review IP

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Inside...

Is this the real life?

A new generation of Augmented Reality (AR) technology

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Contents

Welcome to the Autumn 2017 edition of IP Review

In this edition we've focused on emerging technologies and the ways in which innovators can protect their developments in these areas.

Our main article takes a detailed look at Augmented Reality (AR), which is fast becoming part of everyday life, as foreshadowed by last summer's Pokémon GO! craze. We've looked at patent filing trends and what they might tell us about how this industry might develop. Look out for a follow-up article next issue.

Elsewhere, we try to demystify Blockchain, a technology that has seemingly come from nowhere and is now on the verge of breaking through to the mainstream.

We've also been considering developments in the field of social robotics, another technology that could soon be impacting all of our lives, and ask how innovators can protect features of robot personality within the framework of European patent law.

We also look at potentially life-saving advances in precision medicines, and recent developments in smart grid technology.

We hope you enjoy the issue.

Matthew Howell
Editor

Augmented Reality

Is this the real life?

Augmented Reality (AR) is a technology that has been around for decades, but only in recent years has it managed to break through to mainstream audiences, ultimately on the back of massive advances in smartphone technology. However, AR is still far from reaching its limits, with tech giants Intel and Microsoft pumping resources and funding into the development of a new generation of AR technology.

Here we look at the current state of the art in AR, who and where the major players are and how we might expect to see this technology develop in the near future.

What exactly is AR?

Most of you will be familiar with Virtual Reality (VR), a technology which involves full immersion into an entirely computer-generated fictional environment. AR, in contrast, involves overlaying virtual objects on a real environment. What you see as a user is therefore a combination of your real environment and what the AR application adds to it.

An early adopter of AR was the aviation industry, where head-up displays, which overlay navigation information onto an aircraft pilot's field of vision, are common.

Fast forwarding to the present day, technology has developed to make AR easily accessible to anyone with a smartphone. Take for example the popular Pokémon GO! game released by Niantic in the summer of 2016, which made it entirely normal for us to be walking around catching virtual critters. On the social media side, Snapchat has made its dog filters (amongst others from its renowned set of facial lenses) and dancing hotdogs into an increasingly common form of social communication.

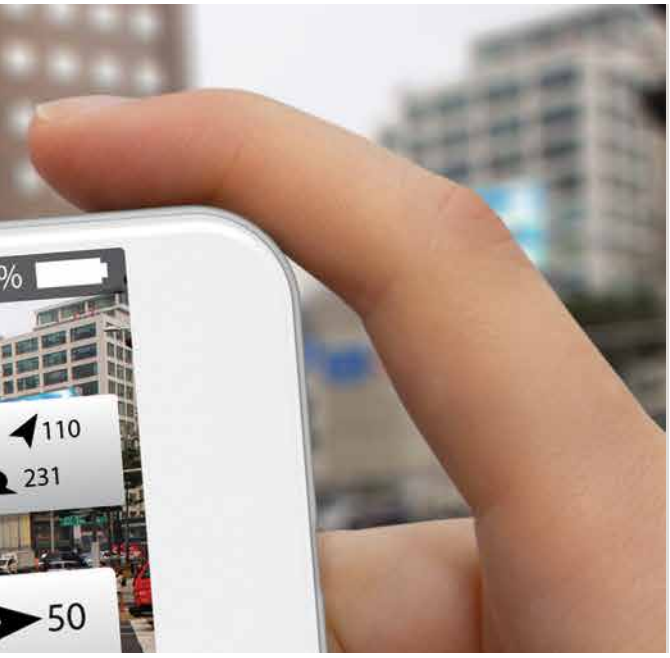
...Is this the real life?

This type of application falls into the handheld/mobile device domain of AR, where developers effectively make best use of our ubiquitous, camera-equipped smartphones to deliver content. With the breakout success of these applications, it will come as no surprise that mobile devices are driving an overall forecasted annual growth in AR of over 50%.

Further innovation

The drive to innovate for new handheld/mobile device AR applications looks set to continue, with new players coming to the party. In the last year we have seen Facebook following Snapchat's success, with the launch of its new AR Studio, which allows for the creation of similar filters to be used on Facebook Messenger. Although the scope of handheld/mobile device AR is considered to be much more than gaming, social media and marketing applications, its ability to thrive is effectively bottlenecked by its own foundations - the smartphones themselves. Companies such as Layar and Wikitudes have long been developing AR browsers - a class of application that shows points of interest as users browse their surroundings through the lens of their phones. However, applications of this type have had a relatively low adoption rate, perhaps because of limitations in their implementation on smartphones. Hence, in order for application developers to make more meaningful, new and exciting content, the right hardware and software platforms need to be in place and accessible to developers.

