Connected Health:

Intellectual Property as ROI – ‘Return on Innovation’.

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1. Introduction

Healthcare is in accelerated disruption with the Internet of Things (IoT) at its core and driven by consumers. Consumerisation of healthcare is empowering patients to monitor their own health and disrupting the usual doctor/patient relationships. The advent of the Smartphone, in particular, means patients are no longer passive recipients of care. Traditional industry operators in the healthcare industry are facing new competitors from tech and innovators in connected health. Through technology, personalised care at home is possible. The vast improvements in healthcare delivery through a preventative model of self-monitoring are only achievable through innovative connected health technology. This paper asserts that the question for connected health is not simply ROI: 'return on investment' but rather more significantly ROI: 'return on innovation' (ROI).

Using the lens of Intellectual property (IP) this paper seeks to define and evaluate the appropriate areas of protection for connected health products that offer ROI. First, a literature review considers theory relevant to connected health, legislation and regulation. It looks at the connected health market value and the high technology market in which connected health innovators seek ROI. Theory and literature on five key areas of IP – patents, copyright, design, trade secrets, trademark - is also reviewed. Data protection is also considered.

Accepting the importance and relevance of the five areas of IP listed above, this paper then engages in a detailed exploration of each through a European/United States (EU/US) comparison. It examines the national agencies involved, requirements, legal aspects and differences across both markets to ensure protection of a connected health product and ROI. Each area uses a case study example to illustrate the IP option.

Subsequent to this, the paper moves to connected health IP in practice. The primary research captures a brief 'in practice' view from five Irish companies currently engaged in connected health IP for ROI. The research conducted was through short questionnaire-based interviews with the aim of securing a non-exhaustive insight into current practice. It identifies respondent companies' ROI in IP across the two markets detailed in this paper – the US and EU.

Each company answered multiple-choice questions on IP activity and EU/US markets, with an additional free text option for some questions to express opinions and preferences. Regarding data protection, the data controller for the research is the author and all data is anonymised with a key identifier held only by the author. Having understood the landscape requirement for IP in five key areas in the EU and US markets and assessed this against a temperature check of five companies currently engaged in these markets, the paper moves to its conclusion.

This paper concludes by firmly establishing IP as central to ROI for connected health.

2. Literature review

2.1 Connected health

Over a decade ago, Poon and Zhang (2008) described a paradigm shift in health care, one that suggests that preventive, pre-emptive and predictive healthcare decisions should be made in a pervasive, participatory and personalised manner. Carroll et al (2016) define connected health as

- An emerging model of care engaging technology to improve patient care.
- Encourages self-efficacy developing client-centred care pathways.
- Evidence-based interventions reduce the need for hospital-led care and empower patients in their homes.
- Promotes improved 'connectivity' between healthcare stakeholders by means of timely sharing and presentation of accurate and pertinent information about patient status.
- Connected health initiatives can achieve this through smarter use of data, devices, communication platforms and people.

Similarly, Caulfield and Donnelly (2013) define connected health as "a conceptual model for health management where devices, services or interventions are designed around the patient's needs, and health related data is shared, in such a way that the patient can receive care in the most proactive and efficient manner possible".

Richardson (2015) describes connected health as patient-centred care resulting from process-driven health care delivery undertaken by healthcare professionals, patients and/or carers who are supported by the use of technology - software and/or hardware. Carroll et al., (2016) consider connected health to be a socio-technical healthcare model that extends healthcare services beyond traditional healthcare institutions. They assert that the exploitation of technological innovations, means healthcare providers can generate accurate and timely information for patients and clinicians to make better decisions. Improved decision-making tools can improve the likelihood of saving lives, save money and ensure a better quality of life during and post treatment (Hunink et al, 2014).

2.2 Legislation and regulation

Food and Drug Administrators

The US regulator Food and Drug Administrations (FDA) Center for Devices and Radiological Health published the Digital Health Innovation Action Plan, in 2017. The plan defines digital health products to include wireless medical devices and mobile medical apps that are regulated by the FDA, health IT, medical device data systems and software.

European Commission

The European Commission aimed to enhance the use of digital technology through the creation of a Digital Single Market (DSM). Launched in 2015, the DSM aims to open up digital opportunities to people and business, and to bring the EU's single market into the digital age. Health is one of the sectors included in this agenda. The Commission holds that digital health and care refers to tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of health and lifestyle.

It is worth noting here, though not applicable until 26 May next year, the new Medical Devices Regulation (2020|) (MDR), will begin to influence connected health innovation also. The 2020 MDR, introduces some new concepts, definitions, classification rules and procedural requirements for medical device software. Some digital health technologies will fall into the scope of the new European MDR.

International Medical Device Regulators Forum

Although not a core focal point, the paper will touch on software as a Medical Device (SaMD). The *International Medical Device Regulators Forum* (no date) (IMDRF) is a voluntary global group of medical device regulators assembled to reach harmonisation on medical device regulation. SaMD is defined by the *International Medical Device Regulators Forum* (IMDRF) as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device".

2.3 High technology markets and the connected health market value

Over the past five years, services and technology have become the fastest-growing profit pool in the healthcare industry, a trend driven by the significant value creation potential of technology-based and enabled innovations (Onitskansky et al, 208). Mohr et al (2006) define companies operating in high technology environments as confronted by a triple threat of market, competitive and technological uncertainty. The high technology market has a number of defining characteristics. Rapidly changing technologies indicate shorter product lives. Increased customer choices, product customisation, rapid technological improvements and global competition all contribute to volatile demand patterns (Mohr at al 2006) (Vairdot, 2014).

The global digital health market is expected to reach $223.7 billion within five years based on increasing penetration of mobile devices, remote patient monitoring, and growing demand for advanced information systems (Liclolai 2019). According to a recent report, over one-third of the world population owns a smartphone and this proportion is expected to increase (Lucintel, 2018).

