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A potential update to the *quid pro quo* of patents? US Supreme Court to review enablement requirement in Section 112 of Patent Act

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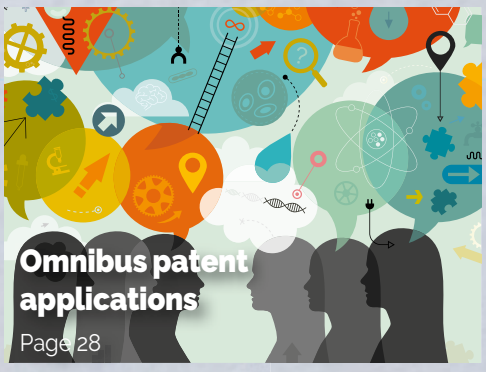
Paul Ratzmann and Melissa Chapman of Fishman Stewart explain the importance of having a 'proper' US patent disclosure for promoting science and the useful arts, and how a pending Supreme Court case may determine if certain disclosure strategies meet current enablement requirements.

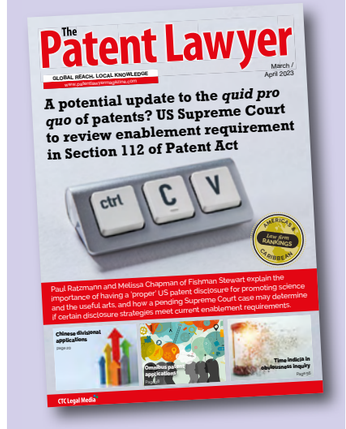
Chinese divisional applications
Page 20



Omnibus patent applications
Page 28

Time indicia in obviousness inquiry
Page 56

CTC Legal Media



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Editor's welcome

The ability to obtain patent protection encourages the continuation of innovation by facilitating commercial opportunities, but granting market exclusivity to a patent holder arguably restricts society's access to these inventions. Our cover story this issue discusses the *quid pro quo* principle of patent protection in the US, expressing some of the "why" reasons protection is granted.

Our guest interview this issue is with Khamzat Asabaev, former M&A lawyer now CEO of SoftSmile, an innovative orthodontics software provider. Khamzat discusses the strategic approach to patenting for aligner software, an innovation driven by the hope of making orthodontic treatments affordable to those in need.

> ***Our cover story this issue discusses the quid pro quo principle of patent protection in the US.***

Further, we have an update on the flexible use of Chinese divisional applications to obtain procedural or substantive benefits; suggestions for the new regulations that are yet to be refreshed since the new Federal Law for The Protection of Industrial Property (FLPIP) was instated in Mexico in 2020; and evaluation of three fatal historic events that could have concluded differently if innovative computer simulations had been available, a future obtainable through patenting; an assessment of secondary indicia factors for ascertaining the non-obviousness of an invention when filing for patent protection in India; and much more.

Special thanks to our *Women in IP Leadership* segment sponsor, Zuykov and partners, which features Eszter Szakács, Partner at Danubia legal, and Elaine Spector, Partner at Harrity & Harrity.

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Enjoy the issue.

Faye Waterford, Editor

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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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Contents

MEET THE EDITORIAL BOARD

Pravin Anand: Managing Partner, Anand & Anand. India

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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Rafael oversees the Patent, Trademark, Copyright, Plant Breeder's Rights, Internet, and Enforcement Groups. Served in the Mexican Association for the Protection of Intellectual Property AMPPI, AIPPI Mexican group. Current Vice-Chair of AIPPI's Standing Committee on PCT. Appointed INTA's Trademark Office Practices Committee 2022-2023.

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Mark's primary areas of expertise are the IP and data-use aspects of academic technology transfer, government funding of basic research, public-private partnerships, and human and animal medical research.

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Noel's practice focuses on the patenting of biotechnological, chemical, and mechanical inventions. He also drafts and negotiates IP agreements, such as research collaboration agreements and licences.

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Eugene is an experienced trial lawyer that represents clients in complex patent matters involving diverse technologies. He has extensive experience and regularly serves as first-chair trial counsel in post-grant review trials (IPR, CBMR, PGR) on behalf of both Petitioners and Patent Owners at the USPTO.

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J.C. is EP Patent Attorney and US Patent Agent. After working for research and Industry, J.C. joined French IPSIDE Law firm in 2009, part of SANTARELLI GROUP and founded IPSIDE INNOVATION as US subsidiary.

Stefan Schohe: Partner, Boehmert & Boehmert. Germany

Stefan works primarily in the fields of information technology, physics and medical devices for domestic and international clients. Apart from prosecution, a main part of his work is litigation, especially pre-litigation advice, representation of clients in court, and coordinating international patent litigation.

Dr. Claudia Tapia: Director IPR Policy and Legal Academic Research at Ericsson. Germany

Claudia's main responsibilities relate to strategy, policy and research in the IP field. Prior to joining Ericsson, Claudia was the Director of IP Policy in the department Patent & Standards Strategy at BlackBerry where she focused on IPR policies in standards, global patent policies, as well as licensing and litigation.

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Formerly a practicing patent litigator, she specializes in European patent matters. She advises and supports her team and clients on all aspects of patent law and litigation strategy across all sectors, with a particular focus on Life Sciences and Technology. Sarah has written extensively on a wide range of topical patent matters, including AI and UPC.

Osamu Yamamoto: Partner, Yuasa & Hara. Japan

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.

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

A potential update to the *quid pro quo* of patents? US Supreme Court to review enablement requirement in Section 112 of Patent Act

Paul Ratzmann and Melissa Chapman of Fishman Stewart explain the importance of having a 'proper' US patent disclosure for promoting science and the useful arts, and how a pending Supreme Court case may determine if certain disclosure strategies meet current enablement requirements.

A *quid pro quo* system

Patent systems exist in most countries around the world and are typically codified into the law of the land. Generally, patents give their owners the legal right to exclude others from practicing (making or using) the patented invention for a limited time. This exclusivity period provides a potentially huge financial benefit to the patent owner, who may commercialize the invention and any innovations that incorporate the invention.

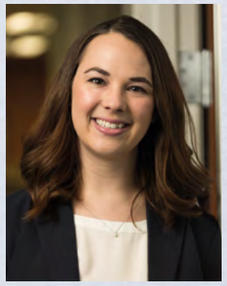
It begs the question: why should a government be willing to grant such power of exclusivity to a patent holder, seemingly at the expense of the free market? The answer lies in a foundational bargain between society and inventors. In the US, this covenant is expressed in Article 1, Section 8 of the Constitution:

> *The Congress shall have the power to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries*

But how is this to be accomplished? The American Founding Fathers recognized the value that science and the arts can play in improving society, but they left out some essential details: they didn't tell Congress how to do it.

The US Congress thereby devised a plan that has now played out for more than two centuries, driving invention and discovery to fascinating and new heights in ways that could never have been anticipated by any stretch of the imagination.

Paul Ratzmann



Melissa Chapman

For this paper, the focus returns to the basic principle, the *quid pro quo* that is expressed at the outset and addresses in some sense the "why" of things – i.e., why the patent right can be granted in the first place. The premise is simple: an inventor is granted a patent and the limited period of exclusivity that comes with it—but in exchange, the inventor must disclose their invention AND tell the world how to make and use it.

This detailed disclosure of patented inventions promotes the "Progress of Science" by driving innovation and development beyond the imagination, both during the life of the patent and after it expires. During the life of a patent, as we commonly call its "limited term of exclusivity," it may not be prudent or feasible to license or purchase the invention. In these cases, there may be motivation to figure out a new way to "design around" the patent to avoid it, while also motivating someone else to obtain their own patent on this new way of doing things.

Moreover, after the patent expires, it passes to the public domain and is free for everyone, spurring yet more innovation. Examples abound as to how groundbreaking technologies can be built upon and become ubiquitous in the larger society.

In one example, the early seeds of the now-omnipresent Global Positioning System (GPS)[1] reach back to 1970. Today, GPS technology has made its way into the pockets of millions of people through smartphones. Not even the inventor could have imagined the impact of that invention when it was first patented. Smartphones themselves may be traced back to digital mobile phone technology developed in 1973 and patented in the US and Germany[2].

Another example is the early development of carbon fiber in Japan (which is now available everywhere) and the role that patenting and licensing[3] early in the process had in supporting and spurring development.

Les Paul, the electric guitar inventor[4], needs no introduction as an early innovator or musician. The electric guitar changed the musical world and led to a new sound and revolution in music that started in the 1960s and continues to this day.

Finally, none of us want to imagine what the world was like before the development of the simple roll of toilet paper, but in 1891 Seth Wheeler imagined a better future and invented something[5] that the world can only be grateful for.

This significant tradeoff has driven innovation and technological advancement worldwide for generations. It has brought brilliant minds to bear on the world's most challenging problems - motivating those minds to improve technology and the world at large.

It must be noted that the invention must meet other requirements, too, such as requirements of patentable subject matter; being novel (meaning it hasn't been previously patented or already known to the public); and being nonobvious (meaning that it is not readily apparent to someone working in the field of that invention). Nonetheless, a proper disclosure is a requirement, and improper disclosure (like publishing or making and selling the patented product to the public for too long before seeking patent protection) may mean you cannot obtain a patent.

1 https://patents.google.com/patent/US3789409A/en?oq=3789409
2 https://www.dpma.de/english/our_office/publications/milestones/mobile/index.html
3 https://www.wipo.int/ipadvantage/en/details.jsp?id=2909
4 https://patents.google.com/patent/US3018680A/en?oq=US3018680
5 https://patents.google.com/patent/US465588A/en?oq=US465588

Proper disclosure

All that to say, what exactly makes a disclosure 'proper' in the US? Amongst other things, 35 USC § 112(a) sets forth the enablement requirement. This section details that patents must "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains... to make and use the invention."

Thus, for an application to be complete, the description of the invention must be enabled – putting enough description into the specification that a skilled person in the art can both make and use the invention without undue experimentation (i.e., the *quid pro quo* as discussed above). The idea is that the specification must put the invention truly into the public domain, such that a skilled practitioner can understand how to make and use the invention, ensuring the public may derive a benefit from the invention once in the public domain.

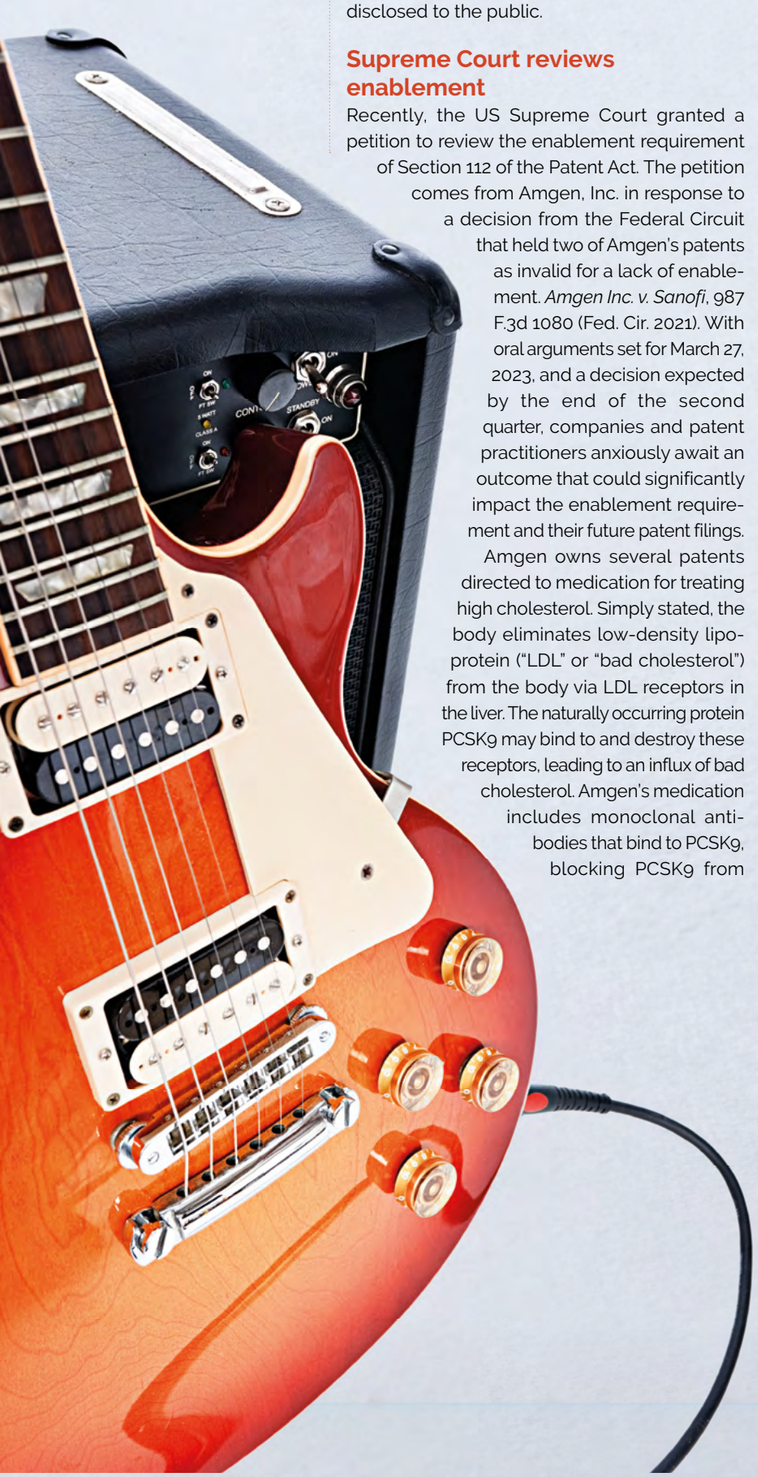
Courts typically rely on several factors in determining whether an amount of experimentation is "undue." The seminal case, In *re Wands*, states that the factors include:

1. The quantity of experimentation necessary,
2. The amount of direction or guidance presented,
3. The presence or absence of working examples,
4. The nature of the invention,
5. The state of the prior art,
6. The relative skill of those in the art,
7. The predictability or unpredictability of the art, and
8. The breadth of the claims.

Résumés

Paul Ratzmann is a partner at Fishman Stewart. Paul is a registered patent attorney and practices various aspects of intellectual property matters including domestic and foreign patent prosecution, due diligence, opinions, and design-around. He has an extensive background in the mechanical and electro-mechanical arts.

Melissa Chapman is a patent attorney at Fishman Stewart who advises clients on various aspects of intellectual property law and enjoys the dynamics of constantly changing technologies. Her practice focuses on procuring patents covering a wide range of technical fields, particularly in the mechanical arts.



