GJE Intellectual Property

Digital Therapeutics: Patent Strategy in Europe

Introduction

The issue of chronic disease is imposing a mounting burden on healthcare systems around the world and set to become a defining healthcare challenge of this generation. Many of these conditions are irreversible, and many more require lifelong medication adherence and lifestyle adjustments for effective management. Patients often struggle to adhere to prescribed medications and implement the behavioural changes crucial for disease management. Healthcare professionals face equal challenges in monitoring patients' compliance with their recommended treatment regimens. Against this rising tide of challenges, health-care systems are increasingly looking to leverage digital technologies for disease management solutions – technologies falling under the umbrella of 'digital therapeutics' (DTx).

As defined by Simon Makin in 'The emerging world of digital therapeutics' published by Nature in 2019, 'Digital Therapeutics are part of the broader digital-health landscape, but in order to be defined as a DTx, a product has to be software-driven, evidence-based, and make a claim to prevent, manage, or treat a medical disease or disorder'. Since that article was written, the digital therapeutics market has continued to grow rapidly, with a recent report by Grand View Research estimating that the global DTx market will reach $55.8 billion by 2027, growing at a compound annual growth rate (CAGR) of 24.6% from 2022 to 2027.

Digital therapeutics may be used independently or in combination with medications, devices, or other therapies to treat a broad range of conditions and frequently offer remote treatments that patients can carry out in physical isolation from a medical professional. Examples of the applications of digital therapeutics include:

- Chronic Diseases: digital therapeutics are employed in the management and treatment of various chronic diseases, including but not limited to diabetes, hypertension, cardiovascular diseases, chronic respiratory conditions (e.g. asthma, COPD), and chronic pain conditions.

- Mental Health Disorders: digital therapeutics solutions offer interventions for mental health conditions, such as depression, anxiety, post-traumatic stress disorder (PTSD), bipolar disorder, obsessive-compulsive disorder (OCD), and substance use disorders.

- Neurological Conditions: digital therapeutics are used in the management of neurological disorders, including attention-deficit/hyperactivity disorder (ADHD), cognitive impairments, and neurodegenerative diseases such as Alzheimer's and Parkinson's.

- Behavioural and Lifestyle-related Conditions: digital therapeutics target behavioural and lifestyle- related conditions, including smoking cessation, obesity, eating disorders, and stress management.

In this period of growth in the digital health market, numerous companies, both innovative start-ups and established healthcare incumbents are striving to disrupt the disease management space, introducing innovative models for managing chronic diseases. The US remains the leading region in the digital therapeutics market, benefitting from the early adoption of digital health technologies in the region, the large patient population with chronic diseases, and the strong regulatory environment. Examples of leading US-based companies include Omada Health, which provides digital care programmes for chronic conditions such as diabetes and musculoskeletal disorders and Click Therapeutics, a biotechnology company that develops software as prescription medical treatments for a wide range of indications, including smoking cessation, major depressive disorder, schizophrenia, insomnia, and obesity.