2.4 IP and Knowledge Transfer Ireland (KTI)

Knowledge Transfer Ireland (KTI) directly supports the development of Ireland's knowledge transfer infrastructure, through engagement with business, investors and technology transfer offices to shape practice. KTI revised its 'Research Priority Areas 2018 – 2023' (KTI, 2018) to include 'Connected health and independent living'. IP is sometimes called IPR or IP rights. The word 'rights' refers to the legal aspect of IP. KTI (2019) defines IP or IPR as:

“Patents, trademarks, service marks, registered designs, drawings, utility models, design rights, business ideas, concepts, inventions, discoveries, breeders’ rights, copyright (including the copyright in software in any code), database rights, know-how, trade secrets and other confidential information, technology, business or trade names, goodwill and all other rights of a similar or corresponding nature in any part of the world, whether registered or not or capable of registration or not, and including all applications and the right to apply for any of the foregoing rights”.

Module notes 7.3 outline the market necessity of IP as:

- The need to protect investment in technology and R&D.
- Acceptance of the concept of ‘intellectual capital’.
- Increased use of licensing.
- Freer dissemination of information.

A recent key legal guide (Hanna et al, 2017) explains that a hybrid of gathering data - software to process, store or use the data and a physical device that presents data may constitute he connected health innovation. As such, IP for connected health innovations tends to involve a combination of forms of IP protection. The report explicitly states “the breadth and intensity of R&D across the connected health space means that innovation has a significant potential for reward, but innovations must be shielded from release into the public domain too early and fiercely guarded.”

2.4.1 Patents

Module notes 7.5 state that a patent is a monopoly to make, use, and sell an invention in a certain country. Bloom et al (2019) echo this - patent is a temporary right to exclude others from selling a protected invention. Ellis (2013) advises that having developed new products or services, companies ought to obtain patent or appropriate relative protection in the hopes of closing markets to competing firms and raising prices.

It is only necessary to file an application initially in one country, usually your own. There is an international convention by which countries recognise the date of first filing which is called the priority date (Module notes 7.5.1).

SaMD is a growing area in which connected health innovators are considering patents. For Caroll et al (2016) connected health encompasses terms such as wireless, digital, electronic, mobile and tele-health and refers to a conceptual model for health management where devices, services or interventions are designed around the patient's needs. The authors expand, connected health implies that peripheral devices may be considered medical devices but the connectivity or the process of integrating them into one service solution may not. This where SaMD can emerge.

2.4.2 Copyright

Modern copyright law accords protection from the instant that the work is created and of expression (Balganesh, 2017). Copyright 'subsists' in a work from the moment it is put in a fixed form. To qualify for copyright protection, 'original' means that the work originated with a person, and that it was not a copy of another work (Module notes 7.6). The work being 'original' does not mean 'unique', as copyright is not a monopoly right.

It is recommended to arrange the assignment of copyright outright, where there is a possibility of legal action at some time in the future that could involve the company's drawings or software. In the case of software, it can be useful to print out a listing of code and get it signed and dated by the software developers (Module notes 7.6).

2.4.3 Registered Design

Pavel (2007) defines the design registration principle as the proprietor of design's certificate, which confirms ownership of rights connected to certain useful article. Designs refer to aesthetic features of a product and are distinguished from previous designs by the requirement to have individual character. Unregistered design right provides a short-term form of copyright in three dimensions for the aesthetic aspects of industrially produced articles. A registered design covers the appearance of a product or part of a product (Module notes 7.7).

2.4.4 Trade secret/secret know how

Trade secret/secret know how are often used interchangeably. *The World IP Organisation* (no date) (WIPO) states "trade secrets are IP rights on confidential information which may be sold or licensed". In general, to qualify as a trade secret, WIPO advises the information must be:

- Commercially valuable because it is secret.
- Known only to a limited group of persons.

- Subject to reasonable steps taken by the rightful holder of the information to keep it secret, including the use of confidentiality agreements for business partners and employees.
- Trade secrets encompass technical information, such as information concerning manufacturing processes, experimental research data and software algorithms
- Tarde secret also comprise commercial information such as distribution methods, list of suppliers and clients, advertising strategies.

Trade secrets can be particularly useful in cases where the innovation is hard to replicate — such as one that relies on an extensive and meticulously created data set and a multidimensional analytic model (Harris 2016) (Lemley 2018). Secret know-how is frequently protected by preventing access to the source code. If the end-user only has a copy of the program in object code it is much more difficult to access the structure of the program (Module notes 7.10). Tight employment contracts are required to retain the use of secret know-how and trade secrets.

2.4.5 Trademark

Trademarks are distinctive names, logos or graphic representations for products or services and are used to make a connection between the promotion of the goods or services and the supplier (Module notes 7.10). The basic concept of trademark law is universal: distinctive signs indicating commercial origin are protected against acts by third parties that would expose consumers to the risk of confusing commodities offered from different sources (Kur, 2012).

Trademarks are used to make a connection between the promotion of the goods or services and the supplier. They can acquire considerable importance because of the goodwill they protect. Trademarks provide indefinite protection for this type of IP (Module notes 7.10).

3. Data protection

Current theory outlined defines connected health as personalised, preventative health care with data sharing at its core. Digital platforms connect, combine and share this data fueling global healthcare innovation. It is worth noting that in terms of the data involved in connected health products, EU General Data Protection Regulation (GDPR) and in the US Health Insurance Portability and Accountability Act (HIPPA,) compliance play a significant role in product development.

The regulations touch upon areas like data encryption, pseudonymisation, consent management, authentication and audit logs. GDPR addresses sensitive personal data, whereas HIPAA deals with protected health information only. Connected health innovators, when considering EU/US markets must adhere to both.

4. Connected health IP

For the software and app development at the core of connected health, the first problem in protecting this innovation is how to define it. Idea protection is not possible but the form of expression of ideas when they are expressed in some fixed form such as writing, diagrams or recordings on magnetic media is possible. It is possible to protect algorithms, flow charts and source code (Module notes 7.10).

This paper has identified five key areas of potential IP protection in connected health innovation. It now examines each, through the lens of an EU/US comparison.

