

Innovation and the Economy

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Government
in danger
of stifling
bright ideas

Policy makers need to embrace a broader vision of innovation, and shape infrastructure and regulation accordingly, writes *Clive Cookson*

Innovation – now seen as the most important driver of growth and productivity – has become one of the biggest buzzwords in politics and economics.

Conferences about innovation are popping up around the globe, while reports promoting and measuring it pour out of the world's think-tanks, universities and research agencies.

Brussels has just this month hosted two separate top-level meetings with confusingly similar titles, the fifth European Innovation Summit and the 2013 Innovation Summit and, next week, the European Council will hold a special meeting about innovation.

The past month has also seen at least half a dozen substantial reports on the topic. One, *Honouring the World Leaders in Innovation* by Thomson Reuters, opens with the statistic

that 28,998 corporate press releases issued on PR Newswire over the past year used the term “innovation” – a finding that will surprise no one on the receiving end of the PR barrage.

"The word has come to embody a kind of mystical formula that has the power to boost global economies, corner consumer market share and bestow cult-like status on tech company CEOs," says the report.

Beyond the mysticism, there is agreement about the factors that can stimulate or stifle innovation – from tax and patents to regulation and research spending – but also argument about their relative importance.

A report issued last week in Brussels by the Organisation for Economic Co-operation and Development looked at tax incentives, which make up more than a third of all public support



for research and development in the industrialised world. It concludes that multinational enterprises benefit the most, as they can use tax planning strategies to maximise support for innovation – creating “an unlevel playing field” that handicaps domestic and young companies.

"Much more needs to be done to help young companies play a greater role in driving innovation and creating jobs," said Andrew Wyckoff, OECD director of science, technology and industry at the launch. "They are the future of the knowledge economy and need the same chance to succeed as the major players. Improving their access to finance and making the tax rules fair for everyone is key."

For the European Patent Office, intellectual property protection is, not surprisingly, a vital factor in driving innovation, as it gives an incentive to develop inventions commercially.

The latest study by the EPO, in conjunction with the EU Office for Harmonisation in the Internal Market, shows industries with an above average use of intellectual property rights (IPR) contribute 39 per cent of economic activity and 26 per cent of jobs in Europe. They pay significantly higher wages than other sectors, with a wage premium of 40 per cent.

Leaders of some of Europe's biggest IPR-intensive companies have written an open letter to the European Commission, European Council and European Parliament drawing attention to an issue – regulation of risk – that they say threatens innovation.

The chief executives of 12 companies with a combined R&D budget of €21bn a year, urge the EU to adopt an "innovation principle" in risk management and regulatory language. "The principle is simple," they write: "Whenever precautionary legislation is under consideration, the impact on innovation should also be taken into full account in the policy and legislative process." The industry leaders "are deeply concerned by the negative impact of recent developments in risk management and regulatory policy on the innovation environment in Europe... Our concern is that the necessary balance of precaution and

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Innovation and the Economy

Patent reforms aim to protect and encourage progress

Global scene
Changes welcomed but companies fear abuse of system, says *Clive Cookson*

Protection of intellectual property helps promote innovation. By giving companies and individuals a financial incentive first to invent and then to develop the invention, patents play an important role in wealth creation.

Two of the world's leading patent systems – those of Europe and the US – are undergoing far-reaching reforms intended to smooth

the way to more efficient IP protection and, their architects hope, more innovation.

The European Patent Convention, signed in Munich in October 1973, laid the framework for a single, harmonised patent system in the EU. The agreement's 40th anniversary will be celebrated today through various activities in the same city.

Although the convention quickly led to the establishment in Munich of the European Patent Office to examine and grant patents, their holders have had to register and enforce them at national level – an expensive and elaborate process.

The dream of a unitary patent, providing Europe-

wide protection, is only now coming to fruition.

The new system will apply to 25 EU members – Spain and Italy are staying out, at least temporarily, in protest at the exclusion of Spanish and Italian as official patent languages – and the compromises inevitably made to push it through will somewhat undermine its efficiency.

For example, the Unified Patent Court that will deal with disputes has a complex structure with headquarters in Paris and subsidiary courts and branches distributed across Europe.

Much remains to be decided before the new system comes into operation, probably in 2015.

Most important will be the fees for the unitary patents, which will need to be low enough to give inventors an incentive to use them rather than continuing to take out national patents, but high enough to finance its operation.

Even so, most IP professionals remain keen on the reform and its potential to level the patent playing field between Europe and its competitors, which already have less expensive unified systems.

On the other side of the Atlantic, the America Invents Act – the biggest overhaul of US patent laws for 60 years – came into effect in March. This introduces a “first to file” rule in

accordance with practice in the rest of the world, in place of the less clear-cut “first to invent” rule. The Act includes a number of other changes and, like the European reform, has been generally welcomed by patent professionals.

The focus of discontent emerging in the US is the behaviour of companies

known by their critics as “patent trolls” or, more politely, “patent assertion entities”. These accumulate hundreds or even thousands of patents and allegedly use them to extort money from more productive companies through opportunistic legal threats.

The White House has called for action against patent trolls, bills in Congress aim to make it harder for them to take enforcement action in the courts, and last month the US Federal Trade Commission launched an investigation of abuses by patent assertion entities.

The issue of patent trolls had largely been restricted to the US. But last month

16 large technology companies, from Apple to Yahoo, calling themselves “a group of global innovators”, sent an open letter to European policy makers.

This warned that the procedures of the Unified Patent Court being drafted could make it easy for patent assertion entities to start abusive legal proceedings in Europe too.

