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When not to patent

This newsletter, as you'd expect, is often full of stories about battles over patents. It's therefore refreshing to read about someone who's actually not convinced he needs to protect his company's intellectual property in that way.

He's Kevin Cox, the chief executive of Imanova, and his IP strategy provides us with our cover story this month. Imanova uses imaging to support drug research and development. It's a non-invasive, low-risk way of looking at the impact a drug is having, and helps determine whether it's reached its target, what's the best dosage, who would benefit from it, and so on.

Obviously, there's potential for IP to be developed here, but Cox says Imanova has taken the strategic decision not to patent the products it develops. He calls it part of the company's mission to make those products available to the academic community, and indeed he encourages academics to use them.

A cynic might argue that making money out of the company's 'imaging biomarkers' would be difficult, if not impossible. Moreover, there's not much Imanova could do to stop other academics playing around with its products and 'doing their own thing' with them.

But Cox is critical of the universities that overvalue their knowledge to such an extent that it is never exploited, and argues that the way to make money is to exploit technology, not patent it.

As it happens, Imanova is based on one of Imperial College London's campuses, where London mayor Boris Johnson cut the ribbon on MedCity back in April. The idea is to create a UK 'golden triangle' of innovation in the life sciences, with London, Oxford and Cambridge at its three corners.

Splendid idea, but I wait to be convinced that it can really challenge the US west coast, for example. Moreover, MedCity's Eliot Forster says it "almost goes without saying" that IP is central to MedCity's economic model.

Wouldn't it be fascinating one day to put Cox and Forster in the same room and listen in to the discussion?

Martin Essex, Managing editor

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Dolly the sheep: the further demise of biotechnology patents
US court denies Teva’s final shot at blocking Copaxone copies

WASHINGTON, DC, US

A US district court has dismissed Teva’s case against the US Food and Drug Administration (FDA) aimed at stopping the administration from approving generic versions of its blockbuster multiple sclerosis drug Copaxone (glatiramer acetate).

The decision came days before eight patents covering the drug were due to expire, on May 24.

Copaxone is Teva’s most lucrative drug and generated sales of more than $1 billion in the three months ending March 31 this year.

On May 8, Teva sued the FDA for denying, without comment, its request to impose clinical trial requirements as a condition of approving generic versions of Copaxone.

The FDA filed a motion to dismiss the case on May 12, arguing that the motion was premature, as it had not approved any generic products, and “Teva does not know if or when, or on what basis, such an approval will occur”.

It added: “In pre-emptively seeking to eliminate competition by enjoining the FDA from approving a generic drug, Teva asks this court to review decisions that have not yet been made and to find injury where none exists.”

US District Court for the District of Columbia Judge Ellen Segal Huvelle dismissed the case on May 14 as “not ripe”, therefore finding the court lacks jurisdiction.

Teva’s rival Mylan, which has said it will market its own version of Copaxone after the patents expire, said it had intervened in the case in support of the FDA.

Mylan’s chief executive, Heather Bresch, said in a statement on May 15: “Teva’s suit against FDA was simply a desperate, last minute tactic, among others, to delay access to more affordable generic versions of Copaxone for patients in the US.”

She added: “Following the court’s decision against Teva, we continue to see no barrier to FDA approval of Mylan’s generic Copaxone following patent expiry, and we look forward to being able to launch this very important first generic product for multiple sclerosis at market formation.”

Teva did not respond to a request for comment.

Lilly’s Alimta dosage patent invalidated at English High Court

LONDON, UK

The English High Court has ruled that a patent covering vitamin dosage regimens for Eli Lilly’s lung cancer drug Alimta (pemetrexed disodium) would not be infringed by generic competitors.

The ruling allows Actavis to launch a generic version of Alimta for administration with vitamin B12 and folic acid after Lilly’s basic compound patent covering the drug expires in December 2015.

Seeking to make a generic version of Alimta, Actavis originally filed the case for a declaration of non-infringement in the UK, France, Germany, Italy and Spain.

Lilly later filed a counterclaim for threatened infringement of its European 1 313 508 patent, which covers the use of pemetrexed disodium in combination with vitamin B12 and folic acid, in the UK.

In the May 15 decision, Justice Richard Arnold also granted declarations of non-infringement regarding the dosage regimen patent in France, Italy and Spain.

In a statement, Actavis said it was the first time that the English High Court had exercised jurisdiction regarding foreign designations of a European patent.

It added that it was pleased with the ruling and that it expected to launch its product after Alimta’s basic patent expires in December 2015.

Lilly said that it plans to seek permission to appeal against the ruling at the Court of Appeal.

Michael Harrington, senior vice president and general counsel for Lilly, said: “We strongly disagree with the ruling.”

He added: “Lilly takes the view that the court did not correctly apply the legal standards in the UK and failed to make the assessments for France, Italy and Spain using the correct approach as required by national laws in those countries.”

According to figures quoted by Actavis, sales of Alimta in the UK, France, Italy and Spain totalled approximately €325 million ($443 million) in 2013.

Actavis and Pfizer settle Celebrex litigation

NEW YORK, US

Actavis has entered into an agreement with Pfizer to settle all outstanding patent litigation related to Pfizer’s arthritis drug Celebrex (celecoxib).

Under the agreement, Pfizer will grant Actavis a licence to market its generic celecoxib capsules in 50mg, 100mg, 200mg and 400mg strengths from December this year.

A spokesperson for Pfizer told LSIPR that under certain conditions, the licence will be royalty-bearing until the patent expires on December 2, 2015.

He added: “The company will continue its defence of the patent, which it believes is valid and was properly granted by the Patent Office, and will pursue all appropriate remedies for infringement.”

On April 17, Teva announced that it too had settled all Celebrex patent litigation with Pfizer.

Celebrex is protected by four patents—the first of which was due to expire on May 30. It is one of Pfizer’s best-selling drugs and generated $2.9 billion in sales in 2013.

www.lifesciencesipreview.com
Sun and Novartis settle on Gleevec

NEW JERSEY, US

Novartis and Sun Pharma’s US subsidiary have settled litigation related to cancer drug Gleevec (imatinib mesylate) in the US, the companies announced on May 15.

As part of the settlement agreement, Novartis will allow Sun Pharma to market a generic version of Gleevec—known as Glivec in Europe—in the US from February 1, 2016.

In 2006, Sun Pharma filed an Abbreviated New Drug Application (ANDA) with the US FDA to make and sell imatinib mesylate tablets in 100mg and 400mg strengths.

In June last year, it filed suit against Novartis at the US District Court of the District of New Jersey seeking declaration that its proposed generic Gleevec product does not infringe Novartis’ 6,894,051 patent, which is due to expire in 2019.

