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Digital Health

IP at the interface of healthcare and digital technology

SUMMER 2022 EDITION

Contents

This issue at a glance

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From the Editor

We are delighted to welcome you to our compilation of recent articles on intellectual property (IP) in Digital Health.

From an IP perspective, and particularly in relation to patents, Digital Health is a one-of-a-kind field. This technology sector has its name for a reason. It falls on the interface of healthcare and digital technologies. Different patentability challenges combine with the different business considerations of healthcare-focussed and digital-focussed companies. Established players vie with new disruptors both small and large and each solving problems from different angles. The articles in this compilation build on these themes. The cross-disciplinary Digital Health team at Reddie & Grose has a broad international client base and deep cross-sector technical understanding and we look forward to continuing the conversation.

P.S. Things move fast in Digital Health! The articles in this newsletter have been updated in places from original publications so that they aren't out of date already!

Dr Robert Sackin • Editor

Meet the Team

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Robert is specialist in drafting and prosecuting patent applications relating to computer implemented inventions. His work has a particular focus on digital healthcare, protecting clients' intellectual property in medical devices and applications. Robert's PhD involved magnetic resonance imaging.
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Pharm Evolution

These days it is hard to find an article that does not talk about how artificial intelligence (AI) or the internet of things (IoT) is influencing our everyday life. From algorithms deciding the adverts we see, to driverless cars speaking to each other, technology is everywhere and we are all having to adapt to the changes it brings.

In the world of intellectual property we can already see how digital tech has impacted traditionally stable sectors such as the automotive industry. In recent years, automotive heavyweights have been forced to take licences from tech companies as they scramble to acquire the protection, and freedom to operate, necessary to develop electric, and ultimately driverless, vehicles. Now the pharmaceutical industry is firmly in the crosshairs of this digital revolution.

It is not that pharma companies have not already dabbled in the world of Medical Technology (MedTech). Computing power was critical to unlocking the human genome; wearable devices already play a critical role helping diabetics manage their condition; and pacemakers have been commonplace for decades. However, crucially, we are now seeing digital technologies move from the periphery to the forefront of pharmaceutical development and patient treatment.

This convergence of the pharma and digital sectors poses significant opportunities for those involved, but with that, comes increased challenges for the IP profession. Patent attorneys working in these sectors have spent decades trying to defend what is patentable in their respective field. As the lines between these sectors start to blur, it will be vital for such practitioners to adapt to ensure they are up to the challenges that await.

The Statistics

With this in mind, it is interesting to see signs in the patent world that some pharma companies are already "going digital". In particular, using the European Patent Office's (EPO's) classification system, we have been able to list - in Tables 1 and 2 - the top 10 filers of European patent applications for MedTech and Pharmaceuticals in 2021. The total number of MedTech European patent applications comes a close second to that of digital communication, with both technology areas totalling around 15,000 applications in 2021. There were around 9000 European patent applications filed in the pharmaceutical field.

The top 10 filers of European patent applications for MedTech are a mixture of big pharma and established medical technology companies with large players filing MedTech patent applications in high volumes more akin to that of the pharmaceutical field.

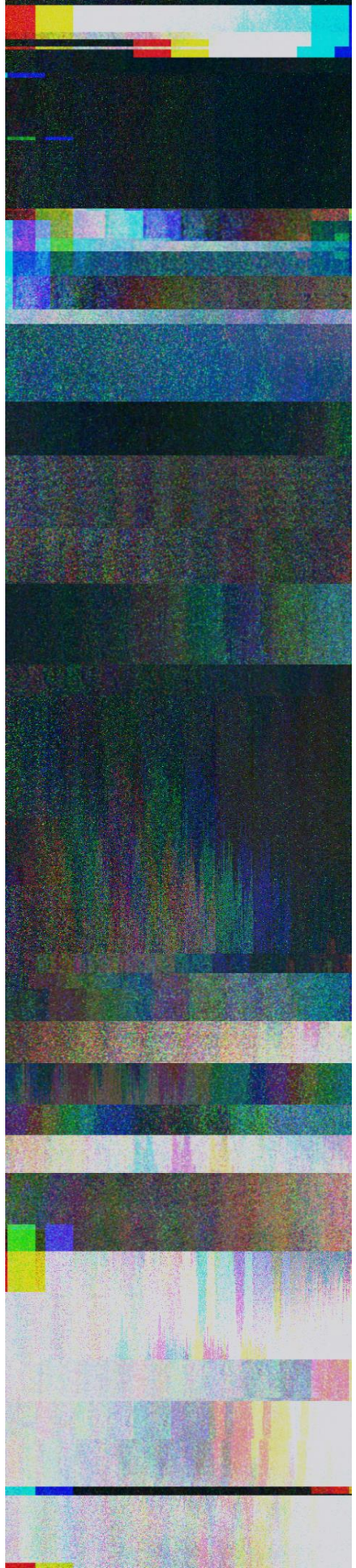
The top 10 filers of European patent applications for MedTech are a mixture of big pharma and established medical technology companies with large players filing MedTech patent applications in high volumes more akin to that of the telecoms sector. Perhaps most notable is Johnson & Johnson, who are the largest filer of pharmaceutical applications with 116 and the top three filer of European patent applications for MedTech, but with nearly five times the number of applications - 555.