4.1 EU/US: Patents

WIPO works to harmonise IP laws, but there are differences between countries. Essentially patents are a system of disclosures - the state assesses each disclosure and, if eligible, will grant a patent which gives monopoly rights to the owner of the invention for a period of time.

US path

- The key body involved is the United States Patent and Trademark Office (USPTO).
- It is possible to patent software developments (e.g. algorithms), that have novel features or those with a hardware element. The software must contain an inventive step. There must be more patentable material than the algorithm.
- The date of inventing is recognised and the inventor has one year from this date in which to validly apply for a patent.
- In January 2019, the U.S. Patent and Trademark Office (USPTO) issued new and very clear guidance that could help connected health innovators. The guidance advises on securing patent protection for connected medical devices that incorporate ‘smart’ technology - SaMD.
- The FDA also offers a pre-certification program for digital health applications. Developers or manufacturers to create adapt or expand software functionalities.

FDA maintains an advice dialogue throughout the process. Excellent example of regulator working to keep up with technology.

US challenges

The 2014 U.S. Supreme Court judgment in Alice v. CLS Bank International, 134 S.Ct. 2347 significantly affected connected health patents. The core findings in this case rejected the claims of connecting a patient to an available doctor – a core product offering - as eligible for patent and deemed it invalid on the basis of 'abstract idea'.

This judgment has negatively affected software patents. Resulting in declines in business method and software patent issuances. Business method patents, a class of patents, which disclose and claim new methods of doing business are possible in the US but not in the EU. Alice has also invalidated many existing software patents that have been subsequently challenged in federal court.

EU path

- Applicants file an application at the European Patent Office (EPO) and can file patent applications in national patent offices. For instance in Ireland with the recently renamed IP Office of Ireland.
- The patent must give a 'technical effect' – the outcome of which could not be achieved without the software and it is a first to file system.
- While the US is quite clear on SaMD, the *EU Medical Devices Regulation (2017/745)* has caused concern. The drafting of Rule 11 appears to allocate a significant proportion of software medical devices to higher classes: "software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa". Making the process more difficult for innovators to use SaMD to patent.

EU challenges

- Harmonisation through the EPO means that granting of a European patent acts as approval for national patents across domestic offices. However to use the protection in each country requires a process called 'national phases', which requires translation into each national language. This can be expensive, a cost borne by the innovator.

- SaMD – outlined in the previous section, will certainly pose challenges before bearing opportunities when the EU MDR take effect next year, as it is already causing confusion through literal reading of the new regulations. Tie will tell if interpretations may vary when applied in practice.

Overall

- For software related patent applications, the USPTO appears to be moving to a patent eligibility standard that is similar to the standard used by the EPO. European patent practice has based its rulings on the premise that a claim containing no technical elements, a purely economic idea or a purely mathematical process, in which no technological or physical features are present, is inadmissible.
- The clear 2019 FDA guidance offers a new route by which to explore patent protection for connected health innovators as SaMD in a post-Alice age. This not the case in the EU where SaMD remains somewhat opaque, particularly with regards to a strict reading of Rule 11.
- Patents are always going to be a difficult path in connected health ROI. However, companies such as Impravata with its wide patent portfolio have shown with the correct application, this will afford strong protection.

Figure 1: Software patents case study:

Imprivata provides authentication and access management technology solutions, including their single sign-on product, which allows doctors and patients to use one username and password across multiple platforms. Rather than shy away from patent challenges, it owns approximately 55 patents related to software and health information technology. Representative of their portfolio is U.S. Patent No. 8,973,091, directed to secure authentication using a mobile device.

4.2 EU/US: Copyright

All member countries of the World Trade Organisation are now obliged to extend copyright protection to computer software.

US path

- Copyright falls under the USPTO remit.
- The entirety of a copyright holder's rights can be passed to a third party. Resale of copyright is also possible in US copyright law.
- US exemption for 'fair use' pertains to use of copyright works for educational purposes or use in commentary. The US is more flexible here than the equivalent exemptions under European laws.

US challenges

'Fair use' could potentially be used as a defense in reverse engineering a software programme. To prevent this misuse, connected health innovators should limit rights to reverse engineer through 'Terms of Use' and 'End User License Agreements'. Both options can prohibit potential for reverse engineering a programme.

EU path

- Copyright is managed by the European Union IP Office (EUIPO).
- The copyright holder of the work is always the creator of the work itself. It is not possible to pass copyrights in their entirety to a third party. This is unless the originator dies, in which case the copyright passes to their estate, or is removed completely.
- An adaptation of the work is also protected, but it is permissible to decompile a program if this is needed for maintenance or for interoperability
- Although copyright has been harmonised in certain respects, categories of works have not. The Irish Copyright Act, 2000 states that copyright protects works "in writing or otherwise," allowing for any form of expression.

EU challenges

- National copyright law poses barriers between member states, despite efforts to harmonise.

Overall

- European copyright focuses directly on the originator of the work in question, whereas US copyright centers on exploitation rights and any potential financial implications.
- The key differentiator in copyright laws of the US and Europe is the scope of exemptions and in particular the US exemption for 'fair use'.
- Harmonisation of copyright laws in the EU remains an issue to be resolved. If there is serious commitment to the digital single market then this will need to be addressed.
- Market differences aside, copyright offers viable IP consideration for connected health ROI. It may be in conjunction with another form of IP.

Figure 2: Software copyright case study:

ViClarity

Irish software company, ViClarity has a software tool that monitors compliance with regulatory standards. The tool was originally designed for the financial services industry. Through effective copyright and licensing, whereby ViClarity retains ownership of its IP, ViClarity's solution is now being used across private health providers in Ireland, in healthcare companies such as Mowlam and MHA. Most recently, the NHS began using its technology solution.

4.3 EU/US: Registered design

US path

- Registered design is covered by USPTO.
- In its *Manual of Patent Examining Procedure (M.P.E.P.)*, USPTO states "the subject matter of a design patent application may relate to the configuration or shape of an article, to the surface ornamentation applied to an article, or to the combination of configuration and surface ornamentation".
- A US design patent covers any new, original and ornamental design for an article of manufacture. It must be non-functional and non-obvious.

