Clarifying the gene pool: Spiral Genetics

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Gene patents

If you were drawing up a list of the greatest human achievements of the past 100 years, you could make a good case for the indexing of the human genome being near the top. When that task was completed after 13 years in 2003, it enabled an entire new area of scientific enquiry. However long it takes, it now seems clear that medicines and therapies based on our understanding of the human genome will play a huge part in the future of medical treatment.

In this issue of the *Life Sciences IP Review* monthly newsletter, we talk to Adina Mangubat, chief executive of Spiral Genetics, about the business of sequencing an individual human genome, and the various IP strategies that accompany it. With personalised medicine the latest buzzword, and countless opportunities to use genetics in agriculture industries, it seems clear that, despite the US Supreme Court’s recent decision in *Myriad*, the industry will continue to grow.

We also hear from the International Federation of Pharmaceutical Manufacturers & Associations. IP in the life sciences industry is always a difficult subject, but in India, the situation is made even more complicated by uncertainty over court decisions and the application of the law. The federation looks at the situation from the point of view of innovative biotech companies, and speculates about what the future may hold.

Finally, we feature the key news in the industry from the past month, as well as a report about an interesting ruling at the EPO and a look at progress on the Unitary Patent Court in Europe.

*Peter Scott, Managing editor*

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EPO decision could trip up US patent defenders
Eli Lilly bids to stop generics cutting Alimta exclusivity

INDIANAPOLIS, US

Eli Lilly has begun its defence of a patent covering lung cancer drug Alimta against generic companies including Teva, Barr Laboratories and APP Pharmaceuticals.

Alimta is an injectable drug for the treatment of non-squamous non-small cell lung cancer. It is made with the active ingredient pemetrexed.

Eli Lilly’s US patent ‘209 covers a way of administering the drug with two nutrients—folic acid and vitamin B12—which protect against Alimta’s side-effects.

In 2010, Eli Lilly brought the case against the generic drug manufacturers at the US District Court for the Southern District of Indiana after they filed abbreviated new drug applications (ANDAs) to market their own versions of Alimta. The ’209 patent, which covers “antifolate combination therapies” expires in 2022.

Lilly’s basic patent covering Alimta’s composition of matter expires in 2017. If it wins its case against the generics, which started on August 19, the company will ensure that it keeps its market exclusivity for Alimta until 2022. An extra five years’ exclusivity is worth an estimated $14 billion to the company, based on Alimta’s sales of $669 million in the second quarter of 2013.

A spokesperson for Eli Lilly told LSIPR: “We believe this patent is valid and enforceable and we are prepared to defend our intellectual property. The significant scientific research that Lilly performed in support of the vitamin dosage regimen patent deserves intellectual property protection.”

The defendants are expected to argue that the administration of Alimta with the nutrients is obvious.

Kevin Noonan, a partner at McDonnell Boehnen Hulbert & Berghoff LLP in Chicago, said that while some have reported the case as unusual, lawsuits concerning method of use patents are fairly common.

“In taking these two vitamins with Alimta will give a better response, and so the question is: is that something someone would know? If the answer is no, and if its results are sufficiently better, you can get a patent on that, which Eli Lilly did,” he said.

He added that once the patent expires, if another company wanted to make a version of Alimta to be administered without the two nutrients, it shouldn’t be infringing. However: “If the FDA required the drug to be made in this way, that would be an interesting question,” he said.

Horizon Pharma settles Duexis case with Par Pharmaceuticals

DELAWARE, US

US-based Horizon Pharma Inc agreed on August 22 to settle its patent dispute over arthritis drug Duexis with generic manufacturer Par Pharmaceutical Companies.

Duexis is a tablet that treats the symptoms of rheumatoid arthritis and osteoarthritis. Its combination of ibuprofen and stomach acid inhibitor famotidine was formulated to cut the risk of the patient developing stomach ulcers through its use.

Horizon has six patents covering Duexis listed in the Orange Book, a list of approved drugs published by the US Food and Drug Administration (FDA).

It launched the case against Par, and its subsidiary Par Pharmaceutical Inc, at the US District Court for the District of Delaware in March 2012, claiming Par is infringing a patent related to the Duexis drug. Par said Horizon’s patent is invalid and unenforceable.

The patent covers stable compositions of famotidine and ibuprofen.

The lawsuit was filed in response to Par’s ANDA, which requested FDA approval to market generic ibuprofen and famotidine tablets.

Under terms of the settlement, Horizon has granted Par a non-exclusive licence to market a generic version of Duexis from January 1, 2023, or earlier under certain circumstances. The parties’ lawsuit will also be dismissed.

The agreements are subject to submission to the Federal Trade Commission and the US Department of Justice.

“We believe this settlement validates the innovation and breadth of the Duexis patent portfolio,” Horizon’s chief executive Timothy Walbert said.
Roche relinquishes patent on breast cancer drug

KOLKATA, INDIA

Drug manufacturer Roche has decided not to pursue a patent application for a breast cancer drug in the Indian market, enabling rivals to possibly produce cheaper versions.

The Swiss-based company has decided against pursuing the application for its Herceptin drug, trastuzumab, following the Kolkata Patent Office's dismissal of applications it had filed.

Herceptin, a biological drug that is used for treating an aggressive form of breast cancer, has been in the sights of drug access campaigners in India, who said the high prices had put it out of reach for poorer residents.

According to news agency Reuters, Roche said in an emailed statement that it “has come to the conclusion not to pursue,” adding, “this decision takes into account the strength of the particular rights and the IP environment in India in general.”

The drug’s active protein was discovered before India’s 1995 deal with the World Trade Organisation to begin protecting drug patents. Roche applied for, and received, a patent in India for a different composition of the medicine.

In 2006, it filed a patent for improvements. But, according to Ralph Loren, partner at Edwards Wildman Palmer LLP, this was Roche’s downfall.

Making reference to the Supreme Court decision last year on Novartis’ cancer drug Glivec, which said patents would not be granted for improvements to drugs, Loren said it was unlikely the application would have succeeded.