In *re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

These principles provide clear guidance to follow so that the invention is, indeed, fully disclosed to the public.

Supreme Court reviews enablement

Recently, the US Supreme Court granted a petition to review the enablement requirement of Section 112 of the Patent Act. The petition comes from Amgen, Inc. in response to a decision from the Federal Circuit that held two of Amgen's patents as invalid for a lack of enablement. *Amgen Inc. v. Sanofi*, 987 F.3d 1080 (Fed. Cir. 2021). With oral arguments set for March 27, 2023, and a decision expected by the end of the second quarter, companies and patent practitioners anxiously await an outcome that could significantly impact the enablement requirement and their future patent filings.

Amgen owns several patents directed to medication for treating high cholesterol. Simply stated, the body eliminates low-density lipoprotein ("LDL" or "bad cholesterol") from the body via LDL receptors in the liver. The naturally occurring protein PCSK9 may bind to and destroy these receptors, leading to an influx of bad cholesterol. Amgen's medication includes monoclonal antibodies that bind to PCSK9, blocking PCSK9 from binding to and destroying LDL receptors so that the receptors can continue eliminating bad cholesterol.

Rather than claim the structural components of the antibodies, Amgen utilized a generic or genus-claiming strategy. Genus claims typically have broader coverage – covering a family, category, or general description which may encompass more specific examples. This strategy is featured often in chemical, biotech, and pharmaceutical industries where, for instance, utilizing a variety of similar chemical structures is possible to achieve a desired claimed outcome. Genus claiming serves a role in preventing obvious modifications to a patent claim in an effort to prevent patent infringement.

In this particular instance, Amgen's patent claims are directed to what the antibody accomplishes – binding to amino acid sequences of PCSK9 to block the binding of PCSK9 to LDL receptors. The antibody may bind to several different amino acid sequences. Thus, the genus claim here does not limit the structure to a specific amino acid sequence and claims a more generic description.

After asserting claims that Sanofi and Regeneron were infringing Amgen's patents directed to cholesterol medication Praluent®, US Patent Nos. 8,829,165 ("'165 patent") and 8,859,741 ("'741 patent"), Sanofi and Regeneron counterclaimed that the claims of the '165 patent and the '741 patent were invalid for lack of enablement. A jury initially decided that the asserted claims were valid. However, the District Court overturned the decision as a judgment as a matter of law, and the Federal Circuit affirmed. *Amgen Inc. v. Sanofi*, 987 F.3d 1080 (Fed. Cir. 2021).

The Federal Circuit's affirmation was based on the requirement that the "full scope" of the claim be enabled, meaning a claim may be insufficiently enabled if it is too broad and insufficient embodiments are described in the specification. The problem for Amgen is that the Federal Circuit found that the claims of the '165 and '741 patents are not directed to a single antibody; instead, potentially millions of currently unknown antibodies fall within the scope of the claim. Additionally, the Federal Circuit held that the claims were far broader than the disclosure provided in the specification and thus would require "substantial time and effort" to "reach the full scope of the claimed embodiments." Therefore, holding that undue experimentation would be necessary to identify undisclosed embodiments encompassed by the claims, the claims were found invalid.

Amgen and those in support argue that the Federal Circuit created a heightened standard for the enablement of genus claims. According to Amgen, the "full scope" requirement asks whether a skilled person in the art could identify and make all embodiments within the scope with minimal "time and effort." In contrast, Amgen argues that quantitatively high burdens of experimentation are not necessarily considered undue experimentation. The defendants did not establish that a skilled person in the art would have to engage in undue experimentation to make any antibody that fell within the scope of the claim, just that the quantity of experimentation required to make every antibody possible within the claim would be too much – a simple argument of quantity versus quality. Supporting amici argue that patentees need only identify a well-defined genus and provide disclosure sufficient to allow a skilled person in the art to make and use the claimed invention, per the statutory language.

Conclusion

A heightened standard for enablement in genus claims will have severe consequences for the pharmaceutical and biotechnology industries and other fields. As the first case at the Supreme Court to consider the enablement requirement in approximately 130 years, practitioners await a decision to see if changes to the requirement will occur. The Court's decision may impact a wide range of existing patents with functional claims and may impact patent prosecution strategies in the US moving forward.

Congress' granted authority includes the requirement that a description of an invention be provided to the public in "full, clear, concise, and exact terms" to enable a skilled person to "make and use" the invention. The Supreme Court will now exercise its authority and determine if strategies like those used by Amgen are sufficient to meet the important *quid pro quo* to promote science and the useful arts as the Constitution intended.

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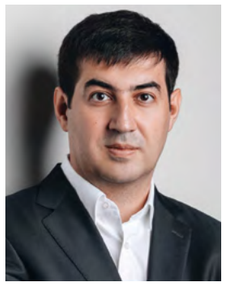
"Amgen and those in support argue that the Federal Circuit created a heightened standard for the enablement of genus claims."

Reshaping orthodontics: An interview with SoftSmile CEO, Khamzat Asabaev

Khamzat sits down with *The Patent Lawyer* to discuss the strategic approach to patenting for aligner software, an innovation driven by the hope of making orthodontic treatments affordable to those in need.

Khamzat started his career at Linklaters in 2009, the leading global firm with headquarters in London. He made a stellar career advising international companies like BP, PepsiCo, Hershey, Goldman Sachs, and others on landmark transactions. He moved to New York in 2014 to get a Masters in Law at Columbia Law School. After graduation, CSL Khamzat continued his career at Linklaters working between London, Moscow, New York, and the Middle East. In parallel, he founded and co-founded a number of startups, most noticeably a braces producer in Switzerland (3D Med) and a car-sharing company in Dubai (Motor).

In 2019, Khamzat was offered a prominent role as Head of Practice in Saudi Arabia. He had to relocate to Riyadh and lead the local Linklaters M&A team. It was time to decide if he wanted to become an entrepreneur or continue building up his corporate career. Khamzat chose SoftSmile and put all his efforts and resources into making orthodontic treatment affordable.



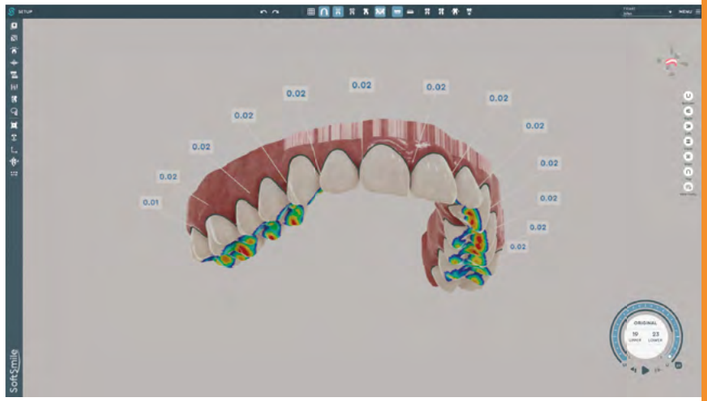
Khamzat Asabaev

Can you start by introducing yourself and SoftSmile?

I'm the co-founder and CEO of SoftSmile, a New York-based tech company with a mission to help people to get affordable, high-quality orthodontic treatment. We've built a digital platform that helps doctors to prepare treatment plans for orthodontic treatment and we use science, automation, and innovative solutions to make treatment faster, more convenient, and more precise. This means that, eventually, any doctor in any part of the world will be able to access the tools required for making aligners which will, in turn, make orthodontic treatment much more accessible.

I was an M&A Lawyer for over 10 years. Meanwhile, a friend of mine, an orthodontist, was experimenting with making aligners. His efforts were pretty successful and he managed to build a new, high-quality product while decreasing the retail price by about 10 times in comparison to the available premium brands. I decided to try and help him, and we opened a production facility in Switzerland a few years ago but it, unfortunately, failed because without proper software we could not address the demand.

When our first company wasn't as successful as we'd hoped, we decided to focus on the key element required for a successful orthodontics treatment - the software. We soon realized that it is a widespread problem and there were no proper solutions on the market. When we introduced



As a lawyer, I believe you should always be ready for potential litigation, that's not to say you know you're doing something wrong but for any business, it's important to know what the potential risks and problems are.

VISION, our product, to the market we received instant interest from market leaders as our product is addressing an unmet need in the industry.

Aligners are invisible braces, used as an alternative to metal braces, which were introduced about 25 years ago by an amazing company called Align Technology. They are producers of Invisalign. Align Technology heavily patented their innovations in the field which has made competition difficult for new market entrants.

What makes SoftSmile different is that we are software-focused: we started from scratch to create software for doctors to use, not the aligners themselves. Very early on, we began patenting our innovations to protect them, and defend if required, as this is the best way to prove the technology is unique. We're a young start-up but our IP portfolio regarding the aligners software is second to only Align Technology, so we are quite proud of the progress we have made.

How did you develop your patent strategy?

Our IP lawyers work to keep our strategy on track: we first patented the core functions and features of the software, the most innovative and distinguished parts, to get those pillars protected and then we focused on protecting additional functions. What's interesting is that we were getting USPTO approvals in two-three months, which according to our lawyers is unbelievably quick, and the explanation we received from the IP counsel is that the solutions were so unique that there was not much comparison to the existing patents.

Can you describe why your IP strategy is so significant?

We are in a market where just a few players have proprietary orthodontic software, we want to protect our innovations because we are quite paranoid that a competitor will attempt to come after us. We work to clear all of our innovations before implementing them.

How does SoftSmile leverage AI in relation to its patent strategy?

AI is at the forefront of innovation today, including in the healthcare and dental sector. I've noticed that we're going toe to toe with huge dental corporations when it comes to AI innovations. It's fascinating that we can see that various companies are going in the same direction, trying to use AI or machine learning across interesting fields. We use AI mainly for producing precise treatment plans.

What do you hope to achieve with your patent strategy?

We want to be confident that we do not infringe anything because we want SoftSmile to be a sustainable solution for doctors and labs, we don't want our customers to worry about any IP problems as a result of using VISION.

How is SoftSmile working to disrupt and reshape the orthodontic industry to make treatments more affordable and accessible to consumers?

For quite a long time, the only option for a doctor to offer aligners would be to collect data from a patient to send to a service provider who would prepare the digital treatment plans and then produce aligners for the doctor to provide to the patient. This results in a markup cost that gets passed on to the consumer. Patients tend to blame doctors for the high cost of aligners but it's not actually the doctor's fault because doctors must buy the product from the supplier. Our software solution gives doctors the ability to produce treatment plans in-house, allowing them to be less dependent on service providers, particularly with advances in 3D printing as doctors and clinics can buy the equipment for making aligners in-house. Supply costs are significantly reduced if produced by doctors in-house, this is how we believe we can disrupt the market.

Do you think it is valuable to prepare for potential litigation? And how would you work to achieve this?

As a lawyer, I believe you should always be ready for potential litigation, that's not to say you know you're doing something wrong but for any business, it's important to know what the potential risks and problems are. From my legal background, I know when company leadership pays attention to potential risks, they are much more likely to solve them before those risks materialize. We are always on alert, that's why we filed for FDA clearance in our first year, which is also pretty unique. It was a costly and timely process but we decided to invest in FDA clearance because it is important to comply with all regulations to be above any potential legal threat. We're very careful about potential legal challenges and having patents is the best way to prepare for any potential conflicts with other parts or products because if someone tries to challenge our software and say that we're trying to infringe, we can prove all of our steps are patented.

What are the future plans for SoftSmile?

Currently, our clients are enterprises but the future plan, and it is why we founded SoftSmile, is to work directly with doctors. This is something that I hope to start in the next three months, this will cut out any middleman as the doctor will have direct access to the technology needed for treating their patients which will, in turn, make orthodontic treatment more accessible.

Wanted regulations for new patent law provisions in Mexico

Victor Garrido, Partner at Dumont, makes suggestions for the new regulations that are yet to be refreshed since the new Federal Law for The Protection of Industrial Property (FLPIP) was instated in 2020.

As broadly publicized domestically and abroad, the new Federal Law for The Protection of Industrial Property (FLPIP) entered into force in Mexico on 5 November 2020, abrogating the former industrial property law (IPL) after it was applicable for nearly 30 years. Reasonably, a new law necessarily cancels or updates former provisions and includes new ones. Consequently, a new law needs ad hoc secondary regulations.

A transitory article in the FLPIP indicates that the IPL regulations shall continue to apply until new regulations be enacted, as long as the IPL regulations do not oppose the FLPIP dispositions. After more than two years from the onset of the FLPIP, refreshed regulations are still missing. While the FLPIP governs a plurality of figures related to industrial property, including trademarks, geographical indications, trade secrets, and others, this article focuses on some of the most relevant patent-related aspects needed to be addressed to adequately supplement the current patent legal framework.

Grace period

The IPL contemplated a 12-month grace period for disclosures made by the inventor or his assignee. As such, the IPL regulations require the submission of information related to the previous disclosure, including date and communication means. On the other hand, the FLPIP expands the grace period provisions for the case when a third party obtained the disclosed information from the inventor or his assignee. Currently, uncertainty arises as to how the grace period can be enforced when the third party obtained the information without the consent of the inventor or his assignee, because the inventor/assignee does not know about the previous disclosure and therefore the IPL regulations are clearly insufficient. It is considered that updated regulations should waive the obligation to provide information related to previous disclosures at the filing date, at least for the case that the disclosure is unknown to the inventor/applicant at that time.

Victor Garrido

> **One of the most controversial patent-related topics brought about by the FLPIP is the regime for the division practice.**

Divisional applications

One of the most controversial patent-related topics brought about by the FLPIP is the regime for the division practice. Although considerably more restricted than in the IPL, the framework for first generation divisions, either voluntary or

Résumé

Victor Garrido is Partner and Head of Patents at Mexican IP firm Dumont. He holds a degree in chemical engineering and has specialized in intellectual property law. He has practiced patent matters for more than 20 years. Victor's expertise lies in a range of patent-related matters, including prior art searches, patentability opinions, drafting and filing applications, counselling in examination, clearance analysis, and opinions for litigation. He has published articles in some of the most renowned international IP magazines and has been a speaker at international events. He is an active member of the domestic IP association AMPPI, and of international associations such as AIPPI, AIPLA, INTA, and AIPF.

required by the patent office, are almost self-governed by the FLPIP itself, but one question would arise about the fate of cancelled subject matter when the patent office requests the division during examination and as a response the applicant decides to restrict the claim set to a single invention without filing divisional applications for the remaining matter. Under the IPL, it was possible to claim said matter in a voluntary divisional application filed afterward during prosecution. Considering the restrictive nature of the FLPIP, its regulations might state that said matter cannot be sought in divisional applications if the same is not filed within the term provided to respond to the division request. If so, stakeholders will need to carefully consider their options before deciding to drop any subject matter during the unity of invention analysis.

