

# Engineering the Future

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## Intellectual protection gets global overhaul

Big reforms in the EU and the US have been accompanied by the wider uptake of patents internationally, reports *Clive Cookson*



The world of patents has had a momentous year. The 40-year dream of a unified European patent is coming to fruition and the US system has had its most fundamental reform for half a century. Inventors worldwide, meanwhile, are making more and more use of patents to protect their intellectual property.

In 1973, a diplomats' conference in Munich started the creation of a European procedure to overcome the costly and inefficient national fragmentation of the continent's patenting system. From the start, some participants envisaged a "unitary" patent that would provide protection across

Europe. What actually emerged from the resulting European Patent Convention was the European Patent Office (EPO) in Munich, an organisation for examining and granting patents that holders then have to register and enforce at national level.

Attempts to introduce a unitary patent for EU member states were revived later in the 1970s, in the 1980s and regularly since. Narrow national interests always sabotaged them until last year, when the project won enough support to go ahead.

If all goes well it could begin operating early in 2015, though the timetable is slipping. "Realistically, we believe that the first half of 2016 is now the

date users should have in mind as the earliest likely start date," says Alan Johnson, intellectual property partner at London lawyers Bristows.

Although the system's efficiency has been somewhat undermined by the compromises made to garner sufficient political backing for the unitary patent and its supporting legal structure, patent professionals are pleased with the outcome.

"There was doubt until the last minute whether this would really happen," says Mark Kenrick, patent attorney with lawyers Marks & Clerk in Manchester. "The overwhelming feeling is that it's good for Europe and will make Europe a more attractive

market in which to file patents. It will be interesting now to see how quickly industry takes to the new system."

"We hope the ratification process will be as quick as possible," says Benoit Battistelli, EPO president. An important issue still to be decided is the cost of annual renewal fees, which will have to be set low enough to give inventors an incentive to file for unitary patents rather than a series of national patents, but which is high enough to finance the system.

No one is expecting a big initial rush by applicants to take up unitary patents. "My guess is that companies will want to test the system and the unified patent court before they put

all their eggs in the same basket," says Mr Battistelli. "It does represent a risk, because if they lose a case they will lose their protection everywhere, while at present if they lose it in one country they can still have it in another."

Mr Kenrick agrees a slow, steady take up is the likeliest outcome. "You are going to be reluctant to trust a new system until it has built up a record - but such inertia is to be expected," he says. "There was considerable reluctance to use the European Patent Office itself in its early days before it had proved itself."

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## EUROPEAN INVENTOR AWARD 2013 THE EUROPEAN PATENT OFFICE CONGRATULATES THIS YEAR'S WINNERS



### INVENTORS ARE THE HEROES OF THE 21<sup>ST</sup> CENTURY ECONOMY

Innovation creates competition, dynamic markets, jobs, prosperity and growth. Ingenious inventions in such technologies as healthcare, transport and communication can improve our lives and protect our environment. Inventors are the champions of progress, refusing to accept the status quo and harnessing the forces of nature to create new products and processes.

The European Patent Office protects inventions with patents. From a field of many thousands of patentees, the European Inventor Award recognises five truly exceptional individuals or teams.

These inspirational inventors secure our future. Most of them dedicate their entire life to improving ours. We thank them for their contribution to society and the economy.

### THIS YEAR'S WINNERS

**INDUSTRY 1A** Claus Hämmerle **1B** Klaus Brüstle  
Soft-close furniture hinge **SMEs 2** Pål Nyrén  
Rapid low cost DNA sequencing **RESEARCH 3** Patrick Couvreur and team  
Nano-capsules for targeted delivery of anti-cancer drugs **NON EUROPEAN COUNTRIES 4A** Ajay V. Bhatt **4B** Bala Cadambi  
**4C** Jeff Morris and team  
Universal serial bus (USB) **LIFETIME ACHIEVEMENT 5** Martin Schadt  
LCD technology

**28 MAY**  
**AMSTERDAM**

**40** EUROPEAN PATENT CONVENTION  
YEARS 1973-2013  
Innovation matters



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## Engineering the Future

# Jury panellist says a little argument is no bad thing

**Inventor of the Year Awards** *Peter Marsh* finds that, while his personal favourites did not always become winners, some disagreement is healthy

If everyone was to vote on whether science and technology has benefited humankind, the overwhelming opinion would be “yes”. But judging the merits of individual technical advances is much harder.

Which should we rate more highly: a way of working out the identity of genetic fragments to treat cancer, or a technique to make electric cars more efficient? Should an invention that has transformed how electronic devices display data on a screen be regarded as more useful than a new way to make steel?

Answering such questions is an important part of a number of competitions, which aim to assess specific technical ideas and give publicity to the winners. Behind these schemes is the notion of rewarding people who have had great ideas – ideas that might touch the lives of millions while the person or people behind them might be largely unknown.

The European Inventor of the Year Award organised by the European

Patent Office (EPO), now in its eighth year, is a mainstay of such competitions. During the judging process, a vast quantity of information about specific inventions was gathered. This was sifted using information from the EPO's internal technical assessors and commissions a panel of outsiders to choose the winners.

This year, as in 2012, I was a member of this panel, which explains why a few months ago I was sitting in a room at the EPO's Munich offices.

My job was to help sort out the relative usefulness of the ideas of 38 candidates the EPO's technical team had shortlisted for awards in five categories. These cover large, and small, companies on the continent; other enterprises from outside it; people working in universities or research institutes; and finally an award for outstanding individuals on the basis of their lifetime's achievements.

In the room were several technical experts from the EPO together with Benoit Battistelli, the forceful French

president of the institution who has used his influence to raise the competition's profile.

Four other panellists were in the room: Wolfgang Heckl, a physicist and biotechnical expert who is head of the Deutsches Museum in Munich, one of Europe's leading technical museums; Blanka Rihova, a professor of immunology from the Czech Republic; Ann Lambrechts, a civil engineer who works at Beakaert, the Belgian metals company; and Jens Dall Bentzen, owner of Denmark-based Dall Energy, a small business that develops biomass energy applications.

Others on the jury could not be present but had cast their votes beforehand. These were Erno Rubik, inventor of the Rubik's Cube; Thierry Sueur, head of intellectual property at the French gases company Air Liquide; Mario Moretti Polegato, an Italian entrepreneur who is the main force behind the Geox shoe company; and Martin Schulz, president of the European parliament.