Claiming there was “nothing surprising”, about the ruling, Loren said, “This was not an application for the underlying drug, it was a secondary patent that was adding to the original. If it were for a patent that underlies the finer details of a drug, that’s worth fighting, but purely an add-on would not.”

Global sales of Herceptin hit 5.9 billion Swiss Francs ($6.3 billion) last year, mainly in industrialised countries. India accounted for only 0.2 per cent of Roche’s total pharma sales in 2012.

The Indian government has allegedly been considering issuing a compulsory licence that would have overridden Roche’s patent and allowed other local companies to produce cheaper versions.

Roche declined to detail how much of the medicine it has sold in India, although it said it had developed “a local pricing strategy”.

But Loren added: “Roche would have looked at this and thought, how much is it worth fighting? India is not a good environment for pharmaceuticals at the moment and at some point, there will be a cheaper version on the market. Roche would have thought they did not want to spend a huge amount of money on something they would be likely to lose.”

IN BRIEF

Sheppard Mullin hires partner in California

Sheppard Mullin Richter & Hampton LLP has announced the appointment of a new partner at its Palo Alto office.

Lorna Tanner, who joins from Foley & Lardner LLP, counsels clients in the pharmaceutical, life sciences and medical devices industries.

Partner Ed Anderson said: “Lorna’s patent prosecution practice dovetails well with our IP practice group and life sciences team.”

The firm’s IP practice group includes 100 attorneys overall.

Drug companies make pact to search for chronic pain treatments

Australia-based research company Bionomics is teaming up with international developer Merck to discover and develop novel small molecule candidates for the treatment of chronic pain.

As part of the multi-million dollar agreement, Merck will have the option to license exclusively a compound from Bionomics for development and commercialisation.

In exchange, Bionomics may receive development and regulatory milestone payments of up to $172 million.

The initial period of the research programme will be two years.

Australia lowers price of more than 400 drugs

Australia has cut the prices of more than 400 drug brands as part of the government’s price disclosure policy (PDP).

The cuts, which range from 12.5 to 16 percent, will affect medicines supplied under the Pharmaceutical Benefits Scheme (PBS).

PDP requires drug manufacturers to inform the government of the lower selling price which results from competition for a PBS drug when its patent expires.

Government ministers claim the cuts will save consumers around A$20 ($17 million) a year.

But research-based industry group Medicines Australia criticised the move for taking place without consultation.
Section 3(d) strikes again in GSK India patent defeat

CHENNAI, INDIA

India’s Intellectual Property Appellate Board (IPAB) has revoked a patent covering GlaxoSmithKline’s (GSK) breast cancer drug Tykerb, in the latest blow to western pharmaceutical companies in India.

The IPAB upheld GSK’s basic patent for lapatinib, a compound which blocks signals within cancer cells that make them grow and divide, but rejected a second patent directed to the salt form of the original compound.

GSK markets lapatinib as Tykerb in countries including the US and India, and as Tyverb in Europe.

Generic drug company Fresenius Kabi Oncology challenged the patents, prompting two separate IPAB rulings on July 27, published on August 1.

Fresenius tried to revoke both patents by citing obviousness, non-Disclosure and Section 3(d), a provision in Indian patent law preventing the patenting of new forms of known substances that fail to enhance the substance’s efficacy.

The section was used by the Indian Supreme Court decision this year to reject a patent directed to Glivec, a leukaemia drug marketed by pharmaceutical company Novartis.

In the GSK case, the IPAB rejected all parts of the challenge to the basic patent, which contains lapatinib as its active ingredient and is set to expire in 2019.

Addressing the patent directed to lapatinib ditosylate, due to expire in 2021, the IPAB first assessed the Section 3(d) provision, saying if the salt “fails this test, it is not an invention”.

GSK had claimed the salt absorbs much lower amounts of water “when exposed to a broad range of humidities, and can be prepared in a stable crystal form”, and therefore had greater therapeutic efficacy.

But the IPAB said that while the properties of the salt may have more advantages over those in the original compound, they “do not result in therapeutic efficacy”.

“Applying Section 3(d) and the decision of the Supreme Court in the Novartis case we find that this is not an invention. The patent deserves to be revoked,” it said of the patent.

The IPAB did press ahead and assessed the remaining objections, finding the patent obvious but rejecting the complaint about non-Disclosure.

A GSK spokesman said it was pleased the IPAB had upheld the basic patent for the lapatinib compound.

“This means that Tykerb remains subject to patent protection until the expiry of the basic patent in 2019. The patent directed to the specific lapatinib ditosylate salt had an expiry date in June 2021.”

He added: “We are disappointed that the IPAB has revoked our later expiring patent for the lapatinib ditosylate salt. This latter ruling only relates to the lapatinib ditosylate salt patent in India and does not affect our basic patent for Tykerb or corresponding patents in other countries. We are studying the IPABs decision but maintain our belief in the inventiveness of the lapatinib ditosylate salt and will consider the possibility of taking further steps before the appropriate authorities to validate this.”

The ruling is another high-profile application of Section 3(d), which has caused some Western pharmaceutical companies to worry about the strength of IP protection in India.

Michael Pears, senior associate at Potter Clarkson LLP, said innovative companies will consider the interpretation of Section 3(d) as a further bar to protecting medicines in India.

While it is fair that there must be an enhancement in efficacy, he said, and that other countries set similar rules, there seems to be a higher inventive step standard in India for pharmaceutical products.

“The equivalent European patent was granted by the EPO, which acknowledged that the ditosylate salt absorbed significantly lower amounts of water when exposed to humidity, and that this could not have been predicted by the skilled person. So, the salt was non-obvious. By not recognising incremental, but genuine, innovation, the decision may well stifle research and development in India. ”

Local lawyers and patient groups, however, have argued that Section 3(d) encourages companies to innovate instead of focusing on patenting minor variations of existing drugs.

IN BRIEF

South Africa urged to improve access to medicines

The Treatment Action Campaign (TAC) and Médecins Sans Frontières (MSF) have called on the UK Department of Trade and Industry to reform the system for examining pharmaceutical patent applications in South Africa.

The TAC and MSF are calling for the changes to ensure patients have greater access to affordable medicines.