Table 1: Top 10 filers of European patent applications for medical technology in 2021

Rank		Applications
1	PHILIPS	653
2	MEDTRONIC	612
3	JOHNSON & JOHNSON	555
4	BOSTON SCIENTIFIC	229
5	BECTON DICKINSON & COMPANY	206
6	BIOTRONIK	185
7	EDWARDS LIFESCIENCES	123
8	FRENESIUS	121
9	SANOFI	116
10	FUJIFILM	110

Table 2: Top 10 filers of European patent applications for pharmaceuticals in 2021

Rank		Applications
1	JOHNSON & JOHNSON	116
2	UNIVERSITY OF CALIFORNIA	90
3	INSERM	87
4	MERCK & CO	83
5	NOVARTIS	78
6	HOFFMANN-LA ROCHE	69
7	SANOFI	52
7	UNIVERSITY OF TEXAS	52
9	BOEHRINGER INGELHEIM	50
10	GLAXOSMITHKLINE	47



There are two striking take homes from this data. Firstly, the numbers for MedTech and Pharma filings differ hugely. If traditional big pharma are to get a foothold in the MedTech scene, might they need to adopt the more "quantity driven" approach to patent filings seen in the telecoms industry? Secondly, Johnson & Johnson aside, there is surprisingly little overlap between leading filers of MedTech patents and leading filers of pharmaceutical patents. Some of this can certainly be attributed to pharma companies partnering with more traditional software companies, but it may also suggest that pharma companies are struggling to identify what is patentable in their digital endeavours, and whether this is something they should be protecting.

So, what challenges can practitioners expect to encounter when protecting innovations in this emerging MedTech sector?

The Digital Side

On the digital side, much innovation in the MedTech sector now relates to methods or systems implemented on a computer. With the development of computer implemented inventions in this space a number of exclusions to patentability need to be considered. The legal nature of these exclusions vary around the world. Even where there is harmonisation, practical application can still vary considerably between jurisdictions.

With increasing applications of "Big Data" techniques in the medical field comes a surge of inventions that rely on processing patient or experimental data. A typical system might involve collecting large quantities of data from a patient via one or more sensors (e.g. a smartwatch or other wearable tech); performing initial processing of the data to clean it up for subsequent processing; and then analysis or use of the resulting data for a particular purpose. This could include training a machine learning algorithm or applying the data to such an algorithm for diagnostic analysis. The data processing might be performed in multiple locations or in the cloud. It might involve processing data from hundreds or thousands of individuals, particularly if machine

learning is applied.

Protectable inventions can be found in any of the aspects of such a system but some need more careful consideration than others with regards to exclusions from patentability. For example, the application of mathematical techniques to process data must be carefully considered in Europe because there are exclusions against patenting mathematical methods and computer programs. The EPO, for example, will focus on whether the mathematical method being employed solves a specific technical problem, such as how to reveal features of the incoming patient data that would not previously have been identified. So whereas a system that identifies small variations in an ECG signal as being indicative of an underlying condition may be patentable, the application of one or more mathematical techniques to patient data for an unexplained or overly general purpose would be difficult to protect.

Careful consideration is also needed with inventions motivated by an administrative or legal problem. Data access, data sharing and compliance with GDPR may lead to novel ways of transmitting and storing data that are specific to the medical field. However, if the sole purpose of the invention is to address these types of issues then it can be difficult to argue that a technical problem (as opposed to an administrative or human created problem!) has been solved. In these situations it is better to focus on the way the invention differs from general data processing systems and the underlying technology needed to implement it. This is likely to bring its own challenges in terms of patentability and freedom to operate as the proposed solutions may be similar to those already used in fields outside of the medical application in question.

The Pharma Side

In addition to the software related exclusions, those working in MedTech will also require a good understanding of the various medical related patent exclusions that exist in a number of jurisdictions. These exclusions may not always be at the forefront of a software practitioner's mind so a collaborative approach with life science practitioners is becoming more common and increasingly important.

For example, one area where AI is already playing an active role in digital healthcare is personalised medicine and diagnosis. It is not uncommon to use AI to detect the presence of biomarkers or other indicators that point to a specific disease and enable medical practitioners to intervene and take prophylactic measures at an early stage. Clearly this has huge upsides for the patient but in many jurisdictions, including the EPO, methods of diagnosis are not patentable. Although in practice this exclusion is usually applied narrowly, careful drafting of patent applications will still be necessary to avoid potentially fatal pitfalls for the patent at a later stage.

We are also seeing an increase in the use of MedTech to assist with treatment of diseases. For example, software embedded in devices may be used to measure parameters or biomarkers to provide bespoke medication or dosing regimens for a patient but, like methods of diagnosis, many jurisdictions exclude methods of treatment from patentability. Over the years claim drafting has developed to sidestep this issue for protecting the use of pharmaceutical substances for a particular treatment but this is not so straightforward if a key part of the treatment arises from a medical device or software. When software lies at the heart of the invention, a balance must be struck between providing details of the problem to be solved without turning the claim into an excluded method of treatment.

The challenges of protecting MedTech inventions also goes beyond exclusion criteria and touches on some of the more fundamental aspects of patent law. In nearly all jurisdictions, patent specifications must include a disclosure of the invention that sufficiently enables it to be carried out by a skilled person. This requirement is often central to patentability for pharmaceutical patents but has traditionally been less critical for software inventions. As we move into the age of digital medicine, software practitioners should be aware of an increased focused on enablement in MedTech patent applications and a collaborative approach with life sciences practitioners will be crucial in helping with this transition.

