International Commercial Court ("SICC").
- We have an open regime for international commercial dispute resolution, with parties enjoying free choice of counsel, arbitrators, mediators, mechanisms and institutions.
- We have a rich pool of global talent based in Singapore, familiar with the region and beyond.
- We also have excellent infrastructure and facilities at Maxwell Chambers to facilitate virtual/hybrid hearings for parties located in different parts of the world.
- Singapore also has advantages specific to IP disputes.
- We have a strong IP regime that is on par with other developed jurisdictions, where innovators and creators are able to obtain protection for their creations, and enforce their rights, effectively.
- We have an IP Court with specialist IP judges and an IP Court Guide which contains customized case management features for IP cases.
- SIAC has IP arbitrators on their panel. We also have mediators, practitioners, expert witnesses specialized in a variety of technical fields.
- Our local insurance providers also offer IP insurance for legal fees and costs awards relating to IP disputes.

IP disputes often have an international character to them, since technologies and innovations may occur in one place, but rarely stay in one place. Hence, there is always value in having a trusted and neutral place to consolidate and settle disputes.

Businesses need to also negotiate proper dispute resolution clauses in their contracts and to carefully consider the governing law, the dispute resolution institution, the seat, and the venue in advance. It should not be left to the last minute – or worse, only when a dispute has already arisen.

That invention is not obvious! Hindsight is worse than you think

Dr. Brent Johnson of Maschoff Brennan identifies the flaws in the current system when applying hindsight to a patent claim or patent application and proposes an alternative system.

A recent newspaper article about the inventor of the traffic light observed: "It seems so obvious now. But then that's the thing about inventions. They're always plain to see in hindsight."[1] As the saying goes, "hindsight is 20/20." The U.S. Patent Office, however, is usually dismissive of this basic insight.

In my experience filing hundreds of patent applications, the U.S. Patent Office is usually dismissive of the effect hindsight has on its determination of obviousness for a claim of a patent or patent application. This should be no surprise. Examiners are simply following the guidance provided by the Manual of Patent Examining Procedure (MPEP)—the Patent Office's official manual establishing ground rules for granting or denying an application. The MPEP is sparing in its guidance on avoiding hindsight, stating: "[h]owever, '[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper.'"[2] This terse statement dramatically downplays the effect hindsight has on the obviousness analysis that the Patent Office performs. The general belief seems to be that so long as an examiner is aware that he or she should avoid hindsight, that awareness of the principle suffices, without more, to avoid the use of hindsight in evaluating whether an invention would have been obvious. In fact, hindsight arguments in response to an Office Action almost always fail. I cannot recall a hindsight argument ever being successful. The examiner is always sure that their rejection is not a product of impermissible hindsight.

This Patent Office view, however, is starkly inconsistent with the well-documented understanding that people are generally incapable of avoiding hindsight, even when overtly attempting to do so. For example, in an oft-cited study by Fischoff, subjects were given a scenario and asked to assign the probability to four different potential outcomes. In one group, no actual outcome was provided to the subjects. In another four groups, subjects were told that one of the four outcomes was the "true" outcome, but were told to respond "as they would have had they not known the outcome."[3] This study found that, in 13 of 16 cases, the mean probability of the "true" outcome was substantially higher for the group that was told to ignore the "true" outcome when responding. On average, the probability of an event increased from an average 25% in the group that had no knowledge of the outcome, to an average of 34% in the group that was told to ignore what it knew. This study demonstrates a principle directly at odds with the MPEP statement.[4] This suggests that deliberately attempting to avoid hindsight is normally unsuccessful.

The process of examining a patent application is very similar to the method used in the study described above. The examiner starts with the patent claims and searches the prior art for references that contain concepts found in the claims. Thus, the examiner, like the subjects of the study above, is aware of the outcome before knowing the situation that gave rise to that outcome. But, like the subjects in the study, the examiner is supposed to analyze the prior art and determine what is obvious as if the examiner does not know what the claims are. While this procedure is highly efficient, it is a terrible way to avoid hindsight bias, and by extension, a terrible way to render an Office Action that accurately reflects whether an invention is obvious.

If the Board or an examiner, applying the prevailing preponderance of the evidence standard for determining obviousness, believes that a claim is 51% likely to be obvious, the hindsight bias reflected by the study described above suggests that the probability that the claims are obvious is in fact about 12% lower, or 38%. It follows that for most cases that seem to be close, the Patent Office is usually wrong when it determines that the claims are obvious. Similarly, for a truly close case, the Board or examiner, failing to adjust for the bias of hindsight, would probably believe that the likelihood of obviousness is about 68%.

Dr. Brent Johnson

> **In fact, hindsight arguments in response to an Office Action almost always fail.**

A paper by Mandel in the Ohio State Law Journal reported a study that was carried out to determine the role of hindsight in obviousness in patent cases.[5] In this study, subjects were presented with one of two hypothetical inventions and the accompanying prior art. In the control group, the subjects were provided with the prior art and the problem that the hypothetical inventor was trying to solve. The subjects were then asked, *inter alia*, "whether, in light of the prior art and information provided in the scenario, a solution to the problem was obvious to a person with ordinary skill in the relevant field."[6]

In another group in the Mandel study, the subjects were also provided with the same information that the control group received, but received additional information and instructions. Specifically, the information provided to these subjects had one additional sentence at the end that said that the hypothetical inventor had come up with a solution, and stated what the solution was. These subjects were then provided with instructions based on Model Patent Jury Instructions that informed the participant of the hindsight problem, warned the subjects about it, and advised the subject not to use hindsight in answering the questions. After receiving these instructions, these subjects were asked the same question as the control group.[7]

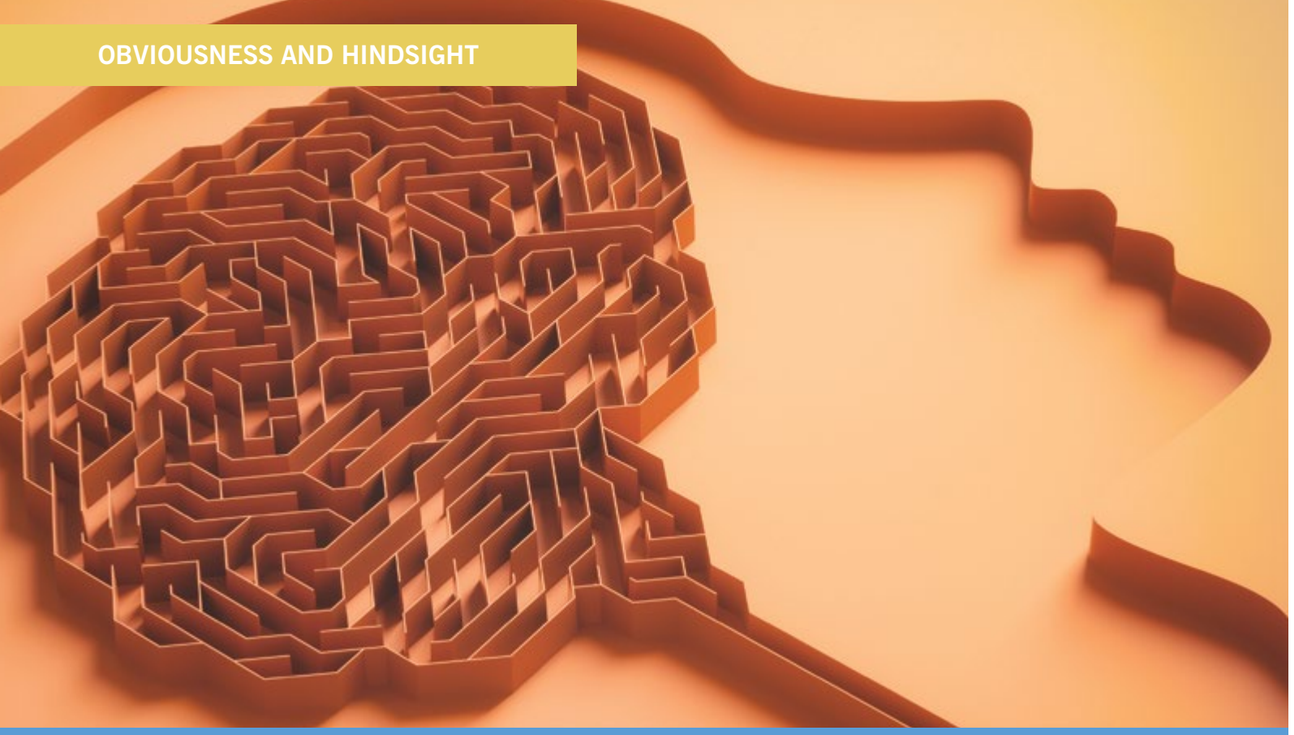
The results in this study were astonishing. For the subjects who were not told about the invention beforehand, only 23% of the subjects believed that a solution was obvious, as compared to 57% of the subjects who were told about the invention and instructed not to use hindsight.[8] Although not directly comparable to the Fischoff results, Mandel's results are consistent with Fischoff and clearly show that a significant number of non-obvious inventions are rejected as obvious by the Patent Office.

The Federal Circuit has recognized the problem with "the trap of hindsight" and normally asserts that "[e]vidence of objective indicia" (or

Résumé

Brent Johnson, Ph.D. is a shareholder in Maschoff Brennan's Orange County, California office. He is focused on patent prosecution, BPAI Post-grant proceedings, IP due diligence, and client counseling – particularly in the areas of pharmaceutical and other chemistry-related technologies.

1 Lee Benson, *The rather unremarkable tale of Lester Wire, and the rather remarkable invention that changed the world*, Deseret News (January 3, 2021).
2 MPEP § 2145 (X)(A), quoting In *re McLaughlin*, 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971).
3 Fischoff, *Hindsight≠Foresight: The Effect of Outcome Knowledge on Judgment Under Uncertainty*, Journal of Experimental Psychology: Human Perception and Performance, Vol. 2, No. 3, 288-299, at p. 293 (1975).
4 A Google search of "Fischoff and hindsight" returned 3,180,000 hits.
5 Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 Ohio St. L.J. 1391 (2006).
6 Mandel, at p. 1408.
7 Mandel, at p. 1408-1409.
8 Mandel, at p. 1409.



"secondary considerations") such as unexpected results, can help to avoid the hindsight problem. However, Mandel found that this is not the case. Specifically, Mandel conducted a comprehensive survey of all reported Federal Circuit and district court non-obviousness decisions for an 18-month period (from July 1, 2004 to December 31, 2002).[9] Mandel found that "secondary consideration appears to rebut what would otherwise have been a holding that an invention was obvious in only one to two percent of reported cases over this 18-month period."[10] Thus, secondary considerations fall far short of overcoming hindsight bias.

The U.S. Supreme Court set forth the standard for obviousness in *Graham v. John Deere (Graham)* in 1965. In *Graham*, the Court stated that "[u]nder § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined."[11] It is interesting that in *Graham*, analysis of the prior art, and not the invention, is the first step in determining obviousness. However, in actual practice, analysis seems to always start with the claimed invention.

Following *Graham*, hindsight reasoning could be significantly reduced by starting with, and focusing on, the prior art rather than the claims. This really should not be difficult for the Patent Office. For example, an obviousness analysis that started with the prior art could be accomplished if the Patent Office followed the following procedure. A first examiner would search the prior art for the subject matter of the claims as is the current practice. The first examiner would then turn the most relevant references over to a second examiner without disclosing the claims or any other information about the invention other than the references that were found. The second examiner would then spend a few hours evaluating the references and listing all of the inventions that the second examiner believed are obvious based upon the disclosure of the prior art references. This list of obvious inventions would then be compared to the claims. If the list of obvious inventions overlapped with the claims, the claims would then be rejected as obvious. -If they did not, then no obviousness rejection would be made. This would be a significant improvement over the current method of examination.

In summary, there is plenty of empirical evidence to show that hindsight bias results in frequent obviousness rejections by the Patent Office for inventions that are not obvious. This could be significantly reduced if the Patent Office divided searching and examination between two examiners, and by having examination carried out by focusing on the prior art without knowledge of the claimed invention.

> **Similarly, for a truly close case, the Board or examiner, failing to adjust for the bias of hindsight, would probably believe that the likelihood of obviousness is about 68%.**

9 Mandel, at p. 1421-1423.
10 Mandel, at p. 1423.
11 *Graham v. John Deere Co.*, 383 U.S. 1, 18 (1966).

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How patents can drive sustainability

Dr. Mathieu Buchkremer of Dennemeyer & Associates examines the patenting trends in sustainable innovations and discusses factors that could assist in propelling sustainability.

Sustainability is rightly at the top of corporate and political agendas worldwide. In November 2022, the latest United Nations Climate Change Conference ("COP27")[1] took place in Sharm El-Sheikh, Egypt. This international gathering marked the 30th anniversary of the adoption of the United Nations Framework Convention on Climate Change. As Egyptian president Abdel Fattah El-Sisi asserted on the conference website: *"In the thirty years since, the world has come a long way in the fight against climate change and its negative impacts on our planet; we are now able to better understand the science behind climate change, better assess its impacts, and better develop tools to address its causes and consequences."*

Dr. Mathieu Buchkremer

Innovation has a vital role in the fight against climate change, and new technologies will be essential in the move to "net zero." This function was recognized at last year's COP26 in Glasgow, where 40 members signed the so-called Glasgow Breakthroughs[2], setting targets to accelerate the deployment of clean technologies in power generation, road transport, steel, hydrogen and agriculture. The summary decision[3] alone mentioned "technology" no fewer than 10 times.

The Intellectual Property (IP) system can support this push toward greener processes by incentivizing the development and commercialization of innovative technologies. Many sustainable inventions, such as alternative fuels, involve significant up-front investment and a degree of commercial risk. To this situation, patents bring legal certainty, providing a competitive advantage and a tool for fundraising. Other forms of IP, such as trademarks, designs and trade secrets, also have their part to play in these ventures.

However, the scale of the environmental challenge is such that we need to carefully consider the function of the IP system as a whole and how it can prop up sustainable innovation. This includes ensuring that IP rights are accessible, patent information is freely available and technology transfer is as smooth as possible.

Trends in sustainable innovation

The European Commission has set out ambitious targets to build a climate-neutral Europe, not least in the Sustainable Europe Investment Plan in 2020 and the European Green Deal, which became legally binding in 2021. Both of these agreements defined commitments that all businesses in Europe must adhere to.

As lofty as the goals are, there is already good progress to boost confidence. The latest edition of the joint European Patent Office (EPO) and European Union Intellectual Property Office (EUIPO) report on IPR-intensive industries and economic performance in the European Union[4], published in October 2022, dedicates a chapter to "Climate Change Mitigation Technologies" (CCMT) and green EU trademarks. Even given the relative newness of these European initiatives, the report notes that according to recent estimates, revenues for environmental technologies and resource efficiency are expected to grow to nearly €10 trillion by 2030 (an annual growth rate of 7.3%).

According to the report, CCMT-related patent applications filed at the EPO by European applicants have grown from around 2,000 in 2001 to some 6,500 in 2019. Filings are led by applicants from Germany, followed by France, the Netherlands, Denmark and Sweden. In Denmark, where the overall number of patent filings is lower, applications for sustainable inventions represent an impressive 18.5% of the total originating from Danish companies.

The report also found that more industries are filing CCMT-related patent applications, ushered by the manufacture of batteries and accumulators, mining of other non-ferrous metal ores, electricity production, electricity transmission and repair and maintenance of aircraft and spacecraft. The contribution of patent- and trademark-intensive companies to employment and GDP has also increased.

In October 2022, the United Kingdom Intellectual Property Office (UK IPO) published a series of mini reports[5] on seven technology areas linked to the government's plan for a "Green Industrial Revolution" (offshore wind; low-carbon hydrogen; nuclear power; environmentally friendly transportation; heat pumps; carbon capture, usage and storage and flood and coastal defense). The reports confirmed that the number of patents being filed worldwide in green technology fields has "significantly increased" over the past 20 years. In particular:

- Wind power has displayed a 300% increase in worldwide patenting activity over the last 10 years.
- Patents for low-carbon hydrogen have more than doubled worldwide over the past decade.
- Worldwide patenting activity in greener vehicles has increased by over 300% in the past 10 years.

> **"Patenting activity for carbon capture and storage worldwide has more than doubled over the past decade."**

- Patenting of heat pumps has increased by more than 200% in the past five years.
- Patenting activity for carbon capture and storage worldwide has more than doubled over the past decade.
- Flood and coastal defense patents have seen increases of over 250% in the past 10 years.

First steps into green fields

While the upward trends in patent filings relating to green technologies are welcome, more can be done to promote the benefits of IP protections to companies working in relevant sectors. This drive is all the more pressing since much of this sustainable innovation takes place in organizations that do not take full advantage of the patent system. In some cases, patents may even be viewed as a barrier to the uptake of technologies. Moreover, the importance of tackling climate change and the strong feelings this objective inspires may discourage some researchers from engaging with the patent system.

Therefore, initiatives to promote awareness of the patent system at a high level are crucial. In 2020, for example, the theme for World Intellectual Property Day (April 26) was "Innovation for a Green Future[6]," and the World Intellectual Property Organization (WIPO) published a range of articles, including a special edition of its magazine[7], highlighting how IP rights can promote sustainable technology.

Making searching and filing easier

On a more granular level, there are also steps to increase the accessibility of the patent system for inventors of sustainable technologies. For instance, the EPO's so-called Y tags[8] (Y02 for CCMT and Y04S for "Smart Grids") in the Cooperative Patent

Résumé

Dr. Mathieu Buchkremer

Mathieu joined Dennemeyer & Associates in Luxembourg as a patent engineer in the fields of mechanics, electronics and software inventions. Active in the field of Industrial Property since 2015 and having worked previously with and for different French and Belgian IP law firms, Mathieu regularly supports startups in their first development steps. He also advises small and medium-sized enterprises, universities and research institutes in their efforts to build up valuable Intellectual Property assets.

1 https://cop27.eg/#/
2 https://climatechampions.unfccc.int/cop26-world-leaders-summit-statement-on-the-breakthrough-agenda/
3 https://unfccc.int/sites/default/files/resource/cma2021_L16E.pdf
4 https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/reports/IPR-intensive_industries_and_economic_in_EU_2022/2022_IPR_Intensive_Industries_FullR_en.pdf#page=7
5 https://www.gov.uk/government/publications/promoting-innovation-and-growth-the-ipo-at-work-2021-22/innovation-and-growth-report-2021-22#green-technologies-patent-landscapes---case-study
6 https://www.wipo.int/ip-outreach/en/ipday/2020/green_future.html
7 https://www.wipo.int/wipo_magazine/en/2020/01/
8 https://www.epo.org/news-events/in-focus/classification/classification/updatesY02andY04S.html

Classification (CPC) system are regularly updated and provide a user-friendly way to search for relevant documents. As reviewing prior art can be as daunting as it can be time-consuming, it is essential to allow innovators to be able to search patent databases quickly and accurately.

Another EPO initiative is the CodeFest on Green Plastic[9], taking place from 2022-23. This imaginative competition aims to help make the know-how contained in patents concerning green plastics more readily available to innovators. Additionally, it hopes to inspire future research and development that supports healthy ecosystems and drives the circular economy for environmentally friendly plastics.

