Foreign filers fly higher in India

New data from India’s patent office has revealed that almost two-thirds of pharmaceutical patents were awarded to foreign companies between April 2010 and March 2013.

The country issued more than 1000 drug patents in the three-year period ending April 2013. The patent office issued 771 of them to foreign companies such as Pfizer, Novartis and Roche.

Eli Lilly was awarded the most patents, receiving 36, mostly for biological products and compounds used to treat diabetes and related diseases.

Pfizer was second with 32 patents, while Roche and Novartis were awarded 22 and 14 patents respectively. Sanofi and Bayer were granted at least 12 Indian patents over the three-year period.

The data also revealed that between April 2005 and March 2010, the patent office issued 3488 patents, of which 3000 were awarded to foreign companies.

Despite this data, India has been accused of favouring domestic companies over international ones.

Roy Waldron, CEO of Pfizer, recently accused India of unnecessarily denying intellectual property rights in a letter to the US Trade Representative (USTR).

In response, the India Patent Association argued that larger foreign companies have flooded the Indian Patent Office with numerous applications, preventing domestic generic companies from producing and marketing affordable drugs to Indian patients.

India attorneys have also leapt to the country’s defence, arguing that Indian courts have taken a balanced view of pharmaceutical cases, although some admit that patent jurisprudence in India is still developing and it does not have a luxurious bed of home-grown precedents to shape its future.

ANDA patent wars escalate in the US

The ANDA patent wars continue to rage on in the US as Mylan Pharmaceuticals, Ranbaxy Laboratories and Par Pharmaceuticals face yet another lawsuit, this time from both Forest Laboratories and Royalty Pharma Collection Trust.

Forest and Royalty Pharma, which filed a joint lawsuit against a number of companies, including Apotex Corp, Hetero USA, Lupin, and related companies and subsidiaries, have accused the companies of patent infringement.

The lawsuit was filed at the in the US District Court for the District of Delaware on 23 September.

USPTO extends rejected patent review system

The US Patent and Trademark Office (USPTO) is extending its rejected patent review programme until the end of year.

The programme helps to reduce patent pendency by giving examiners a limited amount of time to investigate responses filed after the rejection of patent applications.

The programme, which is called After Final Consideration Pilot 2.0 (AFCP.2.0), had been predicted to end on 30 September, but a notice posted on the USPTO website said that will run until 14 December.

The system, which was implemented in May 2012, uses information gathered from the AFCP, which is a predecessor system, as well as input from stakeholders and examiners obtained through the Request for Continued Examination outreach initiative.
A new element to be added to the Periodic Table...

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ANDA patent wars escalate in the US
Continued from page 1

Forest licenses the patents (6602911, 7888342 and 7994220) from Royalty Pharma that cover Forest’s Savella product, which is used as a clinical treatment of fibromyalgia, a disorder characterised by widespread pain.

Forest and Royalty Pharma received notices from the companies stating that they had filed Abbreviated New Drug Applications (ANDA) with Paragraph IV Certifications seeking approval to market generic versions of Savella before the expiration of all three patents.

Mylan, Ranbaxy and Par have an extensive lawsuit collection building over generic drug filings.

In 2011, Mylan was found liable for infringing multiple patents belonging to Teva-owned biopharmaceutical company Cephalon after Mylan filed an ANDA with the US Food and Drug Administration (FDA) to market generic versions of Cephalon’s Fentora.

In 2009, WCRX, along with its subsidiary Mayne Pharma International, accused Mylan of infringing its US patent for Doryx to prevent generic versions of Doryx from entering the market.

Earlier this year, Horizon took issue with Par Pharmaceuticals after it filed an ANDA with the FDA for a generic version of Duexis.

Avanir sued Par to prevent them from marketing a generic version of Nuedexta, for which they have submitted ANDAs.

Pfizer agreed a settlement with India’s Ranbaxy in 2008, resolving litigation between the parties and guaranteeing 30 November 2011 as a date for the release of a generic version.

Forest and Royalty Pharma are seeking damages from all of the accused companies.

USPTO extends rejected patent review system
Continued from page 1

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AFCP 2.0 examiners will also use the additional

Safe harbour
Interpretations of Hatch-Waxman have left US courts in a muddle

Counterfeit drugs
Baker & McKenzie associates look at the global problem of fake medicine

India insight
Avanir Pharmaceuticals enters into another settlement agreement over proposed generic versions of Nuedexta
time to schedule and conduct an interview to discuss the results of their search and/or consideration with the applicant if a response does not place the application in condition for allowance.

There is no additional fee required to request consideration of an amendment after final rejection under AFCP 2.0.

**IP5 proposes faster patent system**

Applicants whose claims are found patentable by one office will be able to speed up the process of their applications in other offices thanks to a new unified system proposed by five of the world’s largest intellectual property offices.

The IP5, which counts the US Patent and Trademark Office, European Patent Office (EPO), the Japan Patent Office, the Korean Intellectual Property Office and China’s State Intellectual Property Office as its members, will launch the comprehensive IP5 Patent Prosecution Highway (PPH) pilot programme from January 2014.

The offices’ leaders, including the EPO’s Benoît Battistelli, met in Geneva to endorse the pilot programme that will see patents granted faster and more efficiently.

Under the new programme, applicants whose patent claims have been found to be patentable by one office may ask for accelerated processing of their corresponding applications pending before the other IP5 offices.

The PPH arrangements will be implemented in the all-inclusive scheme.

“I am pleased that the first ever all-inclusive PPH pilot programme is launched under the PCT (Patent Cooperation Treaty) framework. It is a very promising step on the way of facilitating the life of users in five big economic regions which represent 85 percent of the patents granted in the world,” said Battistelli.

“While the programme allows the offices to gain additional experience in utilising each other’s available work, it will support the aim of promoting the PCT as the primary global framework for work-sharing.”

Further details and requirements for participation in the IP5 PPH pilot programme will be available on all IP5 websites.

**White & Case warns about dangers of unauthorised use**

International companies have been warned about the increasing danger of suppliers’ unauthorised use of intellectual property.

White & Case LLP issued a whitepaper on the threat of the misuse IP in the supply chain in August.

“A company may own or have the legal rights to use all of the IP that it uses in producing its products or delivering its services but if a supplier in its supply chain uses unauthorised IP, the company may nonetheless find itself facing serious legal and business risks,” said Arthur Mitchell, senior counsellor at White & Case, in a statement.

Companies risk serious lawsuits and government investigations that can result in financial costs, importation bans and other injunctions, all of which can be avoided if preventative legal measures are enforced.

White & Case has pinpointed that the risk is high for companies that have an Asian supply chain. The region is fast emerging as the world’s largest producer of unauthorised products, according to the Organization for Economic Cooperation and Development.

The firm proposes a number of solutions in its whitepaper, including companies monitoring their supply chains, and suppliers issuing representations, warranties and covenants that promise unauthorised IP will not be used.

“Even if the company is unaware of the use of unauthorised IP by its supplier, it could still find itself legally liable and suffer reputational damage,” said Mitchell. “The danger is that regulators, customers and competitors could perceive that the company has benefited
from the unauthorised use. If that is the case, the company may be held responsible."

Other measures include compliance training that will educate employees, which can help defend against accusations that they knew about unauthorised IP use.