This in turn invites more significant technological developments such as Google's Tango development platform. The Tango development platform is primarily concerned with enabling computer vision and position/orientation tracking on mobile devices for the purpose



> The large amount of investment and development in the head-mounted display domain has made it quite the wellspring for innovation.

of AR, and is designed to run as a standalone platform using only the devices' on-board sensors and without the use of GPS or other external signals. Already featured on Lenovo's Phab 2 Pro smartphone, the Tango platform effectively handles some of the more technically complex tasks associated with executing AR applications, and will therefore allow for the development of more complex AR applications on mobile devices. This may involve indoor navigation, 3D mapping and environment recognition. This type of development platform will also complement developments in smartphone hardware, where we are likely to see the introduction of depth sensing cameras and more powerful graphics processors.

The future's mixed

Although mobile device AR is currently forecast to be one of the next big things for smartphone tech, it lacks the immersive experience that has been promised to us through countless fictional depictions of AR (e.g. Tom Cruise desperately sifting through virtual screens in The Minority Report). But, similarly to how Star Trek's Personal Access Display Device of the 80s has now become reality in the form of today's tablet computers, a more immersive AR, or mixed reality, is now on the horizon, with the development of head-mounted displays (HMDs) being a domain of rising interest.

Companies working in the HMD domain are focused on creating new hardware platforms that are capable of delivering a mixed reality experience that is a step ahead of "normal" AR.

Mixed reality involves visualising and interacting with virtual objects as though they are part of the real environment. Generally speaking, mixed reality needs a transparent electronic display positioned over a user's eyes, which is then used to display virtual objects over the user's field of vision. Users can control these virtual objects as though they are part of their real surroundings using gestures or other control means.

Although HMDs are currently expensive and out of reach for most of us, they are expected to commercialise in the next 5 years or so as a result of the large investment that has gone into this area in recent years by the likes of Alibaba, 21st Century Fox and JP Morgan. As a result of this investment, the commercialisation of HMDs is expected to break AR into a wider range of application areas including education, healthcare, design and engineering, analytics and entertainment.

A large number of established companies and start-ups are working in the area of HMDs. Some of the biggest players include Microsoft, with its Hololens, and ODG, with its own range of smart glasses. Both of these technologies use the same concept of having a user look through a transparent monitor that displays virtual objects.

In contrast, Magic Leap is known to be developing a HMD that instead uses light field technology to deliver AR. Rather than displaying virtual objects on a transparent screen, this works by projecting light directly into a user's eyes to mimic how we perceive light from real objects. This organic method of visualising virtual objects is expected to create a much more realistic and immersive mixed reality experience, since it can overcome barriers surrounding depth perception and general realism, eventually allowing us to interact more realistically and intimately within an AR environment.

In addition to these methods of AR delivery, HMD developers are also continuously improving on lower level functionality such as environment and body tracking, spatial audio, hardware specifications and other components that are essential for mixed reality applications.

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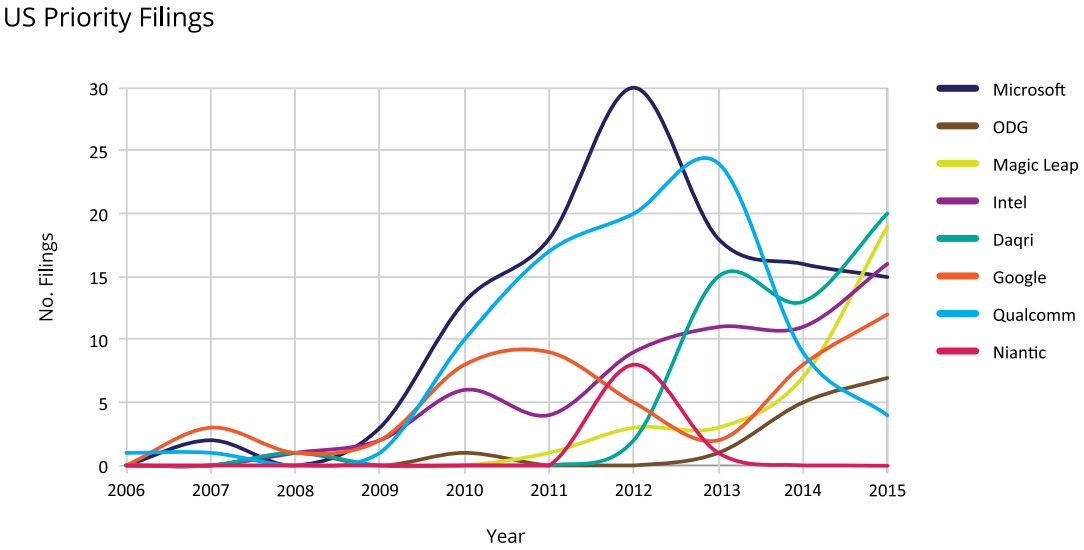
Patent trends and key players



As expected, the large amount of investment and development in the HMD domain has made it quite the wellspring for innovation. This is evident from an examination of the patent filings of some of the major companies involved, as shown in the graph above.

