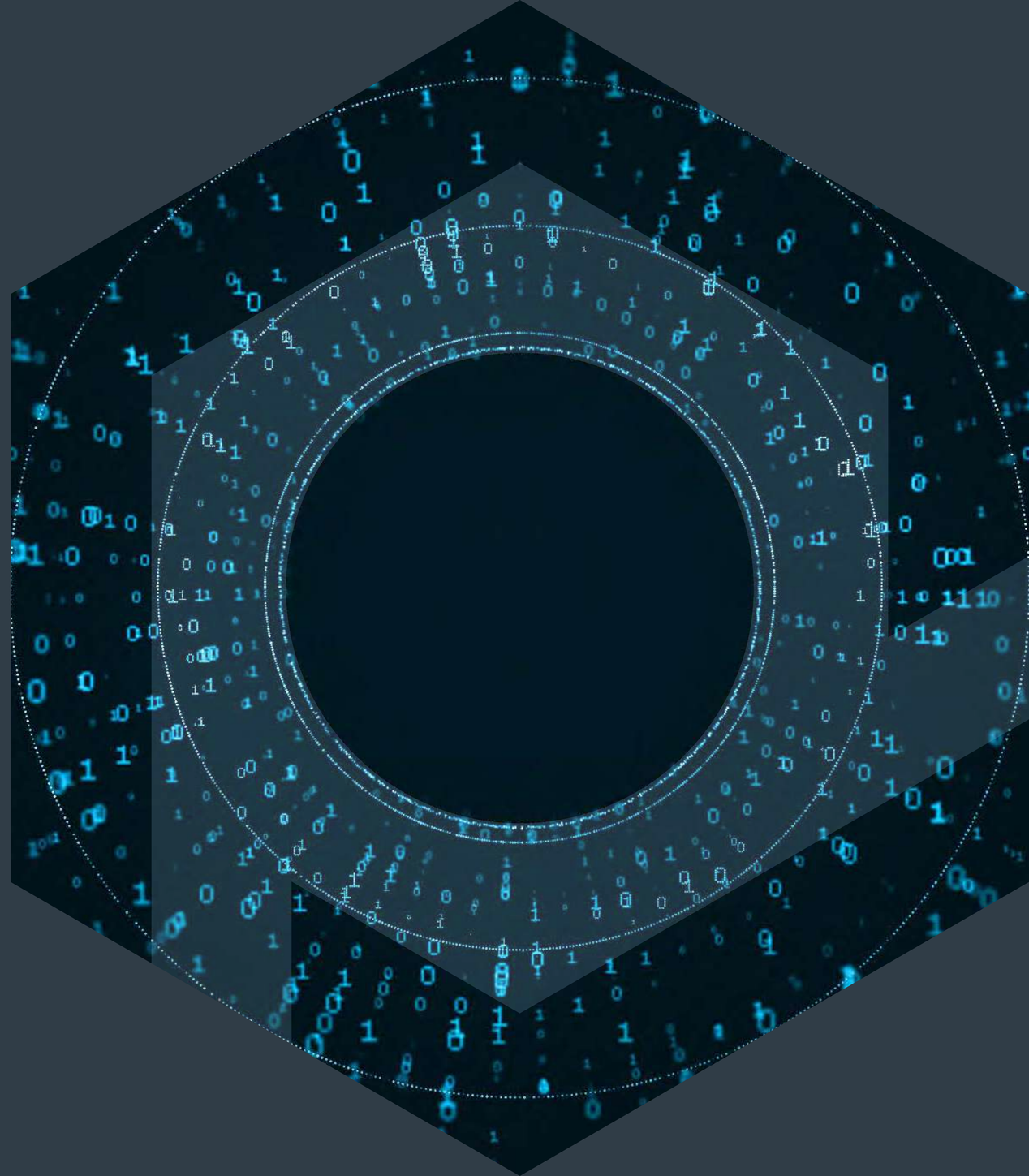
Potter Clarkson

MAXIMISING THE COMMERCIAL VALUE OF **DIGITAL THERAPEUTICS**



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The incessant and increasingly rapid advances in mobile technology and artificial intelligence are driving the definition and development of digital therapeutics at an equally impressive rate.

The misconception that digital therapeutics equates to well-being and digital health apps you can download from an app store has been replaced by an understanding that what we are actually talking about are highly sophisticated digital tools that can improve patient outcomes, or to use Wikipedia's definition:

"A subset of digital health, are evidence-based therapeutic interventions driven by high-quality software programs to prevent, manage, or treat a medical disorder or disease."

The limitless application and benefits of digital therapeutics have understandably caught the attention of big pharma. They can see digital therapeutics offer them the opportunity to increase the impact their drugs will have on their patients and, at the same time, reduce their patients' reliance on local health services.

As a result, pharmaceutical companies have begun to forge strategic partnerships with tech companies.

These collaborations will provide them with the technical capability they'll need to realise the promise of significant improvements to patient outcomes not to mention realise their share of what is predicted to be a $9 billion market by 2025.