Acura ends all Aversion litigation with final Sandoz settlement

ILLINOIS, US

US-based drug company Acura and Novartis’s generic arm Sandoz have settled their patent infringement dispute related to an abuse-deterrent formulation of the painkiller Aversion (oxycodone).

The settlement, which comes two weeks after Acura agreed with Indian pharmaceutical company Ranbaxy to end litigation related to the same drug, also ends all pending patent litigation against the generic companies that filed ANDAs to market their own Aversion generics.

The other ANDA filers are Watson Laboratories, Par Pharmaceutical and Impax Laboratories.

Aversion is a formulation of oxycodone that deters abuse by forming a gel when dissolved in solvents for injection and causing nasal discomfort if crushed and snorted.

Acura filed the case at the US District Court for the District of Delaware, alleging that Sandoz infringed its patent with a generic version of Aversion.

The settlement, announced on May 21, allows Sandoz to launch its generic in the US through a licence granted by Acura.

The licence will come into effect 180 days after the first sale of an Aversion generic by the first company that filed an ANDA to sell such a product.

It is not yet known which of the companies first filed an ANDA.

Under the agreement, Sandoz does not have to pay Acura a royalty if its generic is approved by the FDA. However if it changes the formulation disclosed in the ANDA filing, it must to pay Acura 7 percent of its Aversion generic net profits as a royalty.

Bob Jones, president and chief executive of Acura, said: “We are very pleased to have now concluded all our patent infringement suits concerning Aversion oxycodone.

“We still await the FDA’s guidance on what these generic ANDA filers must do to gain approval on a product considered to be equivalent to our Aversion oxycodone in terms of both efficacy and safety.”
‘Dolly the sheep’ clones cannot be patented

WASHINGTON, DC, US

The US Court of Appeals for the Federal Circuit has ruled that mammals made using the cloning method that created Dolly the sheep are not patent-eligible.

Affirming a decision by the US Patent Trial and Appeal Board (PTAB), on May 8, the appeals court found that while the method for creating genetic clones may be protected by patents, the products of the process are not patent-eligible. It also rejected the three disputed claims of the patent as “anticipated and obvious”.

The patent at issue, ‘233, covers “quiescent cell populations for nuclear transfer”. It is held by the Roslin Institute of Edinburgh, where Dolly the sheep—the first animal to be cloned from an adult somatic, or non-sex, cell—was created in 1996.

The US Patent and Trademark Office, while granting a patent for the method of cloning, rejected the inventors’ claims covering the clones themselves.

In November 2008, the patent examiner issued a non-final rejection of the patent claims, finding that they were directed to non-statutory subject matter, and that they are anticipated and obvious. By February 2013, the PTAB had affirmed the examiner’s rejection of those claims.

The appeals court acknowledged the claimed clones “may be called a composition of matter or a manufacture”, but concluded that the subject matter is not eligible for patenting, as it constituted a natural phenomenon that did not possess “markedly different characteristics than any found in nature”.

Referencing Myriad, in which it was ruled that patent claims covering “naturally occurring” genes were invalid, Judge Timothy Dyk said in the decision: “Here, as in Myriad, Roslin did not create or alter any of the genetic information of its claimed clones, nor did Roslin create or alter the genetic structure of the DNA used to make the clones.

“Roslin’s chief innovation was the preservation of the donor DNA such that the clone is an exact copy of the mammal from which the somatic cell was taken. Such a copy is not eligible for patent protection.”

Nabeela Rasheed, shareholder at McAndrews, Held & Malloy Ltd in Chicago, said: “The court has effectively ruled that the product of creating a new living creature is nothing more than making a Xerox copy.”

Describing the decision as a direct extension of Myriad, Rasheed said “it would be perplexing if it were not for the very real impression that there is now a well-established war on gene-based patents at the Federal Circuit.”

The exceptions to patent eligibility under 35 USC §101 always fell into three distinct categories, she explained: laws of nature, abstract ideas, and natural phenomena.

“Clearly, a clone of a living animal is not an abstract idea, nor is it a law of nature,” she said. “It seems that nothing can be further from being a natural phenomenon than a cloned animal, an exact copy of a previously living organism.”

The courts and patent office appear to be creating a “fourth category” of patent ineligibility, she said. “Where the product has ‘genetic identity’ with something already found in nature, then that product is an exception to patent eligibility, regardless of the level of ingenuity involved in the creation of that product or the fact that such a product simply does not exist in nature.”

Although there seem to be very few workarounds to this position, Rasheed suggests patentees focus on the method. “Perhaps a product by process claim would pass muster under the more stringent 35 USC §101 world?”

“That obviously would place the patentee back on the familiar ground of dealing with anticipation of the claim to Dolly by her parent donor. That being said, the product by process claim analysis is also a murky area and has been clarified only with respect to interpretation of such claims in an infringement analysis and not specifically with respect to patentability.”

For further analysis, see page 22
FTC weighs in on ‘no-authorised-generic’ antitrust case

WASHINGTON, DC, US

The US Federal Trade Commission (FTC) has filed an amicus brief in an antitrust case that concerns a ‘no-authorised-generic’ settlement between Teva and GlaxoSmithKline (GSK).

In the brief, the FTC urges the US Court of Appeals for the Third Circuit to reverse a lower court’s dismissal of the case, which it found to be based on a narrow reading of FTC v Actavis.

In FTC v Actavis, which was decided last year, the US Supreme Court found that pay-for-delay patent settlements can be challenged by the commission on antitrust grounds.

When Teva abandoned its challenge of a patent covering GSK’s anti-epileptic drug Lamictal (lamotrigine), GSK agreed that when Teva introduced its generic version of the medicine, GSK would initially keep its authorised generic off the market and allow the company six months of generic sales.

The US District Court for the District of New Jersey ruled that these so-called ‘no-authorised-generic’ settlements cannot violate antitrust laws under FTC v Actavis, because they do not involve the payment of ‘cash’—in this case, the valuable compensation afforded by the branded company is the agreement not to compete.

However, the FTC said it believes the finding to be erroneous, and that no-authorised-generic agreements raise the same antitrust issues as Actavis.

It claimed that as a result of the agreement, customers would be denied the opportunity to buy generic Lamictal for several years. When a generic version eventually becomes available, consumers would pay more for it than if the companies had offered competing generic products, it said.

“If accepted, the district court’s narrow reading of Actavis would undermine the Supreme Court’s decision in that case and encourage parties to structure potentially anticompetitive reverse-payment settlements simply by avoiding the use of cash,” the FTC said in the brief.