Some IP offices also offer procedural benefits to sustainable technologies. For example, since 2009, the UK IPO has offered a Green Channel[10] for accelerating the grant proceedings of patent applications where the invention holds an environmental benefit. The Office publishes a list[11] of Green Channel publications (over 3,000 so far). To be eligible, applicants must indicate how their invention helps the environment and which actions (e.g., search, examination) they wish to accelerate. There is no additional fee for using the Green Channel.

In a similar scheme, the United States Patent and Trademark Office (USPTO) announced a Climate Change Mitigation Pilot Program[12] earlier this year. Qualifying non-provisional patent applications involving technologies that alleviate climate change will be fast-tracked for examination up until a first action on the merits. Launching the program, Under Secretary of Commerce for Intellectual Property and Director of the USPTO Kathi Vidal said: *"This is part of our ongoing efforts to incentivize innovation — including in key technology areas like climate change — and maximizing that innovation's widespread impact by reducing greenhouse gas emissions."* The pilot will last until June 5, 2023, or until 1,000 petitions have been accepted.

Other patent offices providing accelerated or expedited examination programs include those of Japan, Australia, Israel and Canada. The China National Intellectual Property Administration (CNIPA) also proposes a priority patent examination program for energy conservation, environmental protection, new energies, vehicles and smart manufacturing technologies. And last but not least, the EPO allows applicants to file requests for accelerated search and examination at no additional cost under the PACE program, whether or not the patent application relates to green technologies.

Initiatives such as these demonstrate that the patent system can provide the flexibility needed to advance green technology implementation. Given the success of the existing IP office schemes and the widespread sense of urgency, similar programs will probably be developed in the future. But for such systems to be effective, they need to be communicated and well-understood by inventors and businesses. That means that everyone involved in the IP ecosystem – IP offices, researchers, patent attorneys and IP service providers – needs to understand the opportunities available and explain them to patent applicants.

Promoting licensing

Another promising area of green progress is the promotion of sustainable technology licensing. Many inventions of this kind have the potential to be used in diverse sectors. Consequently, patent proprietors may need support to fully realize the potential of their inventions and the commercial benefits they are due, particularly if they are individual entrepreneurs or startups.

Established in 2013, WIPO GREEN[13] promises a partial solution to this problem. It endeavors to connect seekers and providers of environmentally friendly technologies with a database of patents as well as networking and acceleration projects. To give a couple of examples, the online platform recently hosted a "Women in GREEN" series and a climate change impact survey. WIPO GREEN also celebrates success stories of sustainable innovators around the world to motivate, inspire and champion the development of pivotal new technologies. Its current figures exceed 120,000 listed inventions, needs and experts, 130 partners, 2,000 users and 1,000 facilitated connections worldwide.

Effective licensing can unlock the potential of patents, speed up further progress and expedite the rollout of innovative products to consumers. Given the seriousness of tackling climate change, we must do as much as possible to facilitate sustainable licensing.

Overcoming challenges – now and in the future

Sustainable technology faces some particular difficulties when it comes to gaining IP protection. For a start, these inventions often span different sectors, meaning they can be challenging to classify and search. There may also be specific questions about exceptions to patentability in certain jurisdictions, specifically with regard to biotechnology or computer programs.

Many sustainable innovations produce incremental improvements or use software and artificial intelligence to make existing products and processes more efficient. In these cases, and many others, advice should be sought from a qualified patent attorney as to what aspects of the invention are likely to be patentable, the state of the prior art and how applications should be drafted to achieve the most extensive protection.

Even when patents are not obtainable, other IP rights can still have a role to play. Take some design features that make a vehicle more aerodynamic: These may not be eligible for a patent grant but may be protected by registered design rights or copyrights. Trademarks, including certification marks, offer guarantees to consumers regarding quality and origin and build brand loyalty.

As we have seen, there are challenges surrounding sustainable technologies' commercialization. While some innovations will have specific, obvious uses, others will likely have much broader applications. Expert advice on the most appropriate strategies should always be requested beforehand, and again with a view to raising financing, preparing non-exclusive licensing agreements for platform technologies and/or negotiating an exclusive licensing contract with a trusted partner.

"Qualifying non-provisional patent applications involving technologies that alleviate climate change will be fast-tracked for examination until a first action on the merits."

Given the scale and severity of the climate crisis, the initiatives and opportunities provided by IP offices and organizations around the world signal that the next few years will be crucial to ensuring that the IP system is doing all it can to support sustainable and green innovation. In that regard, patents will play a pivotal role in helping to limit global warming and its knock-on effects.

9 https://m.epo.org/news-events/in-focus/codefest.html
10 https://www.gov.uk/guidance/patents-accelerated-processing
11 https://www.ipo.gov.uk/p-gcp.htm
12 https://www.uspto.gov/about-us/news-updates/uspto-announces-launch-climate-change-mitigation-pilot-program
13 https://www3.wipo.int/wipogreen/en/

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Defending a brand Starting with a search – commercializing your IP in the post-COVID era

Caitlin Kavanagh, Marketing Manager at Minesoft, evaluates the post-COVID patent market, affected by royalty-free licenses granted during the pandemic, to see how PatBase can assist patent owners in regaining commercial control over their assets.

Intellectual Property (IP) is commonly seen as one of the most important economic assets of any corporate entity or research organization. It is a form of property, which, like land can be sold, rented, or mortgaged. Therefore, it has the potential to generate revenue for a business – even indirectly – and like land, its value depends on its quality. The four main types of IP are patents, trademarks, designs, and copyright. This article focuses on patents, since these are of the most economic value to innovative companies.

In certain areas of technology, like the Electronics Industry, there is a focus on filing many patent applications to stake a claim to the technological area. Often these applications can be for very specific parts of a product, like Apple's patent for "Patterned bonded glass layers in electronic devices" which covers just the textured glass and/or matte finished glass that was introduced for the back of the iPhone 11 Pro.

For other industries, patents are equally important. The pharmaceutical industry, for instance, depends on patent protection to support its investments into medical research. A new study published by the London School of Economics and Political Science in March 2020 estimated that US biopharmaceutical companies spent an average of about $1.3 billion to bring each of their new drugs to market between 2009 and 2018. As a result, pharmaceutical companies will vigorously protect their patents until they expire. It is largely recognized that pharmaceutical IP rights are essential for the continued innovation of new medicines and, therefore, exist in the interests of patients and society at large. The patent system is designed to promote innovation and, at the same time, offer a mechanism ensuring that the fruits of that innovation are accessible to society. In the contexts of public health, the challenge for policy makers is to find an optimal balance between the rights of patent owners, who provide technological innovations to improve health conditions, and the needs of the public.

Caitlin Kavanagh

> **A successful return on IP depends on a business' needs.**

The costs to apply for patents, pay renewal fees and maintain a company's patent portfolio get expensive fast, so it is important for patent owners to get a return on this investment. A strong, valid, and enforceable patent is of no value if no effort is employed in commercializing the product or if it is an unwanted product. A successful return on IP depends on a business' needs. For some, a good return would be a new stream of revenue coming from utilizing or exchanging IP for money. For others, a good return can also be a new partnership with a reputable organization or company which could lead to a bigger scope for future research and collaboration.

There are several options for commercializing patents – patent owners can commercialize independently, through assignments or business partnerships. A good starting point for any commercialization strategy is using a reliable patent database, like PatBase, to get a better understanding of the technology landscape, identify other companies working in the same field and estimate the value of your IP.

How has COVID-19 affected IP commercialization?

In reaction to the pandemic, many companies began working in the medical equipment technology area for the first time, to "do their bit". For example, car manufacturers who dedicated their facilities to manufacturing ventilators and similar devices, and others who developed novel technologies such as COVID-19 diagnostics tests or 3D printed PPE. Many of the products manufactured in substantial quantities to meet the demand were already protected by existing IP which was infringed by companies who do not traditionally operate in the sector.

Labrador Diagnostics faced a media storm for launching a patent lawsuit against US start-up BioFire, which was developing diagnostic tests to detect COVID-19. After a few days, Labrador Diagnostics backtracked and announced it would offer royalty-free licences for its patent-protected technology. Similarly, Gilead Sciences, the Biopharmaceuticals company, made a U-turn on its attempt to secure a financially advantageous "orphan drug" status for remdesivir, another potential treatment for COVID-19.

To avoid similar situations occurring, academic institutions, organizations and governments set up innovative, collaborative solutions. The Costa Rican government and World Health Organization (WHO) launched the COVID-19 Technology Access Pool (C-TAP) to facilitate faster equitable and affordable access to COVID-19 health products for people in all countries. The group is currently endorsed by 45 WHO member states and is similar to the Medicines Patent Pool, a UN-backed health organization to help provide treatments for HIV/Aids, Hepatitis C and Tuberculosis in lower-income countries. While University College London's commercialization business, UCLB, set up a rapid licensing website. Initially this was to help distribute the blueprints for the UCL-Ventura breathing aid developed by UCL and carmaker Mercedes, but it is now open to all inventors of COVID-19 treatments.

> **This collective approach to research and development would fit into the increasingly popular open innovation model.**

For pharmaceutical companies that rely on the monopoly that a patent provides, this must be a bitter pill to swallow. In normal circumstances, these IP owners would either demand the infringer take a royalty-based licence, seek an injunction, or sue for infringement and damages. However, on an ethical and reputational basis, none of these options were feasible in the current crisis.

Résumé

Caitlin Kavanagh, Marketing Manager

Caitlin is the global marketing manager at Minesoft and has worked extensively with the support and business development teams. Kavanagh has worked on numerous projects to expand Minesoft's web presence, as well as creating company communications for multiple platforms.

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Collaborating with relevant IP owners at this stage through partnerships or by licensing existing patents could be a way to avoid potential conflict in the post-COVID era and identify strategic and commercial opportunities that are beneficial for all parties. For many companies, particularly those who chose to stay in the market after the pandemic, entering into a formal collaboration agreement with a current IP owner is crucial to provide both a solution to the current challenge and exciting opportunities in the sector for the future. This collective approach to research and development would fit into the increasingly popular open innovation model.

Open vs closed innovation

Traditionally, companies have used a closed patent strategy designed to protect and prolong the lifecycle of existing technologies from competitors. Patents remain a popular way of safeguarding original work, with almost 188,600 applications received by the EPO in 2021 – a 4.5% increase, showing a significant recovery from the small decline recorded in 2020 due to the pandemic.

The patent system benefits both the inventor and the general public. Inventors protect their inventions from imitation by disclosing information to the public, in exchange for owning a limited-time monopoly and securing a large share of the market. For the public, anyone with access to the patent data can improve upon, combine, or invent around the initial patented idea. It is rare for inventors to come up with a brand-new idea, therefore, having access to a high-quality and comprehensive patent database is necessary for all innovative companies.

Companies that know what to look for in patent data can exploit patents in their favor. A prime example of patent exploitation is shown through the evolving nature of the smartphone market. A protectionist approach between Apple and Samsung regarding their intellectual property has led to the concurrent suing of the two tech giants over patents as smartphone technologies have become more closely linked. This defensive patenting might slow down competition, but it may also lead to stifled technological progress due to the trade-off between litigation and innovation.

The high costs and inefficiencies of infringement is one of the reasons that many companies are now seeking a more collaborative patent strategy. For example, Samsung has collaborated with top Android phone makers to share free patents covering Android and Google applications.

Why is commercializing your IP important?

Open Innovation consists of networking with other companies and R&D facilities; interacting with start-up ventures, public research institutes, universities, and external suppliers; and sharing outside information and technology. It does not refer to free knowledge or technology, this collaborative working will often still involve the (sometimes significant) payment of license fees for IP, so companies are still able to benefit from having a monopoly on the invention and potentially even increase their bottom line with the addition of licensing fees.

> **Patent information contains valuable insights that can assist companies in identifying new and emerging markets.**

Companies engaged in commercialization activities are forming strategic alliances for a pro-active intellectual property strategy that aims at sharing technologies rather than hoarding IP as a defense mechanism. According to Acacia Research Corp., 99% of patent-licensing revenue in the US is generated by companies that own 40% of all US patents, therefore, the remaining 60% of patent holders are receiving just 1% of the revenue - there is a lot of money to be made here!

The complexity and uncertainty of the pandemic highlighted the pressing need to formalise new ways of innovating more widely and effectively. There is likely to be increased need in the future for further collaboration, including cross-sector and cross-national innovation, to address major public health challenges.

Conclusion

Whether a company is entering a new sector for the first time, or simply looking to license technology and establish collaboration agreements to increase revenue, formulating an effective IP strategy from the beginning is crucial.

As well as protecting innovations, patent information contains valuable insights that can assist companies in identifying new and emerging markets, monitoring the actions of competitors, and informing the company which parts of their portfolio are most valuable. Beyond this, patent data contains the technical details that allow inventors to build on the ideas of others and continue to innovate for the benefit of all.

Investing in the right tool to take advantage of this data is crucial for any innovative company. PatBase, the international patent search and analysis database, has one of the largest datasets in the industry, ensuring that your research encompasses information from all over the world and is quality checked daily. Intuitive search tools mean that even non-experts can interrogate the data and unearth strategic business and competitive insights. This can be combined with powerful alerting tools on your own or your competitors' portfolios so you can monitor this data without even running a search.

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New procedure for the examination of patent applications related to transgenic plants and elite events in Brazil

Aghata Rodrigues Souza and Marina Castro dos Santos of Vaz a Dias Advogados & Associados address the contents of the Technical Note and the effects on the patentability of transgenic inventions under IP Law.

Patents related to transgenic plants are subject to extensive discussions in Brazil at the moment. The matter relates to the Patent Law (Federal Law 9,279 of May 14, 1996[1]), which extended patent protection to pharmaceuticals, fine chemistry, and other inventions. It further strengthened the property rights of patent holders in general, but it is not very clear when it comes to biotechnology inventions, including transgenic plants.

If one looks at the Patent Law, one may notice that protection of biotechnology inventions as a whole suffer a clear prejudice due to the applicable excluding and restrictive rules, notwithstanding the fact that such inventions may possibly fulfil the patentability requirements. This lack of adequate protection for biotechnology, especially for transgenic plants, is viewed as negative and legally unjustified since Brazil is a country that relies significantly on agricultural production. Further to that, there is a clear policy to support local companies in obtaining innovative biotech products under the existing Innovation Law (Federal Law 10,973/2004).

Under this legal perspective, Brazil signed the TRIPs Agreement that opens to signatory countries the protection of plants by a *sui generis* system besides the patent law, or a combination of these two types of protection. Brazil recognized at its end the protection of plants solely by the sui generis system under the International Union for the Protection of New Varieties of Plant (UPOV Convention 1978) and therefore introduced the plant breeders' rights under the Federal Law 9,456 of April 25, 1997. This law secures rights to those plants that people have bred for desired traits.

> **There is a clear policy to support local companies in obtaining innovative biotech products under the existing Innovation Law.**

Also, legislations of other countries have been recognizing biotech protection, especially plants essentially due to its impact on the competitiveness of seed production, foodstuff, and the pharma industries, for example.

As a result, law restrictions in Brazil make investments in biotechnology development very vulnerable since investors do not seem to have the legal instruments to act against unauthorized third parties and make cease their use in the local market. Further to that, local businessmen and investors have been driven to seek foreign patent protection to biotechnology inventions that leads to a bizarre situation: Brazil is a relevant market and a direct beneficiary of such kind of inventions, especially those linked to transgenic plants, due to its potential agricultural market, but the overall ruling does not match with the market perspectives.

As an attempt to better clarify the Brazilian Patent Office (BPO) technical understanding regarding transgenic plants, especially those related to elite events, the BPO issued the Technical Note INPI/CPAPD nº 01/2022 on

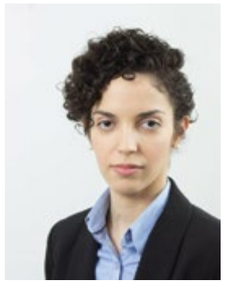
1 https://bityli.com/XSjjoCbs
2 https://bityli.com/HWLVtbSsz
3 https://bityli.com/gKGlOGeH

March 2022[2] so that a flexible interpretation is given to the existing restrictions to the patentability requirements of transgenic plant inventions.

Most specifically, the Technical Note helps create a pattern of examination of what exactly should be protected in the elite transgenic events since elite events are not encompassed adequately by the existing Biotechnology Guidelines.[3] One main concern regarding the patentability of transgenic plants in Brazil is that an isolated gene *per se* and embedded into a specific plant are regarded in principle as a discovery. This understanding does not take into consideration the human intellectual intervention, which would entitle it as a patentable invention. In other jurisdictions, patentability requirements that demand human intervention for transgenic patents as a decisive factor for granting, require it to a lesser extent, as in the US and in the European market. There are, therefore, different interpretations that determine whether or not there is a need for BPO examiners to consider the degree of human intervention and innovation for a transgenic plant to merit patent protection.

This article will address the contents of the Technical Note and the effects on the patentability of transgenic inventions under the existing IP Law, which is considered as a positive development of the laws for the protection of biotechnology inventions.

Aghata Rodrigues Souza



Marina Castro dos Santos

Transgenic patentability in Brazil

According to the Item I and IX of Section 10 of the Patent Law, it is not looked upon as an invention, among others, discoveries and the whole or part of living beings and biological materials found in or isolated from nature, including the genome or germplasm of any natural living being and natural biological processes. Besides, Item III of Section 18 of the Patent Law states what is not regarded as patentable matter: "the whole or part of living beings, except for transgenic microorganisms that meet the three patentability requirements – novelty, inventive step, and industrial application – provided for in art. 8 and that they are not mere discovery".

The sole paragraph of Section 18 further states that transgenic microorganisms are understood under the rule of the law as those organisms, other than the whole or part of plants or animals, that express, through direct human intervention in their genetic composition, a characteristic normally not achievable by the species under natural conditions.

The BPO's Guidelines for Biotechnology Patent applications Examination of December 2018 reinforced the provisions of the Patent law affirming that transgenic plants and their parts are not considered patentable, following up Section 18, III and its sole paragraph. However, the Guidelines affirmed that there is no restriction related to processes for obtaining the transgenic plants, except for the ones involving the use of restriction technology. Still, the Biotechnology Guidelines did not predict the examination regarding the elite events of transgenic plants.

Due to the overall increase of biotechnology inventions and their particularities, there was a need to establish a pattern to examine these applications before the BPO, which justifies the issue of the Technical Note INPI/CPAPD nº 01/2022.

In the biotechnology technical field, an elite event is understood as any situation that has a superior technical effect compared to the other events after a genetical transformation in an organism, which includes plants. To better understand this concept, we shall first understand a genetical transformation process. When one performs any traditional method of genetic transformation, as inserting a different gene into a genome, the results are random and unpredictable. Each result is called a "genetic transformation event", or simply "event". After finishing a genetical transformation process in an organism of interest (e. g., a plant) we have many random events, and the one that presents the best performance is the "elite event". Thus, despite art. 18 (III) of the Patent Law, the transgenic plant is the center of the inventive concept when derived from an elite event. Hence, there was a need for discussing the patentability of these plants. According to the technical note, the BPO defines an elite event as:

"An elite event is an event of transforming a plant (1) through the insertion of a transgene (2) using a stable genetic construct (3), in which this insertion took place at a specific location in the plant genome (4) and gives the plant a superior technical effect when compared to the other events of transformation (5)."

