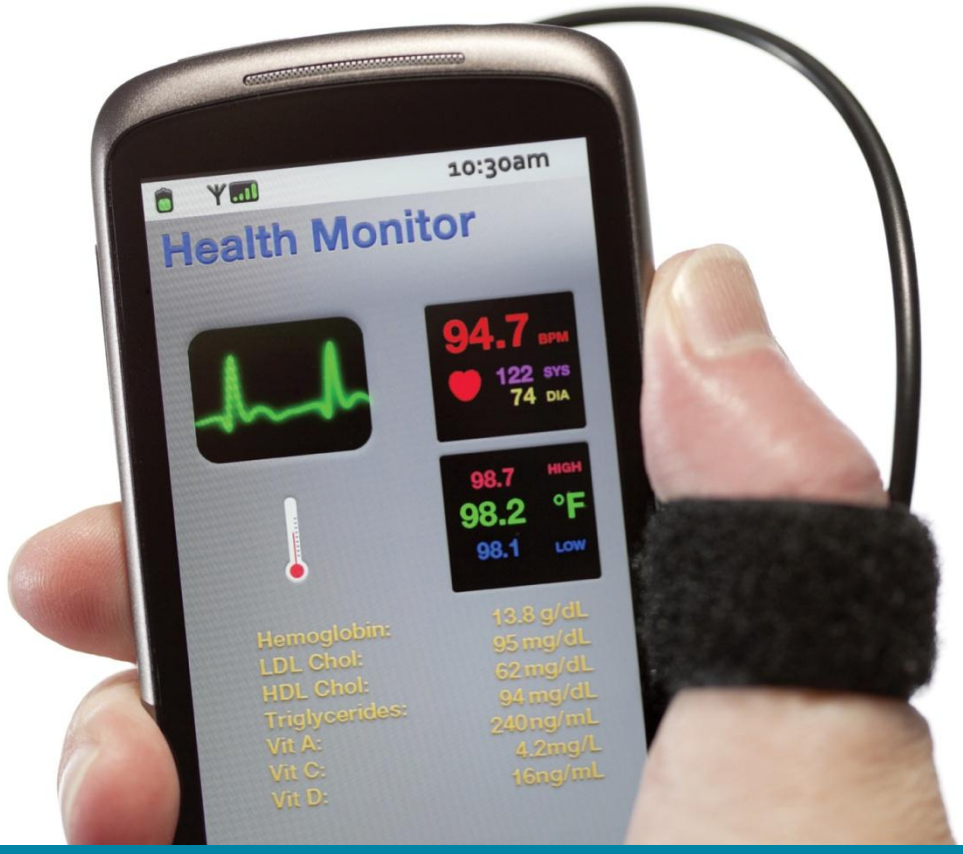
CAMBRIDGE IP

Emerging patent thickets and standards in the medical devices and telehealth space

Innovation, market dynamics and policy options in cross-over technologies



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About CambridgeIP

CambridgeIP (Cambridge Intellectual Property Ltd) is a provider of business and technology intelligence and innovation strategy services to companies around the world. CambridgeIP's work has been covered in leading publications, including the *Harvard Business Review*, *Wall Street Journal* and *Bloomberg*. We have worked with some of the largest global companies. Examples of our products include: competitor mapping and analysis, technology mapping, technology market research, technology evaluation, industry-wide patent landscaping, Boliven.com - a leading online information portal for the R&D community making available over 100 million scientific documents, and training to private and public organisations in high-technology sectors.

CambridgeIP's rigorous methodology and supporting systems enable the gathering and analysis of highly complex science literature datasets with consistently superior quality and delivery times. Benefits are delivered with considerable efficiency when compared to traditional approaches. CambridgeIP's patent data coverage is excellent, achieved by merging patent office data with data from paid-for services to ensure maximum coverage. Working with high-quality datasets allows us to provide high-grade analytics (some of which are an industry-first) in support of strategic decision-making by our clients in the IP policy, IP strategy and R&D strategy fields, and in business strategy more broadly.

CambridgeIP is headquartered in Cambridge, UK, with offices in London, UK, and representatives in Boston, USA, Houston, USA, and Geneva, Switzerland. Our team has extensive experience in science and engineering disciplines, law and economics – enabling us effectively to interpret and communicate results of our research to the full spectrum of stakeholders in high-technology spaces.

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Prior to CambridgeIP, Ilian was a co-founder of an award-winning medical diagnostics university start-up. Since 2001, Ilian has also provided strategic advice on blue chip companies (including a Top 5 global corporate law firm), and technology companies and start-ups. He has advised on innovation policy in the UK, South Africa and Bulgaria. In 1997, Ilian co-founded a 100-employee family business in the electrical industry, which he managed until to 2001. Ilian is an Associate Fellow at Chatham House (the Royal Institute of International Affairs), a fellow in Innovation Policy in Bulgaria's Center for the Study of Democracy, a regular contributor to the Licensing Executive Society and has published widely in both academic and business media on the topics of innovation finance, science-industry technology transfer, service sector innovation and technology policy.
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Puay, a Senior Fellow at Science and Technology Policy Research (SPRU), University of Sussex, is a political scientist with a PhD in International Relations from Johns Hopkins University, Washington DC, USA. Puay is experienced in researching IP-related issues, which includes analysing whether software patents hinder innovation (for the European Commission), the management of IPR in collaborative projects through shared digital tools focusing on US and British defence companies (for the ESRC and the Ministry of Defence), the role of IPR in user-led innovation and if IPRs matter (for NESTA), the role of IPRs in the privatisation of QinetiQ and how they were managed, the protection mechanisms for electronic publishers in addition to copyright and the impact of IPR regimes on innovation and vice-versa. Recently, her work has focused, inter alia, on the study of the strategies deployed by universities to exploit their intellectual assets, the analysis of evolving IP management practices by Higher Education Institutions and models of Technology Transfer Offices and the benefits of publicly funded research. These studies were prepared for the UK Intellectual Property Office, the Gatsby Charitable Foundation and the former Office of Science and Innovation. Puay is currently a member of a four expert group, appointed by DG Research to prepare a report on knowledge transfer and exploitation activities, and IP arrangements, arising from agreements signed between selected Member States and Third Countries. She is also a member of the Intellectual Property Institute, based at Queen Mary College.

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Prior to CambridgeIP, Quentin assisted a venture-backed nanotechnology holding company with a dozen start-ups develop and deliver its IP research and IP portfolio strategy, established major university-corporate research alliances at Cambridge University, was a member of the Lambert Working group on Intellectual Property tasked by the UK government to draft model contracts for industry-university collaborations and Chairman of the Chartered Institute of Arbitrators IP & Electronic Media Group. Quentin also co-founded several start-up companies, including a chemical company and the online complaints resolution hub, GetClosure. Quentin has written articles in leading international

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We would like to thank Kate Gentles, Nick Gray, Paul Denerley, Sarah Helm, Arthur Lallement and Jacqueline Clover for their help in the different stages of this project.

Interactive Results and Datasets on Boliven.com

A selection of the underlying patent datasets and analytics from the patent landscaping exercise will be made available through our online technology intelligence platform Boliven.com. This will enable readers with an interest in this area to explore the datasets underpinning our analysis, undertake their own analysis, as well as to undertake additional patent landscaping through the Boliven.com platform.

The interactive section of the report will be made available in early May 2010, and will be accessible through the following link: www.boliven.com/landscapes/telehealth.

If you would like to be notified of when the section goes live, or have any other questions, please contact Ilian Iliev on ilian.iliev (at) cambridgeip.com.

The 'Landscapes' section of Boliven.com (www.boliven.com/landscapes) provides access to past CambridgeIP patent landscaping research in healthcare, telecoms, energy and other fields.

Executive summary

Patents have become an integral part of company innovation and technology strategies in many high-tech industries. There has also been much debate about the overall effect of patents on innovation, technological change, market structure, and social welfare more broadly in modern economies. The UK Government's Independent Review of IP and Growth (or the 'Hargreaves Review') has focused on several questions that aim to examine the overall role of the patent system in promoting entrepreneurialism, economic growth and innovation, as well as identifying potential barriers to innovation that may have emerged in association with any of these practices.

The UK IPO commissioned a case study with CambridgeIP that would examine some of the questions raised by the Hargreaves Review. The study focused on two broad issues: a) the effects of patent thickets on innovation and market dynamics; and b) the role of technology standards and patent pools as a possible response to the emergence of patent thickets. Our research was based on a case study of the emerging space of Telehealth, and particularly on the use of patents for wireless-enabled medical devices. Our methodology used a combination of patent landscaping around 5 technology areas, interviews with industry experts, and scholarly literature review. The questions examined in the report include:

- an examination of the key drivers and effects of the formation of patent thickets;
- suggested techniques for the measurement of patent thickets;
- a review of different types of standards, and how these relate to patent strategy and market dynamics;
- differences in IP strategy and market positioning of SMEs and large corporations in the context of a patent thicket and technology standards
- the relative role of UK companies in the telehealth space

We also made policy recommendations for the facilitation of innovation and technology diffusion, and consistent with the broad outlines of the existing patent system. We hope these are examined further in the context of the Hargreaves Review, and more broadly. Below we outline some of the key findings of the report.

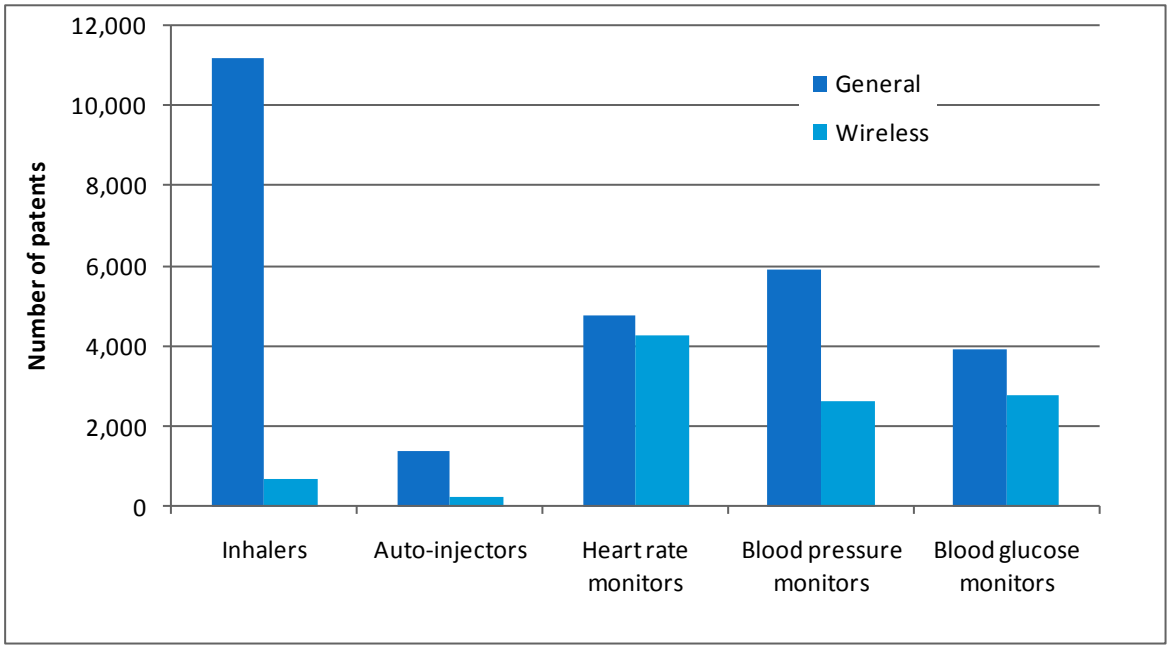
Telehealth as a Focus of the Study

The Telehealth space can be characterised as a convergence sector, developing within the overlap of the medical devices industry and telecommunications industry. In both the pharmaceutical and telecoms industry patents have played an important role in corporate innovation and market entry strategies. Yet there are significant differences between the two sectors in terms of, for instance, relative importance of patent litigation as an enforcement tool; number of patents per product; value of individual patent; uses of cross-licensing strategy; country filing strategies, among many others. Consequently, the Telehealth space is characterised by an increasing overlap and convergence of products and services from companies that have previously operated in fairly separate domains.

The networked medical devices market is characterised by ready-made open interface standards, such as Bluetooth, WiFi or the humble USB port, which make it possible for monitors and drug delivery devices to be connected to mobile phones in order to exploit their ubiquity, connectedness, processing power and the sophistication of their interfaces. The device market in telecommunications is being fiercely fought over by companies such as Apple, Microsoft, Nokia and others. As is typical of consumer electronics markets in general, such players see great value in differentiating themselves in order to increase their appeal over competitors. Our interviews with the industry highlighted the importance of patents in supporting this differentiation. As well as offering utility to the individual user, networked mobile devices hold out the prospect of being able to aggregate health data for the benefit of public health – particularly for the tracking of the source and spread of diseases.

The medical devices sector may be characterised by a lower intensity of competition, and certainly by lower product turnover. The entry of external players from the telecoms and consumer electronics, in combination with interoperability initiatives such as the Continua Alliance standards body may yet lead to an increased diversity of telehealth products on the market place, and a higher rate of innovation.