Microsoft dominated the early stages of innovation in AR, with an initial spike in published priority patent filings in 2012. At that time there was no published activity from ODG, but it is now known that it had many patent applications in the pipeline, because almost 100 patent applications were assigned to Microsoft in early 2014 in a multi-million dollar deal. This IP acquisition by Microsoft may have been key to the development of the Hololens, which was announced in 2015.

ODG has nevertheless continued its own development of a range of smart glasses and has continued filing new applications, as can be seen from the increase in its published priority patent applications from 2013 onwards.

In the meantime, 2014 onwards saw a significant rise in priority filings from Magic Leap, following funding rounds in 2014 and 2016 that resulted in over one billion dollars in total investment from investors including Google, Alibaba and Morgan Stanley - one of the largest investments in AR technology to date.

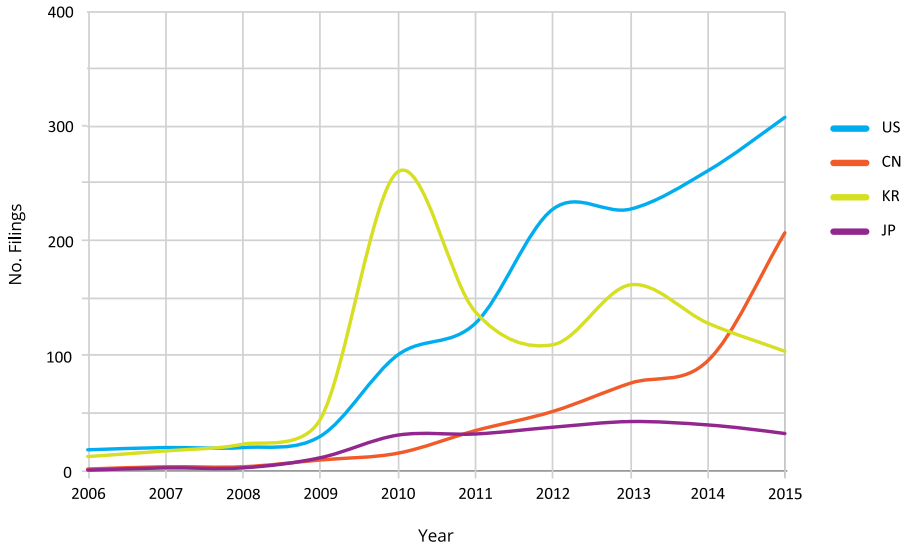
Approaching 2015, there appears to be an overall increasing trend in priority filings for AR-related patents, at least in the USA, which goes hand in hand with the increasing investment in AR technology across the Atlantic. In the HMD domain, this comes from most of the companies previously mentioned, with additional activity from Intel, which has a hand in HMD developer Recon Instruments, and Daqri, with its development of industry-centric HMDs.

The range of subject matter for which patent protection is being sought in the HMD domain varies greatly, as might be expected.

For example, Microsoft has a number of filings related to the actual headgear, including an "eye relief adjustment mechanism" and a "mixed reality headset" which broadly describes a head mounted device with a transparent screen. Elsewhere there are patent applications for "grasping virtual objects" and "tracking hand/body poses".

Magic Leap is active in similar areas, but distinguishes itself from the competition due to its fundamentally different way of delivering AR to a user. Hence, we see filings from Magic Leap for innovations in iris imaging, Fresnel projection, diffraction gratings, and eyelid shape estimation, which have all evolved from its activities in the area of light field technology.

AR Priority Filings



On the mobile device side, Google has been one of the largest contributors to increasing numbers of patent filings in the USA. This could be attributed to the development of its Tango platform. Up until 2013, Qualcomm was also a major filer of AR-related patents, which may have been related to its Vuforia mobile AR software development kit. Since then Qualcomm's AR-related filings have since dropped off, perhaps as a result of the sale of Vuforia to PTC.

This patent filing data only crudely relates to "augmented reality" patent filings, and so does not necessarily capture some of the fundamental enabling technologies driving the mobile device AR domain forward such as AR-centric chips that are being developed by Qualcomm, AMD, Intel and Nvidia, as well as general developments in smartphone hardware that may not necessarily have been explicitly directed towards "augmented reality" at the time of patent filings.

