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January / February 2022

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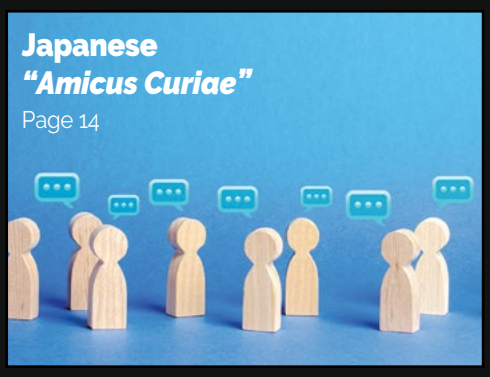
Femtech: the next big technology boom

Sarah G. Hartman, Partner at Brown Rudnick, evaluates the long-overlooked gap in the healthcare market surrounding women's health and how the next big technology boom is about to change women's lives for good.



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CTC Legal Media

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Editor's welcome

With the development of technology continuing at a rapid rate it is no surprise that innovation is beginning to encompass new areas that impact our everyday lives. Our cover story this issue brings us a prediction for the next big technology boom – Femtech. The female health technology market is currently widely underrepresented, with some ads even being censored as inappropriate content, but that may be about to change.

Our guest interview this issue is with Kumar Goswami, CEO of Komprise. We discussed insights into patent strategy for start-ups based on Kumar's experiences.

In addition we have an overview of the Japanese version of the *"Amicus Curiae"*, an update on the Hungarian patent regime, advise about the inventive step in Indian patenting, and a review of the challenges and opportunities of protecting IP in a deep tech start up – plus more!

> **"But that may be about to change."**

We would like to thank this issue's *Women in IP Leadership* sponsor, Zuykov & Partners, for facilitating the interviews with Carolina Vera Matiz of Vera Abogados Asociados & Niti Dewan of R. K. Dewan & Co.

Don't miss chapter 5 of our six-part Diversity, Equity and Inclusion series. This chapter focuses on gender and gender bias in law.

Plus, the 6th issue of The Life Sciences Lawyer.

What hot topics do you think will dominate the patent field in 2022? Contact us to let us know, we will be waiting to hear from you!

Faye Waterford, Editor

Mission statement

The Patent Lawyer educates and informs professionals working in the industry by disseminating and expanding knowledge globally. It features articles written by people at the top of their fields of expertise, which contain not just the facts but analysis and opinion. Important judgments are examined in case studies and topical issues are reviewed in longer feature articles. All of this and the top news stories are brought to your desk via the printed magazine or the website *www.patentlawyermagazine.com*

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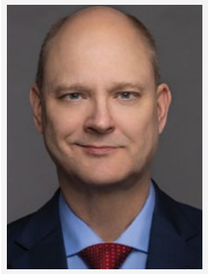
Ken Adamo – Principle, Law Offices of KRAdamo. United States

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

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.



Mark Bloom, CLP®, RTTP™: Patent Agent & Senior Consultant, TechNomos, Inc. United States

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.

Jacqueline Chernys: Senior Intellectual Property Counsel, BASF SE. Belgium

Jacqueline is a lawyer and patent attorney. Jacqueline worked in private practice before becoming lead IP counsel at an international oil and gas company. She has since specialized in the agri-industry, and currently is employed at BASF where she advises on all aspects of IP.

Noel Courage: Partner, Bereskin & Parr. Canada

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.

Eugene Goryunov: Partner, Haynes & Boone. United States

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.

Stefan Schohe: Partner, Boehmert & Boehmert. Germany

In addition to prosecution of IPR for German and foreign clients, a main part of Stefan's work is litigation, especially pre-litigation advice, representation of clients in court, and coordinating international patent litigation. His main technical field is technology.

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.

Sarah Taylor: Senior Practice Development Lawyer, Pinsent Masons' IP practice. UK

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: Managing 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.

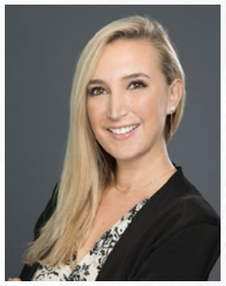
The Patent Lawyer **would like to thank the Editorial Board for their time and support.**

Femtech: the next big technology boom

Sarah G. Hartman, Partner at Brown Rudnick, evaluates the long-overlooked gap in the healthcare market surrounding women's health and how the next big technology boom is about to change women's lives for good.

There are approximately 3.97 billion women in the world,[1] with massive purchasing power of more than $31.8 trillion per year,[2] and control over more than 80% of healthcare decisions.[3] These women have health and wellness needs that differ from those of men. Yet science and technology have overlooked women's health needs for decades. Women were excluded from clinical trials and research until 1993, leaving dangerous gaps in our knowledge of how disease and drugs affect women.[4] And there have been few major innovations in female-focused markets, like the feminine hygiene product market that has had little innovation since the invention of the applicator tampon in the 1930s and the self-adhesive pantyliner in the 1970s.[5] For years, talk about periods, pregnancy, and reproductive health was considered taboo.

But the tide is shifting. Innovators and inventors are taking notice of the enormous gaps in the market, entrepreneurs and investors are jumping on board, and new technologies are emerging that address women's unique health and wellness needs. The femtech movement is here and it's starting to boom. Patent protection is, and will be, critical to its continued growth and success.



Sarah G. Hartman

What is femtech?

"Femtech" refers to the female health technology market – technological innovations that seek to improve health and wellness concerns that uniquely or disproportionately affect women, such as menstruation, fertility, pregnancy, post-partum, menopause, oncology (breast, ovarian, cervical), and more.[6] Innovations in this space include consumer products, wearables and clinical devices, diagnostic appliances, healthcare software, therapeutic drugs, medical devices, clothing, apps, and services.[7] According to CB Insights, the femtech market includes the following categories: fertility solutions; period and fertility tracking mobile apps; at-home fertility monitoring devices; pregnancy and nursing care; pelvic healthcare; general healthcare; period care goods; and women's sexual wellness.[8]

What took so long?

This technology space has only had a name since 2016.[9] Historically, women were left out of biomedical research and innovation and ignored in the analysis of data due to "fears of female hormonal variation complicating the findings."[10] In fact, before 1993, women were prohibited from participating in medical trials because of their varying hormones and fears that they could get pregnant during the trial, which could result in harm to the fetus.[11] Even after the ban was lifted, many medical trials involved only male participants.[12] As a result, much of our medical research and analysis focuses on how drugs and disease affects male biology. Without data on women, there is a large gap in our understanding of how disease and drugs affect them and many drugs and devices have shown to be less effective or even unsafe for women.[13] Lack of research and understanding has led to lack of innovation.

Résumé

Sarah G. Hartman, Partner

Sarah is a Partner in Brown Rudnick's Litigation & Arbitration and Intellectual Property Litigation Practice Groups. She is an experienced lawyer, leader, and strategist who takes a business-minded approach to providing legal counsel on high stakes commercial and intellectual property disputes. Sarah has successfully litigated patent cases involving a broad range of technologies, including computer networking, LED panels and lights, automotive audio technology, mobile applications, map-based communication technology and internet services and systems. She also represents clients in copyright, trademark, and trade secret disputes, and other complex commercial disputes, including in the areas of employment, entertainment, defamation, unfair competition, products liability, class actions, false advertising, securities and finance.

"The femtech movement is here and it's starting to boom. Patent protection is, and will be, critical to its continued growth and success."

1 *Gender Ratio in the World*, https://statisticstimes.com/demographics/world-sex-ratio.php (last visited December 17, 2021).

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3 Dr. Brittany Barreto et. al., *Femtech Lanscape 2021 Annual Report*, https://femtechfocus.org/wp-content/uploads/2021/08/FemTech-Landscape-2021_v2-2.pdf ("*Femtech Landscape*") at 12.

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13 Michelle Llamas, *How the FDA Let Women Down* (Sept. 24, 2014, last modified June 29, 2021), https://www.drugwatch.com/featured/fda-let-women-down/; see also Elizabeth Pratt, *We Don't Have Enough Women in Clinical Trials — Why That's a Problem* (Oct. 25, 2020), https://www.healthline.com/health-news/we-dont-have-enough-women-in-clinical-trials-why-thats-a-problem.

The topic of women's health has also been considered taboo. Society teaches women to be ashamed or embarrassed to talk about their bodies or health and reproductive concerns. Some social media platforms and search engines have even censored ads for femtech products due allegedly to inappropriate content.[14]

In addition, it is well known that men greatly outnumber women in the science, technology, engineering, and math (STEM) industries, with women making up only 27% of the STEM workforce in the U.S.[15] There are more male founders and CEOs, more male venture capitalists,[16] and more men filing patent applications and holding patents.[17] Not surprisingly, though, women are more likely than men to create inventions aimed at benefiting women's health and wellness.[18]

A recent study published in Science found that inventions created by female teams are up to 35% more likely to benefit women's health than inventions created by men.[19] The study notes that fewer women file patent applications, and female scientists are 40% less likely to commercialize their research ideas than male scientists.[20] The researchers concluded that this "inventor gender gap" is partially responsible for thousands of missing patented technologies designed to address problems affecting women since 1976.[21] Ultimately, "who benefits from innovation depends on who gets to invent."[22]

> **"This technology space has only had a name since 2016."**

What changed?

In recent years, there has been a renewed push for innovation aimed at improving women's health and wellness. Women are entering the workforce and their economic power is increasing.[23] At the same time, women are demanding better health and wellness solutions tailored to their unique needs. They are seeking solutions for the root causes of their issues rather than just treatments for their symptoms, and they are turning to the internet and technology to assist. The pandemic has contributed to increased demand for personalized telemedicine and at-home health solutions, such as virtual fertility and pregnancy care.[24] Women are working hard to destigmatize the topic of female health.

In addition, more women are becoming entrepreneurs and CEOs, thus controlling the design and marketing of new products. Venture capitalists are showing interest in this new market and are steadily increasing their investments in femtech.[25] Regulatory agencies are increasingly approving digital applications aimed at addressing female health and wellness needs.[26]

The rise of AI and IoT has also contributed to the growth of femtech, as it has allowed for new types of technological innovations that provide much needed solutions for women's health.[27]

Why are patents important?

Patents are critical to the growth of the femtech industry. Patents are important to protect the novel technological innovations being developed and have been shown to increase funding opportunities and encourage investment in femtech startups. Research suggests that a large percentage of venture capitalists consider patents when deciding whether to invest.[28] And publicly available data confirms that femtech companies active in filing patents have access to higher levels of funding than those that are not.[29] Given that a major barrier to entry in the femtech space is funding, patents can be a critical tool to the success of a new femtech venture.

Although there are many, some examples of patents issued in the femtech space include:

- A patent issued to Progenity for a method for assessing preclampsia — the second most common cause of maternal mortality.[30]
- Patents issued to Proov related to at-home testing for identifying the fertile window.[31]
- Patents issued to MobileODT relating to an AI-powered mobile technology for screening for cervical cancer[32] —the fourth most common cancer in women.[33]
- A patent issued to Eggschain relating to the use of blockchain technology to track and trace the transfer of bio-specimens, which provides information to women and families going through IVF or egg freezing.[34]

These are among the new technologies changing the lives of women around the world.

> **"Given that a major barrier to entry in the femtech space is funding, patents can be a critical tool to the success of a new femtech venture."**

What is the market like today?

The femtech market is starting to boom, with no signs of slowing down. According to the FemTech Analytics report for 2021, the global femtech industry ecosystem includes no fewer than 1,550 companies (which have collectively received $16 billion in investment), 1,000 investment funds, and 30 R&D centers.[35] The majority of femtech companies are based in North America.[36]

Though the global femtech market was valuated at $18.7 billion in 2019, it is expected to grow to $60 billion by 2027,[37] with the global women's health market set to exceed $1 trillion.[38] And investments in this market are increasing. Femtech startups raised $1.3 billion in the first three quarters of 2021, compared with $774 million for the entirety of 2020.[39] Nevertheless, the market is still underinvested and far from saturated. We should expect to see many more femtech innovations, and many more femtech patents, in the years to come.

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39 Morgan Frey, *supra* n.25.

An interview with Komprise's co-founder & CEO, Kumar Goswami

Kumar Goswami sits down with *The Patent Lawyer* to give key insight into the value of patenting and patent strategy for start-ups based on personal experience from setting up a data management company.

Komprise is the industry's only multi-cloud data management-as-a-service that frees you to easily analyze, mobilize, and access the right file and object data across clouds without shackling your data to any vendor. With Komprise Intelligent Data Management, you are able to know first, move smart, and take control of massive unstructured data growth while cutting 70% of enterprise storage, backup, and cloud costs.

Kumar Goswami is the co-founder and CEO of Komprise. He is a serial entrepreneur with over 20 years' experience founding and running startups with successful exits as well as experience in executive management in large enterprises. He really enjoys advising young companies.

Kumar Goswami

Securing a patent for a new technology can be crucial to a startup's launch and development and should be a priority. What was behind your decision to pursue a patent for your Transparent Move Technology™[1] and how has the decision helped to differentiate your company early in its life cycle?

We were building a new team and a new product with some excellent contributors in storage product software. They knew patents from their prior large companies, and Komprise's founders had produced patents in startups we were principals in before. So while furiously producing new software with new ideas, we had a sense of when the right time was to shift gears and patent the most noteworthy aspects of our invention.

The value of a patent for Transparent Move Technology (TMT) is that it lends credibility to the story we were telling investors, employees, customers and partners. It means our approach has real technical merit – not a small thing among Silicon Valley companies. We developed something truly unique and we knew a patent would distinguish our solution from hungry competitors, which it indeed has, and it's a building block for future innovation and patents.

> **If your idea is something one can steal after a general discussion, then maybe it's too simplistic.**

I read an interview you gave in which you were asked to share some things you wish you would have been told prior to leading Komprise. One part of your response referred to the idea that a company, especially early on, shouldn't worry about someone stealing their idea. Does this run counter to the importance of securing a patent or can those viewpoints exist simultaneously?

No, I think it's in line with what I said. If your idea is something one can steal after a general discussion, then maybe it's too simplistic and if it is that simple, why haven't others done it already? Whatever you are embarking on needs to have some heft to it. That said, if you come up with something novel, then you should also take the time to protect it. It's common business sense to do so.

That said, the most important factor in product is whether it is sellable. There is little point in patenting something that is not sellable, and for a startup there is little point in patenting something we could not actually build. So we definitely wanted to start with developing the software and building out an implementation that we could sell.

It was only after the big problems were solved that we went for the patent. This was helpful because we did the hard work to get to the top of the mountain and then knew exactly what to patent. Had we tried to protect each novel idea as it came up, we would have taken much more time, spent more money, and caused more confusion while patenting a number of inventions that were not in the end helpful to us.

Let's stay on the topic of lessons learned. Securing a patent can be a lengthy, costly process – two things (time and money) that most startups can ill afford to waste. What are some things you learned going through the patent process that might benefit other startups and startup founders?

The time of the team is the most valuable resource a young company has at hand. Anything they are doing that isn't their primary job is very expensive, so getting the knowledge from the team into a patent application needs to be efficient. For the TMT patent we had each inventor outline his or her portions, and then we reviewed, critiqued, and revised them all together. Then the team brought in the patent attorney, conveyed this extensive outline, and discussed the claims that could be defended by it.

Another lesson is that the provisional patent application approach is a great way to go. It's a lot less cumbersome and costs significantly less. You have one year from the time you file a provisional to pursue the full patent, which makes a huge difference if you're in the process of developing a key technology. The provisional approach also reduces your risk. If you decide over the course of the year that the patent wasn't worth pursuing, you can cut bait without incurring a large expense.

That makes sense. And yet, even the provisional approach carries a cost. How do you recommend a startup measure the ROI for pursuing a patent? What's the best way to determine whether the value will be worth the expense?

Everything about the company in the early days is about making the product. And the development of a sellable product must be the end goal. Developing and patenting innovations because they are patentable even though they are not required for the sellable product or an anticipated future version of the product is simply outside of the viable business model of a product-oriented startup. But if a significant innovation is required to make the product work, the decision becomes clear. Patenting that innovation, even defensively, meaning to make sure someone else doesn't patent it to block you, has positive ROI.

Also, the ability to say "patent pending" while talking with prospects and investors has significant value on its own and should definitely enter into the ROI calculus. Interestingly, the TMT name for Komprise's first patented technology came from marketing, not its inventors. This highlights even more that patents for a startup should be considered as a part of corporate strategy, not merely as IP protection.

I would recommend that one person, perhaps the CTO, be designated as the point person on patents. This person is responsible for keeping the list of novel ideas, checking with others for anything new they have created, and bringing anything that is possibly patentable to the company leadership. The ROI conversation for each of the ideas can then take place.

> **A patent conveys technical value and merit for your idea, which goes a long way toward reinforcing your positioning.**

The tech industry has a well-earned reputation for being fiercely competitive. Naturally this applies to patents, in the sense that the next great invention can completely disrupt a given industry, rendering older patents (and their owners) obsolete. Given this, how focused should founders be on pursuing new patents or updating existing ones?

The big tech companies create tons of patents, which they use as a negotiating tool. That's not the intent of most startups, including ours. We are creating patents for key components of our platform. Managing unstructured data at scale, which is what we do, is in many respects a green field. The massive onslaught of unstructured data (files and objects) is relatively new and not a lot of work has been done in this area. From that perspective, it is important. You don't want someone to come in and run off with your idea. But you also don't want to patent anything and everything. We are filing patents we think are critical to the business and the functionality we are providing. We think it's important to protect these ideas.

One more question. Considering how difficult it is for a company to secure a patent, how important (if at all) is it for a company to market said patent once it's secured? In other words, should companies spend time promoting patents or, in your opinion, is this type of achievement not particularly meaningful to customers, investors, etc.?

Patents are invaluable for credibility in sales and with investors because they demonstrate that you are solving real technical problems. A patent conveys technical value and merit for your idea, which goes a long way toward reinforcing your positioning.