According to the organisations, South Africa hands out an excessive number of pharmaceutical patents without examining applications to determine their validity.

They claim that it is lagging behind other jurisdictions and has not amended its patent law to implement flexibilities outlined in the World Trade Organization’s agreement on the Trade Related Aspects of IP.

US university announces plan for new life sciences building

Boston University in the US has proposed a new life sciences and engineering building for the eastern part of one of its campuses.

The project for the Centre for Integrated Life Sciences and Engineering Building is part of an overall plan to increase the amount of classroom, laboratory, and research space for science and engineering at the university.

The proposal for the seven-storey building, which will measure 150,000 square feet, must receive further city approval before it can be formally adopted into the master plan.

Miles & Stockbridge welcomes eight

US law firm Miles & Stockbridge PC has expanded its IP practice with the addition of seven lawyers and one patent agent.

The firm welcomed Susan McBee, Chester Moore and David Woodward as principals, Richard Henderson as of counsel, Bryan Jones and David Vanik as counsels, Shazi Jiang as associate and William Stauffer as patent agent.

The team has a particular strength in matters related to the biotechnology, pharmaceutical and chemistry fields.

“This group is a tremendous addition to our growing IP practice,” said Miles & Stockbridge chief executive John Frisch.

US & Africa hands out an excessive number of pharmaceutical patents without examining applications to determine their validity.
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IPAB throws out Indian Vega trademarks

CHENNAI, INDIA

The Intellectual Property Appellate Board (IPAB) in Chennai has cancelled two trademarks associated with versions of Viagra.

The decision concludes a long battle between Indian pharmaceutical companies HAB Pharmaceuticals & Research Limited and Vee Excel Drugs & Pharmaceuticals Pvt Ltd which had filed cross-suits against each other.

The companies both produce and market their own versions of sildenafil citrate tablets to treat erectile dysfunction.

In the first suit, HAB claimed that Vee Excel’s ‘Vega Asia’ trademark infringed its ‘Vegah Tablets’ mark, saying it was similar and had been registered fraudulently. Vee Excel counterclaimed that ‘Vegah Tablets’ was similar to its own trademark, and that it should be revoked.

On July 31, the appellate board found that Vee Excel could have started using the ‘Vega Asia’ mark only in September 2002, after it received its drug licence. It had applied for the mark in April 2002.

HAB had been using ‘Vega’, ‘Vega 50’ and ‘Vega 100’ since 2001, though the ‘Vegah Tablets’ name had only been used since 2002.

The board agreed HAB was the prior user of ‘Vega’, and that Vee’s ‘Vega’ is very similar to ‘Vegah’, although ‘Vegah’ was the mark at dispute. The board ordered ‘Vegah’ to be cancelled as well as Vee Excel’s ‘Vega’ mark.

Justice Prabha Sridevan said in the judgment: “There is no dispute as regards the date of use as the year 2001 by HAB for the trademark ‘Vega’. In respect of this HAB is prior in use. But here, we are concerned with the trademark ‘Vegah Tablets’ impugned herein for which there is no use proved.”

Abida Chaudri, senior trademark practitioner at Baker & McKenzie in London, said that Indian trademark law has some similarities with the old, pre-Europe UK trademark law, and that if this case were fought in Europe, it would have been argued whether ‘Vega’ constituted use of ‘Vegah’. “I can’t see any reference to the argument that Vega constituted use of Vegah,” she said. “Certainly if it had been a European case I would have expected to see that argument to run quite strongly.”

SIPO pulls Viread patent—victory for pharma innovators?

BEIJING, CHINA

The Chinese State IP Office (SIPO) has revoked a patent covering biopharmaceutical company Gilead Science’s HIV drug Viread, Reuters subsidiary news site BioWorld has reported.

Viread (tenofovir) is used in combination with other antiretroviral agents to treat HIV, and may also be used in the treatment of hepatitis B. It was approved by the US FDA in 2001.

Some had speculated that China would issue a compulsory licence for the drug.

Viread was one of the first medicines included in the Medicines Patent Pool, an initiative aimed at driving down the price of HIV drugs for patients in developing countries.

According to BioWorld, Gilead’s patent covering the drug was challenged by domestic pharmaceutical company Aurisico.

While exact details about the patent’s revocation are thin on the ground, a spokesperson for Gilead told LSIPR: “We are currently reviewing the notice from the Chinese Patent Review Board (PRB) and evaluating our options.

“The notice from the PRB refers to one of the patents covering TDF (tenofovir disoproxil fumarate). There is an additional patent covering the compound that is not affected by this ruling.”

The ruling comes one year after the compulsory licence was introduced to Chinese patent law. George Chan, a consultant at Rouse in Beijing, told LSIPR that compulsory licences for patented medicines allow innovator drug companies to make their patented medicines available in times of national emergency, where an extraordinary state of affairs occurs, or where the public interest requires it, for example if the cost of a patented medicine makes the medicine inaccessible to the vast majority of persons in need.

He said that SIPO’s decision may be construed in some ways as a victory for the pharmaceutical industry innovators as a whole—more so than for the generics.

With some earlier reports suggesting that the authorities were considering issuing compulsory licences for Gilead’s patented Viread medicine to allow the manufacture of more affordable generic versions of the patented drug, the invalidation of Gilead’s patent, rather than the authorities issuing a compulsory licence for Gilead’s patent, leaves the status quo intact, and this would favour pharmaceutical innovators, Chan explained.

To date, SIPO has not issued a compulsory licence, he said. If a compulsory licence had been issued, it would have set a precedent that would have had a significant impact on the pharmaceutical industry.

Chan said that the affordability of Viread is especially relevant for China, which is estimated to have at least 30 million people with chronic hepatitis B infections, and Viread is a first-line drug for such infections.

He added that the accessibility of patented medicines for age-related diseases is also taking on greater importance as the median age of China’s population continues to rise.

Some commentary has suggested that the invalidation of the Viread patent is a power play by the Chinese government to establish a position from which it can negotiate lower prices for other drugs, Chan added.