The range of choices before us was set out in papers about individual inventions – plus the people behind them – prepared by the EPO experts. The documentation took us on an intellectual tour of extraordinary breadth. Inevitably, attention tended to focus on ideas that had a particularly wide application.

One example involved a group of scientists and technical experts headed by Ajay Bhatt, an Indian-born engineer who went on to work for US microchip giant Intel. Mr Bhatt was the main brains behind the method of coding individual computers and electronic devices – through a process known as the Universal Serial Bus, or USB – so they can instantaneously recognise each other. Now it is the system used in billions of electronic products worldwide.

Mr Bhatt's group had little difficulty gaining enough votes to take the top award in the non-European category.

The lifetime awards featured the names of some fascinating – yet little

known – people. For instance, there was Helmut List, who runs Austrian company AVL and is behind 50 inventions in fields from automotive drive systems technology to heart analysis machines.

The winner of this category was, however, Martin Schadt from Switzerland.

The candidate shortlist took us on an intellectual tour of extraordinary breadth

land, a multi-talented research scientist who worked out how to use materials called liquid crystals to transmit light. As a result he paved the way to the liquid crystal displays used in countless electronic devices.

Not everyone agreed with my personal favourites. In the industry section I was a keen supporter of a

team of engineers from Siemens, of Germany, which devised coatings for turbine blades, thus improving the efficiency of electricity generators.

But, to my astonishment, no one else rated these ideas highly enough for them to make the top three in this category.

I had more success in promoting David Gow, a UK biomedical engineer. He was the main technical person behind Touch Bionics, a UK business that is a world leader in making artificial hands for people whose upper limbs have suffered from deformity or injury.

Even though I felt Mr Gow's ideas should gain the top prize in the industry section he eventually had to make do in gaining recognition as a member of the top three.

In the high-flown world of technical judging, a little argument is, of course, entirely healthy. Given the overall excellence of the candidates, I really had little reason to feel affronted.

## Fireflies led the way on DNA sequencing

**Small business winner**  
**Pal Nyren**

Development has potential uses beyond health, says *Richard Milne*

Pal Nyren's Eureka moment came in 1986 when he was cycling home from Cambridge university. "It is often when you are not working but are still occupied that things come. Perhaps when you do some physical activity you can do some good thinking at the same time," he says.

What came out of that ride was a quicker method of sequencing DNA called pyrosequencing. Mr Nyren had gone to Cambridge to learn the traditional method of unravelling DNA but was unimpressed, not least because it was being done by hand. "It was very complicated."

He returned home to Sweden, applied for money to develop his method and ran into funding problems. Money materialised for one project but outsiders were sceptical.

"The comments were it would never work," he says. Finally, he drew inspiration to help decipher the DNA code from studying how fireflies light up. That luminescence helps to understand pyrosequencing – essentially it uses a chemical reaction to produce light signals that are captured by sensitive cameras and used to decode the sequence of the DNA bases one at a time.

The results are

spectacular – whereas the first mapping of the human genome took more than a decade it can now be done in a matter of weeks for under \$10,000. DNA sequencing is now both quicker and more efficient. But developing the pyrosequencing method took time. It was 15 years after the Cambridge bike ride that Mr Nyren, together with colleagues Mathias Uhlen and Mostafa Ronaghi, filed a patent for pyrosequencing.

It also did not use radioactive labelling – which entailed scientists handling hazardous materials – as the traditional method did.

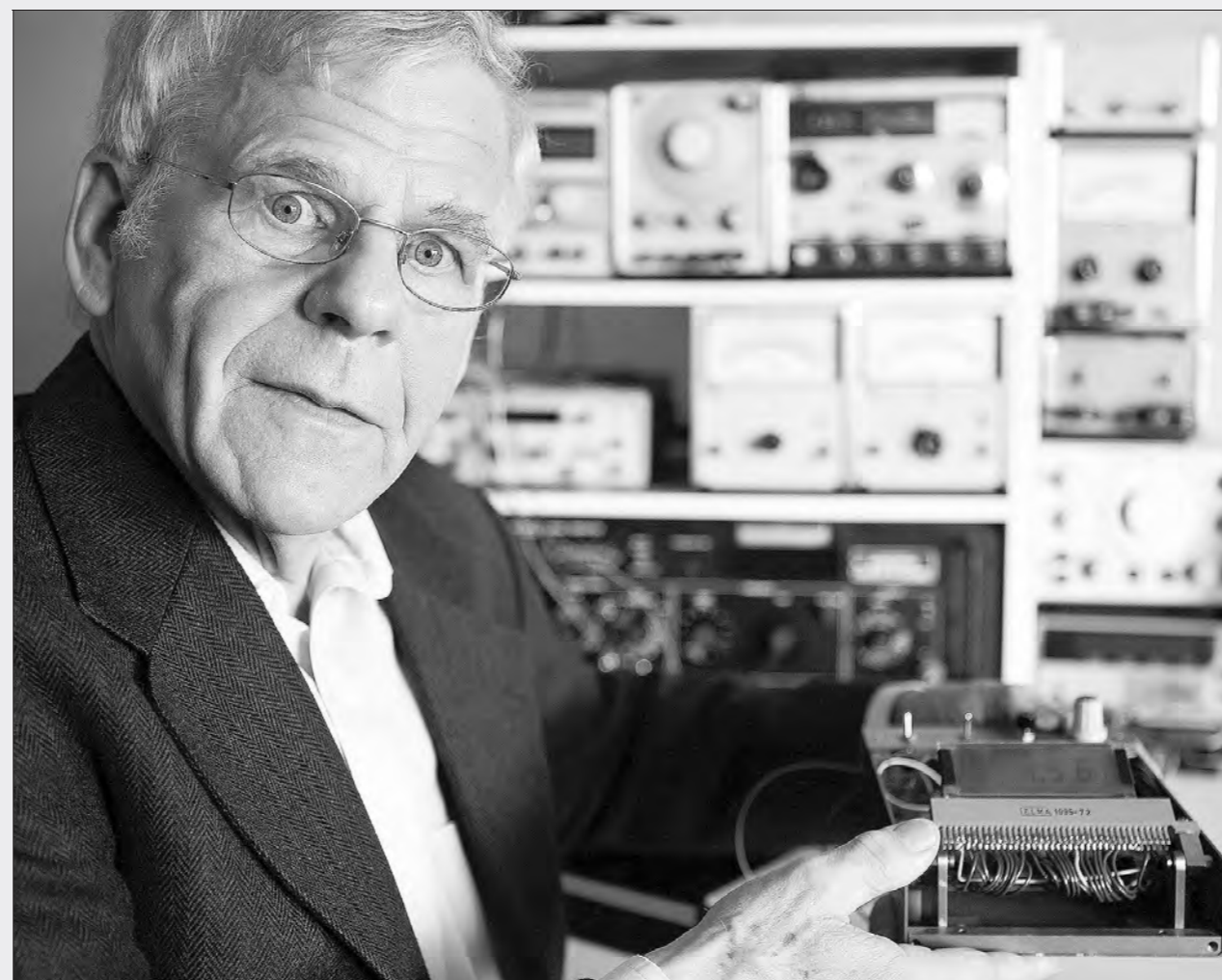
Having unsuccessfully tried to sell the patent Mr Nyren was able to build a prototype to show off his method and he attracted the interest of a healthcare venture capital group.