[1] https://www.komprise.com/use-cases/transparent-move-technology/

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AN INTERVIEW WITH KOMPRISE'S CEO

Japanese version of *"Amicus Curiae"*

Osamu Yamamoto, Partner at Yuasa and Hara, evaluates the implementation of a system similar to the US' *"Amicus Curiae"* to the Japanese patent system, whereby the Courts will invite opinions from members of the public as evidence in dispute proceedings.

Introduction of a new system

A third-party opinion solicitation system, so-called the Japanese version of *"Amicus Curiae,"* will be introduced into patent and utility model infringement litigation. An amendment of the Patent Act to introduce the system will come into force on April 1, 2022.

If the Tokyo District Court, the Osaka District Court, or the Intellectual Property High Court (IPHC) consider it necessary, they can invite opinions from members of the public, which may be used as evidence in the proceedings.

In the age of AI/IoT technology, patent infringement litigation is expected to become increasingly sophisticated and complicated, and court decisions will have a huge impact on the development of related industries. It is expected that the introduction of this system will provide the courts with expert knowledge etc., beyond that provided by the parties in litigation. Furthermore, it will be possible to enable those affected by the judgment to participate in the litigation in some manner, and thus it is expected that the formation of a judgement will reflect the public interest.

Osamu Yamamoto

It is well-known that an *"Amicus Curiae"* system has been used for many years in the United States. In Japan, there is one precedent (explained below) in which the IPHC invited the public to provide opinions. It was a patent infringement litigation case having a huge impact on the development of industry relating to standard essential patents. A large number of opinions were submitted from companies, researchers, and practitioners etc. Since there will be an increased number of cases in which the courts wish to hear opinions from the public in order to judge appropriately, it has been decided that the system should be formally adopted in the Patent Act.

Details of the system

Either party in a litigation case can request the court to apply the third-party opinion solicitation system. In each case, parties need to consider carefully whether the system should be used, taking possible advantages and disadvantages into consideration. A party who wishes to apply the system should make a petition to the court explaining that the case has a significant impact and it is necessary or meaningful to solicit opinions from the public. In doing so, it will also be important to appropriately set out the issues on which opinions are sought from the public. The other party of the litigation may express to the court an opinion that the system should not be adopted. The court will decide whether to solicit third-party opinions contemplating the opinions from both parties.

The scope of issues on which opinions are gathered is stipulated in the Patent Act as "the application of this Act and other necessary matters concerning the case." This means that the scope of issues is broad and is not limited to legal issues and rules of thumb, but extends to such matters as the court considers relevant in each particular case. An example of an issue for gathering opinions would be "how to calculate royalties in each industry for a particular IoT technology," and examples of opinions on the issue may include a "relationship between the contribution of a patent and the method of calculating royalties in the final product in each industry, [...]the situation in other countries,[...]the actual situation of licensing practices, [and] actual practice experience." In litigation relating to AI and IoT-related inventions, the business structure, profit structure, cost structure, etc., tends to be different from those of conventional businesses. Therefore, it is burdensome or difficult for the parties concerned to collect pertinent evidence. Particularly in such a case, it is significantly meaningful to seek opinions from a wide range of parties.

The timing and deadline for submitting opinions will be determined at the discretion of the courts. Overseas companies and organizations etc., need to be careful because only a relatively short period of time may be permitted to submit opinions.

> **"An amendment of the Patent Act to introduce the system will come into force on April 1, 2022."**

There is no limitation on who can submit opinions. Individuals including experts such as researchers, individual companies, industry associations, administrative organs, etc., can submit opinions from their respective viewpoints that will contribute to the judgment of the court regarding the case. The system for inviting third-party opinions is a procedure for collecting evidence by the parties involved in the litigation, and therefore, there are no restrictions on who can be asked to submit opinions by the parties. In addition, since third parties may submit their opinions voluntarily, it is expected that diverse opinions will be submitted to the court.

Under the system, each party inspects and copies the opinions submitted to the court by third parties. Then, each party selects favorable opinions and submits them to the court as documentary evidence. This process was adopted because if third party opinions were to be used as the basis of the court's judgment without prior scrutiny by the parties, it may cause a problem from the standpoint of the

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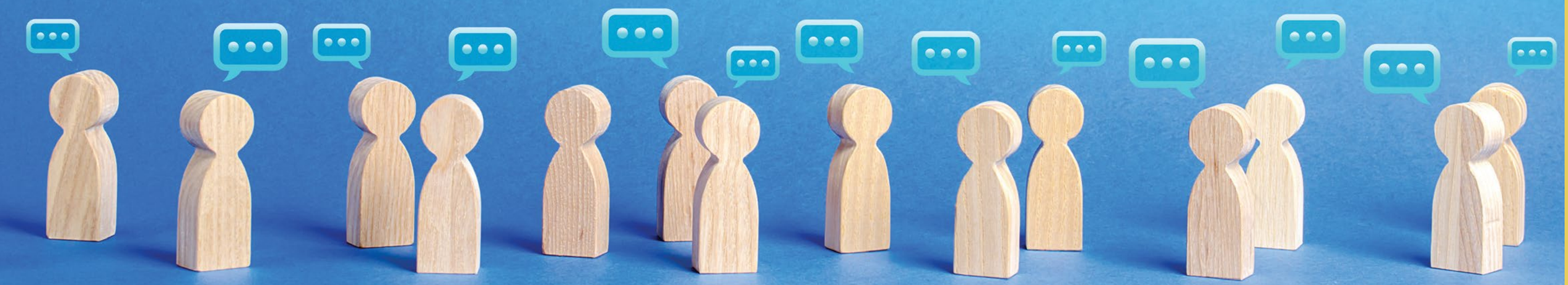
Osamu Yamamoto, Partner

Mr. Yamamoto, is a patent attorney, and a partner of YUASA and HARA. He has extensive experience in pharmaceutical and biotechnology R&D at a chemical company for 10 years before specializing in intellectual property. He has represented a variety of companies in the fields of pharmaceuticals, biotechnology, diagnostics, and food and beverages. He is experienced in all aspect of patent issues.



principles of pleading, where it is the right and responsibility of the parties to collect evidence necessary for litigation. In other words, in light of the principle of civil litigation in Japan, each party can decide whether or not to submit opinions to the court as evidence from among the submitted opinions. Therefore, a situation may arise where opinions of a third party are not submitted to the court by either party and do not constitute documentary evidence. This is a significant difference from the U.S. system.

This system applies not only to patent infringement cases but also to utility model right infringement cases. On the other hand, this system does not apply to cases of infringement of design or trademark rights, litigation for revocation of JPO trial decisions, etc. However, if it is considered necessary in the future, the scope of application of the system may be expanded. Furthermore, even in litigation that is not subject to the system, such as litigation for revocation of a JPO trial decision, it will be possible to solicit opinions in a manner similar to the precedent case described below subject to agreement between the court and the parties.

> **In light of the principle of civil litigation in Japan, each party can decide whether or not to submit opinions to the court as evidence from among the submitted opinions.**

Precedent case

From January 23 to March 24, 2014, the IPHC asked the public to provide information or opinions on the issue of "whether there should be any restrictions on the exercise of the right to claim injunction and the right to claim damages by the patent in the event of a so-called FRAND declaration (declaration that a license shall be granted on Fair Reasonable and Non-Discriminatory terms) regarding a patent that is essential to a standard established by a standardization organization," in the case of *Samsung Electronics v. Apple Japan (2013 (Ne) 10043)*. The IPHC stated that the issue was very important and influential, and therefore it should be considered not only from a Japanese perspective but also from an international perspective. Further, the IPHC considered that the court's decision would have a significant impact on the way technology is developed and utilized, corporate activities, and the public interest.

In Japan, however, there was no mechanism for third parties to submit their opinions, so the law firms representing the parties gathered opinions from the public and submitted them to the court. The trial to gather opinions from the public as a result of consultation and agreement by both parties attracted considerable attention as an epoch-making attempt to realize a mechanism similar to the US *"Amicus Curiae"* system. Since the issue was so influential, 58 opinions were submitted to the IPHC. The judgment summarized the submitted opinions and stated that they provided "valuable and useful material for the court to conclude proper judgments from a broad perspective".[1]

Although such a procedure was expected to be used afterwards, it was not used because a method of opinion solicitation was not stipulated in the law etc.

Expectations to the system

In the US, in the case *Abbvie Deutschland GmbH & Co. v. Janssen Biotech, Inc,* relating to a patented human antibody effective for the treatment of psoriasis and rheumatism, the Federal Circuit Court of Appeal (CAFC) judged all of the asserted claims to be invalid for failing to satisfy the written description requirement, stating that AbbVie did not describe "sufficient representative species encompassing the breadth of the genus," but only "a research plan, leaving it to others to explore the unknown contours of the claimed genus." In the decision, it is stated that "We were aided in our consideration of this issue by *Amicus Curiae briefs* filed by Eli Lilly and Co. *et al.* and Professor Oskar Liivak of Cornell Law School" (111 U.S.P.Q.2D (BNA) 1780, 1783 (Fed. Cir. 2014)).

In Japan, in the defense that a patent right should be invalid in a patent infringement litigation, the determination of the extent to which the right should be granted based on the description including working examples in the application may significantly affect the development of industry. Especially in the field of biotechnology and IT, it is expected that many opinions will be sought from companies, researchers, and practitioners, not limited to technical aspects, and the courts will make highly reasonable judgments in consideration of various circumstances.

> **Although such a procedure was expected to be used afterwards, it was not used because a method of opinion solicitation was not stipulated in the law.**

On the other hand, there is a concern that organizations that are active in lobbying may submit opinions in many cases, and as a result, minority opinions will be less likely to be reflected in litigation. In addition, many of the details of the system have yet to be determined. After the implementation of this system, it will be necessary to monitor trends, such as how often this system will actually be used, how it will be implemented, and how useful the submitted opinions will be.

In any event, we are looking forward with great interest to the first case after implementation.

[1] http://www.ip.courts.go.jp/eng/vcms_lf/25ne10043full.pdf

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The Hungarian patent regime

In the field of patent law, Hungary is considered a central European Country with great IP traditions in the area and having a strict bifurcation system. In the end of 2021 this changed. Gábor Germus of Germus and Partners sits down with *The Patent Lawyer* to tell us more.

Gábor we understand that significant changes on the Hungarian patent regime took place over the past year. What exactly happened here?
I think that the change is rather revolutionary in the context of patent litigation: Hungary, with a strict bifurcated litigation system, has now opened the door towards such a procedural solution where nullity and infringement matters may be heard in the same proceedings. This is meant to have a great impact on the procedural timelines. Another important factor is that the criteria of preliminary injunctions have been further elaborated in order to avoid that preliminary injunction proceedings are decided in an automatism, irrespective of the future fate of the patent.

These are exciting topics indeed. But what is the reason that such amendments have taken place now?
My understanding, also as a member of the preparatory commission, has been that almost every participant has realized that these concerns in some sense reduce the competitiveness of the Hungarian market. The IP profession has had a consensus for a long time that it is not suitable to maintain a system where nullity proceedings may take up to five years and the competition, on the basis of weak patents, is banned although it is quite obvious from the beginning that a given patent, on the basis of which the injunctive relief is sought, is weak. In my view, it has been clear for the IP professionals but also the ministerial officials and economists that the Hungarian industries require a change. A telling indicator is that the number of the patent cases, e.g., pharmaceutical patents, has dropped over the past decade compared to other countries of the same size and the same IP traditions but with more flexible systems. In other words, in my view there has been a general consensus that the procedural frameworks which were appropriate in the late 80s, setting a priority for the Hungarian Intellectual Property Office (HIPO) in nullity matters and allowing the courts the position of a follower resulting in the procedural times as mentioned above, is no longer maintainable.


Gábor Germus

If you were to summarize the changes from a practical aspect, what would you highlight as the most significant changes?
I would mention the expected quickening of the proceedings first, which are affected by several factors. Firstly, you, as a defendant of a patent infringement matter, will have the option as of 1 January 2022, to raise nullity issues already in the infringement litigation, and so avoid proceedings before the HIPO lasting around 18-24 months.

Secondly, the nullity issues will have to be heard in accelerated proceedings, experts are supposed to prepare their opinion within 30 days. These factors all point in the same direction: patent litigation, which as a whole may be completed in a time which is at least compatible with any of the European jurisdictions, and if not more efficient than the system itself, will no longer be a barrier to further improvements. As a second message, I would highlight that nullity arguments are to be heard already in the PI proceedings. Previously, the courts did not have the opportunity to take a preliminary position on validity in the PI phase, now it has changed a lot and we do hope that that the courts will use well this wider scope of discretion.

Thirdly, I would highlight that wrongful PIs will be handled in a more flexible way and that interim injunctions are still maintained on the basis that patents revoked by one of the bodies have jurisdiction over the nullity matter.

> **The nullity issues will have to be heard in accelerated proceedings, experts are supposed to prepare their opinion within 30 days.**

You have mentioned earlier the optional nature of these changes. What does it mean exactly?
Thank you for pointing this out. Here, I have to emphasize an important element of the new law: choosing the new flexible litigation system is not compulsory to the extent that the parties, first of all the new competitor, who believes that an existing patent is weak - leading to them being willing to enter the market prior to the expiry date - may also choose to start nullity proceedings at the Hungarian Intellectual Property Office (HIPO) and follow the traditional route. I personally fully agree with this type of semi-bifurcation; there might be parties who would like to have the HIPO-proceedings on nullity issues rather than that of the court first, and rightfully so because the HIPO has always had very good, skilled experts and has traditional, well operated panels for such proceedings. I would rather compare this optional nature to the opt-in/opt-out system of the Unified Patent Court.

On the other hand, should any third party in terms of the same patent choose to use the new system, it will influence the earlier traditional nullity claim as well. It also may be that the nullity case lodged later at court will be decisive of the first one, should the invalidity grounds and evidence be the same.

You have just touched on an important question: are the courts prepared?
I think they are. I need to specifically mention here that the decisions of the HIPO and that of the Courts have been, in international comparisons, held as high-quality decisions. I have had the privilege to participate in various international pharmaceutical patent litigations and the foreign clients' IP exerts have always been satisfied with the quality of the various decisions - irrespectively of whether or not the said decision was in favor

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Gábor Germus, Managing Partner
Gábor graduated from the Faculty of Law at Eötvös Loránd University in 1994, including a Tempus scholarship to Nijmegen, the Netherlands in 1992. He pursued his studies and research in Koblenz, Germany in 1997 with a DAV scholarship. He is also member to DAV.

He is the managing partner of Germus and Partners. Gábor is an arbitrator at Permanent Arbitration Court attached to the Hungarian Chamber of Commerce and Industry, Budapest.

His working languages are Hungarian, English and German.

of the client. The reasons behind the changes therefore were not, in my view, of a quality nature; the various bodies as the HIPO and the courts somehow were bound by and into such procedural rules that considered bifurcation of a *s* value. I have no doubt that the new system will not result in any type of negative quality change, but I can also see that there may be other opinions which is why I have said earlier that I appreciate if parties choose to continue litigating in the traditional way. I personally would rather choose the new procedural tools.

To what extent is the new system relevant for European Patents, or eventually European Patents with unitary effect?
As for the latter, the European Patents with unitary effect, it is important to note that Hungary has not yet ratified the treaty on the referring court system, the UPC. As for the "traditional" European Patents, I stress that once they are validated in Hungary - i.e., the referring translation obligations have been met, the extent of which is recently re-considered by the case law anyway - the said patents are regarded as Hungarian patents and the courts will have full jurisdiction to take a position on their validity under the national patent law.

It is also worth mentioning that the new regime is willing to make sure that the Hungarian courts or the HIPO shall decide as far as it is possible, and only stay the proceedings with respect to opposition or withdrawal proceedings if it is absolutely necessary by setting the threshold of the requirement of "in specifically justified cases"; i.e., from this follows that the legislator was willing to keep the subject-matter within the Hungarian jurisdiction as far as it is possible in the light of the European Patent Convention. Thus, we can say that national proceedings in European Patent matters still have a future.

When you mention patents, does it mean that the new regime pertains only patents or might other types of IP rights may be affected?
Certainly, IP rights such as Supplementary Protection Certificates are also affected by the new regime given that the relevant proceedings in terms of these IP rights are regulated in the patent act. Actually, I find it very exciting that SPCs are tried immediately at the level of the court system, this will be completely new for us.

What you have just said gives us the impression that the litigation system has been changed to a more generic, friendly one. Do you agree?
Not necessarily, I would rather say that the system is meant to be, in terms of flexibility, very much similar to that of Germany or even the UK. The fact that litigations can be closed in shorter periods of time is a good thing for everyone. Another token in terms of the neutrality of the new system regarding the various sides of the parties is that the legal representatives, patent attorneys, lawyers, and their professional organizations supported the amendments almost over-whelmingly irrespective of their own practice, if they represent rather innovators, patentees, originators, or generics. It has also changed a lot recently, and there is no clear originator or generic litigation practice for patents or law firms and this is the case for large companies too, for instance in the field of pharmaceuticals it is rare that a holding does not have both types of companies.

> **I would rather say that the system is meant to be, in terms of flexibility, very much similar to that of Germany or even the UK.**

Finally, what are your personal expectations for what the new system will lend to you?
The Hungarian Patent Office, predecessor of the current Hungarian Intellectual Property Office (HIPO), was established in the late 19th century, and we have traditional pharmaceutical and other industrial innovative companies with roots back to the early 20th century and good judges and other professionals. I hope that we will have the same number of new cases as we used to have in the early 2010s and Hungary is placed back into the position in the field of IP litigation where it belongs on the basis of its traditions, that Hungary becomes a popular venue for the parties. And of course we, Germus and Partners, with a well-established IP practice and special emphasis on patent litigation, are more than capable of adapting our litigation strategies to the new system, in fact we assume that we can offer our current and prospective clients a more effective service in this regard, in Hungary. And, in excess to that we can also assist our clients generally in the region.

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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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Human innovation and creativity are the engines of progress. At Zuykov and partners, we believe that in order to best develop both Russia and the global economy, we must overcome inequality and achieve diversity. Every year we help more and more women innovators and owners of other intellectual property to protect their rights. We seek to encourage the talents of all groups to participate in solving the problems of humanity that only together can we defeat. Our mission is to create a supportive environment for all women and men and to give equal opportunity for their development in the intellectual property field.