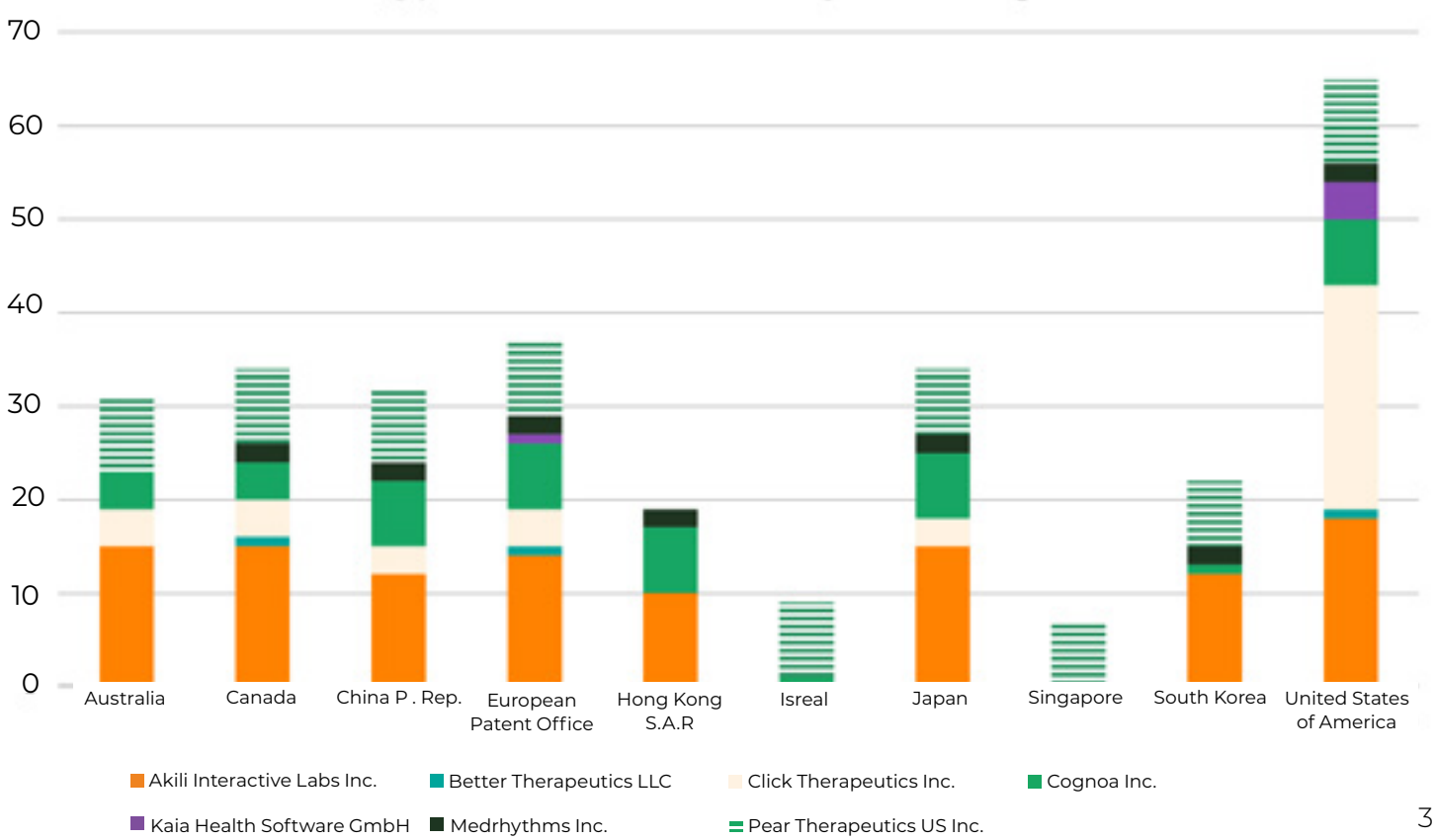
The European market is expanding rapidly however, with a number of leading companies such as Big Health, which offers digital therapeutics for mental health conditions, making rapid progress. With the regulatory environment developing to foster such innovative approaches it is clear that the European market provides significant opportunities for both the new innovative start-ups and the more established incumbents looking to scale up DTx solutions that could transform the landscape of chronic disease management.

Digital Therapeutics and IP

The rapid pace of development of the DTx sector has been reflected in a corresponding acceleration in patent filings, with companies seeking to proactively protect their innovation to secure broad protection for potentially foundational concepts that could secure a significant competitive advantage as this relatively new field matures. Although the costs of developing a new DTx product are significantly less than pharmaceutical therapeutics, research and development costs are still typically high due to the need to perform trials with patients to obtain the required evidence to support the commercialisation of an innovation. Having valid and appropriate protection for the marketed technology can also help businesses obtain further investment, assuring investors that barriers are in place to prevent competitors in the sector from developing corresponding technologies.