The case is pending at the US Court of Appeals for the Third Circuit.
Medtronic and Edwards settle heart valve litigation

MINNEAPOLIS, US

Medical device rivals Medtronic and Edwards Lifesciences have agreed to settle all patent litigation, including cases related to transcatheter heart valves.

The agreement provides that the parties dismiss all pending litigation matters, as well as any patent office actions between them. The parties also agreed not to sue each other anywhere in the world over patents related to aortic and all other transcatheter heart valves for eight years.

Medtronic will pay Edwards a one-off payment of $750 million in addition to ongoing royalty payments until April 2022, based on a percentage of Medtronic's CoreValve product sales, in payments of at least $40 million a year.

Neither Medtronic nor Edwards admitted that their patents infringe, or that any of their disputed patents are invalid.

The settlement on May 20 marks the end of a long-running patent dispute between the companies. In January, the US District Court for the District of Delaware found Medtronic’s CoreValve product to willfully infringe one of Edwards’ patents, and awarded it $394 million in damages.

Reacting to the settlement, John Liddicoat, president of the structural heart business at Medtronic, said: “This agreement brings to an end years of disputes between our companies related to TAVI [transcatheter aortic valve implantation] patents, and allows both companies to make their respective therapies available to physicians and patients around the world.

"With this resolution, we are pleased that Medtronic will be able to continue to provide the CoreValve system, as well as other products, to patients who need them in the US and abroad without the overhang of any potential injunction or additional damages.”

Edwards’ chairman and chief executive, Michael Mussallem, said the company was pleased to reach the agreement.

US hits out at Indian pharma patent protection

WASHINGTON, DC, US

Patent protection in the pharmaceutical sector in India has raised “serious” concerns, the US government said in its annual Special 301 Report, published on April 30.

The US has “growing concerns” about the environment and enforcement of IP in India, it said, although it decided against imposing the strongest possible sanction on the Asian nation.

In the report, which assesses US trading partners’ efforts to protect and enforce IP, the US Trade Representative (USTR) said it has kept India on its Priority Watch List (PWL) but decided against listing it as a Priority Foreign Country (PFC), a country about which it has particularly serious concerns.

The Indian pharma sector was highlighted as one of the most problematic areas in the report, which each year contains a PWL and a Watch List, identifying the countries that are of concern, as well as occasionally listing a PFC.

"In the pharmaceutical sector and increasingly in other sectors, such as the agrichemical and green technology sectors, some innovators face serious challenges in securing and enforcing patents in India,” it said.

Ukraine was listed as a PFC last year, the first time a country had been put in that category in seven years. Prior to the report’s publication there were calls for India to go the same way.

"Many of the submissions made by a wide array of stakeholders in this year’s Special 301 reporting process underscored increasing challenges right holders face, and a number of those submissions sought the strongest censure of India’s IP environment available under Special 301,” the report said.

Despite those calls, the government opted to continue “constructive” engagement and keep it on the PWL.

The USTR said India had made “some limited progress” in improving its weak IP rights legal framework but added that in “many areas” challenges are growing.

“The US encourages India to adopt policies that support both cutting-edge innovation to address important health challenges and a robust generic market. For example, a patent system should encourage the development of inventions that meet the well-established international criteria of being new, involving an inventive step.

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“The US encourages India to adopt policies that support both cutting-edge innovation to address important health challenges and a robust generic market. For example, a patent system should encourage the development of inventions that meet the well-established international criteria of being new, involving an inventive step.

“The US urges India to take specific actions to address the concerns raised, including by means of constructive bilateral engagement,” the report added.

The other countries on the PWL are Algeria, Argentina, Chile, China, Indonesia, Pakistan, Russia, Thailand and Venezuela.

“These countries will be the subject of particularly intense bilateral engagement during the coming year,” the report said.
Genentech refused appeal in Herceptin case

SAN FRANCISCO, US

Justice Colin Birss has refused Roche’s biotechnology subsidiary Genentech the permission to appeal against an English High Court decision in which two patents covering its blockbuster breast cancer drug, Herceptin (trastuzumab), were revoked.

One of the patents, which were invalidated in April after a challenge by Hospira, related to a dosage regimen for trastuzumab, while the other covered the drug’s formulation.

Herceptin is one of Roche’s biggest selling drugs, making worldwide sales of $6.7 billion in 2013. Between 2010 and 2013, European sales of the drugs totalled $9 billion.

Genentech sought to appeal against the decision in relation to the dosage patent, but on May 16 Birss refused to grant permission, finding that it was seeking to argue a new point about the dosage regimen.

In his judgment, Birss said that Genentech wanted to argue that its claimed 8mg/kg loading, or initial, dose followed by three once-weekly maintenance doses of 6mg/kg was inventive, despite the product’s FDA label recommending 500mg, or 7.1mg/kg once every three weeks.

“That is, in my judgement, a new point, or rather includes a series of new points,” he said.

Hospira said in a statement: “Hospira is very pleased with this decision, which helps pave the way for our trastuzumab product.”

A spokesperson for Genentech told LSIPR that it was disappointed with the court’s decision, and that it was in the process of reviewing the decision to determine its next steps.

IN BRIEF

Janssen to open San Francisco lab

Johnson & Johnson’s pharmaceutical subsidiary Janssen has announced it will open a new research centre in South San Francisco.

Janssen Labs @ South San Francisco will accommodate up to 50 independent companies which will work alongside staff from Johnson & Johnson Innovation.

The new incubator will include shared and private lab spaces and offer operational support, education and business services. It is scheduled to open at the end of the year.

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**Turkish company causes row over ‘pharmacist’ trademark**

**ANKARA, TURKEY**

A pharmaceutical company in Turkey has run into trouble after attempting to register the Turkish word for ‘pharmacist’ as a trademark.

Eczacıbaşı registered ‘eczacı’—a move which triggered negative reactions from industry representatives.

The company, whose full name is Eczacıbaşı Holding, was founded in 1942. It makes goods in the building products, pharmaceuticals and consumer products sectors.

Eczacıbaşı registered 45 different versions of the word with the Turkish Patent Institute.

But the Ankara Chamber of Pharmacists (ACP) said that it should be the sole user of the word, and filed a lawsuit at the Istanbul Third Intellectual and Industrial Rights Court.

A temporary injunction was ordered against Eczacıbaşı pending the trial’s outcome.

Süleyman Güneş, head at the ACP, said giving an occupational group’s name to a company would affect the whole pharmaceutical sector.

In a statement, a spokesman for Eczacıbaşı said the trademark registration was “an attempt to prevent unfair competition” through using the word.

“It is known that the eczacı brand brings Eczacıbaşı to mind as an abbreviation,” the company said in a statement to Turkish news website the **Hürriyet Daily News**.