On the other hand, in the case of subsequent generation divisions, more provisions are needed. Specifically, the FLPIP states that divisional applications cannot be voluntarily divided but only when the patent office considers that such division should proceed or otherwise at the patent office's request when a lack of unity is found during examination. Moreover, the FLPIP indicates that the regulations shall establish the conditions under which the patent office is to request a further division. The current IPL regulations are silent about these specificities surrounding subsequent generation divisions. Accordingly, regulations are needed to establish the conditions under which the patent office will allow subsequent voluntary divisional applications. For example, whether lack of unity will play a role or not, or whether the division can claim matter from the specification without being present in the claim set of the application from which the divisional derives, and the like.

One important aspect to be considered is that the FLPIP requires the first original patent application to be pending in order to allow first generation divisions. Regulations are very probable to apply this restriction to subsequent generation divisions. If so, the subsequent generation division system might trigger litigation, because a scenario might arise in which the divisional application lacks unity and the first application is not pending anymore. This situation might result in the impossibility of voluntarily submitting a division or in the patent office asking for limiting the divisional application to a single invention during examination instead of requesting division. Alternatively, at least in the case of lack of unity found during examination of a divisional application, the regulations might try to be flexible and state that subsequent generation divisions requested by the patent office are not subject to the status of the first original application for both voluntary and requested divisions.

> **One important aspect to be considered is that the FLPIP requires the first original patent application to be pending in order to allow first generation divisions.**

Supplementary certificates (patent term adjustments)

Unlike the IPL, the FLPIP allows for the possibility of adjusting the time of validity of a patent for up to five years through a supplementary certificate which will only be granted when the prosecution of a patent application lasts longer than five years taken from the filing to the grant dates and the excessive prosecution time is attributable to unjustified delays by the patent office. Since the adjusted time will correspond to only half of the time delayed by the patent office during the prosecution of the patent application, it is important that the FLPIP regulations specify the patent office's actions or omissions that are to be considered when calculating the term adjustment. Not surprisingly, the IPL regulations do not even consider this issue.

Time window for the bolar exemption

The FLPIP expressly exempts from infringing responsibility to third parties that manufacture, offer for sell, or import a patented product with the exclusive aim of generating information, studies, or tests for obtaining a sanitary registration certificate; that is, the bolar exemption. No time period before the expiration of the patent is signalled in the FLPIP within which this provision is to apply. The secondary health law regulations state that the bolar exemption applies within a term of three years prior to the patent expiration date for allopathic medicaments and within a term of eight years for biotechnological medicaments. It is desirable that FLPIP regulations align with health law regulations as otherwise interpretations by courts would be necessary to establish whether the health regulations can restrict the FLPIP or whether the lack of temporality in the FLPIP implies that the exemption can be exerted any time, which would make Mexico depart from international standards regarding this topic.

The submission of the certificate of deposit of biological material

Under the IPL regulations, the certificate of deposit of biological material was requested to be filed within an unextendible period of six months counted from the filing date under the penalty of abandonment. The practice showed that this provision did not work since in many cases it was not until a patent application was examined that the need for the submission of the certificate was found out; that is, a time long after the expiration of the six-month term. Also in practice, and allegedly contrary to the IPL regulations, the patent office used to request the certificate during examination instead of declaring the application abandoned. Accordingly, FLPIP regulations should take into account this practice and provide for the submission of the certificate at the request of the patent office and not only within a fixed term from the filing date without affecting the filing date of the patent application unless the deposit occurred later than said date.

Reference to the Nagoya protocol

The Nagoya protocol entered into force in Mexico on 12 October, 2014. Since then, patent provisions have not been amended to implement the same, not during the rule of the IPL and neither when enacting the FLPIP in 2020. While there are voices suggesting that there is no need or obligation to address the Nagoya protocol in the Mexican patent law, it is considered that given the raising important genetic resources and traditional knowledge are having nowadays, the FLPIP regulations could contemplate that some basic information be provided when filing a patent application claiming an invention based on genetic resources or traditional knowledge, or otherwise, include a declaration that said basic information is unknown to the applicant at the filing date.

Final remark

Some relevant aspects related to patent prosecution the FLPIP regulations should take into account have been briefly discussed. It can be implied that the current application of the IPL regulations is insufficient for a variety of issues and is creating uncertainty. More than two years after the FLPIP entered into force, supplementary provisions have become urgent. Overall, stakeholders in Mexico's patent system should keep a close eye on the development of updated regulations aiming to fully and effectively implement the current law to make decisions and ensure proper treatment of their matters in the country.

> **Unlike the IPL, the FLPIP allows for the possibility of adjusting the time of validity of a patent for up to five years.**

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Flexible use of Chinese divisional applications

Yingan GU and Dongcheng PANG of Beijing Sanyou IP Agency Ltd. explain how to flexibly utilize divisional applications to obtain procedural or substantive benefits.

After filing a patent application to the Chinese Patent Office, an applicant may sometimes choose to file a divisional application based on the requirement of an examiner or based on their own application strategy. The purpose of this article is to explain how to flexibly utilize a divisional application to obtain procedural or substantive benefits.

I. Brief introduction to divisional application in China

In terms of general principles, as long as a parent application is in a pending status, the applicant can file a divisional application at any time. For example, in the case where the parent application is granted, the applicant may file a divisional application at the latest within two months from the date of receipt of the Notification of Allowance. In the case where the parent application is rejected, the applicant may file a divisional application at the latest within three months from the date of receipt of the Rejection Decision. If the applicant files a Request for Reexamination, or initiates an administrative litigation after receiving the Reexamination Decision which upholds the Rejection Decision, the applicant may still file a divisional application during the reexamination period and during the administrative litigation, as long as the Rejection Decision, Reexamination Decision or a court judgment has not yet taken effect.

Moreover, as for a subdivisional application, that is, a granddaughter application is filed based on the daughter application, the timing for the subdivisional application still depends on whether the parent application is in a pending status or not. If the parent application is no longer in the pending status, principally, subdivisional application is not allowed. However, if the examiner has ever issued a notification to file divisional application for a daughter application, or has pointed out that the daughter application has a unity defect in the Office Action (OA) and the daughter application is still in a pending status, then, a granddaughter application can be filed based on the daughter application.

Yingan GU

Dongcheng PANG

II. Perfecting patent portfolio by filing divisional applications

For an invention patent, an applicant may only amend the claims when a request for substantive examination is made and within three months after receiving the Notification of Entering the Substantive Examination Procedure. In the OA stage, the applicant may only make amendments for the defects pointed out in the OA, and cannot expand the protection scope of the claims or change a technical solution protected by a claim at will. Thus, when responding to the OA, if the protection scope of a claim is too small or the claim cannot cover a technical solution to be protected, it may not be possible to overcome these defects by making amendments; or the protection scope of a granted claim is too large, leading to instability of the patent right, the defects cannot be overcome by making amendments either. In these situations, the applicant can file a divisional application, towards which the opportunity to make amendments voluntarily and appropriately adjust the protection scope can be expected.

In addition, when the Reexamination Decision of the parent application upheld the Rejection Decision, in order to get the application granted, the applicant has two choices: initiating administrative litigation or filing a divisional application. In China, the winning rate of administrative litigation initiated after the Rejection Decision is upheld upon reexamination is usually slightly over 10%. Regarding the divisional application, based on the data of divisional applications which were filed by our company in 2019 and have been closed, the grant rate of divisional applications is about 55%. This grant rate is much higher than the winning rate of administrative litigations. Therefore, when the Reexamination Decision of the parent application upheld the Rejection Decision, it is preferable for the applicant to file a divisional application.

It is self-evident that a divisional application also has the objective effect of extending the examination period, thereby securing a longer time span to adjust the application strategy. For example, when an R&D project takes a long time, the applicant can properly adjust the protection strategy by filing a divisional application based on the R&D progress or the company's strategy, and can use the divisional application to extend the time of the "pending" status.

III. Combining divisional application with PPH to shorten the examination period

PPH (Patent Prosecution Highway) is a business cooperation about sharing examination results among patent examination offices of different countries and aims to help applicants' overseas applications obtain patent rights as early as possible. It specifically means that when at least one or more of the claims included in a patent application filed with the Office of First Filing (OFF, e.g. EPO) is/are determined to be grantable, on this basis, an applicant can make a request for expedited examination with the Office of Second Filing (OSF, e.g. CNIPA). Currently, China has signed the PPH Cooperation Agreement with major countries and regions in the world.

> **"If the parent application is no longer in the pending status, principally, subdivisional application is not allowed."**

To file a PPH request for a Chinese application based on a corresponding application including grantable claims (i.e., a patent application filed by an applicant with the OFF), the Chinese application must meet certain conditions, including: the PPH request should be made after the Chinese application is published, after it enters the substantive examination stage or at the same time as the request for substantive examination is made; the claims of the Chinese application have the same scope as the claims of the corresponding application or have a smaller scope than the claims of the corresponding application; an Office Action has not been issued for the Chinese application, etc.

The claims of the corresponding application are usually amended during the examination process, resulting in such claims being different from the claims of the Chinese application. In this circumstance, a voluntary amendment to the Chinese application is required so that it can meet the requirements for making a PPH request. However, when the corresponding application is determined to be grantable, it may have exceeded the voluntary amendment deadline for the Chinese application, resulting in the Chinese application cannot take advantage of the PPH

Résumés

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procedurally. In order to solve this dilemma, the authors suggest that a divisional application can be filed, and the claims of the divisional application can be amended by the voluntary amendment deadline for the divisional application, so that it meets the requirements of filing a PPH request. By such, the applicant can avoid procedural drawbacks and obtain the advantage of expedited examination through PPH. In a case handled by our company, a parent application is still in the examination process, and its divisional application for which a PPH request is filed has been granted, which realizes the purpose of speeding up the examination.

If the grantable claims of the corresponding application are consistent with those of the Chinese application, filing a PPH request for the Chinese application will not be subject to the voluntary amendment period.

IV. Combining divisional application with a request for deferred examination

In the revised contents of the Examination Guidelines (2020), the content about a request for deferred examination is added. For an invention patent application, an applicant may file a request for deferred examination at the same time as the request for substantive examination is made. The deferable period is one, two or three years from the effective date of the request for deferred examination. Upon expiry of the deferred period, the application is to be examined in sequence. Deferring the examination enables the applicant to have more time to confirm the value of an application and to consider its protection scope, and can also confuse competitors by preventing them from timely informed of the final patent protection scope, which disturbs competitors' product R&D and marketing pace. Moreover, the patent examination standards and examination discretion in China are constantly changing. Therefore, if the examination is in an unfavorable situation, we can wait to see whether the examination standards and examination discretion will change favorably by requesting a deferred examination.

We can also combine the request for the deferred examination with a divisional application to make a more proper application strategy. Specifically, after a parent application is rejected, as described above, an applicant may file a divisional application as a strategy to secure a grant. Under specific circumstances, the applicant hopes to file two divisional applications (divisional application 1 and divisional application 2), and hopes that the divisional application 1 is examined first, then an amendment strategy for the divisional application 2 can be determined based on the examination result of the divisional application 1.

> **"A voluntary amendment to the Chinese application is required so that it can meet the requirements for making a PPH request."**

The application timing of both the divisional application 1 and the divisional application 2 should meet the requirement that the parent application is in a pending status, thus the strategy of filing the divisional application 1 first, then filing the divisional application 2 after obtaining the examination result of the divisional application 1 is not available, because at this moment, the parent application has been closed and is no longer in the pending status in general. Under this situation, a strategy of filing the divisional application 1 and the divisional application 2 simultaneously and making a request for deferred examination for the divisional application 2 can be adopted. For example, for the divisional application 2, the deferred examination by two or three years can be requested. It should be noted that the deadline for voluntary amendment of the divisional application 2 is not deferred. At the end of the deferred examination period, it must have exceeded the deadline for voluntary amendment. Therefore, in order to make more flexible amendments to the divisional application 2 in the substantive examination procedure, the protection scope of the claims in the divisional application 2 needs to be as large as possible, so as to leave enough room for making amendments during the examination.

V. Conclusion

As an institutional arrangement derived from the patent application, the application skills of the divisional application are also constantly adjusted along with the development of the examination practice. However, as a prerequisite for making use of the divisional application, an applicant should pay special attention to the deadlines for filing the divisional application and choose different solutions according to the examination result of the parent application. The author also puts forward that the applicant can make full use of the advantages of the divisional application, and under particular circumstances, consider using it in combination with PPH to overcome the restrictions of PPH to speed up the examination procedure, or in combination with a request for deferred examination to obtain a more favorable protection scope.

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Computer simulations: lessons from the past

Inspired by the EPO Decision G1/19, Susana Rodrigues, Patent Consultant at Inventa, evaluates three fatal historic events that could have concluded differently if innovative computer simulations had been available.

What would have been the consequences of certain past events if a computer simulation had been put at work preventively, solving fatal technical problems?

In this article, three examples of technical problems that led to disasters, because they were lacking a proper technical solution, are discussed. Computer simulations can offer proper solutions to technical problems, either as such or as part of a process, and, therefore, they are very welcome when it comes to preventing the past from being repeated in the future. That's what we can do... in the present.

If, in this very year of 2023, you ask ChatGPT chatbot what computer simulations are used for, you will probably see an answer like this displayed on the screen:

1. Modelling and prediction - computer simulations can be used to predict the behavior of the stock market, the spread of a disease, or the behavior of a new drug in the human body.

2. Design and testing - engineers can use computer simulations to test the aerodynamics of a new airplane design, or to design and test a new computer chip.

3. Training and education - flight simulators are used to train pilots, and medical simulations are used to train surgeons.

4. Research - computer simulations can be used to study the behavior of subatomic particles, the evolution of galaxies, or the functioning of the brain.

5. Entertainment - video games are a form of computer simulation, as are virtual reality experiences.

That's quite a good answer, no doubt about it. However, for those who develop new and inventive simulations based on a computer device and wish to apply for a patent seeking to get rights over their invention's commercialization, not all the uses displayed are eligible for that.

Susana Rodrigues

> **Computer simulations can offer proper solutions to technical problems.**

Entertainment is excluded from patentability because "not being entertained" can hardly be considered a technical problem, or putting it in a straightforward way, games and similar entertainment products fall in the non-inventions category. The European Patent Office (EPO), for instance, considers methods for playing games, if claimed as such, excluded from patentability, under Art. 52(2)(c) and (3) of the European Patent Convention (EPC).

Research can have a great diversity of branches into a field of technologies too vast for being discussed in this article.

The remaining uses above, which yet point at a large wingspan of fields computer simulations can cover, may be patentable and bring a totally different approach in what concerns "technical effect".