In 2011, the UK Intellectual Property Office launched the Supply Chain Toolkit in order to help individuals and businesses to be aware of the increasing risk from counterfeit goods getting into business supply chains.

**UK and Taiwan sign MoU on IP**

The UK and Taiwan have signed a memorandum of understanding (MoU) on intellectual property.

The MoU, which was signed on 17 September, is the first to be agreed between Taiwan and the UK on IP. It will see the two nations exchanging information and cooperating on issues such as internet piracy, patent law compliance and other international IP issues.

Chris Wood, director of the British Trade & Cultural Office (BTCO), said: "Taiwan and the UK are at the global forefront of innovation and the creative industries, so it is vital that the two offices work together to create the right regulatory climate to support this."

The Intellectual Property Office (TIPO), under Taiwan’s Ministry of Economic Affairs, and the UK’s Intellectual Property Office (IPO) will deal with the joint effort, according to the BTCO, which represents UK interests in Taiwan in the absence of diplomatic ties.

In 2008, TIPO signed an MoU with Spain and France on IP protection, while the UK IPO entered into a landmark MoU with the Mexican Institute of Industrial Property in 2012.

**WIPO adds China to Patentscope**

The Patentscope has surpassed 30 million records as a result of the World Intellectual Property Organization (WIPO) adding China’s national patent collection.

The service has more than 34 national and regional patent collections, giving users a geographical diversity of accessible data.

The addition of three million documents from China brings Patentscope’s database up to 32.5 million. Users can search for information about new technologies, which are usually viewable for the first time as international patent applications.

Patentscope users are now able to view bibliographical data for Chinese patents in English from 1985 through to 1995. From 1996, submissions include data in both Chinese and English, as well as description claims in Chinese.

In 2011, Chinese residents filed 415,829 patent applications, the most of any country in the world for a second consecutive year, according to WIPO’s website. Digital communication accounted for 42 percent of all patent applications originating from China in 2012.

"The addition of the patent collection from [China] is another big step forward for Patentscope, which is a unique world-wide service for players in the global race to conceive, produce and market new products," said WIPO director general Francis Gurry in a statement.

"These documents will give users a fresh, important perspective on the workings of one of the world’s most-dynamic economies."

Patentscope allows users to access information and build search queries, with a limitless number of keywords in a number of languages. It can then translate the original query into several languages.

The tool also provides machine translations, which is available on the website to allow users to access information and build search queries, with a limitless number of keywords in a number of languages. It can then translate the original query into several languages.
Balancing act
Could a revamped system be the panacea that South Africa needs?
IPPro takes a look

South Africa’s Department of Trade and Industry issued a new Draft National Policy on Intellectual Property on 4 September to balance ‘the rights of innovators and the rights of humanity’, according to Rob Davies, Minister of Trade and Industry, before his keynote address at the Africa IP Forum in February.

The policy includes a number of proposed amendments to the country’s patent system, which, if enacted, could set a higher standard of innovation for an invention to be deserving of a patent and relax import requirements that have prevented the South African government from sourcing cheaper drugs for the public sector through parallel importation.

Rights groups have hailed the new draft policy, if properly implemented, as a move towards cheaper medicine prices, while drug companies are reportedly wary of the proposed changes.

For almost two years, Treatment Action Campaign (TAC) and international humanitarian organisation Médecins Sans Frontières (MSF, more commonly known as Doctors Without Borders) have campaigned for the Department of Trade and Industry to amend the country’s patent laws, which they argue make medicines more expensive in South Africa.

“This policy is not just about legal technicalities, but will affect the lives of many people living in South Africa. It will have an impact on the ability of medical aid schemes to pay for new cancer medicines for their members,” said MSF and TAC in a statement.

South Africa does not currently have both a pre- and post-grant patent opposition system in place. The situation has led to pharmaceutical companies taking out multiple patents on medicines, with their owners renewing their patents for indefinite periods, by making minimal changes to the compositions in their applications, according to the policy document. “The patent act should be amended to have both pre- and post-grant opposition to effectively foster the spirit of granting stronger patents,” states the policy document.

But the new policy may not be the panacea that activists hope, according to Dr Owen Dean, who is a consultant at Spoor & Fisher. “There is a misconception that if someone has a patent they can hold you up for ransom for it—that’s a fallacy, because there is a provision in the law that states if a patentee is abusing his/her position in terms of the availability of a product and the pricing, one can go to the patent tribunal and obtain an exclusive licence, and those types of licences have been sought and granted before.”

MSF believes that the policy, if it maintains and implements key reforms noted in the draft text, will allow South Africa to make use of legal flexibilities outlined in the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), to which the country is a signatory.

The policy states: “South Africa has a massive disease burden, eg, Aids, HIV, TB, hepatitis, cancer and heart diseases. Patent flexibilities can easily alleviate access to medicines.”

Under TRIPS, and following the World Trade Organization’s Doha Declaration, participating countries can introduce certain “patent flexibilities”, including compulsory licensing, in specific situations.

Dean says that this provision is already included in South African patent law. “There is a misconception, because our patent act does have a compulsory licensing provision that has been there for 50 years.”

But MSF argues: “Even though the patent act already provides for compulsory licences, these provisions have not been used on a pharmaceutical product—in part due to sub-optimal terms and procedures.”

The policy document states that South Africa’s patent law needs to be brought in line with the Doha Declaration, although it is not clear what specific aspects need to be addressed. At the moment, public health emergencies and the high cost of medicines are not included as grounds for issuing a compulsory licence, according to MSF.

South Africa must also remain “committed” to the protection of data in terms of Article 39 of TRIPS, which the country already complies with but is facing pressure from multinational companies to overlook.

The policy document states: “Multinational pharmaceutical companies have lobbied their governments, such as the US, to put pressure on the governments of developing countries not to disclose information from clinical trials to third parties such as generic companies.”

“The information from clinical trials is part of the research that does not need to be repeated by generic companies when they develop their generic medicines. If that is so, the costs for developing generics will be so high that it will frustrate access to public health.”

It adds: “South Africa should remain committed to the protection of data in terms of Article 39, but not to the extent that multinationals are demanding as per their governments as this could compromise access to health.”

The Department of Trade and Industry will accept submissions on the draft policy from the public until 17 October. MSF hopes that several of the issues raised by the draft policy are carried through to the final version and implemented correctly. IPPro
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Drug development is an expensive practice, so pharmaceutical companies need the exclusivity that patents afford them to recover their costs. But in a bid to curb companies over-patenting methods, which reduce the availability of generic drugs, US Congress passed the Hatch-Waxman Act in 1984.

The safe harbour exemption (35 USC §271, to use its codification) protects generic drug companies from infringement liability when developing a drug before a parent expires. However, the scope of protection under the safe harbour has been the subject of considerable uncertainty since its implementation.

"In passing the act, congress sought to balance the needs of the public to obtain cheaper generic drugs as soon as possible after patent expiration while compensating innovators who lost patent term because of time spent getting the patented drug approved. In order to try to balance these interests, the exemption was created to allow generics to perform otherwise infringing activities as long as such activities were related to obtaining federal regulatory approval," explains Dr John Wetherell, partner at Pillsbury LLP.