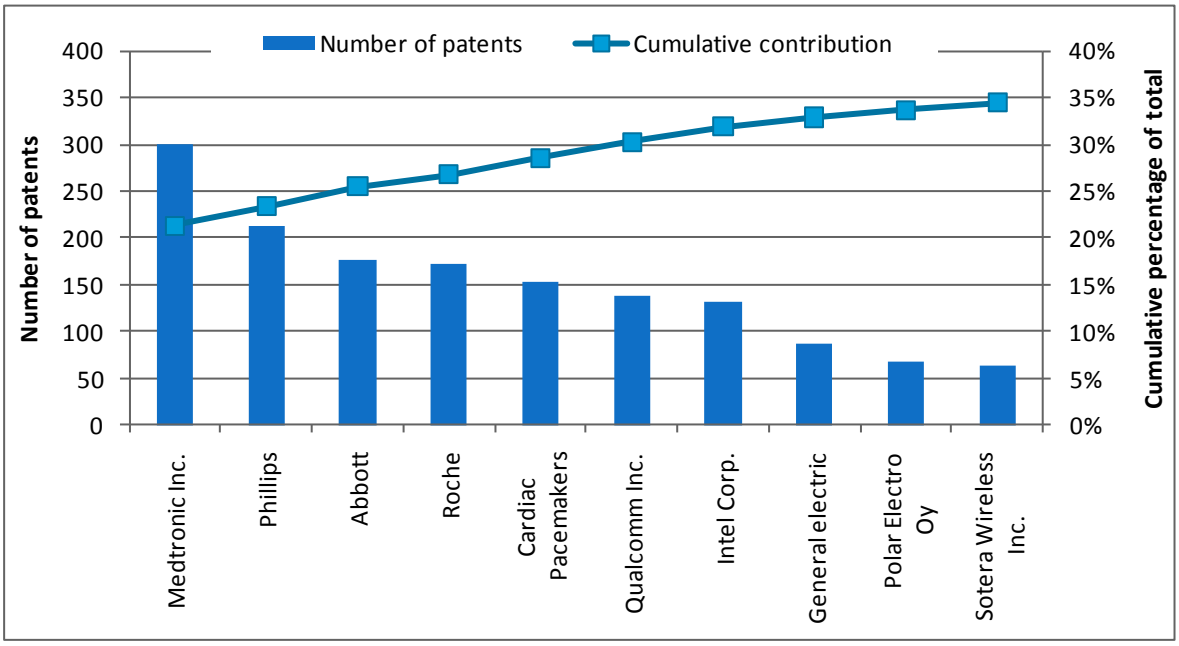
Summary of patent landscaping results



The patent landscaping exercise focused on medical device types, which can be used autonomously by patients, frequently outside of the hospital environment: inhalers, auto-injectors, heart rate monitors, blood pressure monitors and blood glucose monitors. The patent landscaping results showed significant differences in the overall size of the medical devices patent space, but also striking differences in the levels of 'penetration' of wireless technology in medical device systems. The analysis of patent assignees also showed that sectors with a lower penetration of wireless were characterised by a higher level of presence by incumbent players in the medical devices space (both Big Pharmaceutical companies and SMEs). Regulatory barriers primarily related to the higher clinical trial and

compliance requirements of inhalers and auto-injectors were cited as the key factors explaining the different levels of penetration by newcomers in these spaces. External entrants from the telecoms and electronics industry have developed remarkably strong positions in the heart rate and blood pressure devices spaces.

Top ten assignees from all wireless medical device patents



The scholarly and policy literature has thus far not developed adequate measures of competition and market concentration where patents are concerned. In absence of a standard benchmark, we used a relatively crude measure of technology ownership concentration, based on the number of patents and patent applications held by the Top 10 assignees, as a proportion of the total patent space in the specific device area. While this is admittedly a simplified measure, it allows a 'quick first look' at the composition of an industry, and enables comparisons between other spaces. This IP ownership concentration measure provides a look 'behind the curtain' into the composition of the value chain of an industry. A dominant technology licensor may not be 'visible' at the consumer level, as its devices or telecoms protocols are being licensed and integrated into final product. We found that within the individual device datasets, the IP ownership concentration can be as high as 46% within the wireless Autoinjectors space. We also found that the IP ownership concentration is consistently higher in the wireless focused space within medical devices, compared to the respective medical devices datasets (35% vs. 24%).

IP ownership concentration: number of patents by top ten assignees as % of total

Dataset	General	Wireless
Overall	24%	35%
Inhalers	35%	42%
Auto-injectors	41%	46%
Heart rate monitors	28%	38%
Blood pressure monitors	39%	40%
Blood glucose monitors	38%	46%

Emerging patent thicket in Telehealth

Our findings suggest that the number of patents referring to the wireless communication aspect of medical device technology has increased at a much faster rate than the overall number of device patents. There are a number of possible reasons for this, many of which are inter-related:

- innovation effort within the medical devices space is focusing on interoperability and communications functionalities
- patenting in the traditional medical device spaces has reached saturation point, with increased difficulty for patenting of iterative innovations
- patenting is related to the 'translation' of pre-existing wireless communication technologies into the medical devices space
- strategic patenting by key players in the space
- 'natural' technology diffusion trends, from telecoms into adjacent fields(including medical, transport, cleantech)

Whatever the combination of factors, the patent landscaping and interview results suggest the strong possibility of an emerging patent thicket in the medical devices and Telehealth space. That then gives rise to questions regarding the possible impact of such a thicket on innovation and market structure. Evidence we reviewed from other industries suggests several possible negative effects, including:

- patent litigation holdup around key gateway patents
- increased transaction costs, such as information gathering, negotiation and coordination across multiple actors
- increased infringement risks
- R&D effort duplication

The interviewees thought that industry actors' responses to an emerging patents thicket may include increased strategic patenting activity (possibly exacerbating the patent concentration in this space), greater vertical integration and building of proprietary standards, cross-licensing of portfolios between large players, and last but not least, the formation of industry patent pools and standards bodies. Focusing on standards,

interviewees argued that ad hoc, proprietary and de facto standards will not serve the sector well because they are likely to fragment the sector and make applications cost ineffective for major procurers (such as the NHS in the UK). In general, interviewees expect that the sector will develop similarly to the ICT (Information and Communication Technologies) space, with large patent portfolios held by key players, and with no single player having an exclusive or dominant position. However, it is expected that there will also be significant differences in the emerging business models of the Telehealth space when compared to ICT, not least because in the healthcare sector as a whole there are great differences from country to country, which are exacerbated by very complex distribution channels and buying/purchasing models.

Patent Pools and Technology Standards

A strong theme emerging from both the literature and our primary research for this project relates to the development of technology standards as a direct response to the emergence of patent thickets. Our interviews also revealed uncertainty and debate regarding the direction in which standards will develop in the medical devices space. In particular the question of whether regulatory, open or proprietary standards will dominate is as yet unresolved. If a company develops a promising technology platform, one commercialisation option open to it is to promote the inclusion of its technology as core to an emerging standard. This can be done for instance by following a proprietary approach whereby the company controls the emerging ecosystem around its core technology; promoting synergistic standards through an industry standards body (such as ETSI in the telecoms space) or by patent pooling with other industry leaders. Each of these approaches can result in different market dynamics and IP management strategies.

The competitive and market dynamics effects of technology standards can be quite complex, and depend a lot on the type of standard adopted and associated governance structures. One area of concern from a policy perspective may relate to the ability of SMEs to enforce their IP rights, whether within or outside a standard.

Impact of standards and patent pools on competition

Possible pro-competitive effects	Possible anti-competitive effects
• Facilitate equal access to licences for all potential licensees • Speed up access to technology • Integrate complementary technologies • Reduce transaction costs for both licensees and licensors • Possibly clear blocking positions • Avoid costly infringement litigation • Potentially reduce the cumulative licence fee • Protect against patent holder strategies such as bundling essential IPRs with non-essential ones • Non-discriminatory and equal access to all potential licensees (*if* agreed in the portfolio licence conditions)	• Restrict competition between the licensors that participate in the pool, which may result in price-fixing and increased prices • Possibly force licensees to purchase patents that they normally would not have selected • Non-participating firms that hold patents that are substitutes to patents included in the pool may be locked-out of a market • Limit competition in downstream products incorporating the pooled patents, or in markets for complementary goods • Remove incentives for further innovative behaviour • Lock-in into an inferior technology • Dominance by large players at early stages of

• A valuable source of information to would-be licensees about essential IPRs • Decreased switching costs between alternative suppliers	Standard/Pool formation • Standard setting process can facilitate oligopolistic collusion • Risk of a patent holdup by essential IPR holders outside of a standard

Technology standards and patent pools have played an important role in accelerating innovation and technology diffusion in the telecoms and other industries. We investigated in what ways the formation of standards and patent pools may affect innovation and market industry dynamics. Broadly the effect of the introduction of formal standards would be expected to be positive, by decreasing uncertainty, creating a common platform around which other companies can be build their own technologies, and also by stimulating the formation of networks of inventors. However, patent pools and technology standards also come with significant risks, including technology lock-in, the potential for patent holdup if essential IPRs are not included in a standards body, and uncertainty around royalties. In addition, SMEs may face difficulties in participating in multiple standards bodies given resource constraints (see impact tables).

Impact of (formal) standards on innovation

Positive effects of formal standards on innovation	• Decreased likelihood of patent litigation (around essential IPRs) – frees up more resources for R&D • Provides a wide base of third-party technology on which future technologies can be built • A standard-setting body can become the hub of a knowledge network, accelerating innovation in a space, facilitating coordination • Help a technology gain acceptance more widely • Provides SMEs with a platform for collaboration and marketing of their products • Some level of certainty of return on investment (for companies whose IP is included in a patent pool –backed standard) • Provides SMEs with a channel for influence • A standard implemented *before* a major patent thicket evolves can alleviate many of the problems related to patent thickets • Market creation (new products) or increased market access leading to increased revenues • Accelerated technology diffusion • Interoperability rules will lower the costs of designing and producing the products • Improved quality or reliability
Negative effects of formal standards on innovation	• Lock-in to legacy systems • Potential for patent holdup due to essential IPRs that have not been declared prior to a standard • Adoption of standards by smaller firms may be costly and thus could plausibly be a barrier to entry for these small companies • Uncertainty of cumulative royalty burden may discourage new entrants • Danger of dominance by big players • Slow to adapt to new technologies/opportunities

UK Position in Medical Devices and Telehealth

We identified significant technology capabilities by UK-based patent assignees in several medical device areas. These include the UK-based R&D laboratories for key pharmaceutical companies such as GSK, Novartis and Astra-Zeneca, and large SMEs such as Bespak and Vectura. It is also well known that the UK has a traditional strength in wireless and telecoms, currently through players such as Cambridge Silicon Radio, ARM, BT, Vodafone, and many start-ups and SMEs. In addition, the procurement structure of the UK's healthcare system means that the UK is one of the largest consolidated healthcare services markets internationally. The combination of these factors suggests that Telehealth sector provides a unique opportunity for UK industry to build global leadership, while enabling at the same time the provision of more effective and efficient healthcare service.

At the same time, we observed a recent decline in UK positioning in terms of patent filings in all the medical device areas which we researched. There is also a broad EU drop in positioning in terms of patents filed for wireless-enabled medical devices, when compared to the number of patents in medical devices generally. This trend could be seen both in terms of patent authority and assignee location (see the two tables below).

Composition of patent filings by patent authority: general and wireless

Patent authority	% of Patents Filed Patent Authority	
	General patents % of total	Wireless-related patents % of total
US PTO	33.2%	64.5%
EPO & EU national patent offices	21.6%	7.5%
WIPO	16.8%	26.6%
Japan	8.4%	0.1%
China	6.3%	0.8%
Canada	4.3%	0.0%
South Korea	1.7%	0.1%
Australia	3.0%	0.0%
Other	5.0%	0.0%

A key factor that could explain some of these findings can be related to the greater ease of patenting around software and methods under US PTO rules and patent examiner practices, when compared to the EPO and other patenting authorities. Innovations around wireless protocols, interoperability and Telehealth innovations are likely to be software and method intensive. Given that recently telehealth related applications have experienced accelerated innovation, it is to be expected that software and method related patents would have increased in number. Given the well known differences in patenting rules around software and method patents in the US PTO, once again it would be expected that patents filed under the US PTO would be proportionately higher than those filed in other locations. We do not engage here in the broader debate around the pros and cons of patenting of software and methods. However, we received consistent results that UK SMEs in particular may be at a disadvantage compared to their US competitors because they are

unable (or perceive to be unable) to patent domestically software and methods with the same ease as their US counterparts. While large corporations have the resources to optimise their patenting strategy by markets, UK SMEs may have insufficient resources to pursue a differentiated strategy between EU and US. There is a perception that US SMEs (in medical devices and elsewhere) are at an advantage when pursuing collaborations or licensing deals with global companies in the medical devices and Telehealth space. It is also striking that the 'gain' of US companies (and US PTO share of filed patents) is at the expense of key emerging markets such as China and South Korea, which are known to be strong in telecoms and electronics.

Location of assignees: all five medical device fields for Top 10 locations

General patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	8,416	2,399
United Kingdom	2,042	698
Japan	1,842	736
Germany	1,834	839
China	1,009	492
Sweden	792	201
Switzerland	668	370
Italy	418	169
Republic of Korea	338	159
Canada	337	75

Wireless-related patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	5,011	2,359
United Kingdom	262	114
Germany	261	161
Japan	250	122
Israel	226	78
Netherlands	213	148
Switzerland	184	132
Finland	138	57
Denmark	119	48
Canada	114	41

Other possible interpretations include a shift away from Europe (and the UK) of wireless related innovative activities; greater reliance on licensing-in by UK/EU companies (and thus lower rate of patenting); and changes in the patent assignment practices of large corporations. We recommend further research in this area, to examine on a more systematic basis whether and why UK players in the telehealth are indeed experiencing a declining role.

