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US senators want to protect USPTO funding

US Senators want to protect the Patent and Trademark Office (USPTO) from budget sequestration.

Senators Dianne Feinstein, Tom Coburn, Amy Klobuchar and Jeff Flake introduced the Patent Fee Integrity Act into Congress on 13 March, which they say will protect and secure patent user fees and stabilise funding for the USPTO.

The American taxpayer historically funded the USPTO, but in 1990 a 69 percent user fee surcharge was established to make the agency self-sufficient.

Currently, the USPTO is a 100 percent-user fee funded agency. However, its funds are often diverted for other purposes. In 1992, $8.1 million in user fees were diverted, rising to $209 million in 2011.

The America Invents Act, signed into law by President Barack Obama in 2011, created a reserve account in the US Treasury to hold the fees collected by the USPTO that exceed its annual appropriation.

But the law instructs the USPTO to look to appropriations acts for instructions on how to access the money every time it wants more funds. “A more permanent fix is needed,” according to the Intellectual Property Owners Association.

On top of this, the USPTO is under pressure from budget sequestration, specifically the $85 billion sequestration of 2013 government funds that took effect on 1 March.

Politicians have moved to protect the USPTO from budget sequestration in the past, asking that it be added to the list of agencies exempt from future orders, but efforts have so far proved unsuccessful.

The bill introduced into the Senate on 13 March will protect the current user-fee system by placing those fees in a separate fund to prevent them from being raided for other purposes. It also includes provisions to ensure accountability for the USPTO, requiring annual operations and spending plans be sent to Congress, as well as an annual independent financial audit.

“In 1990, Congress made the PTO a self-funded agency, but those funds are frequently plundered for other uses,” said Feinstein. “Since then, more than $1.1 billion in user fees have been diverted. When fees paid by inventors are used for general purposes, they amount to a tax on innovation.”

“The Patent Fee Integrity Act prevents that from happening. If we fail to support the PTO and reduce delays in the patent process, we are contributing to a decline in American ingenuity, and that is something we should all work hard to avoid.”

Coburn added: “Keeping the funds at the PTO is one the best ways Congress can take action on a jobs programme.”

“Instead of letting politicians in Congress raid PTO’s funds to pay for parochial pet projects, lawmakers should ensure that funds raised by patent fees stay at the PTO. Doing so will help shore up the PTO’s finances and alleviate the backlog of hundreds of thousands of potentially job-creating patent applications that are due a review.”

Other bills are currently making their way through Congress, including the Patents and Trademarks Encourage New Technology Jobs Act and Innovation Protection Act, which also aim to protect USPTO funding.

There is massive support for protecting USPTO funding, with patent users large and small calling for reform.

Myriad loses motion to block Ambry cancer tests

Myriad Genetics has been denied a motion to block Ambry Genetics from selling products similar to the company’s gene-based BRCA cancer test.

Myriad filed a complaint against Ambry in the US District Court of Utah in July 2013, alleging that Ambry’s tests infringed its patents, including claims for primers, which are little pieces of DNA used to amplify genes, and methods for analysing the BRCA sequences.

The company sought a preliminary injunction, but in a 10 March ruling, district Judge Robert Shelby stated that Myriad was not entitled to a preliminary injunction, agreeing with Ambry’s assertions about the validity of the patents.

In the district court’s opinion, Judge Shelby wrote: “Myriad has declined to publicly share critical information regarding its classification of variants, including with its own patients. Instead, Myriad retains that information in a private database.”

“In so doing, Myriad distorts rather than serves the patent system’s goal of public disclosure in exchange for exclusive rights. In this way, Myriad has chosen a commercial path that turns much of our patent system policy on its head.”

In June 2013, the Supreme Court ruled that the company could not patent naturally occurring human genes, allowing other genetic companies to market their own versions of the BRCA1/BRCA2 tests.

The tests are used to detect a type of inherited breast cancer by searching for mutations in the BRCA1 and BRCA2 genes that increase a woman’s risk of developing breast and ovarian cancer.

Top court
Discrepancies in rulings can affect inventors and cause uncertainty in patent law

Asia patents
Countries in north-east Asia each have their own nuances when it comes to filing patents

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A look at the case law surrounding the protection of advert slogans in India
“Today’s win is a victory for the entire genetics community. We’ve all believed for years that products of nature should not be patentable and were thrilled with the Supreme Court ruling in June 2013 affirming this principle. We stood by our convictions after Myriad sued Ambry and are exhilarated by today’s ruling,” said Ambry CEO Charles Dunlop.

“Competition stemming from a free market drives all of us to improve and ultimately increases patient access to life-changing information. Our company has been providing innovative genetic testing and excellent service to children’s hospitals and cancer centres for the last 13 years and we are excited to see the industry evolve in this new era.”

China and US drive record patent filing growth

The US and China drove record-level patent-filing activity in 2013 as the number of annual international patent applications exceeded 200,000 for the first time, according to a World Intellectual Property Organization report.

The report showed that the number of filings under the Patent Cooperation Treaty (PCT) applications filed in 2013 amounted to 205,300, representing 5.1 percent growth compared with 2012.

With 57,239 applications in 2013, the US surpassed in 2013 its previous filing peak of 54,046 applications.

China overtook Germany to become the third largest user of the PCT system, with Japan as the second-highest user.

In four technology fields—biological materials, biotechnology, pharmaceuticals, and nanotechnology—applicants from the public sector featured among the top 10.

International industrial design applications filed under the Hague system increased to a record 2990 filings in 2013, representing growth of 14.8 percent on 2012.

International trademark applications filed under the Madrid system grew to 46,829 in 2013, the highest number ever recorded.

In the Madrid system, Swiss pharmaceutical company Novartis tops the list of top applicants, with 228 applications in 2013.

“The new records in international IP filings attest to the importance of intellectual property in the global innovation ecosystem,” said recently re-elected WIPO director general Francis Gurry.

“WIPO’s global intellectual property systems are an indispensable part of the global innovation ecosystem, providing cost-effective options to secure international coverage for the protection of intellectual property.”

US court invalidates Pfizer’s patent for Celebrex

Pfizer is facing early competition this year after a federal judge invalidated a patent for Celebrex, an arthritis drug.

Teva Pharmaceuticals, Mylan and Lupin were just some of the generic companies that argued that New York-based Pfizer’s patent is not different enough from another Celebrex patent expiring in May.

The US Court of Appeals previously invalidated an older patent, but Pfizer then requested the US Patent and Trademark Office reissue a new one encompassing changes to address the appeal court’s ruling.

But district Judge Arenda Wright recently ruled that the changes are not permitted under patent law.

Pfizer said it would appeal against the March ruling, made by the US District Court for the Eastern District of Virginia, as well as “pursue all available remedies”.

Celebrex belongs to a class of drugs called COX-2 inhibitors and reduces the pain for arthritis sufferers by blocking a chemical reaction in the body that causes inflammation.

“It seems likely that odds are in favour of generics launching early,” commented Sanford Bernstein analyst Tim Anderson said in a research note.

Novo Nordisk agrees insulin deal with Caisson

Biopharmaceutical company Caisson Biotech has expanded its HEPtune heparosan-based drug delivery technology agreement with Novo Nordisk.

Novo Nordisk has exclusive rights to sell and market insulin conjugated to HEPtune and non-exclusive rights to leverage the HEPtune technology across other core therapeutic areas including other diabetes treatments, as well as hormone therapy products, obesity and inflammatory diseases treatments.

Under the new licence agreement, Caisson will be eligible to receive up to $167 million from Novo Nordisk in milestone payments, depending on achievements of certain predefined clinical regularity and commercial objectives plus potential long-term residual royalties.

Caisson Biotech chief scientist Paul DeAngelis stated that Novo Nordisk has completed feasibility studies that pre-clinically validate Caisson’s heparosan-based drug delivery technology for product pharmacokinetics and enhanced half-life.

“The HEPtune technology uses heparosan, a naturally occurring sugar polymer produced by the body that is stable and inert in the bloodstream while being biodegradable. Furthermore, HEPtune can be customised with respect to polymer size and conjugation chemistry thus providing flexibility to enhance a variety of therapeutic proteins and peptides,” added DeAngelis.

“As a respected healthcare leader, Novo Nordisk has been an ideal partner and provides...
the infrastructure and expertise necessary to develop these much-needed therapeutic products," said Thomas Harlan, CEO of Caisson.

“We look forward to our continued collaboration under this new licence and to assisting Novo Nordisk in achieving its goal of developing these products and helping more patients.”

UN raises awareness of trafficking dangers

Three UN agencies have launched a joint initiative to raise awareness about the dangers of trafficking.

The campaign was launched on 5 March, and is targeted at tourists urging them to look out for different forms of trafficking, including counterfeit goods.

It was presented at the tourism sector of the International Tourism Bourse in Berlin.

The campaign is a joint effort between the World Tourism Organization (UNWTO), the United Nations Office on Drugs and Crime (UNODC), and the UN Educational, Scientific and Cultural Organization (UNESCO).

The campaign provides guidance to recognise possible situations of trafficking in people, wildlife, cultural artefacts, elicit drugs and counterfeit goods, and wants travellers to take responsibility for the consumer goods they purchase.

The initiative, ‘Your Actions Count – Be a Responsible Traveller’, will strengthen the UN’s ongoing goal of combating organised crime and provide support for the UNWTO Global Code of Ethics for Tourism.

Using the hashtag #traveldon'ttraffic, the UN agencies want to use Twitter to promote their cause.

They have also set up a website dedicated to the campaign, as well as a special YouTube channel.

UNODC executive director Yury Fedotov emphasised the importance of informing travellers about where their money ends up when buying illicit products: “Travellers have a responsibility not to contribute to the profits being generated through organised crime.”

“Whether it relates to the sale of people, animal products, drugs, cultural artifacts or counterfeit goods, it is important that travellers fully understand the exploitative nature of these activities. Awareness campaigns such as this one are critical if potential consumers are to be informed about the adverse effects of their purchasing decisions.”

In January, UNODC launched another campaign, Counterfeit: Don’t Buy Into Organised Crime, to educate consumers about the production of counterfeit goods, and to make them understand the problems caused by purchasing fakes.

SIPO and UK IPO discuss future of IP cooperation

China State Intellectual Property Office (SIPO) commissioner Shen Changyu and the UK ambassador met recently in Beijing to discuss the future of its relationship with the UK Intellectual Property Office (IPO).

Shen said that SIPO and the UK IPO were traditionally “friendly and cooperative partners”.