Before Hatch-Waxman, it was considered patent infringement for a generic competitor to begin an approval process before the expiration of a leading company’s brand-name patent. The safe harbour under Hatch-Waxman initially shielded accused companies if they were ‘infringing’ the patent for the purpose of developing data for the Food and Drug Administration’s (FDA) drug approval process. However, various courts have interpreted the exemption differently, expanding it to cover other activities that congress may not have intended.

The safe harbour states that it will not be an act of infringement to make, use or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs or veterinary biological products.

For early stage innovators developing new biologic and small molecule therapeutics, the safe harbour exemption generally provides a helpful, additional incentive in that certain activities related to the selection, development and approval of new therapeutics, including testing of patented compounds or therapeutics in connection with those pre-approval activities, are exempt from patent infringement.

"Knowing the limits of the safe harbour is important not only to early stage companies developing therapeutics, but also to companies developing generic or biosimilar therapeutics, since there are continued regulatory obligations on the manufacture of such therapeutics."
The split can be viewed as an uncertain balancing act between incentives of the exemption and protection of patent rights," says Theresa Kavanaugh, partner at Goodwin Procter LLP.

The case law behind the safe harbour is varied, and its scope has been extended several times.

When Eli Lilly filed a lawsuit against Medtronic in the US District Court for the Eastern District of Pennsylvania in a bid to suspend Medtronic’s testing and marketing of an implantable cardiac defibrillator, a medical device used in the treatment of heart patients, Medtronic said its activities were “reasonably related to the development and submission of information to the FDA, and thus exempt from a finding of infringement under safe harbour exemption”.

The case went to the US Supreme Court, which ruled that the safe harbour exemption does not apply only to drugs, but also to medical devices.

In Merck KGaA v Integra Lifesciences I Ltd, the court held that the use of patented compounds in preclinical studies is protected under the safe harbour as long as there is a reasonable basis to believe that the compound tested could be the subject of an FDA submission.

The safe harbour exemption becomes more ambiguous in two other cases, Classen Immunotherapies v Biogen and Momenta v Amphastar, which resulted in two Federal Circuit decisions seemingly at odds with each other.

In 2011, the Court of Appeals for the Federal Circuit was asked to rule on whether the safe harbour exemption applied to post-FDA approval activities in Classen Immunotherapies v Biogen. The Federal Circuit ruled that the safe harbour “does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained”.

In 2003, Amphastar filed an Abbreviated New Drug Application (ANDA) for its generic version of enoxaparin and received approval from the FDA in September 2011. Momenta later sued Amphastar for patent infringement alleging that it infringed one of its patents by using the patented method to manufacture enoxaparin for commercial sale.

The US District Court for the District of Massachusetts granted Momenta a preliminary injunction and denied two emergency motions for relief. The court ruled that Amphastar’s activity was not covered by the safe harbour because, “although [it] permits otherwise infringing activity that is conducted to obtain regulatory approval of a product, it does not permit a generic manufacturer to continue in that otherwise infringing activity after obtaining such approval”.

But in August 2012, the Federal Circuit disagreed and vacated the injunction, saying that was inconsistent with Cassen “because the information submitted is necessary both to the continued approval of the ANDA and to the ability to market the generic drug”.

According to Brian O’Reilly, director of O’Reilly IP PLLC, the recent split at the Federal Circuit over the scope of the Hatch-Waxman safe harbour exemption boils down to differing views on the use of congressional intent when interpreting the statute. While the Classen decision relied on congressional intent to conclude that the safe harbour does not extend beyond FDA approval, the Momenta decision found that the language of the statute was clear on its face and had no such time limitation.

“For early stage innovators developing new biologic and small molecule therapeutics, the safe harbour exemption generally provides a helpful, additional incentive in that certain activities related to the selection, development and approval of new therapeutics, including testing of patented compounds or therapeutics in connection with those pre-approval activities, are exempt from patent infringement,” says Kavanaugh.

But Wetherell disagrees that the exemption nurtures innovation, “at least as far as the district courts are interpreting the exemption today”.

“I do not believe that the exemption is having a major impact on innovation in the life sciences sector. The caveat is that we will have to wait and see whether these recent decisions will lead to opening the door wider with respect to additional post-filing activities.”

The Classen and Momenta rulings prove that safe harbour exemption applies to post-FDA approval activities, causing increased confusion around patent enforceability. The Momenta case is also important for companies that have to provide data on drugs to the FDA. Manufacturers that use patented processes in the production of competing drugs are arguably protected by the safe harbour exemption, because their production processes are required for FDA review.

“It is difficult to predict whether the Federal Circuit sitting en banc or the Supreme Court will ultimately overturn the Momenta decision. But what we do know from a string of recent district court cases is that the current law guiding those courts is that the safe harbour can and does extend past FDA approval,” says O’Reilly.

“Consequently, many methods of manufacturing patents in the life science space now have little value. That means that after the Momenta decision, life science companies have less of an incentive to invest in research that relies on those types of patents. And because innovation usually occurs before FDA approval, it seems hard to argue that any freedom gained by the extension of the safe harbour beyond FDA approval will increase innovation in the life science area.” IPPro
Launching its new Medical Product Counterfeiting and Pharmaceutical Crime (MPCPC) unit earlier this year, Interpol described fake medicines and the illicit trade in them as a “problem”, a “global scourge”, and a “threat which puts the lives of millions of people at risk every single day”. Funded by a consortium of 29 big players in the biopharmaceutical industry to the tune of €4.5million over three years, the MPCPC both pronounces the seriousness of the problem and evidences the resolve of enforcement agencies and pharmaceutical companies to combat it. In this article, we consider the extent of this “global scourge” and the various threats it poses, from the very real danger to human health to the effect on the bottom line of brand owners, before examining the challenges faced by pharmaceutical companies and strategies that can be deployed to overcome them.

Why are counterfeit medicines a problem?

Pharmaceutical companies face many of the same challenges as are faced by other brand owners when it comes to counterfeit products entering the market. They result in a commercial impact on any brand owner including damage to reputation, dilution of goodwill in brands and the risk of association with poor quality fake products. However, counterfeit medicines also present their own issues, which makes the threat of such products on the market much greater and the risks more significant.

The primary harm posed by the trade in counterfeit pharmaceuticals is the serious risk to human health. Counterfeit goods may contain too little, too much or (most likely) none of the stated active ingredient. Even if they do not, the delivery of any active ingredient is likely to be ineffective, the fakes can foster drug resistance and the product may contain ‘fillers’ that are at best placebos, which fail to treat the patient’s health condition, and at worst hazardous compounds, which may in themselves constitute a risk to health. Powdered drywall, anti-freeze, wood polish, amphetamine and lead are just some of the examples of dangerous components that have been identified in lab-tested counterfeits.

Far from being harmless, these counterfeits have injured and killed. In 2008, 150 people in Singapore were admitted to hospital between January and May having reportedly taken counterfeit copies of erectile dysfunction medicaments containing glyburide, an anti-diabetic drug, according to the World...
Counterfeit Drugs

Health Organization (WHO). Four died and seven suffered severe brain damage.