- With stricter drawings requirements than the EU, a more detailed examination will take place in the US. The process can take about 14-18 months and the design is published when the design patent issues.
- A US design patent lasts for 15 years and no renewal fees are payable. A grace period permits public disclosure of the design in the 12 months preceding the filing date and a six-month period for claiming priority from an earlier design application.
- There is no Unregistered Community Design (UCD) offered in the US.

US challenges

- UCD can be an advantage for products with short life spans, which programmes or certainly some elements of a connected health innovation may well have.
- Another advantage to UCD is to test a design prior to full registration. An avenue with particular value for startups, with tight budgets.

EU path

- The EUIPO manages the EU Trademark and Design rights.
- *Europa.eu* (2019) qualifies a Community registered design (CRD), a design has to be new, have individual character and not dictated by technical function.
- Design rights can be obtained nationally or at EU level from the EU IP Office.
- A CRD initially lasts five years from filing at the EUIPO and is renewable every five years to a maximum of 25 years.
- The EUIPO conducts a formalities examination and a deferral up to 30 months from filing is permissible.
- An Unregistered Community Design (UCD) protection lasts three years from when made first publicly available within the Community. The UCD extends exclusive right to prevent unlicensed copying of the design or unauthorised dealing, with or without knowledge.

EU challenges

While UCD offers additional avenues in Europe, it is not without some risk. For instance, it could expose the design to imitation in another jurisdiction jeopardising the validity of registering the design at a later date such as the US.

Overall

- Design rights in both US and EU are an advantageous option. The cost is relatively low. For many innovators in the connected health space, both physical and psychological user experience are an important part of success, protecting design can be a critical component of connected health ROI, as with Health Beacon.

Figure 3: Registered design case study:

The potential of registered design as part of an IP strategy can be seen in Dublin and Boston digital health company Health Beacon's 'sharps bin'. The product is a remote monitor that ensures patients keep up with their injectable treatments, allows them to dispose of medication in a safe way at home and communicates adherence to clinical teams.

Design is a critical USP for Health Beacon. Traditional sharps disposal are yellow with warnings on the box and usually hidden or placed somewhere unobtrusive. Patient feedback showed that it acted as a negative reminder of the patient's condition. Health Beacon transformed this with an elegant and simple design, which easily fits into a patient's home. Indistinguishable from any other appliance.

4.4 EU/US: Trade secret

US path

- The federal *Defend Trade Secrets Act* (US-DTSA) provides a uniform federal law governing trade secret protection and enforcement.

- The US-DTSA establishes a federal civil cause of action for "trade secret misappropriation relating to any product or service used in, or intended for use in, interstate or foreign commerce".

EU path

The EU Trade Secrets Directive was adopted in 2016, designed to bring European law in line with stronger provisions in the US and China. *Article 2(1) of the Directive* defines a trade secret as:

- Any information not readily known or accessible;
- Any information that has commercial value due to it being confidential; and
- Any information whereby reasonable steps are taken to preserve its secrecy.

US/EU challenges

- Despite some legal variances, the fact is that the challenges around trade secrets are the same across both counties. The key one is internal maintenance as keeping a trade secret confidential requires tightly controlled and recorded access, underpinned by legal agreements.
- Access to commercially sensitive information must be company controlled. This is achieved through an internal system that takes every step from employee contracts, to clear source code ownership, strict non-disclosures and keeping a fastidious record of all of these engagements**.**

Overall

Trade secrets depend almost entirely on internal efforts taken by trade secret owners, including careful management over who has access to trade secrets, how these are stored and kept in both electronic and hard copy form. Trade secret may be used as the sole protection of connected health ROI as with Fire 1, but it is a safer option as a partner to other IP areas.

Figure 4: Trade secrets case study:

FIRE1

Early last year Irish company FIRE1 announced the close of Series C financing totalling EUR 40 Million. FIRE 1 describes itself as a connected health solutions company developing a novel remote monitoring solution to improve outcomes for heart failure patients. Even though at the time it represented one of the biggest funding rounds for an Irish start up, the exact nature of the product has still not been disclosed outside of investors and researchers working on it.

4.5 EU/US: Trademark

US path

- USPTO operates a two-tiered system for trademark protection - state level or with the federal government.
- The user of a trademark may acquire certain common law rights by being the first to use the mark in business with two types of application: 'use-in-commerce' or 'intent-to-use'. The application must include date of the first use of the trademark and its first use in U.S. practice.
- The standard character mark is the most common. A mark is also considered a 'word mark' if the text font, color, or size is stylised.
- A proposed mark resembling one already registered will not be granted registration in the US.
- In terms of 'opposition period', this is 30 days after publication of the mark application, with a possible extension of up to six months.

US challenges

- The date that the mark was first used decides right of priority rather than 'first to file'. Extreme due diligence is required to ensure that the mark preferred is not in use prior to filing.

EU path

- A European Union Trademark (EUTM) must be registered to receive protection and can be registered for goods or services without use. If not used for five consecutive years, a claim before the EUIPO can render it invalid on this basis.
- The EU has word marks and figurative marks rather than stylised font marks. A word mark is made of words consisting of a set of letters, punctuation or numbers. A logo or a stylised word falls under the figurative mark category.
- In the EU, it is up to the owner of the trademark to monitor and oppose other applications.
- The EU opposition period is three months following publication and there is no extension.

EU challenges

- The challenge with trademarks in Europe lies in the protection offered against identical or similar marks. The fact that this must be self-monitored is an important distinction. It puts an additional onus on an innovator to self-protect, even after registering through official channels.

Overall

- An additional trademark option offered by the WIPO's *Madrid System* is one single application and one set of fees to apply for protection in up to 122 countries. However, this does not circumvent local trademark laws. Third party objections can be raised from country to country.
- In both EU and the US, trademarks are a valid form of IP for connected health innovators and likely used in tandem with other IP to protect ROI.
- Trademarks offer market distinction. In the healthcare market, brands should be aiming for trust and reliability and a trademark should underpin this brand value.