Since the signing of a memorandum of understanding on cooperation in 1996, SIPO and the UK IPO have conducted a range of cooperation agreements in such areas as high-level visits, joint symposiums and exchanges between patent examiners.

This year, SIPO and the UK IPO will conduct cooperation on exchanges between patent examiners, as well as meetings between the heads of the two offices.

Shen said he hoped that SIPO and the UK IPO would further strengthen their coopera-
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tion, and jointly drive the development of IP in China, the UK and globally.

“We are ready to further consolidate cooperation with UK IPO to push forward the development of intellectual property in China and the UK. Meanwhile, we also hope to work together with the UK to jointly promote the improvement of the international intellectual property system,” added Shen.

In 2013, UK applicants filed 24,565 patent applications in China, and were granted 10,243 patents.

Currently, China is working on setting up specialised intellectual property courts and becoming more transparent.

Proposals are on the table for a US-style circuit system, as well as a regional system such as the one about to be implemented in the EU in the form of the Unitary Patent Court.

Natco prevails in Indian Copaxone patent dispute

Teva Pharmaceuticals has lost its bid to prevent Natco Pharma from marketing a generic version of its blockbuster drug Copaxone in India.

Teva owns an Indian patent for a method of making the drug, which made the company more than $4 million in sales. The US patents for the drug are set to expire in May 2014.

In 2007, Teva sought an injunction preventing the generic drug maker from selling its own multiple sclerosis drug, also known as copolymer-1, under the mark Glatimer or any other.

It accused Natco of patent infringement for the use of the “well-known process” to manufacture copolymer-1.

The Israeli-based company also filed to restrain Natco and its partners from exporting the product outside India.

Natco argued that Teva’s patent is invalid due to lack of novelty in a counterclaim.

In his February 28 decision, Justice Murlidhar stated that the Delhi High Court did not “consider it necessary to deal with any of [the parties’] applications”, and dismissed the case.

Natco commented, “We are very pleased with the decision by the High Court to dismiss and take no action in this matter ... We are also pursuing other challenges against this patent.”

Natco added that the Indian Patent Office refused to grant two additional patent applications to teva that would have covered the copolymer-1 product.

Previously, Natco has won complaints against global pharma companies, having prevailed in a case against Novartis for its blood cancer drug Glivec last year and also receiving India’s first compulsory licence to Bayer’s kidney cancer drug Nexavar.

EPO report shows increase in UK patent grants

Patent filings in Europe reached an all-time high in 2013, with patent grants hitting 66,700, an increase of 1.6 percent over 2012.

Companies and inventors from the UK filed 6469 patents at the European Patent Office, which was a 3 percent decline from 2012. Last year, 2062 European patents were granted to UK companies, which was 2 percent more than the previous year, and an increase of 25 percent since 2009.

The UK again provided an evenly spread patent portfolio in 2013, including patents for electrical machinery, apparatus and energy (287 applications), measurement (with 281 applications), organic fine chemistry (276), medical technology (264) and transport (257).

GlaxoSmithKline was the biggest patent filer for the pharmaceutical industry, with 51 applications.

"Demand for patent protection in Europe is up for the fourth consecutive year," said EPO president Benoît Battistelli.
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“This growth is proof that companies from around the world continue to see Europe more and more as a premier hub of innovation. The strong position of European companies in patent-intense technologies once more underlines the central role of these sectors for employment and growth in the EU economy.”

In total the EPO received 266,000 patent filings last year, 2.8 percent more than in 2012 and a new record. The US and Japan again had the bulk of filings, while China and South Korea once more took the lion’s share of the growth.

**Amarin hits AstraZeneca with suit over heart medicine**

Amarin Pharmaceuticals has struck out at AstraZeneca with a suit over the company’s heart medicine Epanova, alleging that the drug infringes its patent for Vascepa.

The complaint filed at the US District Court for the District of Delaware on 4 March, marks the company’s second attempt to protect its rights to the triglyceride-reducing drug within a week.

Amarin is alleging that AstraZeneca intends to market and sell Epanova, following approval of its New Drug Application from the US Food and Drug Association in 2013.

The patent covers methods of lowering triglycerides by administering a pharmaceutical composition that includes amounts of EPA as free acid, and no more than about 30 percent DHA.

The company said that it plans to “pursue this litigation vigorously and aggressively protect its intellectual property rights.”

In July 2013, AstraZeneca completed an acquisition of Omthera, focusing on new therapies for abnormal levels of lipids in the blood, referred to as dyslipidemia, including Epanova.

The suit seeks injunctive relief and monetary damages for infringement.

**Actelion settles row with generic drug makers**

Actelion Pharmaceutical’s quest to affirm that anti-trust laws do not require it to supply its patented blood pressure drug Tracleer to generic rivals has been settled, according to a court dismissal.

If the deal is not consummated within 60 days, the parties have the opportunity to re-enter litigation, according to Judge Noel Hillman’s dismissal on 28 February.

The settlement’s terms were not disclosed.

The Switzerland-based company brought its case to the US District Court for the District of New Jersey in September 2012, seeking a declaratory judgement against Apotex, Roxane Laboratories and Actavis to confirm that anti-trust laws do not compel it to do business with its competitors.

In 2013, Actelion pressed the court for a judgement, saying it is free to do business with whomever it chooses.

In addition, it must follow US Food and Drug Administration restrictions on the distribution of Tracleer, a treatment for lung hypertension that has been linked to severe liver problems.

A New Jersey judge later rejected Actelion’s bid for early judgement and to dismiss counterclaims filed by the defendants.

The Federal Trade Commission urged the court to keep the case alive in an amicus brief, stating that if Actelion’s “legal position was adopted, it could pose a significant threat to competition in the pharmaceutical industry”.

According to Ralph Neas, president and CEO of the Generic Pharmaceutical Association: “The resolution of this case will have profound effects on a multibillion-dollar industry and the prescription drug choices of hundreds of millions of Americans.”

**IP bill faces final hurdle**

An intellectual property bill has been passed in the House of Commons that will see changes to UK patent, copyright and design law.

The reading of the bill took place on 12 March.

It will be returned to the House of Lords, which will either endorse or reject the changes made. If they approve the changes, the bill will receive royal assent and become law.

The bill will see the introduction of criminal penalties for those who “intentionally” infringe registered designs.

The clause was carefully worded in a bid to protect those who accidentally infringe, according to the draft text.

Infringers could be given a 10-year jail term if found guilty.

Iain Wright, a Labour MP and shadow minister for business, innovation and skills, said: “The Indian IP laws include balanced provisions to ensure that IP rights do not hinder the ability of the government to adopt measures for promoting development priorities, particularly in the area of public health.”

“These are fully in line with the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement and reaffirmed by the Doha Declaration on TRIPS and Public Health,” it continued.

Several US companies have pushed for the US Trade Representative (USTR) to include India as a priority foreign country in the Special 301 review for 2014, accusing India of lacking adequate and effective IP protection.

In particular, many are concerned about the country’s decision to issue a compulsory licence.

India granted a compulsory licence to domestic company Natco to manufacture a generic version of an anti-cancer drug produced by patent holder Bayer, claiming it was too costly for the general public.

Under the Indian Patents Act, and in accordance with WTO rules, a compulsory licence can be issued, and the underlying patent sidestepped, if a drug is proving to expensive to access, giving companies permission to manufacture generic versions.

“It is regrettable that India or any other developing countries may be designated as a ‘priority foreign country’ under the Special 301 provisions of the US Trade Act of 1974,” the South Centre said, adding that the mere threat of specific category in the US watch list would violate the World Trade Organization Dispute Settlement Understanding.

The US International Trade Commission (ITC) is also investigating trade, investment and industrial policies in India and their effects on the US economy.

“The continued threat of unilateral trade sanctions by the US to developing countries through US ITC investigations and the Special 301 review undermines the legitimacy of the WTO, particularly the TRIPS Agreement and the WTO’s dispute settlement system.”
Patent Picks
IPPro highlights the latest patent grants in Europe, the US and elsewhere

Oramed Pharmaceuticals has received a patent from IP Australia for oral administration of Exenatide.

The patent, entitled Methods and Compositions for Oral Administration of Exenatide, covers oral exenatide compositions made using the company’s proprietary technology.

TNI Biotech has obtained a patent from the US Patent and Trademark Office (USPTO) for IRT-101 (MENK) for inducing sustained immune response of T-Cells.

The invention relates to methods of stimulating and promoting a sustained natural immune system response, resulting in increased resistance and inhibition of infectious agents, including viruses, bacteria, fungi and parasites, and other immunodeficiency-related ailments.

Noreen Griffin, CEO of TNI BioTech, said: “We are pleased to be able to expand our patent portfolio and believe this patent plus the many other patents surrounding MENK provide us with broad composition-of-matter protection for our suite of immunotherapy treatments.”

IRT-101 is an active immunotherapy with MENK for patients with deficient functioning of the immune system.

The USPTO has granted a patent to XBiotech covering an antibody therapy that treats chronic sterile inflammatory diseases.

Allowing XBiotech exclusive rights, the treatment targets a unique molecule associated with chronic sterile inflammation.

Relating to antibodies and methods for the use of antibodies, the treatment prevents and detect disease progression associated with a key mediator of chronic inflammation.

XBiotech’s vice president of corporate development, Dr Stanley Kim, stated: “The patent further strengthens XBiotech’s intellectual property portfolio which we believe dominates the chronic inflammatory space.”

The USPTO has issued a patent to Stanford University for use of the vinyl chloride reductase (vcrA) gene to quantify microorganisms critical in chlorinated solvent bioremediation.

The patent is entitled Microbial Reduction of Vinyl Chloride. The invention allows practitioners to analyse soil and groundwater for the presence of microorganisms containing the vcrA gene.

The patent follows a previously issued one and covers the detection of vcrA sequences in environmental samples using standard molecular biological methods.

Synthetic Biologics has obtained a US patent covering its drug candidate, Trimesta (oral estriol), in conjunction with a gestagen for the treatment of multiple sclerosis.

The patent covers claims for a gestagen and a second standard of care MS agent, such as glatiramer acetate injection.

“Claims in this new patent further expand Synthetic Biologics’ intellectual property related to our oral estriol candidate, Trimesta, for the treatment of MS and other autoimmune diseases,” stated Jeffrey Riley, CEO at Synthetic Biologics.

“Our objective has been to continue to strengthen our intellectual property covering oral estriol and this patent is an achievement in that direction.”

Zimmer Holdings has received five patents from the USPTO directed to the subchondroplasty procedure, a new joint preservation procedure.

These patents broaden the coverage of the first subchondroplasty procedure patent issued to include new procedure methods, instrument kits, navigation systems, implants and other anatomical sites.