There is therefore significant pressure on pharmaceutical companies to tackle counterfeit products as far as possible and stop them entering the market, not only to preserve public health but to combat the negative publicity and damage to reputation that inevitably follows health scares involving what were thought to be genuine, safe products. Unfortunately, pharmaceutical companies are often tarred with the same brush when it comes to counterfeiters of their products and so maintaining public health and confidence in pharmaceutical products is of key concern.

Counterfeiting is now also a problem that affects the entire pharmaceutical industry. It was perhaps once arguable that the problem of counterfeit pharmaceuticals was largely limited to so-called ‘lifestyle’ drugs: those used to treat conditions such as baldness, wrinkles, acne or erectile dysfunction. Factors including the embarrassment of discussing such conditions with a physician or pharmacist, the easy availability of cheap ‘alternatives’ from illegitimate sources online and the perceived harmless of trying such alternatives combined to put these lifestyle drugs in the vanguard of a burgeoning counterfeit drugs market. A 2010 WHO bulletin reported that almost half of all counterfeit drugs sold on the internet were for weight loss, with fake versions of erectile dysfunction drugs such as Cialis and Viagra also forming a ‘key market’ for counterfeiters in Europe and Asia.

However, increasingly there is a concerning trend for counterfeiting of other mainstream prescription-only products used to treat serious health conditions. Rather than relying upon the traditional online supply routes and spam emails to sell counterfeits, we are seeing more and more counterfeit products entering the legitimate medical supply chain. In June this year, Interpol launched Operation Pangea VI, a global anti-counterfeiting operation involving 100 countries. The operation led to 58 arrests worldwide and the seizure of 9.8 million potentially dangerous medicines worth an estimated $41 million.

Perhaps most concerning was the cross section of pharmaceutical products seized including fake antibiotics, cancer medications, anti-depression pills, food supplements and, of course, erectile dysfunction drugs. Only a few years earlier, following a tip off from Eli Lilly, the US department of Immigration Customs Enforcement (ICE) and the UK’s Medicines and Healthcare products Regulatory Authority (MHRA) worked together on what has been described as “the biggest and most sophisticated such crime that ICE has yet come across.” The case involved counterfeit copies of seven life-saving medications, including Zyprexa, Plavix, Casodex and Tamiflu introduced into the legal UK supply chain in 2007, 7000 packets were successfully recalled and 40,000 were seized by the MHRA.

The size of the global counterfeit drug market is estimated to have reached between $75 and $200 billion. As Christopher Viehbacher, CEO of Sanofi, said earlier this year, this means that approximately 10 percent of all medicines are fake, with the figure rising to as much as 50 percent in some developing countries. Naturally, this trade also hurts the bottom lines of pharmaceutical companies, which lose legitimate sales and have to commit time and resources to the battle against counterfeiters.

How do pharmaceutical companies deal with fakes?

In our experience, pharmaceutical companies are forced to tackle counterfeiting occurring both in the ‘real world’ and via online distribution. As mentioned above, the majority of counterfeits fall into the lifestyle product category, which are almost exclusively sold online either via unauthorised and unlicensed websites or through spam email correspondence. It is therefore important to take action at both ends of the counterfeit supply chain: shutting down unauthorised websites to prevent orders being placed and seizing and destroying counterfeit products that do enter the market.

Enforcement in the ‘real world’

In the real—or non-digital—world, the practical first line of defence in tackling counterfeit products is customs enforcement. Using customs authorities to seize and destroy products at country borders is by far the most effective method of preventing counterfeit pharmaceuticals from entering the market. Once they cross over into the market, tracking them down and destroying them inevitably becomes much more complicated, time consuming and costly. In many jurisdictions, national legislation provides customs authorities with wide-ranging powers to seize products. Often they will rely on rights holders to confirm that suspect products are indeed infringing. Our experience is that the effectiveness of a customs enforcement programme is very much based on the level of resources provided by the rights holder. The more information customs authorities have on what genuine and counterfeit pharmaceutical products look like (and how to spot them), the more likely customs will take action to detain suspect consignments of products. Conducted properly, customs enforcement can be a remarkably efficient and cost-effective strategic tool.

In 2011, counterfeit medicines accounted for 24 percent of all seizures conducted by EU customs authorities. In total, 27,480,538 individual medicines were intercepted, which equates to a total market value of more than £20 million. This figure fell dramatically to 712,220 in 2012, which could indicate that together customs and pharmaceutical companies are winning the fight against counterfeits. However, it is more likely that this drop was caused both by a tightening of anti-counterfeiting budgets within European customs authorities and by there being fewer big seizures which, by their nature, include a very high number of individual products.

It is important to take action at both ends of the counterfeit supply chain: shutting down unauthorised websites to prevent orders being placed and seizing and destroying counterfeit products that do enter the market.

Whereas for consumer goods or other products, rights holders may not see it as economic to take action in respect of all counterfeit cases, we have found that due to the overriding public health and reputation risks, pharmaceutical companies tend to adopt a zero-tolerance approach in their customs enforcement work, seeking destruction of counterfeit goods whether imported in small numbers or, for example,
as part of a consignment of tens of thousands of tablets. This tends to make global customs enforcement programmes for pharmaceutical companies particularly complex and administratively challenging.

While it is often necessary for pharmaceutical companies to take action against all detentions of suspect counterfeit products by customs, it is also important to bear in mind that many of the importers of small quantities of counterfeit drugs are innocent consumers who may not realise the goods are counterfeit and are purchasing them for personal use. We have found that pharmaceutical companies often take a different tack with these smaller infringers, trying to educate consumers as well as preventing the goods entering the market. However, when large-scale consignments of counterfeit medicines are intercepted or where an importer is identified as being a repeat offender, rights holders will invariably want to act decisively and take advantage of the full range of legal tools, including test purchases, civil litigation and criminal prosecutions.

Aside from customs enforcement, the vital contribution made by enforcement agencies—such as the MHRA in the UK—is appreciated by pharmaceutical companies. The MHRA is able to take action when medicines are not declared, when imports infringe a pharmaceutical company’s patent rights and even against sophisticated counterfeiters with complex arrangements; its good work in the UK makes it a valuable second line of defence against counterfeit drugs. Counterfeiters often copy prescription-only drugs that are heavily regulated and this provides a further angle of attack to deal with counterfeit products entering the market.

Online enforcement

WHO estimates that in more than 50 percent of cases, medicines purchased online from illegal sites that conceal their physical address have been found to be counterfeit. This is certainly borne out by our experience. In addition, such sites may offer prescription-only medications without requiring a prescription or with only the most spurious of prescription procedures. This in itself is often illegal and therefore action may be taken to take such sites down even if there is no direct evidence that counterfeiters are being sold on the site.

Pharmaceutical companies undeniably face additional problems when seeking to enforce their rights against an online pharmacy: there will likely be little information readily available, physical addresses for such companies tend not to be disclosed and so cannot be searched, and the relevant companies and individuals will often be located in challenging jurisdictions, making obtaining and enforcing court orders and judgements against them tricky. Cease and desist letters can be effective and are usually worthwhile at least as a preliminary step, but are unlikely to unsettle a sophisticated counterfeiter located abroad. In such circumstances, rights holders may wish to consider conducting a private investigation and possibly a test purchase, for the purposes of intelligence and evidence gathering. This may facilitate civil proceedings or, perhaps more helpfully, may pique the interest of local health authorities and law enforcement agencies.