Policy Options

Finally, we identified a number of emerging policy options, which could be considered for implementation in the emerging Telehealth space in particular, as well as in other sectors important for the UK economy, but also more broadly within the EU. We have listed these in what we consider is the order of least effort/highest impact, with the most difficult options for implementations coming last.

Key policy options

It.	Policy option	Anticipated effect
1	Facilitate emergence of industry standards	Assist private sector in coordinating and accelerating the development of industry standards
2	Collaboration, monitoring and information exchange between Patent Offices and Standards Body	Speed-up patent examinations, and ensure essential IPR patents are revealed early on; better resource uses by patent examiners
3	Establish topical libraries of patents around standards	Improve transparency for SMEs and reduce information gathering and transaction costs
4	Patent offices to assist in identifying essential IPRs	Assist standards organisations with identifying essential IPRs, especially around new applications, and close to the time of establishing a new standard
5	Awareness programs for IP usage for SMEs	Additional awareness programs for SMEs about how to engage with standards bodies and in complex/patent thicket spaces
6	IPC Codes for Telehealth	Establish Telehealth-specific IPC codes to facilitate patent classification and searching (in line with similar practices in nanotech and cleantech)
7	Clarify rules around method and software patenting	Facilitate patenting strategy for companies in the Telehealth space. It would require EU harmonization.
8	Patent Infringement rules clarification	Clarifying an exemption of healthcare practitioners from patent infringement rules may facilitate the road to patenting in medical devices, as the infringement issue will be dealt by and between companies (without direct impact on users)
9	Improve quality of patents in medical devices space	Improved quality of patents will lead to lower levels of uncertainty in patenting strategy
10	Better matching of examiner expertise to the patenting domain	Assist and speed up patent examination, and limit iterations between company and examiner
11	Export support of IP licensing	Support the export of IP intensive services, including licensing-out, through organisations such as the ECGD
12	Investigate patent infringement insurance schemes	Decrease IP risk for SMEs, increase certainty

1 Project aims and overview

In the context of the Government's review of IP, the UK Intellectual Property Office (UK IPO) has launched several sectoral studies focused on the interaction of patent thickets and corporate behaviour. CambridgeIP (in collaboration with Dr Puay Tang) was tasked with performing a case study of patent thickets around the medical devices and interoperability space.

The UK IPO requested "a sector case approach focusing on patent intensive industries to identify the tendency towards patent thickets in mapping technology markets, which may help us in distinguishing between IPR used as incentives from IPR used as a tool for excluding competitors, or the effectiveness of IPRs as a market entry or market change barrier." The project addressed key issues in a range of areas relating to patent thickets, as shown in Table 1.

Table 1 Key areas addressed during the project

Area	Issues
Patent thicket related	Measuring a 'patent thicket/portfolio' Regulatory/policy impact on thicket/portfolio creation Market participant reactions to thicket/ portfolio formations How patent thickets affect: • innovation • market structure • competitive environment (incumbents, new entrants) Barriers to entry
Technology standards	Formation of patent pool and standard in response to thickets/portfolios Effect of entry of external players into an industry (e.g., telecoms into healthcare) How the introduction of a technology standard and/or cross-licensing agreements impact the dynamics of an industry characterised by patent thickets, in terms of: • innovation • market structure • competitive environment (incumbents, new entrants)
Role of policymakers	• Adapting the IP regime • Competition policy • Innovation/industrial policy • Regulation/other (e.g., procurement)
Impact of competition/overlap of standards	Impact of overlapping standards and technology systems on market strategies and IP behaviour
Relative concentration of IPR ownership in the different industry sub-sectors	Looking at IP ownership concentration of Top 10 Assignees as percentage of Total for the five device focus areas: • How IPR ownership may be affecting overall industry structure • How it relates to IP strategies and new entrants
Implications for the UK	UK-owned/UK-based companies (MNEs, SMEs) the UK market

The methodology was based on several parallel streams of research:

- Patent mapping of five medical devices sub-sectors; namely, inhalers, auto-injectors, heart rate monitors, blood pressure monitors and blood glucose monitors
- Conducting an interview programme with key participants and experts from the telecoms and healthcare industries
- Analysis and interpretation using patent mapping, interview and industry literature data

We used the research outputs to address the questions listed in Table 1, and to identify some possible policy actions that may be available to UK and EU policy makers.

While the report is focused on the telehealth space, theh research results should be of relevance to researchers in the IP and innovation policy space more broadly.

2 Previous research on patent thickets and interoperability standards

Before outlining previous research on patent thickets, it is helpful to consider the wider role of IP in the economy. Also, given the extensive research that has been carried out in this area, using a variety of terminology, we define key terms as they are applied in this study. Sections 2.3 to 2.6 then discuss patent thickets in various industries and technology standards, both their effect and how they may be formed.

2.1 Background: uses of IP in the contemporary economy

The reaction of industry players, evolving market structure and the impact of innovation on emerging patent thickets, as well as technology standards, must be interpreted within the context of the options available to technology owners and developers and their clients. We briefly consider the key channels for usage of intellectual property (IP) and technology transfer options open to IP owners, before turning to the question of patent thickets, technology standards and cross-licensing.

A key pillar of the effectiveness of the patent system rests on the extent to which the inventor can obtain returns from the invention in order to compensate for the efforts of the invention process, thus incentivising inventive activity. In addition, the availability of 'easy' licensing routes may incentivise innovation, as there is a greater likelihood of inventors finding a market. Typically, there are two ways in which inventors can exploit a patent: use it or sell it. With the ownership of the patent, the inventor could become a manufacturer himself/herself, either by establishing a factory or by contracting out production to others, as appropriate. Needless to say, within a well functioning IP system the IP ownership rights of inventors need to be balanced with the overall interests of society.

For most complex technologies, however, in order to convert a patent into a successful product there are significant resource requirements, as well as business and technological risks. Therefore, an inventor with limited capacity or resources may choose to license or completely sell the patent to a company equipped to manufacture it. Furthermore, where a large company patents a technology, frequently its managers will find that the technology may be monetised by licensing to users of the technology in other fields, or even to their own competitors. This is an important feature of modern patent usage. Patent licensing has become an increasingly important channel for technology transfer, both nationally and internationally. As indicated by the World Intellectual Property Organization (WIPO, undated), 'licensing not only creates an income source for the patentee, but also establishes the legal framework for the transfer of the technology to a wider group of researchers and engineers, who may, in turn, further contribute to the development of the technology concerned.'

The role of a patent becomes even more important as innovator networks and supply chain relationships become more complex. For instance, where a tightly knit production network

of component suppliers, researchers and designers is engaged in major systems innovation (for example, that of any modern jet airliner programme), there is a high level of interdependency and complementarity in the development and deployment of specific capabilities, and rapid sharing (and use) of knowledge around systems design and deployment (Teece, 2002; Gulati, 1998; Galaskiewicz & Zaheer, 1999; Granovetter, 1985). The ownership and sharing of intellectual property rights (IPRs) in such circumstances may provide a part of the 'glue' that keeps a community or network together. For example, a multinational may license core IP around its technology to a components supplier, allowing it to develop high-end products, but may also prevent the use of such IP by its competitors, and even block its suppliers from working with competitors.

A key channel for the diffusion of IPRs is through the licensing of technology to other parties. As business practices have evolved, there is now a great diversity of licensing mechanisms and models, each associated with different contractual arrangements and implications for business strategy. The following examples illustrate some of the most common channels, with specific industry examples:

- **Patent licensing and know-how transfer**: the classic licensing case, where a company pays for access to a technology that is patented. Typically, the licensee will require some expertise to assist with the knowledge transfer.
- **Sub-contractor licensing**: where the contractor/owner of IPRs licenses a technology/method that helps sub-contractors to manufacture goods up to a certain level of quality or compatibility with other components.
- **Licensing in response to litigation**: where a licence is taken out and royalties are paid in response to loss of a court case or an out-of-court settlement. 'Patent trolls' (or non-practising patent entities) typically extract royalties from companies using a technology where the trolls have either been successful in proving the validity of a patent or have acquired the patent(s).
- **Industry cross-licensing deals:** agreements between key industry players that have large patent portfolios in overlapping areas. Cross-licensing agreements typically allow each of the parties to the cross-licensing deal access to the others' patents, royalty-free or in exchange for royalties. Examples include the semi-conductor and automotive industries.
- **Patent pools (and patent-pool-based standards)**: formation of a patent pool around a priority technology by key industry players, whereby they contribute essential IPRs toward a newly established entity.

2.2 Key definitions for this study

There is an extensive literature around the questions of patents, patenting strategy, patent thickets, standards and on the overall relationship of the patenting system with innovation

and market structure. Consequently, there is also a great variety of definitions around each of these areas. Within the context of this project we are using the definitions in Table 2.

Table 2 Key definitions

Term	Definition	References
Patent thicket	Technology areas that are densely populated by patents referring to a similar technology domain	Shapiro (2001)
Patent pool	An agreement between two or more patent owners to license one or more of their patents to one another or to third parties	USPTO (2000)
Interoperability	The ability of diverse products/systems to work together or to communicate with each other via information and communication technologies	Samuelson (2008)
Compatibility	The capability of two or more parts or components of equipment or system to function in the same system	Farrell & Saloner (1987)
Technology standard	A document established by consensus and approved by a recognised body that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context	ISO/IEC Guide 2 (1996)

2.3 Patent thickets

Defining a patent thicket

Patent thickets are technology areas that are densely populated by patents referring to a similar technology domain. In such cases, patents may have overlapping patent claims that make it difficult for companies to determine whether and with whom they are in conflict, or whom they should approach for a licence. Hence, patent thickets may stifle innovation by increasing the fear of infringement and risk of litigation (Shapiro, 2000). Frequently, a perception of a patent thicket may be a factor in inducing key industry participants to cross-license large portfolios of patents.

Some scholars (e.g., Bessen, 2003) have argued that where the quality of patents may be low (e.g., due to resource pressures or inadequate expertise by patent examiners), incumbents may strategically engage in high-volume patenting to create a ‘patent thicket’ or ‘patent portfolio’. The effects of emerging high-concentrations of patents in new areas of science and technological development on market structure and competition have raised growing attention among policy makers and some market participants. For example, in the biotechnology area, a study by the OECD notes that ‘the rising tide of biotechnology patents has brought concerns that they are being granted too freely and too broadly. Too many patents that cover too much ground will not only harm competition, but will also stifle innovation by making further research riskier, more difficult or more expensive’ (OECD,2005) Well-known examples from other industries include the stem cell and nanotechnology fields.

Theorists have discussed patent thickets as an example of the problem of over-ownership. The 'Smartphone patent thicket lawsuits' which have been much discussed recently exemplifies one possible outcome of patent thickets in which just about every large and smaller Smartphone technology supplier is suing the other.[1] Yet at the same time there has been much cross-licensing among and between Smartphone technology suppliers. For instance, Microsoft recently licensed 74 Smartphone patents from Acacia.

The term 'patent thicket' has tended to be treated in pejorative terms. The key negative effect associated with patent thickets in such circumstances is the high level of transaction costs of negotiating with multiple patent owners, if a licence is needed to avoid infringement. Alternatively, companies can invest in 'invent around' strategies, which may lead to duplication of innovation efforts in the innovation system overall. However, for many industry players the patent thicket issue is simply related to the level of market development in a particular technology area, as well as the scope for innovation. It is useful then to distinguish between 'patent thickets' created by one company as a way of building up a 'thick' patent portfolio in a field; and 'patent thickets' resulting from high levels of inventive activity by competing companies.

The impact of patent thickets

So do patent thickets/portfolios deter market entry, risk hold-up and slow down commercialisation of new technologies, or do they promote innovation and competition? Jacob (2008) pointed out that 'every patentee of a major invention is likely to come up with improvements and alleged improvements to his invention' and that 'it is in the nature of the patent system itself that [patent thickets] should happen and it has always happened' (Jacob, 2008). Carl Shapiro has also noted that patent thickets are formed in several complex technologies, such as software, biotechnology, semiconductors, the Internet, information and communication technologies and nanotechnologies. He argues that patent thickets should be treated as a 'given' in several technologies, being particularly likely in complex technologies.

Shapiro, focusing on the semiconductor sector, argues that while patent thickets may well present the danger of increasing transaction costs through potentially blocking the development of a given product, the central issue is how to deal with multiple patent holders and overlapping patents. He suggests cross-licensing, patent pools and rigorous standard-setting procedures as effective measures to 'navigate the patent thicket' (Shapiro, 2001).

Unlike Shapiro and Merges (Merges, 1999; Shapiro, 2001), Bessen, among others, questions the effectiveness of cross-licensing as a way to deal with patent thickets. He in fact

[1] See http://www.techdirt.com/blog/wireless/articles/20101007/22591311328/meet-the-patent-thicket-who-s-suing-who-for-smartphone-patents.shtml

contends that 'patent thickets can reduce R&D incentives even when there are no transaction costs, hold up or vertical monopoly problems … when multiple firms pursue patent thicket strategies, the net result may be an equilibrium with less R&D' (Bessen, 2004). He further notes that 'cross-licensing sharply reduces the incentive effect of lead time advantages because the winner's profits are included in the bargaining over a cross-licence and are shared in the bargaining solution. In addition, aggressive cross-licensing involves a higher level of socially wasteful patenting activity' (Bessen, 2004). On the other hand, such cross-licensing may have positive effects in terms of accelerated diffusion of technology, and iterative innovation, as more players have access to the same technology platforms on which other innovations can be built (Iliev & Neuhoff, 2009).

Other scholars have presented the disadvantages of patent thickets (Cohen, Nelson & Walsh, 2000; Gallini, 2002; Hall & Ziedonis, 2001). Cohen et al., in particular, show in their survey that many firms obtain patents to 'block' competitors. Bessen concludes 'thickets force entrants to develop a portfolio quickly, possibly providing a barrier to entry. This effect remains to be explored' (Bessen, 2004).