SIPO did not respond to a request for comment.
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**Myriad patent suit enters antitrust territory**

**SALT LAKE CITY, UTAH**

Ambry Genetics, the laboratory sued last month by biotech company Myriad over patents covering the BRCA1 and BRCA2 genes, has hit back with antitrust claims.

Myriad accused Ambry of infringing 10 patents after it began offering tests for breast and ovarian cancer. The suit followed the US Supreme Court’s ruling in June that human genes are not patent-eligible and that struck down several Myriad patents.

In response, Ambry has accused Myriad of trying to monopolise the market despite knowing that its asserted claims are rendered invalid by the Supreme Court decisions in Myriad and Prometheus.

Ambry has also submitted invalidity and non-infringement counterclaims at the US District Court for the District of Utah, where Myriad filed the suit in July with other plaintiffs including the University of Utah Research Foundation.

“Monopoly practices to wrongfully monopolise the market despite knowing that its asserted claims are rendered invalid by the Supreme Court decisions in Myriad and Prometheus,” Ambry claims.

In response, a Myriad spokesman said the company is in the early stages of the litigation and looks forward to presenting its case in court.

“Monopoly practices to wrongfully monopolise the market despite knowing that its asserted claims are rendered invalid by the Supreme Court decisions in Myriad and Prometheus,” Ambry claims.

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Filing antitrust claims in response to a patent infringement lawsuit is unusual but not unheard of, said Andrew Williams, partner at McDonnell Boehnen Hulbert & Berghoff LLP.

Williams said he felt Ambry’s counterclaims will struggle to have much merit because Myriad and its co-complainants have patents covering wide-ranging aspects of the testing for breast cancer.

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Indian patent office strikes down another blockbuster patent

The Kolkata Patent Office has refused divisional patents related to Swiss pharmaceutical company Roche’s breast cancer drug Herceptin.

The news comes days after the Indian IPAB revoked a patent for GlaxoSmithKline’s breast cancer drug Tykerb, on the grounds that it was an incremental innovation that is not adequately inventive.

Roche filed three divisional applications for patents related to Herceptin. According to a statement released by the Kolkata Patent Office on August 5, requests for patent examinations were filed too late, and Roche’s agent did not attend the hearings.

The patent office controller found that Roche’s applications were filed improperly, and treated them as abandoned.

A spokesperson for Roche told LSIPR it was now considering a further course of action.

Roche signs drug licensing agreement with MPP

BASEL, SWITZERLAND

On August 5, Swiss pharmaceutical company Roche signed an agreement with the Medicines Patent Pool (MPP) to increase access to its drug valganciclovir (Valcyte), an oral medicine for the treatment of preventable viral infection cytomegalovirus (CMV).

Under terms of the agreement, Roche will begin licensing and technology negotiations with the MPP to improve access to affordable generic versions of Valcyte, and will slash the price of the drug by up to 90 percent in 138 countries.

CMV causes blindness in patients with suppressed immune systems. It affects about 10 percent of people living with HIV in low and middle income countries, mostly in Asia, and to a lesser extent in Latin America and Africa.

CMV patients in developing countries are currently treated with the injection of medication directly into the eye, which is painful and difficult to administer on a large scale.

“The agreement announced today will make a more affordable oral treatment for CMV available immediately and also catalyse the creation of a sustainable generic market,” said executive director of MPP, Greg Perry.

Daniel O’Day, chief operating officer at Roche Pharma, said: “This agreement demonstrates how working together can improve the availability of treatments for people in resource-limited countries.

“Our aim is to provide access to affordable Valcyte that is produced under quality conditions and increase the number of people who access and benefit from our products.”

The MPP has also announced it will work with other stakeholders to scale up the use of Valcyte in developing countries.

In a statement accompanying the agreement Roche said it will license HIV antiretroviral drug saquinavir to the MPP if needed in future.

Adam Cooke, partner at DLA Piper in London, said that there is an increasing trend for the patent pool model: “Businesses want to improve their credentials in terms of being seen to assist less advantaged populations when they can,” he said.

“I’m sure that Roche would want to help insofar as it’s able to in assisting those suffering from HIV who cannot afford the cost of treatment.”

There may be risks involved in supplying a drug at a reduced price, however. “You want to be sure that it reaches the intended population and doesn’t get diverted en route and then resold at a much higher price,” he said.

The MPP is a UN-backed initiative established in 2010. Its goal is lowering the prices of HIV medicines in developing countries by creating a pool of patents for generic companies to license, and stimulating generic competition.

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KOLKATA, INDIA

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The patent office controller found that Roche’s applications were filed improperly, and treated them as abandoned.

A spokesperson for Roche told LSIPR it was now considering a further course of action.

“In an outside, the administrative requirements for filing and obtaining a patent can look positively Dickensian or Kafkaesque in their complexity—this is the case in most countries,” he said.

“Beyond that we are only aware of the reports regarding the Herceptin patent from the media coverage in India, so we cannot comment or speculate,” she added.

The decision is the most recent in a series of rulings that highlights the challenges brands face when trying to crack the Indian pharmaceuticals market.

In 2012 Roche changed tack in its strategy to enter the market, signing a manufacturing contract with Indian pharmaceutical company Emcure Pharmaceuticals to sell Herceptin and another cancer drug MabThera at a cut price.

In a statement accompanying the agreement Roche said it will license HIV antiretroviral drug saquinavir to the MPP if needed in future.

Jason Rutt, head of patents at Rouse in London, said: “Indian patent law in the pharmaceutical sector is under all sorts of scrutiny at the moment, but this looks more cock-up than conspiracy.

“The consequences for failing to attend to these correctly can often be the loss of the patent application. The statement by the Indian patent office suggests the loss of the application is result of such an error by Roche’s Indian patent agents.”

He added that the decision may be appealable, which would give Roche an opportunity to revive the application depending on the circumstances of the alleged error.
IPAB revokes Allergan eye drug patent

KOLKATA, INDIA

On August 8 the Indian Intellectual Property Appellate Board (IPAB) revoked another patent owned by a Western pharmaceutical company—this time related to Allergan’s eye drug Combigan.