Figure 5: Trademarks case study:

The most effective trademarks are those that did not previously exist. They are instantly recognisable, inherently associated with the brand and ideal if they can convey some product meaning. TickerFit TM is a unique cloud based application enabling clinical teams to provide remote personalised lifestyle interventions to patients requiring cardiac rehab, based on their current health status.

5. Connected health IP – current practice for five Irish companies

Having considered the five core areas of IP for ROI in connected health products through an EU/US lens, we now begin to consider a combination IP approach in practice. This report now shares primary source research from five Irish connected health companies using IP in ROI.

Figure 6 overleaf, displays the core findings on target market, market offer, IP protection in the EU, IP protection in the US and profit derivation. The full multiple-choice questionnaire with responses is contained in the appendices. The questionnaire also contained a free text box to secure additional opinion.

Respondents	Company 1	Company 2	Company 3	Company 4	Company 5
Market offer					
Product					
Service					
Both					
Target Market					
US					
EU					
Both					
IP in EU					
Patent					
Copyright					
Registered design					
Trade secret (Secret source code)					
Trademark					
IP in US					
Patent					
Copyright					
Registered design					
Trade secret (Secret source code)					
Trademark					
Profit/ value broadly derived					
Licences					
Services					
Both					

Figure 6: Connected health IP in practice - responses

5.1 'Current practice' findings assessed

Copyright and trade secret are used by four of the five companies, with additional variations for each. As an IP approach, particularly with what we are aware of in terms of patentability of software, the profligacy of copyright and trade secret in respondents could be considered typical. This paper has already acknowledged the frequency of copyright protection in software. Largely because if activity consists of verbatim replication of the object code in which the program is embodied, copyright is more straightforward and cost effective protection than patenting. This is recognised in the very recently signed Irish *Copyright and Other IP Law Provisions Act 2019*. Its purpose is to modernise Irish copyright law, making better provision for copyright and other IP protection specifically for the "digital era".

Company 1 and Company 4 use copyright and trade secret as protection for their ROI. Company 1 also uses trademark.

Operational in both markets, Company 1 used the free text box to identify the US as the preferred market because it is "more progressed in digital health deployment". Company 4 uses copy right and trade secret, operates in the EU only and prefers this due to "available funding and proximity". Both companies' target markets vary but we see an almost identical combination IP approach.

Company 2 and Company 3 use patent protection in tandem with copyright and trade secret. This is interesting because we know that generally software is not easy to patent. Clearly both of these companies have proven technical innovation. Company 3 has achieved this across both markets under 'connected device'. We cannot assume the patent is in the burgeoning area of SaMD as the respondent has not stated such and the FDA is very clear on software that does not constitute SaMD. We must accept that if it was SaMD it would be sated as such. Using the free text box, Company 3 identifies the EU as the easier of the two markets to navigate due to "more harmonisation in EU than US's state by state laws". If this refers to IP such as copyright, it is curious. Lack of harmonisation here across the EU would seem to pose more challenges than opportunities.

Company 2 has achieved US patent in the area of SaMD. The responded clearly identifies it as such, meaning we can apply what we know about SaMD in the US market. Company 2's use of the free text box commented that the US patent experience was one of "ease of getting the IP protection process started in a very easy and fairly accessible manner". In terms of SaMD regulation, we know the FDA is currently further ahead and far more clear in this area, than the EU. With this in mind, the SaMD patent achieved and comment from the respondent company is in line with current US experience and process for SaMD patenting.

Uniquely, Company 5 only uses trade secret - secret source code - across both markets. The company identifies the EU market as the most easily navigable for its product citing "local regulations and jurisdictions" as the reason. From what we understand of IP in software development, limiting protection to only one option seems risky. The entire protection could potentially become undone through reverse engineering, and therefore obliterate all ROI. A strategic approach would see Company 5 choose at least one additional appropriate option of the five explores in this paper for protection of its ROI.

Finally, considering that these products are in the connected health space, it is unsurprising that the findings show that all of the respondents derive profit from licenses, with three citing services also.

Many software licenses are software sales arranged as licenses to protect the IP (Module notes 8.9). In simple terms, this is akin to leasing IP. It can be used as a means of transferring tech, can assist with monetising trademarks and can be used in 'secret know how'.

6. Conclusion

Services and technology have become the fastest-growing area in the healthcare industry. The market potential is vast. The global digital health market is expected to reach $223.7 billion within five years based on increasing penetration of mobile devices, remote patient monitoring and growing demand for advanced information systems.

Regulators from the FDA - Digital Health Innovation Action Plan - to the EU's creation of a digital single market understand this. Their actions and guidance reflect the reognised value of this market. It is seen domestically too through inclusion of connected health in the Irish KTI research priorities to broadening the scope of the IP office of Ireland to better reflect the 'digital age'.

The defining characteristics of the high technology market - increased customer choices, product customisation, rapid technological improvements and global competition - all contribute to volatile demand patterns and serve to emphasise the requirement for strong IP protection to ensure ROI in this market.

Central to the process of any connected health innovation is product design with the end user in mind. This is where assessment of ROI must begin – what does this product have that is worth protecting? A strategic approach to IP must be part of market planning. The nature of the product, its market(s), company commercial targets and budget will inform the protection of each product and collectively influence the IP approach. This paper has shown that effective protection for ROI in connected health innovations involving software tend toward a combination of forms of IP: patents; copyright; registered design; trade secret; trademarks.

Overall, patents protect technical innovations. Patent impulse is natural in our research system. However, patenting will simply not apply to all connected health innovations. Rather than rush to patent, a connected health solution needs to consider the most valuable element to the product – which may be un-patentable. Equally, innovators must not dismiss IP protection just because patenting may not be the option.