The subchondroplasty procedure is the first procedure to treat bone-based changes within a joint, and addresses an unmet clinical need between early interventions, such as NSAIDs and joint arthroscopy, and total joint replacement, according to a release.

“These valuable additions to our Subchondroplasty Procedure patent portfolio are the result of years of research and development,” Michael Simpson, vice president and general manager of Zimmer Knee Creations, stated in the release.

RXi Pharmaceuticals has obtained a patent from the USPTO for self-delivering RNAi compounds for the treatment of fibrosis.

The patent covers the use of sd-rxRNAs targeting CTGF, including RXI109, for the treatment of fibrotic disorders. It will expire in 2029.

“This is an important step in solidifying our patent portfolio which greatly enhances the value proposition of RXi Pharmaceuticals,” said Dr Geert Cauwenbergh, president and CEO of RXi Pharmaceuticals.

He added: “This issued patent deepens our ability to broadly protect our proprietary and novel technology platform, which includes our anti-fibrotic compounds, reinforcing the potential for future commercial and business development opportunities.”

Synageva BioPharma has expanded its intellectual property portfolio with a new US patent, covering methods of treating lysosomal acid lipase deficiency (LAL).

LAL deficiency is a rare autosomal recessive lysosomal storage disease caused by a marked decrease in LAL enzyme activity.

The disease presenting in children and adults, and historically called cholesteryl ester storage disease, is a cause of cirrhosis and accelerated atherosclerosis.

The USPTO has given Cave Consulting Group four new patents for its physician efficiency methodology and system.

Other patent applications are awaiting approval.

“Our patents protect CCGroup’s novel approach to analysing physician efficiency using medical condition episodes-of-care built from any grouper, using ‘a predefined set of medical conditions for a specialty type’, and weighting these medical condition episodes-of-care together using direct or indirect standardisation to calculate an overall physician efficiency score,” stated Dr Douglas Cave, president of CCGroup.

Tesa Medical has been issued a US patent that covers a device designed to aid surgeons performing anterior cruciate ligament reconstruction and to improve patient outcomes after surgery.

The patent covers the GraftGrab, a device to fix an ACL graft with a single fluid motion to maintain graft tension and reduce surgery time and instrumentation.

Dr Mandi Lopez, a co-inventor, said: “The bio-absorbable GraftGrab is positioned on the cortical surface of the tibial bone tunnel and has a simple mechanism for anchoring the graft immediately after tensioning that minimises the likelihood of graft tension loss,” she said.

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As the pharmaceutical market loses more patents through expiry, veterinary medicine has caught the attention of large players looking for new sources of revenue.

In 2012, a patent cliff saw many companies lose their exclusivity over major blockbuster drugs, leading to a re-evaluation of R&D efforts in order to adopt a more rounded portfolio.

Novartis, Pfizer and GlaxoSmithKline, among others, are expected to see a decline in their revenues due to further patent expirations. Multiple companies are going to lose their exclusive rights to produce many blockbuster drugs within the next three years.

But pharma companies are beginning to see the benefits of delving into the veterinary market.

Less competition exists from generic manufacturers and there are fewer barriers to break through, including lower research and development costs, cheaper clinical trials, and a higher likelihood of approval from the US Food and Drug Administration (FDA).

Evidence of this can be seen with Zoetis. Pfizer spun off its animal healthcare division into a separate company. It was one of the largest recent initial public offerings, raising $2.2 billion, and demonstrated why the animal healthcare industry is a growing market segment.

“This is not to say that Pfizer is the only major pharmaceutical manufacturer seeing the opportunities in the veterinary market,” says Matthew Fedowitz, a partner at Merchant & Gould. “Merck has a substantial animal health division and Sanofi’s animal health division, known as Merial, is just as commanding.”

In fact, many big pharma companies are opening subsidiaries or acquiring smaller companies in a bid to crack the veterinary market, including Bayer’s animal health division, Elanco Animal Health, Boehringer Ingelheim’s Vetmedica and Novartis Animal Health. The Bimedia group also recently acquired Vetpharma Animal Care.

It is not only big pharma companies that are seeing the opportunities in the veterinary market: “Smaller companies that are currently on the human regulatory path are now looking at the veterinary market as a possible path to a faster revenue stream,” explains Stanley Baker, partner at Husch Blackwell LLP.

However, Tom Overbay, partner at Expedite Animal Health, a business development company working in the animal health space, disagrees. “I do not think patent cliff impacts animal health in terms of outside investors. Out of all the deals that I have done, the patent cliff does not seem to be impacting investment decisions.”

“Animal health investment is being largely driven by the fact it closely mirrors the market growth of human health, so I think the
Generic manufacturers have not been focusing on challenging veterinary patents as a strategy for entering the market, as competition has not evolved to the extent that it has in the market for human drugs.

“Without the tremendous costs associated with human drug development—animal health after proof of concept should get a product to market for a range of $3 million to $20 million depending on the therapeutic category,” explains Overbay.

One particular area is the obviousness of claims across different species. “For example, if the USPTO were to reject a patent claim to treating swine as being obvious over prior art to its use in cattle, the patent applicant may be able argue that the claimed subject matter was believed to be ineffective in swine, if the prior art suggested a bias against treating other animals and was solely directed to cattle,” explains Fedowitz.

“Such an argument may be useful in obtaining patent protection across differing species of animals.”

Overbay emphasises this point. “You can argue that veterinary patents are more challenging than human ones.”

“We have all the species that we have to formulate for, a cat is not a small dog, a horse is not a large dog as they have separate and distinct metabolisms and physiology that have to be accounted for in development, so you have to be very specific in your targeting and you can't make the assumption that the formula works as well in other areas.”

Generic manufacturers have not been focusing on challenging veterinary patents as a strategy for entering the market, as competition has not evolved to the extent that it has in the market for human drugs.

“One possible reason for this is because many generic drug companies have not tapped into and recognised generic animal drugs as potential product lines that can yield a significant sources of revenue,” concludes Fedowitz.

Overbay believes that the veterinary space is largely less susceptible to generic competition, because companies are driven by size of the market particularly with regards to the sales of individual products.

“If you are going to invest research dollars into generic products you have to realise that you’re going to get a percentage of a much smaller market, as a blockbuster veterinary product is a $50 to 100 million product compared to relevant terms to human deals, which are multiples larger.”

Players in the veterinary market have to face stiff competition from large pharma and biopharma companies, which patent methods and formulas for ‘mammal’ use that consequently effect animal health filers from gaining exclusive rights for their own inventions.

Patenting of human drugs impacts the freedom to operate in the veterinary field, says Overbay, in regards to cross species use.

“Composition of matter, methods of use, and manufacturing nuances all can impact the ability of a veterinary drug to be able to go to market without the risk of infringement.”

In 1988, the Hatch-Waxman Act was extended to the field of veterinary medicine through enactment of the Generic Animal Drug and Patent Term Restoration Act (GADPTR).

The GADPTR gave generic animal health companies added benefits including, among others, patent term extensions, non-patent exclusivity periods for new drugs and generic marketing exclusivity.

With the creation of the Abbreviated New Animal Drug Application (ANADA) process, the cost of completing an FDA application for approval of a generic was greatly reduced.

“Providing a means for a generic manufacturer to challenge a pharmaceutical company to get their proposed product to market,” according to Fedowitz.

Currently, the FDA says that is has more than 80 ANADAs pending.

Fedowitz believes that generic and approved pharma ingredient manufacturers looking for outlets and product lines that generate moderate revenue “can take advantage of the largely untapped market for veterinary pharmaceuticals.”
Consider them emerged
Emerging markets are a way of overcoming patent expiries, and much more besides, according to a panel of experts

Celine Crowson  
Partner  
Hogan Lovells LLP

Teresa Lavenue  
Counsel  
Hogan Lovells LLP

Michael Wise  
Partner  
Perkins Coie LLP

Dr Michael Roberts  
Partner  
Reddie & Grosse LLP

Paul England  
Senior associate  
Taylor Wessing LLP

Stephen Garner  
Patent attorney  
Mathys & Squire LLP

Blaine Templeman  
Partner  
Sheppard, Mullin, Richter & Hampton LLP

Garreth Duncan  
Partner  
D Young & Co LLP
How and why are life sciences companies turning their attentions to emerging markets?

Blaine Templeman: Life sciences companies turned their attention there a long time ago. Most large pharma companies implemented international growth strategies that included emerging markets decades ago. The focus has become only more intense. As to why—the US system for commercialisation of products is broken in some respects, and some of the problems result in under-served world markets.

As to how, my clients consider not just one, but a number of factors when working on a product—pricing, logistics, partnering and other concerns—in order to develop a holistic plan for product development and commercialisation. A balanced approach serves both the public good and shareholder interests.

Celine Crowson: Some say that the BRIC countries (Brazil, Russia, India and China) account for roughly half of the global population, and that their economies are generally growing rapidly. Some have predicted that China could become the second largest pharmaceutical market after the US by 2015. Thus, some companies believe that for their continued success and growth, they feel that they must expand their business into emerging markets.

Michael Wise: Life sciences companies have turned to emerging markets for low cost manufacturing, R&D opportunities, and to obtain market share in rapidly growing economies that represent an increasing share of the global pharma market. The rise of a less expensive educated work force and the existence of government incentives for foreign investment combined with fewer environmental, health and safety regulatory burdens make emerging markets an attractive location for manufacturing and R&D facilities.

Emerging markets often have unmet needs for medical products compared to saturated markets in developed markets such as the US and the EU.

With expanding economic development in emerging markets, and governmental healthcare reform in countries such as China, meeting these unmet needs provides potential fast-paced sales growth, especially for relatively inexpensive products that have low IP value.

As emerging markets continue to promote research and development and strengthen IP protection and enforcement, life sciences companies will expand R&D investment and include new product releases in these markets.

Teresa Lavenue: Life sciences companies have expanded into emerging markets with strategies beyond merely entering the market with pre-existing drugs. Some conduct research locally regarding specific medical needs of local patients and tailor products to those needs. For example, different viral diseases or cancer types may be more prevalent in an emerging region than in the US or in Europe.

Other strategies involve providing access to drugs or developing new combinations that are less expensive to encourage patient compliance. Further, where a large proportion of the population lives in remote areas and as such access to prescription refills can be problematic, companies have explored whether a different dosage form or formulation may be more appropriate.

Additional strategies relate to identifying genetic biomarkers that may be specific to certain patient populations (the presence or absence of certain biomarkers can influence the effectiveness of certain therapies).

Since patient populations in emerging markets may have different biomarkers, companies are researching this aspect too and may include these patient populations in clinical studies.