Maria Zuykova, Business Development Manager, Zuykov and partners

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.

Carolina Vera Matiz: General Director & Partner, Vera Abogados Asociados

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

Carolina is a Lawyer with a degree from the Andes University in Bogotá, Colombia. She has a Master's degree in Trademarks, Patents and Copyrights from the University of Alicante, Spain. Currently holds the position of General Director and Partner in Vera Abogados Asociados from Colombia.

Carolina Vera Matiz

What inspired your career?

Despite great progress in this field, Colombia is still a male-dominated society and was even more so back when I started my career; however, with consistent effort this can be overcome and people tend to feel much more confident when a woman is in charge of their business matters.

I would advise all women to show total confidence in their ability, competence, and knowledge as well as taking full advantage of their emotional intelligence.

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

IP Management was generally seen as a field in which men were the main protagonists, but as women have begun to show their professional qualities and skills, the path ahead has started to open up and the presence of women in this area has become more accepted and well-regarded. Nowadays, IP management has evolved into a much more balanced profession in this sense.

A great deal is owed to all the pioneering women who went before; they undoubtedly forged the way for today's current set of circumstances and opportunities for women.

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

Our firm is about to celebrate 50 years since its founding and I have been part of our success for half of this time which for me has been a great source of pride and satisfaction to have been able to contribute to the solidity and prestige we are honored to enjoy.

A great deal is owed to all the pioneering women who went before.

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

I have a dual purpose: the idea would be to continue the internationalization process already underway at VERA ABOGADOS, as well as gaining a deeper knowledge in order to author and pen specialist articles and books which may contribute to the wider development of IP in the world.

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

The changes which I would like to see in the IP industry as regards equality and diversity over the coming five years or so would be as follows:

More enterprise undertaken and led by women covered by all areas of IP which would make them more commercial and profitable and allow women to be greater protagonists on the business world stage.

To see more women at the head of their IP companies and greater numbers of women leading non-profit organizations in the field of intellectual property where they can impose their own personal stamp.

For those women belonging to ethnic minorities to be empowered and further taught how to develop and use intellectual property for the benefits, consolidation, and advancement of their respective communities.

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

In my view, there are many valuable projects being undertaken by women in a wide range of industries. Most of these projects are excellent, the main issue is that these women need more financial support and for people to firmly believe in their projects in order to help all women create businesses and enter new markets for their projects to be viably sustainable around the world.

Niti Dewan: Patent & Trademark Attorney, Head of Patents & Business Development, R. K. Dewan & Co.

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

Dr Niti Dewan, a medical doctor and a Patent and Trademark Attorney, heads the Patents Department at R. K. Dewan & Co. She is also responsible for the firm's Business Development, Finance and Administration operations.

With over 15 years of experience in the IP field, Niti's areas of speciality include: patent drafting, patent searching & analysis, international patent filing and prosecution, and IP portfolio management. Niti's primary sectors of speciality are the life sciences, biosciences, pharmaceuticals and chemicals; however, she has extensive experience in carrying out invalidation and freedom-to-operate searches in all fields of technology including automobiles, IT, nanotechnology and material sciences. She frequently advises clients on their IP strategy.

What inspired your career?

I trained to be a doctor and I was practicing - then I met Dr Mohaan Dewan, my husband. He is the principal of our firm and seeing him deal with new inventions and creating brands, seeing how he was helping to protect against infringement and offering strategic advice to clients, was inspiring.

I started working on pharmaceutical and other medical related patents, such as dealing with patent searches, and I really liked the work because I was always at the receiving end of the latest technology and every day was new. There was so much that I could relate to and so much to be witness to. There are the challenges of understanding the latest technology from the inventor(s), and then being able to start advising on the technology - how to protect it in the best way. That was very inspiring for me.

There are also personal advantages – it is nice to work together, I and my husband, and we could travel together for work.

A large part of the rewarding experience for me was really helping the clients with their intellectual assets – protection and building value.

> "If you want to do something then step out of your comfort zone!"

Can you offer advice from your experience?

I feel that sometimes people come across opportunities which are different to what we are trained for or that we've been doing but we fall in a comfort zone. We may find that we've lost interest, but we don't want to leave that comfort zone and then we miss out or we don't grab the opportunity. So, if possible, if you're financially able and your other commitments allow you to step out and take such opportunities, particularly if it's something you're passionate about or something different, then do it!

It takes a little while and there are hurdles along the way, but I think it's very rewarding. So that's a message that I would definitely give to anybody who comes across such an opportunity - if you want to do something then step out of your comfort zone!

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

It was a very long period of learning, especially in the medical field. We do five years of study and then two years of internship; by that time it was really a case of wanting to get out of learning! But I had to start learning again in respect of the IP laws.

Also, a lot of people questioned what I was doing; leaving the medical profession because it's supposed to be the "normal profession" and you're supposed to be helping patients - my colleagues and my family were quite amazed. But I do feel that I've stayed in touch as a lot of my work relates to pharmaceutical inventions and medical device. The change was right for me and now I help the field in a different way. But it was a challenge to balance that transition and the peer reaction.

Another aspect is, because our firm is a 79-year-old firm, people were used to a certain way of doing things. I've brought about a lot of changes to benefit the firm, including introducing information systems and practices like ISO certification. They weren't particularly happy with me coming in with a little experience in IP and then bringing in the management aspect of it, which added challenges. But then they began to see the value this was adding to their hard work and expertise, and what these recommendations and improvements led to. So it became quite nice and now people understand what I'm doing and they respect it. I have much more cooperation now; people look forward to what's coming.

They used to think that I was bossing around just because I happened to be the principal's wife, so I had to prove to them that I wasn't just doing that because I happened to be his wife but I'm doing it because I have researched, am passionate and want to create a better work environment as well as a better client experience. I belong to a business family and know how things run and how things could be improved.

> "We are asking for equal rights and we want to be treated equally but we're also expecting special treatment by creating a meeting for just women."

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

One of the major things was getting one of our largest clients signed up – they are an Indian conglomerate. I got introduced to them at a conference and that led to signing them up and now we've been working with them for many years. I handled their work and then all of their other subsidiary companies were added on to the firm as clients.

Before 2009, we weren't on the international scene very much; we were a very largely domestic firm and with only a few international clients who really wanted a good Indian attorney (we didn't meet them through conferences, they actually came to India and did research and came to us). We wanted more international clients to benefit from our expertise. So, we took the initiative to start attending several international conferences. It helped in understanding the working of our peers from various jurisdictions, learning about best practices in different countries and offered great networking opportunities. I think that I've been instrumental in developing that part for the firm's practice. Before that we had a good reputation in India, so building the international reputation that we have now is a great achievement.

We are now ranked by several publications and we're almost in the top tier in all. We were doing very good work but I realized that just doing good work is not enough; you also need to tell and show people that you're doing that work. I think I've been instrumental in that.

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

For the firm, we feel that we're ready to go to the next level and expand what we are already doing. We do have a great client base now but we would like to work more for international clients. India is becoming a hub for IP activity and we are experienced in multi-jurisdictional filings for our domestic clients. We're one of the major Indian firms who file in multiple countries for trademarks and patents and have been handling litigation for all domestic clients in multiple countries as well. I think that because

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I think the most important part is appreciating yourself; whatever you're doing, whatever percentage of time or whatever level of success you have in one sector or another of your life, it's OK!

we have such experience in dealing with every aspect of IP in so many countries, in 97+ countries, I am extending these services of managing complete worldwide IP portfolio to more foreign companies. We are already doing that for some clients; even our US clients are using us as a primary attorney and we do their primary filings and then go all around the world for them. That's an area that I'd like to expand.

On the personal front, I'd like to spend more time gardening and painting. I don't give these passions as much time as I would like to, so I'd like to do that. During COVID, having to work from home, I set up an art corner for myself so I've been able to paint again and I hope to continue doing so.

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

To be honest, I feel that women have been doing very good work in IP and more and more I see that they are holding prominent positions and are being taken more seriously. Women may have some limitations, but everyone has limitations.

I would really like to see, just like in our firm, equity in the way people are perceived and valued including equal they are holding and based on their qualifications, their experience, their attitude, their productivity - never to do with their race or gender or difference. But I have come across and heard of inequity in different jurisdictions, where designations and pay can be different and that's not a good model. Things shouldn't be based on race or gender or any form of difference. And it's not just about the formal qualification and experience, it's about productivity, attitude, commitment - there needs to be some impartiality there and not based on other factors and that's what I'd like to see in all sectors.

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

There are many International Organizations, for example INTA, AIPPI, APAA, that organize "women in IP" meetings. Sometimes I feel that these are, and I'm a very big feminist, counter-intuitive. We are asking for equal rights and we want to be treated equally but we're also expecting special treatment by creating a meeting for just women. I understand that young practitioners need role models and these initiatives are good for providing mentors and support but I do feel that we could work on a different approach. Perhaps a sector for young practitioners, perhaps different types of groups and better integrated groups rather than increasing the separation by suggesting that we need special treatment by making a group just for women. I find a dichotomy in that approach, that we say we want equality but we also want our own meeting.

There should be more sharing of women's stories where, like this interview, people can read about more and more women doing well and how they've built their business and showing that it's possible for them to run a firm/ organization. I think these can really help in promoting this good and responsible work that we need to be doing.

I think IP is a great career for women because it does provide some flexibility for time to be given elsewhere, with family for example. Of course, there are deadlines, but you can still organize yourself around those. I think working women often beat themselves up a lot saying, "well I've not done this, I've not done that". We want a perfect balance between work and home and family, but with my experience there is no perfect balance - it's what works for you! Maybe it'll be in one direction today and tomorrow it will be in a different direction, but I think learning to live with that and appreciating yourself is very important. I think the most important part is appreciating yourself; whatever you're doing, whatever percentage of time or whatever level of success you have in one sector or another of your life, it's OK! It doesn't need to be that perfect balance between everything that you're doing. I think that's a very important aspect to give us strength and hopefully more women will understand that and not get upset if things aren't doing well in one particular area at all times. I see lots of people take extended leave or maybe even resign and stay at home because we ask too much of ourselves; we shouldn't expect ourselves to be able to work full time and be able to manage our home and have everything perfect all the time. It is very important learning to me that it doesn't have to be perfect, everybody's life is different and we have to be content and happy with whatever we're doing whatever way we view the balance.

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LAW FIRM RANKINGS 2022

The Middle East and Africa

A comprehensive list of the 10 most well-respected law firms from the Middle East and Africa

The Patent Lawyer Magazine
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 Middle East and Africa, 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.

Egypt

Abu Ghazaleh Intellectual Property
Baianat IP
Cedar White Bradley
Eldib & Co
Helmy Hamza & Partners (Baker McKenzie)
Ibrachy & Dermarkar
Maddock & Bright IP Law Office
NAL & Partners
Saba IP
Shalakany

Israel

Cohn de Vries Stadler & Co
Ehrlich Group
Eitan Mehulal Sadot
Gilat Bareket & Co
Liad Whatstein & Co
Luthi + Webb / Webb + Co
Meitar Law Offices
Pearl Cohen Zedek Latzer Baratz
S. Horowitz & Co
Soroker Agmon Nordman

Kenya

Begi's Law Office & Chambers
Bowmans (Coulson Harney LLP)
Clay & Associates Advocates
Dentons Hamilton Harrison & Mathews
ENSafrica
Gikera & Vadgama Avocates
Iseme, Kamau & Maema Advocates(IKM) (DLA Piper Africa)
Kaplan & Stratton
Ong'anya Ombo Advocates LLP
Simba & Simba

Morocco

Abu-Ghazaleh Intellectual Property (AGIP)
Baianat IP
Bakouchi & Habachi - HB Law Firm LLP
Ceader White Bradley
CMS Francis Lefebvre Maroc
IB for IP
Kettani Law Firm
NJQ & Associates
Saba IP
United Trademark & Patent Services

Lebanon

Abu-Ghazaleh Intellectual Property (AGIP)
Alem & Associates
Baianat IP
Cedar White Bradley
Nasser & Associates Law Office
Obeid Law Firm
Raphaël & Associés
Saba IP
Sader & Associates
United Trademark & Patent Services

South Africa

Adams & Adams
Brian Bacon Inc.
ENSafrica
Hahn & Hahn Inc.
KISCH IP
Rademeyer Attorneys
Smit & Van Wyk
Spoor & Fisher
Von Seidels
Webber Wentzel

Nigeria

Aluko & Oyebode
ÆLEX
Allan & Ogunkeye
Banwo & Ighodalo
F. A. Garrick & Co
G. Elias & co
Jackson Etti & Edu
Olajide Oyewole LLP (DLA Piper Africa)
Olaniwun Ajayi
Stillwaters Law Firm

Tanzania

A&K Tanzania
ABC Attorneys
Alin Law Care
Bowmans
Eden Law Chambers
ENSafrica
FB Attorneys
Lexglobe IP Services
IMMMA Advocates (DLA Piper Africa)
NexLaw Advocates

Saudi Arabia

Abu-Ghazaleh Intellectual Property
AlDhabaan & Partners
Al Ajaleen Law & Intellectual Property
Al Hadaf Marks Services LLC (Saba IP)
Al Tamimi & Company
Al-Otaishan Intellectual Proeprty & Technology (AIP&T)
Baianat IP
Cedar White Bradley
Clyde & Co
Kadasa IP

Tunisia

Abu-Ghazaleh Intellectual Property (AGIP)
Achour Law Firm
Baianat IP
Berraies Lawfirm
Cedar White Bradley
Eversheds Sutherland El Heni
Gide Loyrette Nouel
JurisMed
Kammoun Kallel Avocats & Conseils
SMAS Intellectual Property

UAE

Abu-Ghazaleh Intellectual Property
Al Tamimi & Company
Baianat IP
Bird & Bird (MEA)
BSA Ahmad Bin Hezeem & Associates
Cedar White Bradley
Clyde & Co
Gowling WLG
Rouse
Saba IP

Challenges and opportunities in protecting IP in a deep tech startup

Andrew White & Anna Gregson, Partners at Mathys & Squire, discuss the importance of protecting IP as an asset, even years before commercial use, in one of the largest growth opportunity markets.

Deep tech is a term most frequently used in the investment community and tends to refer to businesses that are very research & development (R&D) intensive, using innovative and emerging technologies to solve a particular problem. Deep tech commonly refers to technologies such as advanced materials, synthetic biology, artificial intelligence (AI), or quantum technologies, although many deep tech startups today are combining these technologies – for example where AI and synthetic biology intersect, with 96% of deep tech ventures using at least two technologies. Deep tech companies are therefore very IP-rich, with about 70% of such ventures owning patents related to their products or services.[1]

Deep tech is being seen increasingly as a massive growth opportunity. As shown in figure 1, the amount of capital put into this space has grown fourfold, from $15bn in 2016, to more than $60bn in 2020, and it is estimated that deep tech investments will grow to about $140bn by 2025,[2] with investment in AI and synthetic biology attracting two-thirds of deep tech investment last year.[3]

About 83% of deep tech ventures involve designing and building a physical product. Their digital proficiency is focused on using artificial intelligence, machine learning and advanced computation to explore frontiers in physics, chemistry, and biology.[4]

Deep tech companies are likely to be disruptors; incumbent companies, particularly in industries

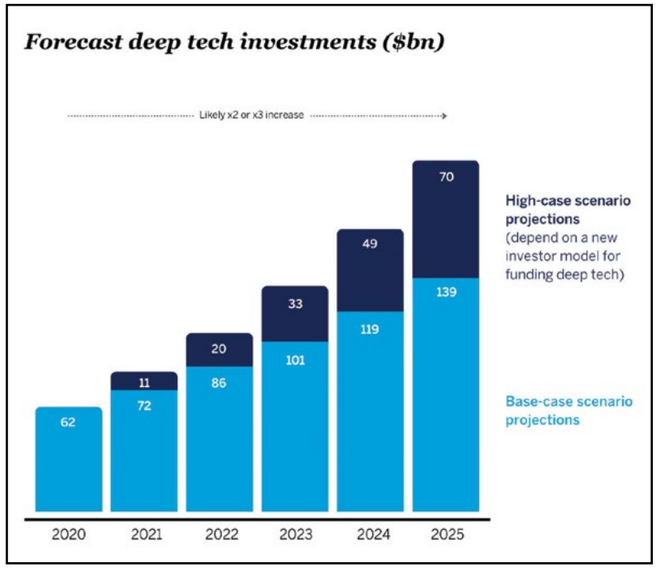

Figure 1 (Data taken from https://www.bcg.com/publications/2021/overcoming-challenges-investing-in-digital-technology)

1 https://www.bcg.com/publications/2021/overcoming-challenges-investing-in-digital-technology
2 https://www.bcg.com/publications/2021/overcoming-challenges-investing-in-digital-technology
3 https://www.bcg.com/publications/2021/overcoming-challenges-investing-in-digital-technology
4 https://www.bcg.com/publications/2021/overcoming-challenges-investing-in-digital-technology

Deep tech investment success stories

Unicorn company	Est. total private investments ($M) at 09.04.21	Est. valuation ($bn)	Valuation year	Sector
Impossible Foods	1500	10	2021*	Plant-based meat
Indigo AG	1200	3.5	2020	Agritech microbiology
Lilium	1200	3.3	2021	Electric aviation
ChargePoint	885	2.4	2020	Electric charging stations
Sila Nanotechnologies	875	3.3	2021	Energy storage materials
Zymergen	875	3	2021	Biomanufacturing
Ginkgo Bioworks	800	16	2021*	Biofoundry
QuantumScape	800	3.3	2020	Energy storage
Desktop Metal	712	2.5	2020	3D metal printing
Graphcore	710	2.8	2020	Cellular agriculture

Figure 2 (Data taken from https://www.bcg.com/publications/2021/overcoming-challenges-investing-in-digital-technology)

like energy, chemicals, and agriculture, will probably be disrupted by deep tech if they don't engage with this community soon.