The IPAB found that Allergan’s patent, which covers a mixture of brimonidine and timolol for topical ophthalmic use, was invalid for obviousness. The combination of brimonidine and timolol, claimed that Allergan’s patent, which covers a mixture of brimonidine and timolol for pressure in the eyes of glaucoma patients. Combigan is an eyedrop solution that treats domestic drug manufacturer Ajanta Pharma claimed that Allergan’s patent, which covers the combination of brimonidine and timolol, was obtained “on a false suggestion or representation”, as there is no data to show that the combination of brimonidine and timolol has enhanced efficacy.

It also said that Allergan’s failure to disclose information about the status of foreign patent applications at the time of the filing at the Indian Patent Office was in breach of the Patent Act. The IPAB agreed and ordered revocation of the patent.

Mohan Dewan, a partner at RK Dewan & Co in Mumbai, said that the recent increase in Western patent revocations at IPAB is due to a spate of applications filed by these companies after an amendment to the Indian Patent Act in 2005. He explained that after the Indian Patent Act was amended, Western companies started applying for the newly available pharmaceutical patents—where only process patents were allowed before—but did so in a way that does not conform to Indian patent law.

“The strategy of filing these applications had been incorrectly angled,” he said, adding that many companies incorrectly applied US or European patent law when applying for Indian patents.

“The mindset of these companies is a problem,” he said. “You have to tailor your specification.”

Thousands sign petition calling for withdrawal of Indian biotech bill

Protestors in India have delivered petitions signed by more than 400,000 people demanding the withdrawal of a controversial biotechnology bill.

The petitions were delivered to Subbarami Reddy, chair of the parliamentary standing committee on science & technology, environment & forests, in protest at the Biotechnology Regulatory Authority of India bill. The bill proposes to set up a centralised single window clearance system designed to lower the bar for genetically modified crop approvals without implementing independent long-term safety assessments.

Receiving the petitions, Reddy assured the delegation that the standing committee will keep public concerns in mind while deliberating.
Knowledge of human genes and their role in driving diseases has become increasingly important in the development of personalised medicines. Genetic sequencing has come on leaps and bounds since the international Human Genome Project (HGP) was completed in 2003—after 13 years and three billion base pairs it had succeeded, two years ahead of schedule, in identifying every gene in the human genome for study.

There are two parts of genetic analysis, explains Adina Mangubat, chief executive of Spiral Genetics, which provides software packages for genetic analysis, or next generation sequencing. The first part of the analysis is the chemistry phase, the second is computational.

In the chemistry phase of the sequencing process, instead of ‘reading’ the three billion base pairs that make up the human genome from beginning to end as was done in the HGP, which is not particularly efficient, the string of information is broken down into 100 base pair-long chunks to make the analysis more manageable.

The sequencer yields thousands of text files, albeit with no way of knowing where each part of the genome came from.

Spiral Genetics provides the computational side of the analysis. Using a set of algorithms and computational methods it can reassemble the genome and compare it to others to find out what the genetic variations are. The information yielded can assist in the development of personalised medicines—treatments tailored to individual patients.

Spiral Genetics and the industry

“Historically our service has been used by a lot of academic laboratories, individual researchers at universities and academic research institutions that are trying to conduct basic research, trying to find out what are the genes that are causing autism or breast cancer, for example,” says Mangubat.

She adds that core laboratories, or outsourcing laboratories, are increasingly using the Spiral Genetics system. Are pharmaceutical companies getting in on the act?

“To be totally honest, at this point, pharmaceutical companies are only starting to
dip their toes into next generation sequencing,” Mangubat says.

“If you look at the historical adoption patterns for any genetic technology, because there are ways to look at DNA before next generation sequencing, the progression always goes from academic institutions to core laboratories or clinical laboratories to pharmaceutical companies. It’s always that progression,” she explains.

**Biofuel and agriculture**

While Mangubat recognises the importance of developing personalised medicines, she encourages people to consider agriculture and plant genomics, explaining that next generation sequencing can play a significant role in developing these industries.

By using the information gleaned from sequencing plant genomes, it is possible to improve crop production and develop biofuel, a sustainable alternative to fossil fuels. Certain strains of algae and the oil seed plant jatropha have been shown to produce biofuels: “If you can sequence all of these strains of all of these different plant species, you can figure out which ones produce the most oil and why, which will help people produce biofuel in a much more efficient way,” Mangubat says.

**IP**

At the time of writing, Spiral Genetics has a number of pending patents, and trade secrets that are being converted into patents as they ‘mature’. There are many innovations Spiral Genetics could patent, Mangubat says, though most efforts are based around the computational methods that facilitate Spiral’s rapid genome analysis.

“We can analyse a whole human genome, from the raw data that comes off the sequencer to getting the list of genetic variants, in three hours, which compared to other groups is really fast,” she says. This is crucial because by quickly processing the data as it emerges from the chemistry phase of analysis, scientists can avoid data backlog, she adds.

**Speed and efficiency: the algorithms**

Spiral Genetics’ computational methods for manipulating data during genetic analysis ‘plug in’ to its underlying distributed computing framework. To analyse the raw data, Spiral makes use of open source, peer-reviewed algorithms which it puts on top of the patented framework to accelerate how fast they work.

The company hasn’t in-licensed any IP, nor licensed its own patents to others: “It’s not really part of our strategy right now, though it could be in the future,” she says.

“It’s not something that we’ll ever rule out but it’s not something we’re actively pursuing.”

She describes the Spiral Genetics IP portfolio as a “smattering”—some patents were filed around the time the company was established in 2009 and others more recently. There are currently three patents and others pending.

As next generation sequencing, or bioinformatics, is a fairly new field, patenting Spiral Genetics’ creations has been largely painless. “There’s some prior art, for sure, but it’s been good in terms of being able to get a strong foothold in a pretty defensible place,” Mangubat says.
“We were essentially taking two technologies that have never really met each other before—when you marry those two you get technologies that people didn’t think of before so it’s been pretty good so far.”

The bioinformatics industry has changed dramatically since the company’s establishment, and the cost of sequencing has dropped significantly, Mangubat says. “Back when we started the company, the chemistry was at a much younger stage of development so to analyse a whole human genome sequence, just the chemistry stage would have $100,000 worth of chemical costs and about 30 days of chemical churning and processing just to get the raw data.