Therefore, an invention must have all five of the abovementioned characteristics to be understood as patentable and only then the examination of the requirements of novelty, inventive step, and industrial applicability will take place. Such characteristics and steps to be completed for an elite event highlight the level of human intervention required for the transgenic plant to be considered an invention (not a discovery). Thus, the idea that it is not possible to patent a transgenic plant invention in Brazil is not entirely true, because if the plant is obtained from an elite event, it can be patentable.

> **The Guidelines affirmed that there is no restriction related to processes for obtaining the transgenic plants, except for the ones involving the use of restriction technology.**

It should be highlighted that to be considered novel, all five distinctive characteristics of the elite event must not be found in a single document of the State of Art during the search. Then, the examiner will determine the closest prior art, following the three following steps to determine if an invention is obvious before the State of Art:

i) Search for a plant of the same species with the same phenotype;

ii) Search for plants of distinct species with the same phenotype, considering the evolutive distance between the plant in examination and the search object;

iii) In case of not finding similar transformations *in vivo*, there will be a search for in vitro descriptions.

Following up the Technical Note INPI/CPAPD nº 01/2022, the invention must show evidence, for the purpose of verifying the "inventiveness", an improvement of the phenotype (an increase of resistance to a herbicide, for example), and an association by gene linkage of a phenotype to another phenotype of interest (e.g., glyphosate resistance and increase of productivity). To better clarify the examination process, see the example below provided in the Technical Note. Consider an invention consisting in the trans-

Résumés

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Marina possesses expertise related to the protection of inventions through patents, topographies of integrated circuits, industrial designs, and software. She has been particularly involved in drafting patents and leading the prosecution of patent applications at the Brazilian Patent Office, especially those related to mechanical vibrations, control and automation systems, as well as industrial products and processes, and mechanical and automation engineering in general. She possesses expertise in drafting strategies for patent litigation based on produced freedom to operate and patent infringement assessments in the Brazilian market.

Aghata Souza is a biotechnologist who graduated from an undergraduate course at the Federal University of Rio de Janeiro (UFRJ) and holds a Master of Science from the same University, specialized in Innovation Management. She has a large experience in research and development of biotechnological processes, including those involving transgenic organisms, and great knowledge of molecular biology and genetic engineering.
As a professional at Vaz e Dias Advogados & Associados, Aghata is a specialist in patent prosecution, mainly those related to biotechnology processes and products, biochemistry, pharmacy, fine chemistry, and related fields. She also holds knowledge regarding protection of plant varieties at the National Services for the Protection of Cultivar (SNPC).

formation of a plant of corn with a determined gene (epsps) to acquire glyphosate resistance. There is a document however in the State of Art that uses the same gene to confer the same characteristics in rice plants. The possible scenarios for this case are: 1) The epsps gene has a slightly different sequence from the state of art document. In this case, it presents novelty, but the inventive step would depend on other elements, as the promoter used, or lineage chosen, for example, 2) The plant presents a greater resistance to glyphosate in comparison to the wild corn, but similar results to State of Art. In this case, even though it would be novel, it would not be considered an inventive step before the anteriority document cited and 3) The plant presents a greater resistance to glyphosate in comparison to the results presented in the anteriority document. In this case, it would be considered novel and inventive.

It is noteworthy that the opinion of a lack of inventive step by an examiner can be reverted through the presentation of experimental results and data showing the technical problem overcome in a non-obvious way before the prior art, as clearly provided in the Technical Note.

Thus, the idea that it is not possible to patent a transgenic plant invention in Brazil is not entirely true, because if the plant is obtained from an elite event, it can be patentable.

Concluding comments

The Technical Note clearly sends the message that transgenic plants related to elite events are subject matters to patent insomuch as the specified features that define an elite event are adequately viewed and confirmed. Further to that, the Technical Note provides that the patentability of a plant can be assessed altogether with its accessory inventions (as of methods, use, compositions, and biological sequences), since their inventiveness depends on the main invention (the transgenic plant). This is indeed a relevant development of the laws of the land, since it opens the possibility for patents encompassing plants as an invention, notwithstanding the limitations imposed by Item III of Section 18 of the Patent Law.

Further to that, such legalities in the patent law may strengthen the property rights of a transgenic plant in the sense that it may simultaneously protect the plant itself, as well as its genetic sequence and other invention accessories responsible for increasing resistance to selected herbicides, for example. This final statement comes from the fact that a transgenic plant may be protected by the plant breeder's rights and the patent rights, which means that unlawful use by a third party of a specific transgenic plant represents an infringement of the breeder's rights and also patent rights, in which the infringed party may seek the necessary legal remedies to cease such infringement (such as search and seizure orders and the award of losses and damages), especially the distribution and commercialization of the plant in the local market.

Nota técnica INPI/CPAPD n° 01/2022. Disponível em: https://www.gov.br/inpi/pt-br/servicos/patentes/pagina_consultas-publicas/arquivos/nota_tecnica_inpi_cpapd_n_01_2022.pdf.

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Patent thicket concerns have started something brewing at the Patent Office: are extensive changes to patent practice on the horizon?

Patrice P. Jean and Andrew Kopsidas of Hughes Hubbard & Reed evaluate the problems patent tickets present and explain why the USPTO is seeking public comment.

On June 8, 2022, a bipartisan group of six senators wrote a letter to the USPTO to voice their concerns regarding patent thickets. Patent thickets are generally described as large numbers of patents that cover a single product or versions of the same product. These senators expressed the concern that the patenting of minor tweaks to delivery mechanisms, formulations, and dosages in the pharmaceutical industry has led to numerous patents covering a single drug or minor variations of a single drug. They noted that "The Patent Act envisions a single patent per invention, not a large portfolio based on one creation." The senators requested that Director of the United States Patent and Trademark Office, Kathi Vidal, investigate whether certain current practices at the USPTO need to be revised to address this issue. They also asked for her thoughts on whether higher examination standards, limited time frames for filing continuation patent applications, or a "second look" review of continuation applications before issuance should be instituted to help address what they perceive as an industry burdened by excessive patent protection that is destructive to innovation.

What the arguments in the letter seem to fail to appreciate is that pharmaceuticals and biopharmaceuticals are often complicated and complex just like innovative products in other fields. There are often many parts of biopharmaceutical products that are indeed separate inventions that are worthy of patent registration – just as would be expected for mechanical devices like cars, computers, and smartphones. What might be considered a minor variation by someone unfamiliar with the technology may be considered a ground-breaking innovation by those skilled in the art. Similar problems can exist in other technologies such as Wi-Fi standards, semiconductors, and telecommunications.

Further, the ability to file patents on foundational technologies that can then be developed more extensively and improved is critical to the progress of research. The protection of innovations with additional patents that claim new and improved variations, formulations, and processes provides protection for innovating companies so that their inventions that they ultimately bring to the market have solid protection that can be enforced against competitors. This allows companies to continue to develop and sustain a deep bench in specific areas of research. The potential for abuse of the patent system does exist, but antitrust laws, punitive damages, and remediation techniques such as mandatory cross licensing can be used to correct the behavior of an entity that illegitimately excludes competitors.

Innovating companies and academic laboratories in the pharmaceutical industry invest millions of dollars in making and improving medicines and devices to cure and treat diseases and ailments so that suffering patients can have a better quality of life. Similarly, on the technology side, companies are generating solutions to some of the most technologically complex problems we face – inventions that were incomprehensible a generation ago. These companies deserve the predictability of knowing that they can protect every aspect and part of their inventions if they successfully participate in the patent registration process and are ultimately issued a claim for an invention. These patent portfolios are protective of patent rights and do not destroy innovation.

On October 4, 2022, the USPTO announced that it is seeking comment from the public on "proposed initiatives directed at bolstering the robustness and reliability of patents to incentivize and protect new and nonobvious inventions while facilitating the broader dissemination of public knowledge to promote innovation and competition," in order to respond to the senators' June 8th letter. Docket No. PTO-P-2022-0025. In this formal Request for Comment (the "Request"), the USPTO asks for feedback not only about the specific issues raised by the senators, but also on other specific topics and initiatives at the USPTO related to (i) prior art searching, (ii) support for patent claims, (iii) RCE practice, and (iv) restriction, divisional, rejoinder, and non-statutory double patenting practice. This Request suggests that there may be a groundswell of sentiment brewing at the USPTO to lobby and institute extensive changes in patent practice rather than simply responding to the issues contained in the senators' letter. Notably, the Request is not limited to patent prosecution and continuation application processes in the life sciences and biopharmaceutical industries.

Patrice P. Jean

Andrew Kopsidas

Résumés

Patrice Jean, Ph.D., is chair of Hughes Hubbard's Life Sciences group, based in New York City. She has over a decade of experience counseling leading and startup pharmaceutical, chemical and biotechnology companies in all areas of intellectual property law.

Andrew Kopsidas is a partner in the Washington, D.C. office, where he handles patent, trade secret, and other intellectual property matters before the Court of Appeals for the Federal Circuit, the U.S. Patent & Trademark Office, the U.S. International Trade Commission (ITC), and district courts across the U.S.

"Patent thickets are generally described as large numbers of patents that cover a single product or versions of the same product."

"Virtually every aspect of the patent prosecution process seems to be up for scrutiny, comment, debate, and possible change based on the issues and initiatives addressed in this document."

For example, the Request notes that "According to the USPTO's records, the number of divisional applications fell from more than 21,000 in fiscal year (FY) 2010 to fewer than 15,500 in FY 2021, while the total application filings increased significantly. At the same time, the filing of continuation applications increased significantly. The USPTO has received feedback that one reason many continuing applications are filed is related to restriction practice." The USPTO does not attribute the increase in continuation applications to any specific industry. Leaders in the Electronic, Internet/Software/IT Services industry have led in the number of USPTO applications filed at the USPTO for years. Presumably, many of these applications come from this industry as well.

The Request asks for input regarding a broad scope of issues, including fees, databases that should be used by examiners during examination, the practice of examination of two or more distinct inventions in the same proceeding, the restriction practice, the rejoinder practice, the practice of non-statutory double patenting, and the offset to patent term adjustment. Virtually every aspect of the patent prosecution process seems to be up for scrutiny, comment, debate, and possible change based on the issues and initiatives addressed in this document. All companies that participate in the patent process should take notice and consider responding to the Request on issues that may have the greatest impact on their businesses. This is important because what certainly could have a destructive effect on innovation is the lack of predictability in the patent registration process.

> **The USPTO has received feedback that one reason many continuing applications are filed is related to restriction practice.**

On November 3, 2022, the USPTO announced that the notice's comment period was extended until February 1, 2023. It noted that this will be the only extension of the comment period. Comments must be submitted through the Federal eRulemaking Portal at www.regulations.gov.

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American Axle: not a lost opportunity

Brian Jackson and Christian Ehret of The Webb Law Firm evaluate the *American Axle & Manufacturing, Inc. v. Neapco Holdings, LLC* case to conclude that the denial of certiorari is a more positive outcome than many first assumed.

The Supreme Court's denial of certiorari in *American Axle & Manufacturing, Inc. v. Neapco Holdings, LLC* on June 30, 2022 may be viewed by some as a lost opportunity to clarify patent eligibility under 35 U.S.C. § 101 ("Section 101"), but a decision in that case may not have provided useful guidance for examining software technologies, such as machine-learning or encryption, where Section 101 rejections are most common and controversial. Since *Alice Corp. v. CLS Bank Int'l* in 2014, the focus of the Section 101 debate has been primarily on software and biotechnology patent applications that are not analogous to *American Axle*, *Alice*, or other precedents. *Alice* itself concerned a business method implemented on a computer, not a technological software process. Due to the lack of relevant Supreme Court guidance, the fate of software-implemented claims – even for technology such as machine-learning, encryption, and network protocols – has been uncertain at the Patent Office, the district courts, and the Court of Appeals for the Federal Circuit.

The Court generated some excitement within the patent community with its invitation to the Solicitor General on May 3, 2021 to file an amicus

> **The Court generated some excitement within the patent community with its invitation to the Solicitor General on May 3, 2021 to file an *amicus* brief.**

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Much of Christian's work involves handling patent and copyright law issues arising in software and electrical technologies. He also handles cases before various US District Courts, appeals before the Court of Appeals for the Federal Circuit and the Patent Trial and Appeal Board (PTAB), and post-grant procedures before the PTAB, including inter partes reviews.

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Brian has prepared freedom-to-operate, non-infringement, and invalidity opinions in the following areas: drug delivery devices; devices and software for guided surgery; devices and software for drug preparation; and devices and software for medical treatment, among others. Brian's training includes a wide range of molecular biology and biochemical techniques. Brian earned his Ph.D. in neuroscience from the University of California, Los Angeles, where he was the recipient of a pre-doctoral National Research Service Award and numerous fellowships.
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brief. Some took this as a willingness to grant certiorari and clarify the *Alice* framework. The Solicitor's response equally excited the patent community by identifying the *American Axle* case as a "suitable vehicle for providing greater clarity" at least in part because both the District Court and the Federal Circuit arrived at the incorrect conclusion concerning eligibility under Section 101 and improperly blurred the subject-matter eligibility inquiry with the separate enablement inquiry. However, despite this encouragement, *certiorari* was denied on June 30, 2022. Clarity will have to come later, preferably with a case that reflects the day-to-day struggle with Section 101 at the Patent Office and in the courts.

The procedural course of *American Axle* is not remarkable. American Axle asserted, among other patents, U.S. Patent No. 7,774,911 ("the '911 Patent") against Neapco Drivelines, LLC. Claim 22 of the '911 Patent is exemplary and is reproduced below:

> 22. A method for manufacturing a shaft assembly of a driveline system, the driveline system further including a first driveline component and a second driveline component, the shaft assembly being adapted to transmit torque between the first driveline component and the second driveline component, the method comprising:
>
> providing a hollow shaft member;
>
> tuning a mass and a stiffness of at least one liner; and
>
> inserting the at least one liner into the shaft member;
>
> wherein the at least one liner is a tuned resistive absorber for attenuating shell mode vibrations and wherein the at least one liner is a tuned reactive absorber for attenuating bending mode vibrations.

Following cross motions for summary judgment, the U.S. District Court for the District of Delaware held that the asserted claims of the '911 Patent were ineligible under Section 101. On appeal, the U.S. Court of Appeals for the Federal Circuit affirmed, agreeing with the District Court that the claims were directed to specific laws of nature, Hooke's law, and friction damping, without specifying the means of practically implementing the law of nature. In doing so, the Federal Circuit compared the asserted claims of the '911 Patent to those deemed ineligible by the Supreme Court in *Parker v. Flook*. American Axle submitted a petition for a panel rehearing and a rehearing *en banc*, in response to which, respectively, the original panel of Judges Dyk, Moore, and Taranto issued a modified order, which nevertheless affirmed the District Court's decision and the full court issued a *per curiam* opinion denying the motion for rehearing. Notably, the *per curiam* opinion included two concurrences and three written dissents (Judge Lourie dissented from the denial, but did not write separately).

The physical nature of the process steps at issue in *American Axle* is likely what garnered more attention than a common software or business method case, but is also the reason that Supreme Court review may not have been helpful. The claims resemble the physical process steps of *Diamond v. Diehr* (curing rubber) and the monitoring steps of *Parker v. Flook* (alarm limits during catalytic conversion), important precedential cases that serve as the foundation for the decision in *Alice*, more than they resemble the typical Section 101 case examined at the Federal Circuit level. The steps in the claims are physical steps carried out in the physical world that result in a manufactured device, making it difficult to apply modern Section 101 jurisprudence such as *Alice* and the numerous Federal Circuit decisions that largely focus on abstract ideas, such as purported mental processes implemented with computers. The analysis of claims combining physical process steps with laws of nature should be well-settled in view of Flook, Diehr, and other earlier cases which remain precedential and can be easily framed under modern recitations of the test, regardless of whether the decision in *American Axle* is correct.

It is reasonable to hypothesize that if the Supreme Court issued a broad decision upholding the Federal Circuit's finding of invalidity, the differing claim structure and focus in *American Axle* could have substantially impacted how Section 101 is applied to physical process steps moving forward. Any decision from the Court could have resulted in a rethinking, or even an overruling, of *Diehr* or *Flook*. Thus, rather than solving an existing problem plaguing the courts and the Patent Office, a decision by the Supreme Court here could have had the potential to create even more uncertainty for Section 101 with minimal benefit.

The present need for clarity on Section 101 at the Patent Office and in the courts would not have been satisfied by a decision in *American Axle* because the vast majority of district court cases and Patent Office disputes concerning Section 101 involve software-implemented claims that are much more complex and technological than those in Alice, where a generic computer was recited in combination with non-technical business method steps. Further, while diagnostic techniques have been largely found ineligible since *Mayo Collaborative Services v. Prometheus Labs., Inc.*, the claims that formed the basis of the ruling there were not representative of modern-day diagnostic methods. Instead, many diagnostic inventions make use of specialized software, such that a clarifying decision in a modern software case would be far more valuable than any guidance that could be gleaned from a decision in *American Axle*.

While some may regret the potential lost opportunity for Section 101 guidance in this Supreme Court term, the current, uncertain status quo of software-based innovations and other new technologies would not have been aided by the Court granting *certiorari* in *American Axle*.

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> **A decision by the Supreme Court here could have had the potential to create even more uncertainty for Section 101.**

Reaching across borders: the Hague Convention of 18 March, 1970 on the taking of evidence abroad in civil or commercial matters

Pravin Anand & Achuthan Sreekumar of Anand & Anand evaluate the positions of witnesses to express why following the Hague Convention is the best practice.

The Hague Evidence Convention – A prologue:

The Convention of 18 March, 1970, on the Taking of Evidence Abroad in Civil or Commercial Matters, also known as the Hague Evidence Convention, aims to provide effective means of reconciling differences between various legal systems and assists and improves judicial cooperation between member countries for collection of evidence in civil and commercial matters and it mentions in non-mandatory terms that it is intended to 'facilitate' discovery and to 'improve mutual judicial co-operation'. India ratified the convention on 7 February, 2007.

The Hague Evidence route is resorted to in cases where a witness who is not party to a civil proceeding is located in a foreign jurisdiction such as India and evidence/deposition is to be collected from the witness for the civil proceeding pending in an overseas jurisdiction such as USA. The standard practice under this convention is for the concerned court of the Requesting State (sender) to address a letters rogatory to the Central Authority of the Requested State (The Ministry of Law and Justice, Deptt. of Legal Affairs for e.g., India) with a copy marked to the Registrar General of the concerned High Court within whose jurisdiction the concerned witness is located. The letters rogatory should also specify the various questions and/or documents or evidence that the witnesses require to answer and produce.

As the above process is through the diplomatic channel and is time consuming, a novel way of expediting the proceeding was developed. In this route, once a copy of the letters rogatory issued by the requesting state is received by the Plaintiffs, they then file an appropriate petition before the concerned High Court invoking the relevant provisions of the Indian Code of Civil Procedure, 1908 whilst highlighting India's obligation under the Hague Evidence Convention. This mechanism has proved to be extremely fast and productive and has been successfully implemented in various cases and the Indian Courts have passed detailed orders in this regard.