Applied sensibly, the unitary system could cut the costs of patent protection in Europe, boost competitiveness and “support the long-term growth of innovative industries”, the group says.

But, it adds, the draft rules may undermine these benefits by creating opportunities for abuse.

Danger of stifling bright ideas

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proportion is increasingly being replaced by a simple reliance on the precautionary principle and the avoidance of technological risk. We see numerous practical examples across a range of technologies, from engineering to chemicals and agriculture to medical sciences”. Curiously, Herman Van Rompuy, president of the European Council, did not mention excessive regulation in a speech on innovation last week. Instead, he focused on the need to improve commercialisation of research and Europe's declining competitiveness in information and communications technology.

“To be blunt, we are lagging behind, and the reason behind this is mainly because we've invested too little in the infrastructure, skill and organisational changes that are needed to reap the benefits of these technologies – and that is a disgrace,” he said.

A document that tries to pull the various points together, *Plan (Innovation) for Europe*, has been published ahead of next week's European Council meeting.

It comes from the Lisbon Council, a Brussels-based think-tank, and Nesta, a London-based foundation that used to be the National Endowment for Science Technology and the Arts and has reinvented itself as a promoter of innovation.

The seven key recommendations in Plan (Innovation) are: complete the single European market; make public innovation funding bold and experimental; build 21st-century infrastructure (including super-fast broadband and smart grids); educate a tech-savvy workforce; embrace social innovation; make innovation open to all; and reform European institutions to support innovation more.

As the plan says: “It will require policy makers and agencies to embrace a broader vision of innovation: one that is not only based on expanding R&D and patents, but also recog-

‘On almost every measure, China continues to exceed expectations’

nises the role of dynamic high-growth businesses, the importance of ‘hidden’ innovation – including innovation in services and social innovation – as well as the power of the new digital technologies that are transforming the world.”

China comes up in discussions of innovation, as outsiders seek to understand its sustained technological and industrial growth. James Wilsdon, professor of science and democracy at the University of Sussex, says: “On almost every measure of research and innovation, China continues to exceed expectations. Its system is not without problems but it is now well on track to becoming a science and innovation superpower by 2020.”

He is the co-author of a report, also co-produced by Nesta, *China's Absorptive State*, that describes rapid progress driven by “absorption”, a concerted push to combine stronger home-grown research capabilities with foreign technologies and knowledge.

Geoff Mulgan, Nesta chief executive, writes in his foreword: “A distinctively Chinese approach to innovation can now be seen in many sectors. It involves not only absorbing the best ideas from around the world but also recasting them and recombining them through ‘re-innovation’.

Some of that is the result of classic R&D. But much involves... hidden innovation – in design, processes and organisational models in manufacturing and services which isn't captured by the traditional measures of R&D.”

To misquote Chairman Mao, when it comes to innovation, we would do well to let a hundred flowers bloom.

Agency and government look for ways to compete

UK system Greater choice in Europe is being offset in Britain by policy changes, tax breaks and increased efficiency, writes *Henry Mance*

James Dyson reckons the UK's system for protecting intellectual property is broken. “Patents are expensive to file in the first place,” the inventor of the bagless vacuum cleaner said last year.

“Then you've got renewal fees – there's no other walk of life where you lose your rights on your work of art if you fail to ‘renew’ it. And then the costs of actually fighting a case are out of this world.”

Others argue that the system is broken for precisely the opposite reason: it gives too much protection to first-movers such as Dyson, making it difficult for competitors to design rival products. Somewhere in the middle of the debate is the Intellectual Property Office, the agency in charge of registering UK patents and guiding British government policy.

The coalition government has given it greater responsibility for nurturing knowledge-based industries, from software to soft rock music.

“We're looking at how what we do affects the whole economy,” says John Alty, the career civil servant who has headed the agency since 2010.

Scrutinising applications for patents and trademarks remains the primary job of the IPO, occupying two-thirds of its nearly 1,000 members of staff.

Last month, the agency passed the

2.5m milestone when it published the patent application for a design by researchers at Liverpool John Moores University for wireless sensors to measure patients' heart rate, blood pressure or temperature.

Yet if quantity alone were a sign of success, it would be failing. The number of patent applications and approvals has fallen sharply since the late 1960s (*see graph*).

In 2008, fewer patents were granted than in any year since 1883, something only partly offset by the emergence of the European Patent Office, which grants Europe-wide patents.

However, the IPO does not judge itself by the number of patents or the speed with which it grants them.

“The most important criterion for our customers is quality. That's difficult to measure,” says Mr Alty.

Mark Jolly, a patent attorney at Brookes Batchellor, says the agency is “friendlier, faster and more reasonable” than its European counterparts.

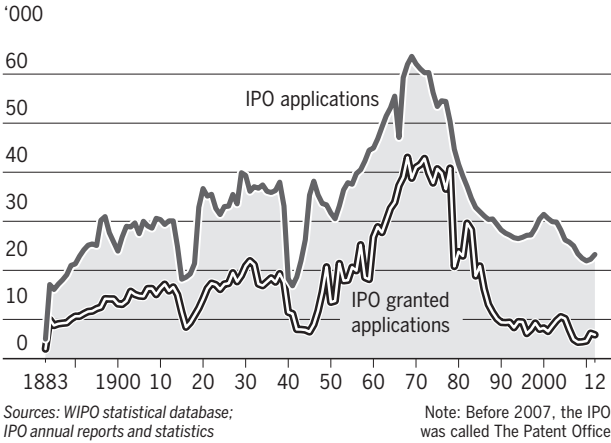
That may become important as, in Europe, companies have greater choice about whether to protect their designs through the European Patent Offices or rival national agencies.