Interestingly, there are very few recent filings from end-application developers such as Niantic, which may either be due to the current innovation trend being placed in other areas, or the difficulties inherent in patenting innovations in software.

Geographical spread of innovation

Taking a geographical view, priority patent filings for AR-related technology here have soared in China in recent years, being led by Chinese smartphone manufacturer Oppo. Further AR-related filings come from Huawei and Lenovo, indicating that China may be helping to drive the growth of the mobile device domain of AR.

South Korea saw surges in 2010 and 2013 which were also led by telecoms companies such as Samsung and LG, as well as the likes of Hyundai, which has been working on a mobile phone application to act as an AR user's manual for their cars.

Meanwhile, Japan has seen a relatively static level of AR-related filings over the last several years, but is in fact home to a handful of companies working in this area. Some of the top filers include Sony, Canon and Seiko Epson, which are all working in the field of HMDs, and Nintendo, which has been working to include AR applications on its 3DS gaming console. Magic Leap has also made some filings there in the last few years.

Conclusions

The AR industry has recently seen large amounts of investment and high market growth predictions, with the mobile device domain leading the trend. The HMD field follows closely as it begins to flourish towards commercialisation for use in a handful of new industries. The increasing amount of innovation in AR technologies is reflected in the corresponding surge in priority patent filings, especially in the HMD domain.

Although it is difficult to pinpoint what is happening using patent filings alone, we can infer from the data that smartphone and related hardware manufacturers are supporting the growth of mobile device AR, by beginning to provide the hardware and platforms for more AR-capable smartphones. This will enable application developers to begin to create a new generation of exciting AR content. US innovators lead the way, but China is ramping up investment and patent filings apace.

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Getting smart with clean technology

An upturn in innovation activity in the area of Smart Grid technology in Europe is signalling a positive development in clean energy generation and distribution. This activity is helping to establish the infrastructure necessary to support an increasing number of large scale energy projects as well as a growing number of localised energy producers.

Smart Grid technology is an umbrella term for interrelated technologies with the common aim of improving existing energy networks. It covers more efficient and flexible energy generation, storage and distribution, and allows consumers to control their personal consumption better. A Smart Grid has the ability to manage a diverse input of energy sources, including renewables like wind, solar, and hydropower, as well as more conventional carbon-based and nuclear fuels. Furthermore, increased interconnectivity and efficient energy storage allow Smart Grids to connect better with the maturing arena of distributed power generation, easing the pressure on central providers.

With the number of patent filings in the area of Smart Grid technology more than doubling in the last three years, we're seeing a strong and sustained increase in R&D and investment as Smart Grid tech continues its transition from the concept stage to a developing marketplace.

Moreover, as energy generation and harvesting technologies become increasingly reliable and accessible, a growing number of individuals and SMEs are entering the marketplace with their own smart solutions, ranging from intelligent thermostats and smart meters to home batteries and generators.

The growing prevalence of de-centralised energy generation calls for an energy distribution infrastructure that is capable of accepting energy from many different sources, storing it efficiently and effectively, and providing it where and when it is needed.

In order for this technology to fulfil its potential, all aspects of the Smart Grid initiative need to evolve together. Supply side innovation needs to keep pace with new developments in the distribution and consumption of energy. For example, without establishing solid communication

lines between homes and power stations, consumers do not have the ability to share usage data collected by a new generation of smart meters. Equally, without advances in energy transport infrastructure, the proliferation of micro energy generation will go unutilised.

Happily, the United Kingdom is leading the way in large scale renewables projects and Smart Grid rollout. A recent government white paper on smart energy investment provides a map showing investment levels in Smart Grid related projects throughout Europe, with the UK at the top of the list, having numerous bodies distributing grants across the whole spectrum of Smart Grid technologies.

More recently, the UK government announced a shake-up in the rules regarding net metering, the mechanism that compensates users who generate some or all of their energy, with the hope of encouraging further investment in this area. At the same time, a newly founded UK Battery Institute is set to award hundreds of millions of pounds in funding to companies undertaking major research in energy storage, capitalising on the rapidly falling cost of battery technology.

Whilst this is good news for users and innovators, the rapid pace of innovation could falter unless care is taken to ensure that this key area of technology continues to develop in a cohesive manner. The question is, how can this be achieved when most innovators view the rest as the competition?

Just as the automotive industry has seen new players drawing market share away from household names, the clean energy sector is experiencing an explosion of SMEs with new and exciting ideas.

But whilst these new kids on the block have the freedom to be daring with their innovation, the financial and logistical realities of rolling out new technologies across a national energy grid are a significant issue – and one that can only be solved by collaboration.

Whether it's multiple smaller entities banding together, or a newcomer pairing up with an established energy provider, resources and technical know-how are being shared on a scale never seen before in this industry.