Professor Ronald Mann, University of Texas School of Law, in his study on the software industry (Mann, 2005) rejects the claims that patent thickets have hindered innovation in the software industry. He offers two broad reasons. First, he claims that direct evidence of high R&D spending in the software industry undermines claims that software patents cause firms to reduce R&D spending. Second, relying on interviews he conducted and publicly available information, Mann shows that the development of young firms in the software industry has not been hindered by large patent portfolios in the hands of incumbent firms. As a corollary, he also asserts that the software industry does not exhibit a tendency to create patent thickets.

At the same time, the strategic IP behaviour of large players may differ significantly even within the same industry. Bessen (2004) makes the contrast between Oracle and IBM in the database industry in the 1990s. Looking first at Oracle, the company has adopted a defensive IP strategy, by obtaining a small number of strong strategically important patents[2]. Oracle obtained its first patent in 1995 and acquired only 161 patents during the 1990s, and is not seen as engaging in heavy cross-licensing of patents. By contrast, IBM (holding one of the world's largest patent portfolios) has a very active cross-licensing program. Hence, the overall behaviour within a patent thicket will depend to a large extent on the patent portfolio strategy pursued by key players (Bessen, 2004).

Harhoff et al. (2007) undertake empirical analysis of patenting activity and the strategic uses of patents by businesses in several sectors. Of relevance to patent thickets, Harhoff

[2] We use the word 'defensive' here in the strategic sense. In a legal sense all patents are 'defensive', as they provide the patent owners with the right to exclude others from use of their patented technology. In practice, different companies make different strategic use of their patents.

found that the proportion of divisional patent applications is growing in some sectors. His interpretation was that some businesses are adopting a strategy to create uncertainty over the actual scope of pending patent applications, thus sending mixed market signals to their competitors. Harhoff additionally identifies and discusses the practice of 'portfolio maximisation' where firms expand their patent portfolios, possibly to improve their positions in cross-licensing and other industry negotiations. Other research indicates sectoral differences in patenting activity, related to differences between 'complex technologies' and 'discrete technologies' (Von Graevenitz et al., 2008).

Two areas that illustrate many of these issues are the stem cell and nanotechnology industries.

Stem cells field: gateway patents in the stem cells patent thicket

The richness of the tree of cellular differentiation provides a platform for the development of a complex and overlapping patent landscape in the stem cells and regenerative medicine space. Moreover, the space is dynamic, with new and exciting fundamental discoveries still being made.

Many commentators already refer to a stem cells patent thicket. Furthermore, overlapping patent claims covering similar cells were made when the full potential of the technology was not yet realised and 'terms of art' had yet to settle into agreed definitions (Baker, 2008). Equally concerning from the perspective of fostering innovation and R&D, several stem cell patents exist that claim broad areas fundamental to the overall space, which could be used to 'block' R&D and commercialisation efforts, thus stifling innovation.

The dynamism of the stem cell and regenerative medicine research environment, in which relatively fundamental discoveries are still being made, drives much of the volume of patent activity. Each step change in the scientific development of stem cells research is mirrored by a corresponding step change in the number of patents. By some estimates, the total number of patents and patent applications in this field has reached close to 6,000, most of it in the last decade.

The problem of blocking patents can be illustrated by patents granted in the USA to the Wisconsin Alumni Research Foundation (WARF). Some observers interpret early WARF stem cell patents as claiming all primate and human embryonic stem cell lines, thus representing a major potential bottleneck to embryonic stem cell research. Unsurprisingly, these WARF patents have been the subject of legal disputes and are under review by the US Patent and Trademark Office.[3]

[3] The history of the WARF stem cell patents is discussed by Loring (2007).

Nanotechnology

A large number of nanotechnology commentators have reported fears over the emergence of a patent thicket in nanotechnology (see, for example, Saberty (2005)) associated with a 'patent land grab' or 'gold rush' by assignees (Bawa et al., 2005). A key feature of many nanotechnology innovations is that they encompass diverse traditional science domains and are often applicable across multiple traditional industry sectors. This in itself might be expected to fuel the relatively large volumes of nanotechnology patent applications observed. However, while there have been some nanotechnology patent lawsuits, fears expressed over particularly large volumes of lawsuits have not yet been realised.

An additional feature of the nanotechnology innovation space is that innovators, including universities and public research institutes, have patented many fundamental innovations. This contrasts with many other fields of scientific endeavour where the fundamental 'building blocks' are unpatented or were made available by government regulation (Lemley, 2005). The result, according to Clarkson and Dekorte (2006) in their study considering the period 2001 to 2003, was thousands of patent applications, spanning hundreds of patent classes examined by hundreds of different patent examiners.

Moreover, as is common in 'young' technology spaces, accepted terms and definitions took some time to emerge. A more recent trend is for some inventors deliberately to avoid using nanotechnology terms in their patent applications, ostensibly to avoid negative investor and public perceptions of nanotechnology in certain application areas. One response by patent authorities has been the employment of specialist nanotechnology patent examiners to consider nanotechnology applications, and the creation of special classification codes for nanotechnology.

Conclusion

The body of literature on patent thickets seems to focus on the potential of transaction costs, hold-up and vertical monopoly. Yet, in the face of an ongoing discussion on patent reform and patent quality and as more complex and cumulative technologies enter the marketplace, the issue of patent thickets will increasingly gain salience and require more evidence as to their effects on innovation and competition. This study is thus timely in contributing to the limited pool of evidence on the role of IPRs through the guise of patent thickets. In summary, the discussion above suggests that the likely impact of patent thickets differs between technologies and sectors. It also implies that policy responses may differ, depending on the perceptions of the effects of patent thickets on the sector/market.

2.4 Technology standards and interoperability

Interoperability, compatibility and standards

Interoperability relates to the ability of a device or a program to operate with/plug into a product or technology owned by another party and manufactured by different companies via 'interface' standards. Significantly, these technologies are often described as cumulative technologies because they build on previous inventions and innovations. Examples can be found in nanotechnology, biotechnology, IT, telecoms, electronics, software and increasingly in medical devices, on which our study focuses. Interoperability is also crucial in the era of digital convergence, where products have to communicate with each other and in which networks, systems, devices, applications or components can seamlessly exchange and use information between them (Frain, 2006).

Compatibility also enables products manufactured by different companies to work together. By 'mixing and matching', compatibility allows a range of products to be available and usable. We can reasonably argue that the benefits of interoperability will be the same as those for compatibility.

Interoperability is often ensured by the development and introduction of standards. According to Farrel & Saloner (1987), compatibility (and interoperability) and standards give rise to following benefits:

- **Network externalities (effects):** many products must be linked to physical or conceptual 'networks' in order to create value. Network externalities arise when the addition of one node/member to a network leads to disproportionate gains in value.
- **Competitive effects:** for consumers, they can directly compare devices and incur lower switching costs. A common platform or standard also means that a greater range of players can focus on building on top of this platform, rather than having to develop their own vertically integrated chain or negotiate individual licences to a technology.
- **Diversity:** compatibility requirements may sometimes limit variety, but systems compatibility that allows 'mixing and matching' can help to increase the range of offerings (e.g., home entertainment systems).
- **Cost savings:** standardisation reduces costs of manufacture and assembly by facilitating greater scale economies and allowing the use of interchangeable parts. It also fosters the development of complementary products, as companies will often gear their production to work with a product that is an industry standard, resulting in cheaper prices, rather than working with a product that has a small market.

Anecdotal evidence such as the recent increase in Smartphone-related patent lawsuits presents a view of what can happen in the absence of standards. Earlier standards in the mobile industry (such as GSM, GPRS and 3G) were part of the domain of the ETSI (European Telecommunications Standards Institute) space, and broadly there was an absence of major patent litigation cases. By contrast, the rise of the Smartphone has been accompanied by

the 'battle of the Smartphone systems', with competing standards and platforms, and increased number of patent litigations.

It is important to note that there are different types of technology standards (see Table 3). Standard types have different implications regarding participants' IP strategies, interaction with peer companies, and the role of regulators.

Table 3 Types of technology standards

Standard type	Detail
De jure standard	A formal standard, implemented through a policy measure or industry agreement. De jure standards may sometimes be obligatory. Appropriate when the entire product category would fail to take off in the absence of standardisation: lack of market or investment due to fear of being locked into the wrong choice Disadvantage: standards process is slow, involving a balancing act and long-drawn-out process among the IPR holders and the standards body
De facto standard	A product or system that has achieved a dominant position by public or market acceptance (e.g. Windows) – may result from competition of multiple standards (e.g. Betamax versus VHS). Quicker to establish than de jure standards, but are typically voluntary Disadvantage: 'winner takes all', since the winning incumbent is able to reap significant price premiums
Open standard	A standard that is publicly (and usually freely) available. This may be a proprietary standard opened up for public use (e.g. Google's Android or Nokia's Symbian) or the result of an open source community work (e.g. Linux)
Regulatory standard	Standards provided/legislated by a regulatory authority. These may be national or international (e.g. harmonised standards through Inter-governmental bodies)
Proprietary standard	A standard created by a company, accepted as a standard for the particular application and ecosystem (e.g. Apple's Apps system). Proprietary standards may be open (as above) or closed (need owner's permission/licence to use)
Industry-backed standard	Industry-based standard, typically administered by an industry body (such as ETSI) and frequently backed by a patent pool. Can avoid the need for regulatory standards, thereby reducing the number of public sector regulations, and providing more flexible mechanisms for updating the standards

Technology standards as a response to patent thickets

Douglas Lichtman, formerly a law professor at the University of Chicago and now a professor at the UCLA School of Law, advocates using the standard-setting mechanism as a means to deal with patent thickets. He also asserts that standards reduce the incidence of litigation, as the standard-setting process 'might be the best way for patent holders to influence the development of the standard and thus to steer it toward an approach that maximises the value of their complementary goods and services. Or this might be the best way for patent holders to encourage widespread adoption of the standard, paving the way for substantial patent royalties in the future' (Lichtman, 2006). Anecdotal evidence from patent-pool backed bodies such as ETSI indeed suggests that the presence of an industry standards body has enabled the moderation of IP disputes.

On the other hand, Lichtman contends that patentees whose patents are revealed after the standard has gained widespread acceptance can extract maximum 'value' from an infringing firm. However, the greater the number of patent holders in this position, the less each can expect to gain from this tactic. Lichtman notes that 'this is the insight that is overlooked in the current literature and also missed in modern licensing practice. If fifteen patent holders can credibly threaten to shut an infringer for six months while that firm redesigns its products and services, the value associated with avoiding six months of disruption must be split fifteen ways.'

2.5 Effect of technology standards on innovation and competition

On balance, the positive impacts from standards according to the literature outweigh their negative impacts. Essentially, standards create an infrastructure for subsequent innovation, including unexpected and novel uses of technology. They may also be a mark of quality, which thus create credibility in the product. Standards can also materially help to form a critical mass in markets for new technologies: 'standards form part of the infrastructure on which a canopy of new products and services are grown' and 'open standards are desirable to enable a competitive process of innovation-led growth' (Swann, 2010). Further possible benefits include decreased risk of litigation, savings from duplication of R&D effort and specialisation and value chain diversification.

On the other hand, standards can result in subsequent lock-in into legacy systems and can also give rise to barriers to entry for smaller companies, due to the costs associated with adopting the standards (Swann, 2010).

Standardisation can promote competition and enhance market growth, which, in turn, helps to drive down prices and improve consumer welfare. Standardisation helps to avoid the problem of losing a technology (a bankrupt supplier cannot support its products) since a seller need not be both financially secure and committed to the industry in order to sell a product (Farrell & Saloner, 1987). However, the specific competitive impact of a standard will differ depending on the type of technology, as well as the type of standard and governance (Belleflamme, 2008).

Then there is always the question: is the chosen standard the best choice? For example, it is widely accepted that the QWERTY keyboard is not as efficient as the Dvorak keyboard; nevertheless, it remains standard for all computers and keyboards.

2.6 Technology standards and IP: formation of standards and patent pools

IPR and the formation of standards

The role of IPR in standards has been extensively analysed (see, for example, Bekkers et al., 2002; Frain, 2006; Lemley, 2002; Samuelson, 2008; and Schmalensee, 2009). Where IPR was once considered a non-issue in key industries such as in telecoms and computing networking (information and communication technologies) for many decades, it is now among the main issues to be resolved for any new standard in these industries. We already

have 'interface standards' for interoperability generally based on wireless/telecom technologies, such as Bluetooth. It remains to be seen whether there will be standards for interoperable medical devices, as this sector is still rather immature.

For the purposes of this study, below is a summary of the main views on the role of IPRs in the standards process (based on Bekkers, Iverson & Blind, 2010b):

- securing freedom to operate/reducing risk of being accused of infringing
- signalling own technological competencies
- facilitating own market entry
- entering into cross-licensing agreements/increasing bargaining power in licensing negotiations (e.g. for lowering or eliminating licence fees)
- influencing technological trajectory or standards competition
- joining patent pools/increasing bargaining position in patent pools
- generating licensing revenue.

However, where the formation of technology standards is backed by patents (by one or more companies), technology standards arrangements can be open to abuse: companies seeking to use technology compliant with the standard may need to pay high licensing fees (Leveque & Meniere, 2009).