The chart below indicates the patent filing jurisdictions of certain leading European and US DTx companies. The main countries targeted for protection tally with those with well-developed health systems and the appropriate regulatory environment to allow the commercialisation of DTx products. Other factors, such as demographics, are also important. Many DTx products target chronic diseases, and protection in markets with ageing populations is often important, which is likely a factor in Japan where it features as one of the top filing jurisdictions.

Filing jurisdictions of leading DTx Companies



The US is clearly still the dominant market for DTx companies and has a well-established regulatory framework for these technologies. However, Europe has emerged as the second leading DTx market and a key jurisdiction for patent filings.

What is crucial for DTx innovators to understand is that, relative to the US, the European Patent Office (EPO) has a very different approach to assessing DTx inventions, which can present challenges if applications are not prepared in view of the legal framework. Digital therapeutics technologies typically fall in the intersection of several complex areas of European patent law. These include:

- the EPO's restrictions on patenting computer-implemented inventions; and in particular, whether the features providing a claimed therapeutic effect can be considered 'technical'

- restrictions on patenting methods for the treatment of the human body by therapy

It is essential that applicants and their patent advisors fully understand these restrictions in order to navigate this complex legal landscape and obtain the broadest patent protection that their innovation warrants.

At GJE, we have surveyed many applications in this area of technology to examine the approach that examiners are applying to digital therapeutics inventions and provide advice on how best to strengthen applications when drafting and arguing against these objections when they arise during prosecution. The remainder of this paper aims to summarise the current approach of the EPO to digital therapeutics inventions and provide practical advice as to the steps applicants should take to achieve the strongest patent protection in Europe.

"We have surveyed many applications in this area of technology to examine the approach that examiners are applying to digital therapeutics inventions."

The challenges for digital therapies at the European Patent Office

The EPO will recognise an invention as patentable when it has new features over the prior art, and these new features provide a non-obvious solution to a 'technical problem' – i.e. a problem that is considered by the EPO to be within the realm of patent protection rather than excluded subject matter, such as business or administrative methods. Typically, the applicant must demonstrate that the new features provide a 'technical effect'.

For conventional therapeutics, this technical effect will usually demonstrate that the new features of the drug provide a therapeutic effect, and this will often be evidenced in the form of experimental data showing the efficacy of the new features of the drug in treating a particular condition. DTx inventions, by definition, have evidence supporting their therapeutic efficacy, but despite this, it is clear that it is much more challenging to obtain granted patents for DTx inventions at the EPO. A rough search we conducted suggests that around 50% of published applications describing DTx inventions have been granted by the US patent office, compared to around 5–10% at the EPO.

So, what is the reason for the difference in approach for the EPO in assessing software-driven, evidence-based therapeutics relative to drugs and other forms of therapy? Is the therapeutic effect derived from a software-based intervention considered to have lesser technical merit than that of a drug compound? To answer these questions, it is necessary to review the EPO's approach to assessing software, or 'computer-implemented inventions', and how this is applied to DTx inventions when there are a number of specific considerations.

> "What is the reason for the difference in approach for the EPO in assessing software-driven, evidence-based therapeutics relative to drugs and other forms of therapy?"

The EPO framework for assessing DTx inventions

European patent law prohibits patents from being granted for 'computer programs as such'. This provision was motivated by the legislators' desire to prevent patent protection from becoming available, in the age of computers, for things now implemented in software that otherwise would traditionally not have been seen as patentable 'inventions'. For example, a computer program that simply automates an administrative process would likely be found to be unpatentable under this provision. However, a computer program (or other invention with software elements) will be eligible for patent protection if it is seen to produce a 'further technical effect' – a phrase that usually refers to the real-world effects achieved by the computer program, such as enabling control of, or yielding information about, a technical system. The existence of such a technical effect suffices to overcome the exclusion of 'computer programs as such'.