In order to help patent applicants, inventors, and examiners identify computer simulations that are eligible for granting a patent, the EPO Enlarged Board of Appeal shed light on the subject by issuing Decision G1/19 on March 10, 2021. This decision intends to answer three relevant questions related to how patentable computer-implemented simulations can be when claimed as such.

The three questions are:

1. *In the assessment of inventive step, can the computer-implemented simulation of a technical system or process solve a technical problem by producing a technical effect which goes beyond the simulation's implementation on a computer, if the computer-implemented simulation is claimed as such?*

2. *If the answer to the first question is yes, what are the relevant criteria for assessing whether a computer-implemented simulation claimed as such solves a technical problem? In particular, is it a sufficient condition that the simulation is based, at least in part, on technical principles underlying the simulated system or process?*

3. *What are the answers to the first and second questions if the computer-implemented simulation is claimed as part of a design process, in particular for verifying a design?*

The headnote of said Decision G1/19 replying to the first question, reads: "1. A computer-implemented simulation of a technical system or process that is claimed as such can, for the purpose of assessing inventive step, solve a technical problem by producing a technical effect going beyond the simulation's implementation on a computer."

Before moving on to answers 2. and 3. of G1/19, let's take a look into the past.

1904: on the 8 of February, in Baltimore, a city of Maryland State in the U. S., a fire outbroke in a basement of a store for dry goods. The fire spread quickly onto the neighboring wooden-based buildings which were connected to each other. Local fire brigades fought against the flames with the equipment and knowledge available at the time, until they realized that their fire hoses weren't able to extinguish the flames on the upper floors of the many buildings. They called fire brigades from other districts for help and their call has been attended. Firefighters from Washington D.C. arrived in Baltimore. "When D.C. firefighters arrived on the scene, they discovered that their equipment was not compatible with Baltimore hydrants. In those days, firefighting equipment met no national standards and varied city by city. Poorly matched and hastily bound couplings emitted weak streams of water. Firefighters ran out of hose as buildings collapsed." – Dolores Monet wrote (see source). The fire lasted for two days, more than 1,500 buildings were burned down, and the disaster was named The Great Baltimore Fire.[1]

> **The conclusion of most experts pointed at inadequate training provided by the airline to the pilots, since they were using a simulator that wasn't predicting fully real situations.**

Technical problem: lack of knowledge related to the way and the speed at which the fire would spread in such configuration against the fire brigade's equipment and hoses capacity and, also, mismatch of the equipment fittings from

Résumé

Susana Rodrigues, Patent Consultant at Inventa

Susana works mainly in applications for registration, drafting and replying to notifications of patents in areas such as physics, materials processing, and computer-implemented inventions.

fire brigades of different districts (in other words, lack of national standards).

Possible solution to the technical problem: computer simulation for modelling and predicting.

1989: In April, at the Hillsborough Stadium in Sheffield, England, an FA Cup semi-final match was scheduled between Liverpool and Nottingham Forest at Hillsborough, a neutral venue. The sold-out game was expected to draw more than 53,000 fans. To prevent problems, fans for the two teams were directed to enter from different sides of the stadium. Due to the limited number of turnstiles to give access to the stadium, a bottleneck formed, and half an hour before kick-off, thousands of fans were still outside. Hoping to ease congestion, Yorkshire Police approved the opening of exit gate C wherethrough thousands of fans entered and, as fans rushed, a deadly crush resulted, with people desperately trying to escape. A few minutes after kick-off the match was halted. Police never fully activated the major incident procedure, poor communications and coordination further complicated rescue efforts. In total, 97 people were killed and more than 760 were injured.[2]

Technical problem: inadequate dimensioning of the entrance turnstiles within the design of the stadium building to let fans of both sides of the match orderly enter.

Possible solution to the technical problem: Computer simulation used for design and testing combined with modelling and prediction.

2001: Two months following the 9/11 attacks on the World Trade Centre, more precisely on November 12, an Airbus A300 of American Airlines Flight 587 took off bound for the Dominican Republic, with 260 people on board. Shortly afterward, the plane spiraled out of control and crashed, killing all 260 people on board and five people on the ground.

The National Transportation Safety Board (NTSB) reported that the overuse of the rudder mechanism by the captain caused the plane's vertical stabilizer (the tail fin) to detach from the plane in mid-air. Without the vertical stabilizer, no plane can fly. The pilot was responding to turbulence caused by another plane which had taken off minutes before, and he over-responded not only by applying too much pressure on the rudder pedal, but also by using the rudder excessively. The conclusion of most experts pointed at inadequate training provided by the airline to the pilots, since they were using a simulator that wasn't predicting fully real situations.[3]

Technical problem: the training on a flight simulator wasn't reflecting reality and the instructions learned were inadequate and confused the pilot.

Possible solution to the technical problem: Computer simulation used for training and education.

> **To solve important technical problems, preventing them from becoming fatal, by bringing new and inventive solutions to the most diverse fields.**

Conclusion

The future will certainly profit from many computer-implemented simulations patented as inventions – and possibly "as such"- that are able to solve important technical problems, preventing them from becoming fatal, by bringing new and inventive solutions to the most diverse fields.

Bearing in mind the two remaining answers to the above-mentioned Decision G1/19: "2. For that assessment [of an inventive step] it is not a sufficient condition that the simulation is based, in whole or in part, on technical principles underlying the simulated system or process." and "3. The answers to the first and second questions are no different if the computer-implemented simulation is claimed as part of a design process, in particular for verifying a design", a computer simulation that is applied to be granted a patent must thus go beyond its implementation on a computer to reach a technical effect. That might be achieved, for example, by its adaptation to a specific technical implementation or by an intended technical use of the data resulting from the simulation[4], as it is suggested above, following the described examples of the past.

1 Source: https://owlcation.com/humanities/Baltimores-Great-Fire-of-1904-and-Its-Legacy

2 Source: https://www.britannica.com/event/Hillsborough-disaster

3 Source: https://www.baruch.cuny.edu/nycdata/disasters/aircrafts-american_2001.html

4 Section 3.3.2, Chapter II, Part G – Patentability, EPO "Guidelines for examination".

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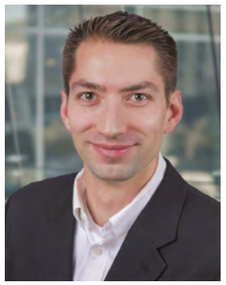
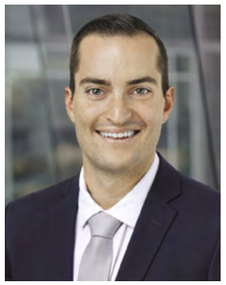
Omnibus patent applications & pitfalls in inventorship continuity

Adam Smoot and Jacob Israelsen of Maschoff Brennan detail the potential complications that omnibus patents present to inventors, cautioning businesses to ensure that inventorship continuity is maintained for full protection.

It is always a bad day at the office when a patent or application loses its priority claim. For businesses, it can be a struggle to walk the line between innovative creativity on the part of inventors and the rigid – and sometimes unforgiving – nature of the patent system. The number of considerations for businesses looking to grow their patent portfolio can be staggering. This article considers one of those many considerations: potential pitfalls associated with inventorship continuity in omnibus patent applications. In particular, we consider the risk of losing a priority date for a patent or application due to failing to meet the continuity of inventorship requirements. And, as those familiar with patents know, losing a priority date often results in an invalidated patent or patent family.



Adam Smoot



Jacob Israelsen

In this article, an omnibus application refers to an application that discloses subject matter covering multiple inventions. Omnibus applications are filed, in part, to address certain circumstances. For example, a business may seek to quickly launch a product line where the products contain multiple inter-related inventions of potentially patentable subject matter in the product line. The business may want a way to get a filing date on the different potential inventions before any public disclosure or sale of the products, and whether due to time or budgetary constraints, including all of the inventions in a single write-up may be most efficient. For example, the omnibus application may provide a filing date for all the inventions as well as describing the way in which they are inter-related. And fundamentally, the omnibus application provides the inventors and/or businesses time to keep a patent family alive by filing a number of continuation applications claiming a priority date back to the filing date of the omnibus application.

Because claims covering only one invention are permitted per filing, multiple continuation applications may be needed to cover all of the inventions. The continuation applications may claim subject matter disclosed in the omnibus application while also claiming priority back to its original filing date.

Additionally, businesses may seek to file an omnibus application to save money on filing fees. Imagine, for example, a client seeking to enforce four patents in five different countries. Nationalizing a PCT application can cost thousands of dollars per application in filing fees alone. By filing an omnibus application, a client can nationalize one application in the five previously mentioned countries instead of four applications in each of the five countries thereby potentially saving thousands in filing fees. Further, filing one omnibus application provides businesses with time to decide which inventions to prosecute in different jurisdictions.

Inventorship continuity in omnibus applications

While omnibus applications have their benefits, filing an omnibus application brings several additional considerations, including inventorship continuity. Though omnibus applications may begin with dozens or hundreds of claims and several corresponding inventors, the inventors listed on any application or issued patent include only inventors of the subject matter *claimed*.[1] For example, an omnibus application may begin with 100 claims and 20 inventors. By the end of prosecution, 20 claims may ultimately be allowed, and those 20 claims may include subject matter invented by 2 of the 20 inventors. From that point, the strategy may be to file continuation applications that may eventually claim all, or substantially all, of the subject matter in the original omnibus application (e.g., all of the original 100 claims or variations thereof). These continuations, and the inventors of the different subject matter for these continuations, may trigger the pitfall of inventorship continuity discussed in more detail below.

Inventorship continuity is the statutory requirement that continuation applications include one or more of the same inventors as the application to which it claims priority. Under 35 U.S.C. § 120, one requirement for a patent to be entitled to the priority date of a previously filed application is to name "an inventor or joint inventor in the previously filed application."[2] Additional clarification for entitlement to the priority date of a previously filed nonprovisional application is given in the Code of Federal Regulations stating: "[e]ach prior filed application must name the inventor or a joint inventor named in the later-filed application as the inventor or a joint inventor."[3]

What about a chain of patent applications in a patent family? Does each application need to include a common inventor? Or must each patent in the chain of priority include a common inventor with the application immediately preceding it in the chain? The Patent Trial and Appeal Board (PTAB), without precedent directly on point from the Federal Circuit, clarified that for purposes of 35 U.S.C. § 120, the question for a chain of patents is not whether each continuation application shares a common inventor with the immediately preceding application; rather, each continuation application needs to have a common inventor with the earliest filed application.[4] Therefore, common inventorship between immediately preceding applications is insufficient to establish a priority date back to the original omnibus application.[5] Indeed, some subsequent IPR proceedings have relied on the

Résumés

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1 *See* 37 C.F.R. §1.63(a)(3).

2 35 U.S.C. § 120; *In re* NTP, *Inc.*, 654 F.3d 1268, 1277 (Fed. Cir. 2011).

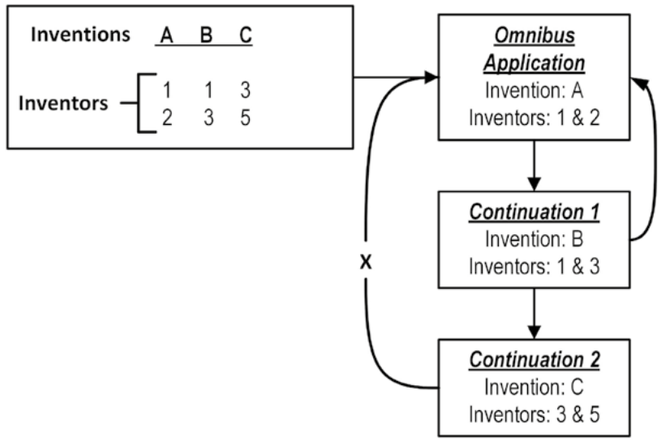
3 37 C.F.R. § 1.78(d)(1); *see, e.g., J&M Indus., Inc. v. Raven Indus., Inc.*, 457 F. Supp. 3d 1022, 1033 (D. Kan. 2020).

4 *See, TruePosition Inc. v. Polaris Wireless, Inc.*, 622 Fed. App'x 915 (Fed. Cir. 2015) (aff'g *Polaris Wireless, Inc. v. TruePosition, Inc.*, Case No. IPR2013-00323 (PTAB., Nov. 3, 2014) (Kim, APJ) (affirming the Board's finding that the patent in question was not entitled to the filing date of the earliest priority application because, while each application in the chain of priority included at least one inventor in common, the patent in question did not share at least one common inventor with the earliest priority application)).

5 *Id.*

fact that all of the patents within a chain of patents included the same common inventor to establish a priority date under 35 U.S.C. § 120.[6]

The ideas in *TruePosition* are more concretely embodied in the following scenario:



As illustrated above, a business may seek to protect three different inventions by filing an omnibus patent application including claims directed toward three distinct inventions ("A", "B", and "C"). Invention A was conceived by inventors 1 and 2, invention B was conceived by inventors 1 and 3, and invention C was conceived by inventors 3 and 5. Claims directed to invention A are chosen to initially prosecute and inventors 1 and 2 are listed. Later, a first continuation is filed, and the second claim set directed to invention B is prosecuted with inventors 1 and 3 listed. Finally, a second continuation is filed, and the third claim set directed to invention C is prosecuted listing inventors 3 and 5. Continuations 1 and 2 claim priority back to the Omnibus Application, seeking the earlier filing date.

If challenged, Continuation 2 is not entitled to the priority date of the omnibus application. Just like the patent in question in *TruePosition*, even though Continuation 2 includes one common inventor with the Continuation 1 (inventor 3), Continuation 2 does not list a common inventor with the original Omnibus Application and is therefore not entitled to the filing date of the omnibus application. Of course, the problem with losing the priority date is that any art developed or otherwise known to a person of ordinary skill in the art between the filing date of the Omnibus Application and before Continuation 2 was filed can be used as prior art against Continuation 2, which was the case for the patent in question in *TruePosition*. Additionally, because Continuation 2 does not properly claim priority to the Omnibus Application, the Omnibus Application itself may also be used as prior art against Continuation 2.[7]

While the above scenario seems relatively simple, it illustrates a concept that can become complex and difficult to manage – e.g., for large omnibus applications including several inventors and several corresponding inventions. For example, in 2017, Telefonaktiebolaget LM Ericsson (commonly known as Ericsson), publicly stated that they filed an omnibus application including "everything [] need[ed] to build a complete 5G network":[8] A patent including over 400 pages and over 130 inventors. Because of the magnitude of the disclosure, keeping track of the 130 different inventors,[9] what the inventors invented, and maintaining continuity of inventorship in each continuation application poses a significant challenge to the company and their counsel. In these kinds of scenarios, the object lesson embodied above is essential to maintaining continuity of inventorship and correspondingly to claim priority back to the omnibus application.