Pravin Anand

Achuthan Sreekumar

Indian Judiciary & the Hague Evidence Convention:

In *Pfizer Inc. and Ors. v Unimark Remedies Limited; Misc. Petition (L) No. 56 of 2016* the Bombay High Court passed an order dated 04.05.2016 allowing a Hague Petition and appointing a Commissioner to record the evidence that was required in a civil and commercial proceeding pending before the US District Court, Delaware whilst holding that not allowing such a petition would not only be most improper but would possibly be in direct contravention of the country's treaty obligations under the Hague Convention. As the evidence to be collected was technical/scientific in nature, the court appointed a scientist and a retired Head of the Chemistry Dept. of a prestigious Indian Institute as the Commissioner. The Court in this case set up a confidentiality club to protect the interests of all parties including the witnesses. The Court also set a deadline for the deposition and collation of evidence and thereafter directed the Commissioner to submit the deposition and evidence collected with the Registrar General of the Bombay High Court, who in turn was requested to forward the same to the Requesting Court.

Similar orders have also been passed by various other Indian courts where the Requesting Court was a USA district court and the witness was located in India. The details of some of such orders are given below:

(a) Order dt. 12.03.2019 passed by the High Court for the State of Telangana in *Teva Pharmaceuticals International GmbH & Ors; v Orbicular Pharmaceuticals Technologies Pvt. Ltd.; O.P. No. 1 of 2019.*

(b) Order dt. 01.07.2009 of the Punjab and Haryana High Court in *Aventis Pharmaceuticals Inc. & Anr. v Barr Laboratories, Inc. & Ors.; Civil Original Petition No.2 of 2008.*

(c) Order dt. 08.12.2008 of the High Court of Andhra Pradesh in *Aventis Pharmaceuticals Inc. v Dr. Reddy's Laboratories Inc.; 2009(1)ALT362.*

Résumés

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Pravin Anand is the Managing Partner and Head of Litigation at Anand and Anand.

The first Indian to be awarded the AIPPI Award of Merit, INTA's President's Award, inducted in the IAM IP Hall of Fame, and recognized as the "Most Innovative Lawyer" by Financial Times, Pravin has experience of appearing in over 2,500 cases in over 43 years of his practice as an IP lawyer. He is credited with strengthening India's IP jurisprudence with a practice encompassing all facets of IP.

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Achuthan Sreekumar, Advocate

Achuthan started his career at Anand & Anand in 2008, handling matters involving traditional IP such as trademarks, copyrights, patents, etc., as well as borderline IP issues such as trade secrets, tortious issues, hyperlinking, spamming, defamation, commercial disparagement, information technology, intermediary liability, domain issues, internet related issues involving impersonation & fraud, etc.

Over the past few years, he has been focusing on expanding practice areas to a range of subjects including Hague Evidence Convention cases, white collar crimes, IP crimes, internet crimes, arbitration, property disputes, cases involving hurting of religious sentiments, criminal offenses, etc., and represents several business conglomerates and individuals who facing issues in this regard, obtaining favorable results.

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(d) Order dt. 14.03.2011 of the Division Bench of the Andhra Pradesh High Court in *Dr. Reddy Laboratories, Inc. & Anr. v Aventis Pharmaceuticals Inc. & Anr.; Original Side Appeal No. 24 of 2008.*

(e) Order dt. 21.6.2019 of the Bombay High Court in *Thompson Coburn LLP & Ors. v Maharashtra Hybrid Seed Company Ltd.; Misc. Petition (L) No.64 of 2019.*

Voluntary evidence – a deviation from the Hague route:

There have been various cases where the witness located in India had agreed to give evidence voluntarily and without going through the Hague route. These proceedings have also been successful. In a recent proceeding, the witness located in India had agreed to voluntarily depose and subject herself to cross-examination in relation to a proceeding pending before the US Bankruptcy Court for the Eastern District of Texas, Sherman Division. The deposition of the witness was conducted and the same was extremely successful resulting in the debtor agreeing to have their claims dismissed before the US Court. However, some disadvantages of voluntary deposition are that the witness may not answer certain questions, may intentionally give incorrect answers as they are not under an oath to give correct statements, the witness may prolong the proceedings.

Conclusion:

Collection of evidence through the Hague route should always be preferred as it is time bound and will always be conducted under the aegis of the concerned High Court in India, giving the best results. Also, the witnesses giving evidence under this route will be under an oath to give correct statements and will also not be able to delay the proceedings by making excuses of non-availability, evidence cannot be produced due to its confidentiality etc. The concerned court can device systems such as time bound orders, setting up of confidentiality clubs, having the evidence sent directly to the Requesting Court etc. to ensure that the proceedings are conducted rapidly and in a productive manner, whilst ensuring that the rights and interests all concerned parties are safeguarded. Therefore, with the intervention of the Indian Courts, the Hague Evidence Convention Route has streamlined the collection of evidence in cross-border cases.

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Lena Shen: Senior Partner, Dakun IP Law firm

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

Lena graduated from Beijing Foreign Studies University and Queen Mary University of London with a master's degree in IP laws.

Lena started her career in IP in 2000 and is a senior partner of Beijing Dakun Law Firm and Dakun IP Agency Co., Ltd. She has rich experience in trademark prosecution and litigation and is well-trusted by her clients.

Lena was ranked as World's Leading Trademark Professionals by World Trademark Review (WTR) during 2019-2022 for prosecution and strategy and received the title of Gold Medal Trademark Attorney awarded by the China Trademark Association in 2019. She is also active on the stage for IP forums at home and abroad. She was the first chair of CET 8 (Asian Issues Group) of FICPI and served this duty from 2015-2022 and has been a bureau member of AIPPI since 2018. She also serves as Deputy Director of International Communication and Development Committee of the China Trademark Association and is a member of the IP Dispute Mediation Committee.

What inspired your career?

When I started my career in IP back to 2000, after I graduating from university, not many of my classmates and friends knew what a trademark attorney or patent attorney was. At that time, I was not sure whether an IP attorney was a good career option and what destination it would lead to; however, I felt it very cool to point at this or that brand to my friends when walking on the street, telling them I registered them for their owners.

One characteristic of a career in IP that I particularly like is that you keep learning and your value increases with your age so it can be a life-long career.

Gradually I found that IP is very important not only to a company but also to a country.

In addition, IP is very international. There have been many international treaties of IP. Cross-border IP protection is very common. So, an IP attorney is a very international profession which is another attractive characteristic to me. I like to communicate with colleagues from all over the world and to help my clients with their IP protection globally.

> **Keeping curious and interested in what you are doing will inspire you to keep learning and keep improving.**

All in all, to step into this career might be an accident but to stay in is by choice and I never regret for my choice.

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

I think first of my current position. My working time can be divided into three parts, my firm work which is my bread-and-butter job as a senior partner of Dakun IP Law Firm, my international association work as a Bureau member of AIPPI and an active member and previous Asian Matters Group chair of FICPI, and my Chinese domestic professional association work for China Trademark Association. The latter two are voluntary positions. I enjoyed all of them though sometimes I am too busy. I am glad to see the clients' problems solved with our help and I am proud to be part of the force likely to promote and push forward the IP protection system globally.

Looking back on my pathway from a green-hand in IP into an experienced IP attorney, I think curiosity, an open mind and dedication are the most important characteristics that have led all the way to today's me.

It is said that curiosity is the best teacher. Very true. Keeping curious and interested in what you are doing will inspire you to keep learning and keep improving.

Being open-minded can bring you more and better solutions and give you chances to know more people. In return, you will get more help and support in your career path.

Dedication to what you do is very important to guarantee the quality and efficiency of the work. Focusing is a craftsman's spirit, which is not easy but rewarding.

If asked, I would like to advise young people: it is not a problem to look around and try different things at the beginning but once you decide what to do, focus! After you spend 10,000 quality hours on whatever you are doing, I am sure you will become an expert in your field. Additionally, don't always seek quick success and instant benefits and remember all that you want will come to you when you are ready.

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

The biggest challenge I had is to learn management skills, one for time management and the other for office management.

In IP, you always have many deadlines to catch, and clients always have urgent matters needing your quick attention and response. How to best use your time to efficiently handle everything is a challenge. I am still learning but one experience to share is to focus: focusing on one job at one time often is more efficient than multitasking.

The role change from being an attorney to taking on a management role was another challenge. I am not a strict person and I feel it difficult to scold others even when they make mistakes. As a manager, sometimes you will need to be strict. As years pass, I am still not a strict manager but setting up clear, reasonable and feasible rules in advance is more important in the firm management, I think.

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

The achievement I value most in my career is to have won the trust and respect of not only the clients but also my peer colleagues. I also harvested good friends from all over the world.

Another important achievement is the self-growth both professionnally and personally. I feel more mature and calmer facing life in recent years. That's probably what people call wisdom gained from getting older.

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

I joined Dakun IP Law Firm in July this year, which was founded by my partner, Mr. Yakai Shi. Mr. Shi is a more experienced attorney in IP, and very smart. We certainly would like to provide the best services to our client and to make Dakun a successful firm and more successful, which is our first goal, and to make Dakun a pleasant place to work in and work with. But we also have another holy grail, which is to assist 100 SMEs in their IP planning and protection and to see them grow and develop. Some day we can proudly say that we have participated in and contributed to their success. We will feel very proud and satisfied when we achieve this goal.

In order to achieve what we wish to achieve, we need to work hard, to expand our client base, and be more professionally and financially successful so that we will have a greater ability to do what we want to do. SMEs often need more help but, generally speaking, have less financial capacity in the early stages.

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

I am a member of the EDI (equality, diversity and inclusive) committee of FICPI. EDI is important. Many international organizations, such as WIPO, AIPPI and so on have organized or is organizing special committees to promote it.

In the Chinese IP profession, women are big players, especially in the trademark field, more women than men. But if you look at the leadership of the firms, IP offices, courts, etc., you will find men are dominating. I wish to see more female leaders in the IP profession. We, women, are the same smart as men.

Certainly, EDI is more than sex equality and inclusion. I hope the whole world, in whatever field, in whichever corner, will become more open to accepting diversity. I believe it will be achieved when more people become involved and concerned and begin to promote.

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

I strongly believe and support the empowerment of women.

At AIPPI we have the Women in IP reception every year, and in China, we have a special wechat group called "Mulan in IP". "Mulan" is a heroine in ancient China and there is a Hollywood movie with "Mulan" as the title telling the story of heroine Mulan. In "women in IP" and "Mulan in IP", we help and support each other; we ask questions in the group and share information and experience in the group. We do not regard each other as competitors but as good buddies and allies.

> **I hope the whole world, in whatever field, in whichever corner, will become more open to accepting diversity.**

Jurisdictional Briefing, Russia: EAPO additions and amendments to Patent Instruction

Dr. Tatiana Vakhnina and Dr. Alexey Vakhnin of Vakhnina and Partners explain the additions and amendments coming into force as of 1 November 2022, in EAPO (comprising Russia, Armenia, and other Eurasian countries).

Résumés

Dr. Tatiana Vakhnina
Dr. Tatiana Vakhnina is a Senior Partner and founder of Vakhnina and Partners, a Eurasian Patent Attorney, Patent and Trademark Attorney of the Russian Federation with extensive experience in IP since the 1970s.

Dr. Vakhnina is one of the first registered Eurasian Patent Attorneys with reg. No. 38.

Dr. Vakhnina is an Honorary Advocate of the Russian Federation, an active member of a number of Russian and International IP Organizations, and the professional community of Patent Attorneys in Russia.

Dr. Alexey Vakhnin
Dr. Alexey Vakhnin is a Co-Founder of the Firm, Partner and Managing Director of Vakhnina and Partners. He is a Eurasian Patent Attorney, Patent and Trademark Attorney of the Russian Federation, with extensive experience in IP since the 1990s.

Dr. Vakhnin is a member of INTA, FICPI, AIPPI, LES Russia/LESI, PTMG, ECTA, etc.

Having a Ph.D. in Medicine (Biochemistry and Immunology), while working on patent matters, Alexey specializes in Medicine, Biotechnology, Biochemistry, Pharmacology, and Pharmaceuticals.

Dr. Tatiana Vakhnina

Dr. Alexey Vakhnin

Summary of additions

The main innovations introduced in November 2022 relate to:

- providing of digital 3D models with the Eurasian applications documents,
- changes in the deadlines for filing objections and appeals,
- optimization of procedures for receiving patents for inventions and industrial designs.

1. Three-dimensional models

From November 1, 2022, it will be possible to include three-dimensional models (3D models) of the claimed objects in a Eurasian patent application. The innovation concerns both inventions and industrial designs.

This innovation is considered the most significant change in the Patent Instructions. Applicants now have the possibility to file digital 3D models in relation to Eurasian applications for inventions and Eurasian applications for industrial designs.

The use of 3D models in relation to inventions and industrial designs is an important step in the introduction of modern digital technologies in patent practice. This innovation will allow the applicants to use the advantages of 3D visualization for additional explanation of the essence of claimed inventions and further visual presentation of the appearance of products.

The decision to begin accepting 3D models of the claimed objects by the EAPO when filing for a Eurasian patent for inventions or industrial designs was made at the 41st meeting of the Administrative Council of the EAPO in September 2022.

"This innovation will greatly simplify the process of filing a Eurasian application and obtaining a Eurasian patent for the applicants. Applicants will have more opportunities to demonstrate the claimed objects, and this would facilitate the process of examination and preparation of a decision for the EAPO examiners. Consequently, the time of prosecution of a patent will be reduced which will result in speeding up market entry. This is specifically important in relation to the industrial designs, appearance of products. This innovation becomes even more called-for, since the demand for granting of a Eurasian patent for industrial designs active in the territory of EAPO member states has doubled in a year." — The President of the EAPO Dr. Grigory Ivliev commented on the innovation.

> **From November 1, 2022, it will be possible to include 3D models of the claimed objects in a Eurasian patent application.**

2. Increase in the time limits for filing appeals and objections

From November 1, 2022, the time limits for filing an objection against the granting of a Eurasian patent for an invention in accordance with rule 53 (1) of the Patent Instruction and an appeal against the invalidation of a Eurasian patent for an industrial design in accordance with rule 116 (2) of the Patent Instruction are extended.

The deadline for filing such objections will be nine months from the date of the publication of information on granting of a Eurasian patent for an invention or a Eurasian patent for an industrial design, respectively.

3. Amending the grant procedure of a Eurasian patent

The additions and clarifications made to Part I "Inventions" of the Patent Instruction relate to the procedures for receiving a Eurasian invention patent and are intended for optimizing the entire prosecution process.

The changes to the procedure of grant now allow introduction amendments in the claims until the notification of grant allowance is issued and forwarded to the applicant.

4. Industrial designs

The additions made to Part II "Industrial Designs" of the Patent Instruction expand the list of checks carried out in relation to the claimed industrial design at the substantive examination stage. The changes expand the methods to exclude elements of the appearance of the product, for which the applicant does not claim legal protection.

In addition, there is now no need for the applicant to provide a paper copy of the previous application if the application is available to the EAPO through the WIPO Digital Access Service for Patent Documents (WIPO DAS).

Patent and Trademark Attorneys of Vakhnina and Partners will be pleased to assist you and your clients, if you have any questions or inquiries on IP matters in EAPO, Russia, Armenia, and other Eurasian countries. Our specialists in Moscow (Russia, ip@vakhnina.ru) and Yerevan (Armenia, office@vakhnina.am) offices are ready to provide more information upon your request.

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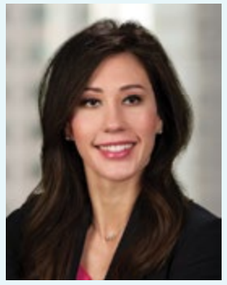
Jurisdictional Briefing, US: patents vs. trade secrets – what makes sense for your invention?

Tina Dorr and Maggie Russell of Cantor Colburn evaluate the differences in the protection offered by patents and trade secrets to provide insight into which protection is best for which type of asset.

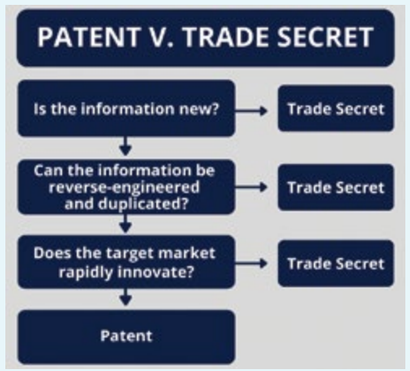
For technology companies, intellectual property is their most valuable asset. A well-curated intellectual property portfolio provides vital financial protection for a range of different business assets, including trademarks, copyrights, patents, and trade secrets.[1] Patents and trade secrets play complementary and, in many cases, overlapping roles in protecting information. While patents protect innovation, trade secrets protect innovation as well as any other information providing economic value.[2]

Given the interplay between patents and trade secrets, determining if a patent or a trade secret is the optimal form of protection is a complex analysis. Patents and trade secrets are often considered economic equivalents, as they are often capable of protecting the same information but weighing the following considerations aids in securing the most valuable protection for the particular information.[3] In determining which is appropriate, consider whether the information is new, whether the information can be reverse-engineered and duplicated, and whether the target market rapidly innovates.



Tina Dorr

Maggie Russell



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1. Is the information new?

First, only information that is innovative and new can be protected by a patent; therefore, if the valuable information is new, the optimal type of protection weighs in favor of a patent. Whether the information is "new" is a legal requirement that the U.S. Patent and Trademark Office ("USPTO") will scrutinize before granting a patent. On the other hand, trade secrets protect a broader range of information, which may or may not be new, and derives economic value from not being known or accessible to those who could gain value from its use.[4]

2. Can the information be reverse-engineered and duplicated?

Second, if the information can be reverse-engineered, and is easily discoverable by analyzing an available final product, and thereby duplicated, then the optimal form of protection weighs in favor of a patent. When a third party can duplicate one's innovative information, they can directly compete in the market, and likely decrease one's profit margin. Third parties also exclude others from making, using, or selling your innovation by obtaining and enforcing a patent themselves. Although the relevant details of the innovation must be disclosed to the public in the patent application, if a third party can reverse engineer and duplicate the innovation, then no harm results from disclosing the details to the public in the patent application.

If the information cannot be reverse-engineered and duplicated, then the optimal form of protection weighs in favor of a trade secret. Information that cannot be reverse-engineered typically relates to internal processes or devices that are only used within the business operations. Thus, when the level of exposure is low, the optimal form of protection weighs in favor of a trade secret.

3. Does the target market rapidly innovate?

Third, if the target market for the information rapidly innovates, then exclusionary rights limited to 20 years is likely sufficient, and the optimal form of protection weighs in favor of a patent. Such temporally limited protection is valuable in cutting-edge technologies, such as computer software and pharmaceuticals, where innovations quickly become obsolete. After such a limited exclusionary period, the invention is dedicated to the public, and anyone can make use of or sell the invention.

On the other hand, a trade secret can be protected for an unlimited period of time, provided the appropriate steps are taken to maintain secrecy. When the information is part of a process that contributes to a slowing innovating market, then the optimal form of protection weighs in favor of a trade secret.

Final Thoughts

Patents and trade secrets are powerful tools to protect technology-based businesses. While they may be used in a complementary manner, it is critical to understand their different scopes of protection and to weigh the pros and cons of each in order to obtain the strongest protection, competitive advantage, and economic value.

Résumés

Tina Dorr, Ph.D., is a patent attorney who represents clients in a large range of technology areas, including chemical, material, life science, mechanical, and semiconductor technologies, as well as fiber and fiber composite technologies for consumer product applications, geotextile applications, and aerospace applications. She provides opinions, performs searches, and counsels clients to develop effective worldwide patent protection. She is also an active leader in the local and national IP community, where she is known for her thought leadership as a regular speaker and author. She co-hosts the intellectual property podcast IP Obsessed.