As can be seen in the figure 2, deep tech companies can also be extremely lucrative, with companies such as Impossible Foods being valued at around $10bn this year.

Pushing technological frontiers

Deep tech has the potential to reinvigorate established sectors, such as drug R&D, where costs to develop a new drug have doubled each decade for the last 70 years.[5] By providing opportunities to apply tools and principles such as network data science and deep learning to overcome the 'biology bottleneck', deep tech has the potential to significantly reduce costs in drug development.

Deep tech also opens the commercial potential of newer sectors, such as synthetic biology, where the confluence of developments in IT, systems theory and biology enables synthetic biology to move beyond the laboratory into commercial use. Despite the emergent nature of synthetic biology, there are already examples demonstrating its scope and disruptive potential, such as designer bacteria capable of producing as diverse materials as precursors for anti-malarials, to spider silk proteins, biologically based logic gates and synthetic organelles.

Why do you need to protect your IP?

Because of their IP-rich and R&D heavy nature, it may be many years before a deep tech startup successfully commercialises its innovation and emerges from the infamous 'valley of death'. IP may be the only real asset a deep tech startup has for a number of years, so protecting that IP and developing an effective IP strategy is therefore critical to its success.

Andrew White

Anna Gregson

Investors recognise this and many will want to see a robust IP strategy in place before investing. Deep tech startups need to engage with IP early and often, developing their own IP pipeline (including patents, trade secrets and other relevant IP) and also considering third party IP and freedom-to-operate. Particularly for products where lead times can be long, such as for new drugs that require regulatory approval, a strong pipeline with downstream IP is vital.

Exit strategy

Depending on its business goals, effectively protecting IP can dramatically affect the exit of a deep tech startup. For example, building up a strong and effective IP portfolio can drastically increase the value of the business, whether the exit is via acquisition or IPO. This may yield a higher return on investment for those early-stage investors, as well as the founding team. In the longer term, for many deep tech startups, a strong IP portfolio is also essential because they may be entering and disrupting a crowded and well-established market. Without strong IP in place, they may not be able to survive. If a startup has patents of their own, these can be used defensively; if sued by a well-established competitor, having patent rights of your own can present you with the option to cross-license rather than engage in costly and time-consuming litigation.

[5] Diagnosing the decline in pharmaceutical R&D efficiency | Nature Reviews Drug Discovery

To patent or to keep secret?

A common question faced by many deep tech startups is whether to patent at all, or whether to keep their innovation secret in the form of a trade secret. For many, the question comes down to whether a third party is able to reverse-engineer or take apart their innovation and determine how it works. For example, can a user of a software platform understand how an AI algorithm works if all the user does is send some data to a cloud platform, and receive some answers in return? In such cases an effective trade secret policy may be sufficient. One benefit of a trade secret policy is that it doesn't have to cost lots of money, and it can last indefinitely, provided the secret can be kept. The obvious downsides are that there may be leakage of your trade secrets over time, and by keeping your innovation a secret it doesn't prevent a third party independently inventing and then patenting their own solution which may in turn limit your ability to work your invention, even if you had been using it prior to their patent filing.

Advantages of a patent are that it encourages investment, collaboration, and joint development work, as the patent holder can freely disclose their invention in the knowledge that they are

Résumés

Andrew White, UK & European Patent Attorney, Partner

Andrew is a partner in the Mathys & Squire IT & engineering team. He manages international portfolios in the medtech, software, telecoms, and automotive fields, and has particular expertise in advising clients on the patentability of Computer Implemented Inventions (in fields such as bioinformatics, AI and blockchain inventions). Andrew advises clients, particularly tech startup and scaleup businesses, on how to successfully navigate the patentability exceptions in these areas, both in Europe and abroad, to obtain patents of commercially valuable scope. Andrew is recommended as "an exceptional patent attorney" in *The Legal 500* and is ranked in *IAM Patent 1000* for being a "trusted mentor to startups".

Anna Gregson, UK & European Patent Attorney, Partner

Anna is a partner in the Mathys & Squire life sciences team, working with a diverse range of clients, particularly startups and spin-outs. She has extensive experience across the biotechnology space, being particularly noted for her expertise in advanced therapeutics (including stem cells, CAR T cells and gene therapies), as well as antibodies, agri-tech and synthetic biology. Anna's commercial focus allows her to support her clients in generating robust patent estates, as well as navigating issues of third party rights and freedom to operate in what are often crowded and complex IP landscapes.

protected by the patent. Patents can also be an indicator of both ownership and technical credibility; they can be used to convince investors that you own the technology that you say you do and that what you are working on is truly innovative.

Partnerships with bigger players

By virtue of their complex and cross-disciplinary nature, many deep tech startups must collaborate to implement their solutions. This presents its own set of challenges and opportunities. For example, the ownership of any resulting IP (often referred to as foreground IP) needs to be established, and for many collaborators they will want a share in this foreground IP. This presents a challenge to the startup who may consider that they hold much of the original (background) IP that attracted the collaborator in the first place.

Deep tech startups should therefore be mindful not only to negotiate a strong and effective IP agreement, but should also consider filing patents before any work begins as part of the collaboration. Filing IP beforehand means it can be pushed into the background IP and therefore the startup can retain ownership of more of the IP in the space.

As with any field, deep tech startups should also be using non-disclosure agreements (NDAs) whenever they discuss any elements of the technology with a third party. However, even if you have an NDA, they are notoriously difficult to enforce and once your idea becomes public it can be very difficult to retain ownership of the innovation. Therefore, if a patent application can be filed even before discussions under an NDA have taken place, this will strengthen your IP position.

> **A common question faced by many deep tech startups is whether to patent at all, or whether to keep their innovation secret in the form of a trade secret.**

Opportunities and challenges

It therefore appears that there are plenty of opportunities for deep tech startups, and the volume of investment pouring in is only set to increase. It is also clear that startups in the deep tech space need to devise and implement a truly effective IP strategy if they are to survive and be successful.

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Jurisdictional briefing: important developments at the Eurasian Patent Office and a new President-elect of EAPO

Résumés

Ms. Bairta Tserenova
Ms. Bairta Tserenova is a Patent Attorney of the Russian Federation and Eurasian Patent Attorney at Vakhnina and Partners. Bairta recently passed a new certification of EAPO to be qualified for Eurasian Industrial Designs.

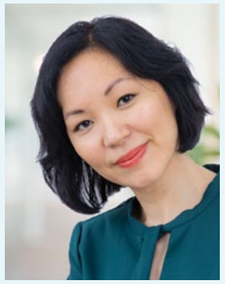
She is an active member of a number of Russian and International IP Organizations and professional community of Patent Attorneys in Russia.

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

Having PhD in Medicine (Biochemistry), while working on patent matters, Alexey specializes in Medicine, Biotechnology, Biochemistry, Pharmacology, Pharmaceuticals.

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

Bairta Tserenova and Dr. Alexey Vakhnin, Russia patent specialists of Vakhnina and Partners, provide an update on patent developments in Russia to bring you up to speed.



Bairta Tserenova

Dr. Alexey Vakhnin

Important developments at the Eurasian Patent Office (EAPO)

After several years of negotiations and adjustment of national legislations, the system of registration of Eurasian Industrial Designs in EAPO has been launched in 2021.

After the EAPO Industrial Designs legislation has been introduced, the Eurasian Patent System allows to obtain legal protection for industrial designs in Eurasian countries, namely: Russian Federation, Republic of Azerbaijan, Republic of Armenia, Republic of Kazakhstan, Republic of Kyrgyzstan and, since November 30, 2021, Republic of Tajikistan.

The priority right for a Eurasian Industrial Design can be claimed according to the Paris Convention.

In order to file an Industrial Design application within the EAPO the foreign individuals or companies (not residents of EAPO member states), will need to assign a representative – a Eurasian Patent Attorney with the qualification in Industrial designs.

With the introduction of the protection of Eurasian Designs, earlier this year EAPO announced the qualification examinations of candidates for Eurasian Patent Attorneys in the specialization "industrial designs". To be admitted to the examination, a candidate should have a status of a Patent Attorney in the area of Industrial Designs, qualified and confirmed by one of EAPO member-states. Being admitted to the examination, the candidate has to pass the test of the knowledge of Eurasian Industrial designs matters.

Our colleague, Ms. Bairta Tserenova, Eurasian Patent Attorney of Vakhnina and Partners, is one of the Eurasian Patent Attorneys who recently received the additional qualification for EAPO Designs.

It is also worth mentioning another useful possibility for Applicants added along with the introduction of Eurasian Designs regulations: since December 1, 2021, EAPO provides the possibility to use the Digital Access Service to refer to the priority documents of World Intellectual Property Organization (WIPO DAS). While claiming the priority on a Eurasian Industrial Design application, the service provides the WIPO DAS access code to this application within the EAPO instead of providing a certified copy of priority application.

The very first Eurasian Design

On October 25, 2021, EAPO has published a Eurasian Design patent number 000001, owned by the Russian Federation, represented by the State Corporation "ROSCOSMOS" which is in charge of overseeing and implementing a comprehensive reform and further development of the Russian Space industry.

This moment marked the beginning of Eurasian Designs, and we expect there are more patents to come. Vakhnina and Partners is always glad to advise on all matters of registration and protection of new Eurasian Industrial Designs and answer all questions of the applicants.

About EAPO

Eurasian Patent Organization (EAPO) is a regional IP organization established on 9 September 1994.

Eurasian Patent system allows obtaining legal protection for inventions and, recently introduced, designs in the countries of the region. Eurasian patents can provide protection on the territory of all participant states.

Applicants typically find it more efficient and reliable to prosecute applications and maintain their patents in force by interacting with the single Patent Office. Prosecution of a patent application in EAPO can be also more cost-efficient as it reduces applicants' expenses related to the prosecution, including patent attorneys service fees, translation expenses and official fees.

EAPO member states are Russian Federation, Republic of Azerbaijan, Republic of Armenia, Republic of Belarus, Republic of Kazakhstan, Republic of Tajikistan, Republic of Kyrgyzstan and Republic of Turkmenistan.

> **"Elections for the next EAPO President were recently held, and the candidate from the Russian Federation, Dr. Grigory Ivliev, was elected to this post."**

New President-elect of EAPO

In February 2022 Dr. Saule Tlevlesova, President of the Eurasian Patent Office (EAPO), leaves her post which she has held for the last six years. During EAPO presidency of Dr. Tlevlesova, a great number of developments of EAPO took place, the number of patent applications filed to EAPO significantly increased, and the EAPO Industrial Designs legislation was introduced to the Eurasian Patent Organization.

Elections for the next EAPO President were recently held, and the candidate from the Russian Federation, Dr. Grigory Ivliev, was elected to this post. At the moment he is heading the Russian Patent Office (Rospatent), and he is going to take the EAPO President appointment in February 2022.

Dr. Ivliev's experience and active involvement into implementation of modern mechanisms of prosecution of IP matters significantly improved internal processes at Rospatent. During the period when Dr. Ivliev has been the head of the Patent Office of the Russian Federation, new levels of quality and efficiency of the examination were achieved, and it is believed that his knowledge will also be called for with his joining the Eurasian Patent Office.

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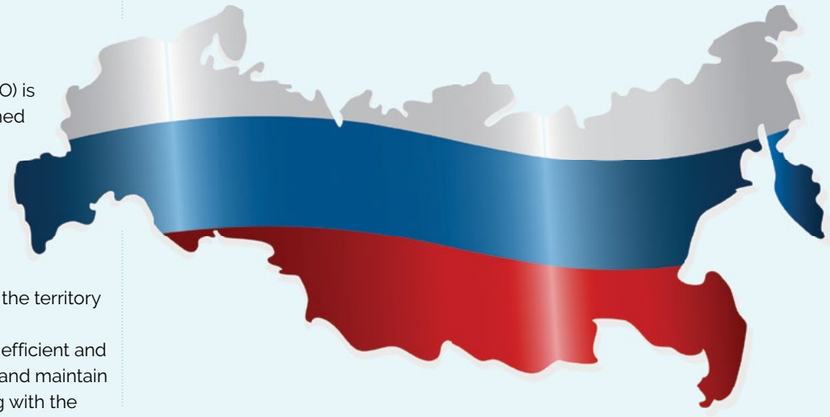
+7 (495) 231-4840
ip@vakhnina.ru
www.vakhnina.ru



Unicolors v. H&M Hennes & Mauritz: a copyright dispute

Bill Frankel & Preetha Chakrabarti, Partners at Crowell & Moring, review the case with thoughts as to how the outcome may affect future copyright disputes.

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A copyright dispute originating in 2016 made its way to the U.S. Supreme Court last fall, with the Court hearing oral argument in *Unicolors v. H&M Hennes & Mauritz* on November 8, 2021. Unicolors, a fabric design company, had sued H&M for copyright infringement, accusing the fast fashion retailer of copying its copyrighted designs without authorization. H&M contended that Unicolors' copyright registration was defective – and therefore unenforceable – because it had improperly bundled both published and unpublished fabric designs in one copyright registration. After the Ninth Circuit sided with H&M on the level of knowledge required when making representations to the Copyright Office, Unicolors sought relief from the Supreme Court.

Unicolors initially asked the Court to determine whether "[t]he Ninth Circuit err[ed] in breaking with its own prior precedent and the findings of other circuits and the Copyright Office in holding that 17 U.S.C. § 411(b) requires referral to the Copyright Office where there is no indicia of fraud or material error as to the work at issue in the subject copyright registration," but slightly modified its question in its merits brief to ask "whether that 'knowledge' element precludes a challenge to a registration where the inaccuracy resulted from the applicant's good-faith misunderstanding of a principle of copyright law."

The Justices seemed inclined to agree with Unicolors and the U.S. Government that Section 411(b) should be read as requiring reasonable and actual knowledge, not merely constructive knowledge, of an inaccuracy in a copyright application to result in invalidity and unenforceability. Counsel and the Court noted that "information" pertaining to copyright includes a variety of factual questions as well as legal conclusions, including whether a work is a "work made for hire," a "compilation," or "derivative work," how the claimant obtained ownership of the copyright, and, principally, the thorny question of "publication." The Justices generally appeared sympathetic to the notion that authors and artists often complete their own copyright applications, and that Section 411(b) should not be implicated, or copyrights held invalid and unenforceable, where the allegedly inaccurate information is an innocent mischaracterization of a fact or an innocent misapplication of the law.

If the Court reverses in favor of Unicolors, it could set a higher bar for proving that a copyright owner had actual knowledge of an inaccuracy, perhaps requiring an intent to deceive the Copyright Office with material and inaccurate information, similar to the approach taken in the patent law.

If the Court upholds the ruling in favor of H&M, copyright registrants with inaccuracies in their copyright registrations may suffer harsh consequences. For one, they may need to re-

darksoul72 / Shutterstock.com

Bill Frankel

Preetha Chakrabarti

> **"If the Court upholds the ruling in favor of H&M, copyright registrants with inaccuracies in their copyright registrations may suffer harsh consequences."**

Résumés

Bill Frankel, Partner

Bill is a partner in Crowell & Moring's Chicago office, and is co-chair of the firm's Patent and ITC Litigation Practice Group. Bill's litigation practice includes patent, trademark, copyright, trade secrets and unfair competition litigation. He also assists clients with evaluating, protecting, procuring, and transferring IP rights.

Preetha Chakrabarti, Partner

Preetha is a partner in Crowell & Moring's New York office and is a member of the firm's Technology & Brand Protection Group within the firm's Technology & Intellectual Property Department.s Preetha's practice consists primarily of litigation, counseling, and prosecution. Her patent and trademark litigation work includes proceedings in front of the Trademark Trial and Appeal Board (TTAB) and involves various industries, from chemicals to pharmaceutical, biotech, software, apparel, fashion, retail, luxury, beauty, and wearable technology. Preetha also performs due diligence relating to intellectual property issues in corporate transactions and assists clients with trademark clearance and the filing of trademark and patent applications with the U.S. Patent and Trademark Office (USPTO). In particular, Preetha advises clients in the retail and fashion industries on how best to manage risks when using and developing intellectual property. Preetha also has experience with administrative law, particularly in the environmental context, including analysis of regulatory issues arising under the Administrative Procedure Act, TSCA, FIFRA, CERCLA, the Federal Food, Drug and Cosmetic Act (FFDCA), and various federal and state environmental laws.

Copyright owners are advised to seek the advice of experienced copyright counsel to insure the best chance of success.

file incorrect applications for registration of their works, which could result in a forfeiture of statutory damages and attorneys' fees. Also, a decision requiring courts to refer disputes to the Copyright Office on demand by accused infringers, without a showing of some scienter, could further burden the Copyright Office – all the while making copyright enforcement more costly and difficult.

Although Justices Sotomayor and Alito acknowledged that copyright trolls might be encouraged if they can easily brush aside mistakes in asserted copyright registrations as "innocent" or based on "misunderstanding of the law" – a concern voiced by H&M – Justice Breyer downplayed the concern, noting that sophisticated litigation trolls likely would be less inclined to make mistakes in copyright applications.

This case highlights the reality that filing a copyright application may require nuanced legal determinations to ensure that the information supplied to the Copyright Office is accurate. Given the government's alignment with Unicolors and the current Copyright Office's general inclination to avoid too much formality, it is likely that the Court will reverse the Ninth Circuit's ruling and side with Unicolors. While this would be frustrating for those beleaguered by copyright trolls, it would be encouraging for artists and designers who rely on copyright registrations to protect their rights and who do not always have the means to hire counsel to ensure that their applications are legally and factually perfect. Regardless of how the Court rules, copyright owners are advised to seek the advice of experienced copyright counsel to insure the best chance of success against validity challenges down the road.

Contact
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How is inventive step determined?

DPS Parmar, Special Counsel of LexOrbis, explains the process of inventive step determination and non-obviousness in India with case examples and analysis from the IPAB.