Whilst it may seem counterintuitive, it's during these collaborative phases that intellectual property plays a vital role.

Before entering any collaborative agreement with a third party or consortium of partners, innovators need to be clear about who owns any existing intellectual property rights and, more importantly, who will own any IP that might be developed in the future as a result of the collaboration.

Further, securing IP rights early on allows SMEs to enter into partnerships with larger partners on a more equal footing, and having substantial IP assets makes them more attractive to investors and/or potential buyers.

At the same time, securing the rights to one's own IP needn't be seen as wholly self-serving. Tesla's well publicised patent give away (discussed in our Autumn 2015 issue), for example, saw the company grant a blanket royalty-free licence to their patent portfolio, opening up the electric car market in an effort to encourage further innovation and a shared investment in an energy infrastructure that will in the end make Tesla's own products more viable.

Patents can therefore be seen as valuable assets to Smart Grid companies of all sizes, and, far from stifling innovation, can provide companies the assurances and freedom to work together for everyone's benefit.

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Blockchain

New kid on the block

Over the past few years a new buzzword has entered the public consciousness: Blockchain. This rapidly developing technology has the potential to alter radically the way that business is done in a huge range of sectors.

At its heart, a blockchain is a distributed digital ledger for storing an effectively immutable record of data. At first, this may seem insignificant: something that only accountants and bankers would be interested in. However, many commentators believe that the transparent, decentralised nature of blockchain has the potential to revolutionise the global economy, changing the world of data management and trust in the same way that the internet revolutionised the sharing of information in the 1990s.

What is blockchain?

To understand blockchain and its potential, it is worth first considering how traditional transactions and ledgers work. Transactions typically require trust between the parties to the transaction. For example, when transferring ownership of a house, the buyer must trust that the seller owns the house and the seller must trust that the buyer is properly paying for the house. To facilitate trust, transactions are typically verified by a trusted central authority, such as a bank or government, and recorded in a centrally controlled ledger (such as a land registry, a bank account, etc). The accuracy and trustworthiness of the ledger is dependent on it being controlled by the trusted central authority.

However, there are a number of shortcomings to the traditional model. What if the trusted central authority turns out not to be trustworthy? What if transactional speed is essential and the delays and red-tape of central authority verification are intolerable?

What if there is no central authority that is trustworthy? Blockchain has the potential to overcome these problems by using a distributed ledger to cut intermediaries out of the transaction process and enable trustworthy, peer-to-peer transactions to take place.

A distributed ledger is one that has no central control. Anyone may see its contents, post transactions to be added to it, verify its contents and verify new transactions before they are added to the ledger. By utilising complex cryptographic processes, it is almost impossible to alter the historical content of a blockchain, and new transactions may be verified by participants to the blockchain using a "consensus mechanism" before they are added to the blockchain. Consequently, control and authentication may be reliably removed from a central authority and distributed to all of the participants to the blockchain.

How is it being used today and what does the future hold?

The first and most famous use of blockchain is the cryptocurrency Bitcoin. This is where the concept of a blockchain was first proposed in 2008 and then implemented in 2009. Since then, almost 1000 different cryptocurrencies have been launched, and whilst at present cryptocurrencies are the most widespread use of blockchain technology, its potential has been quickly realised and exploited in a wide range of other sectors.

Brooklyn Microgrid, for example, is an organisation that is establishing a blockchain-based electricity microgrid. This will enable micro-generators (for example, individuals with home solar panels) to sell their excess power directly to consumers, rather than selling to the electricity grid who then sell on to the consumers. It has the potential to connect energy producers directly to consumers, thereby removing power distribution intermediaries from the transaction process entirely.

In another example, Storj Labs Inc offers a blockchain-based cloud storage system. The system uses a blockchain to allow users to rent out their excess storage capacity in a way that improves security and reduces dependency on a single storage provider.

Whilst most uses of blockchain have focused on recording transactional information, the possibilities for blockchain are not so limited. For example, it has been proposed that blockchain could be used to store personal identity information such as birth certificates and criminal records, secured using biometric encryption, or to enable reliable and transparent status updates to be sent from smart devices such as autonomous vehicles to insurance companies, thereby improving insurance auditing and authentication. Even though blockchain was first conceived less than 10 years ago, it has already made a significant impact on the nature of currency control and financial transactions through its use with cryptocurrencies, and promises to revolutionise a wide range of other sectors in the years to come.

Intellectual Property considerations

There are a number of approaches to handling intellectual property that is generated by blockchain innovations. Some blockchain based companies and development collaborations favour an open-source model, where use of technology is freely available under the terms of an open-source licence. The most notable example of this is the Ethereum platform that provides a cryptocurrency called "ether" and smart contract functionality (computer protocols that can be used to facilitate, verify or perform a contract) on an open-source basis. Another is the Hyperledger Project - an open-source collaboration that includes such high profile members as Accenture, IBM and Intel.