Maggie Russell is an Associate who focuses her practice on drafting and prosecuting patent applications for chemical and material science technologies. Maggie has experience in a wide range of fields including chemistry, chemical engineering, semiconductor devices, mechanical engineering, and material science. Prior to joining Cantor Colburn, she worked as a semiconductor engineer at BAE Systems and authored multiple publications in the *Journal of the Electrochemical Society.*

[1] *See* U.S. Const. art. I, § 8, cl. 8 (explaining congress has the power to protect intellectual property "to promote the progress of science and the useful arts."). *See also Intellectual Property,* CORNELL LAW SCHOOL LEGAL INFORMATION INSTITUTE, *archived at* https://perma.cc/BP8D-H5JQ (discussing the importance of intellectual property in general). The four main categories of intellectual property are: "patent, copyright, trademarks, and trade secrets." Id.

[2] *See* Michael R. McGurk, et al., *The Intersection of Patents and Trade Secrets, 7* HASTINGS SCI. & TECH. L.J. 189, 190 (2015) (discussing the economic value of patents and trade secrets as similarly protecting intellectual concepts). *See also* Margaret A. Russell, *Stifling Innovation: Data Collecting Patents in The Medical Device Industry,* 21 J. High Tech. L. 278, 278 (2021) (discussing the value and interplay of patents and trade secrets).

[3] *See* McGurk, *supra* note 2, at 190 (defining trade secrets and patents as information). "Patents and trade secrets are the only two forms of intellectual property that protect information—patents protect patentable information (innovation), while trade secrets can protect patentable information and any other information providing economic value to the holder. Thus, the same information can often be protectable by patents or trade secrets." *Id.* See generally 1 MILGRAM ON TRADE SECRETS § 1.01 (2019) (explaining trade secrets and patents have different benefits). Notably, upon the expiration of the patent term the invention falls into the public domain such that anyone can use it. *Id.* Trade secrets on the other hand do not have expiration dates, they last as long as they are secret indicating they can have an incredibly long term. *Id.*

[4] *See* 1 MILGRAM ON TRADE SECRETS, *supra* note 3 §1.01 (explaining a trade secret "covers any information (which can be embodied in a physical thing, such as a pattern or device) used in business and lending the opportunity to attain a competitive advantage over others who do not know the information"). Unlike patent protection, where a matter must fall under a statutorily defined category, a trade secret can be just about anything so long as it's economic value to the company comes from not being known to others. *Id.* Explaining that "[t]he essential rights of a trade secret owner are the right to use the trade secret and disclose it to employees and others standing in a confidential or contractual relationship with the owner subject to restrictions on unauthorized use or disclosure." *Id.*

Highlights and challenges of the current patent scenario in Mexico

Sergio Olivares and Mauricio Samano of OLIVARES compare the original and new IP Law to identify continuing challenges and to evaluate when the new IP Law will truly take hold.

I. Introduction:

It is a fact that the last three years have been challenging for companies and law firms around the globe after the COVID-19 breakout. In Mexico, we could say that we had a double challenge because, in addition to reorganizing ourselves internally to deal with the pandemic, we also had a new IP law (LFPPI) that entered into force on November 05, 2020. This new law formalized many practices that we already had but also introduced some changes. As we will further discuss, some changes are positive from our point of view and others represent a challenge for patent owners and force us to be disruptive in designing tailored strategies to ascertain the desired protection in the current scenario.

II. Positive changes

A. Online prosecution

A few years ago, the Mexican PTO (IMPI) developed an electronic platform for filing and prosecuting patent applications. However, before March 2020, only a few law firms used this electronic platform since it had many details that needed to be addressed and was very slow to use. Nevertheless, IMPI improved the platform, and on March 2020, once the pandemic started, suddenly all applications needed to be filed electronically because the Mexican PTO remained closed from March 24, 2020, until July 12, 2020, which made physical filing impossible during this period.

Once IMPI reopened, new filings have continued to be made in the electronic platform since it has several advantages such as cost efficiency (less use of paper and ink and a person does not need to physically go to the patent office to file the application). Applications filed through the online platform have also seemed to enjoy a more expedited prosecution.

> **"It will be quite some time before we see a petition for a Patent Term Adjustment under the new IP law."**

Furthermore, the Mexican PTO developed a new alternative during the pandemic in which it is possible to request electronic conversion for applications that are being prosecuted physically. By paying a small fee, the applicant may switch from physical to online prosecution which has the advantage that responses can still be filed regardless that the Mexican PTO is opened or closed.

B. Patent term extension

The LFPPI includes a scheme to address patent term adjustments derived from unjustified delays by IMPI in prosecuting and granting patents by way of a "supplementary certificate."

The main features of this supplementary certificate are as follows:

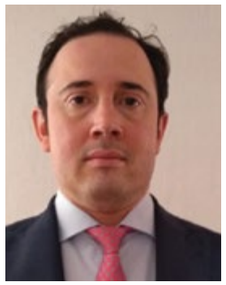
- The duration of the supplementary certificate should not exceed five years.
- The patent holder may request a supplementary certificate only once, by a brief that complies with the requirements set forth in the IP Law and its Regulations.
- The application must be submitted independently when replying to the notice of allowance.
- When the granting of the supplementary certificate is authorized,

Résumé

Sergio Olivares joined OLIVARES in 1987 and has been practicing intellectual property (IP) law for more than three decades. He has been a partner since 1994 and Chairman of the firm's Management Committee since 2009. He is proficient across all areas of IP law, but works most closely with the firm's Patent Group. Mr. Olivares is highly recommended by leading industry publications and directories as a leader in IP. He has been integral to OLIVARES' expansion into new and innovative practice areas; has been at the helm of cases that are helping to shape the standard for evaluating inventive step and novelty for pharmaceutical patents, and was involved in a landmark Supreme Court case that changed the landscape for unfair competition enforcement in Mexico. Mr. Olivares received his J.D. from the Universidad Intercontinental in 1991 and graduated from the Franklin Pierce Center for Intellectual Property in 1993.

Mauricio Samano works in the patent department of our firm. His work in OLIVARES mainly focuses on prosecuting Chemical, Biotechnological and Pharmaceutical patent applications, as well as providing technical opinions regarding patent infringement. He has experience in conducting state of the art searches and drafting patent, utility model, and industrial design applications. Additionally, he has participated in interviews with examiners of the Mexican Institute of Industrial Property (IMPI) and the United States Patent and Trademark Office.

Sergio Olivares



Mauricio Samano

IMPI will notify the applicant so that, within a period of one month, the proof of payment of fees corresponding to the issuance of the certificate's title is submitted.

Additionally, for the processing and resolution of an applicant's request for a supplementary certificate filed before IMPI, the following conditions should be met:

- The prosecution of the patent should have exceeded five years, otherwise, IMPI will resolve the inadmissibility of the petition.
- If the prosecution of the patent has exceeded five years, IMPI will determine the amount of time that corresponds to 'reasonable delays' and will subtract that amount from the prosecution period.
- If the time calculated for the reasonable delays is less than five years, IMPI will reject the request for a supplementary certificate.
- If the time calculated after considering reasonable delays is still greater than five years, IMPI will determine the number of days that corresponds to an unreasonable delay, which will be included in the extension listed in the supplementary certificate, as an extension valid for one day for every two days of unreasonable delay.

The LFPPI (our new law) considers the following to be reasonable delays:

- **I.** The period that elapses between the date of receipt and the date of the favorable resolution of the formal examination;
- **II.** The periods attributable to actions or omissions of the applicant, tending to delay the procedure for granting the patent and the extensions to answer deadlines;
- **III.** The periods not attributable to actions or omissions of IMPI or that are beyond its control, such as those that pass in the substantiation of any means of administrative or jurisdictional challenge or that derive from them, and
- **IV.** The periods attributable to force majeure or fortuitous events.

Any other delays attributable to IMPI are those that will be considered as not reasonable and will be considered for the supplementary certificate.

These new provisions will apply to patent applications that are filed starting from November 05, 2020, so it will be quite some time before we see a petition for a Patent Term Adjustment under the new IP law.

C. Other positive changes:

C1) Article 52 of our new law still provides a 12-month grace period wherein public disclosures made by the applicant or his successor in title do not destroy the novelty thereof, provided that said disclosure was made within 12 months before the filing date or the priority date. Nevertheless, it broadens the activities that may qualify for getting the grace period, including now any disclosure made directly or indirectly by the inventor/s or its assignees, as well as including include any disclosure made by any third party who obtained the information directly or indirectly from the inventor/s or its assignees.

C2) Voluntary divisionals which have been accepted for several years by the Mexican PTO but that were not mentioned in our previous law, are now also specifically contemplated in our new law and specific timeframes for filing voluntary divisionals have also been established. However, as we will further comment, our new law also possesses some challenges in the divisional scenario.

III. Challenges

Indeed, our new IP Law provides specific support for filing voluntary divisionals and establishes the specific timeframes for filing them. However, there are certain aspects regarding divisionals that definitely represent a challenge for patent owners in Mexico.

A. Cascade divisionals

As mentioned in article 100 of our new IP Law, a voluntary divisional application will only be possible if it derives from its parent case. In other words, voluntary divisionals deriving from divisionals will no longer be allowed. The only possible scenario for filing cascade divisionals is if the Mexican PTO requests the further division through a lack of unity objection. In view of this major change, applicants will now have to be creative in developing strategies to secure the possibility of being able to file future cascade divisionals. For example, applicants could file in the first divisional a set of claims that do not comply with unity of invention in order to assure that the Examiner issues a lack of unity objection, thus giving the applicant the opportunity to file further divisional applications in the future.

It is also possible to file multiple divisional applications all deriving from the same parent case. This could of course be an option in case the applicant has a clear idea of what they wish to pursue in each divisional.

B. Limitations on claim scope

As is also mentioned in article 100 of our law, when unity of invention is objected, any invention or group of inventions that are not included in the initial application or in the application that originated the division, cannot be included again in any of said applications. Therefore, when receiving a unity objection, the applicant needs to consider this when deciding the scope of protection that is of commercial interest to them.

C. Double patenting

Double patenting has long been an issue in Mexico and in the practice, Examiners tended to raise double patenting objections when there was scope overlap between the claims of a divisional and that of its parent case. However, double patenting was not defined in our previous law and so, it was feasible to argue that the only scenario in which double patenting existed was if the scope of the claims of the divisional was identical to the scope of the claims of the parent case. This argument proved successful with the Mexican Patent Office.

Article 101 of our new law mentions that a patent will not be granted to matter that is already protected in another patent or if the essential technical characteristics sought to be protected are a non-substantial variation of the matter protected in said other patent. This definitely poses a grey area on how double patenting will be assessed by the Examiners and how they will interpret a "non-substantial variation". The assessment of the Examiners will depend on the pertinent case law that will develop once these cases reach the Mexican courts.

Conclusions

In closing, our new IP Law offers several benefits for patent owners, and we can say that the balance is mostly positive. Hopefully, the grey areas will mostly be clarified once the upcoming new regulations of our new IP law issue; however, said regulations are still under discussion.

Also, it is important to contemplate that our new law applies to all patent applications filed in Mexico from November 05, 2020, and onwards. All patent applications with a national filing date that is previous to November 05, 2020, will continue to be prosecuted according to the provisions of our previous IP Law. By the same token, it is important to consider that divisional applications that derive from a parent case that was filed before November 05, 2020, should also continue to be studied with the provisions of the previous IP Law, regardless that they were filed after November 05, 2020.

In sum, both our new and previous IP laws will coexist for quite some time, and for this reason it will be necessary to consider the applicable law for a certain patent application when designing the prosecution strategy.

> **"Our new IP Law offers several benefits for patent owners, and we can say that the balance is mostly positive."**

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Introduction to China's patent Prioritized Examination program

Dr. Xin Chen, Deputy Director of the Electrical Patent Department at CCPIT Patent and Trademark Law Office, explains the PE program process including important aspects such as requirements, eligibility, and invalidation.

The patent Prioritized Examination (PE) program in China is the main way to accelerate patent prosecution, besides the well-known Patent Prosecution Highway (PPH) pilot program. The PE program is also a choice to expedite the invalidation proceedings for a patent involved in an infringement dispute. Similarly to the PPH pilot program in China, the PE program has no official fees, and is even quicker than the PPH. For example, an invention patent application can get a final decision within 12 months from the approval of the PE petition. Therefore, the PE program is becoming an attractive option for applicants who desire quick patent protection.

However, the PE program is only applicable to cases that meet certain requirements. The China National Intellectual Property Administration (CNIPA) issued the Administrative Measures for Patent Prioritized Examination ("Measures") on June 28, 2017, which came into effect on August 1, 2017. Below we will introduce the PE program in China based on the Measures and our up-to-date experiences.

1. Which types of application or patent are eligible for the PE program?

All three application/patent types, invention, utility model, and design, are eligible for the PE program as long as certain requirements are satisfied (see Items 2-3 for the specific requirements). In particular, the PE program is applicable to:

- Invention, utility model, and design applications during prosecution (hereinafter referred to as "prosecution cases");
- Invention, utility model, and design applications during re-examination (hereinafter referred to as "re-examination cases"); and
- Invention, utility model, and design patents during invalidation proceedings (hereinafter referred to as "invalidation cases").

Note that the PE program is applicable to both non-divisional applications and divisional applications. Also note that, the applicant

Dr. Xin Chen

> **"The applicant cannot request both PE and PPH for the same application."**

Résumé

Dr. Xin Chen is the Deputy Director of the Electrical Patent Department of CCPIT Patent and Trademark Law Office. She has a strong technical background and 14 years' experience in patent prosecution, reexamination, counseling, invalidation, and litigation, especially in the technical fields of software, communication, semiconductor, and optics. She has helped several globally renowned companies obtain patents inside and outside China and has provided them with valuable advice regarding patent prosecution strategies. She has also obtained many favorable results for the clients in patent invalidation proceedings and administrative litigations.

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cannot request both PE and PPH for the same application, i.e., only one of PE and PPH can be used to accelerate the prosecution of an application. Moreover, for a pair of invention and utility model applications filed on the same day with a dual-filing statement, the invention application in the pair is not eligible for the PE program.

2. What are the requirements for a prosecution or re-examination case to request PE?

A prosecution or re-examination case can request PE if one of the following requirements is met:

(i) The application involves national key industries including energy conservation, environmental protection, new generation information technology, biotechnology, high-end equipment manufacturing, new energy sources, new materials, new energy vehicles, intelligent manufacturing, etc.;

(ii) The application involves industries that are specially encouraged by the people's governments at provincial or municipal levels;

(iii) The application involves internet, big data, cloud computing or the like, and the technology or product updates fast;

(iv) The applicant has prepared for or has started implementation, or there is evidence to prove that someone is implementing the invention;

(v) The application is firstly filed in China and then a counterpart with the same subject matter is filed in another country or region; or

(vi) Other situations that need prioritized examination due to the great significance to the national interests or public interests.

3. What are the requirements for an invalidation case to request PE?

An invalidation case can request PE if one of the following requirements is met:

(i) There is a dispute of infringement of the patent involved in the invalidation case, and the party concerned has filed a lawsuit with the court, requested the local IP office to handle it, or requested an arbitration or mediation organization for arbitration or mediation; or

(ii) The patent involved in the invalidation case is of great significance to the national interests or public interests.

> **77,000 PE cases were handled by the CNIPA in 2021, which increased by 31.5% compared to 2020.**

4. How much can the examination be expedited under the PE program?

For an invention application on the PE track, the CNIPA will issue the first office action within 45 days and issue the patentability decision (Notice of Allowance or Rejection Decision) within one year from the approval of the PE petition. For a utility model or design application on the PE track, the CNIPA will issue the patentability decision within two months from the approval of the PE petition.

For a re-examination case, whether the application is an invention, utility model, or design, the CNIPA will issue the Re-examination Decision within seven months from the approval of the PE petition.

For an invalidation case of invention or utility model patent, the CNIPA will issue the Invalidation Decision within five months from the approval of the PE petition. For an invalidation case of a design patent, the CNIPA will issue the Invalidation Decision within four months from the approval of the PE petition.

5. Is there any quota for the PE cases each year?

There is no explicit quota for the PE cases handled by the CNIPA each year. The CNIPA promises that, on the premise that the examination quality and overall pendency are not affected, it will provide as many resources for PE as possible. The quota for the PE cases each year will be determined by the CNIPA according to the statistics such as the examination capabilities in each technical field, the number of patents granted in the previous year and the number of pending cases in the current year. The quota may vary each year and is not disclosed to the public.

According to the 2021 annual report of the CNIPA, 77,000 PE cases were handled by the CNIPA in 2021, which increased by 31.5% compared to 2020.

6. Are the examination standards for PE cases different from normal cases?

The examination standards for PE cases are the same as normal cases. Unlike the Accelerated Examination (AE) program in the USPTO, there is no limitation on the number of claims or independent claims for the PE cases. Also, it is not required that the claims be directed to a single invention. If the claims of an application on the PE track are directed to more than one invention,

the applicant may receive a lack-of-unity rejection and pursue divisional applications later.

7. Is the period for replying to office actions for PE cases the same as normal cases?

For a prosecution case, the office actions for PE cases will have a shorter period for reply than normal cases. Specifically, the period for reply is two months for invention applications and 15 days for utility model or design applications, regardless of whether the office action is the first one or a subsequent one.

For a re-examination or invalidation case, the period for replying to office actions for PE cases is the same as normal cases.

Failure to timely file a reply will result in the PE case going back to the normal track.

8. What is the timing for filing the petition for PE?

For an invention application, the petition for PE can be filed after the CNIPA issues a notification informing that the application has entered substantive examination. For a utility model or design application, the petition for PE can be filed after the applicant has paid the filing fee. For a re-examination case, the petition for PE can be filed after the re-examination fee has been paid. For an invalidation case, the petition for PE can be filed after the fee for requesting invalidation has been paid.

> **For a prosecution case, the applicant needs to file a PE petition form, prior art references, and supporting materials.**

After receiving the petition for PE, the CNIPA will issue a notification to inform whether the petition is approved or not, which typically takes two weeks. If the petition for PE is rejected by the CNIPA, the petition cannot be filed again.

9. Who is eligible to request PE?

For a prosecution or re-examination case, it is the applicant who can file a petition for PE with the CNIPA. For an invalidation case, both the invalidation petitioner and the patentee can file the petition for PE. If there are multiple applicants or patentees, the consent of all the applicants or patentees is required.

In addition, the court, the local IP office, or the arbitration/mediation organization that is handling the relevant patent infringement dispute can request PE for the invalidation case.

10. What are the documents required for filing the petition for PE?

For a prosecution case, the applicant needs to file a PE petition form, prior art references, and supporting materials. In the case of above Item 2(v) (i.e., outbound application), these documents shall be directly filed with the CNIPA. In the

other cases, these documents shall be first submitted to the provincial IP office in the province where the applicant or its agency is located to have the PE petition form signed by the provincial IP office, and then filed with the CNIPA. The provincial IP office usually signs the form quickly (e.g., in several days) if the requirements are satisfied.

For a re-examination case, the applicant needs to file a PE petition form and supporting materials. Except for the case where the application was already on the PE track during the prosecution, the sign by the provincial IP office on the PE petition form is also required before filing the documents with the CNIPA.