Patent law requires determination of inventive step as a mandatory step for grant of a patent. Even during opposition to grant or in the patent invalidation proceedings determination of inventive step is essential to resolve the dispute between the contesting parties. But what legal parameters this determination exactly requires is not easy to understand. Various theoretical and legal premises are set up to arrive at the inventive step of any invention patented or otherwise. For a layman inventive means anything which is done for the first time, and it is the result of the addition of a new idea to the existing knowledge. In 1997, Lord Hoffmann gave an excellent overview of the inventive step in *Biogen Inc v Medeva plc [1997 RPC 1 at 34]* where he observed that:

> "Whenever anything inventive is done for the first time it is the result of the addition of a new idea to the existing stock of knowledge. Sometimes, it is the idea of using established techniques to do something which no one had previously thought of doing. In that case the inventive idea will be doing the new thing. Sometimes it is finding a way of doing something which people had wanted to do but could not think how. The inventive idea would be the way of achieving the goal. In yet other cases, many people may have a general idea of how they might achieve a goal but not know how to solve a particular problem which stands in their way. If someone devises a way of solving the problem, his inventive step will be that solution, but not the goal itself or the general method of achieving it."

This overview set the tone of how the legislature would codify the legal definition of the inventive step for the purposes of the patent law. It may be worthwhile to note that invention

DPS Parmar

Résumé

Mr. DPS Parmar, Former Technical Member (Patents), erstwhile Intellectual Property Appellate Board; Special Counsel, LexOrbis

Mr. D.P.S Parmar heads the Patents Contentious Practice Group at LexOrbis. After joining the IPAB as Technical Member (Patents) in 2011, he has been instrumental in writing some path breaking and insightful decisions on Indian patent law issues. These include establishing legal positions on excluded subject matter under Section 3(d), 3(i) and 3(k), divisional applications, disclosure requirements under Section 8, working statements and compulsory license, to name a few. Before joining IPAB, Mr. Parmar worked with the Indian Patent Office (IPO) for over 27 years and played a vital role both at the administrative and policy levels. He represented India at various rounds of discussions organized by the World Intellectual Property Organization (WIPO) and attended follow-on programs at the European and Japanese Patent Offices. He was instrumental in the recognition of IPO as the 15th ISA and IPEA under the Patent Cooperation Treaty (PCT). He also served as the head of the Intellectual Property Training Institute (IPTI) in Nagpur, which was responsible for providing training to new examiners at the IPO.

“There is no definition of what is obvious and indeed there cannot be, since it depends on the time of the invention, the state of the art at the time of the invention, what was commonly known at that time and above all the invention itself.”

is not defined in any patent law in absolute term. The definition of invention is linked to the relative terms like novelty, inventive step/ obviousness, and industrial applicability. When we look at the patent law in India as amended post 2002, we find that inventive step determination is mandatory duty of the examiner in view of section 2(1) (ja). In 2005, Section 2(1) (ja) was inserted which provided the following definition: ““Inventive step” means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.” This definition perhaps reflects the ruling of Supreme court in *Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries (AIR 1982 SC 1444)* where the court observed that:

> “4. In order to be patentable, **an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop ‘improvement, and must independently satisfy the test of invention or an inventive step**. It must **produce a new result**, or a **new article or a better or cheaper article than before**. The new subject matter must involve “invention” over what is old. Mere collocation of more than one, integers or things, not involving the exercise of any inventive faculty does not qualify for the grant of a patent. [763 H, 764 AB].

This definition provides certain general clues for the examiner on how to determine the inventive step, but it requires a deep understanding of the inventive concept to arrive at the inventive core of the invention which is the essential part of the claimed invention. The examiner should also consider whether the invention as claimed produces a new result, or a new article, or a better or cheaper article than before as observed by the Supreme court in Bishwanath case referred to above.

IPAB on inventive step / obviousness

IPAB has dealt with obviousness in many cases. In *Enercon vs Aloys Wobben [Order No. 123 of 2013]* IPAB observed that:

> “Obviousness has been accepted to be a statement of policy. There is no definition of what is obvious and indeed there cannot be, since it depends on the time of the invention, the state of the art at the time of the invention, what was commonly known at that time and above all the invention itself. **So the ‘jump test’ cannot be the same for a chemical invention and the invention of a super door-knob.”** [para 42]

In para 43 of same IPAB also gave opinion on obviousness in relation to existence of prior art which states that, “the mere existence in the prior arts, of each of the elements in the invention, will not *ipso facto* mean obviousness. For after all most inventions are built with prior known puzzle-pieces. There must be a coherent thread leading from the prior arts to the invention, the tracing of the thread must be an act which follows obviously”.

This obviously means that if the alleged invention lies so much out of the track of what was known before as not naturally to suggest itself to a person thinking on the subject, it must not be the obvious or natural suggestion of what was previously known.

Linking obviousness to reasonable expectation of success

In some cases, obvious determination is linked to obviousness to try for reasonable expectation of success. In Enercon case, referred to above, IPAB explains that the “coherent thread leading from the prior art to the obviousness” or in other words, “the reasonable expectation of success embedded in the prior art which motivates the skilled person to reach to the invention, is the most crucial determining factor in ascertaining inventive step”. Not surprisingly, in *Becton Dickinson And Company Vs Controller Of Patents & Designs, [280-2012],* [Para 32] IPAB curiously observed that “Obviousness cannot be avoided simply by showing of some degree of unpredictability in the art so long as there was a reasonable probability of success”. In another ruling in *Ajanta Pharma Limited vs Allergan Inc., [No.172 of 2013]* [Para 93] IPAB categorically said that “Obviousness does not require absolute predictability of success. All that is required is a reasonable expectation of success”.

Steps involved in determination of inventive step

Curiously, every invention adds new ideas to the existing knowledge and the first step for determination of an inventive step is finding the prior art in the field of the invention. Then, compare the exiting knowledge with the additional knowledge contained in the inventive idea developed by the inventor. According to section 2(1) (Ja), compare that feature of the invention that involves technical advancement to the existing knowledge and ascertain that which makes the claimed invention not obvious to a person skilled in the art. These criteria of inventive step add more complexity to the process of its determination. It poses another question of who should be considered as a person skilled in the art (POSITA or PSITA). The patent law is silent on this, but the MOPO gives guidelines in para 08.03.03.02 of MOPO 2011, how to arrive at the inventive step:

> “Determination of inventive step
>
> a) For determination of inventive step, all or any of the prior art(s) revealed during the search process to perform an enquiry as to whether such prior art(s) disclose(s) the claimed invention, are relied upon.
>
> b) Publications existing on the date of filing of complete specification would be considered as a prior art.
>
> c) However, Indian Applications filed before but published on or after the date of filing of complete specification of the instant application are considered as a prior claiming.
>
> d) Invention as a whole shall be considered. In other words, it is not sufficient to draw the conclusion that a claimed invention is obvious merely because individual parts of the claim taken separately are known or might be found to be obvious.
>
> e) If an invention lies merely in verifying the previous predictions, without substantially adding anything for technical advancement or economic significance in the art, the inventive step is lacking.
>
> f) For the purpose of establishing obviousness of the invention, citing a mosaic of prior arts is permissible, provided such prior art is enabling.
>
> g) If the invention is predictable based on the available prior art, merely requiring workshop improvement by a person skilled in the art, the inventive step is lacking.”

The steps from (a) to (g) in fact reflects over all position of the judicial precedent set in patent law jurisdictions in India and elsewhere. Again, in para 8.9 of the MOPO 2016 a method for objectively analyzing the inventive step is also given which guides examiners to:

“The question of obviousness must be considered on the facts of each case.”

These guiding principles no doubt help the examiner in the examination of the patent applications involving improvement over the existing prior art.

"a) Identify the inventive concept of the claim in question.

b) Identify the "person skilled in the art".

c) Identify the relevant common general knowledge of the person skilled in the art at the priority date.

d) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim.

e) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of inventive ingenuity?"

Supreme court on inventive step

The key case in the Indian context relating to inventive step, and which has been regularly applied in opposition and revocation cases under the Patent law, is *Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries (AIR 1982 SC 1444)*, where Hon'ble Supreme Court expressed opinion on inventive step stating that:

> "The expression **"does not involve any inventive step"** used in Section 26(1) (a) of the Act and its equivalent word "obvious", have acquired special significance in the terminology of Patent Law. The 'obviousness' has to be strictly and objectively judged. For this determination several forms of the question have been suggested. *[Emphasis Added]*

The one suggested by Salmond L. J. in *Rado v. John Tye & Son Ltd.* is apposite. It is:

> "Whether the alleged discovery lies so much out of the Track of what was known before as not naturally to suggest itself to a person thinking on the subject, it must not be the obvious or natural suggestion of what was previously known." [Para25]

Supreme Court in this case categorically asserted that "whether an alleged invention involves novelty and an 'inventive step', **is a mixed question of law and fact**, depending largely on the circumstances of the case."

Assessing obviousness

From the above discussion we must agree that although no absolute test uniformly applicable in all circumstances can be devised, certain broad criteria can be indicated. We find observation of Warren J in *Actavis UK Ltd v Novartis AG [2009] EWHC 41*, quite apt when he stated that:

> "It is in this context always important, in assessing obviousness, as it is with novelty, to bear carefully in mind the statutory words. It is easy to find in the cases words more or less apposite to the facts of the case (e.g., would/could, motive, expectation of success, workshop variants, whether there is a reason for taking the step from the prior art) to describe how the court has made its decisions, using concepts which cannot be of universal application. Time and time again, the Courts have emphasized that the correct question is that laid down in the statute, namely whether the invention was obvious to the person skilled in the art."

Again in *Conor Medsystems Incorporated v Angiotec Pharmaceuticals Incorporated [2008] RPC 28).* Lord Hoffmann cited with approval the observations of Kitchin J in *Generics v Lundbeck [2007] RPC 32* at 72 in considering how a number of different factors should be taken into account:

> 'The question of obviousness must be considered on the facts of each case. **The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success.**' *[Emphasis Added]*

In deciding the obviousness, the examiner must bear in mind that philosophy behind obviousness "is that it would be wrong to prevent a man from doing something which is merely an obvious extension of what he has been doing or of what was known in the art before the priority date of the patent granted." *[Windsurfing International Inc. v Tabur Marine (Great Britain) Ltd [1985] RPC 59 at page 77]*

Way forward

Although no absolute test uniformly applicable in all circumstances can be devised, certain broad criteria can be indicated through these guiding principles. These guiding principles no doubt help the examiner in the examination of the patent applications involving improvement over the existing prior art. But the decision of whether an invention is inventive or not rests with the examiner. If the examiner decides to ascertain the inventive step, then it requires investigation using an objective test which can be applied to any claim as laid down in the above guidelines read with IPAB and courts decisions. However, this objective test needs to use a specific method that is standardized and structured, rather than impressionistic and general, so that a consistent approach can be taken from case to case. The test is to be decided not on general legal principles, as they only reflect and inform the examiner of a general approach that can be taken, but it should be based on the technical facts of the claims at issue. One must understand that the value of adopting the stepwise approach lies in ensuring that the examiner does not go straight to the question of obviousness by reference to a general impression as to the evidence placed before him through prior art citation. In fact, by adopting a structured approach, the examiner ensures that there is a measure of discipline, reasoning, and method in one's approach. This helps in maintaining consistency of approach in different cases involving the issue of novelty. But this approach is not sufficient in every case to arrive at the decision on patentability if the question of obviousness is involved. It is true that it would be wrong to prevent a man from doing something which is merely an obvious extension of what he has been doing, or of what was known in the art before the priority date of the patent granted, but equally true is that it would be wrong to prevent the grant of a genuine patent improvement citing obviousness as a reason if the claimed invention lies so much out of the track of what was known before as not naturally suggesting itself to a person thinking on the subject, or it is not the obvious or natural suggestion of what was previously known or it produces surprising and unexpected results. It is wise to take an expert opinion to deal with objections raised by the examiner on the grounds of obviousness.

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Diversity, equity, and inclusion with Suzanne Wertheim. Chapter 5: gender bias in law

In this six-part series Dr. Suzanne Wertheim, of Worthwhile Research & Consulting, talks to *The Patent Lawyer* about diversity, equity, and inclusion: what it means; the current challenges; DEI in law; gender bias; and what we can all do to improve.

What has your recent research found about women's experiences in the legal workspace?

My research shows that women's experiences in the law are not good, and really quite parallel to other problems that show up in other white-collar work spaces. In fact, I think gender bias in the law is a bit amplified because of how law firms are structured, how promotions go about, and how work is distributed – work allocation in law firms is just so personal rather than being systematized. Any time you don't have a system and are instead relying on personal connections and personal judgments, it's very, very easy for bias to sneak in. The more that you can be systematic and build "bias interrupters" into decisions involving work allocations and promotions, the more that you can have predetermined criteria, the more equitable your workplace will be.

What I see in legal practice is a whole host of thwarted opportunities and numbers that get thinned out every level you go up. I also see a lot of denial that gender bias exists, let alone that it is pervasive throughout law firms and other legal practices.

This relates to the serious problem of the "perception gap," which we find again and again. For most demographic categories, there is a dominant group and an underrepresented group. And again and again, we will see that the dominant group thinks things are fine while the underrepresented group will tell you that things are really not ok. This is true for gender as well as other demographic categories. I'll give you an example from a few years ago.

In a 2016 survey, the Florida Bar found that fully 29% of the female lawyers who responded had been called 'sweetie' or 'honey' by a male lawyer. That's almost a third! In contrast, less than 1% of men responding had something similar happen. Also in that same survey, while nearly half of all female lawyers said male lawyers get to partner faster, only 12% of male lawyers said that was true. What's more, half of the female lawyers said that they had to work harder than their male counterparts to get to the same level, but only 12% of the male lawyers thought this was the case. So what this survey shows us is: 1) you have pervasive bias, which you can see as a headwind slowing down female lawyers, and 2) there is a perception gap where male lawyers, who dominate the higher levels of law firms, do not believe that this pervasive bias exists. Again, based on my experience, this pervasive gender bias in law seems to be a bit stronger, a bit more entrenched, than in some other fields.

Dr. Suzanne Wertheim

> **I also see a lot of denial that gender bias exists, let alone that it is pervasive throughout law firms and other legal practices.**

I was once brought in to talk to the writing team for a television show called *How to Get Away with Murder*. They invited me to come in and talk to them for a few hours about bias in legal and medical workplaces. I told them, "I'm not sure that you did this purposely, but having a Black woman run her own law firm is exactly on point. Because what happens again and again is that women of color and white women who try to succeed at law firms get pushed down so much that they give up. Even though it's hard to start and run your own practice, even though in principle it is easier to slot into an infrastructure that somebody else has built for you, Black women leave and set up their own practices. Because they are so tired of the biased and unpleasant things that are said to them on a daily basis. And they are so tired of watching good opportunities pass them by and go to other people." They were delighted to hear that they had been spot on. It's actually a quite unrealistic show, they weren't really aiming for realism, but in this respect they were spot on.

Law is still a very traditional profession; how do we work to overcome unconscious gender bias that is so ingrained in the profession?

I'll tell you that in my experience of training, both educating undergrads and in anti-bias training, the topic I find the most resistance to is gender bias. The resistance to believing gender bias is real is almost as pervasive as the many subtle ways gender bias gets openly expressed! For people who haven't experienced it, gender bias can be completely invisible, and so feel unbelievable. They haven't seen it, so how can it be real?

And for many people on the receiving end of gender bias, they know they feel bad, but they don't realize that what's going on is systemic and widespread. I hear about a lot of internalization, thoughts like, 'well, it must be me, something that I'm doing.' I encounter a lot of impostor syndrome. For many, many people, impostor syndrome is a very rational response to ongoing external feedback that tells someone, 'I see you as less than'. If you've had a lifetime of messages saying that you're less than, why wouldn't you get impostor syndrome? And then women with impostor syndrome are told, 'get over it', 'be resilient,' 'have grit.' This again puts the focus on the individual and ignores the systematic factors that created the impostor syndrome and keep it in place. How am I supposed to get over feeling like I don't belong when people consistently give me the message that I'm not good enough for them to hire? Or mentor? Or give credit to? Or promote?

> **It's so pervasive and it can go to a level of what feels like satire, but for some people it's deadly serious.**

I've actually created a training where the whole second half is about gender bias. In my early workshops, I was getting so much resistance that I started bringing in data from transgender people. I brought in stories from people who had transitioned as adults, and so had work experience presenting as different genders. These stories can be summarized as "when I was presenting as this gender I was treated this way, now that I'm presenting as this gender I'm treated really differently." And sometimes men would raise their hands and say, "well couldn't time be playing a role? Like, it's not that he's seen as male now, it's that he got better because it was three years later. So this doesn't feel like gender bias to me." That's how strong the resistance can be. I thought I had controlled for all variables, but they dug in and found that time was another variable, and so obviously (to them, the resistant people) time was the answer for the different treatment, not gender.

So, I went one step further and worked to remove time as a variable as well. I found data where the people's interactions were text-based only. And the only thing that changed was someone's name – sometimes they were perceived as female and at other times they were perceived as male. And depending on their text-only gender presentation, they would either be treated better or worse. In their "male" persona, they would be treated with respect and evaluated well. And even with this water-tight data, where literally the only variable changing is gender – and in text form only! Just a name! – I still found that I needed to give example after example. Piles of examples that show that just being perceived as female skews how some people will negatively evaluate your competency and performance. And then, when you look at the actual performance in the studies, either the man and the woman performed equally well, or the woman did a measurably better job.

Another problem is that gender is such a salient category in the English-speaking world (and elsewhere too, of course). For a long time, everybody's been forced to choose one of two genders, male or female. Two options, choose one, nothing else. Doctors will sometimes take an intersex infant and perform surgery to force a gender on them, without the ability to know their gender identity. Here in the US, it's now common to have "gender reveal" parties, which are really sex reveal parties – they're giving the results of a scan of a fetus's anatomy and nothing more. That baby may end up with a different gender identity. Only time will tell.

We are socialized so strongly when it comes to gender that it's very hard to remove those decades of cultural programming and rethink them. We overlay gender on all kinds of things – food, beverages, colors, clothing, posture. You could tell me right now what's a "girly" drink and what's a "manly" drink. What's a "feminine" scent and what's a "masculine" scent. It's just everywhere.