“The only aim is to prevent unfair competition by using a work that denotes the Eczacıbaşı name,” it added.

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**UNDP urges use of competition law to boost healthcare access**

**NEW YORK, US**

The United Nations Development Programme (UNDP) has released a guidebook for low- to middle-income countries (LMICs) on how to increase access to essential health technologies and HIV treatments by using competition law and policy.

Published on May 16, **Using Competition Law to Promote Access to Health Technologies** builds on independent body the Global Commission on HIV and the Law’s recommendation that “countries … proactively use other areas of law and policy, such as competition law, price control policy and procurement law to help increase access to pharmaceutical products”.

Report co-author Frederick Abbott, a professor of law at Florida State University, said that governments and civil society actors in an increasing number of countries have used competition law to promote healthy, open and fair market conditions in the health technologies sector.

“Yet many others are only now recognising the importance of competition law, and are beginning to devote more legislative and administrative resources to the field,” he added.

While access to HIV treatments has increased in recent years, the report said, more patients need to start treatment earlier, and on newer, more expensive medicines.

“Fourteen years ago, the cost of HIV treatment was $10,000 per patient per year. Today, internationally approved first-line treatment regimens are a little more than $100 per patient per year,” it said.

Generic competition was an “indispensable part of this success, and is well accepted as one of the key drivers for expanding access to HIV treatment,” it added.

As an example, it cited a finding by the South African Competition Commission which led two pharmaceutical companies to conclude licences with generic drug makers, and created more competition and lower prices for a number of antiretroviral medicines.

Mandeep Dhaliwal, director of UNDP’s HIV, health and development practice, said that the TRIPS Agreement contains “important flexibilities” for World Trade Organization members to promote access to treatments, although competition law is among the least discussed of them.

“There is a great untapped opportunity for LMICs to incorporate and use competition law to get better value for money and in the longer term to sustain national treatment programmes,” she said.

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**£8.6m of counterfeit medicines seized**

The UK-based Medicines and Healthcare Products Regulatory Agency (MHRA) has seized £8.6 million ($14.4 million) of counterfeit and unlicensed medicines in the UK as part of an international crackdown on the illegal internet trade of medicines.

Among the seized products were potentially harmful slimming pills, diazepam and anabolic steroids.

The crackdown, called Operation Pangea VII, was coordinated through Interpol. It was conducted between May 11 and 21, and resulted in 237 arrests worldwide.

The operation also led to the closure or suspension of 10,603 websites that were illegally selling counterfeit and unlicensed medicines.
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IN BRIEF

Boehringer and Connexios collaborate
Bangalore-based biotechnology company Connexios Life Sciences and German pharmaceutical company Boehringer Ingelheim have agreed to collaborate on research for the treatment of patients with type 2 diabetes.

Under the agreement terms, Boehringer will obtain global rights to CNX-012, Connexios’ programme on AMPK activators. AMPK activators can be used in the treatment of metabolic diseases such as type 2 diabetes.

Boehringer will also be responsible for developing and commercialising the candidates from the AMPK programme.

Shobha Vijayaraghavan, vice president of business development for Connexios, said: “Partnering is key to our business strategy and the partnership with Boehringer Ingelheim, which has shown a strong commitment to the therapeutic area of metabolic diseases, is an important milestone for Connexios.”

FDA quality man leaves
Steve Lynn, director of the FDA’s Office of Manufacturing and Product Quality, has left the agency to join pharmaceutical company Mylan, according to a report on regulatory affairs news website www.raps.org.

Lynn, who has served at the FDA since 2007, will be Mylan’s new vice president of global quality and compliance.

While at the FDA, Lynn also led operations for the agency’s proposed Office of Pharmaceutical Quality, which will oversee the quality of drugs throughout the product lifecycle.

His last day at the agency was May 9.

Mylan quashes morning-after pill dosage patent

LONDON, UK

Generics (UK) Limited, the UK arm of Mylan, has succeeded in invalidating a patent held by Hungarian pharmaceutical company Richter Gedeon at the English High Court.

The patent at suit, (UK) 1 448 207 B1, covers a dosage regimen for the use of levonorgestrel as a method of emergency contraception.

Mylan filed a claim for declaration that the patent is invalid on the grounds of obviousness and insufficiency and should be revoked.

It claimed that the specification of the patent “does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art”.

Richter’s patent covers the administration of levonorgestrel in a single 1.5mg dose, which is easier to use than the established dosage regimen of two doses of 750µg taken 12 hours apart. The judgment said that the two-dose method is “broadly equivalent” in efficacy to other forms of pill-based treatment.

In its case for obviousness, Mylan relied on common general knowledge and research published in 2000 that compared the effectiveness of a single dose of levonorgestrel with the established two-dose method.

As its expert witness, it called upon a clinician with an interest in emergency contraception, while Richter relied on evidence from an expert in medical statistics.

Justice Philip Sales agreed that the clinician who specialises in contraceptive service was a relevant ‘person skilled in the art’, but did not accept “the submission of the defendant that the teaching in the patent is addressed to a team which would include a clinician and a specialist medical statistician”.

Drawing upon Justice Robin Jacob’s judgment on Pozzoli Spa v BDMO SA (2007), which also dealt with ‘inventive concept’ in relation to obviousness, he concluded that the patent was invalid for being obvious.

He added that the insufficiency challenge does not arise on the basis of his obviousness finding.

Neither Mylan nor Richter Gedeon responded to LSIPR’s requests for comment.

Pharma concerned about plain packaging

HONG KONG, CHINA

The pharmaceutical industry, as well as food and alcoholic drink manufacturers, could be under pressure from the spread of plain and standardised packaging, delegates at INTA’s annual meeting in Hong Kong were told on May 12.

“Going too far will make things more difficult in the fight against counterfeit drugs. There are other things that can be done,” said Myrtha Hurtado Rivas, global head of trademarks, domain names and copyright at Novartis in Switzerland.

She was one of a series of speakers who warned that after the introduction of plain packaging for cigarettes in Australia, other jurisdictions were likely to follow and other industries would be hit by similar measures.

Trevor Stevens, a lawyer and trademark attorney at Davies Collison Cave in Australia, said there was no evidence that plain packaging had reduced, or was likely to reduce, smoking rates in Australia.

However, he said, following the government’s successful implementation of the legislation, alcohol and food could both have packaging restrictions imposed.

Ronald van Tuijl, IP trademarks director at the JT International subsidiary of Japan Tobacco in Switzerland, agreed. “History has shown that what happens to tobacco first will happen to others,” he said.

Delegates were told that the US and the EU could both follow Australia’s lead, despite the lack of evidence that plain packaging has reduced smoking rates in Australia.