> "The EPO grants patents to computer-implemented inventions but only when the distinguishing features contribute to the 'technical character' of the invention."

Once the 'as such' exclusion has been overcome, the EPO considers whether any of the technical effects of the invention are achieved by virtue of features that are not present in whatever known technology has been cited as the closest prior art. If the distinguishing features do not produce any technical effect, the EPO will regard these features as being obvious and argue that the invention lacks an inventive step. Conversely, if the novel features do produce such a technical effect, the invention can be recognised as meeting the requirement of an inventive step based on these features, even if they are, when viewed in isolation, software features. This approach reflects a legal fiction that runs through EPO practice, which holds that only features that solve a technical problem can involve an inventive step.

To summarise, the EPO grants patents to computer-implemented inventions but only when the distinguishing features contribute to the 'technical character' of the invention, i.e. when the features provide a technical effect rather than an effect that the EPO considers falling solely within one of the excluded subject matter categories, such as administrative or mathematical methods. This raises the question of whether the provision of digital therapy – the treatment of a health condition with software – is considered to be a technical effect.

Is the provision of digital therapy considered technical? Our survey of the EPO's approach

As yet, there is no established case law specifically on the patentability of DTx. There are no Board of Appeal decisions in which the Board has had to decide specifically on the issue of the technical merit of an evidence-based DTx invention. For this reason, we have assessed a large number of DTx applications at the EPO to survey the approach of examiners on this point. An initial observation is that there is still quite some variation in approach, and different conclusions have been reached even on similar therapy applications of DTx. However, several important conclusions can be drawn from this analysis.

The first point is that the EPO's assessment of the technical merit of a DTx invention varies across different types of therapy and the health condition being targeted. The use of software to control hardware elements such as sensors (to monitor glucose, for example) and stimulators to provide direct, physiological therapy to the body will usually meet this requirement. However, many DTx inventions use purely software elements and provide no direct physical intervention on the body. Moreover, many are targeted at mental health and neurological conditions rather than physical conditions of the body.

We have seen an inconsistent approach from the EPO in assessing software directed at mental health and neurological conditions. For example, a joint Novartis and Pear Therapeutics application, EP3877982, seeks to protect 'Electronic Devices and Methods For Treatment Utilizing Antipsychotics In Combination With Digital Therapies' and essentially claims an app that the user interacts with to document their mental state through the selection of graphical elements. This provides improved efficacy in the treatment of schizophrenia over the use of drugs alone. On this application, the examiner defines the purpose of the invention as 'to treat schizophrenia' and states 'this purpose is considered technical', therefore

In contrast, on EP3956905, filed by Pear Therapeutics and directed to 'an electronic device for treating depressive symptoms associated with multiple sclerosis', the examiner describes the distinguishing features as relating to 'psychological information, which cannot bring about a technical effect serving a technical purpose but rather only a subjective effect -allegedly a psychological therapeutic effect'. Similarly, on EP4176448, again filed by Pear Therapeutics, claiming a system for treating a disease using cognitive behavioural therapy, the examiner states the distinguishing features 'are all non-technical since they related to non-technical subject matter, namely psychotherapy'.

In summary, the EPO approach has not always been consistent. Positively, there are many cases in which a software-implemented therapeutic effect has been recognised as a technical purpose, but the EPO appear to be much less consistent in their assessment of the technical merit of therapy directed at mental health and neurological conditions. It appears that the EPO does not currently consider an evidence-based therapeutic effect in this area on a par with a physiological therapeutic effect, particularly where they do not permit as specific, directly quantifiable measures of the effects of therapy. As described further below, in this area of therapy, it appears particularly important to include data evidencing the claimed therapeutic effect of the software.

"The EPO approach has not always been consistent. Positively, there are many cases in which a software-implemented therapeutic effect has been recognised as a technical purpose."