How can pharmaceutical companies overcome the issues they face?

Faced with a growing trade in counterfeit goods spanning much of the globe and previously unaffected medical goods, pharmaceutical companies need to be familiar with their IP enforcement toolkit. The numerous issues confronting rights holders can be addressed by different strategies, keeping enforcement programmes both manageable and effective, even when maintaining a zero tolerance approach in the face of numerous low-level infringements.

In our experience, pharmaceutical companies should be considering a range of steps to protect their IP rights and tackle the growing issue of counterfeiting, including the following:

- Establish and maintain a portfolio of relevant IP registrations—patents (including supplementary protection certificates) for the products themselves, registered designs for tablets, capsules and product designs, and trademarks for packaging are all useful and can generally be recorded with customs authorities.
- File detailed information on genuine and counterfeit products with customs authorities in key markets to enable customs to easily identify and seize suspect goods.
- Maintain a well-organised, centrally-coordinated programme to respond to customs seizure notifications is essential, especially given the large number of detentions that come with customs notices in multiple jurisdictions. We have found that maintaining an overview of large-scale programmes and administering actions in multiple jurisdictions is one of the biggest challenges faced in dealing with counterfeits on a multi-national scale.
- Analyse and act on intelligence gained to identify trends and address any weaknesses in the supply chain. Customs authorities and online investigators provide a wealth of intelligence that can assist with identifying repeat infringers, significant counterfeiting operations and key markets to focus anti-counterfeiting activities.
- Consider giving legal representatives standing instructions on how to approach low-level infringements—do you want to take a zero tolerance approach?
- Invest in relationships with customs authorities and other law enforcement agencies, particularly in priority markets, is time and money well spent. Customs and law enforcement represent the front line in tackling counterfeiting and so the more information they have, the more likely they are to identify counterfeit products.

Ensure that genuine and counterfeit products can be identified quickly and easily. Pharmaceutical companies often use sophisticated ‘counterfeit indicators’ built into their products that assist with visual identification and assessment. As customs can often only detain products for a limited period of time it is vital that assessments can be carried out quickly and ideally on the basis of photographs and consignor/consignee details without requiring a physical inspection.

- Proactively monitor and target infringing websites selling counterfeit goods.
- Consider using investigators, surveillance and test purchases to combat counterfeiters operating in other jurisdictions, and familiarise yourself with countries’ regulatory environment for such investigations.

Fighting counterfeiting of pharmaceutical products is a complex issue but it is one that does not seem as if it will be going away. The massive trade in fake medicines represents a huge concern for pharmaceutical companies both in respect of the risks to public health and to commercial interests. Enforcement programmes often present the most cost-effective means to tackling a global issue and demonstrate to the market that dealings in counterfeit products is not acceptable and must be prevented.
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Practice makes perfect
Cara Verwholt shares the story of how inovia helped KCI and Dentons to improve communication and streamline the foreign filing process
Kinetic Concepts Inc (KCI) is a leading global medical technology company devoted to understanding, developing and commercialising innovative, high technology transformational healing solutions for customers and patients in more than 25 countries around the world. A pioneer in negative pressure wound therapy, the company’s Vacuum Assisted Closure Therapy (V.A.C. Therapy) has been clinically demonstrated to help promote wound healing. KCI’s proprietary technologies have revolutionised the way in which caregivers treat a wide variety of wound types with V.A.C. Therapy used on more than seven million patients worldwide.

KCI is committed to advancing the science of healing and positively impacting patient care by developing customer-driven innovation to meet the evolving needs of healthcare professionals. To protect its innovations and proprietary approach to wound healing, KCI’s patent portfolio. “More importantly, we needed to free up the time our paralegals and company’s patent validation and patent translation work. The company combines a robust technology platform with a global network of foreign associates in more than 120 countries to create value for its clients.

“We were being inundated with emails from all around the world. We simply couldn’t keep up with the minute-to-minute communication requirements of the business,” says Bill Mason, the associate general counsel of IP at KCI responsible for the management of the company’s patent portfolio. “More importantly, we needed to free up the time our paralegals and attorneys were spending on admin tasks so that they could focus on more strategic, organisational matters.”

As of its founding in 2002, inovia has grown to become one of the largest foreign filing providers in the world. More than 1000 companies, law firms and universities have used its online platform, inovia.com, to reduce the cost and complexity of their PCT national stage entry, direct Paris Convention filing, European patent validation and patent translation work. The company combines a robust technology platform with a global network of foreign associates in more than 120 countries to create value for its clients.

"It was important to us that the platform be embraced by our outside counsel, that it could easily scale to meet the evolving needs of our business and that we could justify and show return-on-investment,” shares Mason.

Throughout its 10-year history, inovia has been instrumental in changing the industry’s way of thinking about outsourced IP solutions—putting an emphasis on cost, quality and efficiency. The introduction of cutting-edge functionality like the ‘1-click quote’ tool and ‘agent choice’ feature, have been quickly embraced by the industry and played an instrumental role in KCI’s selection of inovia, as well as the subsequent long-term relationship that has followed.

At the beginning of the inovia deployment, the KCI IP legal team did routine measurement and cost analysis for upper management and its board. Inovia allowed them to generate accurate and detailed cost estimates for upcoming cases, itemising the service, government and translation costs per country. In instances where KCI selected its own agents, they could easily compare their fees to those of inovia’s agents. This immediate cost comparison proved to be an effective tool for managing its outside relationships and for justifying IP legal costs within the organisation.

“The beauty of inovia is its ability to deliver information quickly, to improve communication with our outside counsel, and the flexibility to customise the inovia.com instruction platform by being able to use our own agents if desired. The ease-of-use, peace-of-mind, and accelerated ROI have been remarkable,” continues Mason.

A win-win for all: KCI, Dentons LLP and its European agent

As KCI began consolidating the number of outside US firms under engagement, Dentons LLP began working with KCI and inovia to help reduce the cost of foreign filing. Not only has inovia saved KCI on time, expense and productivity improvements, but Dentons and KCI’s other US counsel responsible for the bulk of its foreign filings have also benefited.

Diane Godzisz, paralegal with Dentons, explains: “Receiving reminders about upcoming cases removes a layer of stress and replaces it with a layer of productivity. Before inovia, handling a filing for KCI could take half a day to prepare. Filing a foreign application the old way involved preparing an individual letter for each foreign associate. With inovia it takes three minutes to place an order."

Daily communication between client and law firm has improved with inovia and billing practices associated with foreign filings have been simplified. Prior to inovia, Dentons had to set up a docketing and account number in their system for each filing, which proved to be very time consuming. With inovia.com, KCI receives the confirmation of the filing directly from inovia and provides payment immediately.

Before inovia, there was a lot of back and forth for Dentons with KCI on strategy—where to file, the cost associated with filings, confirmation of filings, etc. With inovia.com, these issues have been handled with ease.

As one of inovia’s longest client relationships, KCI views the platform as essential to the execution and management of foreign filing. As budgets continue to be tightened, economic conditions shift and new laws and regulations introduced, inovia has proven to be a constant source of value.