In the pharma field, access to generic medicines could be improved and health budget reductions achieved by other means, said Hurtado Rivas. The pharma industry supports regulation “but major doubts persist whether standardisation and plain packaging will achieve these objectives”, she said.
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Investing in know-how

London-based imaging company Imanova develops ‘imaging biomarkers’ to support the business of drug discovery, and takes a novel approach to protecting its innovations. LSIPR spoke to chief executive Kevin Cox about the company’s strategy.
Given the spiralling costs and ever-present risks associated with developing a new drug, pharmaceutical companies are always looking for ways to shorten the pathway from lab bench to clinic.

Some of the approaches they use—such as big data analysis and virtual organs—could be said to be almost as innovative as the products being developed. But there's another solution: to use existing technologies in a different way. Imaging technologies such as positron emission tomography (PET), usually used to show three-dimensional images of cancerous tumours or brain activity, can also show a drug's interaction with disease targets inside the human body, and play a part in disease function research.

Providing windows

London-based imaging centre Imanova uses a range of different imaging technologies to support drug development and research in its collaborations with academics and drug discovery companies.

As it isn't always possible to rely on data from animal trials, the faster a company can finish them and start the first human clinical trials, the better.

“That's where imaging plays a very significant role,” says Kevin Cox, chief executive at Imanova.

“Because you're able to image a human very early on, in a non-invasive, low-risk approach, you can get real knowledge about what a drug is doing inside the body, or what's happening in a certain disease pathway, and how that's impacted by external factors such as treatments.

“There are very few other technologies that can give you this information for humans.”

This approach has value, not just for academic research but also for the pharmaceutical companies Imanova works with. Instead of continuing to invest time and money in what may be an ineffective drug, companies can decide earlier which candidates to take forward, and progress to the next stage of development.

Furthermore, imaging provides information about dosage levels and helps in candidate selection, and shows whether the drug reaches its target.

“It's a very powerful technique,” says Cox, and one that can potentially save drug development companies lots of money.

Imanova targets pharmaceutical companies as well as biotechnology companies to provide its services. “At the moment we work with the majority of the large pharmaceutical companies worldwide,” Cox says, noting that the firm is currently running about 100 clinical studies.

Once GlaxoSmithKline’s imaging laboratory, Imanova was established as a company in its own right in 2011, after the pharmaceutical company sold the operation to a consortium of three London university colleges—King's College London, Imperial College London and University College London—and the Medical Research Council.

It has two main roles, Cox explains: to support the research of the universities and its partner organisations. But it's also a business. “It's important for us also to take on additional commercial work as a balance to offset some of the grant-funded work that we're doing,” he says.

“We're in an interesting position in that we work with both academics and industry and, theoretically at least, provide an interesting conduit through the innovation pipeline.

“At one end we're working with universities to support some of the basic research on understanding a disease, while at the other end we're helping to support the process of drug development. Then there are all the bits in between, so it's very much a translational capability.”

Cox calls it a full-service proposition: Imanova works from the early stages of a project, right through to clinical applications. Given the sophistication of its proprietary technologies, Imanova employs people across a wide range of different scientific disciplines.

Know-how

While one important arm of its strategy is to work closely with the research groups within the colleges that set up the company, Imanova also has an internal research and development programme, where it develops technologies of its own, and takes a perhaps unorthodox approach to protecting them.

“IP is something that we're constantly grappling with,” Cox says.

“There's potential for IP to be created in the products we develop. We call them imaging biomarkers, or i-biomarkers. These are tool compounds that we use in our imaging studies to provide the information to our customers or collaborators.”

However, Cox says, Imanova has taken the strategic decision not to patent them. “Part of
the mission we have, as defined by our partner organisations, is that we make a lot of those things available to the academic community of the UK and, in some cases, beyond.”

Moreover, it’s unlikely, and probably almost impossible, to make money on imaging biomarkers in their own right, he adds.

“Our IP strategy is very much one of know-how, rather than patenting per se.

“Because a lot of our studies take place in an academic context, even if we patent something then it would be available to anyone who wants to have access, and there’s not a lot we can do to stop other academics taking the molecule and doing their own thing with it.

“Indeed, that’s not what we’re here to do. We believe that one of the reasons imaging hasn’t been exploited to its fullest extent is because there’s been a lack of suitable tools to make it effective and applicable in understanding disease and drug development.”

Instead, Cox seeks to encourage academic institutions to use the technologies, eventually creating a space for the company to grow into, and further develop its business.

“We call it a market driving strategy, where we are trying to create a market for future growth,” Cox explains.

When Imanova does decide to patent, it will be for relatively specialised technologies, but for now Cox feels that the area of imaging biomarker development is an opportunity for innovation.

“Because there is such a limited number of available tools, and because many pharmaceutical companies are developing them in-house, there is a poor use of resource in making these things or developing areas of unmet need.

“We believe it would be better if all proponents of the technology worked more closely together to avoid duplicating and wasting scarce and expensive resources.”

Ultimately, Imanova’s goal is to create a consortium of organisations that use imaging biomarkers, so that their resources and knowledge can be pooled.

“I’m not convinced that we’ll ever get to the position of trying to ‘lock in’ certain approaches or technologies in that area,” Cox says.

“What I think is more likely is that it will become more open and therefore more people will use the technology.”

Cox understands the pitfalls of patenting overzealously. “Universities are so fixed on patenting and protecting and then trying to get value out of that protection that sometimes they completely overvalue what knowledge they have, and it never gets exploited.

“In my view, you get the money only if you exploit the technology—not if you patent it. You can restrict the exploitation if your patenting strategy is too rigorous.”

Imaging biomarkers simply don’t have the same earning potential as pharmaceuticals, at least not yet. Where pharmaceutical companies will patent a molecule in many different ways, because they know they’ll get some value, imaging biomarkers are different.

“There is no incentive to build that IP protection, because you’ll never get the returns on it,” says Cox.

Forging ahead

To stay ahead in its field, Imanova is looking to make a big leap with its imaging technologies. “We’re investing in something that will not just be incremental but will be a major shift in the way the technology is developed and can be applied,” Cox says.

Along with a group of collaborators, Imanova is developing a PET scanner that images the entire human body, and its organs, right down to a molecular level—something that’s never been done before.

“PET technology has been around for about 25 years, but hasn’t been exploited to its full potential, and that’s part of our role.

“This new development will be a step change over and above the existing technologies, if we can get the funding for it,” Cox says.

Amid hopes that the new MedCity (see right) will attract a surge of investment in life sciences, that big step may happen sooner than previously imagined.