I'm on social media a lot for research, and I'm subscribed to a subreddit called 'Pointlessly Gendered.' So examples show up on my feed all the time, and even now, after all these years of research, I still find myself surprised at what people put gender on top of. Like recently there was a Twitter thread about how it's "unmasculine" to be born in the summer. The summer months are feminine? This is the level we're dealing with! It's so pervasive and it can go to a level of what feels like satire, but for some people it's deadly serious. A few years ago, we had an unbelievable wildfire here in California because somebody set off fireworks as part of their gender reveal party. In a forest. During a severe drought. There are really negative outcomes that can result from the cultural need to think about gender all the time, and to have strict ideas about what is and isn't acceptable based only on gender.

> I think the idea of non-binary people and "they/them" pronouns is going to be a new cultural norm as these new generations come up.

I want to make clear that gender and sexual orientation aren't the same thing. They get kind of lumped together in LGBTQIA, but those letters stand for pretty different things. LGB are about sexual orientation, lesbian, gay and bi. T and I are about gender, transgender and intersex. Q and A can be about gender or sexual orientation – queer, asexual, agender.

So there's gender bias and there's bias against people with sexual orientations beyond heterosexual. In my experience, gender bias is way more pervasive in the workplace – for example, gay men, especially if they are white, often make it to the highest organizational levels. (See, for example, Tim Cook, who heads up Apple.) I believe that we're seeing a generational shift with Gen Z. For example, I've seen different polls with between 33% and 51% of Gen Z respondents saying, 'I'm a member of the LGBTQ+ community.'

A few months ago, JoJo Swia, 17 at the time and made famous by an ultra-wholesome channel called Nickelodeon for Children, came out via social media. She lip synched the Lady Gaga song "Born This Way" and wore a t-shirt given to her by her cousin that said 'My Best Gay Cousin'. Siwa said, "I don't have a label, I just wanna tell you that I'm super happy." And I was surprised and impressed to see that her coming out video was celebrated by children and their parents everywhere. Sure, not universally. But the overall response was enormously positive. The idea of this announcement happening so unproblematically even a decade ago is incomprehensible. So I suspect that changes in organizational culture when it comes to gender and sexual orientation are going to come from the newest hires, from Gen Z. And in the next few years, Gen Z will start entering law firms. I'm waiting to see the effect that they have.

I see general differences when it comes to pronouns as well. I give trainings on pronouns, and in our discussions what I'm finding is that people who have children between 10 and 18 have really interesting personal examples of new pronoun use. Either their children or their children's friends. I'm hearing stories about 12-year-olds saying to their friends, "I'm nonbinary and I need you to use the pronouns they/them for me." Kids are practicing at home and their parents are helping them. I think the idea of non-binary people and "they/them" pronouns is going to be a new cultural norm as these new generations come up.

When people complain about using "they" for just one person, I like to tell them about the history of English "you." Once upon a time in English, 'you' was plural only, it was used only for a group of people. But now we say 'you' to a single person as well. For me, and for the rest of speakers of modern English, saying 'you' to a single person is completely unproblematic, because the grammatical shift happened several hundred years ago. So what it looks like is that we're headed for a future where speakers of English don't think twice about using "they" to refer to a single person. Because we're in a moment of cultural and grammatical shift. Grammatical systems get locked in your brain around puberty. And right now we've got 10-year-olds using 'they' for a single person, and then it's going to lock in their brains. And they will have a different grammatical system in their brains than people who are adults today. So that's our near future – people who fluently choose from "she," "he," or "they" to refer to someone. And the sooner you start practicing, the easier it will be for you to use pronouns in that future.

Join us in The Patent Lawyer March/April 2022 for Chapter 6.

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GLOBAL REACH, LOCAL KNOWLEDGE
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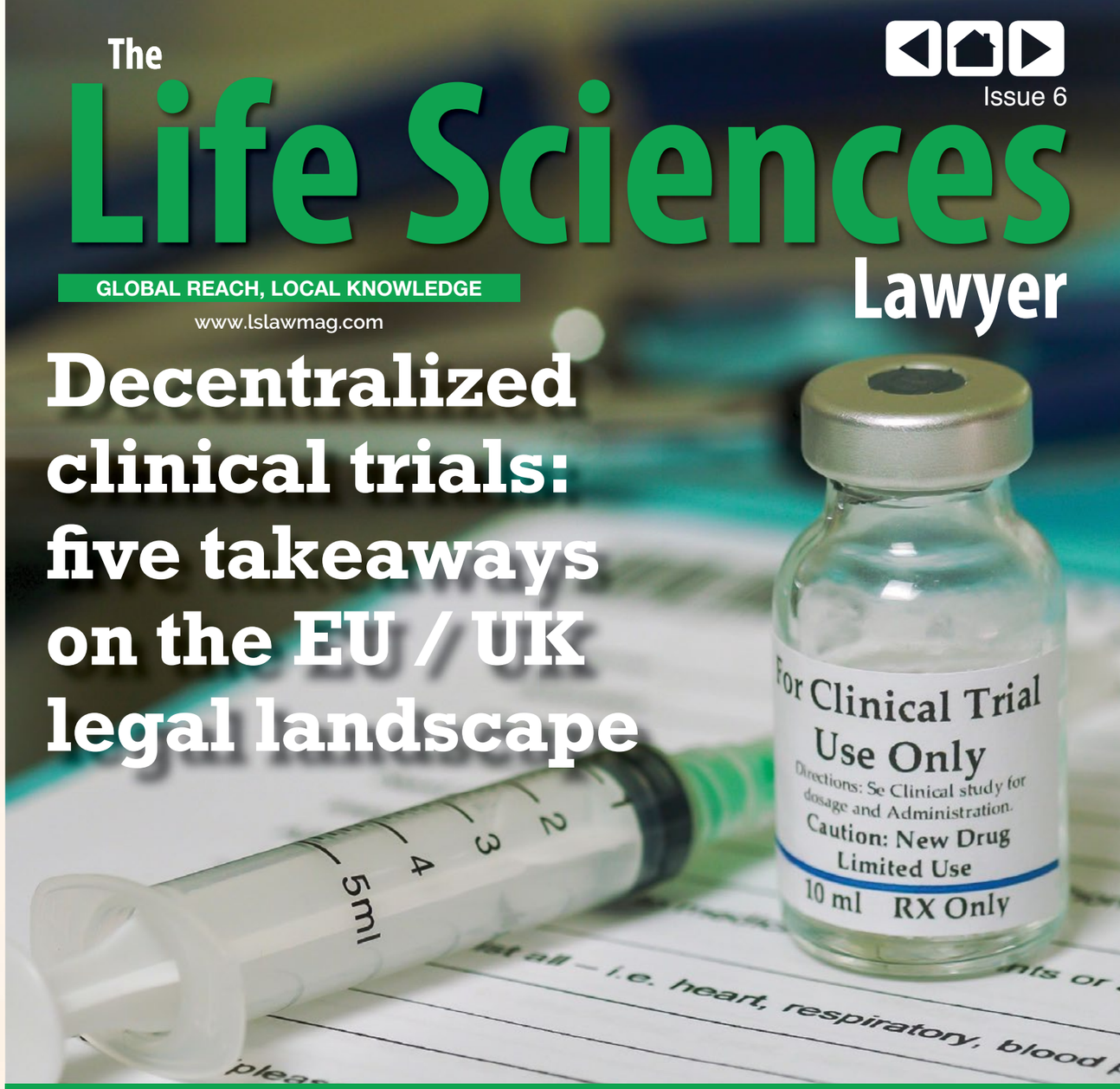
Decentralized clinical trials: five takeaways on the EU / UK legal landscape



Jaspreet Takhar and Julia Gillert of Baker McKenzie evaluate the most important aspects you should know about Decentralized Clinical Trials which are bringing clinical trials to patient's homes.

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CTC Legal Media

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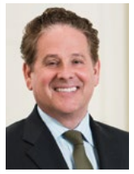

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Bob is a partner at Drinker Biddle & Reath LLP and Co-Chair of the Intellectual Property Group. In October of 2013, he was appointed to a three-year term on the CAFC Advisory Council, was reappointed for another three-year term in 2016, and reappointed in 2019 for an additional three-year term. He is currently serving on the Board of Directors for the American Intellectual Property Law Association.

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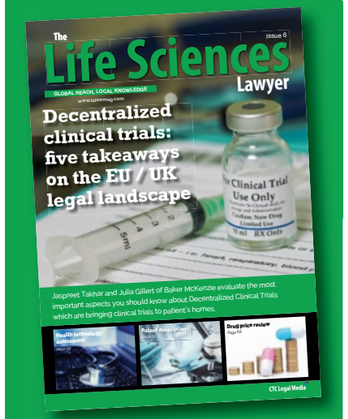

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Editor's welcome

Clinical trails are crucial to the development of new treatments. With patients' needs at the centre of these trials, and perhaps inspired by the COVID-19 era, our cover story this issue discusses the decentralization of clinical trials to improve patient experiences. Bringing a larger proportion of a clinical trial to a patients' home may seem ideal, but it is also likely to complicate the legal position. Baker McKenzie provide five key points for the legal landscape of DCTs.

> **Baker McKenzie provide five key points for the legal landscape of DCTs.**

This issue also sees an evaluation on the new EU Regulation on health technology assessment, and how this correlates with Value-Based Healthcare. The new Regulation aims to contribute towards the formation of a safe and effective health policy delivering the best treatment at the best value.

Then, an explanation of the importance of accurate and detailed patent descriptions, with recent case examples including *Amgen v Sanofi (2021)* and *Juno Therapeutics v Kite Pharma (2021).* Failure to provide a sufficient description could result in damaging losses.

Also, an article reflecting on the Neurim Pharmaceuticals and Merck cases and what the outcomes may mean for the grant or refusal of interim injunctions moving forward.

Plus, an update on Canadian patented drug pricing review and its narrowing landscape.

Enjoy the issue.

Faye Waterford, Editor

Mission statement

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

Decentralized clinical trials: five takeaways on the EU / UK legal landscape

Jaspreet Takhar and Julia Gillert of Baker McKenzie evaluate the most important aspects you should know about Decentralized Clinical Trials which are bringing clinical trials to patient's homes.

Résumés

Jaspreet Takhar, Senior Associate
Jaspreet advises market-leading tech and healthcare companies on issues at the cutting-edge of digital health.

She focuses on the development and regulation of healthcare technology. This includes assessing how digital health solutions can comply with the legal framework for data privacy, medical research and medical devices / pharmaceuticals. Jaspreet also advises clients on the regulation of clinical trials, accessing and using real world data, and the use and regulation of AI and other technologies in the healthcare space.

Julia Gillert, Of Counsel
Julia advises a broad range of tech and healthcare companies on issues across the healthcare ecosystem in relation to digital health.

She helps companies in the pharma, medtech, and healthcare sectors to navigate the strict regulatory regimes they face, often in the grey areas where innovative technological developments outpace the regulation. Julia's practice also focuses on advising companies to manage the regulatory challenges arising from Covid-19 and post-Brexit divergence. Julia advises both UK domestic clients as well as multinationals operating across borders.

Jaspreet Takhar

Julia Gillert

Decentralized clinical trials (DCTs) focus on bringing an increasing proportion of a trial's activities to the patient's home, as opposed to bringing the patient to a trial site. The ultimate aim is to meet patient needs and improve the patient experience, and the key to achieving this is technology i.e., utilizing tools like e-consents, telehealth solutions, and wearables that facilitate remote monitoring. However, when it comes to DCTs, the pace of innovation outstrips the pace of regulation.

The industry is moving rapidly to embrace this new approach, but there are key areas of uncertainty as to how DCTs sit within the legal and regulatory framework.

While we await more formal guidance from regulators, CROs and sponsors are already building on lessons from the pandemic to roll out elements of DCTs on a local, regional, and global basis.

We've set out five points on the legal landscape for DCTs below.

1) No formal statutory definitions (yet), but regulators agree that DCTs exist on a spectrum

Unfortunately, there is no statutory definition of DCTs yet, but several regulators such as the US FDA,[1] the Swedish Medical Products Agency,[2] and Germany's BfArM have acknowledged that DCTs exist on a spectrum.

In its most extreme form, a DCT may be fully decentralized or 'siteless', with a patient never physically setting foot in a trial site. The participant may be enrolled virtually, consent electronically, and self-administer medicines with assessments taking place remotely in the patient's home.

Although fully decentralized trials may not be commonplace yet, we are seeing a proliferation in the number of hybrid trials. These hybrid trials incorporate certain elements of DCTs, such as online recruitment portals, nurse home visits, direct-to-patient clinical supply, and remote monitoring.

2) There are several legal regimes at play

At the pan-EU level, DCTs involve several legal regimes coming together, some of which have not been adapted for DCTs (at least yet).

This means that bringing together these legal frameworks is one of the main challenges facing regulatory and compliance specialists when advising on DCTs. These regimes include:

- **The upcoming EU Clinical Trial Regulation (CTR) and Good Clinical Practice (GCP):** the CTR applies across the EU from 31 January 2022. There are no specific rules in the CTR or GCP prohibiting DCTs, so they are in theory possible, but the DCT must fulfil the requirements of GCP and the CTR, including the key underlying principles of ensuring patient safety and data integrity. (For completeness, the CTR will not apply in Great Britain, where the Medicines for Human Use (Clinical Trials) Regulations 2004 will continue to apply. However, the position is similar for Great Britain to that of the EU.)

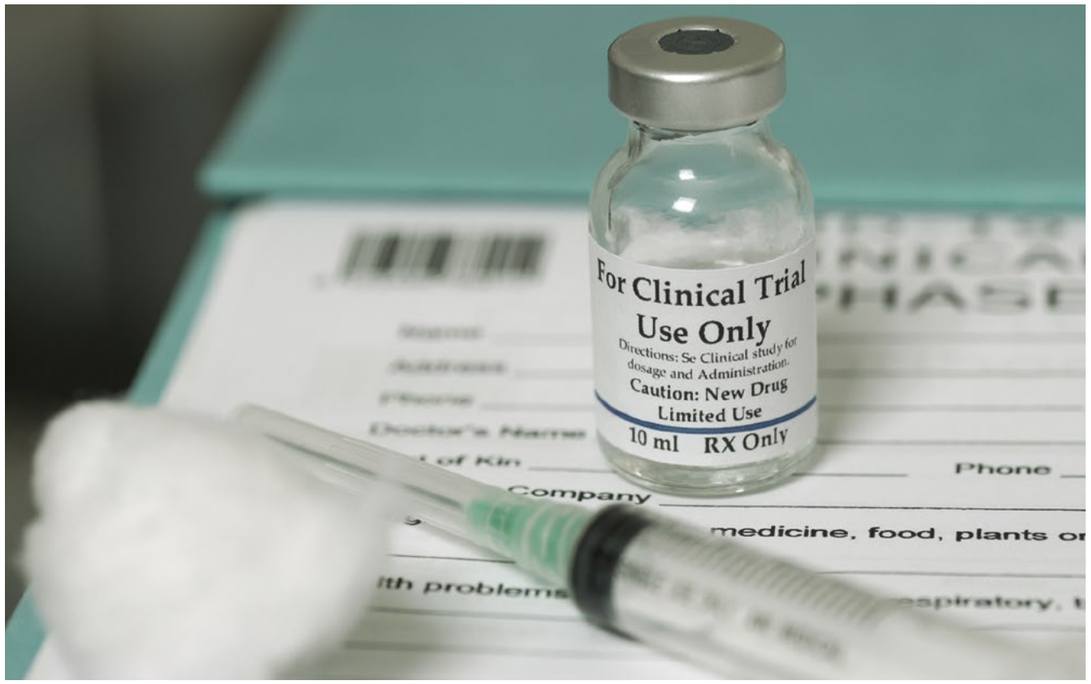
> **"We do not necessarily have robust and complete guidance from regulators on full DCTs, which means there are gaps, questions and grey areas emerging."**

- **The EU / UK GDPR:** data privacy often sits uncomfortably within the healthcare context. Its 'black-and-white' concepts such as data controllers and data processors do not fit neatly into the healthcare ecosystem where parties often assume nuanced roles, and they fit even less neatly into DCTs, where there are complex data flows and relationships between tech providers, hospitals, sponsors, and CROs. We've set out some tips on compliance below.

- **National laws and guidance:** including those issued in light of Covid-19, addressing issues such as dispensing, e-consents, remote access to electronic health records, how home health visits can be conducted, and local laws on medical secrecy and patient confidentiality.

3) Regulatory gaps exist

We are seeing regulators across the globe provide targeted guidance on specific elements of DCTs, such as e-consents, remote source data verification, and remote access to electronic health records. Examples are emerging of more general guidance relating to hybrid trials, including the Danish Medicines Agency's guidance on the implementation of decentralized elements in clinical trials with medicinal products.[3] The



Swedish Medical Products Agency is currently investigating how interventional clinical trials may be carried out on a decentralized basis in Sweden.[4]

However, we do not necessarily have robust and complete guidance from regulators on full DCTs, which means there are gaps, questions and grey areas emerging. Early engagement with the relevant ethics committee and regulator will be key.

4) Data privacy compliance must be built in from the outset

When assessing data privacy compliance, the first and most important step will be mapping the data flows involved in the DCT. This is a key initial question because DCTs typically involve increased access to non-coded patient data by vendors such as nursing service providers, app providers, and IT support.

It will be essential to ensure there are appropriate agreements in place with such vendors. Sponsors are considered to be data controllers i.e., the party that determines the purposes and means of data processing. As controller, a sponsor is required to put in place data processing agreements with any vendors that process data on the sponsor's behalf.[5] To the extent such vendors may transfer personal data outside the EU or UK (as relevant), a valid international data transfer mechanism is required.[6]

As data controllers, sponsors will need to ensure there are appropriate technical and organisational measures to ensure a level of security appropriate to the heightened risk profile of DCTs.[7]

5) And patient confidentiality and medical secrecy must not be forgotten...

DCTs potentially involve the disclosure of confidential patient information to third party vendors, such as tech and app providers. This means that sponsors may need to consider any local laws on medical secrecy and medical confidentiality, and this may include identifying a basis for disclosure of such confidential information to third party vendors.