However, open-source solutions are not always appropriate, and many companies, including some of the biggest software, hardware and banking entities, are pursuing patents to protect their investments in blockchain innovation. Indeed, there is evidence to suggest that some companies are pursuing a two-pronged approach, contributing to open-source projects and also pursuing patents to protect their investment in other areas of blockchain development.

The number of patent filings in this area has been steadily increasing and looks set to continue increasing in the future. Despite the relative infancy of the technology, there are already many hundreds of published patent applications relating to blockchain technologies, and that number may be expected to rise rapidly with increased investment and development. Furthermore, despite the typical 3-6 year timescale between filing of a patent application and grant of a patent, over 100 patents have already been granted in the US alone. There are clear signs that despite the challenges that can be faced in pursuing patent protection for software, protection for blockchain technologies is an achievable goal.

A number of benefits to pursuing patent protection at an early stage of technology growth are clear. For example, as we have seen from other rapidly developing sectors such as telecommunications, when companies contribute to developing standards that are widely adopted, obtaining patent protection for the underlying technology can be hugely valuable. Not only can this provide financial reward in the form of licence fees for technological contributions, but it may also help to reduce the licensing costs for standards essential patents (SEPs) held by other members of the standards body. Patents may also be useful in commercial negotiations, such as acquisition, merger or cross-licensing negotiations, as well as for joining any patent pools that may develop in the future.

There are clear signs that despite the challenges that can be faced in pursuing patent protection for software, protection for blockchain technologies is an achievable goal.

So how should companies handle their blockchain Intellectual Property? The answer will vary from company to company and is likely to depend on many factors, including commercial priorities and overall IP strategy. One thing is certain however: careful thought and planning should be given to the decision at an early stage, with regular reviews and reconsideration in the future, as it may have important commercial consequences for many years to come.

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Social Robotics

Rise of the social robots

Robots have been working alongside humans in industrial environments for decades. These robots have been programmed to perform repetitive, dull or dangerous tasks that require accuracy, flexibility and strength, in lieu of human labour. Their purpose has traditionally been to lower production time and cost as well as to offer standardised quality of products.

In the near future however, it is expected that robots will play a much greater role in our daily lives. These "social robots" will be different from their industrial colleagues, being designed to interact with people in a natural, interpersonal manner – often to achieve social-emotional goals in diverse applications such as education, healthcare, quality of life, entertainment and communication. The term "care robots" is also used for partially or fully automated physical machines that are designed for elderly care or to engage with people with physical or mental disabilities.

Given that robots have limited perceptual, cognitive and behavioural abilities compared to humans, how can a robot be "social"? The answer rests on the quality of the interaction that the robot can offer a human. For example, social cues like nodding when someone speaks might be enough to create a social interaction. Responses of this kind are rich in meaning and may convey a lot to a user, but they do not necessarily require sophisticated technology. This means that to be "social", a robot does not have to be anthropomorphic or behave like an artificial human. There is even research evidence suggesting that "human-ness" or familiarity may have detrimental effects on the quality of human-robot interaction, as it can foster unrealistic expectations in the (human) user. Research suggests that adding social behavior characteristics to simple and functional robotic devices can greatly impact a person's willingness to adopt a technology and even demonstrates promising outcomes in activities related to user motivation and therapy.

In many cases, building a robot or a system with social characteristics takes years of research, development and testing. As in many other industries, patents provide a way to protect this investment and help secure more funding for further research and development, which could in turn create the tipping point for these technologies, helping to bring them to market sooner, to the benefit of consumers.

Academic research in the field of technology forecasting in care robots shows an increasing trend in patent filings since the 1990s. The trend has been recently confirmed by government data from South Korea that demonstrate a sharp rise in patent filings in the field of social robots, which might be attributable to recent advances in Artificial Intelligence. What is particularly interesting is that even though Europe is among the pioneers in robotics, the level of patent filings in social or care robotics does not reflect this. The majority of patent filings in the field of social or care robotic are from China, Japan and Korea.

So why is Europe left behind in terms of patent filings, despite the fact that many European universities and research institutions are leaders in the field? Can the European patent system protect social characteristics in a robot or are there legal barriers that stand in the way?

To answer this question we have to understand two important points about the European patent system. First, the peculiarities of dealing with software or computer program patents and second, the requirement for an invention to have "technical character" in order to be patentable.