For an invalidation case, the party requesting PE needs to file a PE petition form and supporting materials. Similarly, a signature from the provincial IP office on the PE petition form is required before filing the documents with the CNIPA.

For all the cases, if an agency is entrusted to handle the PE matters, a power of attorney is also required.

The supporting materials include the necessary documentation to prove that the case complies with the requirements listed in above Items 2-3. Usually, a brief introduction of the invention and the identification of all applicants (e.g., a copy of ID card for an individual, or a copy of business registration for a company) are required for all the cases.

The other documents included in the supporting materials may vary depending on the cases. For an application meeting Item 2(i)-(iii), a statement explaining why the application involves a specified industry is required. For an application meeting Item 2(iv), proofs showing the implementation or preparation for implementation are required, such as a claim chart between a product and the claims, an invoice or agreement showing the sale of the product, a picture or manual of the product, etc. For an application meeting Item 2(v), the filing receipt by the patent office in the other country or region is required. For an invalidation case meeting Item 3(i), documents such as the notifications issued by the court or the compliant as filed are required.

> **The other documents included in the supporting materials may vary depending on the cases.**

11. Under what circumstances will the PE case be moved back to normal track?

For a prosecution or re-examination case, the case may be moved from the PE track to the normal track if the applicant makes voluntary amendments after the approval of thw PE petition, fails to timely reply to the office action, submits false materials, or is found to be an abnormal application.

For an invalidation case, after the approval of the PE petition, if the invalidation petitioner supplements causes and evidence for invalidation or the patentee amends the claims in a way other than deletion, the case will be moved back to the normal track. In addition, if the invalidation case is suspended for some legitimate reasons, the case may also be moved back to the normal track.

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Stretching timelines in patent matters in the Indian Patent System: the use of "patent agent negligence" and the "pandemic excuse"

Adv. Mohan Dewan, Principal at RK Dewan & Co., evaluates the attempted use of "patent agent negligence" to restore abandoned patents and patent applications in India.

Patent systems all over the world work on fixed and mandatory timelines and due dates. There is a fixed timeline for filing of Complete Specifications (Non-provisional) after a filing of a Provisional, a due date for entry of a National Phase patent application under the PCT and the Paris Convention. A fixed time period within which office actions are required to be responded to and fixed dates for payment of renewal fees. These timelines are important for any industry in order to understand what technology can be used and what is prohibited because it is covered by a patent or a patent application. Therefore, these timelines and priority dates are mandatorily set by the patent laws and rules of a patent system in a particular jurisdiction for the benefit of all industries and in the public interest and for reasons of transparency.

The commercialization of a product or the use of a process depends on this. Ultimately it is a consumer who benefits from a competitive product available at an affordable price. That is why it is inbuilt into a Patent system of a country that the timelines and priority dates need to be complied with strictly. Towards this end, various patent search engines are designed to read this aspect and freedom to operate or freedom to practice opinions are based on adherence to these timelines and priority dates. It is therefore sacrosanct for any good and robust patent system not to disturb these timelines and mandatory due dates, unless there is a very compelling reason to do so. If for perfunctory reasons these timelines and due dates are disturbed, they will bring in an element of uncertainty in the system as a whole. Here it is not the monopoly interest of the Patent holder or the Patent applicant that is at stake, but the interest of an industry and the public at large. This aspect seems to have been lost sight of in a few cases decided by the Delhi High Court recently. Unfortunately, in these cases the issue that was dealt with was only between a Patent applicant, his agent and the Patent Office and what appears not to be considered are the effect that these decisions will have on the industry, commerce and the public at large.

This article refers to two particular cases, let us call these cases as the European Union case passed earlier and recently in the Bry-Air Procon

> **I am particularly concerned with the extension of timelines which happened based on the concept of "Patent Agent negligence".**

Résumé

Adv. Mohan Dewan is a patent and trademark attorney for over 50 years and a practicing senior advocate and jurist. He was in charge of the Intellectual property Law department of the University of Natal in South Africa where he also taught Private International Law.

Having drafted and successfully prosecuted several hundred patent specifications, he has come to be acknowledged as an expert in patent specification drafting.

He has drafted and obtained over 11,000 patents in nearly every technology area from Life Sciences, Molecular material science, to Engineering to Software, Electronics & Telecommunication, and Space Technology.

His area of expertise comprises patent and trademark litigation, technology transfer, and IPR valuation.

His firm R K Dewan & Co. represents over 6,500 clients worldwide. He has several publications to his credit and is actively involved in seminars and workshops on Intellectual Property Rights for training IP professionals and patent office examiners.

Adv. Mohan Dewan

case which primarily relied on "Patent Agent negligence" and to a certain extent on the "pandemic excuse" for restoring irretrievably lapsed patent applications and a patent respectively and allowing writ petitions filed by the applicants/patent holders to enable them to restore their rights. Whether the patent applications are converted to patent rights, whether they are opposed or whether any infringement takes place, only time will tell.

In this article, I am particularly concerned with the extension of timelines which happened based on the concept of "Patent Agent negligence". Negligence is an extremely arbitrary term, and it is not clear what factors can fall under this term to act as mitigating circumstances for the exercise of discretion in favor of an applicant or patent holder in restoring an irretrievably lapsed patent application or a patent. In respect of the professional such as a Patent Agent or Advocate, the term "negligence" is something more than a mere failure of judgment or a mistake or an error committed. Negligence is more deliberate and intentional and a gross failure to exercise care for a matter in which a professional is responsible and which such a professional is ethically duty-bound or expected to exercise. In most cases, negligence involves some harm caused to a client by the failure of the professional to act or by the professional acting in a careless manner. Mercifully both judgments referred to above do not mention the patent agent firm that was presumably "negligent" but the firms and patent agents in question can easily be deciphered from the details of the patent applications mentioned in the judgment. I believe that the judgments did serve to restore the IP rights of several of the holders at the cost of creating uncertainty in the field of patent law in India and created more questions than resolving some issues. These judgments are also likely to create ripples in the Indian Patent System and probably at the Indian Patent Office.

> **"In most cases, negligence involves some harm caused to a client by the failure of the professional to act or by the professional acting in a careless manner."**

The simple facts of the matter in these applications were that Patent applications were filed during various time periods starting from 2009 up to 2014. The fact that these patents have not been granted, in one case for over a decade itself is a cause for raising "eye-brows" about the Indian Patent System. Proper requests for examination were made in each of the cases and examination reports were issued over a period of several years. The Indian Patent Act and Rules prescribe that an examination report is required to be replied to within six months of the issuance of the first examination report. There is also a provision for extending the time for replying to the examination report by a maximum period of three months. If this timeline is not adhered to, a Patent application is deemed to be abandoned under the provisions of Section 21(1) of the Indian Patent Act. There is no provision in the Indian Patent system to revive such an application. There is also no provision for appeal. Hence, the applicants whose patent applications were abandoned had to resort to filing writ petitions. This is what happened in these particular cases.

It is surprising how the authorized patent agents failed to respond to even one of the six patent examination reports over a period of several years and also failed to renew a granted patent and admittedly claimed that they did not receive any one of the examination reports. There is no provision for restoring such abandoned patent applications. Therefore, in the Bry Air cases the applicants resorted to filing a single writ petition claiming "Patent Agent negligence" as a ground for restoring these patent applications/patent. In the pleadings of this case, voluminous documentation was attached including email exchanges between the "negligent patent agent" and foreign attorneys. The petitioners/applicants realized that their patent agent was not diligent in pursuing the matters and was also reporting incorrect status. The petitioners also pleaded that there was no "contributory" negligence on their part and "patent agent negligence" could not be attributed to the petitioners. The statements extracted from the pleadings reflect very poorly on the "negligent patent agent" who apparently lied consistently. The pleadings and averments in the petition resulted in the decision by the Honorable High Court who was pleased to decide in favor of the petitioners and restore the applications which were deemed to be abandoned.

I am also not sure how the Patent Office will react to these "restorations" and how will the Patent module enable these applications to be "resurrected" once they have been deemed to be abandoned. What seems to have been lost sight of is that all the information was in the public knowledge of the applicants themselves because all around the information of what was happening is available to anyone on the IP India website. The petitioners could have accessed the IP India website at any point in time and obtained information about the fate of their patent applications. Does an applicant not have the duty to access information about their own patent applications? If a patent applicant does not check what is going on, does this not amount to a lack of care?

"Patent Agent Negligence" appears to have been established partly on the basis of correspondence exchanged between "foreign agents" of the petitioners and the so called "negligent patent agent" in a few of the cases. The judgment emphasizes this aspect of foreign agents, however, on going through the record only one case that is 34/DELNP/2013 is an application filed in the name of a foreign entity and the remaining six cases were found to be part of this set were all filed in the name of Indian entities where normally no foreign agent should or can be involved. This fact is further confirmed in the judgment where the petitioners themselves aver that the "negligent patent agent" was instructed to represent and take necessary actions in related applications and patents in various foreign jurisdictions. It can be deciphered from the judgment that not only were the Indian Patent applications abandoned but so were the international applications. What is lost sight of is that an Indian patent agent cannot act in foreign jurisdictions and the Indian patent agent must act through patent agents in respective jurisdictions. Were all the patent agents in the respective jurisdictions where these applications were filed also negligent? Instructions in respect of filing and prosecution of patent applications outside India will flow outwards and not inwards, that is from the Indian Patent Agent to the foreign patent agent and not *vice versa* and it is inconceivable that a foreign patent agent will inquire about the fate of an Indian application.

> **"These judgments are also likely to create ripples in the Indian Patent System and probably at the Indian Patent Office."**

Surprisingly, there is a statement in the judgment to the effect that even after abandonment of the patent applications, the "negligent patent agent" had stated in a communication that steps were being taken for restoration of the application and that responses to the first examination

reports were being uploaded. It is said that the patent applicants (petitioners) sent repeated reminders to the "negligent patent agent" and because they were not getting any response, they appointed a new patent agent who, upon inquiry at the Patent Office, "unearthed" the "negligence" in prosecuting the application and the patent. The petitioners could have searched through the records maintained at the IP India website and would have found this information themselves. As I reiterate, the Indian patent office website is open to any member of the public including the applicants.

Surprisingly, it is also stated in the judgment that the "negligent patent agent" admitted his negligence and also gave an affidavit which includes this admission. I have reviewed the documents of the abandoned patent applications and find that it was not a single person that was involved but the power of attorney to act was given to a group of patent agents and also some advocates. Could all of them have been negligent?

What is strange is a statement in the judgment which goes on to say that in other jurisdictions like the USA, the UK, Germany, Australia, etc. the patents of the petitioners have been restored or the restoration is under process and that the affidavit of the negligent patent agent in India was used to restore these patent/patent applications in the foreign countries. Were all the patent agents handling the petitioners' matters "negligent"? The Power of Attorneys filed in each of these cases shows that not only the holders were responsible Patent Agents but also responsible Advocates. Will not "patent agent negligence" amount to professional misconduct?

The judgment also adds a layer to the alleged "abandonment" of the patent applications. The judgment emphasizes the fact that "abandonment" requires a "conscious act" on the part of the petitioner, which would manifest the intention to abandon the application, which means to say that if there is no "manifested intention" no patent application can be deemed to be abandoned or no patent can be deemed to lapse. This finding also brings in a level of uncertainty. Any applicant whose application has been refused can plead that they had "positive intent" to prosecute and that an abandonment was "not intentional" and plead restoration of a patent application or a patent.

The judgment goes on to say that "negligence of a patent agent" is an extraordinary situation, particularly if there is no contributory "negligence" of the applicant. It is hardly likely that in a case such as this an applicant will admit to contributory "negligence" and will plead any statement to show that there was any "intention" on its part to abandon a patent application. The judgment records that "there is nothing on record which indicates that the petitioner has willfully neglected". It is hardly likely that a petitioner making out a case for redressal will put anything on record to show that "it had willfully neglected" to act. Can a patent applicant get away with ignorance of law? A patent agent is merely an agent for the applicant who is the principal. Even if a patent agent was "negligent" will not the principles of "vicarious liability" apply, particularly when public interest is involved. This seems to have been lost sight of. It is true that the abandonment of the patent applications caused extinguishment of "substantive" rights of the applicant/petitioners. But the restoring of the patent applications will also cause creation of liabilities in favor of the general public who can now be sued for infringement of the patents, if granted, because of the restoration order. What is lost sight of is that a patent is a negative right at best. It does not create an exclusive right in favor of an inventor in the invention, but it creates a right to sue another in case of infringement. It is correct that the Honorable Courts and Statutory Authorities are required to do substantial justice and it also must be said that the Courts, while exercising writ jurisdictions, have the power to extend time overriding what has been mandatorily stipulated by the legislature, particularly in extraordinary circumstances. But the danger is that "extraordinary circumstances" may "become normal" and unfortunately, we may see several applicants pleading "patent agent negligence" as a ground for "bending" the statutorily stipulated timelines and mandatory due dates. I am already seeing this happening in a few cases before the Patent Office.

> **"If a patent applicant does not check what is going on, does this not amount to a lack of care?"**

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Pain points in the examination of pharmaceutical patents in Brazil

Daniela Fasoli, Partner at Simoes IP Law Firm, reviews analysis from 263 opinions in pharmaceutical patent prosecution cases in Brazil to highlight the greatest problems facing those working to protect their assets.

Prosecuting patent applications in Brazil is a challenge. When the application involves pharmaceutical inventions, the challenge is taken to a different level. Without deeply understanding the history and reasons for the current PTO' strict examination and, most importantly, without staying updated, the results may be frustrating.

Although pharmaceutical inventions share common characteristics with inventions from other fields, there are elements in the prosecution of pharma patent applications in Brazil that are unique. A set of clear criteria to assist in the drafting and prosecution of these applications, considering not only the legislation, but also the PTO's understanding and practice, helps to speed up the examination and offers applicants greater certainty about the possible results of the examination. Therefore, if Brazil is an important country for the object of a patent - and considering that Brazil accounts for approximately 2% of the pharma global market, being the 7th in terms of revenue with a projection of becoming the 5th in 2023 - there are important issues that need to be addressed before even filing in the country.

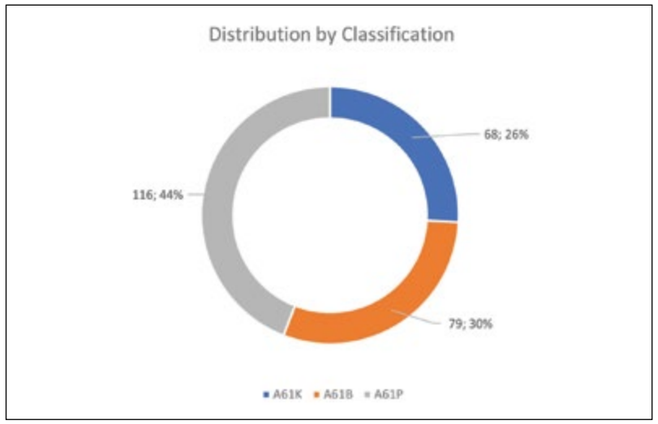
Due to the differences between the practices of the countries and the radical changes in the treatment of pharma patent applications over the years in Brazil, especially in view of restrictions imposed by the local IP Law, changes in the patent term, interference by the Food and Drug administration Agency, ANVISA (no longer applicable to new applications) and controversies regarding incremental inventions, Applicants in this technological field face greater obstacles in the drafting and consequent prosecution of their applications when compared to others.

Daniela Fasoli

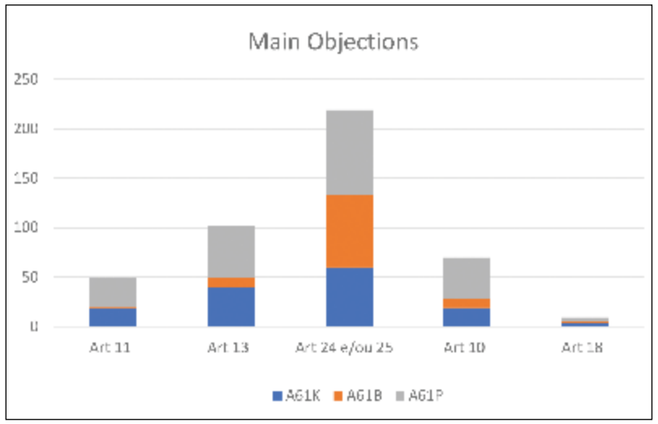
The drafting of pharmaceutical patent applications, especially the set of claims, has a direct impact on the entire examination process - from formal aspects to the final decision - and on the prosecution timeline, with several intermediate opinions, delays and, often, impossibilities of amending the claims to cover the final product of interest in the Brazilian market.

Analyzing office actions

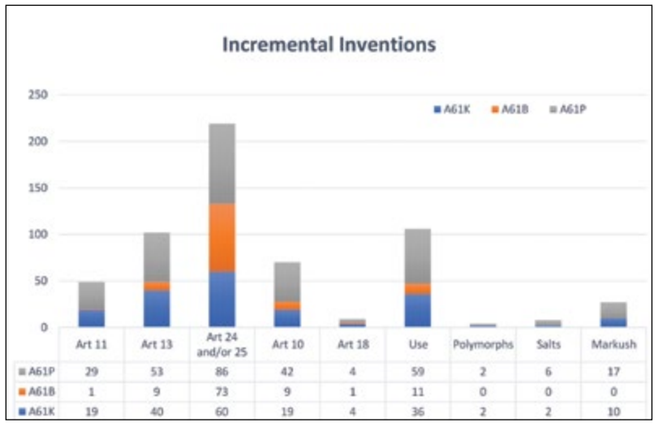
In order to understand how pharma applications are examined, a total of 263 opinions were collected and analyzed (most recent opinions available at the BRPTO's website), among which 68 included the A61K classification, 79 the A61B classification and 116 the A61P classification.



Among the main objections found, we have 219 based on lack of support and enablement (articles 24 and/or 25 of the IPL), 102 of lack of inventive step, 70 including the prohibitions of Art 10[1] of the IPL, 49 for lack of novelty, and 9 including the prohibitions of Art 18[2] of the IPL.



With regard to incremental inventions, the category of "use" being included for containing second medical uses, 106 cases were analyzed with use claims in the set of claims, 27 involving Markush formulas in their set, eight applications claiming salts and four cases involving polymorphic forms.



	Art 11	Art 13	Art 24 and/or 25	Art 10	Art 18	Use	Polymorphs	Salts	Markush
A61P	29	53	86	42	4	59	2	6	17
A61B	1	9	73	9	1	11	0	0	0
A61K	19	40	60	19	4	36	2	2	10

Qualitative analysis

A61K and A61P

Most patent applications related to medicines are included in these classifications.

Despite being much discussed and the large amount of literature and guidelines regarding incremental inventions, the total number of

Résumé

Daniela advises global companies on how to protect, defend, enforce, and manage their intellectual property rights. Her practice encompasses all aspects of intellectual property law, including patent drafting and prosecution, IP litigation, validity and infringement opinions, client counselling in intellectual asset management and appeals before the Brazilian Patent and Trademark Office, especially in the fields of pharma, chemistry, biotechnology, oilfield technologies and nanotechnology.

Daniela is often a speaker on panels around the globe discussing topics including the IP landscape in Latin America.