Connected health offers major advances in data use that can significantly influence health outcomes. As such, it is likely that the highest ROI for patentable connected health products are those that offer technical solutions to the challenge of leveraging health data. Both the challenge and opportunity of SaMD is one that merits significant further research. It will be fascinating to see this evolve and how its use might shift the current status quo. As ROI in connected health perhaps heralds a transition from the hard parameters of 'devices' to wider ones of 'solutions' involving more than one actor in healthcare technology.

Copyright offers many options for connected health ROI . When creating a strong IP portfolio copyright is often the logical partner to other areas such as patent or trade secret. For instance, a patent might protect a very specific element of the computer program. A copyright could be registered to protect the areas likely to be deemed patent ineligible. Copyright can be filed with redaction, used if used in tandem with trade secret these are still protected. It is worth being mindful however, that at times an almost imperceptible modification may occur that is difficult to distinguish and prove. In other cases, it can be challenging to prove copying if public disclosure of code is required as this reveals the protected material.

Design of a product includes technological features, configuration or pattern of a product. Some companies do not consider registered design in ROI, as they fail to look beyond the functionality. However, the distinction in style of product and the value that this brings to end user experience should be considered and assessed from the outset for all connected health innovations. Failure to do so could result in total loss of protection by the time it is deemed an ROI priority. Innovators must also be mindful to register a newer version of any design.

Trade secret law provides an interesting option for ROI and protection for source code. The main requirement is the internal effort to keep the source code secret – employee contracts and NDAs. If these are airtight then it can be efficacious, but reverse engineering will always be a risk. The fact that an innovator has a trade secret does not guarantee exclusive rights over the information in question. If someone else develops the same information, he or she can use it freely. Trade secrets will protect innovators against behavior such as access to protected documents related to secret information, making copies for personal use.

Those innovators who may dismiss trademarks as last minute marketing, do so at their peril. The old adage 'no such thing as an original idea' can often ring true here. Extreme due diligence is required. Trademarks offer valuable ROI as a distinction of values for robust market presence across the board.

As such, this protection should apply in all connected health cases. Trust and reliability are key brand values in healthcare so a trademark associated with this reassurance is important.

The choice and direction of IP for ROI, should be well assessed in any connected health IP and business strategy early on. IP will form a key component for ROI when it comes to license evaluation, upon which it will be subject to stringent review for strength and protection. IP as a key strategic component is relative in both EU and the US. The fact is that if a connected health company wants to be operational in both markets then it must navigate the appropriate product protection in each, at an early stage. Thus in terms of the EU/US comparisons within this paper, which area of IP is more amenable or easily navigable in each market is not the driver. This will not dictate the approach, rather the innovation itself – the value requiring protection - will. The informed and strategic connected health innovator understands the differences between IP options across markets, to ensure maximum ROI in all.

This paper has sought to understand both landscapes fully and identify the options for connected health ROI in the EU and US detailing the rigors and differences. We know that patent as ROI in connected health can be difficult, but that SaMD currently offers more advantage in the US market. Harmonisation laws in the EU can present challenges to copyright protection. Protecting design is key in each market with EU offering a little more flexibility with UCD. Trade secrets are only truly successful through internal company management across both markets. Trademarks offer the same positon potential but crucially in the EU, monitoring of the mark is down to innovator.

Across both jurisdictions, it is clear that a combination of IP option will usually apply to ROI in connected health. This is evidenced by the real life current practice of each of the companies interviewed for this paper. Each used more than one of the five areas identified as valid IP options, reinforcing the combination theory and that each target market must be well understood to inform this combination. Invariably, the size of the Irish market means that connected health companies focus on wider EU and US market to scale and grow – deeper research into some of the current IP practice as case studies would be interesting to build on the short insights shared by the five companies in this paper.

Ultimately, we are living in a data driven world. The big opportunities for connected health to transform healthcare, patient care, clinician practice are only increasing. The challenge for connected health innovators will be to leverage and use data successfully in different areas of the healthcare market. The means to achieve this and IP in protecting the means will be central to all ROI in connected health.

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Appendix 1: Connected Health IP survey

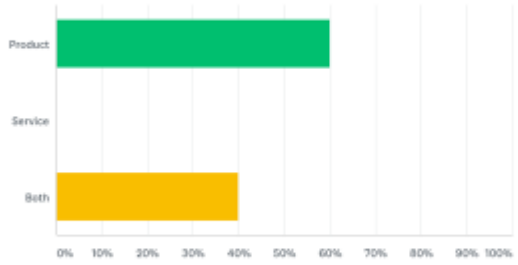
Connected health IP

Tuesday, December 03, 2019

Powered by SurveyMonkey

Q1: Please tick which applies

Answered: 5 Skipped: 0



Powered by SurveyMonkey

Q1: Please tick which applies

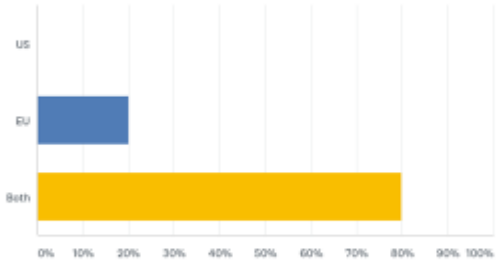
Answered: 5 Skipped: 0

ANSWER CHOICES	RESPONSES	
Product	60.00%	3
Service	0.00%	0
Both	40.00%	2
TOTAL		5