“You get the money only if you exploit the technology—not if you patent it. You can restrict the exploitation if your patenting strategy is too rigorous.”

MedCity and collaborations

On April 8, London mayor Boris Johnson cut the ribbon on MedCity, an initiative of his office combined with King’s College London, Imperial College London and University College London aimed at boosting the life sciences industry in the UK’s south east, at Imanova’s base on Imperial College London’s campus in Hammersmith.

Cox predicts that if MedCity pulls together the universities’ capabilities, then the so-called ‘golden triangle’ life sciences cluster of Oxford, Cambridge and London can start to compete with the likes of the US clusters in Boston and on the west coast.

“London is a powerhouse already,” Cox says. “One of the drawbacks over the years has been that the individual components, whether they are academic or commercial, haven’t been pulling together in a coherent sense.

“MedCity will create a much more cohesive ecosystem, where all the components are available in a relatively small geographic area, and should be attractive for organisations wishing to invest in centres such as London.”

“If that is one thing that MedCity helps to achieve, then it’s moving us in the right direction.”

For analysis, see page 18
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CLUSTER FOCUS: MEDCITY

MedCity: forging links in London’s life sciences industry

London’s MedCity is working to boost collaboration between businesses in the area and invigorate the UK’s so-called ‘golden triangle’ life sciences cluster, with its three major centres in London, Oxford and Cambridge. LSIPR heard from Eliot Forster, who chairs MedCity, about the initiative.

While London, Oxford and Cambridge have long been centres for innovation in the life sciences, with researchers there discovering penicillin and the structure of DNA, for example, the world around the ‘golden triangle’ with the three cities at its corners is changing.

The life sciences industry has undergone some significant adjustments in recent years. As blockbuster drugs fall off the ‘patent cliff’ and research efforts turn from small molecule therapeutics to biologics, the UK is changing its life sciences strategy so that it may stay competitive globally.

In 2011, the government launched its Strategy for Life Sciences initiative, aimed at making the UK a “world-leading place for life sciences investment” by adopting three key strategies: building a life sciences ecosystem, attracting, developing and rewarding the best talent, and creating incentives to promote healthcare innovation.

On April 8 this year, three London university colleges—Imperial College London, King’s College London and University College London—along with the Mayor of London, strengthened the bonds between the three research hubs of the golden triangle with the establishment of MedCity, a new medical research initiative aimed at boosting collaboration between London’s life sciences businesses to cater for future medical needs.

“There have been some major changes in the life sciences industry, such as the way in
which biotechs have grown around the world to begin to feed pharmaceutical medtech companies’ pipelines,” says Elliot Forster, who chairs MedCity and is chief executive of biotechnology company Creabilis.

“The needs of the health community and the needs of patients are ultimately different from how they’ve been in the past,” he adds.

“It’s much more difficult in some areas than it’s been in the past to look after a single patient, and understanding the data that fit with individual patients and addressing those needs are more complicated.”

The recent surge in mergers, acquisitions and IP exchanges in the life sciences industry indicates a working strategy for dealing with change: collaboration.

Launched with £2.9 million ($4.8 million) of funding from the Higher Education Funding Council of England and £1.2 million ($2 million) from the Mayor of London’s office, MedCity aims to encourage collaboration between life sciences companies and the academic base in London, in addition to attracting life sciences companies to the area.

King’s College London hopes that “MedCity will consolidate the cluster’s strengths, give them a coherent collective identity and showcase the expertise of the south-east cluster as the global landing place for international businesses and investors.”

MedCity, which was opened officially by the Mayor of London, Boris Johnson, will also partner other UK-based research hubs, and has already signed a cooperation agreement with Cardiff’s new life sciences hub and the Northern Health Sciences Alliance, a partnership between universities and National Health Service (NHS) hospital trusts in the north of England.

Forecasting healthcare

True to the UK’s strategy of adapting to a changing industry, instead of first identifying key research areas, MedCity’s role is to predict the healthcare needs of the future, Forster says.

“What we’ve tried to do with MedCity, which is perhaps a little different from some clusters, is to anticipate what the future might look like,” he says.

“MedCity has a responsibility to reflect the market back to its constituents; to help all those people who are in the MedCity environment understand what the market is doing.”

An ageing population means an expected rise in the incidence of degenerative diseases, such as osteoarthritis, dementia and cancers.

Forster continues: “As the market moves towards those areas, we would aim to quickly follow in the first instance then, with time, anticipate those needs and begin to drive that.”

MedCity’s constituent parts cover a broad range. The initiative brings together higher education institutions and the medical research units within them, as well as the NHS and government, both local and national.

There’s also involvement from the charitable sector: Cancer Research UK and the Francis Crick Institute, which focuses on developing an understanding of why certain diseases develop, and how to diagnose and treat them.

Nurturing start-ups

Forster says one of MedCity’s goals is to create a “front door” for businesses and individuals who want to interact with the London life sciences environment. “The goal is to make the pathway easier for them, and for international companies that may wish to set up research and development or innovation centres, or manufacturing in the region, as well as make new investments in start-up companies,” he says.

“Part of our aspiration is to help drive investment—by making it clear that the greater south east is an area where investors can find good ideas and good people—and to help support those people on their entrepreneurial journey.”

As a whole, Forster says, the UK is becoming a more attractive place to start up biotechnology companies, in part because of the Intellectual Property Office’s Patent Box scheme introduced last year, which provides an incentive for innovation by applying a lower rate of tax on profits earned from a company’s patents.

However, the country’s south-east region certainly has its draws, one being the “nearness of everything”, he adds.

“Everything you may need to be a successful start-up in life sciences already exists: the people are there, the resources are there and finance is there,” he says.

Not to mention the different support services, including professional services, that will help companies carry out clinical trials or manufacture drug supplies. “It all exists in a relatively close proximity,” Forster says.

Global competition

The success of the companies based in the cluster will also depend on their adopting a good IP strategy, which Forster describes as “essential”.

“It almost goes without saying that IP is completely central to the economic model that MedCity relies upon.”

The arrival of the Unified Patent Court (UPC) could make enforcing patents easier for companies based in the cluster. Currently expected to come into force by early 2015, the UPC’s London court will hear cases relating to chemistry, including pharmaceuticals and the life sciences.

Forster has no illusions about the mountain MedCity has to climb to begin to rival established clusters, such as those in Boston and on the US west coast. However, it has something of a head start. “The first biotech started in Boston in the 1960s, so it’s taken 50 years to get to the position they’re in now,” he says.