"After the significant results and cost savings we saw in the first few years using inovia, we haven’t had to continue to monitor costs or justify the spend," concludes Mason. “We are confident in the savings, productivity and efficiencies inovia.com brings and are grateful for the cost-conscious services inovia provides.”
When in Rome, do as the Romans do

Prathiba Singh and Ashutosh Kumar of Singh & Singh Law Firm outline principles to be followed for the grant and enforcement of patent rights in India

The headline quote of St Ambrose conveys perhaps the best advice for applicants processing their patent applications in India, ie, due care must be given to the provisions of the patents statute in India and to have an India-specific patent prosecution strategy. Having a well formulated patent prosecution timeline and strategy for prosecuting a patent application in India will help inventors not only in obtaining the patent protection for their invention, but will also enable them to withstand a counter attack of invalidity of patent in an infringement suit.

The provisions that need to be properly considered by patent applicants are Section 8 and Section 146 of the Patent Act 1970. In addition, for pharmaceutical or chemical or such related patents, special care has to be accorded to comply with the requirements of Section 3(d).

The purpose of this piece of writing is not to guide about the procedural requirements of patent procurement in India but to highlight the importance of processing a patent application from the point of view of enforcement of such a patent in a court of law in India.

Requirements under Section 3(d) and patent lifecycle management strategies

It is a well known fact that often patent holders, particularly in the pharmaceutical filed, adopt various means and methods to maximise market exclusivity of their patented products/drugs. This is popularly known as an evergreening strategy, or patent lifecycle management. A good example is filing a subsequent patent application for a different polymorphic form of an already patented compound or a patent application for different formulation of main compound etc. In India, Section 3(d) has been considered as one of the biggest obstacles in the patenting of such inventions. However, Section 3(d) can prove to be more lethal at the time of enforcement of basic patent itself, if this provision does not form a part of patentee’s checklist during the time of formulating its patent lifecycle management strategy. Such strategies though helps patentees to prolong a monopoly over their patented products in many jurisdictions, but in India, the same may itself equip a defendant in a patent infringement suit with substantial grounds to raise the defence of non-infringement as well as the defence of a patent’s invalidity.

The reason is simple, in order to obtain a derivative patent, a patentee is required to prove that the invention claimed in the patent application is patentably distinct from the invention claimed in the basic patent, ie, to show that the subsequent invention is novel and non-obvious over the invention claimed in the basic patent and the teachings of the basic patent are not sufficient to arrive at the derivative invention. Nothing harms patentees in distinguishing inventions in the aforesaid manner as long as the patentee successfully obtained the patent protection in respect of subsequent improvisation.

However, in India Section 3(d) is a major barrier for patentees to execute their patent evergreening strategies. Therefore, refusal or abandonment of patent applications for derivative inventions, on the grounds of Section 3(d), may pave the way for the other market players to exploit the non-patented variants of basic patents’ inventions because, as per a patentee’s own stand, its subsequent patent application for the derivative invention, the non-patented variant is patentably distinct from the invention claimed in the basic patent and thus it does not fall foul the basic patent’s claims. This simply means that if no patent protection is given to the variant then others are free to commercialise it and compete with the patented product.

The potent question is whether such patent holders can use their basic patent to prevent others from exploiting the non-patented variant of its patented product? There can be many difficulties in filing an infringement suit on the basis of the basic patent in order to injunction the exploitation of non-patented variants, because in doing so the patent holder will have to bear an insurmountable burden of reconciling its two contradictory stands, ie, the stand taken in the rejected or abandoned patent application for the secondary invention and the stand in the infringement suit.

Therefore, if the patent holders argue that the non-patented variant falls within the scope of the basic patent’s claim they may invite the attack of insufficiency and the biggest evidence that can used against such patentees will be their own admissions in the applications for derivative inventions. In the recent past, such situations have led to the dismissal of infringement suits and refusal to grant interim injunctive relief.

Therefore, a lack of proper attention to Section 3(d) while devising patent prosecution strategies may put patent holders in a checkmate situation where admissions/statements made by them in any subsequent applications, either in India or abroad, will make their patents vulnerable to an invalidity attack, and even if a patentee somehow manages to justify its
stands and thus prevent the revocation of its patent, it may still lose the battle on the front of infringement issue.

Is Section 3(d) insurmountable?

Since the time of the Novartis judgement, Section 3(d) is viewed as a provision that is anti-patent. However, as the Supreme Court itself declared in the judgement, “incremental inventions” are patentable if they satisfy the tests of Section 3(d). To qualify for patent protection under this section, a patentee must show:

- L arity at the time of filing the application as to which is the “known form”;
- The comparison in the derivative patent ought to be made with the nearest “known form”;
- Clear and unequivocal stand in the patent specification that the new form is better than the old and known form; and
- Comparative data either in the patent specification or during the examination process to establish that the new form is significantly better in efficacy than the old form.

If these factors can be borne in mind while prosecuting a patent application, then section 3(d) can be satisfied and it would not be the ‘albatross’ it is portrayed to be.

Section 8: treading unknown paths

Another provision that has become a huge burden to patent applicants and their agents in India is Section 8 of the act. Under the provision, patent applicants are required to submit details to the patent office pertaining to the corresponding applications filed in other jurisdictions, in relation to the same or substantially the same inventions, till the grant of patent in India. Along with this, Section 8 also empowers the patent office to ask applicants to furnish any other details pertaining to the prosecution of corresponding foreign patent applications. More importantly, failure to comply with the requirements of Section 8 is also grounds for revocation of patent.

This provision has become a nightmare for patent applicants and agents because no one knows exactly how to comply with the mandate of Section 8. Moreover, the observations and discussions made by the Intellectual Property Appellate Board (IPAB) in its recent decisions have made this provision more uncertain and complex than it was earlier. A literal interpretation is being made of this section to stretch it to mean that a patent applicant is required to file before the patent office every piece of paper filed in different jurisdictions. Such an interpretation is seen in Section 8 is not only unreasonable but also neglects the very fundamental principle of law, ie, “Lex neminem cogit ad vana seu impossibilia” (the law compels no one to do vain or impossible things). Therefore, Section 8 cannot be interpreted in the manner that makes it impossible, physically as well as commercially, to comply.

Now, the important question that arises here is that in the absence of any clear legislative and judicial guidance, how do applicants comply with the requirements of Section 8? A careful consideration of the facts of various cases involving the issues of the violation of Section 8 reveals that not a single patent has been found in violation of the section merely because of the non-furnishing of some trivial or irrelevant information. In all cases, the information or details that had not been provided to the patent office were all information or details that would have had a material effect on the grant of patents.

There are two categories of non-compliance of Section 8:

- Concealment of most important corresponding application details or details as to rejection of patents in many jurisdictions; and
- Non-filing of all documents relating to patent prosecution.

It is physically impossible and commercially unviable to file all patent prosecution documents from every jurisdiction, especially considering the huge translation costs and the quantum of paper involved. Filing the list of patents or applications in different jurisdictions along with granted patents in such jurisdictions ought to be held to be sufficiently compliant. Moreover, in this day and age when patent databases are accessible online by patent offices, to add the need to file reams of paper before the patent office when the prosecution history in different jurisdictions is accessible online at the click of a button, is to increase the burden on patentees. The act is one which is passed to “grant patents”, not reject them. Hence, the interpretation of the provisions has to be in the right direction.