What does the future hold?

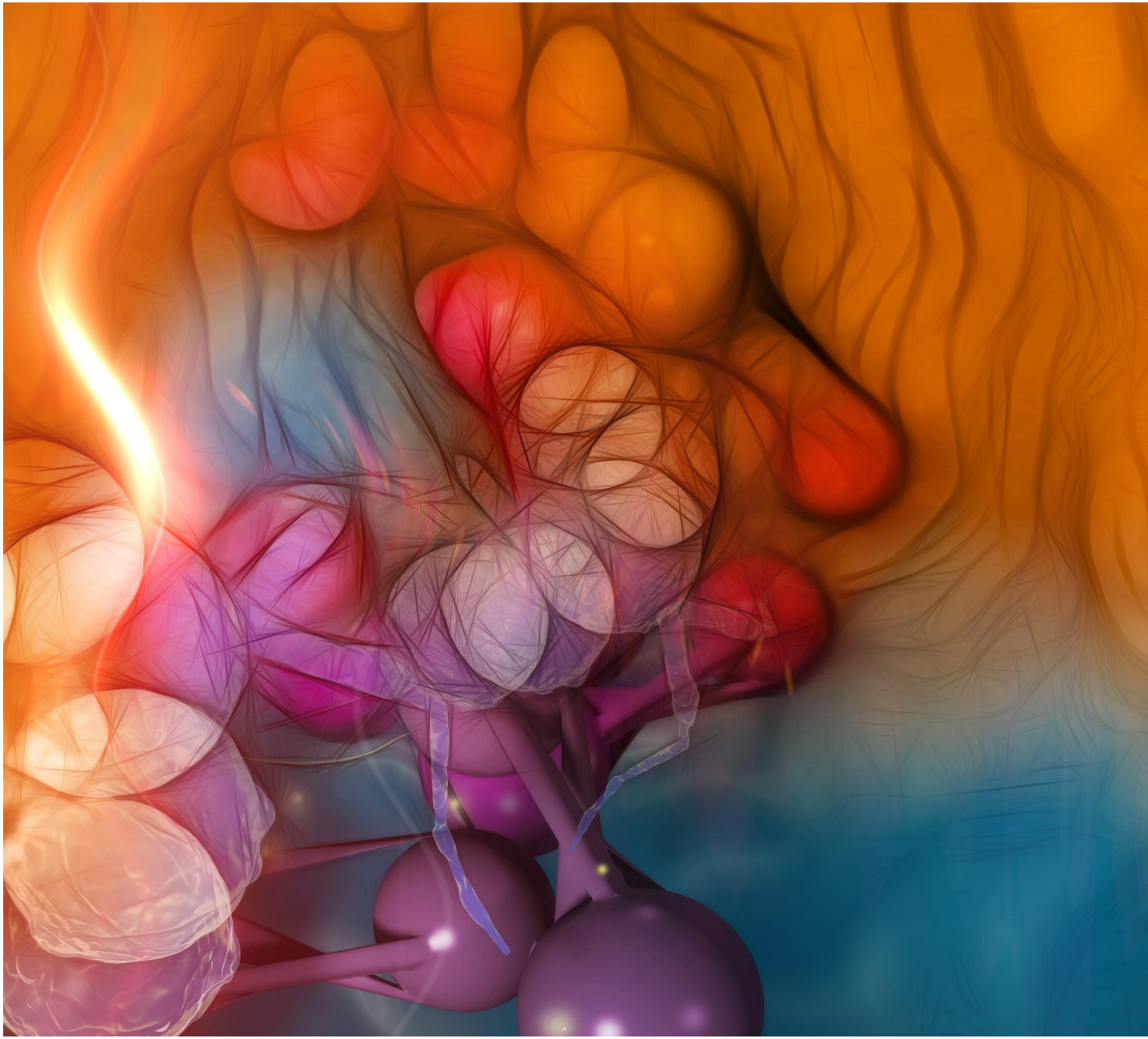
There is no doubt that AI, big data and bioinformatics represent incredible opportunities for pharmaceutical and tech companies whilst at the same time providing significant new challenges for patent systems and practitioners around the world. As technology plays an ever increasing role in the development and application of new treatments we will not only see it shape the style of pharmaceutical patents but also how patent offices assess their patentability. With the skilled person often being defined as someone "possessing average knowledge" and "being aware of what was common general knowledge" how long will it be before AI not only drives innovation in the pharmaceutical sector but also takes on the mantle of the person skilled in the art?

Author: Dr Robert Sackin, Zack Mummery & Duncan Nevett

The Digital Healthcare Revolution:

Computational Modelling

There are very few areas of technology that develop at the same astounding pace as computers. The impact that this has on our daily lives extends beyond the obvious improvements in processing power in our smartphones. The unrelenting advance of computer technology drives change and inspires innovation in virtually every industry. One of the key industries where innovation driven by computer technology has had the most profound effect is healthcare. According to statistics released by the EPO in 2021, medical technology accounted for the largest proportion of European patent applications filed, while pharmaceuticals and biotechnology were the fastest growing.



Developments within the Digital Healthcare sector itself come from a number of different areas of technology, both emerging and established. This mini-series of blogs will highlight the impact that cutting-edge research in different fields is having.