That led the three colleagues from the Stockholm Royal Institute of Technology to set up the company Pyrosequencing in 1999 to help sell the method. Four years later, the pyrosequencing technology was sold for \$53m to research company Qiagen.

The sequencing instrument industry generates worldwide revenues of \$1.6bn a year and pyrosequencing's growth prospects are good. Mr Nyren highlights an array of medical uses for the technology, such as determining the right cancer treatment for patients and investigating hereditary diseases.

He also underlines possible non-medical uses such as energy or food production.

**Lifetime achievement** Light dawned as crystals dimmed



**Flatscreen genius:** Martin Schadt's pioneering work made the \$100bn LCD industry possible

The interview is coming to an end when Martin Schadt notices my Dictaphone. "How long does it last before you change the battery?" he asks. More than a year, I say. He nods approvingly and inspects the flatscreen display with curiosity.

His interest is natural. After all, it is his pioneering work that made possible the \$100bn liquid crystal display (LCD) industry that today is behind the screens of everything from laptops to watches and televisions.

Mr Schadt's scientific aptitude was evident from a young age. In his youth in the small village of Füllinsdorf in Switzerland, he made rudimentary radios from spare parts. He also

caused the odd explosion. There followed an apprenticeship and military service, after which he studied physics at evening classes followed by a PhD.

Mr Schadt spent two years in Ottawa, where he registered his first patents for his invention of the solid-state organic light-emitting display.

He then took a job with watchmaker Omega before he moved to Roche, the Swiss pharmaceuticals giant. Here, in 1970, the breakthrough came.

Mr Schadt and colleague Wolfgang Helfrich had been experimenting with the idea that it was possible to "unwind" the spiral structure of liquid

crystals, substances that are neither fully liquid nor fully solid.

This process, they thought, would switch the crystals from transparent to opaque, which would make them suitable for creating shapes, such as digits, on a display screen.

Initially, the experiments were not successful. But as he looked through his microscope one Saturday, he saw the brightness of his liquid crystal molecules dim for the first time. The approach had worked.

As LCDs needed far less voltage than had been first thought, they could operate with conventional batteries and be adapted to many commercial uses.

"What came later on was the major work to develop today's field-effect LCD technology and compatible liquid crystal materials. All the progress and the excellent displays you see today are the result of better understanding of both the material properties and the physics of the electro-optical effects on which field-effect LCDs are based," he says.

With his team at Roche, he invented tests to measure the performance of LCDs. This allowed them to design mixtures with specific physical properties, which, in turn, encouraged Roche to start producing liquid crystals in 1972.

**James Shotter**

## Toxins used for sake of cure

**Research winner**  
**Patrick Couvreur**

*Andrew Jack* looks at the work of a pioneer in the field of nanotechnology

When Patrick Couvreur was a young scientist in Belgium, he drew inspiration from the laboratory of Christian de Duve, the Nobel Prize-winning biologist. The latter's research on cell digestion gave Professor Couvreur the idea of seeking ways to treat diseases using potentially toxic products without harming healthy cells.

In the late 1970s, Prof Couvreur – now director of the physical chemistry, pharmacotechnology and biopharmacy unit at Paris-Sud university – began to work with Prof Peter Paul Speiser at the Swiss federal institute of technology in Zurich on the potential of nanotechnology.

"The big problem of anti-cancer drugs is that we have significant toxicity," he says. "The effective dose is very close to the toxic one." His idea was to surround drugs that had been injected into the body, keeping them inactive until they reached their "target".

He used a polymer coating around drugs to test on animals before the development of biodegradable coatings for human consumption.

These coated drugs are nanoparticles, smaller than red blood cells, and allow higher concentrations of otherwise toxic medicines to pass through the body. Prof Couvreur moved to

France, where greater resources were available for research.

In Paris, he helped to co-ordinate work between academia and the pharmaceutical industry, founding the company BioAlliance to help translate his experiments into drugs that could be tested in mice and later humans.

He patented his discoveries and worked to raise production of the experimental treatment required. Testing of the product, Livatag, is under way, with BioAlliance recruiting patients for a late-stage Phase 3 clinical trial.

More recently, he created Medsqual, another Paris-

'I'm only a researcher, not a developer... I think the barriers are too great'

based company. This was to advance his work by combining the cancer treatment gemcitabine with squalene, a lipid or insoluble compound, that stops tumours for pancreatic cancer growing. He is examining the combination of nanoparticles and magnetic nano-crystals moved by magnetic fields.

His products are moving towards regulatory authorisation, commercialisation and wider use. "I'm only a researcher, not a developer," he says. "I don't have the competence to do all the scaling up, preparation and so on. I think the barriers are currently too great."

## 'Mr Fixit' just wanted to make the connections

**Non-European winner**  
**Ajay Bhatt**

*Chris Nuttall* talks to the man who came up with the idea for the USB

Ajay Bhatt has come across products that he never imagined would use the Universal Serial Bus (USB) that he first dreamt up 20 years ago.