Working of patented invention in India

Section 83 of the act provides the general principle for working of the patented invention in India. The provision obliges patentees to commercially exploit their invention in India to its fullest possible extent. Based on the principle, Section 146(2) of the act mandates that every patent holder shall furnish information, in Form 27, regarding working of the patented invention on a commercial scale in India. Though non-compliance with this provision does not lead to revocation of patent, ignorance of this provision may lead to penal consequences such as a fine, which may be as much as $1600, or imprisonment of up to six months.

Moreover, non-working of the invention in India may also become a ground for grant of a compulsory licence. However, the most fatal consequence of non-working of an invention in India is the denial of right to get a temporary injunction in a patent infringement action. Therefore, commercial exploitation of patentable inventions and regular filling of Form 27 with the patent office must be treated as an indispensable, particularly from the point of view of enforcing such patent in a court of law. Form 27, however, requires enormous revamping as it seems to follow a straight-jacketed approach and does not take into consideration licences issued on the patent as part of a broad portfolio where a monetary consideration cannot be attributed for each patent. The form needs to also take into account various confidentiality clauses and permit filing of working details under strict terms of confidentiality.

India has often been stigmatised as an anti-patent country because of the various decisions or judgements holding against patent holders. However, a careful analysis of all of these cases clearly show that India’s image as a hostile nation for a patent holder is nothing but a burden shifting exercise to cover up the patentees taking for granted various statutory provisions and ignoring the nuances of Indian patent law.

In reality, if due care is given to the provisions of Indian patent law right from the beginning of patent prosecution, then life will become much easier for patent holders/applicants in obtaining strong patent protection, as well as in enforcing such patent rights, in India. IPPro
Map out a path through the IP maze

Every business generates intellectual property, and audits can help to get a handle on it, says Stephen Carter of Mewburn Ellis LLP
It is an often underappreciated fact that virtually every business generates intellectual property.

IP, including technical innovations, brands and designs, are important assets for a business. IP rights, if exercised correctly, provide a business with the opportunity to gain exclusivity in its IP, allowing it to maximise the return on investment in creating the IP.

Some IP rights come into existence automatically. One example is copyright. Stronger, ‘registered’ rights, such as patents, registered trademarks and registered designs, need to be actively sought. Especially in the case of patents, it is vital that the protection is sought before the technical innovation to be protected is made public.

IP is understandably not always the first thing on an entrepreneur’s mind when setting up a new business or expanding a business in a new direction. Indeed, as an initial idea takes off, IP may get entirely forgotten in the multitude of activities and issues that compete for the attention of the early stage business. Even after the initial start-up phase, opportunities to capture and protect IP may continue to pass by unnoticed, as the business focuses on establishing itself in the market. However, a lack of attention to IP may come back to bite a business. For example, profits may fall as a competitor takes market share with a copycat product, counterfeit products may tarnish the image of the business or a would-be investor may demand reassurance about the IP owned by the business before making an investment.

Recognising the role IP can play in the success of a business and identifying the IP that has been and will be generated are important first steps on the path through the (sometimes puzzling) maze that is IP. Without a good path, you can be lost before you even get going.

One way to start to map out a path through the IP maze is to commission an IP audit.

**IP audits**

An IP audit is a review carried out to look into the existing IP assets of your business and provide advice and guidance towards identifying and maximising the value of that IP. It is also intended to help ensure that potential future IP assets are identified and properly managed.

An IP audit will typically cover a wide range of areas, not only considering current and future IP assets of a business and which of those assets warrant protection, but also exploring potential issues involving ownership of IP assets that are being generated and other peoples’ IP, as well as giving guidance in relation to approaches to IP capture going forwards and IP strategy.

**Focused protection**

The audit can help a business to decide where to focus its efforts in relation to IP protection. Securing IP rights, especially the stronger registered rights such as patents and trademarks, is an expensive business. Without focus, expenditure on IP can rapidly spiral out of control.

In deciding where the focus should be a business should consider what it is that gives you the edge over the competition. A business should be careful to take account of its (actual or potential) revenue streams. There is little point in focusing efforts and resources on a product or service that is only ever going to find a small market, no matter how unique or innovative it may be, if in doing so there is no budget left for seeking protection for a less exciting product or service that nevertheless accounts for a main stream of income.

**Is it yours?**

Identifying the existing and potential future IP assets is a first step, but it is equally as important to determine whether the business actually owns the assets. This crucial question is often overlooked to the downstream detriment of the business, who might later find themselves in a position where they have invested in protecting IP rights that are not theirs in the first place or fail to secure an investment because they cannot demonstrate to an investor that they own the rights.

The laws governing ownership of IP rights are complex and all too often businesses fall into the trap of assuming that if they have borne the cost of developing something they must necessarily own the outcome of that development—this is just not true.

An IP audit can look closely at the relationships between the business and the individuals creating the relevant IP to establish where the ownership of the IP lies and what needs to be done, if anything, to ensure ownership sits with the company.

**Other peoples’ IP**

It must not be forgotten that your competitors may well have their own IP rights. It is important to be aware of the impact that rights of others could have: at worst, halting your activities completely.

Prudent businesses will have in place strategies for dealing with this, which may include watching the IP filing activity of known competitors or publishing information about your developments to block others from later obtaining patent protection for the same thing.

An IP audit can start to look as these issues and help to develop a plan to address them.

**UK IPO—IP Audits Plus**

The UK Intellectual Property Office (IPO) offers support to innovative companies for conducting IP audits through a scheme known as IP Audits Plus.

The scheme works on a referral basis and can only be accessed by businesses that are engaged on one of the IPO’s partner support schemes. They are GrowthAccelerator, Welsh Government, and Scottish Enterprise (including Highlands and Islands Enterprise). At the partner scheme a business’s nominated contact may suggest to them that they are suitable for an IP audit.

If the business goes ahead with the IP audit, their nominated contact oversees and submits an application to the IPO on its behalf. If the IPO accepts the application, the business can choose an IP professional to conduct the IP audit.

Once the Audit is complete, the IPO picks up the tab (up to a maximum of £3000, including VAT). So, if a business can access this scheme then it can get a good handle on its IP position without having to pay a penny.

**GrowthAccelerator**

GrowthAccelerator is a unique government-backed service led by successful business growth specialists. It is aimed at ambitious, innovative businesses and, in addition to giving access to the IPO’s IP Audit Plus scheme, will work with a business to review their current position and develop a bespoke growth plan specific to the needs of the business. The scheme offers support by way of coaching, workshops and masterclasses, and also offers match funding of up to £2000 for senior managers to hone their leadership and management skills. More information is available at www.growthaccelerator.com

**Map a path through the maze**

To have the strongest IP position possible, a business needs to consider IP from the outset. However, for businesses that come late to IP, it is still possible to build an IP position through the use of automatic IP rights and the capture of any registered IP rights that are still available. It is therefore never too late for a business to improve or recover its IP position, even if it seems that the path through the IP maze has become overgrown with time.