Powered by SurveyMonkey

Q2: Is your market

Answered: 5 Skipped: 0



Powered by SurveyMonkey

Q2: Is your market

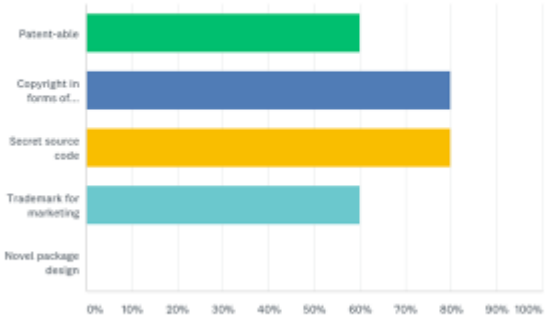
Answered: 5 Skipped: 0

ANSWER CHOICES	RESPONSES	
US	0.00%	0
EU	20.00%	1
Both	80.00%	4
TOTAL		5

Powered by SurveyMonkey

Q3: Please tick all that could apply to your product/service

Answered: 5 Skipped: 0



Powered by SurveyMonkey

Q3: Please tick all that could apply to your product/service

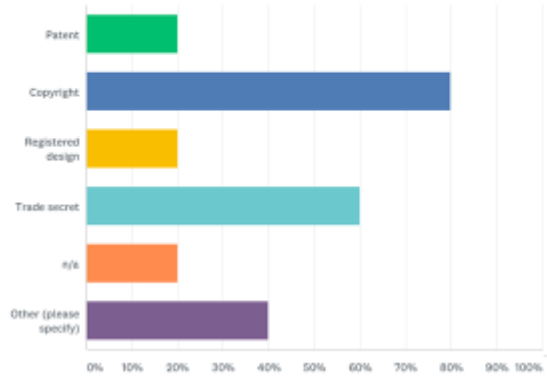
Answered: 5 Skipped: 0

ANSWER CHOICES	RESPONSES	
Patent-able	60.00%	3
Copyright in forms of expression	80.00%	4
Secret source code	80.00%	4
Trademark for marketing	60.00%	3
Novel package design	0.00%	0
Total Respondents: 5		

Powered by SurveyMonkey

Q4: How do you actively protect your IP in EU?

Answered: 5 Skipped: 0



Powered by

Q4: How do you actively protect your IP in EU?

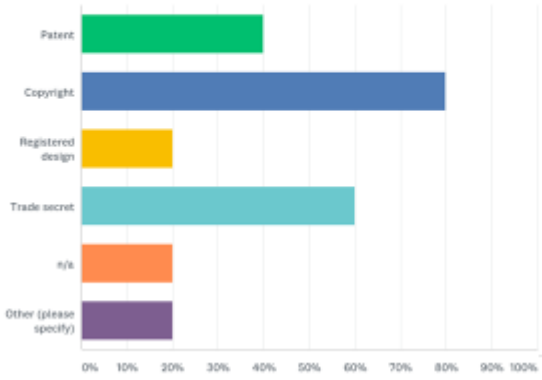
Answered: 5 Skipped: 0

ANSWER CHOICES	RESPONSES	
Patent	20.00%	1
Copyright	80.00%	4
Registered design	20.00%	1
Trade secret	60.00%	3
n/a	20.00%	1
Other (please specify)	40.00%	2
Total Respondents: 5		

Powered by SurveyMonkey

Q5: How do you actively protect your IP in US?

Answered: 5 Skipped: 0



Powered by

Q5: How do you actively protect your IP in US?

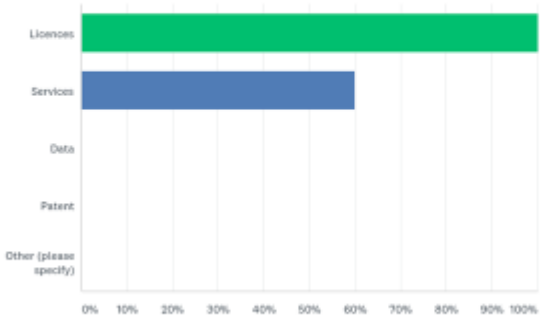
Answered: 5 Skipped: 0

ANSWER CHOICES	RESPONSES	
Patent	40.00%	2
Copyright	80.00%	4
Registered design	20.00%	1
Trade secret	60.00%	3
n/a	20.00%	1
Other (please specify)	20.00%	1
Total Respondents: 5		

Powered by SurveyMonkey

Q7: Where is your profit/ value broadly derived from?

Answered: 5 Skipped: 0



Powered by SurveyMonkey

Q7: Where is your profit/ value broadly derived from?

Answered: 5 Skipped: 0

ANSWER CHOICES	RESPONSES	
Licences	100.00%	5
Services	60.00%	3
Data	0.00%	0
Patent	0.00%	0
Other (please specify)	0.00%	0
Total Respondents: 5		

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Appendix 2: Presentation questions to answer

1. David Richardson

Question

Thanks for the presentation. It was interesting to read about an emerging regulated market, where regulations are trying to keep up with the technology. I found it very interesting the different ways in which the IP can be protected.

With regards registered design, is it easier to register a design than getting a patent and how much protection does a registered design give an inventor?

Answer

Hi David,

Thanks a million. I think we reviewed one another's actually. Love the design thinking piece providing such positive results for your company.

I agree that connected health is an interesting space, not least for the reasons you have identified. A rapidly emerging part of this space (and one John mentioned afew times) is Software as a Medical Device (SaMD). I include it somewhat in the paper, though it is not a big focal point. EU lags behind the US here actually in terms of regs and guidance. There is an interesting paper on this - Carroll, N., Richardson I., Travers M. (2016) 'Software-as-a-Medical Device: demystifying Connected Health regulations', *Journal of Systems and Information Technology*', 18, (2), pp 186 -215. Found here: https://www.lero.ie/content/software-medical-device-demystifying-connected-health-regulations.

So, to your direct question – ultimately for connected health a combination IP approach is required. Central to the process of any connected health innovation is product design with the end user in mind. This is where assessment of ROI must begin – what does this product have that is worth protecting? A strategic approach to IP must be part of market planning. The nature of the product, its market(s), company commercial targets and budget will inform the protection of each product and collectively influence the IP approach.

It is definitely easier to register a design in terms of length of time, cost, approval, than patent but not advisable for this to be your only protection. Overall, patents protect technical innovations. Connected health offers major advances in data use that can significantly influence health outcomes. As such, it is likely that the highest ROI for patentable connected health products are those that offer technical solutions to the challenge of leveraging this health data. SaMD will play an increasing role here in terms of patentability. Though even if a patent was achieved through SaMD registering the design would also be advisable, as part of the overall IP stagey.