The issue with software patentability in Europe is not new. Computer programs "as such" are excluded from patentability according to the European Patent Convention. However, the EPO's case law and practice has evolved to a stable position that a computer program can be patentable, provided that it brings about a further technical effect that goes beyond the normal interactions that occur between the computer program and the hardware on which it is run.

The second consideration is that, in order to be patentable, an invention must have "technical character".

Generally, creations in engineering and technology are entitled to patent protection, provided that they meet the legal requirements of novelty and inventive step, since, as a rule, such creations will inherently have technical character. However, in the field of social robotics, patentability may not be so straightforward, because the effects of an innovation in terms of improving the robot's social characteristics (or improving a human user's perception of the robot's social characteristics) may not be regarded as technical.

For example, a nodding robot may be a creation that results in a better robot in terms of its interaction with the user, because the nodding function gives the impression of improved social interaction. Patenting the "social interaction" aspects of the robot may be challenging, however, due to the requirement for technical character in an invention. That said, patent protection should still be available for the nodding mechanism (provided that it meets the requirements of novelty and inventive step), as that mechanism will have the required technical character.

Of course this does not necessarily apply in other jurisdictions. For example, Google was recently awarded a US patent for adapting a robot's personality according to the user's mood. The patent raised an interesting discussion in sections of the robotics community about the ethics of protecting something as broad as a robot personality, which seems to be permissible under US practice.

The broad concept of a robot that can get social cues from the environment and behave accordingly to increase user satisfaction might not be considered technical enough to be patentable under European practice. The concept of personality per se would likely be considered as lacking technical character. In order for a patent to be granted, specific technical processes and structures that give rise to personality characteristics would need to be disclosed.

Even though the concept of a social feature may lack technical character, there might still be a way to achieve some protection in Europe for such systems. For example, a robot that can detect nuances in the user's tone of voice via a novel speech recognition interface can be considered technical and could lead to a patentable invention, as long as the patent is drafted with the technical effect in mind.

As in many other industries, patents provide a way to protect investment and help secure more funding for further research and development.

As the field of social robotics matures and innovators seek to protect their developments via European patents, we expect the question of what constitutes technical character in areas like robot personality to be explored in more detail. In the meantime, companies and research institutions that are already active in the field or plan to enter in the near future should recognise that they will need to provide a detailed technical disclosure of their inventions in order to demonstrate the technical character required under European patent practice. That is not to say that innovation in this area will not be rewarded by patents; a new and inventive system based on sophisticated interaction between a user and a robot is still patentable, if patent protection is sought for the actual technical processes and effects that give rise to the "softer" interaction aspects and not for the "softer" interaction aspects per se.

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Patenting precision medicines

Introduction

Traditionally, pharmaceutical products have been designed as "one-size-fits-all", working across as wide a patient population as possible. Medications that produced no effect in a large number of patients, or even produced severe side effects in some, often would not make it to market or would not survive once on the market. One unfortunate example is rofecoxib (Vioxx®). This was a leading osteoarthritis treatment up until a high-profile withdrawal due to allegedly inducing heart attacks in a small number of patients. Even where there are no side effects, if a patient does not respond to a medication, valuable time can be lost before switching to an alternative treatment, as can occur when prescribing cancer therapies.

Precision medicine aims to predict how individual patients will respond to a medication, and thereby provide medications that are more tailored to the patient. This prediction is often done by identifying specific biomarkers that are linked to the patient's condition and to the way the drug works. There are many biomarkers that can be used to make such a prediction, such as the presence of specific gene sequences, proteins or metabolites, or even a multiple biomarker signature. Once identified, these biomarkers can allow for a faster and more cost-effective precision medicine treatment approach.

One well-known example of precision medicine at work is the use of the drug trastuzumab (Herceptin®) for treating breast cancer. The drug is only effective in patients where the HER2 gene is overexpressed, while in other breast cancer patients there is no effect or sometimes even a harmful effect. By testing for overexpression of HER2 in breast cancer patients, it will be known in advance if trastuzumab is likely to provide any benefit.

More recently, the FDA approved Merck's pembrolizumab (Keytruda®) for treating solid tumours that have a specific biomarker referred to as MSI-H or dMMR. This appears to be the first time a drug has been approved for a disease characterised only by a biomarker. Some commentators predict that the pharmaceutical industry will move further in this direction, particularly with the recent recommendation by England's Chief Medical Officer that cancer patients should be routinely offered DNA tests to help with selecting the most appropriate treatments.

Patentability

The ability to obtain patent protection is critical in the pharmaceutical sector, as pharmaceutical companies need to be able to recoup the huge costs involved in developing effective new drugs. This is perhaps even more important in precision medicine. Identifying biomarkers that correlate with a disease is hard enough. Identifying biomarkers that predict how a drug will affect a disease is a much more daunting prospect for a pharmaceutical company. It is therefore critical that suitable incentives prompt researchers to undertake this expensive but potentially life-saving work.