Can inventorship continuity concerns be avoided?

The purpose of this article is certainly not to dissuade the use of omnibus applications in appropriate circumstances. Rather, this article simply serves to caution inventors, businesses, and counsel to ensure that inventorship continuity is maintained to fully protect inventions disclosed in omnibus applications. To avoid these and other inventorship concerns, it is important for patent applicants to carefully document the inventorship of disclosed subject matter.

Additionally, there is no real substitute for substantive, strategic discussions with a patent practitioner. It may be possible, for example, to include a claim in each of the continuations that may include subject matter invented by a common inventor listed in the omnibus application.[10] Alternatively, as another example, two or more smaller omnibus applications may need to be filed instead of one large omnibus application if the subject matter in different inventions is too different to maintain at least one common inventor throughout. Regardless of the discussion's outcome, creative solutions can be reached to maintain priority dates throughout the life and growth of a patent family. These conversations and considerations may be the difference between claims entitled to a priority date and claims that are invalidated by prior art.

"Common inventorship between immediately preceding applications is insufficient to establish a priority date back to the original omnibus application."

Contact

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6 *Thorne Rsch., Inc. v. Trustees of Dartmouth Coll.*, No. IPR2021-00268, 2022 WL 1797706, at *5 (P.T.A.B. May 31, 2022); *Corp. v. Corp.*, No. IPR2020-00323, 2021 WL 2742603, at *7 (P.T.A.B. June 30, 2021).

7 *See, Nat. Alternatives Int'l, Inc. v. Iancu*, 904 F.3d 1375, 1383 (Fed. Cir. 2018); Dennis Crouch, *Strict Priority Claims: Unforced Errors in Priority Claiming – Results in Invalid Patents*, PATENTLYO (Oct. 1, 2018), https://patentlyo.com/patent/2018/10/priority-unforced-claiming.html.

8 *Ericsson Files Landmark 5G Patent Application*, ERICSSON.COM, (Nov. 16, 2017), https://www.ericsson.com/en/news/2017/11/ericsson-files-landmark-5g-patent-application.

9 *Id.*

10 It is an open question, with decisions going both directions, whether an application alone can satisfy the common inventorship requirement or whether the granted patent itself must satisfy the common inventorship requirement. *Cf. Celgene Corp. v. Fresenius Kabi USA, LLC*, 2015 WL 8023233, at *3 (D. Del. Dec. 7, 2015) *with Ex Parte Richard J. Arnott*, 2017 WL 2598724, at *4–6 (P.T.A.B. June 12, 2017).

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Women in IP Leadership

Celebrating achievements and continuing the empowerment of women

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We give special thanks to Zuykov and partners for their dedication and support in continuing the empowerment of women in IP by facilitating this opportunity.

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

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

This segment is sponsored by Zuykov and partners, who, like *The Patent Lawyer*, are passionate to continue the empowerment of women. Zuykov and partners' sponsorship enables us to remove the boundaries and offer this opportunity to all women in the sector. We give special thanks to Zuykov and partners for supporting this project and creating the opportunity for women to share their experiences, allowing us to learn from each other, to take inspiration, and for continuing the liberation of women in IP.

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

Eszter Szakács: Partner, Danubia Legal

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

Eszter is an attorney-at-law and partner of Danubia Legal, Budapest, representing and advising prominent international clients in the field of IP. With over 15 years of practice, her main focus is the enforcement and commercialization of patents, know-how, and trade secrets. She advises and represents clients from various industries and is particularly experienced in pharmaceutical patent litigation and regulatory issues, including CJEU proceedings (C-492/16, C-688/17). She authors several articles in the field of patent law, including publications of the EPO and regularly speaks at conferences in this field. She is a vice president and secretary of EPLAW (European Patent Lawyers Association) and Vice-Chair of Women in Licensing Alliance in LESI (Licensing Executives Society International). She enjoys recurring recognition in the field of patents and life sciences in MIP Top 250 Women in IP, IAM Patents 1000, IP Stars, Who's Who Legal and WIPR Leaders.

"Embrace all the opportunities that allow you to train your soft skills."

What inspired your career?

Throughout my childhood and my young adulthood, I was attracted to creativity and communication and tried various performing arts. Yet I also have a really rational mind and find joy in all works of logic. Following law school, I was not sure what legal path I would take but, upon the recommendation of a friend, I interviewed for an IP boutique law firm and I found the opportunity to work in such an interesting field quite appealing. I also liked the possibility of working with foreign clients, across several industries, mostly in English. It was not really a conscious choice of legal field at the time but very quickly I began loving every aspect of it.

My interest in creativity was fulfilled by dealing with innovations, meeting inventors of fascinating creations, writing articles, while my reason-driven other half enjoyed the challenge of understanding technology, complex market issues, and most of all, developing bullet-proof legal arguments in litigation. I have also realized that IP law and patent law specifically is very international, especially in Europe today as we are at the gates of the Unified Patent Court and it gives the opportunity to work with international teams on various legal cases and also to build an international network via taking part in professional associations.

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

My track has been quite straightforward as I progressed from junior associate to partner. However, my tasks have become diversified over time. As an associate, my job was mostly technical in the sense that I completed legal work on the cases handled by the firm. As I have progressed though, not only have the legal tasks and the connecting responsibility increased but also the use of my soft skills has become increasingly important in building client relationships, a professional network, cooperating on various projects in international associations, and last but not least taking part in the management of the internal issues of a law firm's daily life.

> I find it also important to reach a balanced approach in terms of enabling professionals of different ages.

In my current position, I am a patent litigation partner working on the trending multijurisdictional cases in Hungary as well as doing technology transfer contract work and advising on litigation strategy and pharmaceutical regulatory questions. This is the "day job" part. I have also been active as a member of the European Patent Lawyer's Association, where I am currently the Vice-President and secretary of the association. My other favorite professional association is the Licensing Executive Society International where I used to be Vice-Chair of the Young Members Committee and currently hold the position of Vice-Chair of the Women in Licensing Alliance. My advice is: find a legal field that you are committed to, then dive deep to obtain knowledge that becomes your initial value proposition in all aspects of your professional life, and embrace all the opportunities that allow you to train your soft skills from articles, presentations, and conferences to client meetings and interacting with your firm. The two will come together at one point and reward you with a very satisfying career in the IP legal profession.

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

I have been very lucky with starting in a very supportive and encouraging work community with great superiors and peers, I would say that is indeed very important to find. Obviously, as the volume of tasks increase and diversify, stress appears and is hard to handle. Very often, I have felt that I undertook way more than what I can realistically handle. I also used to be very shy (let's be honest – super scared) about presenting at international conferences and I have not been a natural when it comes to certain management tasks as I am not a very strict person. What I handle much better now than in the beginning is stress as I've tried various time management and collaboration techniques, and also learned how to compartmentalize the stress in my brain when there is a need to overcome a tide of a busy period. I also learned to say no sometimes. Very cliché but very important, equally so, to use it wisely. Regarding the presenting part, the only thing that helped is that I did it again and again until I stopped fearing it. And as for the management part, I try to replace strictness (which does not come naturally to me) with clear communication regarding my expectations in work and also put an emphasis on maintaining a supportive and understanding work atmosphere.

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

I could not really name a specific achievement and most things I have achieved are a great deal due to others giving me support and opportunities, even at a young age. I am proud of having earned a good professional reputation in my field, especially on the international level. It feels really good to have the trust of my peers, clients, and most of all, my colleagues.

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

In the field of IP one can and should never stop learning. I have found a legal field that I really love and I would like to continuously improve and remain on top of all professional developments. Needless to say, the launch of the Unified Patent Court seems to be the most determining event in patent litigation for the currently practicing generations.

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

I am pleased to see that international DEI movements and principles are more and more common and I hope they will become natural in the next years on a national level and in all types of IP firms. While a great proportion of law school graduates are female in Hungary, female representation is much lower in partner/leadership roles which tells me there is still much to improve. I find it also important to reach a balanced approach in terms of enabling professionals of different ages. I think IP industry players, be it law firms, industry firms (many of them being global brands having the ability to reach millions with their messages) or international organizations are in a good position to be early adaptors of DEI movements and openly promote them by applying them in their organizations. I'd like to see more and more firms in the IP field joining and promoting these practices.

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

I think it would be important for all organizations to make conscious efforts in helping the advancement of women in their careers. In the Women in Licensing Alliance of Licensing Executives Society International, I have gained experience with mentoring which I find a great opportunity for female professionals to learn from and support each other. I have been amazed by the support and guidance I have received from more senior female colleagues whom I've met in the course of my work or in professional associations. I hope I can give back some of this by continuing to support mentoring in the organizations I am involved in, by way of setting up formal mentorship structures, training mentors, encouraging senior women to become mentors, and celebrating successful mentorship stories.

Elaine Spector: Partner, Harrity & Harrity

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

CTC Legal Media

Elaine is a patent attorney with over 25 years of experience in intellectual property law. She is a partner at the IP boutique, Harrity & Harrity and has a degree in mechanical engineering. She is the first female partner in the firm's history. Elaine hosts Driving Diversity[1], a weekly diversity vlog, as well as quarterly webinars in a series called Diversity Dialogue[2]. She also co-chairs Harrity's Diversity Committee and is dedicated to improving diversity in the field of patent law. She serves as vice chair of IPO's Diversity and Inclusion Committee, and co-chairs the IPO D&I Outreach Subcommittee.

What inspired your career?

When I was a child, my favorite subject was math. My dad was an engineer, and as a result, I had this inclination and ability to fix structures. If something broke, I would figure out how to piece it back together. When I was in high school, a family friend asked me what I wanted to do when I grew up. I remember saying, "Well, I'm really good at math and science and my dad is a mechanical engineer, but I love the law." I loved debate – that's just part of who I am – and practicing law gives you the opportunity to exercise that. He was the one who then told me I could go into patent law, which requires both a law degree and a hard science degree like mechanical engineering. This conversation fortunately planted a seed very early on in high school. A lot of people don't find out about patent law until later on in their education or after they begin working in the STEM field. When I entered college, I declared my major as mechanical engineering and went straight from my undergraduate degree to law school, knowing a career in patent law was what I wanted to pursue.

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

I've been practicing since 1996, but I actually passed the agency exam in my second year of law school and worked part-time in 1995 at an IP boutique in a D.C. suburb.

[1] https://harrityllp.com/thediversitychannel
[2] https://harrityllp.com/thediversitychannel

> **This is where I want to encourage other women; I want other practitioners to know that they can step back into their careers when their children are older.**

I started out at a small firm, and after two years of experience doing litigation and patent prosecution, I moved on to a larger IP boutique with about 150 attorneys. It was there that I flourished, practicing in many diverse areas. Because of my small firm background, I knew all about trademarks, trademark litigation, patent prosecution and patent litigation. This meant I was pulled in to work on a lot of different projects, which was really exciting for me.

I then started a family, which shifted my priorities a bit. I moved to a general practice firm and reduced my schedule. But when my kids were seven, five, and three, I was pulled into a litigation, even though my hours were reduced. The trial lasted four weeks in a federal court in Texas, which was a three-hour plane ride from my children. I couldn't go back to see them. After the trial, I knew that my work situation had to really change. I decided to leave that position and went to Johns Hopkins as a Tech Transfer Intellectual Property Manager. I was there for about six years when I saw an ad for a position at my current firm, Harrity & Harrity, with the catchphrase, 'work where you want, when you want, and how much you want.' The concept of remote work and flexible hours sounded great; I could continue to do what I loved, for as many hours as I wanted, on a schedule I chose, all while staying at home. It provided an invaluable opportunity for me to really flourish in and enjoy my career, without having to commute or leave my family.

Based off my experiences, there's a lot of things I can say in terms of advice. Circumstances are seeming to get better for those coming up, as more firms were forced to provide some sort of remote, hybrid, or flexible option during the pandemic. However, something I'm glad I did for myself was taking more time for my family when I needed it. I could have been more direct about saying "no" to certain projects. I felt like I couldn't say no to that trial. But in reality, I was in a good position to say, 'I'm working at reduced hours, my kids are very young, I really don't want to do this'.

On the other hand, there are likely some women – and men for that matter – that don't mind that separation, enjoy long travel, and want to be included on those types of projects. We need to open the conversation up, because everyone has different goals. I personally wanted to be around my children more when they were young, and it was a big sacrifice to be away from them for four weeks. So, looking back I wish I would have said that it wasn't going to work for me, but I wanted to be a team player. I think that's the hard part about being in a career where women are underrepresented – you want to be a team player, you're tough, you're saying yes to everything and sometimes you compromise yourself. But you don't need to do that. You're talented and whole without saying yes to everything. You come to the table as who you really are when you do set those boundaries and say no.

There's still a gap in supporting women in their careers when they have families, depending on whether they want to be full-time or whether they want to work reduced hours. We need to find a way to advance women regardless of their time commitments, so that they are not stuck on the 'mommy track.' My advice to other women in the field is to always advocate for your whole self and the value you bring. We are more than just attorneys - we are moms, sisters, daughters, friends, wives. But, that doesn't mean that we are any less of an attorney, and by showing that you can be an incredible attorney while on the job, while still taking the time to nurture all of your other roles, you can advocate for the flexibility you deserve without missing out on upwards movement.

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

The greatest challenge was the work/life balance and boundaries around that, making sure that I could say no to things that did not work for my family. Trying to find that balance and setting boundaries for myself was difficult, as I'm sure it is for many other working women.

Now, I'm in a different position where my children are grown, and the amount of time I can dedicate to work has changed. As my children grow older and start to step out into their own lives, I have a little more free time, and it opens up the door of possibility into my career. I have a son who went to college, I have another who's going to college in the fall, and I have a daughter who's still home for two more years, but I have more flexibility in my schedule now. Also, when I was commuting to D.C. from Baltimore, it was two hours each way which was wasted time. Being able to work from home and be present means I can then travel more easily for conferences. I can go for a week without worrying about the kids. This is where I want to encourage other women; I want other practitioners to know that they can step back into their careers when their children are older. That's what I did at Harrity and my career is flourishing in ways I never imagined.

Being at home is an interesting thing as well – taking care of young children is the hardest job that you will ever have. The days that I was home with them were so wonderful but also very challenging. But I don't regret the time I took off to be with them. I think if all lawyers were able to understand the amount of effort and time it takes us to care for young children through parental leave, then they could maybe understand how we can better support our women. I see posts by women on LinkedIn who have young children and they're barely surviving. I'd like to see us find a better balance in the United States; for firms to give new parents a reasonable amount of paid time off to bond with and care for their child and return to work when they are ready to give it 100%.