“To a degree, we are in competition with other offices,” says Mr Alty.

Such competition has been evident in the UK government's decision to



Patent applications and approvals in the UK



James Dyson, here with his fanless heater, complains of the expense of filing and renewing patents

Pressure grows to tackle litigious trolls blighting start-ups

Battleground

David Waller finds that the actions of these entities are nothing new

In 1903, Henry Ford was sued by a patent attorney called George Selden demanding a royalty on every car sold. The action threatened to bankrupt his fledgling company, stifle innovation and hold back economic growth.

So, the “patent trolls” that blight many start-ups today are nothing new. In the 19th century, they were known as “patent sharks” and targeted farmers in large numbers, armed with patents on barbed wire and sliding gates.

But in the 21st century their impact is growing at an alarming speed and is having a profound effect on high-tech companies, particularly in the US.

A recent report by the US Government Accountability Office found “the number of overall defendants in patent infringement lawsuits increased by about 129 per cent” from 2007 to 2011.

Many of these suits involve non-practising entities (or NPEs). They are rarely the inventor of a patent and often purchase patents from existing companies or companies that no longer exist. They do not

sell products or services but make most of their money through licensing or enforcing those patents. As a result many of these NPEs are regarded as patent trolls.

The GAO report estimated that NPEs “brought about a fifth of all [patent] lawsuits” between 2007 and 2011.

Another study, by Boston University, found that more than 5,000 companies were named as defendants in patent troll lawsuits in 2011,



costing them more than \$29bn.

While the patent system can be a vital tool in the protection and promotion of intellectual property, weaknesses in the licensing process, particularly in the US, have led to the development of a complex mesh of overlapping patents.

Although the issue of patent thick-

ets was first identified in the US, concern about its global impact led to it being examined by the UK Intellectual Property Office this year.

Simon Mounteney, IP lawyer at Marks & Clerk Consulting, says: “A product, such as a mobile phone, can be protected by hundreds of patents, which means that if you control one of those patents, you have enormous leverage over the manufacturer and can extract a high price to prevent legal action that could halt production.”

The tendency to allow overly general patents, which is central to many of the problems in the US today, was also responsible for threatening to driving

Ford off the road. Selden's patent described an automobile, but later attempts to build a car to the patent's specifications ended in failure. Yet Selden claimed the patent covered every gasoline-powered car built.

After an eight-year battle, Ford won. But US companies, particularly start-ups, are likely to agree an out-of-court settlement rather than risk the costs of litigation, which may stretch to millions of dollars.

Patent trolls are a “much bigger problem in the US than the UK partly because companies can't recover costs in the US”, Matt Dixon, IP lawyer at Harrison Goddard Foote, points out. “As a result, companies that are facing legal action

often conclude that it's not worth fighting and pay up.”

Pressure is building in the US for an overhaul of the system, with Patrick Leahy, Senate judiciary committee chairman, planning to introduce legislation in coming weeks. The US Federal Trade Commission also announced a review last month of alleged abuses of the patent system, following a call from the White House to tackle patent trolls.

Although patent legislation is traditionally a federal issue, Vermont and Nebraska have used the states' consumer protection acts to fight trolls, and Vermont has passed legislation to help the victims of trolls deal with the lawsuit

in a less expensive way.

However not all NPEs can be described as trolls. Many countries, including France, Korea, Taiwan and Japan, have established state-sponsored entities that seek to monetise the intellectual property developed by companies and universities.

France Brevets was set up in 2011 and now controls hundreds of patents. It was initially focused on France, but about 10 per cent of its patents derive from other European countries, with the company anticipating further global expansion.

Jean-Charles Hourcade, France Brevets' director-general, says the organisation aims to boost innovation by monetising intellectual property in a way that benefits innovators through long-term agreements.

Although litigation over patent infringement is only taken as a final resort, Mr Hourcade says, some campaigners fear France Brevets may become an aggressive vehicle of French protectionism.

“If we defend a patent right, it can be for a French company or not and the company we are linked up with would expect us to defend their rights,” he says.

The problems in today's patent system may be more varied than the colour scheme of a Model T Ford but the protection of intellectual property and the need to combat patent trolls remains as relevant today as it was 100 years ago.

David Waller

Backlash

Tech industry watches intently as company uses anti-mafia legislation to fight alleged extortion

When the founder of FindTheBest received a letter accusing his Californian comparison shopping website company of patent infringement, he decided to fight back.

Instead of agreeing to a pre-court settlement of \$50,000, Kevin O'Connor put aside \$1m and prepared for a lengthy court battle with Lumen View Technology. Convinced his company had not infringed the patent and angered by what he regarded as the aggressive stance being adopted, he decided to turn the tables on what he sees as a “troll” by launching his own legal action.

Using legislation introduced to combat the mafia, he countersued under the Racketeer Influenced and Corrupt Organizations Act claiming extortion. The case is due for pre-trial hearing in November. It could have a profound impact on innovation.

“These patent trolls come after young companies with frivolous claims and try to bully them into settling, because they know it's cheaper to pay than to fight,” he says. “This patent troll picked the wrong company to bully and I've personally committed \$1m to right this wrong.”

Lumen View Technology could not be reached for comment.

Last month, Mr O'Connor and Danny Siegle, FindTheBest's director of operations, met senior politicians in Washington to call for reform of the patent system. They warned the current process is “killing some companies, limiting the growth of others and persuading some not to enter the tech sector” because they are afraid of legal action.

“If you are a company and the patent office issues 40,000 software patents each year, how are

you meant to know whether you have infringed one of these patents,” Mr Siegle says.