USB cables and connections charge our phones, transfer files to memory sticks, transmit pages to printers and are responsible for all manner of data exchanges.

Personal fans for cooling and slippers heated for cold days were among the unusual devices using the USB he discovered on a trip to China this month.

Mr Bhatt, an executive at Intel, the world's biggest chipmaker, had become an electrical engineer after growing up in India with a fascination for gadgets.

"I was a Mr Fixit as a kid. I was always very curious about how things worked and I would take things apart and try to put them back together."

Dismantling PCs and rebuilding them was a daunting task for consumers in the late 1980s and early 1990s as they tried to make different components and peripheral devices work together through different types of connections.

"When I first joined Intel and started digging into the personal computer architecture, I saw that things were unnecessarily complicated, both for developers and users.

"Computers were just very hard to use, it was

really a nightmare."

He spent three weekends trying to make components in a PC work together. "That's when I decided something had to be done. The notion of 'plug and play', how I just connect something and it works, was the beginning of USB."

After making a proposal to Intel and beginning work, the quest widened to include other companies, including Microsoft, IBM, Compaq and DEC.

Universal Serial Bus, originally known as "hierarchical serial bus assembly", refers to combining the signals sent between different parts of a computer and peripheral devices into one central stream in which requests can be translated and prioritised.

The standard began to take off around 1998 as Microsoft introduced proper support for it in its



**Plug and play:** Ajay Bhatt demonstrates his device

Windows operating system and Apple included it in the iMac.

Its capabilities have increased over the years. The latest 3.0 specification offers data transfer speeds of up to 10 gigabits per second, up from just 12 megabits per second with 1.0 in 1996.

The USB can provide up to 100 watts of power, enabling peripherals such as an external hard drive to run off a laptop's port without the need for its own power supply.

Other standard

connectors such as serial and FireWire ports have fallen by the wayside while billions of USB-enabled devices entered the market. Multimedia Research Group estimates 4.5bn devices with USB ports will be sold in 2013 alone.

Mr Bhatt says the key to USB's success is that the standard has evolved so older devices are not made obsolete.

"Things you bought 15 years ago, they work today – we were able to expand the technology in a compatible way."

**Industry winners**  
**Claus Hämmerle and Klaus Brüstle**

*James Shotter* on a method to stop drawers slamming

Some of the most successful inventions are those that rid people of the mundane yet persistent everyday nuisances.

So it is with the Blumotion soft-close system, a device designed to stop the slamming of drawers and cupboard doors – a problem that has plagued households since hinges were first used thousands of years ago.

Since it was patented in 2001, the device, which is based on the ideas of inventors Claus Hämmerle and Klaus Brüstle, has been a huge success for Julius Blum, the Austrian furniture company that employs them. Its profits

have reached €1.26bn, an increase of about a quarter in the past five years.

This has brought benefits for the western Austrian region of Vorarlberg, where the company is based. At the last count, 4,400 of Julius Blum's 5,750 global staff were located in the mountainous area and about €100m of activity in the regional economy is linked to business that other companies do with Julius Blum.

Mr Brüstle says the key to success in the world of invention is "a healthy portion of curiosity and the consistent desire to make something new".

As well as its inventors' curiosity, Julius Blum drew on customer feedback and ideas from the automotive industry.

The system is built around a piston housed in a pressure tube filled with hydraulic liquid. When a door or drawer is closed, the piston is forced through the liquid. As there is only enough space

in the tube for a small amount of liquid to squeeze past the piston, it is gradually slowed down, preventing the door or drawer from slamming.

An important feature of the damping system is that it is speed-sensitive. The harder a door is closed, the more resistance the system provides, meaning that the door still will not slam.

The inventors are working on ways to refine their creation. "The challenge for developers... is and remains the need to accommodate as much technology as possible in the smallest possible space," says Mr Hämmerle. "In the latest generation of hinges... the damping system is integrated into the hinge boss."

In an effort to support such advances, Julius Blum annually reinvests 4 per cent of its profits into research and development. This provides more chances of ensuring its hinges continue to evolve.



## Engineering the Future

# Patent renewal fees trouble Europe's small businesses

**Unitary system** Decision over how much to charge remains delicate, writes *Nuala Moran*

While the streamlining of the application process offered by a EU-wide patent system is likely to be broadly welcomed by large companies, the – as yet – unspecified cost of annual renewal fees is a worry for smaller businesses.

The system should make life simpler. Currently patents granted by the European Patent Office (EPO) must be registered and enforced nationally. In future there will be a choice of either registering a patent country by country, or as a unitary patent providing protection across the 25 signatory states. While the new system will only cover EU members, the existing European Patent Convention has 38 members; the two will operate in tandem.

Costs in the unitary system will be cut by ending the requirement to translate a patent into the language of every country in which it is to have effect, and by creating the Unified Patent Court (UPC) to provide a single jurisdiction for dealing with disputes.

After 40 years of effort, little more than 18 months remain before the single European patent is scheduled to come into operation in 2015. But two issues – the location of the UPC and the decision of Italy and Spain to opt out in protest at the designation (in line with the EPO regime) of having English, French and German as patent languages – are colouring the process and its eventual operation. Nationalistic horse-trading over the UPC's home leaves it unified in name only. Its headquarters will be in Paris. Subsidiary courts will specialise in patents involving chemicals (including pharmaceuticals) and life

sciences in London, and engineering and physical sciences in Munich. This structure will be buttressed by several local and regional divisions in member countries. A court of appeal and a registry to keep records of all cases will be based in Luxembourg.