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

My greatest achievement has come recently. When I joined Harrity in 2017, it was a smaller firm of about 14 lawyers, and they were all men. But they had the intention of becoming more diverse, and because we are a small firm – we're up to about 45 practitioners now – we could move very quickly on new initiatives without much red tape. I'm obviously passionate about supporting other women in law, but I wanted to do more to help improve the overall diversity of the patent field, which is significantly less diverse than general law due to the STEM degree requirement. My co-chair in the firm's diversity committee, John Harrity, was the managing partner at the time, so I was fortunate to have his backing on this diversity journey. During the six years I have been at Harrity, our committee has launched numerous external diversity initiatives to improve the pipeline with regard to the patent bar, all with visible impacts.

A lot of people say that we shouldn't focus on the pipeline issue, as the issue of diversity and supporting diverse practitioners extends beyond that. However, if you look at the statistics with regard to diversity in the patent bar, it is, at its foundation, a pipeline issue. Women only represent about 20% of the patent bar in the United States, and racially diverse women represent about 2%. In an article we wrote for the *ABA Landslide Magazine*, we identified that there are more patent practitioners in the United States named "Michael" than there are racially diverse women. That statistic is unbelievable.

So, I'm most proud of the diversity initiatives that we have launched since I've been here. I love the fact that young women look up to me and see me as a role model, as someone who is flourishing in this profession. And in return, I am reaching my hand back down to them to pull them up alongside me. I think oftentimes, women kill their strong and men kill their weak. I've had those experiences in my career. Of the few women I have worked with, a couple of them have been very difficult, competitive, and unkind. Taking time to mentor these young women is so important; my door is always open.

This has been my greatest accomplishment thus far, and I hope my greatest accomplishment at the end of my career will be a diversified patent bar, to really see true diversity that is representative demographics of our country, and to know I made an impact in getting there.

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

My future aspirations relate to further developing our DEI initiatives that aim to improve the diversity of the patent bar. One of our programs, *Patent Pathways*, focuses on the least represented group of the patent bar - racially diverse women, and specifically Black women - to try and bring the numbers up. In the first year, we had 20 Black women take part in the program. We paid for all of their patent bar review preparation classes, their exam and registration fees. We delivered almost a year of training in patent drafting and prosecution, and provided each participant with two mentors, one in-house mentor and one law firm mentor. Then, we line the participants up with jobs at partnering law firms. We have 20 law firms that have agreed to interview and hire at least one participant at the end of the program, and almost half of our current participants have already accepted job offers, including one who will be starting at Harrity in April.

For 2023-2024, we're scaling our program up to 50 Black women. There are only about 400-500 Black women who are registered to practice currently. If we increase it by 50 each year, we're seeing a significant increase percentagewise. Once we get the numbers up to where they should be, we will shift the program to help the next least represented group until the patent bar is diversified.

Right now, we're reaching out to women who have already aspired to obtain a career in STEM. Many of them don't know they can practice patent law without a law degree in the United States. You just have to have a hard science or engineering degree to sit for the patent bar exam and become a patent practitioner. They can enter the profession rather easily once they have obtained their undergraduate degree in an approved field and they pass the patent bar. Getting that word out to the correct audience is one of the key determinants in the success of this program. Finding and educating women at the undergraduate level is the low-hanging fruit. I used to work at Johns Hopkins Technology Ventures, and I have been giving lectures to freshmen mechanical engineering students for many years. During my lecture, I include a slide that says 'Do you know that you can practice patent law without going to law school?'. I explained that, when you graduate with your undergraduate mechanical engineering degree, you can sit for the patent bar exam. I had a swarm of students coming up to me after class who were interested. They had never been told that patent law was a career option for them without going to law school. And if you want to go to law school, there

> **During the six years I have been at Harrity, our committee has launched numerous external diversity initiatives to improve the pipeline with regard to the patent bar, all with visible impacts.**

> **We must mentor and be role models for the next generation, so that they not only want to enter this profession, but feel supported in doing so.**

are law firms that will pay for it. This isn't something that is commonly shared in undergrad. So, getting that key piece of information out is incredibly important in driving more people, especially those within minority groups, to pursue patent law.

With that said, we do need to go back earlier, back to high school and middle school, and really think about the messages we're sending to girls about STEM. That will be another iteration of our program. Many people don't know about patent jobs in high school, and I think that is part of the issue with the profession - many fall into this career rather than actively pursuing it, and this needs to change. We're going to reach deeper and expand to help support women and other underrepresented communities who are interested in STEM.

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

I would like to see the patent community take an active role in shifting the statistics through engagement in various programs. For my colleagues that are in-house, there is a platform called *ADAPT*. It's a coalition of various companies including Microsoft, Amazon, Meta, Google, Cruise and Disney. *ADAPT* stands for *Advancing Diversity Across Patent Teams* and it provides a platform for in-house patent attorneys and law firms to get engaged in various DEI programs. ADAPT provides templates for organizations to create their own programs, but also highlights the wonderful programs already out there that are seeking additional support, including Patent Pathways.

While becoming Mansfield certified helps advance underrepresented groups into leadership roles, there is a much larger problem to fix. What I love about our Patent Pathways program is that law firms are now coming together to address the foundational issues by encouraging more diverse practitioners to enter the field. Together, our firms are volunteering to mentor, hire and train our participants - that's a huge collaborative step for changing the numbers with regard to diversity in the patent bar.

I really would like to see more firms and corporations not just talking the talk and actually taking action to make these initiatives successful. My firm can't do it by itself; we need the patent community at large to step up and get involved in programs like ours.

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

I think through mentorship and DEI programs like *Patent Pathways*, empowerment of women can be expanded into the IP sector. We have another program specifically directed towards women called the *Harrity for Parity Women's Workshop*. It is a four-day virtual program for undergraduate and law students geared towards an introduction to the practice of patent law; patent skills and career training; resume building and interviewing; networking, and more. The workshop includes an array of female guest speakers - women who are prominent in the patent field, including equity partners and chief IP counsel at various corporations. We want to show women where this amazing career can lead them and allow them to hear from and interact with other women who are on a similar path, as well as those who have already found success. I also want to emphasize that women need to support each other. We must mentor and be role models for the next generation, so that they not only want to enter this profession, but feel supported in doing so.

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LAW FIRM RANKINGS 2023

The Americas and The Caribbean

A comprehensive list of the 10 most well-respected law firms from the Americas and the Caribbean

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GLOBAL REACH, LOCAL KNOWLEDGE

Throughout the next few pages, you will view a comprehensive list of the 10 most well-respected law firms from the Amercias and the Caribbean, in alphabetical country and company order. Our focused list is derived from a multifaceted methodology, which uses months of industry research and feedback from our readers, clients, and esteemed connections around the world. All firms are ranked top 10 in their jurisdiction but are displayed alphabetically to avoid bias.

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Borden Ladner Gervais
Fasken
Gowling WLG
Norton Rose Fulbright
Olser, Hoskin & Harcourt
ROBIC
Smart & Biggar
Torys

Costa Rica

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Consortium Legal
ECIJA
Eproint
Facio & Cañas
IDEAS
Nassar Abogados
Tactic Estudio Legal
Zurcher Odio & Raven

Guatemala

Arias
BLP
Carrillo & Asociados
Central Law
Dentons Muñoz
IDEAS
Mayora IP
Novales Abogados
Palomo Abogados
Viteri & Viteri

Honduras

Aguilar Castillo Love
Arias
BLP
Bufete Casco
Bufete Durón
Bufete Mejía & Asociados
Casco & Casco
Consortium Legal
Dentons Muñoz Zacapa
García & Bodán

Panama

Alfaro, Ferrer & Ramírez
Arias, Fábrega & Fábrega
Cedeño & Médndez
CLD Legal
Estudio Benedetti
Fabrega Molino
Guinard & Noriega
Icaza, González-Ruiz & Alemán
Jimenez, Molino & Moreno
Morgan & Morgan

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IDEAS
LatinAlliance
Romero Pineda & Asociados

Mexico

Arochi & Lindner
Basham, Ringe y Correa
Becerril, Coca & Becerril (BC&B)
Calderón & De La Sierra
Dumont
Goodrich, Riquelme y Asociados
OLIVARES
Santamarina + Steta
TMI Abogados
Uhthoff, Gómez Vega & Uhthoff

Nicaragua

The Caribbean

USA North America - West

Dorsey & Whitney
Greenberg Traurig
Holland & Hart
Kilpatrick Townsend & Stockton
Knobbe Martens
Lewis Roca
Morrison & Foerster
Perkins Coie
Schwabe Williamson & Wyatt
Torrey Pines Law Group, PC

USA North America - Mid West

Barnes & Thornburg
Bejin Bieneman
Brooks Kushman
Dickinson Wright
Faegre Drinker Biddle & Reath
Fish & Richardson
Harness IP
Honigman
Jones Day
McAndrews Held & Malloy

USA North America - North East

BakerHostetler
Ballard Spahr
Cantor Colburn
Choate Hall & Stewart
Duane Morris
Fish & Richardson
Goodwin Procter
McCarter & English
Morgan Lewis & Bockius
Venable

USA North America - South

Alston & Bird
Baker Botts
Bradley Arant Boult Cummings
Burr & Forman
Fish & Richardson
Finnegan Henderson Farabow Garrett and Dunner
Haynes and Boone
Kilpatrick Townsend & Stockton
Patterson Intellectual Property Law
Stites & Harbison

Jurisdictional Briefing, Spain: the Unitary Patent is coming, and Spain is still out

Isabel Álvarez and Estefanía Cruz of H&A detail Spain's current position regarding the UPC with advice for those patenting in Spain and EU member states.

Résumés

Isabel Álvarez is a patent adviser in the Chemistry and Biotech department. She has a M.Sc. in Biochemistry, and a Ph.D. in Molecular Biology. Her practice is mainly focused on biotech, pharma and food fields, wherein her main tasks involve prior art searches, drafting and prosecuting patent applications, as well as preparing patentability, infringement and freedom to operate reports.

She is also in charge of SPC prosecution in Spain and Portugal.

She has been a qualified European Patent Attorney (EQE) since 2016 and is a member of an Examination Committee for the European Qualifying Examination of the European Patent Office.

Estefanía Cruz is a patent consultant in the Chemistry and Biotech department. She has a M.Sc. in Chemistry. Her work experience is focused on drafting and defending patent applications before different patent offices both national and international, in the area of chemistry and pharmacology. She also performs background searches, patentability and infringement reports.

She has worked in different industrial property agencies in Madrid as a patent consultant since 2000. She managed the Industrial Property of a biotechnology company in 2008 and 2009.

She has given lectures on industrial property in the Master in Biotechnology of the Aliter Business School.

On February 17, 2023, Germany ratified the Unified Patent Court Agreement. Accordingly (UPCA), thus, the Unitary Patent Court (UPC) and the Unitary Patent (UP) can officially begin on June 1, 2023.

Likewise, on March 1, 2023, the sunrise period began, in which the applicants for and proprietors of a "classic" European patent, as well as holders of a supplementary protection certificate (SPC) issued for a product protected by a "classic" European patent, can opt-out their applications, patents or SPCs from the exclusive competence of the UPC.

From the 25 EU states that signed the UP Regulations, by late February 2023 17 have ratified the UPCA: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia, and Sweden. Only two Member states, Spain and Croatia, remain completely out of the UP package.

Spanish Government's main reason for not being involved in the UP package is that Spanish is not one of the official languages of the UP, which could have detrimental consequences for Spanish companies.

For example, in order to produce effects in Spain, unlike "classic" European patents, UPs will not need to be translated into Spanish. Thus, Spanish companies will not benefit from the disclosure in Spanish of UPs. This is particularly problematic for SMEs and private inventors, applicants and proprietors, who may not know the UP official languages (English, French and German).

Likewise, these SMEs and private individuals will suffer the legal uncertainty arising from being expected to respect the rights conferred by UPs which have not been translated into Spanish.

Furthermore, Spanish companies and private individuals will be forced to plead in English, French or German in invalidity and non-infringement declaratory proceedings before the UPC central division, which will make the whole process more expensive for them.

Obviously, none of these problems are applicable to Spanish Patent Attorneys, since they have and continue to prosecute patents in these languages before the EPO, especially in English (the most common language of "classic" European patents).

Spanish companies will still be able to obtain Unitary Patents and enforce them before the UPC. However, the costs of litigation in the UPC will be higher than in a Spanish court.

In this sense, it is important to highlight that some Spanish courts are highly specialized in patents and have generated a solid case law, which makes them very reliable. This will be very beneficial especially at the early stages of the new UPC scenario, e.g. in infringement proceedings concerning inventions protected by a UP and a European patent validated in Spain, since the latter will be under the exclusive jurisdiction of Spanish courts.

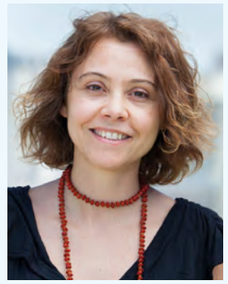
However, by not being part of the UP package from the beginning of its creation, Spain lost the opportunity to host one of the UPC local divisions and therefore having more influence in the system's development, as well as having Spanish judges participate in the newly conformed Unified Patent Court.

As the pre-grant phases of the UP and the "classic" European patent applications remain the same, European patent attorneys from Spain will continue to represent their clients and carry out their prosecution work just as they have always done.

From now on, applicants having their European patents and seeking both unitary effects and protection in Spain, will need to combine the UP with the "classic" validation. As an additional translation of the European patent will be needed during the transitional period, it will be wise and cost effective to have the European patent mandatory translation performed into Spanish, as this translation may also be used for validation purposes.

It is important to highlight that while enforcing or challenging "classic" European patents nationally will still require separate actions in each country of interest, Unitary Patents and "classic" patents which may not opt-out will be vulnerable to revocation in all UPC-participating states over a national prior right (national application of which the filing date is prior to the filing or priority date of the enforced or challenged patent, and which was published on or after that date) in any of the UPC-participating states. Thus, validating a European patent individually in EU member states, while perhaps sometimes more expensive than obtaining unitary effects, may present considerably lower risks to its owner.

Now that the UP is officially starting, let us see if the Spanish Government changes its mind and joins the UP and UPC. Some rumors point out that this may happen during the EU presidency of Spain in the second half of the present year.



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Eurasian Patent Office: Development Trends and Prospects

Dr. Alexey Vakhnin has been discussing with Dr. Grigory Ivliev, the President of the Eurasian Patent Organization, current developments in IP at EAPO. Vakhnina & Partners are glad to introduce, prepared exclusively for *The Patent Lawyer Magazine*, the summary of the essentials of the Eurasian Patent System provided by the Head of the EAPO, Dr. Ivliev, and recent innovations at the EAPO.