“We don’t need to travel along the same learning curve, because much of what is needed is already here; it simply requires navigation to find it.”
SUBJECT MATTER ELIGIBILITY: INTERPRETING THE USPTO GUIDELINES FOR ‘NATURAL’ PRODUCTS

The new examination guidelines do not carry the weight of law, and it is not likely that their more extreme aspects will withstand judicial scrutiny, but practitioners need to keep tabs on court decisions, says Courtenay C. Brinckerhoff.

On March 4, 2014, the US Patent and Trademark Office (USPTO) published examination guidelines designed to aid examiners in applying the principles of recent Supreme Court decisions addressing when inventions relating to laws of nature, natural phenomena, and natural products are eligible for patenting under 35 USC §101.

While the guidelines respond directly to Molecular Pathology v Myriad Genetics, Inc, 133 SCt 2107 (2013), and Mayo Collaborative Services v Prometheus Laboratories, Inc, 132 SCt 1289 (2012), they also draw from older Supreme Court decisions, such as Diamond v Chakrabarty, 447 US 303 (1980), and Funk Brothers Seed Co v Kalo Inoculant Co, 333 US 127, 131 (1948), and reach subject matter far beyond the ‘isolated DNA’ at issue in Myriad and the personalised medicine methods at issue in Prometheus.

Indeed, many have criticised the guidelines for broadening the exceptions to patent eligibility and threatening to discourage investment and innovation in biotechnology, pharmaceuticals, and personalised medicine.

The guidelines outline a three-step process for analysing a claim for subject matter eligibility, with the crux of the new analysis embodied in step three.

Step one asks whether the claim is directed to subject matter that falls under one or the four categories in §101 (process, machine, manufacture or composition of matter). For most claims, the answer will be ‘yes’. (If the answer is ‘no’ then the claim is not patent-eligible.)

Step two asks whether the claim involves an abstract idea, law of nature, natural principle, natural phenomenon, or natural product. If the answer is ‘no’, then the claim is patent-eligible. If the answer is ‘yes’ because the claim involves an abstract idea, the claim must be analysed under the Bilski guidelines set forth in the Manual of Patent Examining Procedure (MPEP) §2106(II).

If the answer is ‘yes’ because the claim involves a law of nature, natural principle, natural phenomenon, or natural product, then step three is that the claim must be analysed under the new guidelines to determine whether it claims “significantly more” than the law of nature, natural principle, natural phenomenon, or natural product.

Significantly more

The guidelines outline a multifactored analytical framework for answering the “significantly more” question. Examiners are instructed to analyse the claims based on their "broadest reasonable interpretation", to consider every relevant factor, and to assess whether "the totality of the relevant factors" weighs for or against eligibility.

If satisfied, factors (a)–(f) of the guidelines weigh towards eligibility, while factors (g)–(l) weigh against eligibility. The guidelines indicate that the list of factors will be supplemented "as the developing case law may generate additional factors over time".
For single element product claims directed to a “natural product” only factors (a) and (g) are relevant. Such a claim will be eligible under the guidelines only if factor (a) is satisfied and the analysis determines that the claimed product is both “non-naturally occurring” and “markedly different in structure” from naturally occurring products.

(Factor [g] is the converse of factor [a], and applies when the claim recites “something that appears to be a natural product that is not markedly different in structure from naturally occurring products”.)

What is natural?
The far-reaching scope of this guidance is illustrated by the list of exemplary “natural products”.

Natural products include, but are not limited to: chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc); foods (e.g., fruits, grains, meats and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (e.g., rocks, sands, soils); nucleic acids; organisms (e.g., bacteria, plants and multicellular animals); proteins and peptides; and other substances found in or derived from nature.

The potential impact of this guidance is underscored by the examples which state that a cancer-fighting compound isolated from a tree is not patent-eligible (although a chemically modified version of the compound is) and that calcium chloride and gunpowder (the latter a mixture of naturally occurring potassium nitrate, sulphur and charcoal) are both “natural products” that are not patent-eligible.

For multi-element product claims (e.g., articles of manufacture or compositions of matter), all factors could be relevant. However, the guidance instructs examiners to consider only whether claim elements or steps other than the “natural product(s)” support eligibility. Thus, a claim directed to a composition with several “natural product” components may not be eligible for patenting under the guidance.

This is illustrated by the example of pomelo juice, which explains that a composition comprising pomelo juice and a preservative is not patent-eligible unless the preservative is restricted to synthetic preservatives. Extrapolating this example to pharmaceutical compositions, a composition comprising a drug that is a “natural product” (e.g., a compound that occurs in nature, even if made synthetically) and a pharmaceutically acceptable carrier would not be eligible for patenting unless the carrier is restricted to synthetic carriers.

For method claims relating to a law of nature, natural principle, or natural phenomenon, all factors could be relevant. Indeed, because most of the factors were drawn from cases where claims like this were at issue, the analytical framework outlined in the guidance is more familiar for this class of claims. For example, factors that weigh in favour of patent eligibility include claim elements or steps that impose meaningful limits on claim scope, that are more than pre- or post-solution activity, that involve a machine or transformation, or that are more than well-understood, routine, or conventional.

Factors that weigh against patent eligibility include elements or steps recited at a high level of generality or that “amount to nothing more than a field of use”. While this aspect of the guidelines is consistent with how the USPTO has been applying the Supreme Court’s decision in Prometheus, the examples appear to misapply the machine or transformation factor, finding for example that a claim reciting the use of flow cytometry does not recite a machine, and that a claim that recites that DNA primers are “extended” does not recite a transformation.

Another puzzling aspect of the guidelines is its treatment of method claims that involve a “natural product”. The guidelines subject all claims that involve a law of nature, natural principle, natural phenomenon, or natural product to the same analysis, including method of making and method of using claims that involve a natural product. As a result, claims directed to making a composition by combining specific amounts of specific “natural product” components may not be eligible under the guidelines.

Likewise, claims directed to a method of treatment that involves administering a drug that is a “natural product” may not be patent-eligible unless there are other elements or steps that satisfy one or more of factors (a)–(f). Although the guidelines do not include any examples of a method of treatment claim that is not patent-eligible, the example that is patent-eligible includes so many details (patient population, dose, administration period), that examiners are rejecting claims that recite a new method of treatment at a more general level.

Comment and interpretation
The USPTO is accepting comments on the guidelines, and particularly seeks alternative interpretations of the Supreme Court precedent and additional examples of eligible and ineligible subject matter. Applicants who face rejections under the guidelines should study the examples and consider whether the examiner misapplied the guidelines, made incorrect findings under the factors, or failed to give supporting factors sufficient weight.

Applicants pursuing subject matter that is not eligible under the guidelines should study the Supreme Court precedent and consider whether their claims would be eligible under alternative interpretations. Applicants also should watch for new Federal Circuit and Supreme Court decisions on patent eligibility, and confirm that the USPTO is applying the most recent interpretations of the ‘judicial exceptions’.