Before joining Simões IP, Daniela worked as a Corporate Director of an international IP Company. She was responsible for managing all IP legal and technical services Departments from 10 countries of Latin America and Europe. As a pharmacist, Daniela also has field experience in the pharma industry.

[1] Article 10 - The following are not considered to be inventions or utility models:
VIII – operating or surgical techniques and therapeutic or diagnostic methods, for use on the human or animal body; and
IX – natural living beings, when found in nature or isolated therefrom, and natural biological processes.

[2] Article 18 - The following are not patentable:
III – living beings, in whole or in part, except transgenic microorganisms meeting the three patentability requirements – novelty, inventive activity and industrial application – provided for in article 8 and which are not mere discoveries.
Sole paragraph – For the purpose of this law, transgenic microorganisms are organisms, except the whole or part of plants or animals, that exhibit, due to direct human intervention in their genetic composition, a characteristic that can normally be attained by the species under natural conditions.

cases that effectively refer to said inventions was not expressive in the analyzed opinions. The particular analysis of these opinions concluded that there is a tendency towards unspecific objections to the type of invention, and common to other applications on this classification, in particular the lack of enablement and support of the claims.

Precisely, from the reading of the technical opinions issued by the PTO, it is noticed that there is a great difficulty for the applicants to overcome objections related to enablement and support of the claims (Art 24 and 25 of the IP Law). These objections correspond to ~40% of the total of the different types of objections formulated in the opinions analyzed in these classifications.

In the case of national applicants, 81% of all opinions analyzed in the A61K classification and 69% of all opinions analyzed in the A61P classification contained objections based on Articles 24 and 25 of the IPL.

Objections referring to novelty and/or inventive step, in the case of foreign applicants, had similar results to the international phase of said applications - that is, both objections and responses and consequent result/decision, in most cases, were identical compared to examinations carried out in other jurisdictions, especially Europe. This means that the PTO's understanding and practice are similar to the European ones, which makes it easier for international applicants to prosecute their applications in Brazil. No new prior art references were found in any of the analyzed cases, being the references cited in the examination the same cited in the examination of foreign counterparts. The difference is only noticeable in specific cases, in which third party observations were submitted. In a few of the observations, new prior art was cited and subsequently considered by the PTO.

In the case of national applicants, it seems more difficult to file counter arguments to objections regarding novelty and inventive step.

In the A61K classification, 62% of patent applications from domestic applicants had issues related to novelty and/or inventive step versus only 25% for foreign applicants.

A possible explanation for this fact is that the prosecution that took place in other jurisdictions encourages applicants to adapt their patent applications accordingly. This is emphasized nowadays, due to the creation of preliminary opinions.

> **There are elements in the prosecution of pharma patent applications in Brazil that are unique.**

A61B

As expected, the profile of inventions and, consequently, of the objections formulated by the PTO during the prosecution of patent applications in the A61B classification is different from that found in the opinions of the A61K and A61P classifications.

As such inventions are mostly objects ("medical devices"), no incremental inventions are included. Only a few uses have been identified and, for most, it is only the simple use of the apparatus.

Despite the different profile of the inventions, surprisingly, the results found after a qualitative evaluation of the opinions is quite similar to that found for the A61K and A61P classification cases. Here too, there is a great difficulty for the applicants to overcome objections related to the sufficiency of description and support of the claims (Art 24 and 25 of the IPL). These objections correspond to 92% of the total of the different types of objections formulated in the opinions analyzed in these classifications.

Clarity & enablement

"Clarity and precision" and/or "enablement" are the points that generate most problems in the prosecution of patent applications in the pharmaceutical area, corresponding to more than twice the number of objections to the second most frequent problem (inventive step) in the analyzed opinions.

The difficulty is not unique to the Applicants. In the PTO's technical opinions, a confusion can be seen between the application of articles 24 and 25 by the examiners. Most of the analyzed opinions pointed to the use of both articles, cited together.

According to Art 24 of the IPL, the object of the patent application must be sufficiently described in the specification, in a clear and complete way, in order to allow its reproduction by a skilled person and must contain sufficient conditions that guarantee the reproduction of the invention and, when applicable, indicate the best way of execution.

Art 25 of the IPL, in turn, establishes that the claims must be based on the specification, characterizing the particularities of the application, and defining, in a clear and precise way, the subject matter of protection.

Specifically for pharma cases, the Patent Application Examination Guidelines - Block II - Patentability, established by Resolution No. 169 of 07/15/2016, makes some punctual references to the matter in chapters VI (Markush-type Claims) and VII (Compositions).

According to item 6.9 of chapter VI - Markush-type claims, the sufficiency of description of a group of inventions represented by a Markush formula would only be satisfied if it allowed each invention in the group to be executed by a skilled person, based on the specification, and not just some of the alternatives present in the claims. In this case, it would not be correct to extrapolate that compounds with substituents belonging to different chemical classes could be obtained by the same preparation method, since the nature of the reactions would be different. The PTO goes on to state that the specification should include clear examples of how different substitutes foreseen in the Markush could be incorporated into the final product. This text, as written, has led many examiners to adopt a rather strict stance and led to a practice of requesting limitations of these claims containing Markush formulas to the illustrative examples.

In chapter VII - Compositions, the terms "clarity and precision" are used in item 7 to rule the use of qualitative and quantitative definitions of compositions. In addition, Article 25 is also cited to justify that independent composition claims defined solely by their use, form of administration or mechanism of action would not be accurate, causing the matter to be unclear. It is important to note, however, that item 7.10 establishes that dependent claims may limit the scope claimed in its independent claim by establishing the use, form of administration or mechanism of action of the composition. This is usually forgotten by the examiners and attention should be paid to the matter when replying to Office Actions in Brazil.

> **This is usually forgotten by the examiners and attention should be paid to the matter when replying to Office Actions in Brazil.**

Conclusion

The examination of patent applications involving pharmaceutical inventions in Brazil is, in fact, peculiar. Although much is said about incremental inventions in the country, as shown above, the reality is that, despite being very interesting to discuss, they correspond to a minority of the cases.

The problem for pharma applicants prosecuting in Brazil lies in the details. It is essential to pay attention as early as the drafting of the application. Examples of claimed embodiments must be faithfully included in the specification, as well as preferred ranges of variables used in the involved methods.

During examination, submitting strategic amendments and knowing when and how to contest objections especially based on the PTO's guidelines is of fundamental importance and should be an attentive and specific practice.

Knowing how to navigate this sea makes all the difference when prosecuting pharma applications in Brazil.

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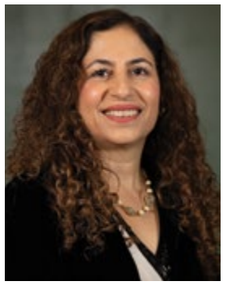
Defining "equivalent" in patent Infringement under the Doctrine of Equivalence

Rachna Bakhru and Suvarna Pandey of RNA, Technology and IP Attorneys compare cases to identify key findings for defining Doctrine of Equivalence, drawing interesting conclusions relating to sequences over elements.

The Infringement under the Doctrine of equivalents is not defined under the Patent Act of India. Therefore, the courts have interpreted the Doctrine in various case laws, and the current legal position on this topic is determined by the court decisions/Judge made law. The Doctrine of equivalents arises in the context of an infringement action. If an accused product or process does not infringe a patented invention, the accused product or process may be found to infringe under the Doctrine of equivalents. In India, there have been few cases on the "Doctrine of Equivalence" in patent claim infringement; analyzing the applicability of the Doctrine of equivalents:



Rachna Bakhru

Suvarna Pandey

1. In *Raj Prakash v. Mangat Ram Chowdhry & Ors.*, ILR (1977) 2 Del 412, decided on March 25, 1977, the Division Bench of the Delhi High Court held "It is the pith and marrow of the invention claimed that has to be looked into and not get bogged down or involved in the detailed specifications and claims made by the parties who claim to be patentee or alleged violaters". Thus, to determine whether the patent has been infringed, the patented article or process must be compared with the infringing articles or process. Unessential features in the infringing article or process are of no account. Suppose the infringing goods are made with the same object in view attained by the patented article. In that case, the minor variation does not mean there is no piracy, and a person is guilty of Infringement if he makes what is in substance the equivalent of the patented article. Some trifling and unessential variations have to be ignored.

2. Likewise, in *Ravi Kamal Bali v. Kala Tech & Ors.* (2008) 38 PTC 435, the Court held that the usage or the purpose of the material produced by Defendant was the same as that of Plaintiff, and the nature of the material was substantially the same. That marginal difference in steel quality accounted for no difference from the patented invention.

3. In the case of *Bajaj Auto Ltd. v. TVS Motor Company*, the Court held that 'a person is guilty of Infringement if he makes what is in substance the equivalent of the patented article. Some trifling or unessential variation have to be ignored.' Therefore, it was held that Bajaj Auto Ltd. had made out a prima facie case for Infringement against TVS Motor Co. and an ad-interim injunction in favor of Bajaj Auto Ltd. was granted.

4. In *Sotefin SA v. Indraprastha Cancer Society and Research Centre & Ors.*, *C.S.* (COMM) 327/2021, the Court held that to determine Infringement, it is imperative to reach a finding that 'all essential elements' of the suit patent are present in the infringing process and applied the Doctrine of Equivalents to test if the Defendant's process infringed the suit patent. The court also relied on the pith and marrow doctrine (i.e. an infringement may be established if the Defendant's device, process, or method enclosed all the essential elements of the patent) to examine if the substituted element in the infringing product does the same task, in substantially the same way, to accomplish substantially the same result.

Thus, the Indian courts have recognized the Doctrine of Equivalents when deciding patent infringement cases. The present position followed by the Indian courts is similar to the practice followed in the E.P. and the U.S. In Europe, the extent of the protection is not defined solely "by the strict, literal meaning of the wording used in the claims," while the Court also considers "any element which is equivalent to an element specified in the claims." Thus, if a product or process is not substantially different from the elements of a patented invention, it can be considered to be infringing. This approach is similar to that followed by the Indian courts.

[1] https://www.fmc.com/en
[2] https://www.natcopharma.co.in/

Résumés

Rachna Bakhru, Partner

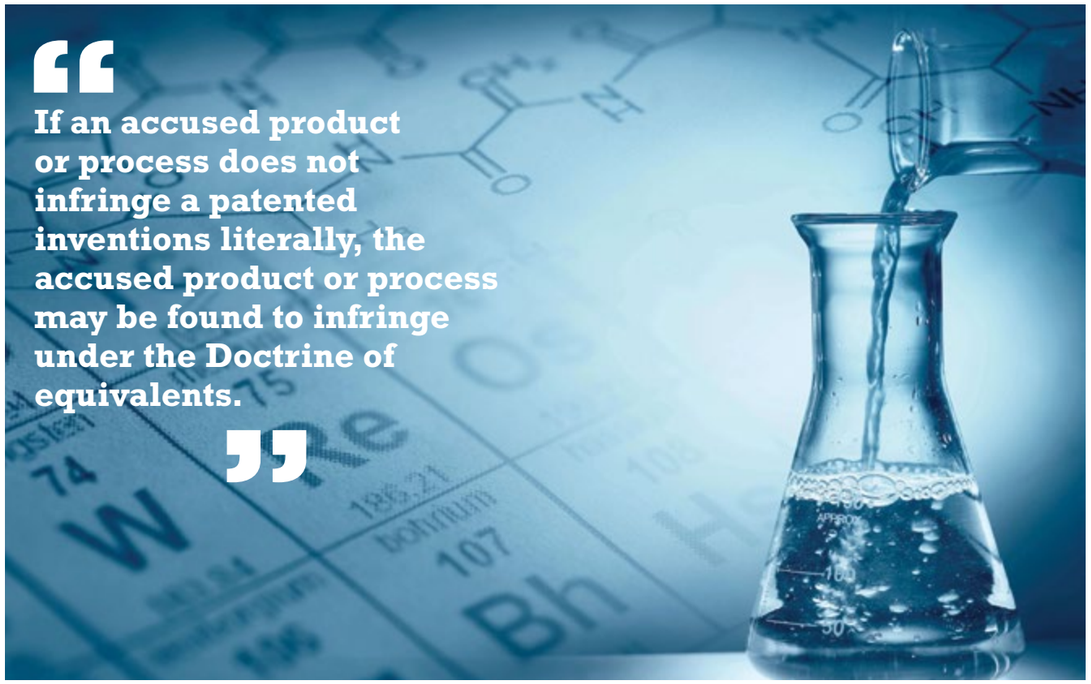
Rachna Bakhru is a Partner with RNA, Technology and IP Attorneys, an IP specialist law firm. She qualified as an Electronics graduate from Delhi University, followed by a diploma in Business Administration and a degree in Law. She is a registered Patent agent and a member of the Bar Council of India.

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.



The U.S. also considers the Doctrine of equivalents in the context of an infringement action. If an accused product or process does not literally infringe a patented invention, the accused product or process may be found to infringe under the Doctrine of equivalents (as per *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 41 USPQ2d 1865, 1875 (1997).

In the most recent case of *FMC Corporation & Ors. vs Natco Pharma Limited*, decided September 2022, the Delhi High court decided the Infringement of a chemical process patent and examined in detail the Infringement under the "Doctrine of Equivalence." The process patent was owned by FMC corporation[1]. FMC had sought an injunction against Natco[2] for Infringement of their patent related to 'METHOD FOR PREPARING N-PHENYL-PYRAZOLE-1-CARBOXAMIDES'. Natco, in their process, had replaced organic sulfonyl chloride with Inorganic Thionyl chloride, an important reagent in a specific step of the claimed process.

The Court, in this case, appointed scientific advisors for expert opinion in the matter and considered the following important technical and legal factors while deciding the patent infringement:

- **Difference between claimed process and Natco/Defendant's process:**

a) The claimed method combines (1) a carboxylic acid compound, (2) an aniline compound, and (3) a sulfonyl chloride, to manufacture 'Chlorantraniliprole' (CTPR).

b) The Court noted that the description of the patent discloses that though the reactants can be combined in a variety of orders, such as combining sulfonyl chloride with carboxylic acid to form a mixture and then combining the mixture with aniline, however, for preparing N-Phenylpyrazole-1-Carboxamide, the preferable order of combination is to combine the acid and aniline to form a mixture and then combine the sulfonyl chloride with the mixture, as this order allows convenient control of the coupling process and the rate of reaction is readily controlled by simply controlling the rate of addition of sulfonyl chloride compound.

c) **Natco/Defendant's process:**
The process is in two stages:
i) Stage 1: 3-Bromo-1-(3-Chloro-2-pyridinyl)-1H-pyrazole-5- carboxylic acid is reacted with thionyl chloride in acetonitrile to get corresponding acid chloride intermediate.

> **Thus, if a product or process is not substantially different from the elements of a patented invention, it can be considered to be infringing.**

ii) Stage 2: 2-Amino-5-chloro-3, N-dimethylbenzamide, acetonitrile and 3-picoline are charged and then reaction mass from reactor 1 is added to the above reaction mass. The resulting product is further purified to obtain CTPR.

- **The Court thus addressed the following important questions in this case:**

i) **Whether 3-Bromo-1-(3-Chloro-2-pyridinyl)-1Hpyrazole-5-carboxylic acid and 2-Amino-5-chloro-3, N-dimethylbenzamide, used in Defendant's process for preparing CTPR are the same as claimed in the suit patent?**

ii) **Is the reagent thionyl chloride used in the Natco process for converting the pyrazole carboxylic acid to acid chloride the same as the reagent used for coupling the pyrazole carboxylic acid with aniline as set out in Claims 1 to 11 of IN 298645? Do thionyl chloride which is an inorganic chloride, and sulfonyl chlorides which are organic chlorides, have different physical and chemical characteristics?"**

Court's observation:

- **Sulfonyl chloride is an essential element of the suit patent and thionyl chloride used as a reagent in Natco's process, differs from sulfonyl chloride in its physical and chemical properties.** In Natco's process, thionyl chloride is used as a chlorinating agent to react with carboxylic acid to displace the -O.H. group present in the acid and replace it with the chlorine atom to form an acid chloride, while in the Plaintiffs' process sulfonyl chloride is added to the mixture of a Carboxylic acid, Amide, Analine and a Base to activate the process and thus acts as a 'coupling agent' to control the rate of reaction as well as the yield produced by it.

- **In the context of the sequence and nature of the chemical reaction, the Court held that:**

The suit patent process and the Natco process are distinct and different. Sulphonyl chloride is an essential element of suit patent, and the use of thionyl chloride as a reagent coupled with a different sequence of the reaction, cannot be termed as an insignificant, trivial, or insubstantial change in the Natco process, and thus, the process prima facie does not come under the rigors of Doctrine of Equivalents.

Conclusion:

Based on the Court's analysis, the application for an injunction was dismissed, and Defendant was permitted to launch its product, CTPR, with a caveat that the process claimed in the suit patent shall not be used. The Court held that the suit patent process and the Defendant's process are distinct and different based on- Different reagents coupled with a different reaction sequence, which is a substantial change, not amounting to the Infringement under the Doctrine of Equivalence. The present order thus clarifies that it is essential to consider if the mode of action of the reagent/component in the accused/Defendant's product is similar to the claimed reagent /component. The parties may not assume that replacing the components from the same categories would work similarly.

> **The mode of action of the reagent is important to consider for analyzing the infringement of the claimed invention by the accused product.**

This is the first case where the Court has emphasized the functioning of the reagents/ chemicals in the infringing process compared to the claimed process. Thus, for establishing infringement, the mere presence of the same reagent will not be sufficient; instead, the reagent should work on the same mechanism to achieve the same result.

FMC is likely to file an appeal before the Division bench of the Court against the order, and it will be interesting to see how the higher courts analyze the Doctrine of equivalents in the present case.

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Overview on the patentability of applications related to Artificial Intelligence

Luciana Bach and Thiago do Espírito Santo of Montaury Pimenta, Machado & Vieira de Mello evaluate the patentability of AI inventions in Brazil compared to other jurisdictions.

As a result of the great technological advances achieved in recent years, Artificial Intelligence (AI) has become popular and, thus, research and technologies making use of it are being developed on an increasing scale. Today the use of AI isnotoriously recognized in several fields of application in everyday life, such as financial markets, industry, agriculture, transportation and even entertainment.

According to the Brazilian Patent and Trademark Office ("INPI"), the definition of AI has evolved over the years, but basically it refers to systems or machines that replicate human intelligence to perform tasks and that can be iteratively improved based on the information they collect, in a process of self-optimization, without the need for the intermediary of human activity to configure them. This happens through the interconnection of millions of data and pattern recognition, thus achieving processes very close to perfection. In this way, failures resulting from human action, influenced by external factors, are practically null by using AI.

Initially, the field of AI was divided into two: "rules-based" and "neural-network-based". The first taught computers to act based on logical rules (IF/THEN). The second was intended to replicate the architecture of biological neuron networks – receiving and transmitting information (hence the origin of its name).

From 2012, neural networks began to stand out in the form of "deep learning" and the focus of this type of AI was destined to several

> **"The following personal assistants stand out: SIRI – from Apple, ALEXA – from Amazon, CORTANA – from Microsoft and GOOGLE ASSISTANT– from Google."**

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applications such as deciphering human speech, translating documents, recognizing images, predicting consumer behavior, identifying frauds and driving autonomous vehicles. In this scenario, the following personal assistants stand out: SIRI – from Apple, ALEXA – from Amazon, CORTANA – from Microsoft and GOOGLE ASSISTANT– from Google.