Michael Roberts: Life sciences companies need to be mindful of not only established markets for their products (and/or services), but also markets that may become commercially valuable in the near or medium-term future. This is particularly important in the life sciences field where product development can take several years. IP protection needs to be put in place, and regulatory hurdles need to be overcome before a product can be put on the market for sale.

Early planning allows life sciences companies to be best placed to be successful in emerging markets.

Paul England: As with so many other product industries, life sciences companies see the emerging markets as an opportunity to reach a vast new body of consumers. But for the big small-molecule pharma companies, in particular, there is an added impetus. This is that the gains to be had from such markets can ease the burden of funding research into new drugs to replace those going off patent.

In addition to this, access to emerging markets with sufficiently strong IP protection affords opportunities to tap into local scientific expertise and other skills for the purpose of research, development and manufacture of new drugs.

Stephen Garner: Maintaining access to affordable healthcare is very important in the emerging markets, where the costs of patented drugs can be prohibitive. In India, for example, it is estimated that patented drugs account for less than 10 percent of total drug sales. Regulatory authorities in some emerging markets may also seek to prevent or delay the patenting of new drugs.

As a result, emerging markets are often viewed as favouring domestic companies and generic drug producers. This discourages foreign investment and can limit the availability of new medicines.

Innovator drug companies rely on the 'reward' of a patent to recover the huge costs associated with bringing a new medicine to market. However, the duration and scope of protection available is severely limited in some emerging markets, with countries setting special requirements for patenting pharmaceuticals, which are more stringent than for any other technology.

It can also be more difficult to obtain the range of patent claims, eg, to new medical uses or specific formulations, needed to provide optimum protection for pharmaceuticals.

Even once a patent is granted, innovators are at a disadvantage when it comes to enforcing their rights in emerging markets. National courts in these countries are often perceived to favour generics over innovators.

Patentees are also more likely to see their technology subject to compulsory licensing, resulting in a loss of control for the patentee over who uses their technology and what royalties they receive.

Despite these challenges, the slowing of sales in developed markets means that companies no longer have an option to ignore the tougher emerging ones.

Garreth Duncan: There are a number of reasons that emerging markets are becoming much more important in the strategies of the research-based pharma industry. One reason is to help counteract the drop in revenue caused by patent expiries on blockbuster drugs.

The big squeeze on government spending that most countries, particularly in Europe, have gone through in the last few years has increased pressure on pricing in these countries, and so is also a big factor as this makes it much more difficult for the industry to make a return on the $500 million to $1 billion investment it typically takes to bring a new drug to market based on established markets alone.

Pharma companies assess markets based on factors such as a country’s population size, incidence of the disease in that population, and the likely price that can be charged for the drug in that country.

The emerging markets of greatest interest—China, India, Brazil and Russia—all have large populations and rapidly growing middle classes who have access to and are able to pay for much more than they could even a decade ago. These two factors combine to make the market for pharma products in these countries much more worthwhile than before.
How are life sciences companies adapting their IP strategies when entering emerging markets, where laws tend to differ from those in the US and Europe?

**Garner:** Life sciences companies are struggling to adapt their IP strategies to obtain commercially meaningful protection in emerging markets.

The scope of patent protection available in emerging markets is typically narrower than elsewhere in the world, especially in the pharma field. There are also more limited options in developing patent portfolios for drugs, which can lead to a shorter duration of protection in emerging markets.

In view of this, drug companies are focusing their IP specifically towards their (pre)clinical candidates, to guard against generic medicines rather than similar products from competitors, and are placing more emphasis on their earlier patent applications, which expire sooner.

The approach taken to patentability is forcing innovators to alter both the timing and also the content of their patent filings to ensure that they maximise the protection available.

Despite improvements, emerging markets are also perceived to offer weaker patent enforcement options. Patents generally have to accept that their monopoly position is more easily undermined, with national courts often viewed as acting less favourably towards innovators when considering both the scope of protection provided by a patent and also the extent of any alleged infringement.

Compulsory licences may also be more readily available in the emerging markets and patentees therefore need to price their technology carefully, especially in the pharma sector. Life sciences companies also need to consider carefully the effect that entering an emerging market will have on their global patent strategy.

**Duncan:** In terms of patenting new active pharma ingredients, I don’t think the strategy is that much different for emerging markets or more established markets such as the US, Europe and Japan. The difficulties that pharma companies encounter in emerging markets are more based around secondary pharma IP such as new formulation technology and second medical uses, as well as the lack of patent term extension and the lack of regulatory data protection (or, where it exists, its shorter duration) in many emerging markets.

Breaking into many emerging markets is seemingly as much about marketing strategy than IP strategy. However, to counteract the less favourable IP regime in these countries, it’s likely that pharma companies would look to lobby national governments (especially in countries where they have a lot of research jobs) to put more pressure on emerging market countries to conform their patent laws to international standards such as the World Trade Organization’s (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

However, this is a long, drawn out process that will take much time and patience.

**Roberts:** It is critical that IP advisors to life sciences companies keep up to date with IP law and practice in emerging markets. This will have an effect not only at the very early stages of enacting IP strategy—for example, drafting a new patent application that is expected to be prosecuted in emerging markets—but also at later stage of prosecution or litigation of different forms of IP such as patents, trademarks or registered designs. IP advisors should have a good relationship with reputable IP attorneys within the emerging markets.

**Crowson:** Life sciences companies are focusing time and resources to attempt to fully understand both the legal and practical implications of IP law in emerging markets. This often includes engaging local counsel to provide insight into the IP environment and to understand how to work within the local culture to protect the IP most effectively. Life sciences companies are looking at obtaining multiple levels of IP protection beyond just patents. For instance, they may pursue patent protection on a drug compound, but maintain the method of making the compound as a trade secret.

Companies may employ unique methods to assist in tracking or monitoring infringing activities or products. One such example...
takes a closer look.

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In addition to India, the majority of emerging markets, including Brazil and China, have no provisions for patent term extension. Also, many South American countries forbid the patenting of second medical uses. Many emerging market countries, such as Brazil, are using the provisions permitted by the WTO Doha Declaration to apply compulsory licensing on HIV/AIDS drugs.

But it’s not just legal measures the research-based pharma companies are up against, you only need to look at the hysteria the Gleevec case in India generated to see the general hostility to IP from many in these countries.

Wise: The main IP challenges in emerging markets are the limited scope of protection and the difficulties in enforcing IP rights. The laws and regulations regarding IP protection and enforcement in many emerging markets countries are unpredictable and still evolving. For example, some countries (eg, India and China) were late to provide patent protection for new chemical entities used in pharmaceuticals. Additionally, the lack of awareness among the general public regarding IP laws and regulations, less experienced and fewer qualified patent examiners, judges and government officials involved in the enforcement of IP rights, and governmental protectionism, especially on the local level, add to the challenges of obtaining and enforcing IP rights in emerging markets.

Lavenue: Further, the lack of reliable redress for patent infringement causes much concern among life science companies entering emerging markets. Companies are forced to consider whether they should continue to conduct business in regions where there is rampant, even government condoned or sanctioned IP misappropriation. Does the loss of income due to grey market sales outweigh any gains made on legitimate sales?

In addition, a company may need to balance the investing of millions to create drugs/products for treating smaller patient populations in emerging markets against diminished IP protection in those markets.

Roberts: My opinion is that key IP challenges are: (i) the scope of protection afforded by registrable IP in emerging markets; and (ii) the enforcement of registered IP.

England: A particular difficulty presented by IP is its territorial nature. Different countries have different laws and standards of protection for IP. Consequently, a patent or trademark that is enforceable in one country may not be enforceable in another, or not as quickly or effectively. Furthermore, some countries abide by very different standards of validity, making some products more difficult to protect than in others. Issues of compulsory licensing may also be faced in some countries, as well as endemic problems of counterfeiting.

These issues are typically highly complex, and getting them right can make an important difference to the success or failure of a product.

Crowson: With patent expiring in developed nations, life sciences companies realise that the revenue from the patented drug will likely be quickly and drastically reduced by generic sales. Thus, companies may consider entering emerging markets as promising new sources of revenue for their drugs and products. However, because relevant patents are expired or may not have ever been obtained in an emerging market, or because there is considerable IP theft in the market, companies may consider selling a branded generic, or working with a local partner to manufacture and distribute drugs/products. Some companies may consider selling a drug as a generic by forming an alliance with an already well-established generic manufacturer in the emerging market to conduct bioequivalence studies and to make and distribute generic drugs.

Roberts: In my view, for many emerging markets it is expected that patents will be enforceable. Patent protection therefore remains a gold standard to underpin commercial success in emerging markets. However, for those...
emerging markets where other factors may impact more significantly on success, and for example where there is an environmental bias towards generic rather than innovator companies, the absence of a patent may be perceived as less of an obstacle to success. Such emerging markets may be more attractive to market products as due to go off-patent.

England: In very broad terms, patent expiry on blockbuster drugs results in market competition for originator companies from generic pharmaceuticals and places pressure on profit margins. This is exacerbated by the need for the research-based companies who produced those drugs to find new products. However, the cost of the research to find new drug candidates is very high. Hence one of the ways in which a company can continue to grow revenue and fund this research is to find large new markets.

Templeman: Patent expirations are one of the primary drivers. The other factors include the need to expand profits and the desire to improve public health.

Duncan: Everyone knows the effect patent expiries have had on research-based pharma companies’ revenue over the last few years. For example, when Pfizer’s patent for Lipitor expired in 2011/2012, its 2012 annual report indicates they lost $5.6 billion in sales of the drug, which almost accounts for the entire $6.3 billion decrease in the whole company’s revenue that year. Similarly, when AstraZeneca’s patent for Seroquel expired in 2012, it lost $3 billion in Seroquel sales—more than half of the company’s decrease in revenue that year.

Both companies have turned to emerging markets as a way to fill the gap. Pfizer have set up an emerging markets unit, results being available from 2010 onwards. Its 2012 financial report indicates emerging markets revenues increased 7 percent in 2012 compared to 2011, primarily due to volume growth in China, Brazil and Russia, and specifically mentions it’s a result of more targeted promotional efforts for key innovative and established products, including Lipitor, Norvasc and Lyrica.

Similarly, AstraZeneca’s 2013 full year results, published last month, illustrate this. It has specifically targeted emerging markets as a growth area, and it’s been successful; while its revenue in the US and Europe were both down 9 percent in 2013 compared with 2012, its revenue in emerging markets was up 8 percent over the year, mainly driven by China.

The US is worried that the ‘Indian IP model’ will be copied by other countries—what is your view on this?