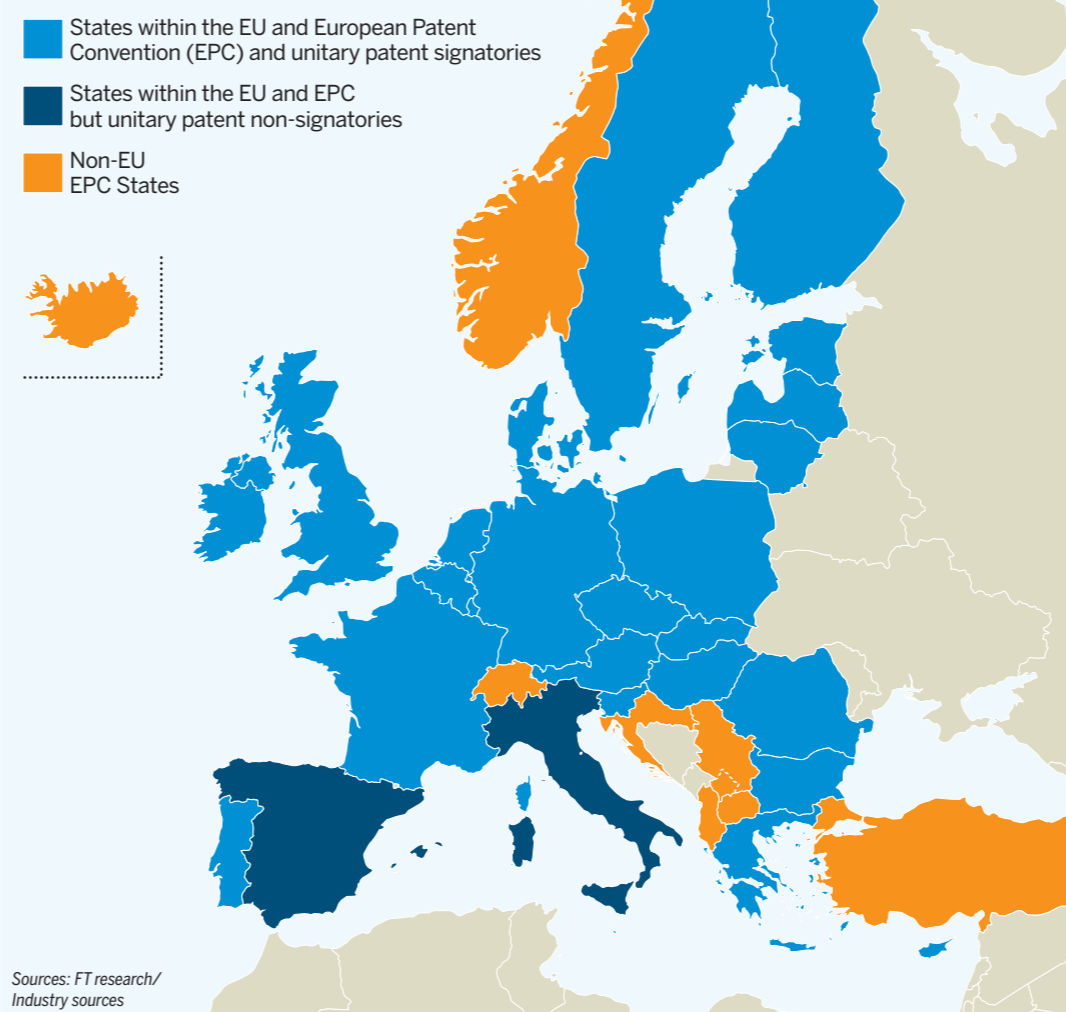
A mediation and arbitration centre is to be established, with seats in Ljubljana and Lisbon, to provide a forum for settling disputes before they are brought to law.

The committee in charge of implementing the UPC agreement held its first meeting on March 26, setting early 2015 as the target for the unified court to start operations. Input from industry, patent judges and practitioners “will be needed throughout the [implementation] process”, says Paul van Beukering, manager of the intellectual property unit at the Netherlands ministry of economic affairs, who chairs the committee.

One of the most delicate tasks will be setting the annual fees for renewing unitary patents. Since, on average, companies register patents in four of the 25 countries in the revised system, there will be little incentive to take out a unitary patent if the renewal fees cost much more than four national patents. Having the fourth and fifth-largest European markets of Italy and Spain on the outside will compound the difficulty of developing an attractive fee structure.

Margot Fröhlinger, EPO director for patent law, agrees there is a need “to strike a delicate balance” to ensure the system is self-financing yet “affordable”. But she notes renewal fees – bureaux in different countries fix costs unilaterally using different

### European patent system member states



criteria – are important sources of income for national offices.

The EPO will in future collect renewal fees, keeping half and disbursing the rest to national patent offices based on a formula that aims to favour countries with less well-developed patent systems. The objective is to boost intellectual property protection across the continent.

Once established, the UPC will deal with disputes relating to unitary and traditional EPO patents registered in participating countries. This explains the apparent anomaly of why Italy is a member of the UPC, despite staying outside the single patent system.

It leads Ms Fröhlinger to feel “hopeful, though not yet optimistic” that Italy will become a full member.

Companies are starting to weigh the implications for their intellectual property strategies. The question of renewal fees is a “big uncertainty for small and medium-sized companies”, says Nick Wallin, patent attorney at lawyers Withers & Rogers in London. “If the cost for a unitary patent is equivalent to three to four national patents, business will be happy. If it’s

equivalent to the cost of six to seven national patents that would be pushing it, especially as Spain and Italy are outside.”

Such considerations are unlikely to affect big companies and Mr Wallin says US and Asian clients are likely to file more patents in Europe. “From their perspective, the value of a patent is related to how easy it is to enforce. Having one court to litigate leads to a notional increase in value.”

These attractions will have to be weighed against the fact that patent protection, or the ability to challenge a patent, will be wiped out in 25 countries if a case is lost.

MEPs approved the single patent in December 2012. “Instead of paying millions to patent attorneys, translators and administrative fees, Europe’s SMEs will instead be able to use the money to develop their products,” says Cecilia Wikström, MEP of Sweden’s liberal Folkpartiet.

Eliot Forster, chief executive of Creabilis, a biotech company in Luxembourg, feels it will be a while before the benefits are seen. “For that reason, I’m agnostic at this time.”

# Protection gets global overhaul

Continued from Page 1

In the US, the main provisions of the America Invents Act, the biggest overhaul of the country’s patent laws since 1952, came into effect in March.

Among many other provisions, the legislation replaced the distinctively US “first to invent” rule – in which an applicant who proved an earlier invention, for example through laboratory documentation, could claim patent rights over someone else who applied more quickly. There is now a more clear-cut “first to file” rule similar to that in the rest of the world.

This reform has been welcomed by patent professionals as an improvement in its own right and as a step toward greater global uniformity (though the US system still retains some peculiarities of its own).

The European system and the US reform are both likely to increase the number of filings in those regions – accelerating the existing global trend to patent more actively.