He wants organisations that wish to enforce a patent to be made to detail it in their initial letter and to explain how it has been infringed, to reduce the risk of dubious claims proving successful.

“You have no idea when they will be coming after you and they often time it so it comes after a funding round when you have capital. It is very hard to operate when you have these landmines.”

Faced with a court battle that typically costs at least \$300,000, most small companies settle when confronted with a troll, but Mr O'Connor decided to treat it as a moral issue, rather than a business decision, and fight. High-tech companies across the US are following his case with interest.

Innovation and the Economy

The factory has moved to the office

Manufacturing

New technologies that transform the way products are developed and brought to market are just the start of changes to come, reports *Sarah Murray*

From customised hip replacements to new materials, technology is opening up a range of possibilities for manufacturers. But while the advances are spawning a new breed of products, they could also spark a transformation in the business models and structure of the manufacturing sector itself.

First, technology is revolutionising the way materials and surfaces can be manipulated. Nano-engineering can create synthetic materials with new capabilities, such as better thermal conductivity. Polymers with high thermal conductivity could replace metals or ceramics, for example, while nanofluids that can transfer heat could act as industrial coolants.

In addition, computational materials science can simulate a substance's properties. "It can be synthesised and, with a reasonable degree of certainty, it will behave as we predicted," says Martin Schmidt, professor of electrical engineering and associate provost at Massachusetts Institute of Technology (MIT). "This removes the Edisonian [trial and error] approach to generating materials for products," he says.

Meanwhile, 3D printing (also known as additive manufacturing) turns digital designs into objects by building up thin layers of materials, enabling the creation of products that are much more complex than could be created simply in the past.

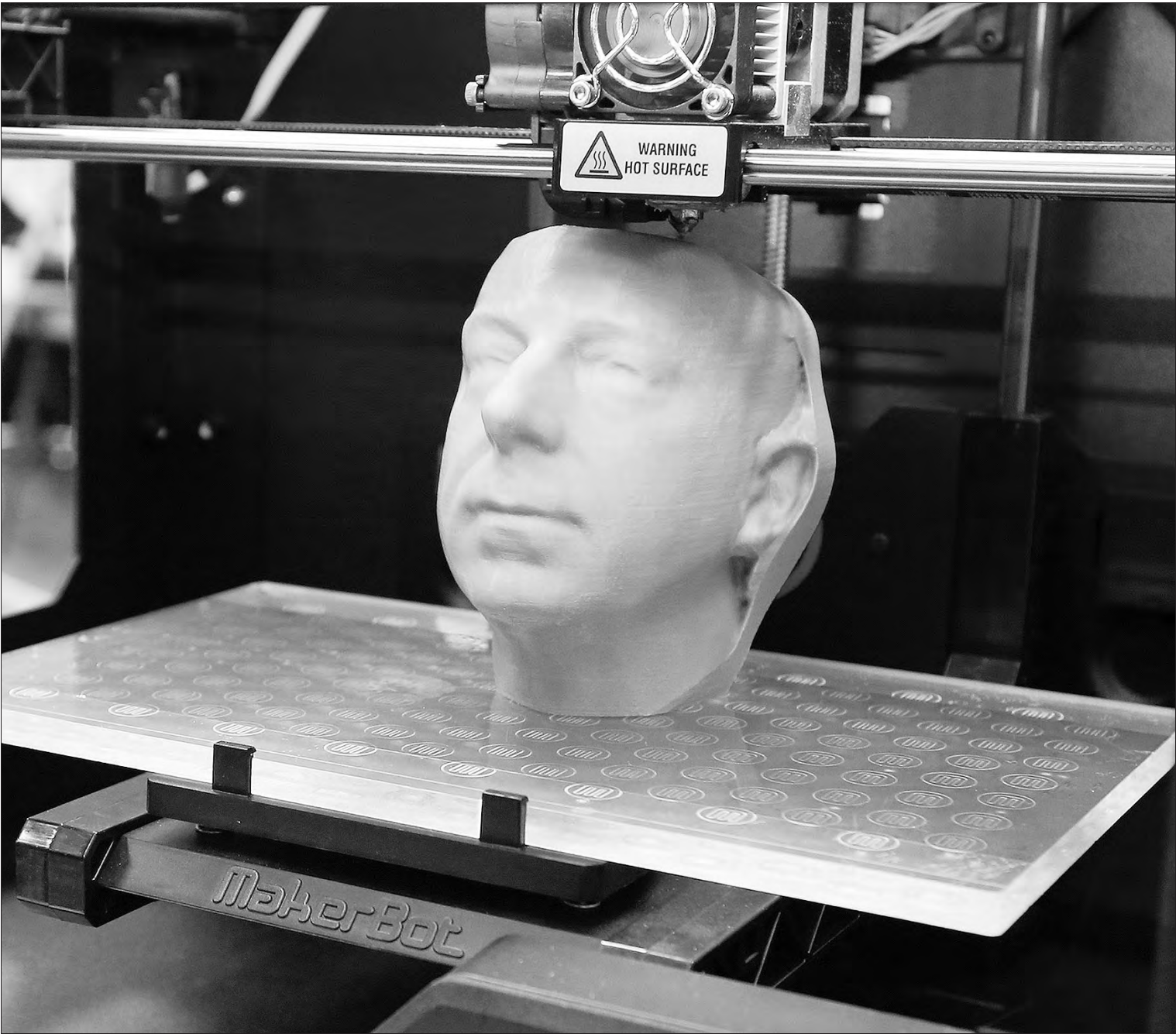
Chris Williams, director of Virginia Tech's Design, Research, and Education for Additive Manufacturing Systems lab, says: "When you do it layer by layer, you can create any shape – and from an engineering and design perspective, that's game changing."