In this article we focus on the role that computational modelling is having in the Digital Healthcare revolution, and highlight some exciting recent applications of computer simulations in a modern healthcare setting.

The Living Heart Project

In the healthcare sector, one of the emerging trends is the shift away from the traditional "one size fits all" approach to therapies towards personalised treatments that are tailored to the patient's individual genetics and physiological characteristics.

The Living Heart Project provides a profound demonstration of the role that computational modelling will play in the personalisation of healthcare. The project represents a collaboration between 30 organisations, including more than 100 cardiovascular specialists from across research, industry and medicine. The project is led by Dassault Systèmes® under the Simulia™ brand.

The initial goal of the project is to develop and apply a realistic computer simulation of a human heart – a so-called "digital twin". To achieve this, Magnetic Resonance Imaging (MRI) data of the person's heart is collected and used to create a virtual three-dimensional model of the heart. This 3D model is then transformed, using sophisticated mathematical modelling of the electrical and mechanical tissue properties, into a realistic beating model of the living heart.

These digital twins have widespread potential applications: they can replace real patients during the design and testing of new drug therapies and can be used to accurately predict the efficacy of different implant designs. For example, a patient who is in need of a stent (an implant for opening a blocked blood vessel) could have different designs of stent tested via simulation using the digital twin of their heart before undergoing surgery.

While in the short to medium-term the project is focused on modelling the heart, the long term goal of the project is to expand the work to other organs.

Virtual Assay

Bringing a new therapeutic drug from small-scale *in-vitro* tests through to widespread clinical adoption is a challenging and expensive process. Before any new treatment can be accepted for therapeutic use in humans, it must first undergo a thorough pipeline of pre-clinical testing to make sure that the compounds used are safe and effective at treating the target disease.

Conventionally, animal experiments play a significant role during the preclinical testing stages, and often find favour due to the possibility of producing animal models that mimic various human pathologies. However, it has been shown that the effectiveness of therapeutic drugs in animal experiments and the subsequent effectiveness during human clinical trials does not always correlate.

In addition, two people will very rarely respond to the same dose of the same drug in the same way due to natural variations in physiology. The use of animal testing therefore raises both ethical and translational questions, and research into the replacement, reduction, and refinement of animal models in preclinical testing is a very active field of research.

Researchers from the Department of Computer Science at Oxford University have therefore developed a computational modelling-based approach to reducing the reliance on animal models in the drug development pipeline. The software, called *Virtual Assay*, uses data collected from a large number of human subjects to create a population of virtual models that can be used to simulate and predict the effects of various drugs on a naturally variable population.

A study published in 2017 evaluated the performance of the computational-modelling approach at predicting whether various reference compounds would cause abnormal heart rhythms. The results were promising, with the Virtual Assay software achieving 89% predictive accuracy, compared to 75-80% accuracy achieved in similar studies using animal models.

Using fluid dynamics to reduce infection risk during the COVID-19 pandemic

The impact of computational modelling on the healthcare sector is not confined to the development of new therapies. During the COVID-19 pandemic, researchers worldwide have been focussing their efforts on understanding, predicting, and preventing the spread of the SARS-CoV-2 virus.

As we know, the virus is carried by airborne respiratory droplets, typically expelled when an infected person coughs. Therefore, finding ways to reduce the risks of airborne transmission is crucially important. One environment where this is of particular importance is in hospitals, where large numbers of infected patients in close proximity presents a heightened risk to hospital staff.

When the St. Francis hospital in France needed to expand their capacity for COVID-19 patients, they were faced with the challenge of keeping contaminated areas separated from the rest of the patient population. The hospital team collaborated with a team of scientists from Dassault Systèmes® to investigate ways to reduce the flow of contaminated air out of the designated COVID-19 treatment area into the main hospital.

The scientists used a 2D floorplan of the hospital wing to create a detailed 3D model, taking into account various factors that influence the flow of air through the building – open/closed windows, heat sources such as radiators and computers, air extraction vents, and the patients themselves. Virtual patients were placed within the model, and fluid dynamics used to investigate how virus particles expelled by those patients would spread through the building. Based on the model, the scientists found that the containment of the virus could be improved by opening/closing certain windows at key locations throughout the building.

The examples above are just the tip of the iceberg when it comes to applications of computational modelling in a healthcare setting. In such a fast-evolving and competitive area of technology, protecting your company's next big innovation has never been more important.

Patenting Computer Models in Europe

Regrettably, despite the obvious benefit that computational models provide key industries, it is not straightforward to obtain patent protection for pure computational models – particularly in Europe. This is because a European patent can only be granted for an invention, but this definition of an "invention" does not cover programs for computers, mathematical methods and mental acts (which cover computational models in their purest form), as these are not considered to be inherently technical.

However, computational models may patentable when the model is applied within a technical field – such as

Digital Healthcare. In such instances, a patent may be awarded where the contribution of the model is new, involves an inventive step, and serves a technical purpose. Some examples of the use of computational models for a technical purpose in the Digital Healthcare industry include:

- controlling a specific technical system or process, for example an X-ray apparatus, or processing the image data produced by such systems;
- deriving the body temperature of a subject from data obtained from an ear temperature detector; and
- providing a genotype estimate, and corresponding confidence level, based on an analysis of DNA samples.