Patent pools

This final section looks at patent pools, which may also be used as a coordination mechanism to facilitate access to patents. There is widespread agreement among policy makers and economists that patent pools may benefit both IP owners and customers. IP owners benefit by having access to a relatively certain source of royalties across a wider market then they would have been able to access on their own. Customers (consumers or technology users) benefit by having a predictable access to a technology, and avoiding the costs of invent-around. However, the strength of patent pools depends on how complementary the patents within a pool are, and also the extent to which they include all essential IPRs. Well-known patent pools include the essential IPRs patents underpinning the ETSI managed standards, as well the MPEG patent pool around the MPEG video standard[4].

Patent pools, as defined in Section 2.2, are in essence a 'one-stop shop' where all members to the pool may have access to the desired patents. Patent pools may also allow non-members to license the patents at the rate established for the members. In other words, patent pools may address 'the tragedy of the anti-commons' (Heller & Eisenberg, 1998) which occurs when rational individuals (acting separately) collectively 'waste' a given resource by under-utilising it. This happens when too many individuals do not have rights of use of a scarce resource because rights owners can block each other's use of the resource.

[4] See the MPEG Industry Forum for a discussion of the different industry associations and patent pools underpinning the MPEG industry standard: http://www.mpegif.org/patents/

It is arguable that IPR problems and patent pools are most likely to occur in sectors where there is a need for compatibility standards, as many parties may hold essential patents for one single technology.

Arguably, pools will work best in well-defined small technology areas when the players in these areas believe that a pool will help to increase their market size, thus offsetting lower fees. Undoubtedly, pool formation is resource intensive and the determination of essential patents may be a difficult process especially if there is a varied, large and fragmented implementers market.

Patent pools can foster innovation, technology transfer and competitiveness. They, in theory, increase firms' incentives to invest in R&D because of lower risks of litigation, and improved licensing schemes and increase expected profits for participating firms. On the other hand, patent pools could restrict innovation because prospective members of the pool do not know what share of expected profits will accrue to them or they may expect too much profit (Heller & Eisenberg, 1998) and thus may be tempted to behave in an anti-competitive manner.

Policy makers and competition authorities are frequently concerned about the potential anti-competitive effects of patent pools. The experience of patent pool and standards bodies such as ETSI has developed a body of best practice guidelines around the contribution of essential IPRs, governance mechanisms, voluntary vs. enforced membership, and royalty setting mechanisms. The resulting body of knowledge and expert networks and may facilitate the formation of patent pools and standards bodies in the future and in other fields (see Bekkers et al., 2010a).

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3 Background: the emerging technology space of Telehealth

3.1 Overall context

The emerging technology space of Telehealth is the result of the convergence of two previously separate industries: medical devices and telecoms. The medical devices field offers a particularly fascinating case for the study of patenting, licensing and standards, both because of the need for interoperability (in a situation where the lack of interoperability could pose a threat to human health or even life) and because the field sits at the intersection of two sectors, healthcare and ICT (particularly mobile communications), where patents and standards have very different histories and characteristics, and where different players, including regulators, are influential.

The development of medical devices with communications capability is still a relatively new phenomenon. Until recently, devices such as heart-rate monitors, blood pressure monitors or blood glucose monitors were stand-alone units providing direct read-outs to professionals or to the individual user, connected neither to external databanks for reporting or benchmarking, nor to servers for diagnostic processing, nor to remote professionals for diagnostic interpretation. Drug delivery devices such as inhalers and auto-injectors were (and largely continue to be) disconnected from the broader healthcare information systems network, often posing problems of patient compliance monitoring. All of this, however, is changing very rapidly, particularly as medical devices become integrated with wireless communications (primarily for local-area data management) and with cellular mobile communications (for wide area communication, and on-board processing by apps downloaded to smartphones).

Technical innovation in networked medical devices has often been driven by two distinct but often convergent factors: the need for mobility (for example, when measuring heart rate in a patient during exercise) and the need for remote monitoring (for example, the measurement of blood glucose levels in diabetics, whether by professionals or carers, when they are at home). Both of these requirements are well met by wireless communication, whether it be in the local area or on the cellular network, which is now close to ubiquitous in developed and developing countries. The patent landscape analysis (Section 4) shows that patenting activity has been greater in devices for physiological measurements than in drug delivery devices, reflecting the former's greater need for information to be transmitted, and diagnostic processing power accessed. Stronger regulatory aspects associated with drug delivery compared to diagnostic measurements could also play a role. Additional factors likely to lead to increased development in Telehealth include:

- pressures by medical services purchasers (such as the NHS) and medical insurance companies (in the USA) for decreased healthcare costs through innovation
- a shift towards well-being monitoring and 'at home' care
- the ubiquity of smartphones and falling costs of computing
- a push by telecoms and electronics players into a potentially profitable market

- a greater need for compliance monitoring in drug delivery platforms, particularly as more complex targeted medicines enter the market

From a patent policy perspective it is also important to bear in mind that as a result of the enabling of Telehealth solutions, it is very likely that value and innovation will focus to a large extent on the value chain that is being opened up through the interconnectivity of medical devices. Innovation will not be limited to chipsets and hardware kit. Increasingly, it is likely to come from the integration of data across different devices, its import and querying of electronic patient records, automatic alarm systems when multiple readings are found etc., and therefore it may be easier to obtain patent protection under the US PTO, compared to the EPO and other patent jurisdictions. As we see in the patent landscape, these trends are already apparent when we look at wireless-enabled medical device patents.

3.2 IP strategy in telecoms and healthcare industries

There are two main influences in the mobile telecoms patenting/standards space: practices in consumer electronics, where competing patents and proprietary standards typically vie for dominance in a marketplace until one or a small number come to dominate; and, to a lesser extent, the history of telecoms as a regulated industry with interoperability requirements being mandated by the regulator.

The healthcare industry, on the other hand, has historically been heavily regulated by clinical authorities whose objectives have included preventing market entry until safety, and sometimes effectiveness, has been demonstrated by extensive trials. The very heavy costs of these trials make it essential that the company conducting them can guarantee a return through the exclusivity of a patented product. Having said that, many medical devices (as opposed to drugs) have come into common usage without there ever having been trials, and the same is true of many of the latest generation of mobile phone apps, including health, fitness and wellbeing apps.

In order to understand the interplay between IP and market structure in the focus space, it is important to understand the history of each of these spaces, the inherited norms and how IP was being used in these industries. The differences are summarised in Table 4.

Table 4 IP strategy differences between pharmaceutical and telecoms companies

IP characteristic	Healthcare	ICT
Size of patent portfolio	100s–1000s	1000s–10,000s
IP value	Exclusivity Licensing revenue	Freedom of action Product differentiation Revenue Cost advantage Business Influence
Average financial value of patent	Typically very high (~USD1,000,000s)	Typically very low (USD1,000s)
Litigation	Key weapon to maintain exclusivity	Tends to be avoided due to high cost
Volume of patent per product	Few defining patents to cover lead compounds, formulations and dosage	Single product can have 100s of patents due to more incremental innovation and integrated technology
Patent ownership	Company generally owns all patents Fundamental patents might be acquired from a university or research partner	Multiple patent holders, high level of interaction amongst various players Patent owner could be independent, large corporation or SME. High degree of variability
Filing strategy	File as research progresses Long patent process with high levels of research to support each step	One patent filing round per invention Reliance on patent boards to review invention for appropriateness of filing
Priority date	Priority date is critical; and can be difficult to ascertain depending on number of applications filed	Priority date is important, but relatively straightforward due to singular filing
Inter-related cases/filings	Frequently get patent applications spaced to extend the IP protection due to 'new developments'	Less coordinated actions and less frequently used
Country filing strategies	up to 75 countries in a patent family	5–10 countries in a patent family
Patent versus product launch	Product launched after patents are granted Longer product lifecycle	Product launched before patent Shorter product lifecycle
Extension of patent terms	Look for every opportunity to extend term of patent ('evergreening')	Not a priority in the space
Special rules	Development often takes 7+ years – so the SPC rules exist to extend the patent an extra 5 years for those patents in life sciences that take longer to get to market	Not applicable
Interoperability standards	Not applicable	Key consideration in IP
Legitimate copy manufacturers	Generics play a key role and IP dictates how they operate	Less of an issue; but access to patents is relevant
Collaborative innovation	Universities, suppliers, contract researchers (increasing), various players during the stages of research	Universities, suppliers, customers, end users, competitors, communities (open source)

Source: Chawton Innovation research, 2010, see http://chawtoninnovationservices.co.uk

3.3 Telehealth and standards

At a superficial level, the communications environment into which Telehealth-enabled medical devices are being introduced appears to enjoy a high level of interoperability, in the sense that devices in nearly all countries and on nearly all networks and technologies

support the same basic forms of communications such as voice, SMS and HTML. Below this level, however, there is still fragmentation, with over 25 different operating systems working on mobile phones, including many incompatible variants of an 'industry standard'

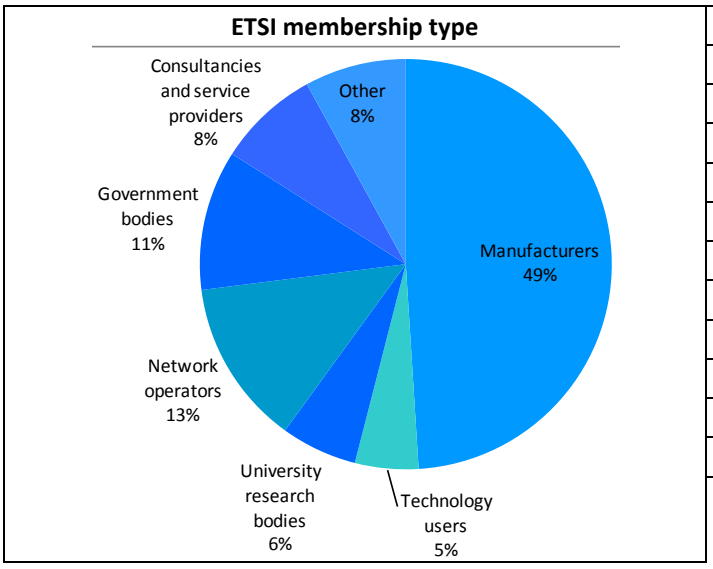
Currently, there are two standards organisations that seem to be particularly important in determining the interoperability standards in the Telehealth space: ETSI and the Continua Alliance.

ETSI

The success of GSM, GPRS and 3G can be largely attributed to the enormous political backing behind ETSI as a means of promoting global market leadership for the European telecoms industry in its early years, and now serving the *global* telecoms industry. It is not clear that any such similar force is at work in the Telehealth domain as yet.

ETSI was created in 1988, primarily around the GSM standard setup in 1987. The initial patent pool was setup by Motorola, Nokia, Ericsson and other equipment manufacturers. However, over the years, with additional standards added to ETSI's portfolio (including 2G/GPRS/2.5G, 3G, WiFi and other telecoms standards), the size of the patent pool has extended. Patents entering the patent pool are based on essential IPR declarations made by contributing members prior to the release of a new standard, or upon joining the organisation. The group has had very strong political backing from the European Commission, as it was seen to promote European leadership in the telecoms space. Today, ETSI's membership comprises in excess of 300 manufacturers, and more than 80 network operators, R&D service providers and regulators. Figure 1 shows that the UK has a particularly strong representation within ETSI, representing 19% of the total membership. ETSI is also playing an important role in adapting and translating its standards for relevance in the Telehealth space.

Figure 1 Analysis of ETSI membership



Manufacturers: top 10 countries		
	Number	**% of total**
United Kingdom	62	19%
Germany	46	14%
USA	45	14%
France	40	12%
Netherlands	15	5%
Switzerland	14	4%
Denmark	12	4%
Italy	11	3%
Finland	9	3%
Sweden	9	3%

Source: Membership list on ETSI website www.etsi.org

Continua Alliance

One particularly important standards body specifically focused on Telehealth is Continua Alliance, which has been successful in bringing together players from the telecoms, pharmaceutical, medical devices and electronics industries, and has already certified a number of medical devices products. It was started in 2006 by ICT and medical device companies (Intel, Samsung, Sharp, IBM, Phillips and Medtronic), with the objective "to create a rich eco-system of interoperable health and fitness devices, focused on busy professionals, elderly patients and chronic sufferers" (Continua Alliance website). As shown in Table 5 and Figure 2, the alliance has certified a large number of devices in recent years, which have substantially enriched the Telehealth ecosystem.