“Now with the new genome DNA sequencer you can do it in a day and it costs $2,000 to $3,000.”

Unsurprisingly, this fall in costs has opened the market, so how is Spiral Genetics using its IP strategy to stay ahead?

“As with many things, the Myriad ruling is a double-edged sword. The great thing about it is that all of a sudden many of the genes discovered to be highly correlated with particular diseases can now be tested for without licensing.”

She predicts “an explosion” of new diagnostic companies that will drive down the price of diagnostics for the consumer, and turn it into a process that is no longer only available to the very rich.

“The code of who you are?”

Spiral Genetics’ use of peer-reviewed algorithms, as opposed to proprietary algorithms, may also give the company an edge. Scientists would prefer to use peer-reviewed algorithms so they know exactly what’s happening to their data, Mangubat explains.

“Scientists are really not fans of black boxes,” she says.

“They want to know what the inner workings are like, so being able to guarantee that what is happening to their data is known and has been reviewed by their peers, and being able to accelerate it, is really important.”

**Myriad**

In June this year the US Supreme Court ruled that human genes are no longer patent-eligible. As a company whose bread and butter is supplying researchers lists of genetic variants with a view to creating personalised medicines, has it been affected by the ruling in any way?

“It hasn't had an impact on us yet, but I think that it will in terms of new players in the market,” Mangubat says.

“As with many things, the Myriad ruling is a double-edged sword. The great thing about it is that all of a sudden many of the genes discovered to be highly correlated with particular diseases can now be tested for without licensing.”

She predicts “an explosion” of new diagnostic companies that will drive down the price of diagnostics for the consumer, and turn it into a process that is no longer only available to the very rich.

She says the ruling brings Spiral Genetics potential new customers too, although there is a downside. “As genes aren't patentable any more, it really demotivates a lot of the corporate investment in research on these particular genetic markers because it’s really hard to monetise if everyone has access to it.”

She says that most of the genetic discovery is now in the hands of the academic researchers.

“They’re the groups that have done a lot on discovery in the past,” she says. “It really doesn't make much sense for a company that’s for profit to try and do that research because there’s no guarantee of return on their investment.”

**The future**

With the industry evolving so rapidly, it isn’t easy to predict what direction Spiral will take next. Mangubat thinks that in 15 years’ time, everybody may have their gene sequence in their medical records, and personalised medicine will have taken off.

However, regulatory measures will always lag behind scientific innovation, she says, which could hinder progress in the industry. Striking a balance between ensuring people’s personal data is not compromised, or used maliciously, while allowing a certain degree of openness to allow for research will be challenging, though it could determine the shape of the industry and how it evolves.

The Health Insurance Portability and Accountability Act (HIPAA), which came into force in the US in 1996, allows for the protection of patient data, while the Genetic Informational Nondiscrimination Act, passed by US Congress in 2008, ensures that genetic information may not be used for discriminatory purposes—for example, by insurance companies looking for reasons not to cover an individual.

Mangubat says there are still some grey areas, however. “If you are a research subject—a participant in a research study—your data, as you’re not technically a patient, doesn't technically fall under the jurisdiction of HIPAA. You are not guaranteed to be protected in the same way that you would be if you were a patient.”

Realistically, all genetic data will eventually be found to be identifying data and will therefore fall under the HIPAA jurisdiction, she says.

“Because what is more identifiable than the code of who you are?”
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Can India have its cake and eat it?

There has been much debate about whether there is a global deterioration of IP, and many commentators would suggest that India is leading the charge. Andrew Jenner and Ernest Kawka reflect on the experiences of innovative biopharmaceutical companies in India.

In late 2011, India adopted a National Manufacturing Policy to boost gross domestic product from 16 percent to 25 percent by 2022. The policy aims to aggressively increase domestic manufacturing capacity, especially in high technology areas. One mechanism to achieve this goal is by adopting measures that "ensure access for Indian companies to foreign technologies" by "leveraging the strength of India's large market." The official policy further elaborates that one way to ensure access to foreign technologies requires India to overhaul its IP regime "to enable more collaborative innovation."

During the 2012 general assemblies of the World Intellectual Property Organization (WIPO), India proclaimed that "while fully recognising the importance of IP rights for innovation—diffusion of technology also merits serious consideration." This tone appears to overlook the spirit of India's 2011 policy. In fact, many foreign inventors have experienced increased difficulty in obtaining and enforcing IP rights, particularly patents, in India. It seems that India's IP regime reform includes "supporting" its national industry at the expense of foreign inventors.

Notwithstanding the international legality of its policies, it is highly questionable whether India's treatment of foreign patent applications and grants is sustainable. There are four main areas that have caused many innovative stakeholders to rethink India's commitment to innovation:

1. Requiring foreign inventors to prove certain aspects of their inventions not available at the time of patent application;
2. Creating barriers to patent enforcement, namely the inability to obtain preliminary injunctions during the course of judiciary proceedings;
3. Issuing compulsory licences or invalidating granted patents based on dubious rationales; and
4. Requiring foreign inventors to meet unnecessary and overly burdensome procedural rules in order for a patent application to be considered by India's Patent Office.

Biopharmaceutical innovation

The situation is even more worrying for research-based biopharmaceutical companies in India. Due to the complexity, uncertainty, and capital required to research early-phase molecules, biopharmaceutical research and development is largely dependent on robust IP rights. For instance, it is estimated that for every 5,000 to 10,000 investigated pharmaceutical compounds, only one will become a marketed medicine. In addition, that process is estimated to cost more than $1.2 billion. In order to recoup the large amount of investment required to bring a medicine to market, companies need a certain level of certainty to reap the fruit of their labours.

Legal certainty is a key ingredient for sustaining biopharmaceutical innovation. Due to the global nature of biopharmaceutical innovation, inventors need a level playing field in order to take full advantage of diffusing technologies and know-how around...
the world. In this manner, it is important for governments to strike the correct balance of short-, mid-, and long-term policies affecting innovative biopharmaceutical companies.