However, increased collaboration has the potential to increase risk. This risk is not only linked to market regulation and market acceptance but also in terms of access to, and use of, health data and how the ownership of the final digital product is defined and commercialised.

We are now entering healthtech's next phase and that phase is digital therapeutics. It will see digital health become a powerful and validated tool to complement traditional drug therapies prescribed by doctors.

It also means moving into the more science-driven end of the spectrum where the software is classed as a medical device and is regulated accordingly.

We are very close to the stage where medicine and software work side-by-side, with doctors prescribing an app in combination with drugs to deliver a better therapeutic outcome for the patient.

This means that from an IP perspective, it's not just about patenting pharmaceuticals in the traditional way. It is vital for every digital therapeutics venture to consider wider issues such as protecting the underlying health data and software algorithms. Moreover, it will involve finding the right way to obtain patents that map to drug/device labels."

FIONA LAW, PARTNER,
PATENT ATTORNEY

My belief is we are only just scraping the surface of digital therapeutics which is incredibly exciting.

We really are witnessing a truly transformative tech manifest in action. However, as always, huge potential comes with huge risk. This means IP has an enormous role to play in every project's success.

This is a legal tightrope. On one hand you have the traditional difficulties that envelop the protection of computer software and data-driven innovation. On the other you have the demands of the pharmaceutical industry, an industry that has rightly always placed great value on IP regulatory protection and clinical evidence.

Walking the tightrope will require and needs both a very different mindset, and people from different technical backgrounds who can collaborate to the same extent as your pharma and tech partners have had to in order to get you to this point."

PETER FINNIE, PARTNER,
PATENT ATTORNEY

WHERE ARE WE TODAY

Investment in digital therapeutics companies in the US alone is growing by an average of 40% every year. This level of investor interest isn't a coincidence. It is driven by the global healthcare industry's growing demand for digital therapeutic tools, demand that is driving up the speed at which the supporting technologies are being developed.

And a faster rate of development is making an ever greater volume of data available. This is allowing digital therapeutics companies to derive even more accurate and wide-ranging insight from this data.

More importantly, the increase in data has provided even more compelling evidence that these digital interventions really do work, particularly – according to studies – within the fields of cancer, asthma, drug addiction, schizophrenia and insomnia.

This combination of advancement and demand has understandably caused the rate at which new personalised delivery mechanisms (including apps, smartphones, and wearables) are reaching the market to soar. Manufacturers are understandably looking to capitalise on patients' current demand for more convenient and informative solutions and physicians' demands to manage their patients' wellbeing digitally, remotely and – of course – more cost-effectively.

However, there are several obstacles the providers of digital therapeutics need to navigate:

1. REGULATORY APPROVAL
2. RATE OF ADOPTION
3. INTRODUCING THE REQUIRED OPERATIONAL INFRASTRUCTURE
4. ADDRESSING CAPABILITY GAPS

1 REGULATORY APPROVAL

Regulators are still building a regulatory framework to support digital therapies. They are trying to define the criteria they will use to balance the measures they have always used for drugs with the new criteria they'll need to use to evaluate the design, software and connectivity of the associated delivery devices.

This is likely to become even more complex as AI and machine learning become more involved, forcing a new approach to regulatory approval. AI is a moving target, and that is difficult to regulate.

At the time of writing the US Food and Drug Administration (FDA) has been urged to look at three key areas to help them align their approach to the needs of digital therapeutics:

- New guidelines covering multi-functionality, changes to the software in/behind an existing device and the clinical approach to 'Software as a Medical Device'.
- The introduction of a 'Software Precertification Program' that would replace the need for a premarket submission for certain products and, potentially, allow for reduced submission content and/or a faster review of the marketing submission.
- Hiring new staff with a deeper understanding of software development and its application.

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2 RATE OF ADOPTION

While digital therapeutics are growing in popularity, special attention still needs to be paid to the likely rate of adoption by both patients and healthcare providers, with a clearly defined path to reimbursement.

Depending on which area of digital therapeutics your business is involved in, you will need to make major strategic decisions as to how you will approach the promotion and sales of your product. You will also need to define the way you see it integrating into the daily lives of your patients and the working practices of their physicians.

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3 INTRODUCING THE REQUIRED OPERATIONAL INFRASTRUCTURE

Digital therapeutics need to close the gap between doctors and patients. They must allow both to exchange information so doctors can intervene appropriately (including prescribing alternative dosages or treatments) in near real-time rather than waiting for the next appointment or for the patient to ask.

This has been particularly important during the COVID pandemic as patients and physicians seek technology solutions to remote medicine. This has increased all parties' interest in digital solutions further still.

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Successfully bridging the gap between technology and treatment requires everyone in the digital therapeutics value chain to adopt a new way of working.

Pharmaceutical companies have the drugs but require innovative and effective digital solutions that can improve outcomes whilst satisfying the relevant regulatory constraints.

Meanwhile, tech companies have the data gathering and analytic capabilities and the ability to maximise the application of cutting-edge technologies like AI and voice command and the power to design and manufacture the most consumer-friendly portable/wearable units.

As a result, the traditional ‘buy or build’ response both parties would have tabled in the past is arguably not workable. Instead, we’d suggest that at this time, it may be more prudent for pharmaceutical and tech companies to start from a more central point, collaboration.