A further challenge arises where computational models are used when providing a medical diagnosis. This is because in many jurisdictions, including Europe and the UK, patents cannot be granted for methods of treatment or diagnosis performed on animals or humans. This is to ensure that medical practitioners are not prevented from operating on patients due to the monopoly provided by a granted patent.

However, this exclusion only applies to the extent that the computational model is able to deduce a medical diagnosis for curative purposes: simply collecting, analysing and reporting data is permissible so long as a medical professional is able to make a final diagnosis based on that data. The extent to which the computational model is able to determine a final diagnosis is therefore a key factor in whether a patent may be obtained for such models.

At Reddie & Grose, our experienced multidisciplinary Medical Devices and Digital Healthcare team are on hand to advise on the IP challenges of the Medical Technology industry and to provide advice for seeking and securing patent protection.

Author: Bruce Torrance & Dr Ben Hipwell

On the horizon

Standard-essential patents are coming to the pharmaceutical industry

Until now the pharmaceutical industry has not had to deal with standard-essential patents (SEPs), but are things changing?

SEPs arise when a technical standard incorporates technology that is protected by a patent. Technical standards are vital for many industries, including the pharmaceutical industry. However, most technical standards applied to the pharma industry to date relate to harmonising rules such as for packaging or labelling of medicines. These standards often have a legal or regulatory origin.

By contrast, innovative standards setting organisations (SSOs) propose road maps for further technical development, setting goals and inviting members from industry and academia to contribute to developing a new standard. By setting ambitious technical goals for the new standard, members propose innovations, which are typically small improvements that cumulatively add up to a large performance improvement for the new standard. The new standard is a collaboration based on multiple improvements made by its members.

In the mobile telecommunications sector 3G, 4G and 5G are all examples of communications protocol standards that significantly improved on the preceding one.

SSOs allow contributors to apply for patents for the inventions they contribute to the standard, and if the technical standard cannot be implemented without infringing a given patent, then that patent is an SEP. This is clearly an excellent position for the holder of an SEP, since no one can implement the standard without infringing its IP. However, as a counterweight in the process, SEP holders are contractually required to offer licences for these patents on FRAND (Fair, Reasonable and Non-Discriminatory) terms. As a result, a technical standard such as 5G might be covered by hundreds or even thousands of patents owned by many different parties.

To simplify the licensing process, patent pools are often used. Owners pool their patents and licensees deal only with the patent pool rather than each owner separately. Royalties are then distributed among the contributors to the pool.

In language that parallels the pharma industry, there is a divide between innovators, who contribute to the technical standards and can apply for patents based on their contributions, and implementers, who make products according to the technical standard and may need licences to avoid infringement. Of course, parties can be both innovators and implementers.

The business model for innovators in the pharma industry usually relies on exclusivity. Therefore, we are unlikely to see SEPs for medicines. One area where we may see SEPs emerging, however, would be covering tools that support the industry. Particularly where there is a desire for interoperability or sharing/communicating data.

To date we have not seen many (innovative) standards setting organisations in the pharma industry, but they do exist. An example is the MPEG-G technical standard for compressing and processing genomic data. MPEG – the Motion Picture Experts Group – is a standards-setting organisation with a long history of developing technical standards for new audio and video compression technologies. MPEG also has experience of licensing SEPs to users of its technologies. Perhaps seeing some synergy with its previous work on compressing multimedia data, MPEG has moved into genomic data. MPEG has not revealed yet what patents or licensing terms will apply to MPEG-G, but we know that patent applications have been filed for MPEG-G

technology, and we can expect SEPs and a patent pool for licensing to arise.

What MPEG represents is the effect that an external body can have on any given sector. As traditional tech companies continue to have an increasingly louder voice in the pharma sector, what is stopping them bringing their approach to patents with them? Furthermore, if standardisation is in the interests of a sufficient number of stakeholders, then industry bodies, or governmental or intergovernmental bodies such as the International Organisation for Standardization (ISO), National Institute of Standards and Technology (NIST) or British Standards Institution (BSI), may take the lead.

An example candidate for standardisation in the pharmaceutical world is 3D-printed personalised medicine. Based on the needs of an individual patient, a medicine – eg a tablet – can be manufactured on a per-patient basis with a personalised dose of the active ingredient. If this technology is adopted, then it will make sense if 3D printers for medicine all work in the same way regardless of who made the 3D printer. There are numerous technical hurdles to solve before this becomes a reality, but an SSO might help by setting an ambitious road map to a standardised approach and by establishing FRAND terms from the start, using patent pools to collect royalties.

Standardisation might also be beneficial for wearable sensor technologies. We have seen rapid development of sensors for detecting health parameters such as heart rate, electrodermal response and blood pressure. Although these sensors are not yet sufficiently accurate or reliable to use in commercial products (eg smart watches) for medical grade applications, this is one aim for this technology. If an SSO were to step in we could see faster development towards a standard suite of sensor technologies that meet the stringent criteria for diagnostic and monitoring use in the healthcare field.

Even without complete standardisation involving SSOs and SEPs, some aspects of this licensing approach may become prevalent in the pharmaceutical industry. Patent pools, for example, may have their place.

Patent pools for medicines have not been universally welcomed in the pharmaceutical industry. The Medicines Patent Pool has been successful but its scope is limited. In 2020 the World Health Organization proposed a COVID- 19 Technology Access Pool to share

access to patented technology and regulatory test data. The pharma industry did not engage with it. Instead, mRNA vaccine technology has been licensed on a more ad hoc basis with separate licence agreements between companies. Innovators are financially incentivised to rely on exclusivity by patenting their medicines and enforcing these patents directly.