The guidelines do not carry the weight of law, and it is not likely that the extreme aspects of the guidelines will withstand judicial scrutiny. To have the guidelines overturned, however, innovators will need to challenge them in court. Only then will the ability to protect IP and investments in biotechnology, pharmaceuticals, and personalised medicine be preserved.

Courtney C. Brinckerhoff is a partner in the chemical, biotechnology and pharmaceutical practice of Foley & Lardner LLP and editor of PharmaPatentsBlog.com. The views expressed in this article should not be attributed to any other members of the firm or its clients. She can be contacted at: cbrinckerhoff@foley.com

“TO HAVE THE GUIDELINES OVERTURNED, HOWEVER, INNOVATORS WILL NEED TO CHALLENGE THEM IN COURT.”
The further demise of biotechnology patents

With the Federal Circuit relying on the precedent set by the *Prometheus* and *Myriad* decisions, Dolly the sheep has been summarily declared ineligible for patent protection. Nabeela Rasheed sums up the implications.
The US Federal Circuit has recently been called upon to apply the Prometheus and Myriad decisions to a particularly famous project: the creation of Dolly the cloned sheep.

In March 2012, the Supreme Court pronounced in Prometheus v Mayo that a claim to a method of optimising a therapeutic regimen in which the method was defined by specific steps is ineligible for patent protection. Later, in The Association for Molecular Pathology v Myriad Genetics, Inc, the Supreme Court held that a naturally occurring DNA segment is a product of nature and does not become patent-eligible merely because it has been isolated, although complementary DNA (cDNA) is patent-eligible because it is not naturally occurring.

These decisions are directly relevant to the creation of Dolly the sheep, the first mammal to have been cloned out of a fully differentiated adult cell. Dolly was born after Ian Wilmut, Keith Campbell and colleagues at the Roslin Institute, part of the University of Edinburgh, and the biotechnology company PPL Therapeutics fused the nucleus of an adult, somatic mammary cell from a sheep with an egg from another sheep to develop into the baby sheep. Dolly—arguably one of the most famous farm animals—was an exact replica of the original farm animal from which the somatic cell nucleus was taken. This was hailed as a significant scientific breakthrough by many, not least the Federal Circuit in In re Roslin Institute, which recognised ingenuity of the scientists at the Roslin Institute.

In 2001, the US patent office granted a claim to a method of creating Dolly. However, in 2003, with the loss of one of the scientific teams, the patent was found to be invalid. The Roslin Institute claimed that the claim was invalid because it did not distinguish Dolly from other sheep. The Federal Circuit held that the claim was invalid because it did not distinguish Dolly from other sheep.

In 2004, the US patent office granted a claim to a method of creating Dolly. However, in 2006, the Federal Circuit held that the claim was invalid because it did not distinguish Dolly from other sheep.

In 2007, the US patent office granted a claim to a method of creating Dolly. However, in 2008, the Federal Circuit held that the claim was invalid because it did not distinguish Dolly from other sheep.

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In 2015, the US patent office granted a claim to a method of creating Dolly. However, in 2016, the Federal Circuit held that the claim was invalid because it did not distinguish Dolly from other sheep.

In 2017, the US patent office granted a claim to a method of creating Dolly. However, in 2018, the Federal Circuit held that the claim was invalid because it did not distinguish Dolly from other sheep.

In 2019, the US patent office granted a claim to a method of creating Dolly. However, in 2020, the Federal Circuit held that the claim was invalid because it did not distinguish Dolly from other sheep.

In 2021, the US patent office granted a claim to a method of creating Dolly. However, in 2022, the Federal Circuit held that the claim was invalid because it did not distinguish Dolly from other sheep.

In 2023, the US patent office granted a claim to a method of creating Dolly. However, in 2024, the Federal Circuit held that the claim was invalid because it did not distinguish Dolly from other sheep.

Unfortunately, the court observed that Dolly did not possess “markedly different characteristics from any found in nature”. This decision that a cloned animal—something that previously had belonged in the realm of science fiction, and was brought into the realm of science fact only by the recognised ingenuity of the scientists at the Roslin Institute—is patent-ineligible is a direct extension of the Myriad decision and is emblematic of the demise of biotechnology patents and, more specifically, of gene-based patents.

Prior to these three decisions, there was a sense of comfort that the exceptions to patent eligibility under 35 USC §101 fell into three distinct categories: laws of nature, abstract ideas, and natural phenomena. Clearly, a clone of a living animal is not an abstract idea, nor a law of nature. It seems that nothing can be further from being a natural phenomenon than a cloned animal—an exact copy of a previously living organism.

However, the Federal Circuit held that the claim to a “live-born clone of a pre-existing non-embryonic donor mammal” is patent-ineligible because the DNA of the donor was “preserved” in the newly created animal so that the clone has a genetic identity that is identical to that of the parent.

With In re Roslin Institute, in combination with Prometheus, Myriad and the fallout of those cases, the courts and the US Patent and Trademark Office seem to be creating a fourth category of patent invalidity:

namely, where the product has “genetic identity” with something already found in nature, then that product is an exception to patent eligibility, regardless of the level of ingenuity involved in creation of that product, or the fact that such a product simply does not exist in nature.

It seems clear that these cases have provided significant fodder for challenging the validity of many patents, and those may be beyond redemption. But perhaps one can mine these cases for use in drafting future cases.

One possible area meriting further consideration is the wording in the In re Roslin Institute opinion that Dolly did not have “characteristics” that could be described as “markedly different” from any found in nature. This wording would seem to reflect a similar tone in Myriad, in which the court stated that the decision did not stretch to innovative methods of manipulating genes or new applications of knowledge about the new genes.

Perhaps this requires further consideration of functional claim limitations, which point to some characteristic that was not evident in the material in nature. For example, could the Roslin Institute have described Dolly with pink wool or some other feature that could be engineered into the animal as a marker to distinguish it from the parent and from nature? This may be an avenue to pursue, as the court did note that Roslin Institute’s arguments about differences between the clones and their donor mammals were unclaimed.

However, if this direction is followed, then the patentee may be forced to add meaningless limitations to its claims to ensure that the claims can be tested under 35 USC §§101 (anticipation) and 103 (obviousness).

Nabeela Rasheed is a shareholder at Chicago-based McAndrews, Held & Malloy. She can be contacted at: nrasheed@mcandrews-ip.com

Nabeela Rasheed has a PhD in biochemistry. Her practice concentrates on counselling, acquisition and enforcement of IP rights for her firm’s biotechnology and pharmaceutical clients.
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