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HOW COULD COLLABORATION WORK IN PRACTICE?

The world of digital therapeutics is likely to be very different in three years let alone ten but at this point in time, a fully collaborative joint venture probably offers pharma and tech businesses the most straightforward and cost-efficient route to establishing a new digital therapeutics vehicle.

However, this is likely to be the first time pharma companies have had to work this closely with digital or tech specialists. This means that when tackling each of the points your objective has to be to find a way to marry the very different expertise of the founding members to create a viable digital health business.

You will need to achieve a hybrid that combines healthcare with technology. You will also need to make sure you have all the requisite understanding of disease, treatment, pharmacology, the regulatory environment, software development and how best to manage, analyse and utilise the data you'll collect.

Having had extensive involvement in a number of this type of venture, there are several ‘watch outs’ we would always highlight in our initial discussions with the relevant parties:

Define everything clearly from day one. Who owns what and how will all parties be remunerated?

Innovation goldmines are often present in the data that are generated during collaborations. Defining ownership and usage of the data is paramount.

Create a business model that allows all partners to recognise the greatest return from all the potential revenue sources.

Ensure you have the combined capacity to manage the increase in demand your partnership will generate.

Try to keep the number of partnerships under control; working with too many parties can make progress difficult to manage.

While your partnership will drive your business, never lose sight of what is best for the end users (patients and clinicians) and make sure their needs are always addressed.

WHY SHOULD A NEW DIGITAL THERAPEUTICS VENTURE TALK TO POTTER CLARKSON?

Irrespective of whether you are the pharmaceutical partner or the tech partner there are two key legal areas you will need to address to protect your assets, market position and future revenues:

1. INTELLECTUAL PROPERTY

Effective IP management must start as early as possible by identifying all the innovation present and then constructing the IP strategy you'll need to deliver your business plan, always bearing in mind which partner owns what if a collaboration is involved.

This is far from easy to action. If it is to be effective and enforceable, your strategy must be approached from both a pharmaceutical and technology point of view. It also needs to pay particular attention to the nuances of protecting software and clinical innovation.

2. LEGAL

It is highly likely that once you start to put your business plan into action you will find that you need to add a stronger legal structure to protect your planned trading arrangements.

Depending on your proposed business model this could require you to enter into a new set of domestic or cross-border legal agreements, contracts or licensing arrangements with your partners, suppliers and customers.

And given the nature of today's highly competitive healthcare industry, you could also find yourself in need of experienced representation should your position or your IP be challenged.

There are three reasons we believe Potter Clarkson are the best choice for providing both the IP and legal security you will need to progress your digital therapeutics venture:

1. A WEALTH OF DIRECT EXPERIENCE

We can provide specific examples of the digital therapeutics projects we have advised on and explain how our proven multi-disciplinary approach has benefitted our clients commercially.

Aside from providing a solid foundation for the digital health businesses we've worked with, we can also explain how we work closely with the investment community to make sure that should you need investment, your offering is attractive to potential investors.

2. A TRACK RECORD OF INTERNAL COLLABORATION

We can provide a number of examples of how we have assembled hugely experienced multi-disciplinary teams of attorneys from across our technical departments.

This unique way of working allows us to deliver both the required mix of pharma and tech expertise and the additional commercial and strategic input you'll need.

3. COMPREHENSIVE COVERAGE

These teams are supplemented by our in-house IP solicitors who are on hand to deal with a much wider range of commercial law requirements. They will make sure the legal agreements, contracts and licencing arrangements underpinning any joint venture are not only fully enforceable but also represent the best commercial interests of all parties. They will help you carry out your commercialisation strategy.

As we are talking to colleagues rather than external advisers, the ability to work in tandem with our solicitors will make the whole process more cohesive, more efficient and more cost-effective for you.

SPEAK TO OUR EXPERTS

Peter Finnie
Partner
UK and European Patent Attorney

+44 (0)20 300 500 13
peter.finnie@potterclarkson.com

Fiona Law
Partner
UK and European Patent Attorney

+44 (0)20 300 500 18
fiona.law@potterclarkson.com

OUR ACCOLADES

You can be truly confident in our abilities – we are recognised as a top-tier firm in Europe, having received accreditations from the IP profession's leading benchmarking organisations and programmes.

CHAMBERS AND PARTNERS UK

LEGAL 500

MIP IP STARS

FINANCIAL TIMES

IAM PATENT 1000

WTR 1000

Recognised for his "extensive technical and commercial expertise", Peter Finnie is a "leader in the field" who works with a long and growing list of European start-ups, advising them on the development of their IP strategies."

IAM Patent 1000: The World's Leading Patent Professionals 2020

Fiona is a delightful person to know and has proven very effective in guiding our overall patent strategy. I can unequivocally say that she is the best patent agent I have worked with in over 45 years in the industry."

IAM Patent 1000: The World's Leading Patent Professionals 2020

Potter Clarkson
UK Sweden Denmark Germany
E info@potterclarkson.com

POTTERCLARKSON.COM