It can be difficult to implement patent pools and to determine the appropriate licence fees for various different types of implementers. This is because they can be ad hoc in nature – a consequence of not being developed from the outset with an end goal in mind in the way that a technical standard would be. There is more potential for a successful patent pool if there is a logjam such that nobody can exploit a technology without infringing patents.

CRISPR technology might be an example where a patent pool is appropriate. There are a few foundational patents relating to the basic technology that are owned by a small number of entities, as well as many more patents relating to variations that are owned by a larger number of entities. If a patent logjam appears in this field then a licensing solution based on a patent pool that allows the technology to be exploited might develop. If this solution doesn't develop commercially then governments may intervene. For example, the Manufacturers Aircraft Association patent pool in the US was established in response to a patent logjam that was preventing the development of the US aviation industry in the early 20th century. The other stick that governments have is compulsory licensing, a tool that many on the innovator side of the pharmaceutical industry would prefer governments stayed away from.

Technical standards, and associated SEPs, are coming to the pharmaceutical industry one way or another. This is no bad thing if it leads to considered and well thought out standards, and will help avoid problems such as trying to implement and license ad hoc patent pools. We may well see players from the telecoms and digital technologies fields leading the charge with their wealth of experience participating in the standardisation process. Pharmaceutical companies will need to be prepared and embrace the process to ensure that they have an adequate say (and achieve adequate benefit) in the end results.

Author: Dr Chris Smith, Robin Ellis & Pete Sadler

IT'S NOT JUST A BOX

IP and particularly patents are a key tool used by the pharmaceutical industry to protect new drugs, formulations, and even new uses of a known compound. IP protection is not only available for active ingredients and associated formulations. Increasingly, significant innovation is happening around ancillary technology such as packaging and administration devices.

Pharmaceutical packaging may seem like an area in which there is little innovation. Drugs are often dispensed in blister packs within simple cartons. However, we are now seeing developments to packaging technology which assist with patient compliance, safety and quality control together with developments which help distinguish the product in the marketplace.

Innovative carton systems have been developed that introduce child resistant properties or tamper evident features so that a consumer knows if packaging has been opened. Often the child resistant and tamper evident features can be built into the carton structure, but the requirement for automated high speed assembly and the need to produce cartons at a competitive cost introduces constraints on the carton design and provides significant challenge to the designer. It is thus unsurprising that a carton that overcomes these challenges to provide tamper evident and child resistant functionality can potentially be patentable.

There is a whole range of packaging solutions that deal with improving patient compliance. At the simpler end of the spectrum, this could be a printed blister pack in which each blister is labelled with a day of the week. Packaging innovators are now developing packaging solutions which use inbuilt microprocessors to record the date and time at which each tablet is removed from the package. This information could be relayed back to a healthcare professional to monitor patient compliance. When coupled with a patient monitoring system, this technology could facilitate analysis of efficacy and pharmacokinetic properties at the patient level, which could assist with clinical trials or enable a personalised medicine approach. This type of advanced packaging solution will be potentially patentable, and there may even be multiple inventions that can be protected, for example the software responsible for the dose monitoring, the packaging carton itself and the overall packaging system including the microprocessor.

Patent protection of administration devices such as inhalers or injectors, can be a valuable tool for pharmaceutical companies to prolong patent protection around a particular active ingredient. A distinctive shape or external appearance can be protected by registered designs, while innovative dosage mechanisms or patient monitoring systems may be protectable by patents.

Administration devices are becoming increasingly complex. Smart inhalers are being piloted by the NHS which enable usage tracking, reminders, and monitoring of inhaler technique. The information recorded by the inhaler can be transmitted to a smartphone for relaying back to a healthcare professional. A linked smartphone app can help patients track their usage, remind patients to administer the drug and help patients improve their inhaler technique.

Next generation administration technologies are also being developed which can assist with implementing a personalised medicine approach. An administration device could be used to monitor certain biomarkers or the administration device could be coupled to a separate monitoring device. By monitoring the response to a drug, the dosage provided by the administration device could be automatically adjusted.

This kind of innovative system could be protected by multiple patents, including patents covering software, sensors, administration mechanisms, the device itself and the overall system. While in some jurisdictions methods of treatment and diagnosis are excluded from patentability, these

exclusions can often be avoided by careful drafting of patent applications.

Another area in which software and digitisation are being put to use are in the supply chain, to monitor products from manufacture to patient.

Within the supply chain, the use of technology to track products down to the blister packet or even the individual tablet level is a powerful new tool in ensuring the integrity of the supply chain, helping prevent counterfeits from entering the supply chain and giving the patient confidence that they are taking genuine medication. This tracking can be enabled by the use of codes, such as QR codes, that can be printed on packaging. Scanning this code at each stage of the manufacture and distribution chain can build a history for each packet of medication, enabling the supplier to monitor their products and the patient to verify that their medicine is genuine.

The use of QR codes can further improve patient safety by providing access to additional, easy to comprehend information related to their medicine. Examples of this information include videos providing demonstrations of how to administer the medication, as well as information in a variety of different languages or accessible to those with visual or hearing impairments, such as an audio or a large font patient information leaflet. By making instructional and safety information more easily accessible and digestible to patients, who are not medical experts, patient compliance and safety can be improved.