Wise: Countries in emerging markets generally have weaker IP protection and enforcement than in developed markets. However, many countries in emerging markets have joined or are trying to join the WTO to take advantage of the economic benefits of General Agreement on Tariffs and Trade (GATT). Strengthening IP protection through TRIPS is typically a prerequisite to join the WTO. India and China revised their IP laws to join the WTO under TRIPS. As economic growth and education advances in emerging market countries, domestic IP flourishes, which fosters better protection and enforcement of IP rights.

Finally, countries in emerging markets that seek to transition from a labour-intensive economy to an innovation-driven economy must strengthen IP protection and enforcement. Consequently, the ‘Indian IP model’ is unlikely to be a model of choice for countries in emerging markets.

Crowson: India’s Intellectual Property Appellate Board (IPAB) has upheld compulsory licences to generic manufacturers on pharmac products. Affordability and product access were cited as justifications for such compulsory licences, and the licences have lowered drugs’ prices dramatically (although in some cases manufacturers have retained a royalty on sales by Indian generic manufacturers).

The mechanism of compulsory licencing in India is based on Section 84 of India’s Patents Act, which provides that an interested person may apply for a compulsory licence to work the patented invention on any of the following grounds: the reasonable requirements of the public with respect to the patented invention have not been satisfied; the invention is not
available to the public at a reasonably affordable price; or the patented invention has not been worked in the territory of India.

**Lavenue:** Some companies consider whether a compulsory licences can be avoided by forming a partnership with a local company to make and sell drugs locally at a reduced price (with lower costs and increased volume). Some wonder whether reducing product prices in an emerging market will raise the prices in other countries.

Additionally, lost revenues for a product may cause a life sciences company to spend less on R&D and product development. Will less risk be taken on newer technologies?

All of these concerns may make other countries wary of or not eager to embrace a compulsory licence approach with abandon. Rather, the focus may be on encouraging life sciences companies to invest in emerging markets by myriad other means.

**Roberts:** The TRIPS agreement allows WTO countries to grant a compulsory licence under a patent, subject to various provisions and safeguards. It is of concern that WTO countries might grant compulsory licences too easily, thereby undermining the patent system. Innovator companies have avoided compulsory licences in some emerging markets by reaching agreements on providing drugs at affordable prices.

Whatever model is adopted by emerging markets to ensure important drugs remain accessible, my view is that international trade laws should be respected.

**England:** India has a well established generics industry that manufactures and supplies the market with off-patent small molecule pharmaceuticals. This is a significant feature of the Indian economy and one that it is keen to protect. There is no reason to suppose that other countries, with different approaches to the life sciences industry, should therefore necessarily follow the ‘Indian IP model’.

In any event, the life sciences business is changing, with biologics and biosimilars becoming ever more important.

This means that companies will adapt to new business models that are not split on the simple generics versus originator basis that is a familiarity of small molecule pharma.

**Garner:** Each emerging market presents its own challenges but the issues that affect innovators within them rarely occur in isolation. India may be leading the way with its tough stance on pharma patents.

When India issued its first compulsory licence to Bayer’s patent for the anti-cancer drug Nexavar, effectively breaking Bayer’s monopoly in order to lower the price of the drug, alarm bells started ringing for pharma companies worldwide. The predicted flood of compulsory licences in India has not materialised, possibly because of international pressure.

Nevertheless, compulsory licensing is just one mechanism available to limit the effect of patents driving up drug prices. The demanding approach to patentability taken by the Indian Patent Office is just as effective and is seen as a model for emerging markets, eager to support their generic drugs industries.

**The Indian Patents Act places onerous restrictions on the patentability of pharmaceuticals, for example prohibiting patents to new forms, formulations or combinations of known drugs.**

The Indian Patent Office has also set a high bar for assessing inventiveness.

These requirements combine to make patenting pharmaceuticals in India a significant challenge, severely restricting the ability of innovators to obtain meaningful protection for authorised drugs.

In view of the increasingly strict requirements for the regulation and authorisation of drugs, and the time taken to bring a new drug to market, emerging markets are in danger of removing the incentives to obtaining patent protection for pharmaceuticals if they adopt the Indian model. Innovators risk the gradual erosion of their patent position in emerging markets if such an approach is taken.

**Templeman:** As is always the case, there are many good things going on in India. Product innovation and scaling of production are two of those good things. We can learn much from Indian companies, namely, how patent protection must be balanced with the health needs of consumers.

**Duncan:** The Indian IP model is certainly a matter of concern for the research-based pharmaceutical industry. In my view, Section 3(d) of India’s Patent Act is a violation of the TRIPS agreement, which India has signed, as it imposes an additional patentability criterion for pharmaceuticals compared with other inventions.

The TRIPS agreement clearly says you can’t do this, as it specifies that patents should be available for all inventions without discrimination as to the field of technology.

However, now India’s Supreme Court has affirmed the section in the Novartis Gleevec case, it will undoubtedly give encouragement to other countries that are hostile to pharma IP. Argentina and the Philippines already have a parallel to India’s Section 3(d), and other countries are considering it.

The only thing that could reverse this tide would be a challenge to Section 3(d) at the WTO. There’s currently a moratorium on WTO members bringing non-violation complaints under the TRIPS agreement at the WTO. At the last WTO ministerial conference in December 2013, it was discussed whether the moratorium should be lifted, or conversely turned into a permanent feature. The moratorium was extended once again, with the understanding a final agreement should be reached by 2015.

Although many countries supported the view that the moratorium should be indefinite, the US and Switzerland disagreed.

If the moratorium is eventually lifted, a challenge could be possible. However, in view of the high awareness of this issue, and the negative publicity that supporters of the law would inevitably generate, does any organisation have the will to see such a challenge through and take the brickbats that will inevitably fly in their direction?
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Hatch-Waxman cases in the Wild West
There are strategic implications to consider when litigating Hatch-Waxman cases in the Eastern District of Texas, says Brian O’Reilly of O’Reilly IP

Is Hatch-Waxman litigation moving to the Wild West? For the last 10 years, non-practicing entities (NPEs), or so-called patent trolls, have preferred the Eastern District of Texas for patent cases. But during that time, the district has seen little in the way of Hatch-Waxman litigation. That is changing, and changing fast. Branded pharmaceutical companies are filing more and more Hatch-Waxman cases there, and with success. If history is a guide, the eastern district may become a preferred venue for Hatch-Waxman cases in the near future with serious consequences for all parties involved.

Preferred patent jurisdictions
NPEs, suing on what some would argue are weak patents, have long sought to file in the Eastern District of Texas for multiple reasons. PricewaterhouseCooper’s 2013 Patent Litigation Study revealed that the district has the largest number of NPE patent cases. The entities view the juries there as sympathetic to patent holders, with PwC finding that the district has the highest patent trial success rate at 57 percent. Juries there are also known for handing down large verdicts—the district has the sixth highest average patent damage award at $10 million. And perhaps most importantly, the judges rarely grant summary judgement in patent cases, ensuring that the patent holder can present its case to the jury.

No other patent jurisdiction in the country is looked on as favourably as the Eastern District of Texas by NPE patent holders. Some jurisdictions are even viewed as outright hostile to patent holders. They have longed viewed the Northern District of California, home to much of the technology industry, as unsympathetic to patent holders (the Northern District of California has one of the lowest patent success rates at 23 percent, according to PwC). Other jurisdictions are viewed in a more balanced manner, but most still routinely entertain summary judgment motions in patent cases.

Preferred Hatch-Waxman jurisdictions
Hatch-Waxman plaintiffs view jurisdiction selection differently than NPEs because their strategic concerns are very different. Hatch-Waxman cases are bench trials, so the potential make-up of the jury is of little concern to
plaintiffs. Unpredictability works in favour of NPEs; the potential of large damage awards is their leverage to force settlement. But for Hatch-Waxman plaintiffs, unpredictability works against them; in Hatch-Waxman cases, it is usually the defendant that uses the potential for invalidating the patents as leverage for settlement. Consequently, Hatch-Waxman plaintiffs want predictability in addition to a friendly jurisdiction.

Hatch-Waxman plaintiffs have traditionally sought that predictability in a few well-regarded jurisdictions. Delaware, home to many branded pharmaceutical companies, has long been a preferred venue. With only four federal judges, plaintiffs see it as predictable, experienced in pharmaceutical issues, and friendly to patent holders. New Jersey is the other preferred jurisdiction. Many branded pharmaceutical companies call it home and view it similarly to Delaware.

This experience with Hatch-Waxman cases is a self-reinforcing attribute: the more experienced judges in a jurisdiction become, the more cases plaintiffs file there, and the more experienced the court becomes. This explains why from January 2006 to August 2011, Delaware and New Jersey combined to handle 68 percent of all Hatch-Waxman cases, according to Understanding Current Trends and Outcomes in Generic Drug Patent Litigation: An Empirical Investigation by Xiangnong Wang of Stanford University.

But for branded pharmaceutical companies, a judge’s expertise in Hatch-Waxman can be a double-edged sword. Branded companies feel very confident of their chances for success on pioneering patents for new chemical entities (NCEs) in Delaware and New Jersey. Throughout the history of the Hatch-Waxman statute, Delaware and New Jersey combined have only invalidated one NCE patent and that case is currently on appeal to the Court of Appeals for the Federal Circuit. On the other hand, judges in these jurisdictions usually look upon follow-on patents, such as formulation patents, with skepticism.

Because of their experience and expertise, lawyers often have a difficult time changing these judges’ minds. I have seen, first-hand, judges in these jurisdictions look with skepticism on defendants challenging an NCE patent and look with skepticism on a plaintiff asserting a formulation patent. These impressions are hard-wired, probably based on an accurate understanding of pharmaceutical patents, but nevertheless undesirable if a party’s case depends on changing the judge’s impression.

Increasing Hatch-Waxman cases in the Eastern District of Texas

Despite the Eastern District of Texas’s reputation as pro-patentee, historically few branded companies brought Hatch-Waxman cases there. The district tried its first Hatch-Waxman case in August 2011 (Pozen Inc v Par Pharmaceutical et al, 6:08-cv-437), ruling in favour of the plaintiff on validity and infringement. Before that case, plaintiffs brought few Hatch-Waxman cases in the district.

Since then, Hatch-Waxman plaintiffs have taken an increasing interest in the Eastern District of Texas. Since the Pozen case, plaintiffs have filed a number of Hatch-Waxman cases there. And Hatch-Waxman plaintiffs have found further success in the eastern district.