Copyright offers many options for connected health and software protection. When creating a strong IP portfolio copyright is often the logical partner to other areas such as patent or trade secret. Design of a product includes both the technological features and shape, configuration or pattern of a product. Some companies do not consider registered design, as they fail to look beyond the functionality.

However, the distinction in style of product and the value that this brings to end user experience, brand and market position should be considered and assessed from the outset. Failure to do so could result in total loss of protection when it is deemed a priority. Again design alone will unlikely suffice to protect the ROI for a connected health innovator. It should be included in tandem with other options. Perhaps a combination of trade secret and registered design or registered design and copyright.

2. Georgia Bayliss Brown

Question

I found your presentation informative and was particularly interested in the potential issues and challenges section.

I felt that it would have been helpful to get a better understanding of the HIHI call that you referred to; so, my question to you would be: Please can you better describe the HIHI call and how it contributes to the development of innovations, and how foreground and background IP are dealt with as a project/concept receives funding or support through this call?

Answer

Thanks Georgia and for your interest in HIHI. I included the call slide merely as a local example that Connected Health is a rapidly growing high tech industry here in Ireland as much as globally. I find that really interesting and it supports the significant market potential point, made in the presentation. The pointed rise connected health solutions that we work with is also the motivation for my own professional development here. That was part of my challenge with this topic – educate myself on an area that my day to day does not demand. As a result, deepen my level expertise and offer a 'value add' to clients going forward. I am now (I like to think!) in a position to offer more insight and guidance in the areas first, should a company so require it. However even with any guidance I can give, they will still need to engage with the TTO or a relevant patent lawyer – as appropriate.

As for the HIHI call and IP - it is the very same process here as the overall IP approach by HIHI, outlined in the pres. We do not deal with IP at all. Rather we connect companies to the relevant TTO, with whom we have built relationships. We strongly advise all of the client companies to consider the IP requirements for their product, if they have not when they arrive to our door – be that through the call or cold approach.

It is a question used to assess progression for all call entries and if they have not completed requisite IP steps then usually they will not make it through to the next stage. This likely forms part of the feedback among other areas that require attention prior to engagement with HIHI. Largely, they have looked at IP, as they are so far along the regulatory pathway when they arrive to us – CE marked.

As for Background IP - pre-existing intellectual property that someone brings to a ‘research project’ - this is owned entirely by the company. The clinical team is testing a CE marked product. Clinical investigative work as necessary is complete to the level required for the marking and appropriate measures to protect a product have been engaged with.

As discussed, companies, come to us with a CE marked product for a study, not research per se. In theory, a CE marked product can be used off the shelf by a clinical team. An advantage to the clinical teams that we broker studies with is that usually the CE marked product is not currently reimbursed or available in the system. We are not looking for ‘something new’ in a pilot study. Rather we are testing functionality in a real life clinical setting and perhaps conducting cost savings and bottom line impact in terms of resource, capacity saved from moving from a paper based system to a digital one (as an example).

In fact, that latter piece was one of the evaluation pieces for ViClarity. I use this company as an example in the presentation that applied a software solution originally designed for the financial services sector to the healthcare setting. In that case, as with all of our clients, HIHI is not conducting research that may yield foreground IP rather validating the functionality in a particular setting. Similar to background IP, it is not an issue we deal with.

3. Henrique Coimbra

Question:

Your presentation was very informative, I didn't know about the Health Innovation Hub Ireland (HIHI) so it was great to learn about it. Sounds like a very strategic hub to foster innovation in Ireland, especially due to the fact that Ireland attracts so many medical device companies, with great multinationals and start-ups thriving here.

I would like to know about some examples of how the HIHI is partnering with major international companies, so my question is, are there any examples within HIHI of the development of connected health software/hardware in conjunction with major players (such as Fitbit, Google, Apple)? If so, what are the main IPR constraints to deal with in such example?

Thanks

Answer

Thanks Henrique. There are no examples of HIHI doing this as we facilitate pilot and validation studies of CE marked products. We are not involved in development but testing usability in real time clinical settings. The products are very far along the regulatory process when they get to us. We are not involved in IPR but rather connect clients with relevant TTOs, if they have not engaged in appropriate IPR. I cover this in the HIHI slide as my motivation for learning about IPR for connected health - it was to challenge myself. I used the EU/US comparison as IPR differs here. However, I will take your question in theory in terms of an innovator partnering with major players and the IPR here.

For ROI through merger or acquisition between a connected health innovator and an established corporation a solid IP portfolio is required. The innovator must ensure they have clear record of what they have and how this is protected. This may include:

•Patents and patent applications (including patent numbers, jurisdictions covered, filing, registration and issue dates)

•Confidentiality/NDAs with employees and consultants

•Trademarks

•Key trade secrets and know-how

•Technology licenses

•Software and databases

•Source code or object code escrows

The above IP information will likely form part of any merger or acquisition agreement, contained in a ‘disclosure schedule’. The disclosure schedule may comprise - contracts, IP, employee information, NDAs.

Apple is developing a track of acquisitions in the healthcare space, which you would imagine parts of the above apply. Recently acquired:

- 2019: Tueo Health has developed technology that can alert parents or caregivers about potential asthma-related issues in sleeping children to help better manage the child’s asthma.
- 2017: acquisition of sleep tracking company Beddit.
- 2016: purchase of personal health data Startup Gliimpse – which led to some of the foundational technology behind its Apple Record System.

A HIHI related example of poor IP protection is a sleep apnoea start up, I worked with last year. The device is an add on to a CPAP machine - positive airway pressure machine used with breathing masks, for moderate and severe sleep apnoea. The client felt that IP was not a valuable use of its limited budget. Despite the fact that for a pilot study an established CPAP manufacturer would be aware of this new, add on, which improved performance of its portfolio product. Without the IP, there is nothing to stop an established manufacturer claiming the sleep apnoea add on product into its portfolio. As a result, the innovator has lost all potential ROI. The product never went to HIHI study phase as it still had a regulatory pathway to follow.