In fact, the pharmaceutical industry is going one step further by not just providing easily accessible generic medication information, but is enabling patients to access personalised information related specifically to them. Linking medication to a user's profile, again using QR codes or the like on a medication packet, allows the patient to access information specific to their health plan, and can enable ongoing interaction with medical professionals ensuring continued compliance and enabling health plans to be continually adapted and updated.

The pharmaceutical industry is a famously savvy user of the patent system to protect its innovations, at least when it comes to protecting medicines. Digital healthcare is now opening up a new frontier of innovation, presenting new challenges and opportunities for utilising the patent system to gain a commercial advantage. By protecting the software used to implement the digitisation of

healthcare, as well as the physical aspects of the medication and packaging that are involved, healthcare and pharmaceutical companies can add another layer of protection sitting around their key products.

Trade marks and designs can pay a key role in protecting branding and the appearance of pharmaceutical packaging. Current trends in pharma packaging continue to focus on the traditional approach of registering distinctive (and sometimes non-distinctive) elements, features and combinations as trade marks and Registered Designs.

The primary aim of trade marks is to identify the product of a particular manufacturer to enable a purchaser to repeat (or avoid) a previous purchasing act. Trade marks have other functions too – they help to maintain market share for brand owners and, where brand owners invest in anti-counterfeiting measures, increase patient safety by making counterfeiting more difficult.

Trade marks are much more than just brand names – they can be packaging, the shape of goods, colours etc. Recent changes to UK and EU trade mark legislation have cleared the way for registration of many different categories of trade marks, some of which will be of interest to the pharma sector. In addition, Registered Designs offer a way for brand owners to protect new and novel products / features of products where trade mark protection isn't viable.

The traditional perception of packaging might be cartons and containers, both of which may function as trade marks (and can also be the subject of Registered Designs). However, packaging can also extend to capsules (in which drugs are delivered), devices (such as inhalers or injectors) and may also encompass pills themselves. Under appropriate circumstances it is possible for all of these forms of packaging to perform a trade mark function and to build brand loyalty.

We now see manufacturers of generic pharmaceuticals investing in so called branded alternatives. Why? Because there is a demand for these products in the market, a greater profit margin over non-branded generics and because brand loyalty creates barriers to competitors entering the same market.

One only need compare the cost of a generic pharmaceutical versus the branded equivalent to understand the economic power of branding. Own label Ibuprofen retails in supermarkets for as little as 50p whereas an equivalent sized pack of branded Ibuprofen retails through the same stores for nearly five times as much.

Pharma is also investing in added value offerings as part of packaging – some of these are driven by legislation (e.g. use of unique identifier codes and anti-tampering features being introduced as a result of the Falsified Medicines Directive) whereas others are driven by a desire to engage more with patients – for example the use of QR codes on pack.

Other value add propositions which may be key to driving patient engagement and brand loyalty in the pharma sector include those linked to sustainability and patient safety. For example, the offering of recycling schemes for certain forms of plastic packaging may resonate well with patients on the basis of green credentials. The adoption of child resistant blister packs and holographic safety features on packs are other features which aim to improve the overall patient experience. Many of these features and initiatives cannot be protected by trade marks or by Registered Designs (one exception being holograms), but may form part of a new battle ground to win the hearts and minds of patients as branded alternatives go head to head with established brands.

Innovations around pharmaceutical packaging represent an opportunity for pharmaceutical companies to improve patient compliance, reduce counterfeiting, provide personalised medicine solutions, and protect key branding. Many recent developments in this space include a software or digital health component, demonstrating another way in which software and digitisation is having a transformative impact in the pharmaceutical and healthcare space.

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INNOVATIONS IN DIGITAL HEALTHCARE

Technologies such as Artificial Intelligence (AI), Augmented Reality (AR), Robotics and Machine Learning (ML), are increasingly being leveraged across society to enhance the way people live their everyday lives. In recent years, healthcare has become an area of particular focus, with innovative technologies being adopted to monitor health, assist in diagnosis, and manage and treat disease.

From the perspective of European patent law, these new digital health technologies present no new patentability challenges in themselves compared to traditional medical device technology or software in general. However, the coming together of medical device technology and software combines two traditionally separate areas of patent practice which have their own separate issues. On the one hand, under European law, additional hurdles are placed in the way of obtaining patents for software. On the other hand, inventions relating to healthcare technology, pharmaceuticals and medical devices must navigate various medical exclusions. The combination of these two traditionally separate areas of technology means that applicants are often presented with a unique set of challenges.

That said, with the right team of experienced patent attorneys working collaboratively, many of these challenges can be overcome at an early stage by the careful drafting of patent applications.

Medical Challenges

Under European patent law, methods for treatment of the human or animal body by surgery or therapy are excluded from patentability. Diagnostic methods practiced on the human or animal body are also excluded. The rationale behind these exclusions is to avoid the situation where a medical professional is prevented from treating or diagnosing a patient due to the existence of a patent right.

In the case of a method of treatment or diagnosis involving a pharmaceutical product, these exclusions can easily be overcome by reformulating the patent specification to refer to a medical use as opposed to a method of treatment. For example, under European law it is possible to protect a compound for use in treating a disease. However, this reformulation is not available in the same way for medical devices, so care must be taken not to fall foul of these exclusions.