Table 5 Recent news items related to Continua Alliance (most recent first)

Date	News summary
05/10/10	Continua certifies web-based healthcare services and first Continua-certified mobile phone to be unveiled at digital healthcare plaza
28/09/10	Continua Health Alliance releases 2010 design guidelines, and adds new member
01/07/10	Continua Health Alliance promotes the use of in-home healthcare to the House Committee on Veterans Affairs
14/06/10	Continua Health Alliance and Vignet Partner to provide new mobile reference interoperable software for various Smartphone platforms. Alliance has selected Vignet, a leading provider of person-centric connected health platform and solutions, to develop this
15/03/10	Continua Health Alliance expands global impact through support of European initiatives Continua has strengthened its engagement with the European Union on personal health connectivity through the receipt of funding from the European Commission (EC) for a 12-month project called Smart Personal Health. Smart Personal Health aims to promote awareness and a deeper understanding of the need for interoperability among personal health systems (PHS), devices and other eHealth systems across Europe
28/04/10	Bluetooth software leader Stonestreet One joins Continua Health
01/03/10	European project promoting personal health system interoperability launches with support from Continua Health Alliance, ETSI and IHE-Europe
06/01/10	A&D Medical introduces new Continua Health Alliance(TM) USB cable
04/01/10	Continua Health Alliance announces the first end-to-end connected health solution based on Continua standards

Source: Continua Alliance website: http://www.continuaalliance.org

Figure 2 Different devices and products launched under Continua Alliance standard

Certified devices
Pulse oximeter
Pulse / heart rate
Blood pressure
Thermometer
Weighing scale
Glucose metering
Cardiovascular fitness monitor
Strength fitness equipment
Independent living activity
Medication monitor

Company + product name/use
Certified products
Nonin 2500 PalmSAT® Pulse Oximeter
Nonin Onyx® II 9560 Wireless Fingertip Pulse Oximeter
Roche Accu-Chek® Smart Pix Glucose Device Reader
A&D Medical UA-767PBT-C Blood Pressure Monitor
A&D Medical UC-321PBT_C Weigh Scale
Cypak CPX186 Continua Converter Cable
OMRON Bluetooth Home Blood Pressure Monitor
Omron Continua Certified Weighing Scale with a Body Composition Monitor Using Bluetooth Wireless Technology
Omron Pedometer with Bluetooth Docking Station
Continua Bluetooth Manager for Windows manufactured by Toshiba
Texas Instruments MSP430 USB Agent Platform
Panasonic TOUGHBOOK H1 with Blood Pressure Monitor, Cardiovascular and Weighing Scale device specializations by Bluetooth
Wipro Continua x73 Manager USB Reference System
Freescale i.MX Linux AHD Reference Platform running LNI HealthLink/OXP-Libraries and Continua certified as a Manager supporting the Blood Pressure Cuff device specialization
HealthLink USB Manager with Weighing Scale (OXP lib, PAN client C++ library), winusb Shim
eHealth Bluetooth(r) Gateway
Elbrys Networks' Secure Personal Sensor SDK
Texas Instruments AM/DM37x Linux Reference Platform
FORA D40 Blood Glucose and Blood Pressure Monitor with Bluetooth Technology

Other standards

It is likely that a number of other standards will become relevant to the Telehealth space, as the market evolves. For example, since smartphones will provide an important data delivery and communications platform, the different Smartphone operating systems and developer standards will become an important part of the environment, such as Google's Android or Apple's Apps development environments. It is also likely that there will be a number of regulator standards, in particular around eHealth records and how these interact with data sources in the Telehealth system. Finally, the FDA and clinical certification bodies that focus on medical devices are also likely to evolve the relevant regulations for medical devices and interoperability.

4 IP Landscape® of selected medical device technologies in telehealth

We had several objectives in performing the patent landscaping analysis, in the context of the overall project, including:

- quantifying the emerging Telehealth space in terms of interoperability-related patents, and in comparison
- helping understand the extent to which a patent thicket may be developing in the medical devices interoperability/wireless space
- providing data to help interpret the findings in the interviews
- identifying the technology ownership structure of these spaces
- helping understand geographic filing trends and differences between device types
- helping understand the geographic location of patent filers.

While a large number of device types occupy the Telehealth space (see Appendix D Example Medical Devices) we limited our research to five device types within two areas: drug delivery devices (inhalers and auto-injectors) and devices for physiological measurements (heart rate monitors, blood pressure monitors and blood glucose monitors). We used CambridgeIP's RedEye patent landscaping platform, and using a patent search strategy focused on:

- building patent datasets for each of the devices
- developing subsets focused on wireless communication technologies (including RFID, Bluetooth, WiFi and Zigbee).

These subsets comprise the overlap between the two technology spaces and are expected to comprise patents related to the (wireless) interoperability of medical devices.

As illustrated in Figure 3, the complexity of the space is considerable, with a variety of device types and interoperability standard types. Some of the standards are backed by a patent pool, while others are 'open standards', and yet others are backed by public sector agreements. As it is not possible to identify directly patents that form parts of standards or patent pools, the resulting datasets, we believe, form a good proxy for the interoperability-related patents specific to medical devices. Our patent landscape therefore attempted to quantify this complexity problem, and demonstrate how the mixture of patents, patent owners and trends differs between the different focus areas of the project.

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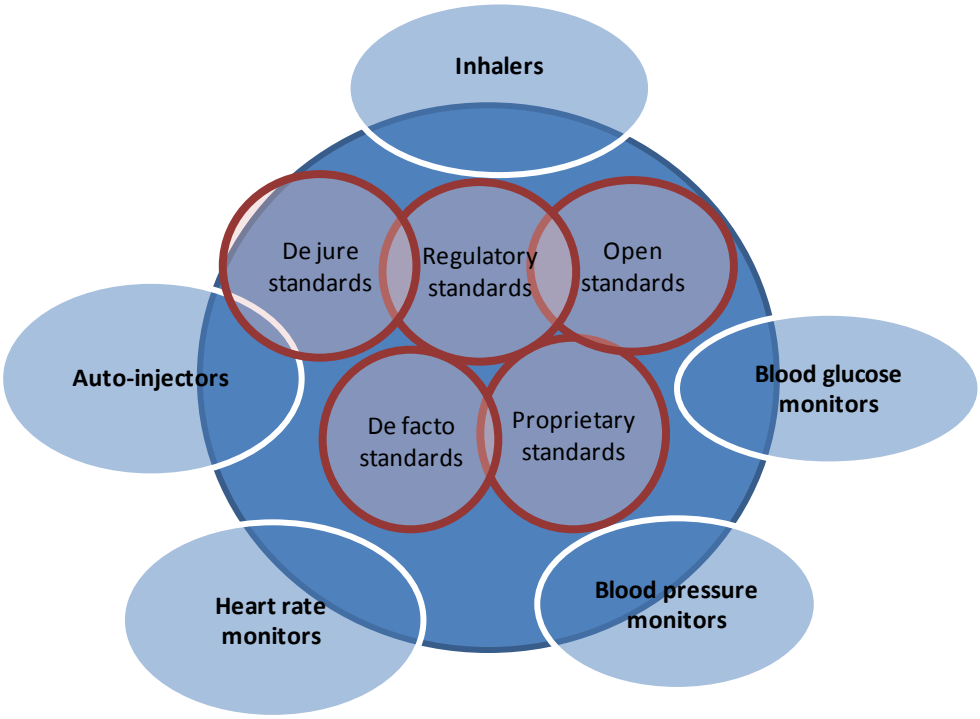
Figure 3 Device types and standard types – examples



4.1 Overall trends

As shown in Figure 4 and Table 6, there is a total of 26,503 patents and patent applications[5] relating to the five medical device technologies analysed. Of these, 8,362 (32%) mention wireless communication in conjunction with these devices in the patents.

[5] Throughout this patent landscape section, the results refer to both patents and patent application. Within this project we did not examine in detail differences in patent granting rates, the relative mixture of patents and patent applications, or patent family sizes. For brevity, we refer to 'patents' within the text and analyses.

Figure 4 Summary of patent landscaping results

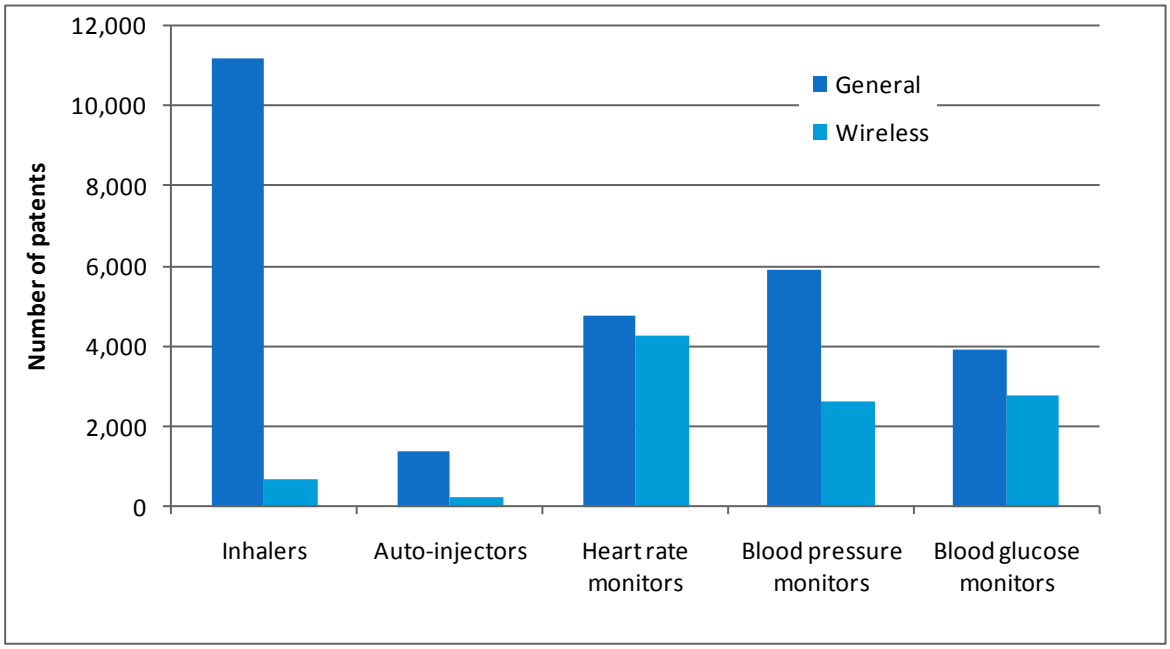


Table 6 Data summary from patent landscaping results

Dataset	General	Wireless	Wireless as % of general
Inhalers	11,163	693	6%
Auto-injector	1,394	214	15%
Heart rate monitors	4,771	4,261	89%
Blood pressure monitors	5,891	2,607	44%
Blood glucose monitors	3,900	2,788	71%
Total	**26,503**	**8,362**	**32%**

As discussed below, there is a significant variation in the proportion of wireless patents between the different device types. Drug delivery devices (inhalers and auto-injectors) show a much lower proportion of patents relating to wireless communication than physiological measurement devices (heart rate, blood pressure and blood glucose monitors). One interpretation could be that stronger regulations around drug delivery devices have inhibited innovation and the penetration of wireless devices, as well as more radical designs. By contrast, the relatively simple physiological measurements of blood pressure and heart rate monitoring devices may have made these an easier entry point for electronics manufacturers. For example, heart rate monitors have the highest proportion of wireless-enabled devices. Anecdotal review of associated products suggests that many of these patents relate to devices that are to be used in sports and leisure activities.

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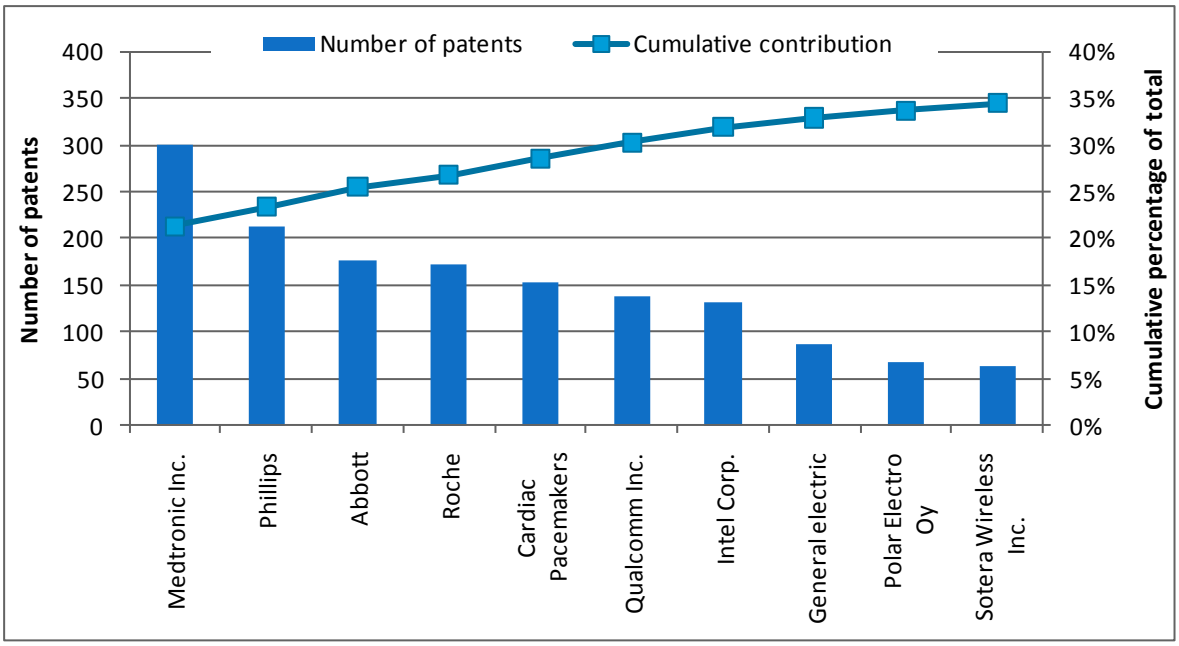
Key assignees: overall devices and multi-device systems

We undertook some further global analysis of the assignees in this space, whereby we totalled all the patent datasets across device categories with a mention of wireless (8,362), and analysed the top assignees emerging, as shown in Figure 5. As a measure of market concentration, the top ten assignees hold 35% of all patents in the dataset. But it is also interesting to note that six out of the top ten are 'external entrants' into the medical devices space: Phillips, Qualcomm, Intel, General Electric[6], Polar Electro and Sotera Wireless.