A good starting point for any business is to use an IP audit to map out a path through the IP maze. **IPPro**

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**Stephen Carter**

Partner, patent attorney
Mewburn Ellis LLP

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www.ipprolifesciences.com
The London Patent Summit  
Pharma Anti-Counterfeiting Congregation 2013  
Pharmaceutical Law in Turkey & MENA

Location: London  
Date: 7-8 October 2013  
www.londonpatentsummit.com

The London Patent Summit is an annual meeting platform for patent regulators, policy makers, Board-level patent managers, as well as patent experts and investors in a dialogue designed to address and to discuss best practices and solutions to enhance global, regional and national patent management strategies.

Location: London  
Date: 8-9 October 2013  
www.virtueinsight.com

This conference will gather government bodies, pharmaceutical companies and solution and technology providers to discuss the in-depth insights into the strategies and cutting edge technologies for pharmaceutical anti-counterfeiting.

Location: Turkey  
Date: 6-7 November 2013  
www.informa-ls.com/CQ5219IPPRO

This year is our 2nd annual meeting and we are delighted to include representatives from the Ministry of Health, Turkey, the competition authority, Turkey as well as leading lawyers from across Turkey, Middle East and North Africa. This meeting covers key legal developments and also provides critical regulatory updates that legal professionals need to know. Topic themes include: competition law; IP, pricing and reimbursement; compliance; and corruption and regulatory law.
Industry appointments

Kilpatrick Townsend & Stockton LLP has elected Susan Spaeth as its managing partner.

She focuses her practice on intellectual property and complex/technical litigation, particularly patent litigation, licensing and counselling.

Spaeth has represented biotechnology, medical device and high technology companies in various federal district courts, the US International Trade Commission and in European patent litigation.

She also regularly assists clients with patent portfolio development, product analyses to determine patent infringement, negotiation of IP agreements and establishing strategies to exploit the use of IP.

She served as managing partner of Townsend and Townsend and Crew LLP, which merged with Kilpatrick Stockton in 2010, between 2001 and 2007.

“I greatly appreciate this opportunity to serve our clients, attorneys and staff in a truly meaningful way,” said Spaeth.

“It is a privilege to be a part of a firm that for more than 153 years has not only been counselling some of the world’s top companies and organisations but has been at the forefront of providing pro bono services to those in need. I am confident that we will continue to successfully build on the firm’s solid foundation.”

Freehills Patent Attorneys has appointed Damian Slizys as a partner in its pharmaceutical and biotechnology practice.

Slizys focuses on chemistry and pharmaceuticals and advises clients on patent strategy and freedom to operate as well as patent drafting, filing, and prosecution.

He has also coordinated opposition proceedings and has provided both scientific and legal advice in a number of patent litigation matters.

Slizys has acted for a number of international and Australian clients, including biotech development companies, universities, research institutes and multi-national pharmaceutical companies.

He has experience in guiding applications through to grant in jurisdictions in the Asia Pacific region, including India and China.

Before joining to Freehills Patent Attorneys, Slizys was a partner at another Melbourne-based intellectual property firm.

Jones Day has moved partner Warren Nachilis to its Boston office from New York.

Nachilis is co-leader of the firm’s global licensing and technology transactions team.

He has experience in a broad spectrum of technology areas but focuses on pharmaceuticals, biotechnology, medical devices and electronics.

He practices a range of IP-related matters including licensing, joint ventures, joint development agreements, development and supply agreements, technology issues, and strategic IP counselling.

“Nachilis is a well-known and extremely well regarded licensing and technology transactions attorney, and we are thrilled to have him leading that practice in Boston. Given the heavy focus on intellectual property in the Boston area, we are confident that [his] move will serve our clients well,” said Traci Lovitt, partner-in-charge of the Jones Day Boston office.

The US Patent Trial Appeal Board (PTAB) has hired Brian Murphy as administrative patent judge.

Brian Murphy was an IP partner at Edwards Wildman Palmer LLP. With his recruitment, there are now 170 PTAB judges.

The PTAB was created to replace the Board of Patent Appeals and Interferences. The PTAB hears objections to patent validity as well as appeals and other proceedings.

He has more than 25 years experience trying patent litigation, licensing and counselling.

Murphy is also a Hatch-Waxman specialist, and his clients include a number of well-established companies including GlaxoSmithKline, Daiichi Sankyo and Du Pont Air Products Nanomaterial.

Scott Wofsy, chair of Edwards Wildman’s IP department, said that Murphy is well known in New York patent circles and will be “influential addition” to the PTAB.

“[His] decision to enter into public service at a time of historic change in US patent law is something that, as a firm, we’re really proud of,” added Wofsy. IPPro
IPPro takes five with Jamie Keating Lord, an up-and-coming associate at Jenner & Block

How did you get into intellectual property law?

Prior to law school, I worked as an intern at Dow AgroSciences, in its intellectual property group. I really enjoyed the work I was doing because its caseload was exciting and complex, so I decided to continue a path in IP.

What do you specialise in and why?

I specialise in patent litigation and my focus has been on chemical cases. I specialise in this area because the work is challenging and interesting, and I get to work with a team of attorneys that I really enjoy.

What is a typical day for you?

My typical day depends a lot on the status of the cases that I am currently working on. If a case is in the early stages, I’m typically in charge of managing discovery, interviewing potential witnesses and making sure the appropriate discovery is being filed. Later in the case, a typical day could involve preparing witnesses for depositions, taking or defending depositions, and drafting motions for summary judgement. If a case is readying for trial, a typical day could involve preparing pre-trial orders, and preparing witnesses and witness outlines for trial.

How do you prepare for an especially difficult case?

Often cases are either difficult because the technical issues are very complicated or because they are extremely expansive. Either way, in order to prepare for an especially difficult case, I like to make sure I am as familiar with the technology as possible because it lays a foundation for the rest of the case.

Is there a case you are most proud of, and why?

One of the cases that I’m most proud of is a case where we represented Dow Chemical Company against Nova Chemical Co. We secured a victory for Dow in 2010 before a jury for more than $60 million, which was affirmed on appeal. I’m most proud of this win because it is a case that I’ve worked on for nearly seven years. I started working on it as a first year associate at Jenner & Block and was able to see it through to trial years later. Having been part of a team that invested so much time on a case that resulted in successful outcome is a great feeling.

What are your ambitions?

My ambitions are to keep advancing my career as a patent litigation attorney, by being a successful working mother that has a good balance of work and family.

Do you have any advice for students thinking of getting into IP law?

My advice would be to focus on your grades because IP is a niche market and good grades will help you stand out amongst the crowd. I would also suggest trying to get a mentor in the IP field to get a better understanding of what IP lawyers do and to confirm your interest in the field. IPPro

Jamie Keating Lord is a member of Jenner & Block’s litigation department and patent litigation and counselling practice. She is also a member of the firm’s hiring committee. She has significant experience litigating intellectual property issues related to a variety of technologies including pharmaceutical products, chemical products and processes and mechanical products and processes. She also has experience with contractual disputes involving supply agreements, joint development agreements and IP ownership issues. Lord also maintains an active pro bono practice and dedicates more than a hundred hours each year to her work.

Lord is active in several professional and community organisations, including the Chicago Bar Association and the Federal Circuit Bar Association. Lord has spent a significant amount of time working with the Constitutional Rights Foundation’s Lawyers in the Classroom Program teaching CPS students about constitutional law. She is also a member of the Professional Board for PAWS Chicago.
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