In addition to an increase in filings, anecdotally, the Eastern District of Texas is now a major consideration for Hatch-Waxman plaintiffs. In past years, when discussing where to file Hatch-Waxman cases, I rarely heard substantive discussions about filing in the Eastern District of Texas (for the majority of my career, I represented Hatch-Waxman plaintiffs before moving over to the generic side). Recently, however, I have heard repeated discussions about the perceived benefits of filing in the district, especially for perceived weaker formulation patents.

Plaintiffs’ interest in the Eastern District of Texas will only increase with time. As discussed, one of plaintiffs’ major reservations in filing in the district has been the lack of predictability because of the judges’ lack of experience with Hatch-Waxman cases. And as previously discussed, one can see the self-reinforcing role of experience in jurisdiction selection through the disproportionate share of cases filed in Delaware and New Jersey. So as the Eastern District of Texas judges try more Hatch-Waxman cases, plaintiffs will increasingly feel more comfortable filing cases there, thereby creating a virtuous feedback loop that should drive Hatch-Waxman filings in the eastern district for years to come.

Implications of shifting Hatch-Waxman cases to the Eastern District of Texas

What is good for plaintiffs is usually bad for defendants. Plaintiffs are filing cases in the Eastern District of Texas because they think it gives them a strategic advantage, and it likely does. Plaintiffs and defendants, however, are now faced with the next stage of this development: whether defendants will successfully challenge plaintiffs’ right to bring Hatch-Waxman cases in the eastern district of Texas.

The two main ways in which defendants can challenge plaintiffs’ right to bring Hatch-Waxman cases in the Eastern District of Texas is lack of personal jurisdiction and improper venue.

Personal jurisdiction in Hatch-Waxman cases is still a largely unaddressed issue at the Federal Circuit. Some courts have found that the fact that a generic company has sold pharmaceuticals in the jurisdiction creates general personal jurisdiction. There is a legitimate argument that this is an overly aggressive application of Supreme Court precedent and that more than sales of pharmaceutical drugs in a jurisdiction is required to create general personal jurisdiction. This is an issue that generics may seek to address through appeal.

Regardless of the case law, however, smaller generic companies may be able to challenge personal jurisdiction. If a smaller generic company does not have any approved drugs, and has no presence in Texas, it may be able to argue lack of general personal jurisdiction. This could give smaller, newer generic companies an advantage over some of the more established players (there are also multi-district litigation issues that may arise in this context that are important strategically but beyond the scope of this article).

Challenges to venue are also a tactic that generic company defendants may use to try to avoid the Eastern District of Texas. For the last five years there has been a struggle between the Eastern District of Texas and the Federal Circuit over venue in NPE patent cases. Although the topic is too large to address here, the overarching theme of the cases seems to be that if there is no connection to Texas and there is another venue that is clearly more appropriate than Texas, the court should move the case there.

For many Hatch-Waxman cases, however, venue challenges may be difficult. Many Hatch-Waxman cases involve numerous defendants. Consequently, Texas may be as appropriate a jurisdiction as any other jurisdiction in the country. For smaller cases, with one or two defendants, though, venue challenges may be an effective tool.

Regardless of what side of the Hatch-Waxman landscape parties find themselves, it behooves them to think about the strategic consequences of litigating in the Eastern District of Texas. And depending on one’s conclusions, it is imperative for parties to think about strategies for staying or leaving the Wild West.
When the Supreme Court weighs in

Michael Kiklis of Oblon, Spivak, McClelland, Maier & Neustadt LLP explains how discrepancies in rulings can affect inventors and cause uncertainty in patent law

FRANKI WEBB REPORTS
In what circumstances does the Supreme Court take on a patent case?

The Supreme Court’s jurisdiction is completely discretionary; they don’t have to take any cases that they don’t want. In the case of patent law, they’ve taken cases mostly to determine the correct legal standard, but they’ve also taken cases when an area of patent law is not in line with other areas of law, for example, the standard for granting an injunction. If there were a serious question about whether the US Court of Appeals for the Federal Circuit is using the correct standard, then the Supreme Court would probably take that case. The Federal Circuit is the appellate court that hears all patent-related appeals, either from district courts or the US Patent and Trademark Office (USPTO).

How do district courts and the Federal Circuit view the Supreme Court? Do they welcome its intervention?

I don’t dare speak on behalf of judges, but I think when the Federal Circuit is split—as we have in the CLS Bank case right now, which is in front of the Supreme Court—there is the need for the Supreme Court to step in. The CLS Bank case involves the standard for determining whether computer-related inventions constitute patent eligible subject matter. When the CLS Bank case was at the Federal Circuit, the judges were deeply divided, prompting one of the judges to write a concurring opinion actually encouraging the Supreme Court to take the case. The Supreme Court is set to hear the CLS Bank case on 31 March, and sometime thereafter we will receive their guidance on patentable subject matter for computer-related inventions.

Supreme Court justices are known to take particular standpoints in areas such as the patentability of genes—what effect does this have on the certainty of patent law?

When it comes to patent law, the Supreme Court has shown little deference to the Federal Circuit, the US government and even the patent office. For example, in the Bilski decision, the Supreme Court rejected the Federal Circuit’s attempt to use the machine-or-formation test as the sole test for determining patent-eligible subject matter.

Also, in the Prometheus case, the Supreme Court rejected the US government’s argument that virtually any step beyond a law of nature should render a claim patent-eligible.

And, as another example, in the Myriad decision, the Supreme Court showed no deference to the patent office’s long held practice of issuing gene patents. So, this lack of deference that the Supreme Court has shown to the Federal Circuit, the US government as well as the USPTO—which are this country’s experts in patent law—is leading to some uncertainty. The Supreme Court is reshaping patent law, and we all need to strap ourselves in and wait to see what happens.

How have patentable subject matter requirements changed with Supreme Court intervention, in say the last few years?

There has been a narrowing of patentable subject matter in the last few years. If you look back at the Bilski decision in 2010, which related to a business method, the justices decided the case 5-4: five justices for the majority and four justices joined concurrences. All justices believed that the patent was invalid, but the rationale for why was the point of contention between the justices. Luckily, the justices rendered a very narrow decision in that case.

Bilski was followed by Prometheus, a couple of years later. That case dealt with a law of nature, and in a unanimous decision, the Supreme Court seemingly resurrected the point-of-novelty test from decades ago. This test identifies patentable subject matter by determining whether the claim without the law of nature—or abstract idea as the case may be—is otherwise novel. This test was first announced in a Supreme Court case known as Flook in 1978, but the Supreme Court resoundingly repudiated that doctrine in 1981 in the Diehr case. So this point-of-novelty test has sat untouched since 1978, and now in a unanimous decision, the Supreme Court kind of resurrected it, which is a narrow test for patent eligibility.

After Prometheus, the Supreme Court issued the Myriad decision that I mentioned above, and in that case, the Supreme Court held that genes are not patent eligible subject matter. That case was a virtual unanimous decision. Therefore, we’ve now seen two basically unanimous decisions from the Supreme Court in which they found the scope of patentable subject matter to be fairly narrow.

So, we’ve seen this narrowing in the past few years, and the Supreme Court now has in front of it the CLS Bank case, in which it is going to address the patent eligibility of computer-related inventions. It will be very interesting to see if they broaden subject matter eligibility or narrow it. My concern is that the Supreme Court is going to continue down the road of narrowing subject matter eligibility.

Will we see more patent cases being taken up by the Supreme Court as the Federal Circuit finds it harder to decide what is patentable subject matter?

I think the Supreme Court under Chief Justice John Roberts is very interested in patent law. They’ve already ruled on one patent case in January and there are five more that they are going to rule on this term. They’ve shown a particular interest in all areas of patent law, not only involving patentable subject matter, but also patent claim definiteness and attorney-fee cost shifting, which is when the losing party pays the other side’s legal fees. The Supreme Court has shown interest in many areas of patent law, beyond patentable subject matter. I think it is fair to say that the Supreme Court is going to continue to be involved in patent law.

The US is looking at another round of patent reform—how do judges view this, given that the America Invents Act was only signed into law in 2011?

The pending patent reform legislation deals with companies that do not practice their invention, but merely want to make money off of their patent. They do so by suing companies for patent infringement. In the US, we call those companies ‘patent trolls’ or non-practicing entities. This patent troll issue has become a problem in the US, and it’s being addressed by the states, Congress, and even the executive branch.

I’ve read some articles by judges that say they don’t believe any more legislation is actually needed to combat this problem. Rather, they believe the tools are already in place to deal with this issue, through Rule 11 of the Federal Rules of Civil Procedure and Section 285 of the Patent Code. Rule 11 sanctions a party for advancing a frivolous argument in court. Section 285, on the other hand, addresses cost-shifting of legal fees in exceptional cases such that your opposition may have to pay your legal fees.

I believe the patent system is a rather delicate thing, and it’s intended to incentivise inventors to innovate, which is great for the economy. My concern is that we may be overcompensating in addressing the patent troll issue, and if we do, we may actually be harming our system by reducing this incentive. If that happens, there may be less innovation and less product development, including high technology.

US Litigation
The rapid and significant growth of patent filings in northeast Asia (China, Japan and South Korea) is contributing to the strongest rate of global intellectual property growth in nearly two decades, according to the World Intellectual Property Indicators 2013. For the first time, China residents accounted for the largest number of patents filed worldwide (560,681 in 2012). In addition, China’s State IP Office (SIPO) accounted for the largest number of applications received by any single IP office (652,777). Japan ranked second in applications received (342,796), and South Korea ranked fourth (188,915).

Filing in these countries comes with a unique set of challenges, from learning new laws and filing processes, to effectively searching patent databases in local ideographic languages, to translating to and from these languages. According to a recent study by the Steinbeis Transfer Institute of Stuttgart, Germany, patent errors arise most frequently with Asian languages. As a result, enterprises seeking to do business in these Asian countries are seeing a longer time-to-grant for their patents, additional office actions and limited scopes of patent rights, which can result in years of lost revenues.

Having someone on the ground that knows the language, culture and filing process of each country—including where to find case histories and related art—is invaluable, and in some cases, required by law. Those filing for patent protection, however, should be familiar with key requirements in these three countries to facilitate patent protection.

### China

**Laws**

While China established protection for inventions, utility models and designs in its 1984 introduction to patent law, its 1992 amendment extended rights to microbiological products and pharmaceutical and chemical inventions. Chinese patent laws include:

- No mistranslation amended: an applicant must provide SIPO with a written request, description and abstract, and a series of claims in either Chinese or English with Chinese translations included. Amendments related to errors in translation are not allowed.
- Grace period: there is a six-month grace period for public disclosures if the invention was shown in international exhibitions sponsored or recognised by the Chinese government or published at certain predetermined academic or technological conferences.