The Eurasian Patent Convention established the Eurasian patent system in 1994 that allowed applicants to obtain regional legal protection along with the national patent registration procedures.

The Eurasian patent system is one of the most successful integration projects throughout the Eurasian region that had been gradually developed in line with global trends, including cross-border economic links. In 2019 the competencies of the Office were broadened through the adoption of the Protocol on Industrial Designs to the Eurasian Patent Convention.

For almost 30 years the single Eurasian patent has proved itself as an important legal mechanism for the business community.

Advantages of the Eurasian patent system

The Eurasian patent system is a cost-efficient and simple procedure granting a single patent through filing a single application in a single language and paying a single set of fees, as well as involving a single Eurasian Patent attorney.

Neither additional validations nor translation of the application into national languages are required. The unified Eurasian patent for an invention is valid in eight countries since the date of its grant. It can be optionally maintained in the countries of interest to the applicant paying the annual fees only for the selected countries.

As to Eurasian designs, the regional system for industrial design protection keeps the entire advantages provided for the inventions, namely the single registration procedure and the unified nature of the granted patent. The protection covers seven countries (Turkmenistan is in the process of acceding the Protocol). Thus, the unified nature of the procedure remains the same for the renewal process.

EAPO
EURASIAN PATENT OFFICE

> **“Our regional system, with its huge geographical coverage, is being used by applicants from 133 countries around the globe.”**

Users of the system

Our regional system, with its huge geographical coverage, is being used by applicants from 133 countries around the globe.

The top-filing applicants represent the USA, Russia and European states. According to the statistics, Top-15 remains pretty stable every year. As of today, the EAPO received more than 68,000 patent applications for inventions. Annually, more than 3,600 applications are filed and more than 2,700 patents for inventions are granted. In 2022 we noted the highest patent activity level for the past 10 years.

Increasing patent activity in China is a recent trend. In terms of Eurasian applications for inventions, Chinese applicants had been 11th place three-four years ago. In 2022, China topped 5th, though the growth potential is still very significant.

The vast majority of applications, around 80%, entered the regional phase under the PCT procedure. Since July 1, 2022, the EAPO is functioning as an International Searching Authority and a Preliminary Examining Authority under the PCT which allows international applications to go through the entire lifecycle of the examination process within the regional Office.

Since June 1, 2021, the filing of applications for industrial designs is available too.

Patent quality

The Eurasian patent is a "strong" one since it is granted following the patent search and substantive examination procedures with a relevant decision. In order to guarantee the impartiality and quality of the examination results, the decision to grant a patent or refuse the application is taken by three different examiners, representing different EAPO Member States. Additional activities are implemented to ensure the diversity and the widest possible geographical representation at the EAPO. The high professional potential and qualification of EAPO examiners are provided through continuous additional training programs involving the best examiners from eight EAPO Member States.

Due to the EAPO system for managing the examination quality, as well as the opposition and appellation system, the quantity of opposition remains extremely low. Overall, we revoke around 0.04% of patents a year under the invalidation procedure.

Given the advantages of the opposition, last year we extended the deadline for submitting objections under the administrative procedure.

The Patent Law Treaty (PLT) provisions are duly implemented in the EAPO regulations. In order to increase the patent search quality, we use the Collective Patent Classification (CPC). Moreover, in cooperation with several IP Offices, EAPO implements the Patent Prosecution Highway (PPH) programs.

Digitalization

The EAPO is a highly digitalized IP Office, including the paperless patent workflow within the Office since 2015. Furthermore, in 2022, we initiated granting electronic titles of protection,

> **"The vast majority of applications, around 80%, entered the regional phase under the PCT procedure."**

that are available in users' personal accounts, as well as on web-portal.

We adapt the processing and examination of applications as well as our administrative procedures taking into account digital technological capabilities. Since November 1, we provide another high-tech opportunity for disclosing the nature of inventions and industrial designs in Eurasian applications, based on the World Intellectual Property Organization (WIPO) Standard ST. 91 on 3D models and 3D images. Thus, the application materials can contain 3D visual representations of objects for IP rights protection. This provides applicants with a great opportunity to demonstrate the unique features and properties of their IP rights more accurately and clearly.

We develop and enhance our information systems to make e-services as convenient as possible and meet the needs of applicants.

Development prospects

We aim to reveal the entire potential of the regional integration related to IP. The EAPO possesses ambitious development plans based on the interests of its Member States. We rely on their support and reflect the needs and demands of applicants from all over the world.

The EAPO adopted measures to optimize the examination of Eurasian applications, improve examination quality and make the process of regional patenting more attractive to Eurasian and foreign applicants. We are currently expanding the EAPO Pharmaceutical Register (Pharm Register) by adding national patents – the relevant decisions have already been taken by the EAPO governing bodies and national patents have already been included in the Register.

We are now working on joining the Hague System for the International Registration of Industrial Designs. Its Geneva Act permits the accession to the Hague System by an intergovernmental organization. The EAPO's accession to the Hague System will increase the worldwide accessibility of the Eurasian System for the Legal Protection of Industrial Designs. The EAPO Member States had already expressed their support of this initiative and we are now carrying out consultations with WIPO on the procedural and legal aspects of the accession.

Furthermore, we are ready, with the support of the EAPO Member States, to expand the number of regionally protected IP rights, i.e. to create a Eurasian registration system for trademarks and utility models.

The Eurasian Economic Union (EAEU) regional trademark registration system is currently under development. The relevant Treaty came into force in April 2021, at the same time, the procedural framework is still on the way. We believe that the system has a significant

Résumés

Dr. Grigory Ivliev

Dr. Grigory Ivliev has served as the EAPO President since February 11, 2022. He is a Former Head of the Federal Service for Intellectual Property (Rospatent).

Eurasian Patent Office (EAPO) is an executive body of the Eurasian Patent Organization, administering the regional patent registration system, covering eight countries of the Eurasian region.

Member States: **Azerbaijan, Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia, Tajikistan, Turkmenistan.**

Objects for IP rights protection: inventions and industrial designs.

Dr. Alexey Vakhnin

Dr. Alexey Vakhnin is a Eurasian Patent Attorney, Patent and Trademark Attorney of the Russian Federation, Partner and Managing Director of Vakhnina and Partners.

Dr. Vakhnin is Vice-president of the Chamber of Patent Attorneys of the Russian Federation; member of INTA, FICPI, AIPPI, LES Russia/ LESI, PTMG, ECTA etc.

Dr. Grigory Ivliev, President of the Eurasian Patent Organization

potential for further development, since the EAEU trademark, in its current state, has no single nature – each of the five competent national Offices decides on whether to grant protection or not and collects its national fees according to the rates specified in the Treaty.

From our perspective, it is vitally important to identify a single Office to administer this System. The EAPO could play the role of such an Office.

Ensuring the regional judicial protection of IP rights is now crucially important. With the growing number of objects for IP rights protection and related transactions, the number of disputes increases as well, and their technical complexity also steadily rises. We are promoting initiatives aimed at improving the dispute resolution system for Eurasian IP rights and creating a single jurisdiction for their consideration. We are not limited to judicial mechanisms and also studying the modalities of introducing Eurasian arbitration and mediation to resolve IP-related disputes.

The EAPO is cooperating with Uzbekistan and Mongolia to engage them in integration projects and further expand the coverage of the Eurasian patent system.

Since 2022, the EAPO has been holding its international conference entitled "IP Eurasia". On September 21, 2022, the Office held a large-scale conference dedicated to the protection of innovations in healthcare. We plan to make this conference an annual event and bring up relevant topics for discussion.

The EAPO is happy to cooperate with all interested organizations. We are convinced that the IP system is the basis for the development and progress of society in all countries. The Office offers the applicants a convenient regional patenting service. Now we can proudly say that we built a single Eurasian ecosystem with a population of more than 208 million and more than 1.8 trillion US dollars GDP. The needs and demands of the applicants and rightsholders are our priority. In our work, we strictly adhere to the provisions of international treaties related to IP, and we are ready to collaborate with the applicants and rightsholders to ensure strong IP protection in the Eurasian region.

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Time indicia in obviousness inquiry – old is gold?

Manisha Singh, Partner, and Neha Ruhela, Senior Associate, of LexOrbis assess secondary indicia factors for ascertaining the non-obviousness of an invention when filing for patent protection.

"Only God works from nothing. Man must work with old elements" – words of a federal judge that signify the importance of prior art in patent law.

Prior art is any evidence that an invention claimed was already publicly known or available, fully or partly, before the effective filing date (priority date) of a patent application. Prior art evidence may be used to determine the inventive step or non-obviousness of an invention – a fundamental requirement of patentability that is common across all jurisdictions. During opposition, invalidation, or revocation proceedings, patent challengers frequently cite prior art documents to demonstrate the obviousness of an invention.

In principle, there is no time limit in patent statutes on the age of the matter that may be considered as prior art. Thus, it would be tempting to assume that prior art lasts forever, and that its teaching value does not erode over time. However, this presumption of a perpetual knowledge hub would likely dampen innovation space and growth. In the absence of reasonable time criteria especially for obviousness, new ideas could slowly dry up. Therefore, it becomes crucial to understand whether an aged prior art can be helpful to determine obviousness (for the patent challenger) or lack thereof (for the patent seeker).

Primary tests, secondary indicia

For determining an inventive step or non-obviousness, various approaches have been laid down in examination guidelines and practice manuals of patent offices. Also, several tests have emerged over the years from decisions of courts/authorities across different jurisdictions. United Kingdom (UK) endorses the four-step *Windsurfing/Pozzoli* test and European Patent Office (EPO) prescribes a 'problem-and-solution' approach for analysing an inventive step. In *KSR v Teleflex (2007)*, the United States (US) Supreme Court recommended a flexible approach to the 'obvious to try' test. In India, a five-step obviousness test was propounded by Delhi High Court in *Roche v Cipla 2016 (65) PTC 1 (Del)*. These tests will guide the substantive examination of the inventive step.

> **The common directive in all these well-established tests is to assess what the existing knowledge is and how the person skilled in the art would move from the existing knowledge to the subject invention.**

The common directive in all these well-established tests is to assess what the existing knowledge is and how the person skilled in the art would move from the existing knowledge to the subject invention. In the obviousness analysis, the examiner or fact-finder in the patent office or the Court adjudicating the issue would need to identify the elements in the prior art and compare the same with the claims of the subject invention in question from the point of view of a person skilled in the art. If the differences are not obvious to the skilled person and demonstrate a technical advancement over the prior art on the priority date of the application, then the patent would be liable to be granted.

To augment the main technical test, a few non-technical secondary factors can also be considered to ascertain the non-obviousness of an invention. These are generally referred to as 'secondary considerations' in the US or 'secondary indicia' in EP. In *Graham v John Deere 383 U.S. 1 (1966) and KSR*, the US Supreme Court held that secondary considerations such as commercial success, long-felt but unsolved needs, failure of others, etc. may also be relevant in obviousness inquiry. Evidence as to secondary factors can be provided by the applicant in defending obviousness. If a *prima facie* case of obviousness is established, the burden shifts to the applicant to come forward with arguments or evidence to rebut. Rebuttal evidence may relate to any of the secondary factors.

Prior art's age

'Terrel on Law of Patents' opines that the age of the prior art and why it was not done before is one of the factors to be considered while deciding on obviousness. EPO specifically recommends 'the age of documents' as secondary indicia in the assessment of the inventive step. Recently, while disposing of two patent appeals, the Indian judiciary applied the time factor consideration for dated prior art and reversed the Controller's finding of obviousness. Thus, it can be safely reasoned that the age of prior art or time indicia may infer non-obviousness depending on the facts of the case. Further, it is also argued that the time factor stems from another secondary indicia 'long-felt but unmet need'. Let us explore this temporal aspect through various case laws:

Manisha Singh

Neha Ruhela

Case laws in Europe

In *Brugger v Medic-Aid Ltd [1996] R.P.C. 635*, the UK Patents Court substantiated the consideration of the time factor and its proximity to long-felt need –

> *"The fact that a piece of prior art has been available for a long time may indicate, contrary to first impressions, that it was not obvious to make the patented development from it. It is useful to bear in mind in this regard the concept of long felt want. This is a particularly efficient expression. An apparently minor development which meets a long felt want may be shown to be non-obvious because, although the prior art has long been available, the development was not hit upon by others notwithstanding that there was a need for improvement (the 'want') and an appreciation of that need (the 'felt')."*

In T 273/92, EPO's Boards of Appeal held that a period of 23 years between the publication date of the closest prior art and the priority date of the contested patent in an economically

Résumés

Manisha Singh, Partner

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

Neha Ruhela, Senior Associate

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

significant and frequently studied field could normally be viewed as an indication of the presence of inventive step. In T 1192/09, the Board considered 12-year-old prior art as an additional indication of the non-obviousness of the claimed invention.

In T 295/94, the Board held that the age of prior art known long before might only be an indication of an inventive step of the subject invention if a need for the solution of an unsolved problem had existed for the entire period between the date of the prior art and that of the invention. If any other art during this period discloses the possibility to solve the problem, then the argument of the age of the oldest prior art would not be helpful in the existence of an inventive step.