However, 3D printing is also opening the door to designers and entrepreneurs who previously might not have had the time or money to produce prototypes.

"Digital is making things that were once really difficult really easy," says Steve O'Connor, a designer in the London office of Ideo, an innovation consultancy. "Anyone can 3D print something, so there's a democratisation of manufacturing."

Timescales between innovation and product launch are shortening and barriers to entry for innovators and entrepreneurs have been lowered.

Cultural changes paved the way for this. "What the app idea has given us is that that anyone can be a software developer," says Prof Williams. "Now



Head start: a MakerBot Replicator 3D printer

Reuters

'Digital is making things that were once really difficult really easy'

Steve O'Connor

that's the same for physical ideas."

Another advantage of 3D printing is that it accelerates the pace of the physical production process. Items that once took months to make can now be finished in a matter of hours.

This, combined with the ability to turn out short production runs, means developers can launch products, receive instant feedback and adapt the design accordingly.

"That changes the way businesses start thinking about the market and the way they compete," says Mr O'Connor.

The machines that make things are also changing radically. The advent of "human-assistive" robots, by combining their capabilities with those of humans, is creating a hybrid approach to robotics.

These robots have the ability to learn, explains Prof Schmidt. "You can take their hand, grab an object, move it to another place and set the

object down, and they will learn that function," he says.

"The high cognitive skill areas, you leave with humans. But there are areas where robots can help you."

Technology is the catalyst for another transformation – the rebuilding of an industrial landscape in which companies can turn round ideas fast.

This was possible in the past, when companies were vertically integrated, argues Suzanne Berger, a political science professor at MIT. "They had plants, lots of manufacturing specialists and cash," she says. "Getting an innovation into the market rapidly was not a problem for vertically integrated companies."

This changed with the advent of outsourcing and digital technology, which permitted web-based transfer of engineering designs, allowing the separation of R&D and production.

Now, with 3D printing streamlining

production, products can be made closer to the markets in which they will be sold. And, because of the lower costs of both 3D printing and human-assistive robotics, smaller, nimbler companies can open factories.

Prof Berger, who is author of a book, *Making in America: From Innovation to Market*, believes this could help rebuild domestic manufacturing.

Some believe technology could pave the way for even more revolutionary forms of manufacturing – with products manufactured on the way to market, inside a shipping container, say.

"You have the opportunity to convert raw materials into product in transit," says Jordan Brandt, a technology futurist in the Manufacturing 2020 Team at Autodesk, the 3D software company.

"In super-optimal supply chain, value is added at every stage in the supply chain. So, we have to rethink what 'factory' means."

Gap between the best and the rest is increasing

Assessment

Tables ranking countries for their innovation throw up surprises, says *Clive Cookson*

Measuring innovation is a growth industry in its own right, with several organisations publishing indicators to show how well countries and/or companies are performing.

Indeed, innovation measurement is so important for the European Commission that it produces two such reports. Its annual EU Innovation Union Scoreboard, published for several years, has been supplemented with an Indicator of Innovation Output, issued for the first time last month.

While the scoreboard assesses performance against a broad set of 24 innovation metrics, including inputs and outputs, the new indicator focuses solely on four outputs: technological innovation measured by patents; percentage of jobs in knowledge-intensive activities; competitiveness in knowledge-intensive sectors; and employment in fast-growing companies in innovative sectors.

The results of the indicator show Sweden, Germany and Ireland as the top three EU members when it comes to innovation. Not surprisingly, other countries in north and west Europe score highly and the poorer nations of central and eastern Europe do worst. The EU as a whole is more or less even with the US on innovation output but scores well below Japan.

The broader EU Innova-

tion Union Scoreboard gives broadly similar results to the new output indicator, although there are some differences. Sweden and Germany are again the top two, followed by Denmark and Finland.

Although the reports show the EU as a whole improving its innovation performance year on year, this overall gain conceals a widening gap between the best performers and the laggards, some of whom are making little or no progress.

On the global level, a collaboration between Insead (the international business school), the World Intellectual Property Organisation and Cornell University publishes an innovation index that ranks 142 countries on no less than 84 indicators.

This too shows a gap growing between rich and poor nations. Although the

top 10 and indeed the top 25 in this Global Innovation Index 2013 are the same as last year, their relative positions have changed. The top two are still the same – Switzerland and Sweden – but the UK has, perhaps surprisingly, moved into third position. Britain does not rate so highly in the EU's innovation rankings. Biggest upward mover is the US, from 10th last year to fifth this year.

One reason why the gap between the top 25 innovators and the rest is increasing, according to the

'The elements required to develop the talents around innovation have yet to be defined'

authors, is that innovation success leads to a virtuous circle, where investment attracts further investment and talent. Poorer countries are having a hard time catching up from their lower financial base.

Bruno Lanvin of Insead says: "Beyond the obvious ingredients for innovation – public, private investment, education and R&D – there is an ecosystem that needs to be built around factors that may be more difficult to define and measure, which have to do with the fact that innovation is not just the result of innovation, but it's also a mind-set."

He adds: "The elements required to develop the talents around innovation, the degree of co-operation, have yet to be defined and measured."

Meanwhile, Thomson Reuters assesses innovation

at the level of companies rather than countries.

Its Global Top 100 Innovative Companies report is a list, based mainly on patent analysis, rather than a ranking, but interesting deductions can be made about national performance – some at odds with other innovation measurements.