**Filing paths**

As in other countries, foreign entities can file for patent protection in China through either the Patent Cooperation Treaty (PCT) or Paris Convention. To get a patent approved more quickly, the application should consider filing directly in China via the Paris Convention. If patents have previously been granted and validated in other countries, the Patent Prosecution Highway (PPH) between SIPO and the European Patent Office (EPO)—and other important patent offices—will significantly expedite the examining procedure in China. SIPO recognises the result of the EPO examination and may grant a patent directly on the claims that EPO allowed. Thus, if the inventor files an application with EPO first and then files the same application in China, inventors should consider filing a PPH request to expedite the examination and decrease overall costs of obtaining a patent in China.

**Translation issues specific to Chinese**

In addition to ideographic characters, Chinese employs a radically different sentence structure than other languages with Germanic or Latin roots. For example, while English uses verb
tense to indicate whether an event has happened or will happen. Chinese uses adverbs and context clues. Translation into an Asian language such as Chinese requires a full understanding of the original source, followed by what some call a ‘transcreation’, done sentence-by-sentence.

If the original concept in a sentence is not fully understood, the translation of that sentence will easily reveal the misunderstanding.

Other translation issues with the Chinese language include two different writing systems (traditional and simplified): not using articles such as ‘the’, ‘a’ or ‘an’; and plurality, as Chinese does not employ the concept of adding an ‘s’ or other such letters to indicate more than one, instead requiring a qualifying phase such as ‘a plurality of’.

Japan

Laws

Japan’s patent law is based on the first-to-file system, whereby the first party to file is granted the patent. The inventor must submit a request, specification, claims, any necessary drawings, and the abstract to the Japan Patent Office (JPO). Japan patent law allows an application in foreign languages (currently only in English) if the applicant submits a Japanese translation within 14 months from the filing or priority date. However, like in China, the applicant may not amend the foreign language file.

The following laws also apply:

- Patent agent: enterprises that have their premises established outside of Japan need to hire a patent agent residing in Japan. Often, this person is a Japanese patent attorney, although it can also be an administrative figure with an address in Japan. Often, the patent agent is the project manager, ensuring that the process of patent filing goes smoothly, including the translation of legal documents from English to Japanese.
- Request for examination: filing patents in Japan can be intricate because of the extra steps after filing the patent application. For example, a request for examination must be submitted within three years of submitting the application or the patent will not be granted and will be considered withdrawn. This request essentially establishes that an application has been filed and that it is ready for JPO review.
- Grace period: Japan allows a six-month grace period for disclosures made through an experiment, publication, or a presentation at a study meeting or an exhibition, or when the invention becomes publicly known against the applicant’s will. Such disclosures do not form part of the prior art. This exemption is much broader than the one available under European patent law, but is significantly narrower than that provided under US patent law.

Filing path

As in China, foreign entities can choose to file via PCT or the Paris Convention. If previously filed in other countries, they can request participation in the PPH.

Prior art contained in Japanese patents

Published Japanese patents contain a vast amount of crucial information when filing a patent in Japan. However, these previous patents have been filed in Japanese, which makes the research process difficult for foreign filers.

While the EPO’s Japanese IP translation system (providing Japanese-to-English translation) may simplify the search for prior art, it should not replace a human translator for the patent application itself.

Translation issues specific to Japan

A Japanese patent requires a complete translation into Japanese characters. To complicate this further, the Japanese language uses four different alphabets: the phonetic hiragana and katakana; the traditional Chinese character-based Kanji; and the Romanised western alphabet. In many cases, technical terms can be rendered in more than one alphabet and choosing one over the other may result in different interpretations (eg, kanji is generally interpreted more narrowly than katakana).

South Korea

Laws

- Patent agent: as in Japan, South Korea does not allow foreign companies or individuals with addresses outside of South Korea to file patent applications to the Korean IP Office (KIPO) without being represented by a Korean attorney or agent.
- Filing process: as in China and Japan, foreign entities can choose to file via PCT or the Paris Convention, or if previously filed in other countries, additionally apply for participation in the PPH. If PCT is chosen, a Korean national phase application must be filed within 31 months of the PCT filing date (or 31 months of the earliest priority date, if priority is claimed), and a Korean translation should be submitted upon filing. Although allowed in China and other countries, Korean translations cannot be filed later. Accordingly, the system requires that the specification is translated into Korean efficiently and on time.
- Amendments: unlike the universal process, where new matter should be avoided at all cost, South Korea accepts an addition as a legal amendment. The new matter issue is not raised as long as the added limitation is deemed obvious from the specification teachings or drawing illustrations.
- Grace period: as long as the invention is filed in South Korea within one year from the date of public disclosure, the invention is not deprived of novelty or inventive-ness. While certain countries accept the grace period for a PCT application based on the grounds that the basis application was filed within one year from disclosure, South Korea does not.

Requirements for specification: unlike in the US, South Korea does not impose a duty of disclosure (ie, an information disclosure statement). However, the recent trend is that a specification lacking prior art patent data in the background section will be rejected and an office action issued for lack of clarity. However, the addition of prior art patent data is not deemed to be a new matter issue.
- Substantive examination: like Japan, China and Europe, KIPO reviews patentability of an application only upon receipt of a request for substantive examination. The deadline for filing a request for substantive examination is five years from the patent filing date (or five years from a date of PCT filing in the case of a PCT national phase application).

Translation issues specific to Korean

Like Chinese or Japanese, Korean is a character-based language, and thus the risk of mistranslation is very likely.

A different word order from that of English or Chinese also hinders translation technology and causes a higher likelihood of translation errors.

Challenges accepted

As an increasing number of foreign entities seek protection for their IP in these north-east Asian countries, knowing the unique challenges of filing in these countries—and partnering with those intimately familiar with the language, culture and laws—will ultimately reduce office actions, decrease the risk of litigation and speed up time-to-grant.
The growth story of the Indian market has been nothing short of extraordinary. With the opening up of the Indian market to foreign brands, as well as the growth of Indian industry, there has been a new-found awareness of advertising. Innovative advertisement strategies and detailed advertisement campaigns are therefore becoming increasingly popular in the highly competitive Indian market.

Today, we see a large number of campaigns that are built around catchphrases/slogans that usually establish an immediate connection with the brands they are used to endorse, and have a very high recollection value among the target audience. For instance, the slogan ‘Utterly Butterly Delicious’ can only relate to the well-known dairy brand, Amul, and ‘King of Good Times’ is undoubtedly Kingfisher. With elections being around the corner, Tata Tea has revived its famous campaign that is best summed up by the slogan ‘Jaago Re’ (which loosely translates to ‘wake up’, symbolising the need for the masses to become more politically aware).

It, therefore, becomes necessary to examine the law relating to the protection of slogans in India. Indian trademark law and copyright law do not specifically recognise slogans as within the scope of the respective statutes, however, a need is felt to afford some protection to the effort, skill and creativity that goes into formulating large-scale advertisement campaigns, and to protect the reputation and goodwill that such slogans and campaigns develop in a particular brand.

Copyright law
Regarding the protection of slogans under the law of copyright, there appears to be a lack of clarity regarding the stance that the courts have taken pertaining to granting such protection to advertising slogans. The Division Bench of the Delhi High Court granted Pepsi an injunction against its competitor, Thums Up, for the slogan ‘Yeh Dil Maange More’, in the matter of PepsiCo Inc & Anr v Hindustan Coca Cola (2003), holding that “slogans which form the theme of the advertisement of the applicant’s products are entitled to copyright protection”.

Following this decision, the Copyright Board granted the registration of the slogan ‘Sampurna Suraksha Ki Guarantee’, while recognising the same as a literary work, in the Kamdhenu Ispat case (2010). At the same time, however, the lead single judge of the Delhi High Court held in Godfrey Phillips (2012) that, slogans, however distinctive they may have become, are essentially a set of words that form part of ordinary everyday language, and cannot be the subject matter of copyright protection as they involve no creativity.

Anusuya Nigam of Singh & Singh Law Firm LLP analyses the case law surrounding the protection of advertising slogans in India
It must be noted that making advertising slogans that have an instant ‘brand connect’ is not an easy task, and requires a large amount of effort to be put into it, and usually, companies invest huge amounts of time and money into their creative teams, with a view to boost sales. Such effort should be recognised, and protection should be granted to the resulting works.

While, at the same time, it must be borne in mind that the function performed by advertising slogans may not be of the nature that should be protected under copyright law. Slogans/catchphrases are adopted with the intention of creating a distinctive image of a particular product that the consumers would be able to relate to immediately, and that over a period of continuous use, would become synonymous with the brand. Therefore, more appropriate protection for advertising slogans lies in trademark law and the law of passing off.

Trademark law

Advertising slogans are implicitly covered within the scope of the definition of trademark under the Trade Marks Act, 1999, inasmuch as slogans are “marks” that are capable of being represented graphically; perform the essential function of “distinguishing the goods and services of one person from those of others”, and are used for the purpose of indicating a “connection in the course of trade” between the goods or services and the person having the right to use the mark.

There are various examples to suggest that slogans perform the function of trademarks. For instance, Polo's unique slogan 'The Mint With The Hole' adds to the distinctiveness of the brand, and the slogan relates exclusively to Polo. Slogans often become so distinctive of a product, that the trademark affixed on the can was actually ‘Pan Vilas’.

The same is also evident from a rise in the number of applications in the trademark registry for the registration of slogans as trademarks.

However, a perusal of the decisions given by the courts reveals that most often, courts do not protect slogans, either on the ground of the words being part of common language, or due to a finding of lack of distinctiveness. The Bombay High Court granted an injunction in favour of the slogan ‘Hamara Bajaj’ and restrained the use of the name ‘Hamara Bajaj’ as a movie title (2013). While in the case of PriyaGold (2011), the Delhi High Court restrained the defendant from using the slogan ‘Maango Haq Se’, which was a mere juxtaposition of the words in the slogan of the plaintiff, being ‘Haq se Maango’ (which translates, in the context of the advertisement, to demanding the best quality of biscuits). At the same time, the Calcutta High Court found no distinctiveness in the slogan ‘Taller, Stronger, Sharper’ in the Horlicks case (2009), and therefore did not restrain a competitor from using a very similar slogan ‘Sabse tallest, strongest, brightest’.

Similarly, Gatorade (2010) did not succeed in an infringement suit for the slogan ‘Rehydrate Replenishe Refuel’, which it has been using since as early as 2002, as the Delhi High Court held that the words were part of common everyday language. Further, the court did not find any distinctiveness in the slogan ‘Shaq Badi Cheez hai’, and held that the defendants’ slogan ‘Swad badi cheez hai’ did not amount to passing off in the Godfrey case discussed above.