Case laws in the United States

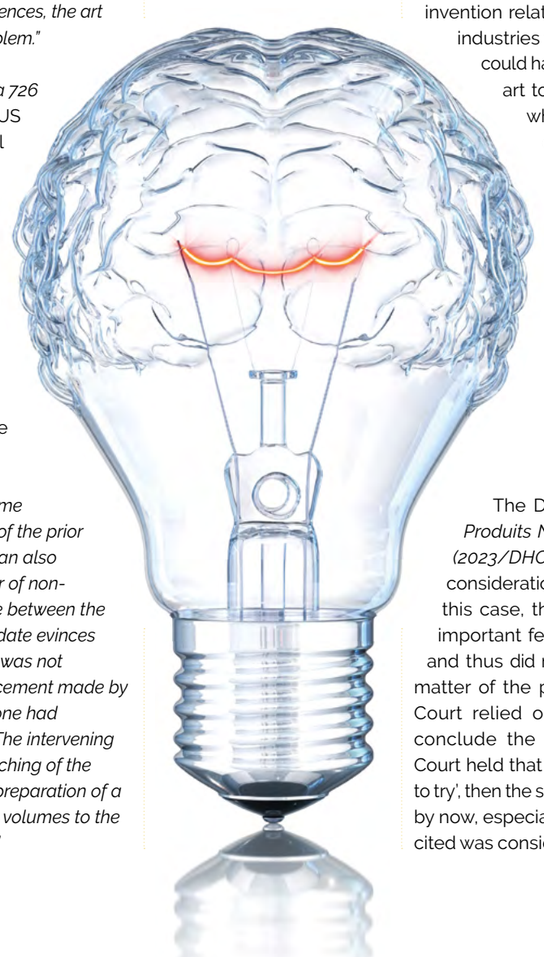
In *re Wright* (1977), the US Federal Court of Customs and Patent Appeals relied upon a 100-year-old patent in holding the appellant's invention obvious based on a combination of references. It was held that:

> *"The mere age of the references is not persuasive of the non-obviousness of the combination of their teachings, absent evidence that, notwithstanding knowledge of the references, the art tried and failed to solve the problem."*

In *Leo Pharmaceutical Ltd v Rea 726 F.3d 1346 (Fed. Cir. 2013)*, the US Court of Appeals for the Federal Circuit overturned PTAB's finding and held that the patent in issue was not obvious due to secondary considerations including the time factor. The subject patent was challenged for being obvious to the skilled person by combining three prior art disclosed 22, 14 and six years ago. The relevant extracts of the decision are:

> *"The length of the intervening time between the publication dates of the prior art and the claimed invention can also qualify as an objective indicator of non-obviousness … The elapsed time between the prior art and the patent's filing date evinces that patent's claimed invention was not obvious to try … until the advancement made by the inventors of the patent, no one had proposed a new formulation … The intervening time between the prior art's teaching of the components and the eventual preparation of a successful composition speaks volumes to the non-obviousness of the patent."*

> **In T 1192/09, the Board considered 12-year-old prior art as an additional indication of the non-obviousness of the claimed invention.**



Case laws in India

Besides providing a primary obviousness test, the landmark judgment Roche also discussed secondary considerations emanating from various authorities including *KSR*. Recently in *Avery Dennison Corporation v Controller of Patents (2022/DHC/004697)*, the Delhi High Court held that the age of the prior art cited is a relevant consideration for determining if the subject matter of a patent application would be obvious to a person skilled in the art or not.

Interestingly, in addition to technical inquiry, Avery suggests a time factor sub-test for inventive step analysis:

> *"One of the sure tests in analyzing the existence of inventive step would also be the time gap between the prior art document and the invention under consideration. If a long time has passed since the prior art was published and a simple change resulted in unpredictable advantages which no one had thought of for a long time, the Court would tilt in favor of holding that the invention is not obvious."*

In this case, the Court noted that if the subject invention relating to products used in bulk in industries was so obvious, any third party could have made the changes in the prior art to arrive at the subject invention, which has not happened. The non-obviousness was inferred from:

- the 18-year time gap between the closest prior art and the subject patent; and
- lack of any other prior art during this significant gap addressing the problems and suggesting any solutions close to the invention.

The Delhi High Court in *Societe Des Produits Nestle SA v Controller of Patents (2023/DHC/000774)*, reaffirmed the time consideration for inventive step analysis. In this case, the closest art was silent on an important feature of the patent in question and thus did not completely cover the subject matter of the patent application. Further, the Court relied on the age of the prior art to conclude the Roche obviousness test. The Court held that if the differences were 'obvious to try', then the same would have been attempted by now, especially considering that the prior art cited was considerably old (20 years old), which is a clear indication of non-obviousness.

Avery and *Nestle* cases pronounce the time indicia sub-test that goes in the favor of applicants and eventually resulted in grants, that too, at the appellate stage. Both verdicts, indeed, are pro-patentability on the time factor and disregard aged prior art. As the *Nestle* decision relates to a composition, it is likely to be well-received by patent strategists in the pharmaceutical and biotech sector.

Conclusion

Inventive step or non-obviousness is a mixed question of law and fact. Secondary factors including the age of the prior art may be utilized by patent seekers while defending the related objections. Courts may also support a finding of non-obviousness resulting from the application of secondary considerations. Secondary indicia cannot replace the technical primary test but can complement it usefully.

With the formation of a dedicated IP Division in the Delhi High Court, an innovative and liberal dimension to the interpretation of the Indian Patents Act is being added perennially. Indian Courts practically begin to apply the 'age-of-the-prior-art' factor in the assessment of an inventive step. There can be no blanket rule on time indicia such as a cut-off point for prior art. As can be seen above, the relevancy of the 'old-aged-prior-art' argument depends on the facts and circumstances of each case. Intuitively, it can be proposed that – the older the prior art, the more its age helps indicate non-obviousness. Wrapping up and turning back to the title query whether old is gold – well, sometimes it may not be!

> **Secondary indicia cannot replace the technical primary test but can complement it usefully.**

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The results of the national program Digital Economy of Russia in the field of IP protection in 2022

Ludmila Lisovskaya of Zuykov and partners details the recent developments at the Russian Patent Office that bring acceleration and efficiency to applicants.

The digital economy is an economic activity based on digital technologies aimed at improving the quality of life. Digitalization has affected almost all aspects of human life, social, political, and industrial spheres. She did not bypass the Russian patent office.

In the field of intellectual property, new information systems are being introduced, such as Rospatent Online, which is a personal account for the provision of public services in a single user window that allows the applicant to electronically obtain patents and certificates, track the stages of consideration of applications. Another example is the *Turnover of Rights* service which fixes the assignment of rights, provides an overview of license agreements, thereby creating all the conditions for accelerating the commercialization of the results of intellectual activity.

The transition to electronic document management, full automation of formal checks of applications and applications, the availability of a huge amount of patent documentation and other information related to the protection of intellectual property objects, as well as the possibility of attaching 3D models of the claimed objects to the application materials - all this made it possible not only to expand and improve the quality of services provided by the federal executive body, but also to simplify the procedure for conducting patent searches and research, speed up the processing of applications, and, in general, reduce the burden on the federal executive body, increasing its efficiency.

Ludmila Lisovskaya

One of the brightest examples of digital solutions in 2022 developed by Rospatent as part of the national program *"Digital Economy of the Russian Federation"* was the search platform, which is designed to search for information about technical solutions around the world using artificial intelligence. It covers 26 countries and organizations, about 50,000 new patents, and has processed more than 10 million requests to date. The capabilities of the platform allow to search for such specific and complex objects as formulas of chemical compounds, amino acid and nucleotide sequences; in addition to patent search, analyze the development of the state of the art in the framework of patent research or the formation of a patent landscape. In the near future, it is also planned to release a corresponding mobile application, which will make it even more convenient to use this digital product without being tied to a computer.

In 2022, Rospatent actively began work on the development of a prototype of the Russian pharmaceutical register of patents, which provides for a unified register of active substances with pharmacological activity protected by a patent for an invention. Now only the pharmaceutical registry of the Eurasian Patent Office (EAPO) is in operation, where the first Russian patent was entered in October 2022. *The EAPO Pharmaceutical Register* mainly includes information on Eurasian patents containing information on the active substance of a medicinal product with an assigned international non-proprietary name. In fact, the *Russian Pharmaceutical Registry* will be a similar tool for pharmaceutical patent specialists and experts from national offices to assess the patentability of new inventions.

Another promising online service related to the integration of departmental information systems, which is worth mentioning, is *EAPO-Online*. This system will allow a Eurasian application to smoothly go all the way from filing through a personal account on the Rospatent website to entering directly into the EAPO system, without any problems calculating and paying state fees online.

Further development of such services for interaction with applicants, integration with external government platforms, including international ones, will significantly facilitate paperwork and speed up the processing of applications.

In addition to creating new information systems using artificial intelligence, as part of the development and digitalization, Rospatent expanded the volume of data storage systems, increased the amount of computing power, and created conditions for updating the jobs of department employees.

In addition, the Patent Office has been constantly updating its information resources this year. For example, the site was regularly filled with useful information for applicants, feedback was organized in the question-answer mode, interactive platforms were created for training and communication with users.

> **Rospatent expanded the volume of data storage systems, increased the amount of computing power, and created conditions for updating the jobs of department employees.**

The results of such active work of the national program speak for themselves. In 2022, *more than 70% of applications for registration of intellectual property objects were filed electronically,* 50% of applicants refused to receive certificates and patents on paper, every 20th application was filed with an attached file for a 3D model. The successful operation of the online software registration service was recorded, which is not surprising, because it allows the user to submit an application with the entire package of materials in a few minutes and reduce the registration time for a computer program or database from three to 10 days.

The impact of digitalization on the field of intellectual property over the past year is quite noticeable, but the Digital Economy of the Russian Federation program in the future involves the introduction of many modern and promising innovative technologies. It is obvious that even greater progress will be achieved in the work of Rospatent, which is still gaining momentum.

Résumé

Ludmila Lisovskaya has worked as Patent Specialist and a Chemical Specialist with Zuykov and partners LLC since 2017. Ms. Lisovskaya specializes in Patent search on inventions and utility models, Preparation and filing of patent applications on inventions, utility models, software and database, Response preparation on request for substantive examination on inventions, utility models, software and database applications, etc. Her previous professional experience also includes working as a Head of Department in the preparation and implementation of new technologies, at JSC "Togliatti Institute of nitrogen industry".

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Clinical trial agreement negotiation and the role of patents

Mark G. Bloom, CLP®, RTTP™, details the IP issues that need to be considered during clinical trial agreement (CTA) negotiations and why protecting patent rights are essential in the development and commercialization of new drugs and medical devices.

CTAs are essential legal documents that govern the terms and conditions of clinical trials. These agreements cover a wide range of issues, including confidentiality, publication, liability, indemnification, and intellectual property. One critical aspect of CTAs is the negotiation of patent rights, which is crucial to ensure that the interests of both the sponsor of the clinical trial and the designated clinical investigator and their employer are adequately protected.

The role of patents in clinical trial agreement negotiations

Patents play an essential role in the development and commercialization of new drugs and medical devices. They provide legal protection for the development of and the financial investment in inventions and discoveries that form the basis of these products. In the context of clinical trials, patents can have several essential functions, including:

Protection of intellectual property

Patents provide legal protection for new human and veterinary drugs, diagnostics, biologics, medical devices, and other inventions. Such rights are often the primary technological and financial asset of the company, especially in entrepreneurial spin-offs and spin-outs; for example, from academic technology transfer programs. Patents can be used to protect the results of a clinical trial, including new drug formulations, dosages, delivery methods, and new uses of existing technology. Before a clinical trial can take place, the technology at issue must be adequately protected by patents(s).

Mark G. Bloom

> **Several critical issues arise in the negotiation of patents in clinical trial agreements.**

Commercialization and third-party investment

Patents are the primary tool for commercializing new drugs, medical devices, and diagnostics. A strong patent position will significantly "de-risk" technology licenses, mergers and acquisitions, and third-party capital investments.

Negotiation of clinical trial agreements

Patents are a key consideration in negotiating clinical trial agreements. The parties involved in the clinical trial need to agree on how to handle any intellectual property rights that arise during the course of the trial. Such rights can also impact data generated during the clinical trial, the ability of both parties to publish the results of the clinical trial at the appropriate time, and issues of data confidentiality.

Critical issues in patent negotiations for clinical trial agreements

Several critical issues arise in the negotiation of patents in clinical trial agreements, including the following:

Ownership

Ownership of any intellectual property rights (IPR) that arise during the trial is a universal issue in CTA negotiations. The sponsor typically owns any potentially patentable subject matter that arises from the clinical trial, especially if the IPR is directly related to the clinical trial technology, such as an improvement; however, the investigator may have contributed to the development of an invention that is not directly related to the underlying clinical trial technology. In this case, the investigator (or their employer) may claim co-inventorship and a resultant co-ownership share in any such invention.

Licensing

Licensing is another important issue in patent negotiations. The sponsor may want to license any patents that arise from the trial to other parties, such as a pre-existing licensee or a new industry partner. If the investigator or their employer are deemed co-owners of the invention, then they will likely want to negotiate a share of any downstream licensing fees or royalties that could be generated from the invention.

> **The sponsor may want to license any patents that arise from the trial to other parties, such as a pre-existing licensee or a new industry partner.**

Publication rights

The publication of trial results is another critical issue in CTA negotiations. The sponsor may want to delay publication, while the investigator may want to publish the results immediately. The ability to publish trial results is critical to academic-based investigators; therefore, striking a reasonable "balance of the equities" as to publication versus keeping confidential is needed.

The use of clinical trial data in patent applications

Clinical trial data can be used in patent applications to support claims related to the efficacy (i.e., the invention works for its intended purpose) or safety of a particular invention.

When using clinical trial data in a patent application, it is important to provide a detailed description of the data and its relevance to the invention, including information about the trial design, patient population, treatment regimen, and statistical analyses of relevant trial subject outcomes.

The use of clinical trial data and the "public use bar" to patentability

Courts will consider the following general factors when assessing whether or not a use is "public" or "experimental":

(1) the length of the test (or experimental) period;

(2) any confidentiality agreement on record (though the presence or absence of a confidentiality agreement is generally not dispositive);

(3) any records of testing;

(4) any monitoring and control of the test results;

(5) the number of tests; and

(6) the length of the test period in relation to tests of similar inventions.

See *Eli Lilly and Co. v. Zenith Goldline Pharms., Inc., 471 F.3d 1369, 1381 (Fed. Cir. 2006).*

A properly conducted clinical trial will arguably meet all of these factors. Further, in most clinical trials, the underlying technology has been claimed in one or more patent applications long before the (very public)

Résumé

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He is a member of the Bars of Massachusetts, New York, and Wisconsin and is licensed to practice before the USPTO, various Circuit Courts, the US Court of Federal Claims, the US Court of International Trade, and the US Supreme Court. Mr. Bloom is a Certified Licensing Professional and a Registered Technology Transfer Professional.

human clinical trial phase of product development. As such, clinical trial data is typically used in follow-on patent application filings, such as continuations and continuations-in-part, via inclusion in "working examples." Since the clinical trial data necessary to demonstrate efficacy and safety for regulatory approval purposes (hopefully) remains considerably higher than the standard necessary to demonstrate patentable utility under 35 U.S.C § 101, such working examples should provide excellent support to prove utility or enablement as to a specific use, e.g., an anti-cancer agent. For inventions that arise de novo in a clinical trial and that are not directly related to the underlying clinical technology being tested in the trial, the importance of the timing of a patent application filing cannot be overstated: as all patent attorneys know: file *before* any public release of relevant information.

Conclusion

In conclusion, patents are a crucial consideration in negotiating clinical trial agreements. The parties involved in the trial need to agree on the management of any intellectual property rights that arise during the trial, including ownership, licensing, publication, and indemnification. Negotiating patent issues in a CTA is a complex process that requires the input of legal and technical experts to ensure that the interests of both the sponsor and its clinical site(s) are adequately protected.

"As all patent attorneys know: file *before* any public release of relevant information."

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