Demonstrating a causal link between claimed features and the therapeutic effect

Although the EPO recognises a therapeutic effect as being technical, a common objection found in the applications surveyed is that the claim features are not clearly defined and sufficiently limited to be credibly linked to the effect. This relates to a key difference between pharmaceutical therapeutics and DTx. Whereas for the former, data can often be collected to show that a specific claim feature (for example, the inclusion of a specific amount of a certain compound) is directly linked to an improved therapeutic outcome, for DTx, the therapeutic effect may be provided by the use of a software program including a large number of features; therefore, it may be more difficult to link a particular feature to the improved therapeutic outcome. It also appears that often applicants have not clearly set out the link between features and the effect, including the provision of data to evidence the link.

For example, on Novartis/Pear Therapeutics' application EP3956905, although the alleged technical purpose (treating schizophrenia) was acknowledged as technical, the examiner held that 'the claim is not sufficiently limited to ensure that this technical purpose is actually served by the distinguishing features over the whole claim scope'. This type of objection was extremely common. For example, on EP3928328, 'Systems And Methods For The Treatment Of Symptoms Associated With Migraines', the examiner's position was that 'at the current level of detail, the independent claims are not sufficiently limited to ensure that the features actually produce a technical effect serving a technical purpose over substantially the whole claim scope' and 'there is no causal link between the broad inputs, the mathematical/algorithmic processing steps and the actual provision of a technical effect'.

"Applicants often fail at convincing the examiner that the claimed features have a causal link to the described therapeutic effect."

In summary, even if the purpose is accepted as technical, applicants often fail at convincing the examiner that the claimed features have a causal link to the described therapeutic effect. There are a number of reasons for this. In some cases, the features can be more difficult to define, for example, where the user interacts with the software in various ways, through the provision of prompts, display of visual data, and interactions with a GUI. Applicants often struggled to clearly define the specific features involved in the required interactions that allegedly lead to the therapeutic effect. Furthermore, the applications we surveyed often did not provide data to show that the claimed features resulted in the alleged therapeutic benefit. Whereas the provision of such data is routine for pharmaceutical therapeutics, this was much less common in the DTx applications surveyed – perhaps related to applicants' representatives generally having an engineering/software background and being less experienced in providing data when drafting applications.

Digital therapeutics and the medical methods exclusion

The European Patent Convention (EPC) prohibits the patenting of 'methods for treatment of the human or animal body by surgery or therapy'. In practice, this provision is implemented by applying the rule that a method cannot be patented if it contains one or more steps that constitute a method step for the treatment of the human or animal body by therapy. A consequence of this approach is that any claim that recites one or more such method steps is not allowable, even if it includes other features that would, in isolation from the therapeutic method step, meet all the requirements for patentability. This is different from the approach to computer programs, where the presence of non-technical features in a claim that also contains features producing a further technical effect is no obstacle to patentability.

This provision is relevant to some digital therapeutic technologies because they may be seen as embodying a method of treatment by therapy, such as in the case of a software application that is intended to have a therapeutic effect on the user. As noted above, this prohibition is absolute in the sense that a claim containing one or more therapeutic steps can never be patentable. The EPO determines whether a method step is 'therapeutic' based predominantly on whether it produces a therapeutic effect when performed, and usually, any method with steps that produce such an effect (and is practised on the human or animal body) will be found to fall inside the exclusion.

A squeeze between Inventive step and the medical method exclusion

As noted above, patent applications for digital therapeutics technologies are at risk of running into difficulties under European law's provisions on both software and therapeutic methods: their software elements risk being treated as non-technical computer program features, while the invention as a whole may be interpreted as a therapeutic method of the kind that is barred from patentability.

"Patent applications for digital therapeutics technologies are at risk of running into difficulties under European law's provisions on both software and therapeutic methods."