Let's take a wearable device as an example. Let's imagine a wearable device is able to measure a particular characteristic of blood flow, process the collected data, use the processed data to diagnose certain cardiovascular conditions and send a report to the patient's GP.

The device clearly relates to diagnostics, but this does not mean that patent protection is not available. While certain methods of diagnosis are not patentable, the device used to carry out the diagnosis is potentially patentable. The wearable device is going to include multiple potentially patentable products. For example, the sensor may be potentially patentable. Similarly, the combination of the sensor together with a processor and output might represent a patentable device or system. However, care must be taken when seeking protection for the software and methods which underlie the device.

A method of diagnosing a cardiovascular condition by measuring the value of a blood flow parameter using a wearable device, comparing the value to a threshold and then determining whether the patient has the cardiovascular condition based on the comparison is likely to be excluded from patentability in Europe. However, if the clever part of the invention is the way in which the data is analysed and processed, then the method could focus on that aspect and avoid the diagnostic method exclusion. Similarly, if the method relates to the collection of the data but stops short of diagnosing a disease, then the method is unlikely to be excluded. In short, careful drafting of the patent specification can help to avoid this exclusion.

Digital healthcare is also being utilised to help treat diseases and is a key tool in personalised medicine. For example, a device might measure the level of a particular biomarker and then administer a tailored dose of a drug based on the biomarker level. In this case, care would need to be taken to avoid the method of treatment exclusion, but the device itself would potentially be patentable, and the method of measuring the biomarker may also potentially be patentable. Just because the device relates to treating a disease, does not mean that patent protection is not available.

Software Challenges

There is a misconception that computer programs cannot be protected by patents in Europe. Although it is true that the European Patent Convention includes an exclusion to computer programs, it is limited to the extent that the invention relates to the computer program itself rather than what it does or how it does it. Software implemented inventions are patented all the time in Europe, you just need to know what to look for.

The key is whether the software, when executed, exhibits a "technical effect". Although there is no legal definition of what this means, case law at the European Patent Office (EPO) has been built up over decades to establish where the boundaries lie. Software controlling a real-world device, such as a dialysis machine, is likely to meet the requirement. Likewise, software processing data derived from sensors to produce a tangible result may also be patentable.

Taking the above wearable device example, software would be needed to analyse the blood flow sensor data. Merely transforming data from one form to another is unlikely to meet the technical effect requirement unless the transformation is motivated by, and addresses a problem with, the underlying system in which the software executes. For example, if the sensor data arrives at unpredictable time intervals, adapting the software to take this into account may be patentable. Similarly, if the software is specifically adapted for the hardware it operates on to take into account the limited system resources of a wearable device then this aspect of the software might be patentable.

It is also worth noting that modern healthcare is becoming all about connectivity. Data is being produced and shared between systems at ever increasing rates. Software involved in such connected systems might be patentable but it is important to take into account what the software is doing. Software with an administrative or organisational purpose is

less likely to exhibit the required technical effect because the EPO considers administrative matters to be non-technical. In the example above, software that sends a report to the patent's GP would likely fall within this category, so this aspect of the software would not be patentable. Likewise, software that addresses privacy and regulatory issues will often not be considered technical where the issue being addressed by the software stems from legal obligations rather than underlying technical problems with the system.

Conclusion

Patent protection is an important tool to protect innovations and help secure or maintain a strong position in the market. As digital healthcare technology continues to grow and become ever more important in our modern lives, companies operating in this space should remain confident that European patent protection remains available to protect their key innovations. Many of the challenges in this sector can be overcome by careful drafting and management of patent applications at an early stage, so it is highly recommended to engage with a firm of patent attorneys with expertise spanning software and life sciences before seeking patent protection in this sector.

Author: Pete Sadler & Zack Mummery

HERE TO HELP

In a sector that blurs the lines between technology areas, the digital health team at Reddie & Grose includes members of our patents, registered designs and trade mark groups.

On the patents side, our world-class life sciences, electronics, software and advanced engineering departments work together to provide the best solution. Our team has extensive experience of advising research and development departments and a deep understanding of the key issues in an often complex legal and business environment.

We help businesses in their due diligence and analysis of whether they are free to launch their products. We protect their innovations by preparing and prosecuting patent applications – building portfolios of rights to protect their commercial interests – and protect their exciting new brands with registered trade marks. We are also skilled in assisting clients to enforce their IP rights, filing oppositions and cancellation/ revocation proceedings against third party rights, helping to defend our clients' position in infringement proceedings and defending clients' rights in oppositions and cancellation proceedings brought by third parties. Our support of multinational clients is more than just managing their global IP portfolio and defending crown jewel IP rights. We understand that every stage of a product's development offers a unique challenge and our experience of working in established and emerging markets enables us to think beyond the law and devise IP strategies tailored to the commercial objectives of our clients.

In our support of start-ups and SMEs, we have the commercial expertise to protect their innovation and ensure that their businesses are attractive to investors. We pride ourselves on listening to our clients and offering expert and pragmatic advice that is tailored to our clients' needs. Avoiding a 'one size fits all' approach has allowed us to build up many valued long-lasting client relationships. We would be delighted to provide you with further information about our services and to organise a free initial consultation.

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At the start, it can be difficult to decide whose expertise is most appropriate for a project. Please start with the person you think is most appropriate. Our team leads can then build a team tailored for your project.

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