India is attempting to strike this balance in a formal national debate on innovation and IP rights. In a policy brief resulting from that debate, Indian stakeholders recognised the importance of robust IP rights in a knowledge economy, and called for the “improvement of the institutions that grant IP rights and … those that are responsible for its enforcement.” However, since 2011, innovative biopharmaceutical firms have witnessed an unfortunate deterioration of IP rights in India.

Meeting India’s patentability criteria
In order to receive a patent, an invention needs to be patent-eligible subject matter and must be “new, involve an inventive step, and capable of industrial application.” Section 3 of India’s Patent Act generally outlines types of inventions that are not patent-eligible subject matter. Subsection (d) of that section further requires:

“...For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of a known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy ...”

In order for any of the enumerated inventions in Section 3(d) to receive a patent, an applicant must show an ‘enhanced efficacy’ of that invention during formal patent review. Enhanced efficacy, as India’s Supreme Court described in Novartis v Union of India, must be “specifically claimed and established by research data” in the affected patent application. Notwithstanding the legal concerns relating to India’s obligations under Article 27.1 of WTO’s TRIPS Agreement, biopharmaceutical patent applicants are now faced with a practical problem: enhanced efficacy data is not normally available until up to eight years after applying for a patent.

Disclosing information to prove enhanced efficacy in a biopharmaceutical patent application may be impossible because it is unknown at the time of applying for a patent. Moreover, delaying the date of patent application until such data are available carries a substantial risk that the invention will not be patentable because it likely to become publicly disclosed (eg, primarily through patent applications in other countries). In many circumstances a medicine’s efficacy is determined once clinical trials are conducted.

Patent enforcement and preliminary injunctions
Article 28 of TRIPS outlines the rights conferred by patent grants. It provides:

“A patent shall confer to its owner the … exclusive right … to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing [the affected patented product].”

In the event a patent is allegedly infringed, the typical recourse for a patent owner is to seek judicial intervention to permanently enjoin the infringer from “making, using, or offering for sale” the patented product. However, only a judiciary body can determine whether infringement occurred. That process, usually a conventional court trial, may take years. In order to ensure the alleged infringer ceases the possible infringement, courts provide patent owners with an opportunity preliminarily to ‘prove’ that the patent is in fact being infringed and that that act is causing the patent owner irreparable harm. This opportunity is called a preliminary injunction.

When a bona fide request for a preliminary injunction is rejected, infringers are essentially allowed to infringe for the entire duration of the trial. In other words, the main tactic for a defendant infringer in that circumstance is to delay the case for as long as possible. Unfortunately, biopharmaceutical patent owners in India are regularly witnessing such tactics. The Indian judiciary has become more and more reluctant to issue preliminary injunctions.

Compulsory licences and patent invalidations
While TRIPS permits the use of compulsory licences under certain circumstances, routine use, or the threat of use, of compulsory licences discourages the introduction of new medicines. Even though allowed under TRIPS, compulsory licences are an option originally intended for use in extraordinary circumstances. Frequent use of compulsory licences weakens IP regimes because they undermine the incentive for inventors to invest in risky research.

Yet, a number of commentators applaud the frequent use of compulsory licences. This line of thought often focuses on short-term objectives rather than on solutions which can be sustained long term. In addition, recurrent use or threat of compulsory licences has a negative effect on attracting foreign investment. In the biopharmaceutical sector, the absence of foreign investors from a market may lead to reduced investment in public health.

History has demonstrated that compulsory licences are less effective than other access initiatives. For instance, voluntary agreements between patent right owners and potential licensees not only disseminate the underlying technology, but also the related expertise and know-how. In the last decade, India has issued and regularly threatened to issue compulsory licences on a wide range of biopharmaceutical medicines.

In 2012 India’s Controller General issued a compulsory licence relating to a cancer treatment, thereby enabling an Indian generic manufacturer to produce and sell the medicine without risk of patent infringement. Similarly, India has threatened to consider compulsory licences for at least
three other medicines since 2007. The Indian government has indicated that compulsory licences are needed because the affected medicines are not accessible to all Indian patients. Yet voluntary negotiations to strike agreements with the patent owners are frequently one-sided, leaving little room for real discussion. In the *Nexavar* case, Natco argued that the simple sending of a letter constituted negotiation with the rights holder.

Similarly, biopharmaceutical firms require a level of certainty to ensure that reviewed and granted patents will withstand threats of infringement. Naturally, patent-granting authorities are tasked with striking a balance of efficiency and accuracy when substantively reviewing patentability, but the quality of patent review should be maintained at a high level. In 2013 alone, at least five biopharmaceutical products in India have had their respective patents invalidated, while those patents are still in force in the vast majority of other countries.

Nearly all of these invalidations were based on the invention not satisfying the patentability criteria or definition of invention found in India’s Patent Act. Moreover, the reasoning in many of these cases adopted drastically broad interpretations of the Patent Act, therefore creating a disparity between the standards applied by India’s Patent Office and the judiciary.

Yet another area of growing concern for a number of innovative industries is the premise that in order to ‘work’ a patent (failure to supply to market with a product covered by patents can be grounds for a compulsory licence) it must be manufactured locally. This is part of a growing trend where preferential market access (PMA) or ‘forced localisation’ policies require extensive local content requirements on procurement of electronic products by the government and private sector entities in the information and communications technology sector. Another example is India’s national solar policy, which promotes the use of solar energy in India but inhibits investment from foreign firms.

**Patent application requirements**

Regulatory and administrative agencies often require certain levels of formal procedures to maximise efficiency and quality. For instance, many countries require inventors to follow certain procedures to submit a patent application to a relevant patent granting authority. These procedures are usually designed to maximise an authority’s efficiency in reviewing patent applications while minimising the burden on a patent applicant. After all, a patent is a trade-off between an inventor and a government: for a fixed period of time an inventor can exclusively own what is covered by the patent, but is required to publicly disclose the invention. After that exclusivity period expires, the invention is made public.

One common procedural requirement for obtaining a patent in nearly all countries includes the disclosure of patent applications relating to the same or similar inventions in foreign countries. In India, this requirement is outlined in Section 8 of the Patents Act. However, unlike nearly all other countries, India’s Patent Office requires that an inventor not only disclose any foreign patent applications (and related material), but also provide translated versions of those documents.