The World Intellectual Property Organisation (Wipo) says the number of international applications under the Patent Cooperation Treaty, the nearest thing to a global system, rose by 6.6 per cent in 2012 to 194,400, following a 10.7 per cent increase in 2011.

In Europe, too, the EPO reports a record number of filings last year: 94,060, 2.3 per cent up on the previous year.

Francis Gurry, Wipo director-general, attributes the growth to three main factors. First is the long-term trend for companies, their accountants and stock markets to put more value on intangible as opposed to physical assets.

“The increased value of intangibles adds to the demand for patents and other intellectual

property,” Mr Gurry says. The second factor, he notes, “is the increased public attention being paid to the patent system. A few years ago no one was talking about patents. Now you’ll find something in the papers about them every day – and that affects the way companies manage their patents.”

Third is the geopolitical and economic rise of east Asia, in particular China. “In 1994, Japan, China and South Korea filed 7.6 per cent of all international patent applications. Now they account for 39 per cent,” Mr Gurry says.

194,000

Patents filed under Patent Co-operation Treaty in 2012

3,906

Patents filed by Chinese company ZTE in 2012

The top individual filer in 2012 was ZTE, the Chinese telecommunications equipment company, with a remarkable 3,906 applications. This was 1,080 more than the previous year and 955 above the second-placed company, Panasonic of Japan.

Third and fourth places in the filing league were taken by Sharp of Japan (2,001) and Huawei of China (1,801).

In parallel with the vast increase in patenting by Chinese companies abroad, the country has introduced a greatly improved domestic patent system to protect Chinese inventions.

Mr Kenrick of Marks & Clerk says: “Although we still hear horror stories about corruption and favouritism in Chinese courts, the Chinese patent office itself is working very well.”

# US genes decision may depend on strands in Myriad argument

### Supreme Court ruling

DNA patent case remains hard to call, reports *Stephanie Kirchgassner*

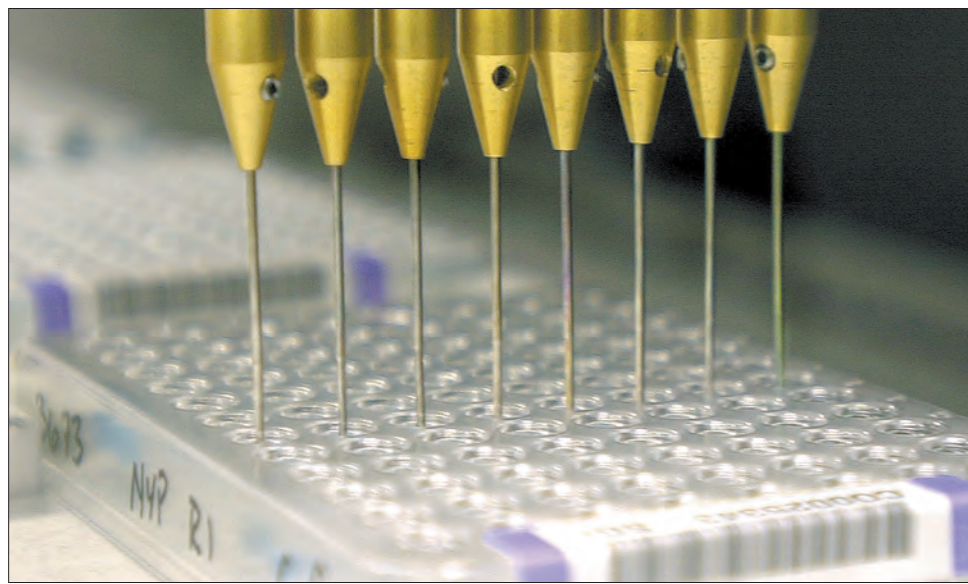
It was obvious from the questions they asked and analogies that they dreamt up that the nine US Supreme Court justices hearing one of the most important and complex patent cases in a decade were not wholly comfortable with the subject at hand.

The question before them – whether human genes could be patented – seems straightforward on the surface. Yet as the arguments turned to talk of recombinant DNA and whether isolated DNA fragments were found in nature or were a product of man, the judges quickly turned to quizzing attorneys with more accessible analogies involving baseball bats and chocolate chip cookies.

In June the Supreme Court is set to release its decision on whether genes may be patented, in a ruling expected to have broad implications for a biotechnology industry that is valued at \$83bn. Just how far reaching the case will be for other patent holders is difficult to determine before the ruling is announced. Most experts agree that it will trouble the likes of biotechnology group DuPont, drugmaker GlaxoSmithKline, and Amgen, the bio pharmaceutical company.

The case before the court centres on the actions of a Utah company, Myriad Genetics. Myriad created a monopoly in the US when its co-founder, Mark Skolnick, became the first scientist to isolate, sequence and patent two gene mutations that have a high risk of breast and ovarian cancer, BRCA1 and BRCA2.

While Myriad insists that it never stopped any scientists from performing research on the genes, it has long held exclusive rights for all clinical use of the BRCA mutations, including genetic tests for



Gene genie: DNA samples being tested by robots at a Myriad plant in 2001

patients who worry that they carry the mutations.

In its challenge to Myriad, the American Civil Liberties Union has argued that the longtime practice of patenting genes in humans defied a rule of patent law that says things found in nature, such as elements on the periodic table, could not be patented. While proponents of the patents argued that the isolated fragments of DNA in question could not – in and of themselves – be found in nature, the ACLU has relied on the arguments of scientists who have said such fragments do indeed occur through natural processes in the human body.

When they heard the case in April, the majority of the nine justices seemed sceptical about whether these kinds of genes should continue to be patented. But they were also wary of dealing too great a blow to entrepreneurs and companies that have come to rely on the promise of patents to raise investor capital and pursue scientific research.

Most experts believe, based on the questions and comments heard in court, that the majority of justices may decide to invalidate patents on isolated DNA, including the main patents in question in the case of Myriad. But they are expected to maintain the patent protection for what

is known as complementary DNA, or cDNA, which is essentially synthetic and used for many medical and agricultural purposes.

Scientific and legal experts are trying to gauge just how disruptive the case may be. Before it was heard, one patent expert predicted the results could be disastrous.