Likewise, the Karnataka High Court held in the Reebok case (2007) that the slogan ‘I Am What I Am’ was not distinctive of Reebok, and no prudent consumer would be mistakenly confused between the products of the plaintiffs and the defendants, despite the fact that they were using the identical slogan for identical goods.

Therefore, it appears that the view taken by courts at present, as regards to advertising slogans, is largely fact-based, and varies from case to case. Further, courts should recognise that advertising slogans perform the functions of trademarks, and are covered within the scope of the definition of trademark. Just like common dictionary words are often granted trademark protection, on the basis of a registration, or on a finding of acquired distinctiveness, the same treatment also, rightfully, should be afforded to advertising slogan.

But with the rise in the number of advertising slogans being used, and creative and innovative campaigns being adopted, it is felt that the courts will protect, in the times to come, the intellectual property rights in advertising slogans. IPPro
Novartis Pharma’s head of intellectual property, Paul Fehlner, spoke to attendees of the Global IP Exchange in Munich via video link about the structure of his group in a company that operates in multiple markets around the world.

His company splits its IP team into product groups, with each having its own dedicated patent and trademark attorney, who in turn work with local patent and brand teams in different jurisdictions.

But because the “flat world” complicates the global IP strategy, each country in which Novartis and its subsidiaries operates has its own manager, who coordinates with business and IP teams.

This is because product teams cannot be active in every market. Country managers act as early warning systems where they are not actively present, and as invaluable sources of information. “With every level of resources, it’s possible to work on contacts and relationships,” said Fehlner.

He added that even a company of Novartis’s size is unable to dedicate unlimited resources to IP. It has teams in the US, Europe and China, and is putting one together in India.

But “local actions cannot undermine the global IP strategy”, said Fehlner. The country manager needs to keep product teams in the loop to avoid adversely affecting other potentially more valuable markets and areas for the business.

He said: “We all need to keep each other informed so we’re all in the loop.”

Having said that, Fehlner went on to stress that senior management must not be bombarded with information. Novartis management will be informed of an issue if it is going to affect an important product, is a cost in the millions of dollars, or has the potential to attract a lot of publicity.

He Jing of AnJie Law Firm told attendees of the exchange that China wants to make court decisions available online so that its legal system can become more transparent. This will provide IP professionals with statistics and information from which to work from.

Three expert working groups are also looking at how the country can introduce specialised IP courts. Proposals are on the table for a US-style circuit system, as well as a regional system such as the one about to be implemented in the EU in the form of the Unitary Patent Court.

While a timeframe is “not set yet”, the China-EU partnership known as IP Key could help to bring plans to fruition, he said.

The new EU Commission project, IP Key, focuses on IP protection for all users in China. The Office of Harmonization for the Internal Market (OHIM) is providing more than €7 million in funding and is leading the project, while the European Patent Office is providing patent expertise.

Benoit Misonne of IP Key said that experts working on the project are forging relationships with key Chinese ministries, including the Ministry for Information and Technology, as well as all enforcement agencies.

The project’s aim is to look at “addressing systematic issues” rather than everyday problems, explained Misonne. The plan for 2014 is to raise awareness about all forms of IP in China and provide technical expertise and set up databases.

Jing added that from China’s perspective, partnerships such as IP Key “open up a window” for legal professionals, giving them greater access to their European counterparts.

Attendees of the exchange also heard that a commercial aim will yield more resources for the fight to protect a brand online.

A presentation on online brand protection examined the “effective business model” of using the internet to both advertise and sell counterfeit products, with infringers using online marketplaces such as eBay being a prime example.

Many online marketplaces are set up in jurisdictions where IP is difficult to enforce. They also facilitate infringement rather than infringe rights themselves, complicating any enforcement strategy.

Counterfeiters using online marketplaces are doubly difficult to enforce against because it is a “high volume game”, attendees were told. The more high-end the brand, the more attention it attracts, and listings offering counterfeit goods for sale can number in the thousands in the worst cases.

The task of taking down thousands of listings can be expensive. Attendees were told: “If you can find a commercial relevance for protecting a brand in a certain area, you can get the appropriate resources [to tackle the problem].”

For example, if sales and marketing colleagues can be convinced that an online marketplace can be cornered if counterfeiters are taken out of the picture, they will become valuable allies in the search for greater resources with which to protect a brand. IPPro
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K&L Gates LLP has added Michael Verga as a partner in the firm's intellectual property procurement and portfolio management practice in Washington DC. Verga joins K&L Gates from Kilpatrick Townsend & Stockton LLP.

With nearly 25 years experience in the practice of IP, both in-house and through private practice, Verga focuses on the strategic development and enforcement of IP portfolios including patent application drafting and prosecution, due diligence, and licensing in the electrical, software, computer, and mechanical technology fields. He advises clients in a variety of industries including telecommunications, networking, medical devices, energy, agriculture, construction, software, optics, and semiconductors. With degrees in law and electrical engineering, Verga formerly served as in-house counsel for a medical device company and as a flight simulation engineer.

“We are excited to welcome Verga to the firm and expand K&L Gates’ IP services to our clients,” said David Case, administrative partner of K&L Gates’s Washington DC office.

“His years of legal and industry experience have given him a nuanced understanding of technology design and development that will be invaluable in helping our clients protect their intellectual property assets worldwide.”

Wilmer Cutler Pickering Hale and Dorr LLP has welcomed Tara Elliott as a partner in the firm’s IP litigation group in Washington DC.

With more than 20 years of experience, Hale focuses on a broad range of civil litigation and arbitration matters, including business torts, unfair competition, anti-trust, patents and other intellectual property, and other complex commercial disputes.

His experience includes litigating matters in state and federal courts throughout the country at both the trial and appellate levels. Hale is active in all phases of litigation disputes, including pre-litigation counselling, law and motion practice, complex discovery, and jury and bench trials.

Prior to joining LTL, Hale served at Manatt Phelps & Phillips LLP for more than 12 years as an associate and later a partner in the IP and commercial litigation groups. Before Manatt, he served as a litigation associate at Coudert Brothers LLP.

Hale began his career at Cooper, White and Cooper in San Francisco.
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His addition is a big win for LTL,” said partner Enoch Liang, who heads LTL’s San Francisco office.

“He brings tremendous experience and we look forward to continuing to build on our success in intellectual property litigation.”

The US Patent and Trademark Office (USPTO) has appointed former AOL lawyer Sarah Harris as general counsel.

Her position becomes effective on 21 April.

She fills the role after Bernard Knight resigned in August 2013 to return to private practice.

Harris is responsible for overseeing an office with more than 100 lawyers and paralegals and three deputy general counsels.

Harris has been with AOL since 2007 and previously had IP positions with Cooper Industries and Hewlett-Packard.

She managed AOL’s IP policies and strategies for managing issues, including patent litigation, copyright, trade secrets, defamation, publicity rights, trademarks and domain names.

“We are thrilled to welcome Sarah Harris as the USPTO’s new general counsel,” said deputy director of the USPTO Michelle Lee.

“She has a stellar record directing a global patent and trademark portfolio while leading a team of talented and skilled IP professionals. She is a great addition to our strong leadership team at the USPTO and will play a key role in the agency’s mission to foster innovation and economic growth in our 21st century economy.”

In February, David Kappos left the agency to return to private practice. The USPTO has been without a director since acting director Teresa Stanek Rea left the agency in November.

The coordination committee of the World Intellectual Property Organization (WIPO) has appointed Francis Gurry as director general of WIPO for a second term.

Committee Chair Ambassador Fode Seck declared Gurry the consensus nominee.

Gurry won in that round of voting with 46 votes, with 20 votes for Geoffrey Onyema of Nigeria, 10 votes for Panama’s Alfredo Suescum Alfaro and seven votes for Juri Sellenthal of Estonia.

The candidate with the least number of votes after the first round is out of the running, according to the rules.

Before the second round of voting began, Suescum and Onyema were withdrawn. Consequently, Gurry was selected as the consensus nominee.

Gurry offered his “heartfelt and profound thanks” to member states from all regional groups for the support given to him.

“I think that the world of intellectual property is a challenging one, but one with great opportunities,” Gurry told delegates.

Stating his main goal is to “maximise opportunities for all member states.”

“Let me say that I am deeply honored by your support and I am profoundly grateful to you and look forward to working with you all,” said Gurry.

The Coordination committee, which comprises 83 member states, held one round of voting from a list which originally included four candidates.

Gurry will serve a six-year term.

Wiggin and Dana LLP has expanded its IP practice with the addition of four new partners in its New York office.

Joseph Casino, Michael Kasdan and Abram Kasdan, who previously practiced with Amster, Rothstein and Ebenstein, join, as does Sanna Palla, who arrives from Kaye Scholer LLP.

In his nearly 20-year career, Casino has been lead counsel in patent litigations in many jurisdictions throughout the US, including the ITC. His cases have involved a wide variety of technologies, including consumer electronics, medical devices, automotive equipment and batteries. In addition to his litigation practice.

Casino counsels clients on the strategic development of their patent portfolios and negotiates complex licence agreements.

Kasdan will continue to focus his practice on negotiating, defending and asserting IP rights before the courts, the USPTO, the US ITC and in private arbitration and mediation.

As well as being trained in electrical engineering, Kasdan also works on a broad range of technologies. He focuses a significant part of his practice to advising start-ups and early stage companies on evaluating, obtaining, valuing, licensing and developing patent portfolios and trademarks.

Casino and Kasdan have each worked in-house for a major Japanese corporation in Japan, and are well-versed in Japanese corporate culture.

Kasdan will continue to concentrate his practice on all aspects of patents involving complex technologies. With more than 15 years of research and development experience at a number of prominent research laboratories, Kasdan has hands-on, in-depth knowledge covering a wide range of technologies, including electronics, optics, semiconductor processing and materials science. In addition to litigating and negotiating licences, he oversees patent prosecution programs for his clients.

“Based on current and projected client demand, we targeted intellectual property as an especially promising growth area for the firm,” commented Bob Benjamin, chair of Wiggin and Dana’s executive committee.

Casino, Kasdan and Kasdan have practiced together for many years as a team handling the IP needs of domestic and international clients.

Palla focuses her practice on the fields of pharmaceuticals, biotechnology, drug delivery systems and medical devices, with an emphasis on Hatch-Waxman patent infringement cases for branded pharmaceutical manufacturers and on the emerging patent litigation system in India. IPPro
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Allen Sun
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