An important issue affects the patentability of such developments, however. There is likely to be overlap between the patient groups defined by a biomarker and the more traditional patient groups defined by the disease in general. Using the Merck example previously mentioned, Keytruda was already known as a treatment for non-small cell lung cancer. Therefore, it is inevitable that certain patients with a MSI-H or dMMR variant of non-small cell lung cancer tumour would already have been treated with Keytruda. Can a patent claim covering treatment of a patient group that overlaps with a patient group that was already being treated be allowable?

Patentability options

Consider an example where drug D has previously been used for treating patients with condition C. It is then determined that drug D is actually only effective in the subgroup of patients with biomarker B.

What, then, is patentable? Drug D is known and its use in patients with condition C is known. The biomarker itself was already present in the bodies of certain patients. What is new is the identification of how biomarker B is predictive of drug D's effect on condition C, and applying this in determining the treatment approach.

One option is claiming a method of testing a patient for biomarker B. While there are ways to draft suitable diagnosis claims that cover these test methods, product claims covering the drug are usually more valuable. This is because it is typically easier to identify and stop an infringing supply of the drug, as opposed to policing the carrying out of a diagnostic test.

In many countries around the world, medical use type claims are available. These claims confer patentability in situations where there is a novel and inventive use of the drug. With medical use type language, the following claim may appear suitable: "Drug D for use in the treatment of condition C in a patient with biomarker B". However, drug D has already been used in all patients with condition C, so the use in patients with biomarker B has inevitably already been performed. Would this claim be allowable?

According to the European Patent Office (EPO), for a claim's novelty to rely on the new patient group, the selection cannot simply be arbitrary. The Technical Board of Appeal of the EPO stated that "the use of the same compound in the treatment of the same disease for a particular group of subjects, could nevertheless represent a novel therapeutic application, provided that it is carried out on a new group of subjects which is distinguished from the former by its physiological or pathological status." Therefore, the biomarker must be linked to the way in which the human body responds to a condition or the way in which the condition operates within the human body. It was confirmed that this applies even where the new patient group overlaps with known patient groups.

For an inventive step to be acknowledged, a functional relationship between the biomarker and the improved technical effect should be established. Evidence of the relationship between the biomarker and how the treatment acts upon the condition is critical. Where the relationship can be described at the biochemical level (for example if the biomarker is part of a pathway involved in the disease), in vitro or preclinical data may be sufficient. If a relationship has been established without any biochemical understanding (for example if the correlation was established through statistical analysis), clinical data is more likely to be required.

It therefore appears that the above claim language should be allowable at the EPO. However, in other jurisdictions, further distinction may be required. Example claim language to achieve this could be:

"Drug D for use in the treatment of condition C in a patient that has been characterised as having biomarker B." or even:
"Drug D for use in the treatment of condition C in a patient that has been characterised as having biomarker B using method M."

It would, of course, be advisable to push for the broadest claim in any given jurisdiction, but ensure there is basis for these additional limitations if needed.

Conclusions

The European Patent Office has recognised the importance of developments in precision medicine and is paving the way for the incentive of patent protection to drive research. Crucially, even in situations where there is overlap between a known patient population and a new patient population, the possibility for obtaining patent protection still exists. This is important news for innovators, physicians and patients, as we should see more research in this area leading to more effective treatments.

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W&R Team

New partner and senior associates at Withers & Rogers

We are delighted to announce the promotion of Russell Edson to partner at Withers & Rogers. Russell is based in our London office and is a key member of our Advanced Engineering group, with particular experience in mechanical technology areas including oil exploration and extraction, medical instruments, automotive, aerospace, packaging and manufacturing technology.

We are equally delighted to announce that three of our associates, Chris Froud, Jennifer Unsworth and Philip Horler, have been promoted to senior associate.

Chris is a patent attorney in our Electronics, Computing & Physics group, and works with clients on a wide range of physics-related technologies, with a particular interest in autonomous guided vehicles. Chris is based in our Sheffield office.

Jennifer is based in our Midlands office and is a member of our Advanced Engineering group, specialising in technologies relating to aerospace, automotive, medical devices and home improvements industries. She also has a keen interest in assisting clients with design protection.

Philip is also a member of our Electronics, Computing & Physics group, based in London. Much of his work is in the area of electronic circuitry and semiconductor design. He also has significant experience with computer implemented inventions, including encryption and blockchain related technologies.

Clients who work with Russell, Chris, Jennifer and Philip will appreciate the expertise, knowledge and commitment that they bring to their work and to the firm as a whole, and we are pleased to be able to recognise and reward their contribution with these promotions.

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