“Synthetic DNA sequences, designed by humans, may be excluded from this prohibition but the invalidation of patents claiming human genes will

‘The invalidation of patents with human genes will wipe out vast amounts of private investment’

wipe out vast amounts of private investment, and be a body blow to the biotechnology industry,” says Andrew Torrance, professor at the University of Kansas law school.

A study published by Nature Biotechnology found that the extent to which certain patent claims would be affected by the ruling would be determined by how the justices define the “line of demarcation” between the “natural”

and the “invented” DNA. It is unclear whether the high court would draw distinctions between human and non-human genetic sequences.

The question of what patents are at risk is complex. The study, which was led by Gregory Graff of Colorado State University, used algorithms and other methods to sift through more than 70,000 patents. It determined that 15,359 of them contained claims that were similar in nature to those held by Myriad.

Of these, 39 per cent involved human sequences, seven involved other mammals, 12 per cent involved plants, 21 per cent involved microbial sequences and another 21 per cent were seen as using “synthetic” claims of DNA.

The study found that the companies with the most at stake were pharmaceutical or biomedical companies. But big agricultural technology firms, focused on plants and microbial genes, such as DuPont, the largest holder of US gene patents, also stand to lose.

Whatever the court decides, the authors noted, the future seems to lie not in the controversial patents that Myriad established in the late 1990s, but in the “non-natural” genetic constructs that most experts believe will be safe from the Supreme Court.

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## Engineering the Future

# India's stance on compliance raises fears of copycat action

**Big pharma** Western companies worry that attitudes to property rights may create an example for others to follow, says *Amy Kazmin*

Throughout the 1990s, India was the *bête noire* of western pharmaceutical companies. It was a country that did not recognise drug patents and had a large generics industry churning out low-cost copycat medicines for domestic use and to export to other developing countries. India was expected to fall in line with global intellectual property rights standards in 2005 when New Delhi adopted a patent law ostensibly compliant with its obligations to the World Trade Organisation, which it joined in 1995.

However, the refusal in April of the Supreme Court to grant a patent to Swiss group Novartis for its cancer drug Glivec is seen as the latest sign that Indian attitudes towards drug patents are little changed.

The ruling follows a series of recent Indian decisions to override or revoke patents on cancer and hepatitis C drugs from "big pharma" companies such as Bayer, Pfizer and Roche. These rulings have raised hackles among western companies and fears that other emerging markets could soon follow India's lead.

"We still don't have an ecosystem [in India] that encourages patents," Ranjit Shahani, managing director of the territory for Novartis, says. "Most of the patents granted are either revoked or violated, or a compulsory license is issued."

Jason Rutt, a patent lawyer at Rouse, an intellectual property law firm, says: "The trend that has emerged is that India is an unfair place for innovative pharmaceutical companies. Pharmaceuticals are a

global market and you would expect everybody to behave the same way in each country."

India's parliament deliberately drafted the patent law to set a high standard for inventiveness and to ensure sufficient flexibility for generic companies to provide low-cost medicines if the original patented drugs were too expensive for local consumers. Indians buy around \$13bn worth of drugs a year – tiny compared with the US at \$400bn – but the market is growing by more than 10 per cent annually. India exports about \$13bn worth of pharmaceuticals a year, about 40 per cent of which go to the US and the EU.

India's law tries to prevent "ever greening" – the practice of companies renewing patents on old drugs by making minor changes – under section 3d, which states new patents can only be issued on previously known molecules if the modified versions show much improved efficacy.

Unlike most countries, where only governments can seek a compulsory license authorising production of low-cost copies of patented drugs, India permits generics companies and patient groups to apply directly to patent authorities for such licenses.

Western companies fear other developing nations, such as South Africa, may take the cue and dilute patent laws – making it tougher to obtain or extend patents and easier for patents to be overridden.

That is worrying for the industry as it seeks growth in emerging markets to compensate for pressure on margins in advanced economies and tries



**Kiran Mazumdar-Shaw: others are wanting to follow India's path** Getty

to fund innovative drug research. "India has said: 'We are the thought leaders in terms of the ever greening of patents,'" says Kiran Mazumdar-Shaw, founder of Biocon, a Bangalore-based biotech company. "Others are jumping into the fray saying: 'This is a good decision and we want to follow the path.'"

Yet given the high stakes, India is likely to come under intense pressure to adhere more closely to global patent practices.

Pfizer has appealed to the US government to make India's failure to adequately protect intellectual property an important issue in bilateral relations.

The response of western governments has so far been muted. But India's Congress party-led government is considering a batch of compulsory licenses for costly cancer drugs. If those go ahead, western pharmaceutical companies will surely find a way to make their fury felt.

"If you are a country that has a patent law, and a WTO commitment, don't make it a sham," says Mr Shahani. "There will be a point where the red line will be crossed."

# Big companies urge action against 'trolls'

**United States**

**Copyright cases brought against wealthy defendants have soared since 2010, writes *Richard Waters***

The US Congress eventually overcame its internal divisions over patents to pass the America Invents Act in 2011 more than half a century after it had last considered the subject.

With claims of patent abuse escalating steadily, there are already plenty of voices urging it to act again – this time with greater haste.

The calls have been prompted by a reported surge in patent lawsuits brought by so-called "patent trolls" – outfits that amass patents purely so that they can bring lawsuits for infringement against wealthy defendants, often forcing them into out-of-court settlements to escape costly court battles.

Cases brought by these "patent assertion entities" have soared since 2010, when they accounted for 29 per cent of cases in the US, according to Colleen Chien, an assistant professor at Santa Clara University School of Law. By last year the proportion had climbed to 61 per cent, prompting warnings that a flawed system was in danger of becoming completely dysfunctional.

This has led to a fresh round of proposals for legislation to cure the alleged flaws in the US system for granting and enforcing patents: that it allows too many poor-quality patents, favours nuisance suits and leaves courts ill-equipped to weed out abuses.

"We have way too many patents," Richard Posner, a US appeals court judge who has taken an outspoken stance on the issue, said this month. This has worked to the advantage of trolls, who have been able to use overlapping or loosely worded patent claims to bring cases.

Proposed solutions by Mr Posner and others include legislation to narrow the range of patents that are issued or can be used as the basis of a lawsuit. Only patents that relate to a product or process that is actually in use should be enforceable, he said.