Among the applications mentioned and in view of their functionalities, the driving of autonomous vehicles is more complex, since this platform needs to be connected with several sensors of the vehicle itself, in addition to a GPS and a traffic analysis system, considering traffic lights, possible obstacles and other vehicles. Despite all the complexity involved, there are prototypes and even some autonomous models being commercialized that prospect this reality, and efforts are now focused on finding ways to make this technology accessible to the entire population in the near future.

The reality is that the last two decades has seen an explosion of technologies that have completely modified the way of living in an interconnected digital world. The way of negotiating, innovating, producing and creating have been directly impacted and are growing exponentially.

According to information available on the WIPO's website, while AI is currently the most prolific new technology in terms of the number of patent applications and granted patents, Internet of Things (IoT) is estimated to be the largest in terms of market size, followed by big data technologies, robotics, 3D printing and the fifth generation of mobile services (5G).

AI at the INPI:

A study entitled Artificial Intelligence in Machinery and Equipment, prepared by the Nucleus for Intelligence in Industrial Property, in partnership with the Brazilian Agency for Industrial Development (ABDI) and the Ministry of Economy, in April 2022, revealed that the number of filings related to machinery and equipment involving AI at the INPI has been exponentially growing since 2009, when analyzing data from the overall sample, and a more accentuated growth as of 2016, when considering only resident filings, as shown in the figure 1 (below left).

> **The reality is that the last two decades has seen an explosion of technologies that have completely modified the way of living.**

According to the study, the concentration of patent applications by applicant country (origin of technology) is as follows: United States: 2,181; Brazil: 576 cases; Japan: 563 cases; France: 276 cases; Germany: 225 cases; Netherlands: 222 cases; Sweden: 217 cases; China: 155 cases; Switzerland: 116 cases and England: 105 cases.

It is possible to observe that, although there is a substantial difference in relation to the United States, Brazil is in a prominent position compared to other countries of great relevance on the world scenario.

Referring to the data obtained in the study, a survey was carried out to detect the main applicants of patent applications related to embedded AI to identify whether they are concentrated in a restricted or distributed group. Among the top applicants in the overall sample, the following stand out: Nissan: 248 cases, Microsoft: 238 cases, Qualcomm: 152 cases, Scania: 129 cases, Boeing: 124 cases and Philips: 114 cases. Note the predominance of companies related to the transportation area, wherein the sum of the filings of these companies represents approximately 18% of the overall sample.

According to the study AI in Machinery and Equipment, 91% of the overall sample of AI-related applications refer to patent applications linked to some type of machinery or equipment.

Further, it also revealed that the top five functional applications of AI identified in machinery and equipment are: Computer Vision (3,223), Control Method (546), Distributed Artificial Intelligence (312), Speech Processing (75) and Natural Language Processing (74).

Finally, it is further important to note that, unlike the applicants in the overall sample, which are mostly companies, the resident applicants are distinguished by a strong presence of universities and research centers. Such fact reveals a good opportunity for companies interested in signing technology transfer agreements or in joint development with these institutions.

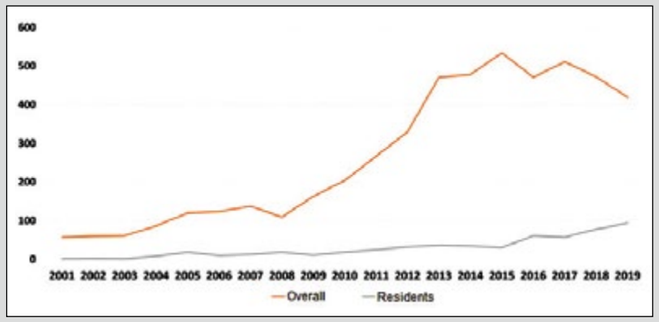

Figure 1 (Source: ABDI's Website)

How to protect an invention that uses AI in Brazil?

In Brazil, an invention that uses AI is outlined by the Guidelines for Computer-Implemented Inventions – IIC (INPI PR No. 411/2020) which states that: "artificial intelligence (AI) techniques, including machine learning and deep learning tools, among others, when applied to the solution of technical problems, may be considered an invention".

It is also noteworthy that, like any patent application, in addition to meeting the patentability requirements set forth in Article 8 of the Brazilian Industry Property Law (IPL), the application must comply with the descriptive sufficiency requirement, that is, the description of the invention must be sufficiently clear and precise for a person skilled in the art to be able to reproduce it.

Therefore, the technical problem to be solved by the invention must be explicit in the specification, as well as the input variables used by the system and how this system will manipulate them to solve the technical problem.

It should be noted that there is an impediment to patent protection when the AI supports the application in methods that cannot be considered an invention, as the provisions of Article 10 of the Brazilian IPL, such as operative or surgical methods or commercial, accounting or financial methods.

What about inventions generated by AI?

According to the provisions of Article 6 of the Brazilian IPL, the inventor is referred to as a person.

The INPI recently published on its website that the INPI's Specialized Federal Attorney's Office understands that it is not allowed to indicate or appoint AI as an inventor in a Brazilian patent application, based on the provisions of Article 6 of the Brazilian IPL, as well as the Paris Union Convention and the TRIPS Agreement, according to opinion No. 00024/2022/CGPI/PFE-INPI/PGF/AGU.

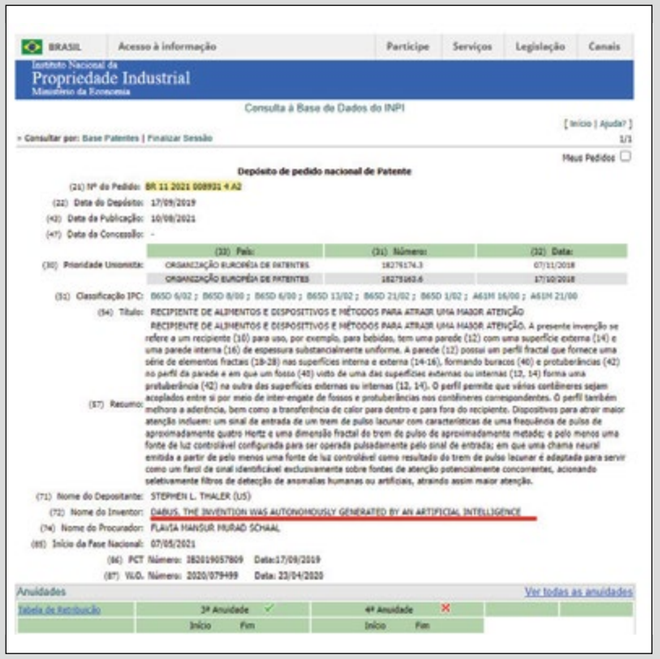

Figure 2 (Source: BPTO's website)

Luciana Bach

Thiago do Espírito Santo

Résumés

Luciana Bach Alvarenga Franco is a Partner and patent counsel at Montaury Pimenta, Machado & Vieira de Mello. Luciana is a telecommunications engineer with approximately 20 years of experience acting in patent prosecution. In particular, Luciana works in the telecommunications, electrical, electronic and mechanical fields. Luciana's professional experience includes the preparation and prosecution of patent applications in Brazil and internationally, as well as reporting, preparing suggestions for response and responding to official actions.
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Thiago Guimarães do Espírito Santo is a Partner and patent counsel at Montaury Pimenta, Machado & Vieira de Mello. He is an electrical engineer who graduated from Rio de Janeiro State University in 2014 and he has been working in the area ever since.

Thiago uses his expertise to assist national and international clients in the area of industrial property, more specifically related to the processing of patent applications in the electrical, electronics, telecommunications and mechanics fields.
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In this regard, patent application BR 11 2021 008931 4 (WO 2020/079499), filed under the authorship of an AI called "DABUS" was withdrawn from the Brazilian national phase. See figure 2.

In addition, there is a Bill PL 21/2020, known as the Legal Framework for AI, drafted by congressman Eduardo Bismarck, which aims to establish the rules, principles and guidelines that must be followed by public authorities, companies, various entities and individuals for the development and application of AI in Brazil.

The text, which is pending assessment by the House of Representatives, establishes that the use of AI will be based on respect for human rights, human dignity and democratic values; equality, non-discrimination, plurality, free initiative and data privacy, among other points. For this, the text details a series of rights and duties of the so-called AI agents, which can be development agents or AI operation agents, as well as the creation of an AI impact report, to be prepared by these agents, describing the technology, including risk management and containment measures.

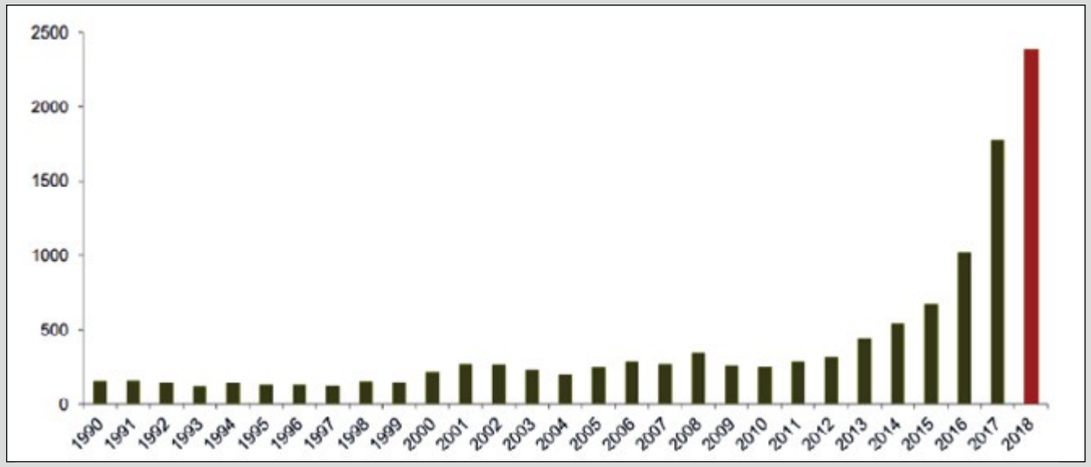

Figure 3 (Source: EPO's website)

AI in other jurisdictions:

- **Europe:**

As in Brazil, the number of AI-related patent applications has grown exponentially since 2012 at the European Patent Office (EPO), as can be seen in the chart above:

The European patent legislation has many similarities with the Brazilian one, such as the evaluation of novelty and inventive activity requirements of the invention, as well as the non-patentability of certain matters, such as discoveries, scientific theories, mathematical methods, aesthetic creations, schemes, rules and methods for performing mental acts, games or business, computer programs *per se*, and presentation of information.

With respect to the examination of applications involving AI at the EPO, the Appeals Division rendered a decision (T 161/18) that refused a method for assessing cardiac output of blood pressure based on an artificial neural network with weight values determined by learning. Initially, the Examination Division found that the application did not comply with the inventive activity requirement. In turn, the Appeal Division maintained the rejection, but for different reasons. In the appeal phase, it was considered that the application did not present descriptive sufficiency in relation to the input data used for training the neural network, making it impossible for a person skilled in the art to reproduce the invention. And, since the person skilled in the art could not implement the invention, the technical effect generated by the claimed neural network would not contribute to the inventive activity.

Another important point is that the person skilled in the art must have the means and capacity for routine work and experimentation. In addition, the examination of patent applications with mixed complexity may require expertise in several fields, for example, a machine learning

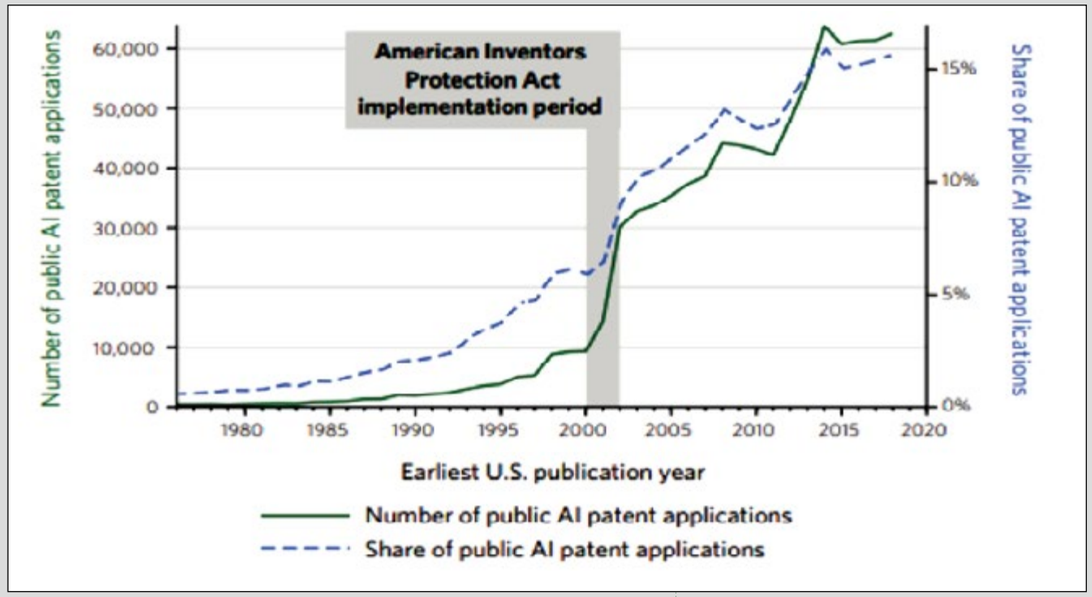

Figure 4 (Source: USPTO's website)

specialist and an aerospace engineer, thus forming a "team skilled in the art".

The understanding of the European Patent Convention (EPC) signatory countries is that their patent system is robust enough to handle technical developments in the field of AI. Regarding the authorship, the understanding is that the inventor is the person who created the invention by his or her own creative activity.

- **United States:**

As in Europe and Brazil, the number of patent applications related to AI grows exponentially in the United States, as can be seen from the graph above.

A more significant increase can be seen from 2002 onwards due to the changes made by the American Inventors Protection Act (AIPA) at the end of 1999 and its implementation period (in gray in the figure). The horizontal axis of the graph refers to the year of the first pre-grant publication of a patent or a patent application, or the year that a granted patent was published.

The main US Patent Court confirmed on August 5, 2022, that AI is not considered an "individual" under the US Patent Act and therefore AI cannot be appointed as an inventor of a patent.

According to the USPTO, current statutes, case law and patent regulations limit an inventor to a human being and preclude a broad interpretation that would encompass an AI machine.

Then, it is observed that the decision of the American Federal Circuit only reinforces what was decided in other foreign jurisdictions.

> **"There is worldwide agreement regarding the fact that AI cannot be considered as the inventor of a patent application."**

Europe, the UK and Australia have taken a similar stance on AI as an inventor. On the other hand, South Africa — the only jurisdiction in which the patent was granted to DABUS — does not substantively review patent applications or conduct an examination on the merits, so it is believed that this issue has not been sufficiently debated in that country.

Therefore, it is noticeable that there is worldwide agreement regarding the fact that AI cannot be considered as the inventor of a patent application. However, with the fast evolution of AI experienced around the world, a review and subsequent adaptations of legislative actions will be necessary to update the current laws that govern patents in this regard.

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Diversity, equity and inclusion: disability

Megan Rannard, Associate at Marks & Clerk and member of IP Inclusive, provides an insight into the difficulties facing those with disabilities when entering and integrating into the workforce and offers some first steps for promoting inclusivity.

Interviewing for a new job or a promotion can make even the bravest among us quiver in their boots. The desire to make a good first impression and the uncertainty of how others may perceive you can cause sleepless nights and weeks of nerves. We all have questions that we hope we will be asked so that we can put our best foot forward and hopefully get the job.

Speaking from my own personal experience, the uncertainty of people's perceptions can be a huge worry for those with disabilities and many will unfortunately have had unpleasant encounters with strangers or even friends. When it comes to events such as job interviews, the question of when to disclose a disability, or whether to disclose at all, often has no clear answer and the fear of the potential impact this may have on career opportunities (even if simply as a result of unconscious bias rather than active prejudice) should not be underestimated by interviewers and employers. The fear of being viewed as "less capable" and therefore missing out on opportunities for career progression affects not only disabled individuals at the interview stage - figures suggest that around 80% of people with disabilities acquired these conditions later in life, and so the difficult questions and worries around disclosure and its impact can affect individuals at any time during their career and often without warning.

Megan Rannard

Résumé

Megan is an Associate and Chartered Trademark Attorney at Marks & Clerk - she joined the IP profession in 2017 having completed a law degree at the University of Kent. Megan is committed to raising awareness, and promoting inclusion and equality for disabled professionals in particular based on her personal experiences with an invisible disability. She is actively involved in IP Inclusive, being a member of the Advisory Board and sitting on the committee for IP Ability (the IP Inclusive community for disabled people, carers and their allies).

> **The act of disclosure avoidance can itself have an adverse effect on an individual's wellbeing.**

For those with visible disabilities, the choice to disclose is often automatically taken away but for those with invisible disabilities, or disabilities that can fluctuate between being visible and invisible, it can be much easier to hide symptoms and avoid disclosure in order to try to prevent the risk of experiencing negative bias in the workplace. The act of disclosure avoidance can itself have an adverse effect on an individual's wellbeing. Those hiding their disabilities may often work extra hours to somehow compensate for this, which itself will lead to exhaustion and burnout. Without appropriate adjustments, working practices may exacerbate symptoms and make it much more difficult for an individual to maximize their potential.

It is therefore crucial to acknowledge and openly discuss the difficulties that can surround the disclosure of disabilities and resulting requests for reasonable adjustments if required. It is almost inevitable that discussions about disability will be deeply personal and often quite uncomfortable for the individual concerned. As interviewers and employers, companies should therefore take active steps to make hiring and promotion processes more accessible to individuals with disabilities and to counteract the notion that the disclosure of a disability may have negative implications for employment opportunities and career progression.

To do so requires a change in the way that we address disability as well as the promotion of a safe environment in the workplace in which individuals feel comfortable to disclose their disabilities, if they choose to do so. A culture of inclusivity and equal opportunity must be clear and visible throughout a business, including to those external candidates interviewing for positions.

Unfortunately, there is no single solution to creating a safe and inclusive workplace environment in which individuals will feel comfortable or even empowered to disclose their disabilities if they wish to do so. The process will take time and requires consistent effort at all levels of a business. To get the conversation started, some ideas for businesses to improve inclusivity and equality of opportunity for those with disabilities could include (a non-exhaustive list!):

- Becoming a Disability Confident Employer under the UK government scheme and promoting this status in job advertisements (as well as internally);
- Acknowledging or including accessibility considerations in job advertisements;

> **A culture of inclusivity and equal opportunity must be clear and visible throughout a business, including to those external candidates interviewing for positions.**

- Regular training on unconscious bias and inclusive practices for all employees, including those with hiring or promotion responsibilities;
- Having a clear and readily accessible policy for requesting reasonable adjustments so that individuals do not feel that they are requesting something unusual.

Ultimately, the decision to disclose a disability is a deeply personal one and there is no legal obligation to do so. Therefore, when a person chooses to disclose, they should be treated with respect and a collaborative approach should be taken with regard to their personal requirements. Studies have shown that diverse and inclusive workforces are advantageous to businesses and so we should aim to promote a workplace culture in which those who wish to disclose their disabilities feel more secure in doing so.

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