For example, the Thomson Reuters list includes no British companies while there are 12 French companies, more than from any other European country. Yet, France only appears at number 20 in the Insead/WIPO/Cornell index, while the UK is third.

Although differences in methodology can explain some of the discrepancies, the science of measuring the mysterious ingredients that make up successful innovation still has a long way to go.

Question of trust depends on openness

Commentary

ANNE GLOVER and JAN MARCO MÜLLER

Do you trust business? Which societal groups do you trust most? Usually scientists and doctors rank very highly in opinion polls, while industry turns up near the bottom.

Journalists and politicians rank even lower, but still the polls reflect a widespread uneasiness when dealing with industry and business generally. Such views damage the climate for innovation.

There is a widespread belief that publicly funded research is "good", while industry-funded research is "bad". The latter is not seen as impartial, even if industrial researchers publish in the same peer-reviewed journals as academics, often in partnership with researchers from universities.

Lately, the contacts scientists have with industry have come under scrutiny. There has been increasing pressure from NGOs and lobby groups asking that scientists "with industry relations" should be excluded from advisory panels of the European Commission and its agencies, such as the European Food Safety Authority (EFSA) in Parma or the European Medicines Agency (EMA) in London, saying that they would not be able to act as independent experts.

It has been research policy for many years, and rightly so, to foster relations between industry and academia to bring these two worlds closer together. Only through such dialogue can we accelerate the transfer of knowledge to the market to create products for a better life and raise European competitiveness.

It is one way to ensure taxpayers get a return on their investment in academic research.

Removing scientists who work with industry from advisory panels would not only demotivate them to work with industry and to provide advice, but it would also cut off expertise we need to develop evidence-based policies.

At the bottom of all of this is a fundamental mistrust of industry and industrial R&D by society – and this mistrust is increasingly hampering our ability to innovate.

We trust industry where it suits us: in the toothpaste we use, the pizza we buy or the car we drive. But people seem to have a problem in trusting industry when it comes to influencing policy making.

Why is this so?

A large part of the problem is rooted in the way industry has behaved and – partly – continues to behave when doing business and talking to the public. One example is the debate about genetically modified organisms. If we dissect the anti-GMO arguments, it appears that most Europeans do not have a problem with GM technology per se – taking a gene from one place and putting it in another. We have done this for



Anne Glover: transparency

millennia, albeit on a trial and error basis, we just called it selective breeding.

The problem people have with GM seems to be more one of business ethics. It is about multinational companies controlling our food and showing aggressive marketing behaviour. There are similar examples in energy and pharmaceuticals.

If this is the problem, let us talk about it – and here we expect industry to engage with its critics and examine its practices.

Society, which pays for research, should have a say in how it is used. And we expect the same from NGOs.

We need transparency on all sides. With freedom of information legislation, ombudsmen and formal public engagement procedures, the public sphere has done a lot to be transparent.

Science has led the way, because publishing based on peer review is a fundamental principle. Yes, there can be actual or perceived conflicts of interest in a complex world. But there are also

There is a belief that publicly funded research is 'good', while industry funded is 'bad'

clear ways of handling them, such as declaring them in a public manner. It is not rocket science.

When was the last time you used Wikipedia? If you trusted the information, did you read who wrote the article and try to find her or his conflict of interest statement? No, you did not. In fact, there are no such statements on Wikipedia and you cannot see whether the article was written by an industry representative, a scientist or a high school student.

We trust it because it is open to all, and we believe that the collective brain is able to sort out the misinformation (which also exists on Wikipedia).

So why not apply this principle to policy making without any taboos as to who contributes? That is what we would call "open policy making".

Anne Glover is chief scientific adviser to the president of the European Commission, and Jan Marco Müller, is assistant to the chief scientific adviser

Biosimilar drugs show the copycats keeping up with creators

Pharmaceuticals

A new market is opening up in complex generic biological drugs, says *Andrew Jack*

In the next few weeks, a long-heralded disruptive pharmaceutical event will become reality, when Hospira launches a drug across Europe to treat rheumatoid arthritis.

Yet the US-based company's Inflectra will not be a new product. Instead, it represents a different sort

of innovation: it is the first generic complex biological medicine, providing health systems with a "biosimilar": a lower-priced equivalent to Merck and Johnson & Johnson of the US's blockbuster Remicade.

It also highlights the evolving global nature of the industry, since the underlying producer of Inflectra, and more than half a dozen prospective biosimilars in the pipeline, is Celltrion, a South Korean company that licensed the drug to Hospira.

While "small molecule" chemical drugs have long been generic, and some simpler biologicals such as insulin and human growth

hormone have already been approved in many parts of the world, Inflectra is a monoclonal antibody, a far more sophisticated product.

It is the first in a series of such molecules approved by the European Medicines Agency that collectively represents a significant commercial threat to the products that original drug developers long shielded from the aggressive generic price competition faced by chemical-based medicines.

Paul Greenland, Hospira's vice-president for biologicals, says: "This is a momentous occasion. It's a big day for Hospira and it sets the scene for the future for biosimilars globally."

Some "originator" companies have cautioned about the economic threat to innovation from generics; others have warned of the risks to patient safety, since biological copies are never identical.

Their lobbying has helped delay finalisation of a "pathway" for approval by the US Food and Drug Administration.

Even so, it seems biosimilars will not offer the same threat of price erosion as more traditional generics.

In Europe, regulators have approved Inflectra without requiring Hospira or Celltrion to conduct full clinical trials to show equivalence for each "indi-

cation" or medical application for which Remicade was originally approved.

Nonetheless, the manufacturers had to carry out extensive trials in patients for the pivotal application in rheumatoid arthritis, raising the entry barrier far beyond the requirements for chemical drugs.