Local laws on medical confidentiality often run in parallel to data privacy laws. This means there may be certain overlap between data privacy laws and medical confidentiality laws, but in many jurisdictions, they are ultimately different regimes with different focuses. You may need to conduct separate exercises to ensure compliance under both regimes.

> **Early engagement with the relevant ethics committee and regulator will be key.**

1 https://www.fda.gov/about-fda/oncology-center-excellence/advancing-oncology-decentralized-trials
2 https://www.lakemedelsverket.se/en/permission-approval-and-control/clinical-trials/medicinal-products-for-human-use/decentralised-and-virtual-interventional-clinical-trials#hmainbody1
3 https://laegemiddelstyrelsen.dk/en/news/2021/guidance-on-the-implementation-of-decentralised-elements-in-clinical-trials-with-medicinal-products-is-now-available/~/media/5A96356760ED408CBFA9F85784543B53.ashx
4 https://www.lakemedelsverket.se/en/permission-approval-and-control/clinical-trials/medicinal-products-for-human-use/decentralised-and-virtual-interventional-clinical-trials
5 Article 28, EU GDPR; Article 28, UK GDPR
6 Article 44, EU GDPR; Article 44, UK GDPR
7 Article 32, EU GDPR; Article 32, UK GDPR

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The new EU Regulation on health technology assessment

Ricardo Costa Macedo, Partner, & Rafael Cunha Jóia, Junior Lawyer, of Caiado Guerreiro discuss how the new Regulation correlates with Value-Based Healthcare in the EU.

In the context of a global pandemic caused by the Covid-19 virus, the emergence of new health technologies, such as new vaccines created from mRNA, is a structural component, and as such, indispensable to health systems. In fact, the connection between technology and health has never been so close. This connection is enabling new technologies to treat new and old diseases, improving the quality of life of patients, and increasingly focusing the treatment on their individual needs and the outcome of such treatments.

> **In fact, the connection between technology and health has never been so close.**

The technological bases of care have increased dramatically in the last century, particularly in terms of equipment, medical devices, and medicines. While generating unequivocal health gains, health technologies also raised questions regarding financial sustainability of health systems with consequences for patient effectiveness as well as resource allocation.

The concept of health technology assessment

The expression health technology is used to cover any aspect of healthcare, including prevention programs (example: vaccination programs), diagnostic tests, a device or piece of equipment, a drug or a procedure, being that health technology assessment (HTA) is a form of a policy that examinates short and long-term consequences of using a healthcare technology. It is a multi-disciplinary process that summarizes information about the medical, social, economic, and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. This procedure aims to contribute to the formulation of safe and effective patient-centred health policies in order to deliver the best treatment that brings most value to the patient.

The goal of HTA is to inform the development of safe and effective, health policies that are patient focused and seek to achieve best value as defined by decision makers. HTA supports decisions such as:

- Should treatment A be reimbursed in a national healthcare system?
- For which patients should it be provided?
- What are the characteristics of the patient and the disease which best suit the treatment?
- What is its cost and effectiveness of such treatment?

HTA may look at the impact of a technology on an individual patient, on a group of similar patients, on the healthcare system as a whole, or on all of these. HTA may also use modelling, where specific assumptions are used to make an estimate or 'best guess' to predict, for example, the cost of using a technology in a certain setting or in a certain patient.

Correlation between health technology assessment and Value-Based Healthcare

Value-Based Healthcare (VBH) is accompanied by considerable ambiguity concerning the very meaning of the concept. Despite this ambiguity, it is safe to say that this new way of looking at health management argues that the value in health care consists of what matters most to patients, meaning, the health status they achieve (outcomes) and the price they must pay for it (costs). According to this new method of health care delivery, providers should focus on generating maximum value for their patients by helping them achieve the best possible outcomes and by doing so in a cost-efficient way. The use of this approach can include a reduction of costs to achieve better health and the increase of treatment efficiencies and patient satisfaction.

Given the fact that VBH focuses on health status (outcomes) achieved by a certain treatment and the price the patient must pay for it (costs), in a cost-efficient way, new technologies and the information available regarding the use of said new technologies plays a decisive role in implementing a VBH system. To that end, the process regarding health technology assessment can provide a precious help in assessing the added value of new or existing health technologies – medicines, medical devices and diagnostic tools, surgical procedures, as well as measures for disease prevention, diagnosis, or treatment – compared with other health technologies. HTA can be used not only to guide different authorities about whether a new treatment or other technologies should be available on the national health service, but also to assess if a certain treatment for a certain disease or a specific condition provides value in terms of health status for that particular patient in a cost-efficient way. HTA can therefore provide information to support decisions about priorities in healthcare or specific decisions about whether new treatments should be introduced, what is the cost-effectiveness of its use in certain patients and its positive or negative effects. By using this detailed information patients and health care providers can decide which of the available treatment options best meets their needs

> **This procedure aims to contribute to the formulation of safe and effective patient-centred health policy in order to deliver the best treatment that brings most value to the patient.**

HTA can also be used as a tool to implement a VBH system through a health economics assessment. In this regard, the assessment of a new treatment can be made through principles of economics that are applied to health and healthcare. In this perspective health economics can be used to provide evidence to support value for money considerations. Health economics data may cover both direct costs (such as the number of drugs used by a patient or the number of hospital visits in a given period) and indirect costs (such as the cost of time lost from work). The economic data combined with clinical effectiveness data leads to cost-effectiveness estimates.

HTA process and its considerations about health economics, cost, effectiveness, application to certain patients and comparison with procedures, drugs or medical devices is shaping the way health care providers look at the needs of their patients. In doing so, HTA can serve as a precious tool of data that allows health stakeholders, including government decisions and hospital management, to implement a real

Ricardo Costa Macedo

Rafael Cunha Jóia

Résumés

Ricardo Costa Macedo, Lawyer and Partner at Caiado Guerreiro, head of the Life Sciences and Intellectual Property groups.

Mr. Macedo´s practice covers a wide range of contentious and non-contentious patent, trademark, and other IP-related rights, such as trade secrets and unfair competition, in particular in the pharmaceutical, home care, food, and insurance sectors. Moreover, he has vast knowledge in regulatory matters in these sectors.

Mr. Macedo graduated in 1998, from the Faculty of Law of the Catholic University of Lisbon. He undertook postgraduate studies in information society law at the Faculty of Law of the University of Lisbon in 2000 and in commercial law at the College of Law, London in 2003.

Rafael Cunha Jóia, Junior Lawyer at Caiado Guerreiro

Rafael Cunha Jóia is a member of the Life Sciences and Intellectual Property groups. Mr. Jóia has been focusing his practice on the health and insurance sector, in relation to which he covers a wide range of matters.

Mr. Jóia graduated from the Faculty of Law if Lisbon, University of Lisbon in 2019 and concluded his Master of Laws (LLM) in Commercial and Corporate Law in the Faculty of Law of the Catholic University of Lisbon in 2021.

VBH system, focusing on creating value treatments with good outcomes for the patients in a cost-efficient way, using new technologies or assessing from all the medical options that can be applied to a certain patient the ones who suits them better.

HTA Regulation in the EU

The HTA process is currently performed by 50 HTA agencies across Europe. Nevertheless, approaches vary from country to country which means a fragmentation of HTA criteria with serious negative impacts on the European health market and patients in its Member States.

To support cooperation between HTA bodies, the European Union has made substantial investments. Two Joint Actions have been carried out together with a number of projects. A third Joint Action was launched in June 2016 and run until 2020. This third Joint Action focused on developing common assessment methodologies, piloting, and producing joint clinical assessments and full HTA reports, and on developing and maintaining common criteria. In addition, following the adoption of the Cross-Border Healthcare Directive (Directive 2011/24/EU), the HTA Network was established in 2013 to provide strategic and political guidance to the scientific and technical cooperation at Union-level.

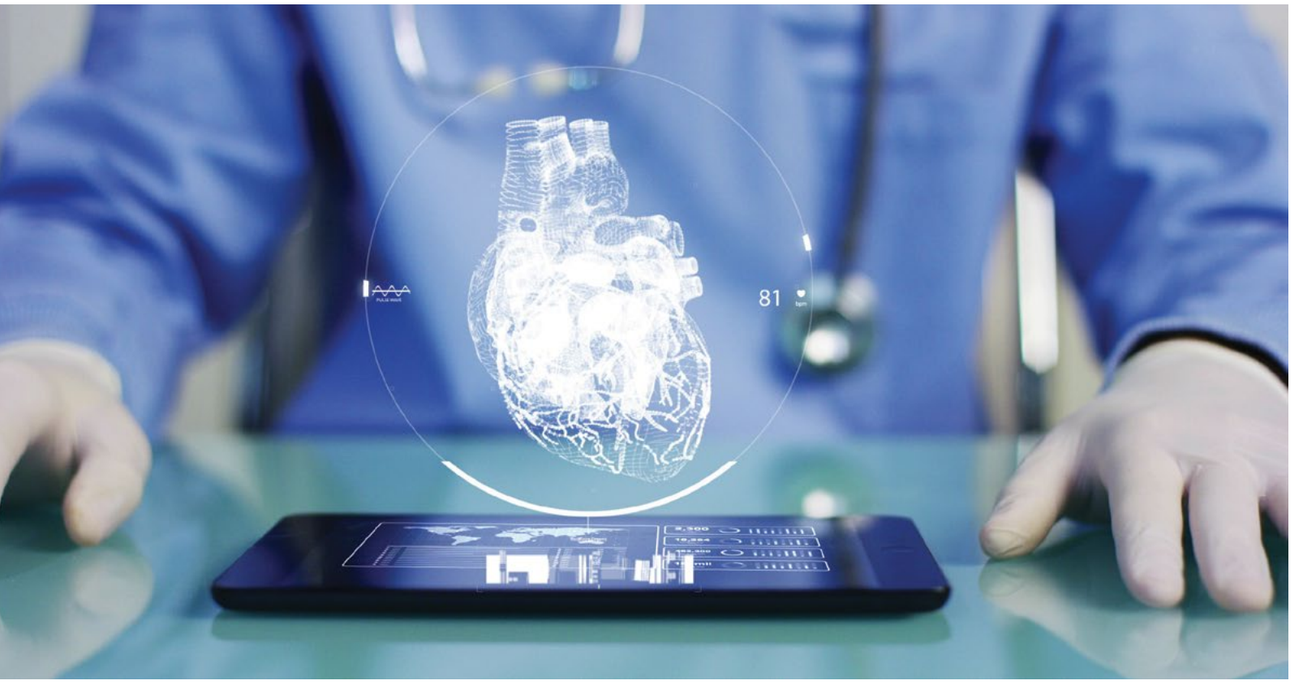
Following the negotiations set on June 22, 2021, the Council of the European Union and the European Parliament reached a provisional agreement on the European Commission's proposal for a European health technology assessment regulation (HTA Regulation), which aims to harmonize the clinical benefit assessment of health technologies across the EU.

> **Value-Based Healthcare (VBH) is accompanied by considerable ambiguity concerning the very meaning of the concept.**

This provisional agreement which now establishes the new Regulation (EU) 2021/2282 of the European Parliament and of the Council Of 15 December 2021 aims to achieve the following specific objectives:

- Improve the availability of innovative health technologies for EU patients;
- Ensure efficient use of resources and strengthen the quality of HTA across the EU;
- Improve business predictability.

This new Regulation establishes a **support framework and procedures for cooperation on health technology assessment at an EU level and common rules for the clinical assessment of health technologies** (article 1 of the regulation proposal). The Member State Coordination Group on Health Technology Assessment (the Coordination Group) is formally established in Article 3 along with its composition, roles, and responsibilities to oversee the joint work referred to in Chapter II. This joint work is based on the annual work program of the Coordination Group which is outlined in Article 4 of the Regulation. The annual work program provides clarity on the planned work of the Group and allows health technology developers to foresee any expected involvement they may have in the joint work for the year ahead.



The joint clinical assessments will be one of the main proponents of the future joint work, being those assessments limited to: **(i)** medicinal products undergoing the central marketing authorization procedure, new active substances and existing products for which the marketing authorization is extended to a new therapeutic indication, medicinal products undergoing the central marketing authorization procedure, new active substances and existing products for which the marketing authorization is extended to a new therapeutic indication **(ii)** certain classes of medical devices and *in vitro* diagnostic medical devices **(iii)** potential impact on patients, public health, or healthcare systems (e.g., burden of disease, budget impact, transformative technology) **(iv)** significant cross-border dimension, and **(v)** Union-wide added value.

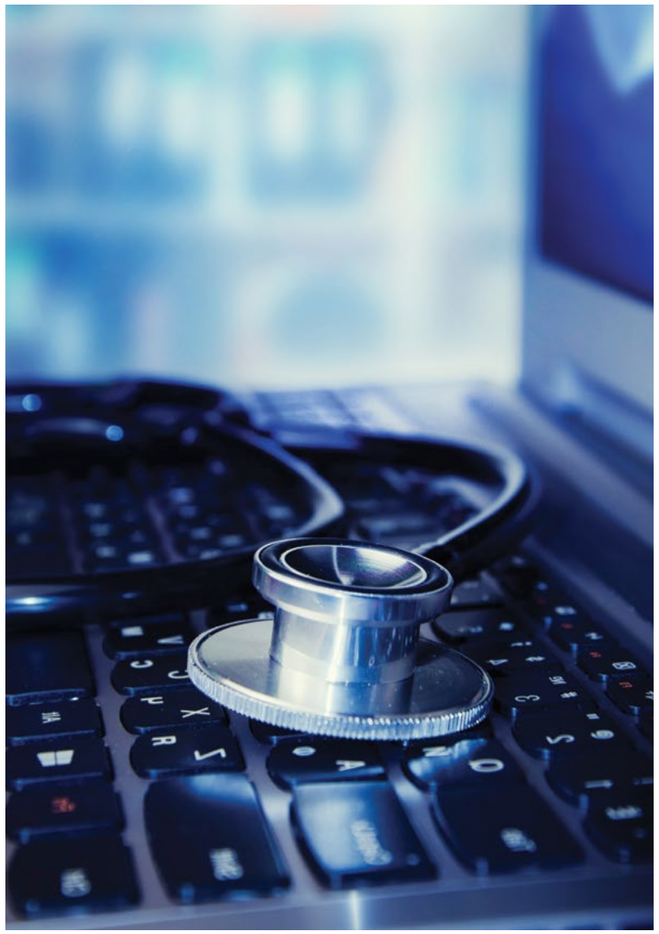
Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 provides for progressive implementation of the amount of joint clinical assessments during the transitional period. This means that the number of joint clinical assessments will increase gradually during the first three years after the date of application, considering specific selection criteria.

Chapter III of the Regulation lays down common rules for carrying out clinical assessments at Member State-level which will then be developed in detail in tertiary legislation. These rules will ensure a harmonized approach to clinical assessment across EU Member States.

Closing notes

Common rules in all EU Member States about HTA can serve as grounds for establishing a deeper VBH system. The correlation between, HTA criteria, mainly the criteria that sets rules to assess the health status (outcomes) achieved by a certain treatment and the price the patient must pay for it (costs), in a cost-efficient way, can be a precious help to implement a real VBH system in the European Union. With this regulation patients will be empowered, and medical personal better informed by having access to a Joint Clinical Assessment report that is of high scientific quality, transparent and accessible to the public.

To establish a VBH system it is necessary to provide the right tools that enable medical personnel as well as health care providers to compare various health care options, choosing among them the ones that offer a better treatment to the patient, with better results and at an efficient cost. The new EU Regulation could set equal criteria for different Member States, serving as a driver for the implementation of a European-wide VBH system.



> **These rules will ensure a harmonized approach to clinical assessment across EU Member States.**

Although we do not yet know the full extent of what the Joint Clinical Assessment report will present, this Regulation can establish a true cooperation in HTA, giving a real opportunity to relate the cost-benefit of each treatment to individual patient considerations, implementing what may be the beginning of a real VBH system.

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Deficient patent description can be fatal

DPS Parmar, Special Counsel at LexOrbis, explains why patent descriptions can be crucial for patent grant and enablement with reference to India and US cases *Amgen v Sanofi (2021)* and *Juno Therapeutics v Kite Pharma (2021).*

Meeting the sufficiency of description is the primary requirement to obtain a patent and it serves well as a ground for invalidation of a patent. The courts of all patent jurisdictions are raising the standards of satisfying the statutory requirement for enablement and written description of a patent application in the context of inventions. For example, in two precedential decisions by the US Court of Appeals for the Federal Circuit, *Amgen v Sanofi (2021)* and *Juno Therapeutics v Kite Pharma (2021)* both involving invention relating to antibodies, the court ruled in the former case that "the claims are far broader in functional diversity than the disclosed examples" and in the latter case court held that "a person having ordinary skill in the art would not have been able to determine which scFvs would bind to CD19 in a way that distinguishes them from scFvs that do not bind to CD19 because the specification presented a limited number of examples, and did not disclose structural features common to the members of the genus to support that the inventors possessed the broader scope of claims." In both cases, the court favored opponents' assertion on lack of sufficiency of the description to enable the person skilled in the art to work the invention without undue experimentation and revoked the patents.

DPS Parmar

> **The opponent must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention.**

Résumé

Mr. DPS Parmar, Former Technical Member (Patents), erstwhile Intellectual Property Appellate Board; Special Counsel, LexOrbis

Mr. D.P.S Parmar heads the Patents Contentious Practice Group at LexOrbis. After joining the IPAB as Technical Member (Patents) in 2011, he has been instrumental in writing some path breaking and insightful decisions on Indian patent law issues. These include establishing legal positions on excluded subject matter under Section 3(d), 3(i) and 3(k), divisional applications, disclosure requirements under Section 8, working statements and compulsory license, to name a few. Before joining IPAB, Mr. Parmar worked with the Indian Patent Office (IPO) for over 27 years and played a vital role both at the administrative and policy levels. He represented India at various rounds of discussions organized by the World Intellectual Property Organization (WIPO) and attended follow-on programs at the European and Japanese Patent Offices. He was instrumental in the recognition of IPO as the 15th ISA and IPEA under the Patent Cooperation Treaty (PCT). He also served as the head of the Intellectual Property Training Institute (IPTI) in Nagpur, which was responsible for providing training to new examiners at the IPO.