Figure 5 Top ten assignees from all wireless medical device patents



Market structure

Table 7 illustrates the IP ownership concentration rates in terms of the percentage of the total number of patents held by the top ten assignees for each of the device types. This could be used as a proxy for market concentration in a space, although it may vary significantly from market shares in terms of revenues. This shows that the medical devices space overall is relatively fragmented: when looking at the overall medical devices patent dataset (the sum of the five device spaces), the IP ownership concentration of the top ten assignees is around 24%. However, ownership concentration is higher in the wireless space, which is consistent with the trends for a novel technology where frequently the leaders in a

[6] It is worth noting that both Phillips and General Electric have been very active in complex medical instrumentation, such as in X-Ray and Ultrasound scanners. Their entry into personal care medical devices (such as the classes examined in this report) is likely to have built on their medical industry experience in the industry.

technology space may enjoy temporary leadership on the back of innovation. The heart rate monitor space has the lowest IP ownership concentration rate, consistent with the relatively low barriers to entry we believe characterise this device type (see Section 4.4).

Table 7 IP ownership concentration rates: number of patents held by top ten assignees as % of total

Dataset	General	Wireless
Overall	24%	35%
Inhalers	35%	42%
Auto-injectors	41%	46%
Heart rate monitors	28%	38%
Blood pressure monitors	39%	40%
Blood glucose monitors	38%	46%

Geography of patent filings and assignee locations

Table 8 and Table 9 below show a clear difference between the patent authorities where patents in the medical device field are filed compared to where patents from the wireless subset of patents are filed. There is a significantly higher proportion of wireless-related patents being filed in the US PTO compared to overall medical device patents. WIPO patents also represent a larger proportion in the wireless-related subset. All other authorities, including the EPO, provide a much smaller proportional contribution to the wireless related patent subset compared to the overall medical device patent dataset.

Table 8 Number of general patents by country

Patent authority	Number	% of total
US PTO	8806	33.2%
European Patents (EPO & National)	5715	21.6%
WIPO	4456	16.8%
Japan	2235	8.4%
China	1680	6.3%
Canada	1151	4.3%
South Korea	458	1.7%
Australia	792	3.0%
Other	1210	5.0%

Table 9 Number of wireless-related patents by country

Patent authority	Number	% of total
US PTO	5395	64.5%
WIPO	2221	26.6%
European Patents (EPO & National)	630	7.5%
China	70	0.8%
Japan	12	0.1%
South Korea	7	0.1%
Other	27	0.0%

Table 10 shows the geographic location of the assignees with the US at the top for both datasets. While the UK remains in second place in both datasets, it provides a much smaller proportion of the wireless patent subset than of the overall device dataset. Germany and Japan are closely matched in third and fourth place for both datasets. The Netherlands is a lot higher in the ranking of wireless-related device patents than in pure medical devices, presumably due to the strong contribution from Phillips in this area. Without further research it is not possible to come to a conclusive interpretation of the significant differences in geographic location between the two datasets. It is possible that companies are either developing or re-locating to geographic locations where they feel they can get the best protection for their technology – in this case the US. There may also be a self-selection bias, whereby UK medical devices companies focus R&D activities in areas they are more certain they will get patent protection.

Table 10 Location of assignees

General patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	8,416	2399
United Kingdom	2,042	698
Japan	1,842	736
Germany	1,834	839
China	1,009	492
Sweden	792	201
Switzerland	668	370
Italy	418	169
Republic of Korea	338	159
Canada	337	75
Netherlands	328	181
France	300	131
Israel	281	96
Finland	212	49
Taiwan, Province of China	185	65
Australia	161	56
India	93	55
Russian Federation	121	35
Ireland	57	46
Spain	55	33

Wireless-related patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	5,011	2359
United Kingdom	262	114
Germany	261	161
Japan	250	122
Israel	226	78
Netherlands	213	148
Switzerland	184	132
Finland	138	57
Denmark	119	48
Canada	114	41
Republic of Korea	88	52
China	78	52
Sweden	77	40
Taiwan, Province of China	68	40
Australia	54	32
Italy	41	25
Ireland	34	29
France	18	10
Netherlands Antilles	17	2
New Zealand	15	12

Rate of increases of patenting activity

As will be seen in the device-level analyses below, the number of patents referring to the wireless communication aspect of medical device technology has increased at a much faster rate than the overall number of device patents. There are a number of possible reasons for this.

It is only **one new aspect of a mature technology** and therefore development is accelerated. The devices already exist and have undergone all necessary testing in their previous form (without wireless communication aspects). The resulting integrated technology is therefore subject to less further testing and thus the innovation process is not held up for long period of time (government standards/tests have been mentioned as something that can slow down innovation). This could be an indication of accelerated innovation when less testing is required.

Another possible explanation is that the **wireless communication technology already existed** outside the medical device space and it was only a matter of applying it in the

correct way to the existing devices (an integration issue). This could mean less R&D is needed compared with developing technology from scratch.

Considering the large rate of increase in the number of patents, it is most likely that both of these factors could be playing a role. However, the result could be that a patent thicket forms in this field due to the fast increase in the number of patents while patent examiners are still in the process of learning about the new technology. In such cases it is worth considering whether a patent application should be assigned to an examiner who is a specialist in the wireless communication or in the medical devices field; as well as what is the trade-off between expertise in one area, and missing out on valuable knowledge from another field.

In all datasets we observed a spike in the number of wireless communication-related patents in 2001, which could be due to the release of Bluetooth v.1.1. Although Bluetooth had already been around for some time (and no doubt companies were already conducting R&D into the uses of this technology), the 2001 standardisation addressed many of the previous issues associated with this technology.

IPC code migration

We also found differences in the IPC composition of the general device and wireless-related device datasets, with the use of IPCs in the medical device specific to telecoms, such as G06F 'Electric digital data processing' and G06Q 'Data processing systems and methods ...' (see Appendix C). A more detailed analysis may uncover relevant patents in other 'niche' IPC areas too, which may have implications for both patent examiners and patent agent practitioners. Depending on the evolution of the Telehealth space, it may also be appropriate to develop IPC categories specific to Telehealth.

4.2 Inhaler devices

Inhalers are complex devices, with many areas of patentable inventions, such as metered dosing, designs aimed at particle dispersion, optimised designs for particular formulations, as well as user feedback mechanisms. The drugs that go into the inhalers are all patented and patentable. Where the patent of a drug has expired, generic companies are now playing a key role. Needless to say, the respiratory diseases market for Asthma, COPD and other conditions is a very large one. Consequently, the inhalers industry has seen one of the highest rates of patenting in the medical devices industry.

Timeline: evolution of patent filings of 'pure' devices and wireless-related device patents

Figure 6 shows the increase in the cumulative number of patents in the general auto-injector space, as well as the cumulative increase in patents relating to auto-injectors and wireless communication, while Figure 7 shows the annual number of applications. The total number of device patents including a wireless component has grown significantly since 2001, reaching 600 patents. We would expect that a more detailed patent landscape analysis would uncover other inhaler-focused patents related to wireless interoperability,

so this is likely to be an understatement. Nevertheless, inhalers are a late comer to the wireless enabling of devices. Interviews with industry participants support the view that thus far the inhaler devices have had a limited level of telemedicine enabling.

Figure 6 Inhaler and wireless-related inhaler patents: cumulative number of applications[3]

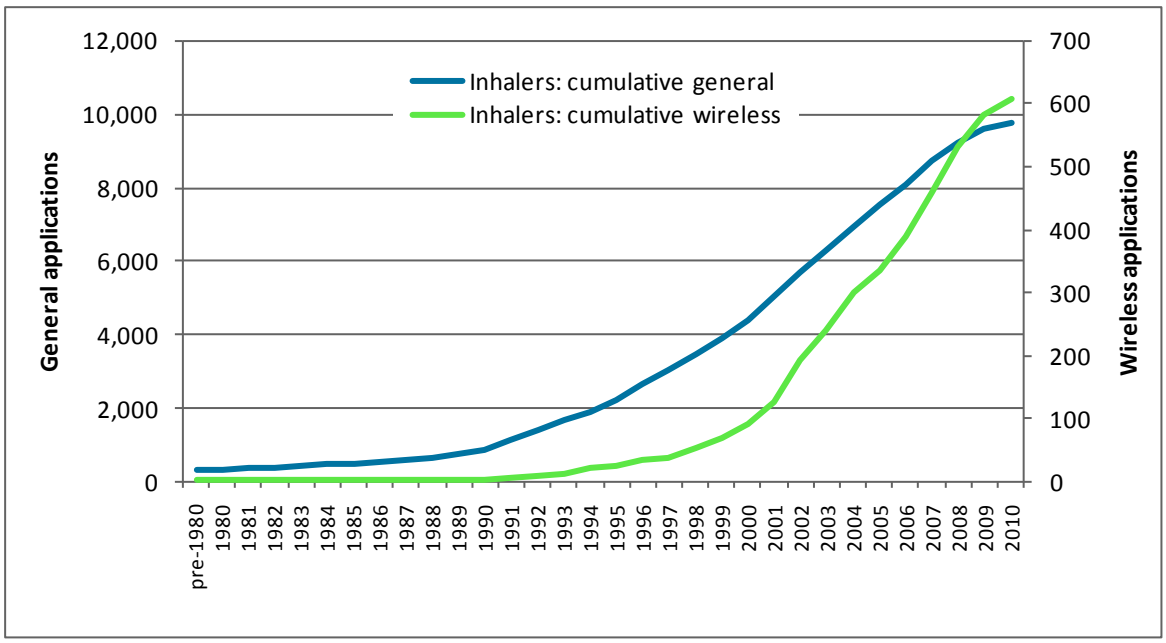
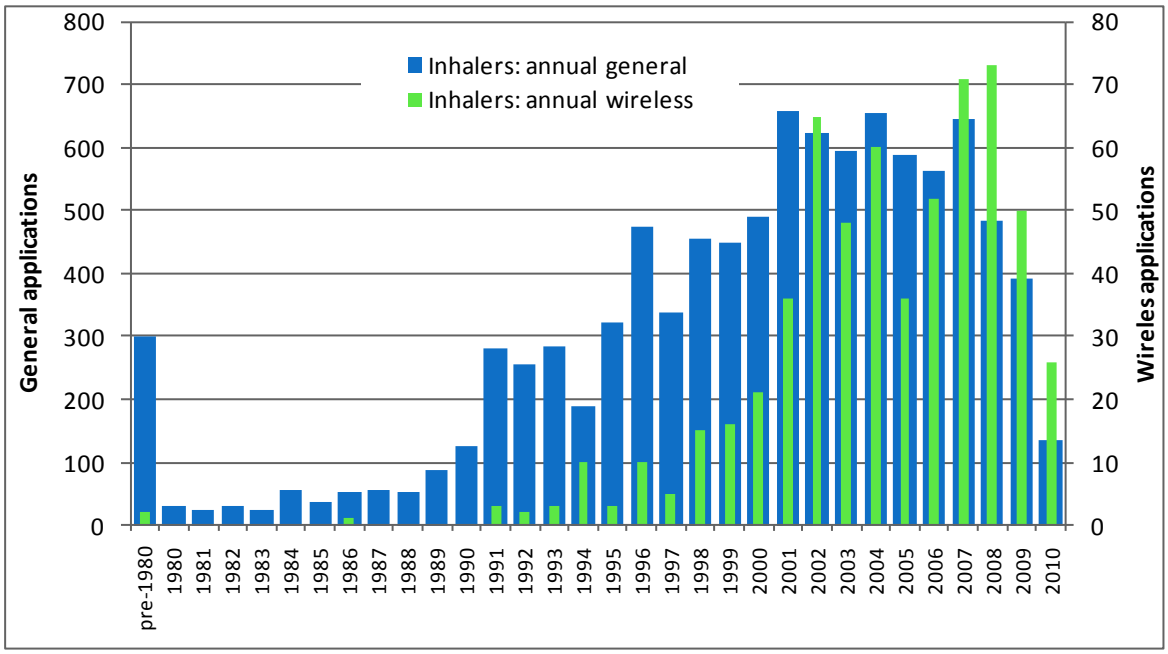


Figure 7 Inhaler and wireless-related inhaler patents: annual number of applications



Key players and market structure

Table 11 shows that the inhaler space is dominated by healthcare sector companies in *both* the general *and* wireless-related patents. As discussed later in the interview section (Section 5), the predominant business model in this space has been that SMEs and device specialists (such as Vectura, Bespak, Cambridge Consultants) have focused on developing new device designs, which are in time sold or licensed out to big pharmaceutical companies such as Astra-Zeneca and Novartis. These in turn have focused on both in-house device development, as well as developing pharmaceutical formulations, and taking the devices through trials. The very high levels of regulatory requirements are probably one factor that has stopped inhaler designs from evolving as fast as the devices in the monitoring fields. Consequently, there are relatively few 'new entrants' from the telecoms space even in the 'wireless' dataset. As seen in Table 7 earlier, the top 10 assignees account for 35% of all the patents identified in the space, while in the wireless space this is 42%. This shows a fairly consolidated patent ownership space, although not the highest rate in the study.