Hospira will also have to market Inflectra to doctors, and monitor its use to identify any potential differences in safety compared with Remicade. Such higher costs, Mr Greenland hints, will mean relatively modest price discounts of only 20-25 per cent on Remicade.

The costs and other hurdles mean that a number of

generic companies appear to have slowed their progress in developing biosimilars.

So too have some of the originators. Merck, which originally pledged to develop "biobetters" or enhanced versions of its own biological drugs, has been slow to show progress.

'Given the cost of development, no one will have the money alone'

Paul Bisaro
Actavis

But other companies have forged partnerships more actively. Sandoz, one of the world's largest generic companies, has the benefit of its Swiss innovator parent Novartis to help support biosimilar developments.

Amgen of the US has linked with Actavis, a large generics company, creating a joint venture for the production of four biosimilar monoclonal antibodies. Each party invested \$400m.

Paul Bisaro, head of Actavis, says: "Given the cost of development, no one will have the money alone. We've assumed \$200m per biosimilar product, compared with \$2m-\$15m for a normal generic."

Yet there is still much potential for newer monoclonal antibodies, offering sales growth to replace the first generation.

For example, Edwin Moses, head of Ablynx, a British biotech company that has formed partnerships with AbbVie, Boehringer Ingelheim, Merck, Merck Serono and Novartis, highlights the scope for his company's smaller nanobodies platform technology for a range of monoclonals.

They can further boost efficacy, reduce toxicity and be cheaper to produce.

Despite copycats, competition in biologicals is still spurring innovation across the drugs sector.

Innovation and the Economy

Kremlin seeks to monetise the field of science

Russia Linking R&D to enterprise challenges the centralised state, reports *Isabel Gorst*

Change is coming to the 289-year-old Russian Academy of Sciences. Once famous for work that won it 18 Nobel Prizes and helped put the first man in space, the Academy has failed to keep up with the times. A law rushed through last month transferred control of the independent RAS and its real estate portfolio to a government agency. Many academicians protest that the law is no more than a state land grab, but even they admit that reforms are overdue.

Since the Soviet Union's demise in 1991, many of its best scientists have taken better paid jobs abroad. Those who remain have struggled to adapt to the new economic order, where brilliant ideas are valued only if they translate into profitable ventures.

"Russian scientists need to learn how to commercialise their inventions," says Leonid Melamed, a former scientist and chairman of Team Drive, a management company focused on pharmaceuticals. "It's the missing link in Russia's drive to innovate."

The country faces a huge challenge to modernise its \$1.9tn economy and reduce dependence on oil and gas resources that, although substantial, will not sustain long-term growth.

The Kremlin has launched a series of high-profile initiatives including Rusnano, the state nanotechnology company, and Skolkovo, a technology park on the outskirts of Moscow.

Founded in 2007, Rusnano aims to develop nanotechnology and high technology in Russia.

Led by Anatoly Chubais, architect of Russia's mass privatisation programme in the 1990s, the company has committed Rbs161.3bn (\$5bn) to microelectronics, healthcare, energy and machine building among others.

Priority is given to projects that transfer technology to Russia and boost research and development, says Sergey Filippov, its spokesman.

One of its biggest endeavours is a \$760m joint investment with Domain Associates, a US venture capital company that specialises in medical technologies. Launched in 2012, the partnership buys equity stakes in US life science companies that pledge to conduct trials in Russia and transfer intellectual property rights for medicines they develop. Mr Melamed, whose Team Drive is involved in the partnership, says the rate of return on innovative pharmaceuticals is high, thanks to strong demand in Russia.

Government tax incentives and other privileges have persuaded foreign auto, agricultural vehicle and shipping groups to establish manufacturing bases.

Responding to a health ministry pledge to buy locally made medicines, pharmaceutical companies including Novartis and Sanofi-Aventis are building plants and R&D facilities.

Skolkovo shares the same goal as Rusnano of spurring Russian innovation, but instead of equity investments it provides grants to start-ups involved in information technology, biomedicine, nuclear technologies, energy saving and space.

The idea is to build bridges between science and innovative enterprises by bringing together inventions, research and development, venture capital, and business education.

Thanks to state incentives, Cisco and Siemens are among those that have committed to establish R&D operations at the techno-park.

Ideally, Skolkovo officials say, the Russian Academy of Sciences should collaborate in R&D programs, but



New era: the Russian Academy of Sciences
Dreamstime

Scientists need to learn how to commercialise their inventions. It's the missing link in Russia's drive to innovate

Doctor prescribes boost for biomedicine in EU

Medicine
Partnerships fund helps keep research at the cutting edge, writes *Andrew Jack*

Michel Goldman, a Belgian doctor, set up the Institute for Medical Immunology in 2004 to build bridges between academia and industry in Wallonia. A decade later, he runs an organisation with the same initials pursuing similar goals on a far more significant scale across Europe.

The Innovative Medicines Initiative (IMI) aims to create EU partnerships to boost biomedical projects. As it makes the case for fresh funding from the start of next year, it can already point to some achievements with global impact.

IMI has used EU funding to gain support from academic institutions and pharmaceutical companies across Europe, so they can collaborate on projects that would otherwise prove too difficult or costly.

Industry and the European Commission each pledged €1bn, and 42 projects involving 4,500 scientists got under way, resulting in the publi-

cation of more than 300 academic papers to date.

The plan was to build on Europe's strength in medical and pharmaceutical innovation, reinforce its position as a centre of research and development, and prevent a brain drain of expertise and investment to other parts of the world.