Sufficiency and enablement requirement in India

The statutory requirement for written description, support, and enablement can be found in section 64 (h) of Patents Act, 1970, which states that "the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection".

Accordingly, where insufficiency and lack of enablement are taken as a ground to revoke a patent, the opponent must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without undue experimentation.

Determinants of lack of sufficiency requirement

The determination of sufficiency at the examination stage is guided by the statutory requirement relating to presenting the description in the complete specification under section 10 (4) which states that:

"(4) Every complete specification shall—

(a) Fully and particularly describe the invention and its operation or use and the method by which it is to be performed;

b) Disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and

(c) End with a claim or claims defining the scope of the invention for which protection is claimed."

The Patent Rules lay no further guidelines to ascertain how this statuary requirement can be determined. But in practice, the examiner normally uses various factors for determining the adequacy of the disclosure in the specification. These factors may depend upon their knowledge in the field, the extent and content of the cited prior art. This means that at the examination stage sufficiency requirement determination is purely linked to determine the scope of the claims. It further means that at the examination stage it is not linked to the determination of lack of the enablement requirement. Therefore, if the applicant describes the invention and its operation or use, and the best method by which it is to be performed, it is sufficient for examination purposes in the Indian context. However, if this requirement is not met it may be used as a ground to oppose the patent at pre-grant (section 25(1)(g)) or post-grant stage (section25(2)(g)).

Position in the US

In the US, the examiner is guided by judicial rulings relating to the determination of the sufficiency of description and enablement. For example, in re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988), the court set forth that this determination requires a conclusion reached by weighing the following factual considerations (popularly known as the "Wands factors"):

"Factors to be considered in determining whether a disclosure would require undue

> **Simply stated, a patent application is said to be enabled if the application provides sufficient details that enable a person of ordinary skill in the field of the invention to practice the invention.**

experimentation have been summarized by the board in re Forman. They 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 claim."

Accordingly, the patent description satisfies the written description requirement when it reasonably conveys to those skilled in the art how to practice or work the claimed invention without undue experimentation. Simply stated, a patent application is said to be enabled if the application provides sufficient details that enable a person of ordinary skill in the field of the invention to practice the invention. Any deficiency in the description entails the refusal of a patent by the examiner. In case the patent is granted the deficient description carry the burden of invalidation at any stage of the patent. However, in order to invalidate a patent for lack of enablement, in the US a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation'. This is what happened in the recently decided invalidation of antibody patent case viz *Amgen v Sanofi (2021)* and *Juno Therapeutics v Kite Pharma (2021).*

> **Any deficiency in the description entails the refusal of a patent by the examiner.**

A word of caution

Deficient description can prove fatal to the granted patent as it is likely to face invalidation on the ground of insufficient description or lack of enablement. The patentee must ensure that the specification is well-drafted disclosing the complete scope of the claimed invention and providing at least one working example sufficient to enable a person skilled in the art to make and use the invention without exercising inventive skill. A well-drafted specification can minimize the risk of refusal during the examination of the application and at subsequent stages when a patent is challenged on the grounds of not meeting sufficiency of disclosure and enablement requirements. This is particularly required for the complex inventions that are directed to antibody technologies and other unpredictable technologies as we have seen invalidation of such patents above. The more complex and unpredictable inventions are, the more cautious approach in presenting a specification that meets the enablement and written description requirements is desirable. The first aspect of drafting particularly antibody applications would be to give a sufficient number of representative examples across a broad range of the claimed significant features of the invention. Secondly, it is advised to have one claim with a narrow scope that can trace back the support from the specification and examples. Finally, the drafter should avoid using functional elements in the language such as 'binds', 'blocks bindings' or 'interact with' as such terms in the language are normally construed narrowly during the interpretation of the claims. The cautiously drafted specification with examples of the common elements is no doubt beneficial to rebut enablement or sufficiency of description challenge at any stage of the patent. In the Indian context, the examiner is not guided by the elaborate guideline like "wands factors" for determination of enablement, but the ground of insufficient description or enablement is a major line of attacking a patent. In the past, the erstwhile Intellectual Property Appellate Board (IPAB) has refused to allow amendment of claims as the proposed amendments were not supported by description in an appeal case *Diamcad N.V. BELGIUM vs Asstt. Controller [Order no. 189/2012]*. This clearly shows that the addition of new matter in the specification is not allowed and the failure to disclose the 'best mode' remains a solid ground for challenging the validity of a patent in India.

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Interim injunctions for patent infringement in the aftermath of Neurim Pharmaceuticals and Merck

Professor Mark Engelman, Barrister at The Thomas Cromwell Group, reviews the outcome of recent cases and what they mean for interim injunction in the field of life sciences.

Not all infringements of intellectual property rights involve the same class of causes of action. For example, passing off is a form of deceit/malicious falsehood and its roots live there. There is no requirement to establish damage in order to consummate the cause of action. Damage is to be inferred. Patent infringement, by contrast, is a statutory tort and damage is an essential ingredient.

Damage of course is also an essential ingredient in the successful prosecution of an interim injunction. The test has long been laid out in *American Cyanamid v Ethicon [1975] AC 396.* It reads as a sequence of steps to be decided by the Court when determining whether an interim injunction should be granted or refused. Those well-known steps comprised consideration of: (i) whether there existed an arguable case; (ii) whether if the injunction were not granted the Claimant would incur a loss unquantifiable in money terms, if not then the injunction would be refused. If so, then the Court goes on to consider whether if the injunction was granted the Defendant would incur a loss unquantifiable in money terms, if that is then established, the injunction would be refused. On the premise that both parties suffer an unquantifiable loss, the Court will proceed to the next step and consider the balance of convenience. In essence, the test took the form of, in computer science terms, a logic tree.

Professor Mark Engelman

Focusing more precisely upon the two questions associated with the respective parties' losses, the questions the Court poses, is whether the respective party's losses could be compensable by damages as an "adequate" remedy. Two recent judgments have changed not merely how the questions are framed but the step-wise nature of the test itself.

Within the space of 11 months The Irish Supreme Court and English Court of Appeal have both dissembled the American Cyanamid test turning it from a four-step sequence to a multifactorial test in which the stages vary from those laid down in American Cyanamid and then questions what is meant by the term "adequate" as it relates to a party's damages. Both judgments

Résumé

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concerned pharmaceutical patent disputes however both have repercussions in the approach a Court should adopt to the grant of interim injunctions across all areas of law.

Damages in patent disputes have historically accommodated a number of different heads of loss. The most obvious represented by the loss of business profits caused by the diversion of the patentee's sales in his invention to the Defendant. Damages in respect of a Defendant's unlawful sales would be calculated on the basis that the patentee would have made equivalent sales to those of the Defendant.

Damages have also been recovered for the loss of a patentee's network of distributors arising from loss of product turnover.

It is also often been successfully argued that a patentee has suffered a loss of profits through a reduction in the price of his products which otherwise enjoyed a market monopoly when that reduction is necessitated in order to compete with the infringer's products.

In *Neurim*, the English and Welsh Court of Appeal, considered an appeal against the grant of an interim injunction brought by the Neurim for infringement of its patent for melatonin, an hypnotic, marketed under the brand name Circadin. Upon learning of the imminent launch of a generic pharmaceutical, Sylento, by Mylan, which fell within Neurim's patent claims, Neurim sought injunctive proceedings to prevent its sale. It was alleged for the purposes of the then existing American Cyanamid test that Sylento would cause Neurim to lose sales of Circadin, the diversion referred to earlier, and also depress the price at which Circadin could be sold. Harm would also be caused to Neurim's distribution networks. Consequential losses would arise from the closure of Neurim's R&D programmes and associated redundancies. These, Neurim said, were unquantifiable heads of loss.

Mylan, as respondent to the injunctive proceedings, also laid claim to unquantifiable losses. It claimed the loss represented by missing the opportunity to launch a product for which Mylan had obtained marketing authorisation during a period over which Mylan would have enjoyed (without other generic competitors) a valuable "first mover" advantage in the hypnotics market place. Its price of Sylento would be significantly higher in those circumstances.

The High Court below had decided that *Neurim's* damages associated with both diverted sales and price suppression could be estimated from the respective sales data of both parties such that they could "properly be calculated". As to *Neurim's* consequential losses, it was rich enough to absorb them. The High Court found they would arise in any event when

> **It reads as a sequence of steps to be decided by the Court when determining whether an interim injunction should be granted or refused.**

Nuerim's patent expired in 2022, some two years following the date of the hearing before the High Court judge.

Similarly, Mylan's "first mover" losses were considered by the High Court to be merely transitory in nature because, were the interim injunction refused, many other generic companies would be fast behind it. The first instance judge recognised such damages would be difficult to quantify but that did not mean, however, that a damages remedy to Mylan would be "inadequate" for that reason alone.

The injunction application failed because the patentee failed at step two, its damages were considered to be an adequate remedy and not unquantifiable.

The Court of Appeal applied the four-stage test of American Cyanamid. Floyd LJ when addressing Neurim's claimed unquantifiable loss stated that whilst in some cases "damages as a remedy falls so far short of the perfect, that the remedy can no longer be described as adequate", but going on to decide, this case was not one of them.

Floyd LJ, in the lead judgment of the Court of Appeal, focused upon the central issue under appeal: whether the calculation of the damages to which Neurim and its distributer Flynn would be entitled, were they to succeed in obtaining a permanent injunction at trial, was of such complexity as to render their remedy in damages inadequate. He pointed out that the patentee had put into evidenππnce both its actual and forecast sales turnover. The Defendant had also evidenced its "actuals". Those were sufficient to quantify the patentee's losses in price suppression. Whilst Floyd LJ accepted that after the period of launch of Mylan's drug estimates of *Neurim's* price depression would become more difficult, in Floyd LJ's words: "damages are, however, to be "assessed liberally", from which one is to infer, any estimation of damages is not intended to be an exact science. It upheld the High Court's refusal to grant the interim injunction."

The Court of Appeal made no reference to a very significant earlier judgment of the Supreme Court of Eire in *Merck Sharp & Dohme Corporation v Clonmel Healthcare Limited S:AP:IE:2018:000107* which had been handed down 11 months earlier. Naturally, judgments of the five-man Supreme Court of Eire are not binding upon the English and Welsh Court of Appeal. But the Merck judgment might well have had impact. It opened with the ominous words: "this appeal raises important questions as to the proper approach to the application for an interlocutory injunction, which is an important remedy in many different disputes."

Merck held two patents for simvastatin and another for ezetimibe, statins for the treatment of cholesterol. It marketed its patented invention under the brand Inegy which combined the two ingredients.

The High Court had granted Merck an interim injunction against a generics company on a without-notice basis but refused it when it returned on-notice. The High Court found Merck's damages to be an adequate remedy despite the emergence of a generics company into its market. A judgement which aligned with that of the later judgement in Neurim. It also considered whether the generics company would lose its first-mover advantage were the injunction to be granted. It concluded it would but such losses were also quantifiable.

The Court of Appeal upheld the judgment of the High Court and Merck appealed to the Supreme Court.

Again, before the Supreme Court, the generics company argued that damages were an adequate remedy for the patentee, and once that had been decided, it was argued that on American Cyanamid principles, the High Court need have progressed no further into the stepwise test. It also queried the entire approach to the American Cyanamid test.

The Supreme Court thus went on to discuss the principles governing the grant of interim injunctions in general as laid down in American Cyanamid. O'Donell J. stated:

> "It should not, in my view, be approached as though it (American Cyanamid) were the laying down of strict mechanical rules for the control of future cases. It is apparent, for example, that there is some ambiguity in the judgment about a matter which arises in this case, which is whether the question of adequacy of damages is part of or antecedent to the balances."

That statement made early in the leading judgment heralded an attack by the Supreme Court upon the mechanistic approach which had routinely been undertaken by the Courts when applying the American Cyanamid test. He stated:

> "In my view, the preferable approach is to consider adequacy of damages as part of the balance of convenience, or the balance of justice, as it is sometimes called."

Concluding:

> "While a structured approach facilitates analysis and, if necessary, review, any application should be approached with a recognition of the essential flexibility of the remedy and the fundamental objective in seeking to minimise injustice, in circumstances where the legal rights of the parties have yet to be determined."

> **As to adequacy of damages to either applicant or respondent, O'Donell J. considered it unnecessary to treat it as a science.**

As to adequacy of damages to either applicant or respondent, O'Donell J. considered it unnecessary to treat it as a science. Putting it prosaically: "The fact that it is in theory possible to gather every feather does not mean that it is not more convenient to stop the pillow being punctured in the first place."

The Court decided that the inadequacy of damages to both parties was balanced and that other factors operated in determining where the balance of convenience lay. They, like the evaluation of the prospects of success at trial, should be taken into account. Had the stepwise approach in American Cyanamid been deployed, the Court would not have got that far down the logic tree, but would have stopped at whether damages were inadequate for the patentee and gone no further. But it didn't.

O'Donall J. concluded his lead judgment with what would be heretical to the doctrine enshrined in American Cyanamid, a step-wise sequence of the American Cyanamid factors but entirely out of step to that envisioned by American Cyanamid: a determination was to be made on the merits of success at trial, and if positive, whether the action would in fact proceed to trial. Then the court would consider the balance of convenience. That would include a consideration of the adequacy of damages to both parties. He commented that in commercial cases that question should be approached with some scepticism. Any difficulty in their calculation was to be consigned to operate merely as a factor which might point in favour of the grant of an injunction.

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The scope of Canadian patented drug price review narrows

Noel Courage and Nyrie Israelian, of Bereskin & Parr, summarize a recent case which reviewed the pricing of the Alexion drug Soliris, resulting in a strengthened position for innovator drug companies undergoing pricing review.

The Canadian Patented Medicine Prices Review Board regulates prices of patented medicines. Any thread of connection between an approved medicine and a Canadian patent can trigger the Board's jurisdiction to review price. For this reason, companies sometimes weigh a trade off between having Canadian drug patent protection and triggering price review versus dropping their drug patents and avoiding price review.

The Board was recently reined in by the Federal Court of Appeal (**FCA**) in a case involving the Alexion drug Soliris.[1] The Court held that the Board must stay within its mandate of preventing excessive pricing. The Board does not have the power to pursue a more general mandate of ensuring reasonable pricing, price-regulation, or consumer protection at large. As well, the Board's decision was unreasonable by making an unprecedented departure from its *Compendium of Policies, Guidelines, and Procedures* ("*the Guidelines*") to require that the price of Alexion's drug Soliris be lower than that of all seven comparator countries. The Board decision was quashed, and the case was sent back to the Board for redetermination.

Noel Courage

Nyrie Israelian

In its initial decision, the Board found that Alexion priced Soliris excessively and ordered Alexion to forfeit excess revenues earned between 2009 and 2017. In making this decision, the Board relied upon the list price of Soliris being higher than the price in one of the seven countries used for comparison purposes. In other words, the price of Soliris had to be lower than all seven comparator countries. This was the first time the Board had ever imposed that requirement. Alexion applied for judicial review to the Federal Court.

The FCA stressed in its decision that case law establishes that the excessive pricing provisions in the *Patent Act* are directed at controlling patent abuse, and not reasonable pricing, price regulation, or consumer protection at large.[2] The FCA rejected the Board's arguments that the case law and certain statements in Parliamentary debates established a "consumer protection" or "reasonable" pricing mandate for the Board.

In making its initial Soliris decision, the Board considered the price of Soliris on provincial budgets, the fact that the price of Soliris had been under scrutiny in other jurisdictions, and that Soliris was priced lower in the United States. The FCA found that the Board did not, in a satisfactory manner, explain why these reasons were relevant to "excessive" pricing under section 85 of the *Patent Act*, indicating that the Board exceeded its statutory powers by pursuing a general price regulation mandate.

Further, the FCA took issue with the Board's explanation for its significant and unprecedented departure from the *Guidelines*. The Board justified this departure by citing "unique circumstances", but it did not specify what those circumstances were to an extent satisfactory to the FCA. The Board noted that a report from the United Kingdom criticized the price of Soliris as potentially unreasonable and that while Canadian prices for drugs were generally lower than those in the United States, Soliris in Canada exceeded the price in the United States at some points. The FCA described these reasons as "thin and impoverished", stating that "it is not enough to allude vaguely to 'unique circumstances' and then just name two circumstances that do not appear to be unique and that fall short of logically supporting the sort of significant, unprecedented departure from the Guidelines the Board took here".

The FCA also found that the Board failed to provide an adequate explanation for its inconsistent decision to use, under section 85 of the *Patent Act*, the lowest international price of the seven comparator countries as the benchmark to determine if a price is excessive, and then under section 83 of *the Patent* to order a remedy based on the highest international price.

The Federal Court of Appeal granted Alexion's application for judicial review, quashed the Board's decision, and remitted the matter to it for redetermination. The FCA concluded by stating that on redetermination, the Board is free to make whatever decision seems appropriate based on a reasonable interpretation of the legislation, but cautioned that in making its decision, the Board must ensure that a reasoned explanation is discernable on the key issues.

> **"The Board must ensure that a reasoned explanation is discernable on the key issues."**

The Board has requested leave to appeal to the Supreme Court of Canada. Alternatively, the Board may just redecide the case in the manner required by the FCA. In the meantime, this case strengthens the position of innovator drug companies that are undergoing pricing review and negotiations with the Board. We will monitor the effect of this case on the Board's interpretation of its mandate, as well as any implications for the Board's draft new guidelines and regulations that the federal government continues to postpone.

Résumés

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[1] *Alexion Pharmaceuticals Inc. v Canada (Attorney General)* [2021] FCA 157. Leave to appeal to the Supreme Court of Canada has been requested.

[2] The FCA stated that the PMPRB excessive pricing provisions may be constitutionally suspect as outside the power of the federal government if they were aimed at reasonable pricing, price-regulation, or consumer protection at large.

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