Not all the recent analyses of the patent system have been so alarmist.

According to the Brookings Institution, the Washington think-tank, the number of patents awarded in the US has indeed risen quickly over the past decade. But, judged by patents per head, it said this brought it to the same level that it was at for much of the period from 1875-1950.

The rise in rhetoric against patent trolls is a clear attempt by big companies to turn public opinion their way, according to Nathan Myhrvold, founder of Intellectual Ventures, a patent-investment body whose own lawsuits have stirred up some complaints. Big companies have always fought against paying inventors for the use of their work and have much to gain from painting the trolls as the villains, he says.

The complaints about trolls have spilled over into proposed legislation. This month, Charles Schumer, New York senator, put forward a bill that

**Patent owners could be forced to disclose their identities in legal cases**

would give the US Patent and Trademark Office the power to judge disputes over business method patents, taking the cases out of the courts and also taking away one of the trolls' most potent weapons.

In another direct attack, the End Anonymous Patents Act, introduced by House of Representatives member Ted Deutch, would force patent owners to disclose their identities – something that would end a tactical advantage enjoyed by some litigants, according to Brad Smith, general counsel of Microsoft.

While such bills have taken narrow aim at supposed abuses, reform proponents argue that procedural changes in the courts and other adjustments are needed to repair the system's flaws.

The problems, according to Mr Posner, include a Patent and Trademark Office that is understaffed and under-resourced, even after a change to its funding arrangements in the 2011 Act. He blamed a district court system that lacks the expertise needed to weigh patent cases properly and a Federal appeals court that leans instinctively in favour of enforcing patent rights.

# China fails to live up to its history as a great nation of innovation

**Asia**

**Patti Waldmeir finds that filings for patents have ballooned but the quality is lacking**

China can claim to be the birthplace of some of the oldest and most important discoveries ever made on earth – gunpowder, the compass and papermaking among them.

However, it is still one of the world's junior members as far as systems for protecting intellectual property rights are concerned. Patent filings have risen in recent years, partly because Beijing has declared that innovation is the key to building sustainable economic growth.

Two years ago, China surpassed the US to become the world's biggest filer of patent applications.

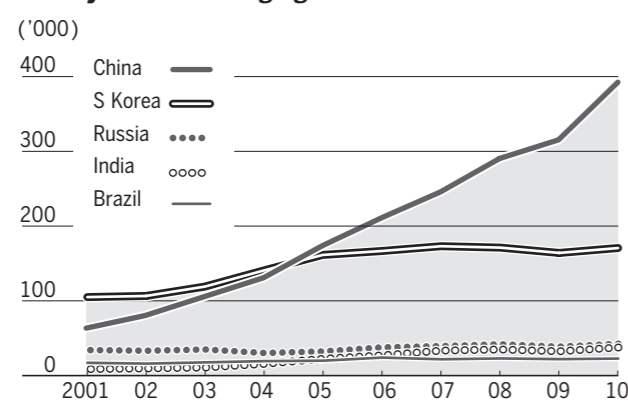
Patent experts inside and outside China say the impressive number of patent filings does not tell the whole story of the country's current levels of innovation.

Their argument is that the growth in volume has not been matched by a similar growth in quality.

China's patent office says it received more than 2m applications last year, and granted 1.25m of these, but only 217,000 were of the highest quality in China's patent system.

China grants three types

**Annual number of invention patent applications filed by the five emerging economies**



Source: Thomson Reuters

of patents, comprising those for "invention" and also patents that require a lower level of innovation. The latter are "utility model" and "design" patents.

Elliot Papageorgiou, a member of the EU Chamber of Commerce working group on intellectual property rights in China, calls utility model patents, "patents lite".

"Compared with those steeply-crowned invention patents in developed countries, many of ours are patents that are for small improvements, utility models or design," Tian Lipu, director of the State Intellectual Property Office said last month.

However, he added: "Something is better than nothing, and low-quality patents are much better than imitation or copyright infringement."

The EU Chamber of Commerce recently published a study of Chinese patent

quality, Dulling the Cutting Edge: How Patent-Related Policies and Practices Hamper Innovation in China. This shows patent filings have ballooned in recent years.

However, the EU study projects that by 2015, a key target date identified by China for the development of its patent system, "there might be over 2.6m less-than-'highest-quality' patents filed in China." It estimates that the number of "highest-quality" patent filings in 2015 would be substantially lower. Furthermore, the gap between the two looks as if it will be widening, not closing.

The study forecasts that "39 per cent more total utility model applications than total invention patent applications [will be] filed in China in 2015, 28 percentage points more than the comparison rate between the two in 2011".

But some legal experts

believe China's patent system, which relies heavily on grants for small or marginal innovations, is where it should be given its current stage of development.

Confucian tradition once encouraged the Chinese to share and even copy inventions and the idea of protecting them as individual property is relatively recent, notes an article in a recent edition of *The International Lawyer*.

The EU Chamber of Commerce's Mr Papageorgiou also says there is nothing "intrinsically bad" about China's utility model patent system.

"For a developing economy it makes sense to have utility models," he says. "It gives small investors a chance to get on to the inventor's ladder."

The bigger problem is that various levels of government give monetary incentives for patent filings, which encourages low-quality or even worthless applications, he says.

The EU study goes on to conclude that despite marked improvements in China's patent laws in recent years, foreign companies still "do not typically file patents on breakthrough inventions in China".

This was "given the magnitude of the threat of Chinese entities to use illegally acquired [intellectual property rights] from foreign firms to very seriously jeopardise those companies' business operations, not just in China, but also abroad".

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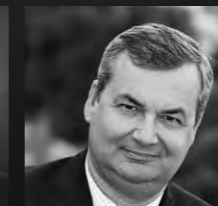
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Turkey's Energy Minister, Mr Taner Yildiz, is the latest VIP to agree to speak at the opening keynote session for POWER-GEN Europe.

Yildiz is joined, by a quartet of industry heavyweights, comprising Reinhold Mitterlehner, Austria's Federal Minister, Economy, Family & Youth; Philippe Cochet, President of Alstom Thermal Power; Alexander Novak, Russian Minister of Energy, Ministry of Energy, Russia; and Marc H. Hall Director for Energy, Wiener Stadwerke, Austria.

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