Mr Goldman says he is particularly proud of two projects: a programme on autism that has developed a clinical trial network, an animal model and possible drug "targets" for the condition; and the European Lead Factory, which shares and tests compound libraries of experimental medicines to assess their potential efficacy.

"The fact that IMI has been shown to be workable in Europe is helping others to reflect," he says. He points to interest in other parts of the world, including the US and Japan, in starting similar projects.

IMI remains focused on early-stage research to identify promising approaches to diagnosis and treatment, ahead of the "competitive" stage when companies develop experimental medicines and test them in patients before marketing approvals and sale.

But the organisation has recently branched out to support

clinical work where the scientific challenges are high and the financial incentives for companies are modest, including Combacte, a programme to tackle antibiotic resistance. IMI also works with the European Medicines Agency and others on post-launch surveillance of vaccines. Ironically, many of the drug companies, which are fiercely competitive and defend their intellectual property rights aggressively, have lined up to work on IMI programmes. Indeed, some of the more vocal critics have been academic institutions.

The League of European Research Universities has expressed concerns that IMI funding does not cover the academic partners' full direct costs or overheads – drug companies also have to contribute significantly from their own resources. The League has also cautioned over the loss of control of researchers' intellectual property rights.

This year, Italy's Mario Negri Institute pulled out of its planned participation in Combacte, because it felt it did not have sufficient control over trial design, access to data or freedom to publish on an experimental drug that GlaxoSmithKline planned to use in tests on patients. Other academic partners have been more positive, stressing that, the benefits of partnership in a Europe-wide network and accelerating work on antibiotic resistance outweigh the drawbacks. Such reactions gave Mr Goldman hope that IMI will be able to proceed with enhanced funding from the European Commission as well as its industry partners totalling €3.5bn in a second iteration beginning in 2014.



In focus: medical research

University ties with industry offer mutually assured development

Collaboration
Changes to licensing intellectual property have given a fillip, says *Nuala Moran*

Intellectual property (IP) is the spring of innovation, but can be one of the greatest obstacles to collaboration between academe and industry and commercialisation of publicly funded research.

At issue are how to put a price on early-stage university IP that requires significant financial investment to realise its value, and who owns IP arising from collaborative research.

Universities may complain they are being short-changed while companies renege their expectations are unrealistic. For some, the crux is that the universities place the emphasis on using IP as a revenue source, rather than a way to forge collaboration with industry.

Removing money from the equation can help, as shown by a scheme introduced in January by the University of Manitoba in Winnipeg, Canada. IP arising from collaborations is made available with no upfront fees, in return for royalties on any products that make it to market.

Since then, "the language has changed" says Digvir Jayas, vice-president of research: "Before, companies perceived it as difficult to work with the university; now, they are much more enthusiastic."

A similar initiative, Easy Access IP, has been adopted by 18 universities in Europe, Canada and Australia since it was devised by the University of Glasgow in 2010.

Alison Campbell, who was responsible for King's College London joining the scheme and is now director of the Central Technology Transfer Office in Ireland, says such measures change the culture and provide a channel for universities to make better use of the results of research.

"The key message is: industry finds it easier to engage. Companies like what Easy Access IP is doing, and it is underpinning new and more constructive relationships," Ms Campbell says.

Critics of Easy Access IP say that IP is only made available under the scheme if technology transfer offices have failed to find someone to buy a licence.

But Ms Campbell says the rights on offer are more likely to be for early-stage research that requires significant investment to reach the point where it will attract private capital.

Offering such IP without charge represents a readiness to make better use of research outputs to stimulate commercialisation.

Ms Campbell says: "It gives the signal that universities want to be involved in innovation and opens the door to industry to explore collaborations."

Under Easy Access IP, rights are granted in a standard, one-page agreement. To date, 60 per cent

of approaches from industry have been converted into licences, as opposed to 30 per cent before.

"It is introducing efficiency into the system," says Ms Campbell.

And such improvements are needed, according to the House of Commons Select Committee on Science and Technology, which said in a March 2013 report, "Bridging the valley of death: improving the commercialisation of research", that there are not adequate mechanisms in place for leveraging academic research to provide economic benefits.

IP is made available with no upfront fees, in return for royalties on any products

The question of how to promote strong university-industry links is under study in an investigation led by Andrew Witty, chief executive of GlaxoSmithKline (GSK), the pharmaceutical group. Interim findings published in July said "universities can play a stronger role in realising the economic benefits of research insights".

There is a lot of experimentation going on to find more productive ways of collaborating and GSK is a prime exemplar. GSK's collaborations include Cambridge university scientists

coming to work in the company's laboratories; a joint project with AstraZeneca investing £3m over three years to fund Manchester University's Collaborative Centre for Inflammation Research; an EU Innovative Medicines Initiative project to develop new antibiotics; and an open competition in North America in which academics submit ideas for drug discovery projects, with the winners gaining access to the company's resources and expertise to take projects forward.

Big companies such as GSK have the reach to collaborate with many institutions. For small and medium enterprises (SMEs), it can be hard to tie up with one, but most of the 31 licences under Easy Access IP since 2010 are with SMEs. "They have been able to get access in a swift and easy way that has really added value," Ms Campbell says.

David Baynes, chief executive of Fusion IP, a London-listed university technology commercialisation company, notes that some institutions fear pressure to increase the intensity and time spent on corporate relationships risks reducing research universities to a supporting role in industrial strategy, but says they are paying more attention.

"Part of the academic community is more interested in pure research and finds collaboration a distraction, and that's fair enough. But there is now a bigger portion of academics interested in collaborating with industry," he says

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