More concerningly, this particular combination of exclusions creates an opportunity for the patent examiner to adopt a 'squeeze' position, whereby an argument that one exclusion does not apply appears to concede that the other does. For example, if the examiner were to object that the invention as claimed lacks an inventive step on the grounds that its software features do not appear to produce any further technical effect, the applicant might argue that the software does achieve a technical effect because of the therapeutic effects it has on the patient. The examiner would then reply that, if it is the case that the invention as claimed produces a therapeutic effect, it is excluded from patentability as a therapeutic method. We have seen examiners adopt this position in the prosecution of real applications.

Once it arises, this 'squeeze' position can be difficult to escape. In an application directed to an invention whose central aim is the production of a therapeutic effect, it is natural that the claims will contain all of the features that are needed to produce that effect. This, however, can bring the claim within the therapeutic methods exclusion, and, typically, a patent specification will not contain basis for removing such steps from the main claim (particularly under the EPO's strict rules on basis for amendments). The hazards outlined above should therefore be considered when drafting the application, since escaping the trap by later amendments can be extremely difficult, if not impossible.

Because the EPC states that the provision on therapeutic methods does not apply to products, the risk of this trap arising can be reduced significantly by claiming the invention in terms of a product – for example, by directing the claims to a processor or other device configured to carry out the relevant steps. Such a claim may still be susceptible to objections on the grounds that it does not achieve a technical effect over the relevant prior art, but arguments about the technical effects produced by the invention are unlikely to provoke further objections under the therapeutic methods provision.

If there are aspects of the invention beyond the core set of method steps involved in producing the therapeutic effect, these can be claimed separately and may be considered patentable on their own. For example, any new hardware (or indeed new ways of operating or controlling known hardware) could be claimed without explicit reference to the therapeutic method in which they are employed. Claims of this nature are unlikely to fall under the therapeutic methods exclusion because they do not, in isolation, produce a therapeutic effect of the kind that the exclusion is concerned with. Moreover, there will often be a good case to be made for their technical character under the provisions on computer-implemented inventions, since they relate to the strictly technical developments that enable the therapeutic method to be performed.

Preparing strong patent applications for DTx inventions in Europe

Although challenging, we assess that there are steps that applicants can take to significantly improve the chances of securing grants for DTx applications in Europe. Applicants should take steps to ensure:

- A technical effect is clearly defined – this may be in the form of an improved therapeutic outcome provided by the claimed features.

- Whenever possible, data should be provided to evidence the therapeutic effect.

- Claims should be drafted that clearly define the specific technical features linked to the therapeutic outcome to ensure that the therapeutic effect can be argued as provided over the whole claim scope – often DTx applications fail due to the claims being considered too vague, without the required technical detail.

- A device or system claim should always be included as a means to circumvent the method of treatment objections.

Although grant rates for DTx inventions have significantly lagged behind the US, there are signs that the EPO approach is softening, with a recent increase in the number of grants in Europe, even in areas where it would conventionally be assumed it would be particularly challenging to convince the EPO of technical merit. For example, Better Therapeutics Inc. recently secured a grant, albeit of narrow scope, on EP3628101 for a 'method and system for managing lifestyle and health interventions' – a subject matter that might be considered particularly challenging in Europe. Furthermore, it is clear that the EPO is willing to acknowledge a technical effect and, therefore, patent eligibility of DTx. If applicants are able to draft claims that clearly define the technical features and can argue a causal link to the technical effect, it is possible to secure strong protection for DTx inventions in Europe.

GJE's multi-disciplinary HealthTech team combines experienced attorneys across technical fields to provide expert advice on the protection of the full range of HealthTech applications in Europe and globally. Please get in touch to speak to a member of the team.

"If applicants are able to draft claims that clearly define the technical features and can argue a causal link to the technical effect, it is possible to secure strong protection for DTx inventions in Europe."

Gill Jennings & Every LLP

The Broadgate Tower
20 Primrose Street
London EC2A 2ES

T +44 (0)20 7655 8500
F +44 (0)20 7655 8501

gje.com