The High Court of New Delhi in *Hoffmann-La Roche v Cipla* found that an Indian patent may be invalidated if an applicant fails to provide translated copies of all relevant foreign patent applications and correspondence to India’s Patent Office. This requirement creates an enormous financial burden for innovative biopharmaceutical companies, and provides no benefit to India’s Patent Office because the material disclosed relates to the same invention. This is one example of measures that cause an undue procedural burden for foreign applicants.

While it is important for countries to develop robust national manufacturing policies to encourage domestic industry, foreign investment should be seen as complementing this objective rather than as something to be undermined. It is unclear from the biopharmaceutical industry’s experience whether India’s National Manufacturing Policy is complementary to its debated national IP rights strategy.

India is building a significant amount of expertise and has the potential to be a global leader of biopharmaceutical innovation. However, the laws, regulations and guidelines relating to medicinal IP rights must be transparent to provide foreign and local inventors the needed certainty to mitigate the significant costs incurred during R&D and product launch. If India truly wants to create an environment where health innovation can thrive, there needs to be a collective understanding that such an ecosystem can be built and sustained only through:

- The creation of a consistent long-term innovation strategy which takes into account economic, trade and health objectives;
- Developing staged and targeted programmes to build capabilities which can compete globally, including improvements to regulatory frameworks;
- Building platforms for coordination and collaboration between academia, and public and private institutions; and
- Developing a robust and predictable IP system.

There is huge potential in India but a delicate balance needs to be found to create mutual benefit for all parties. Unfortunately, many innovative industries believe India presents a risk too far and are starting to move investments elsewhere. The time for action is now, to ensure the policies of today do not destroy the vast potential for the economic growth of tomorrow.

**References**

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The BIO IP Counsels Committee Fall Conference will be held November 6-8, 2013 at the Capital Hilton Hotel in Washington, DC. The conference is a must-attend event for in-house IP counsel of biotech or pharma companies. Relevant, timely educational sessions give practical tips for real challenges. Hear USPTO representatives and industry experts discuss the next wave of patent reform, Myriad implementation, indirect infringement and federal circuit cases to watch. Fun evening events provide an informal atmosphere for networking. To read attendee testimonials, review the program agenda and register for the event, visit www.bio.org/ipcc. Register early and save!
Austria first to ratify UPC agreement

Austria has become the first country in the EU to ratify consent to the Unified Patent Court.

The ratification, announced by the Austrian Foreign Ministry, marks a significant step toward the proposed Unified Patent Court (UPC) becoming a reality.

The agreement for a UPC is part of the unitary patent package which includes the creation of a unitary patent right covering the majority of EU states.

The UPC, which will have headquarters in London, Paris and Munich, is designed to simplify the process of patent litigation.

Instead of having to conduct parallel procedures in multiple national courts, parties will arrive at qualified decisions applying to all states in which the patent is valid.

Claiming Austria had assumed a “pioneering role” with regard to the proposals, Austrian vice chancellor and foreign minister Michael Spindelegger said he was proud to announce its accession.

"Until now, seeking approval for an EU-wide patent was a costly, laborious process that deterred many," Spindelegger said.

"However, thanks to the agreement reached on the patent package for unified patent protection, things are set to change."

However, according to Christian Gassauer-Fleissner, partner at Gassauer-Fleissner Rechtsanwälte GmbH in Vienna and current president of the European Patent Lawyers Association, the government had ratified the proposals too soon, leaving "many open issues" pending.

"This concerns the fees which will have to be paid by the users and which will have a considerable impact, in particular on small and medium-sized companies.

"As of now it is still unclear what the costs will be for users and for the republic. However, issues also concern the rules of procedure, which are far from being finalised.”

Claiming the government had previously shown cost-related concerns, Gassauer-Fleissner said it had ignored calls for a localised chamber.

“Despite clear warnings from patent agents and patent lawyers that omitting the creation of a local chamber in Austria will inevitably lead to a brain drain away from Austria, the government, because of uncertainty related to costs, was, and to my knowledge still is, hesitating to create one.”

The agreement will come into force once 13 member states, including the UK, France and Germany, formally ratify the proposals.
EPO decision could trip up US patent defenders

A decision from an opposition division of the European Patent Office may have “far-reaching consequences” for US patent holders, Solveig Moré tells LSIPR.

At the European Patent Office (EPO), GlaxoSmithKline (GSK) challenged a patent owned by US research group the Institute for Systems Biology (ISB), on numerous grounds of opposition including lack of novelty and inventive step.

ISB’s application for a European patent (EP) is directed to the medical use of a peptide that induces an immune response and is based on an international patent application claiming priority of a US patent application filed in 2001.

Until recently, the US Patent and Trademark Office required that all patent applications name the inventor as the applicant, whereas international applications claiming US priority will often name a company, usually the inventor’s employer, as the applicant.

The named applicants of the US priority application and the EP application differed in this case. The opponent argued that in this situation ISB could be entitled to the filing date of the priority application only if it produced an assignment executed before the EP filing date, i.e., a written transfer of the priority right executed in the priority interval.

While the patent was maintained in amended form by the EPO, the EPO accepted GSK’s argument on priority and decided that ISB is not entitled to the priority date. Evidence submitted showing that the inventor was an employee and was obliged to transfer the invention to ISB was apparently not considered sufficient.

Solveig Moré, a partner at Uexkull & Stolberg in Munich, explained that the decision is still open to review from the Board of Appeal.

“Where the applicants of priority and international or EP applications are different companies, there are decisions that require a written assignment of priority right executed within the priority interval.”

“Where the applicants of priority and international or EP applications are different companies, there are decisions that require a written assignment of priority right executed within the priority interval.”

If the decision stands, it could introduce problems for other US patent holders defending their patents at the EPO, she said.

“Quite a number of US priority applications are filed in the names of the inventors, so similar problems may arise for these cases if there is intermittent art,” she added.

“This consequence may be avoided if either the transfer of priority rights is documented, or the priority applications are filed with the assignee as applicant, which is possible under the new rules.”
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