Table 11 Top assignees of general and wireless-related inhaler patents

General patents			
Index	**Assignees**	**Number of patents**	**Percentage of patents filed in last 5 years**
1	Astrazeneca	715	33%
2	Boehringer Ingelheim	703	64%
3	Glaxo Group	603	30%
4	Chiesi Farmaceutici Spa	304	42%
5	Vectura Ltd	290	57%
6	Norton Healthcare	234	32%
7	Innovata Biomed Ltd	188	27%
8	3M Company	166	30%
9	Novartis	163	25%
10	Elan Pharmaceuticals	140	0%
11	Schering Plough	121	31%
12	Orion	118	19%
13	Canon	108	93%
14	Microdrug Ag	107	28%
15	Microdose Therapeutx Inc.	102	77%
16	Trudell Medical Int	102	35%
17	Cambridge Consultants	93	43%
17	Bespak plc	93	19%
19	Asta Medica Ag	83	1%
19	Valois	83	67%

Wireless-related patents		
Index	**Assignees**	**Number of patents**
1	Glaxo Group	60
2	Boehringer Ingelheim	38
3	Novo Nordisk AS	20
4	Searete LLC	18
5	Pneumoflex Systems LLC	17
6	Astrazeneca	14
7	Vectura Ltd	11
7	Schering Plough	11
7	Sandoz	11
10	Dexcom Inc.	9
11	Jones Anthony Patrick	8
13	Innovata Biomed Ltd	7
13	3M Company	7
13	Abbott Laboratories	7
15	Canon	6
15	Allegiance Corp.	6
15	Rand Paul Kenneth	6
15	Nexus6 Ltd	6
15	Teijin Ltd	6
15	Medtronic Inc	5

Geography of patent filings and assignee location

The inhaler space is the only one where patents filed under European jurisdiction are higher than those filed in the US PTO (see Table 12). It is also the space with the lowest 'wireless' penetration. When we look at the geography of filings distribution in the wireless space (see Table 13), the position is significantly reversed, with the European share of patent filings going down from 28.3% to 11.8%. It is interesting that WIPO (representing PCT filings) remains significant in the wireless dataset. Given the observations in the next datasets, where the 'wireless' space is more developed, it may be expected that as wireless technologies penetrate deeper into the inhaler space, the overall proportion of European filings will continue to decline.

Table 12 Number of general inhaler patents by country

Patent authority	Number	% of total
European Patents (EPO & National)	3,160	28.3%
US PTO	2,941	26.3%
WIPO	1,931	17.3%
Canada	753	6.7%
Australia	606	5.4%
China	448	4.0%
Japan	274	2.5%
South Korea	166	1.5%
Other	884	7.9%

Table 13 Number of wireless-related inhaler patents by country

Patent authority	Number	% of total
US PTO	382	55.1%
WIPO	226	32.6%
European patents (EPO & National)	82	11.8%
Japan	0	0.0%
China	0	0.0%
South Korea	0	0.0%
Other	3	0.3%

Turning to the location of assignees (shown in Table 14), what is particularly striking is that in the overall dataset UK-based assignees (with 2,042 patents) come second behind the USA (with 8,416 patents). Yet when we look at patents filed in the last 5 years, the UK-based assignees have fallen to fourth position, behind Germany, and Japan. When we look at the 'wireless' inhalers dataset, the UK-based assignees (with 262 patents) are now a much more distant second to the USA (with 5,011 patents), just ahead of German assignees with 261 patents. But if we consider patents filed in the last 5 years, the UK's position has actually fallen to sixth, behind Germany, the Netherlands, Switzerland and Japan. Factors behind the rapid decline in 'IP share' of UK companies could be related to multinational

pharmaceutical divestment from the UK and refocusing of R&D activities elsewhere in the value chain and changes in SME patenting trends, as well as the lower ability to patent in software and methods (closely related to wireless). Another possible reason is that some large pharmaceutical companies have harmonised their patent filing strategies, by for instance filing out of only one location (e.g. where their patent function is located). Further analysis of Inventor geographic location and case studies could provide further clarity on this point.

Table 14 Location of assignees: inhaler patents

General patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	2,949	689
United Kingdom	1,628	493
Germany	1,045	482
Sweden	679	145
Italy	353	143
Switzerland	307	133
Japan	252	151
Canada	194	42
France	163	69
China	156	75
Denmark	115	32
Finland	106	13
India	88	52
Russian Federation	77	16
Netherlands	72	28
Australia	61	20
Israel	46	21
Republic of Korea	43	16
Spain	34	26
Taiwan, Province of China	34	10

Wireless-related patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	325	149
United Kingdom	123	39
Germany	51	43
Denmark	29	11
Israel	26	10
Japan	24	13
Sweden	13	2
Netherlands	9	7
Switzerland	8	6
New Zealand	6	5
Italy	5	4
Austria	3	0
Belgium	3	2
India	2	2
Luxembourg	2	0
Republic of Korea	2	2
Australia	1	1
Barbados	1	0
China	1	1
Croatia	1	0

4.3 Auto-injectors

Similarly to inhalers, there are many aspects of an auto-injector that are patentable, ranging from the needle insertion, extraction and shielding mechanisms, dosage and automation mechanism, to the communications and control aspect of the device. Again, there may be aspects of the manufacturing and assembly process that may not be patentable and kept as trade secret. In addition, due to the 'visual' nature of auto-injectors, industrial design may be of importance. By comparison to inhalers, auto-injector design is less constrained with the type of formulations it can be used for, as it is a more versatile device. The traditional key application area of personal insulin management of auto-

injectors (and pen injectors) has in recent years been supplemented with a larger range of disease treatments that require more complex, but self-administered medications. It is likely that future developments in the auto-injector space will consist of a significant element related to telemedicine, particularly in relation to dosage and compliance communications.

Timeline: evolution of patent filings of 'pure' devices and wireless-related device patents

Figure 8 shows the increase in the cumulative number of patents in the general auto-injector space, as well as the cumulative increase in the number of patents relating to auto-injectors and wireless communication, while Figure 9 shows the annual number of applications. The 'penetration' of wireless-related patents in the auto-injector space is about 15%, higher than that of inhalers, but still fairly low compared to monitoring devices. It is overall a much smaller space compared to inhalers, with accelerated growth since 2000 in both general and wireless-related patents.

Figure 8 Auto-injector and wireless-related auto-injector patents: cumulative number of applications

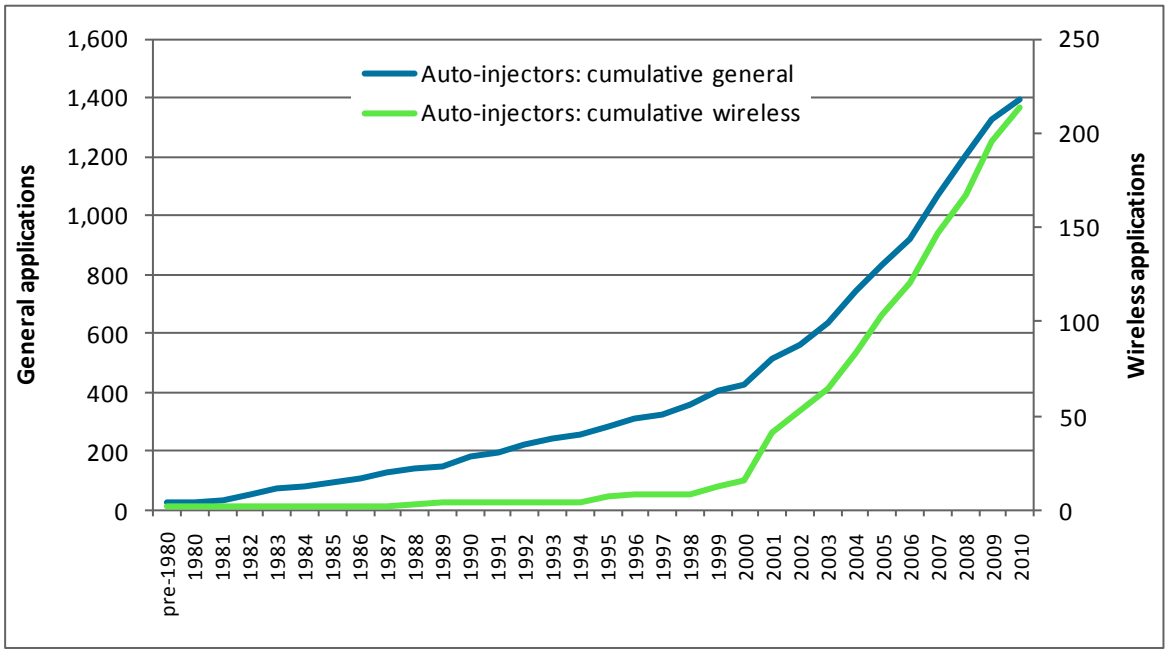
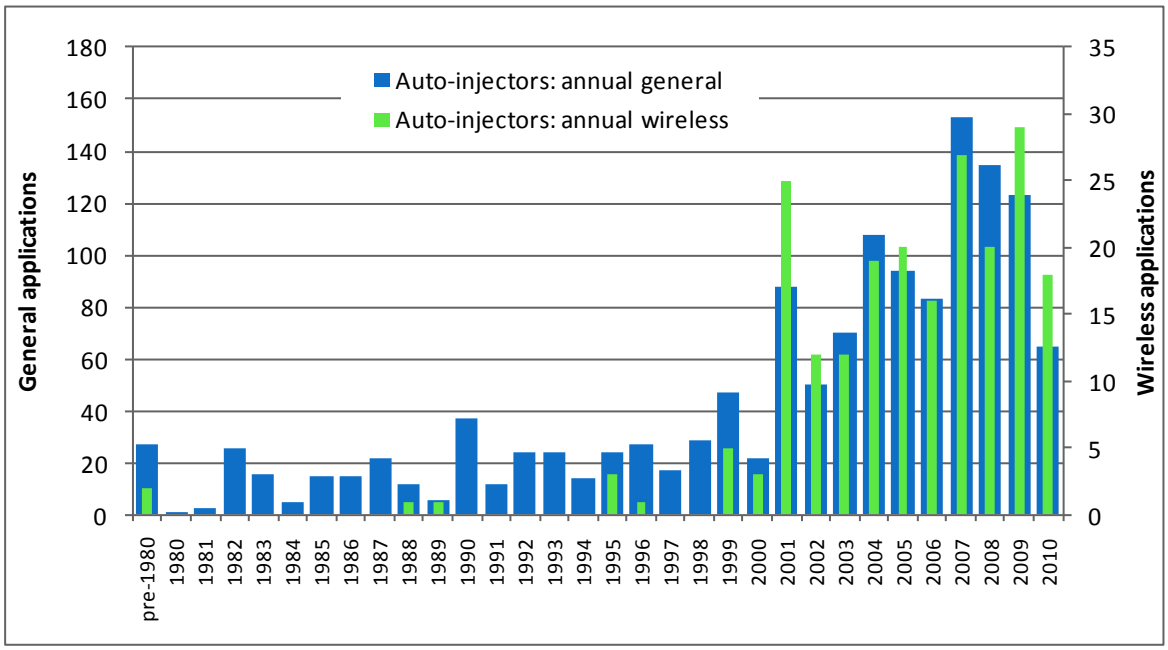


Figure 9 Auto-injector and wireless-related auto-injector patents: annual number of applications



Key players and market structure

Looking at the composition of key players in the overall auto-injectors space and the wireless-related patents (shown in Table 15), there is a much greater diversity of players in this field than in inhalers. There is a combination of pharmaceutical companies (such as Sanofi-Aventis, Glaxo and Novo Nordisk), medical device specialists (Abbott and Becton Dickinson) and various SMEs. Companies that have been active more recently in this space tend to have a larger portfolio in wireless-related auto-injectors. For example, Lifescan Inc., which ranks 16th in general auto-injector patents ranks first in the wireless-related patents, and 78% of its patents in this space were filed in the last 5 years. Similarly, Intellijject has all of its auto-injector patents granted in the last 5 years and many of these refer to wireless communication. Other larger players appear to be pursuing market share with continued innovation. For example, Novo Nordisk features tenth in the general auto-injector list and third in the wireless ranking.

Table 15 Top assignees of general and wireless-related auto-injector patents

General patents			
Index	**Assignees**	**Number of patents**	**Percentage of patents filed in last 5 years**
1	Becton Dickinson Co.	98	68%
2	Meridian Medical Technologies	75	53%
3	Sanofi-Aventis	62	97%
4	Medical House Ltd	52	100%
5	Tecpharma Licensing AG	50	72%
5	Dupahr International Research BV	50	0%
7	Dupahrl Technology Inc.	37	0%
8	SHL Group AB	31	81%
9	Alza Corp.	29	38%
10	Novo Nordisk AS	28	71%
11	Cilag Gmbh Int.	27	93%
11	Owen Mumford Ltd	27	89%
13	Milestone Scientific Inc.	22	55%
13	Abbott	22	86%
15	West Pharmaceutical Services Inc.	21	100%
16	Lifescan Inc.	18	78%
17	Intellijject LLC	15	100%
18	Pharmacia & UP John AB	14	0%
18	Nemoto Kyorindo Co. Ltd	14	29%
18	UCB Pharma SA	14	100%
18	Glaxo Group	14	0%

Wireless-related patents		
Index	**Assignees**	**Number of patents**
1	Lifescan Inc.	12
2	Novo Nordisk AS	10
2	Mallinckrodt Inc.	10
4	Abreu Marcio Marc	9
4	Dexcom Inc.	9
6	Roche Diagniostics Gmbh	8
7	Becton Dickinson Co.	5
7	Intellijject LLC	5
7	Pharmacia & UP John AB	5
10	Meridian Medical Technologies	4
10	Milestone Scientific Inc.	4
10	Henry Schein Inc.	4
10	Frontier Plastics Ltd	4
10	David Daniel	4
10	Therasense Inc.	4
16	HRL Laboratories LLC	3
16	Alcon Research Ltd	3
16	Mdatalink LLC	3

It is interesting that the IPR ownership concentration is higher than that in the inhaler space, with the top 10 assignees accounting for 41% of all general patents and 46% of wireless-related patents.

Geography of patent filings and assignee location

In the auto-injector space, patents filed under European jurisdiction are at the same level as those filed in the US PTO, both at 24.2% of the total (shown in Table 16). There is also significant patent filing activity in key Asian locations (Japan, China and South Korea), although this is also the area with the lowest wireless-related penetration. However, turning to the wireless space (see Table 17), similar patterns to those in the inhalers space emerge, with the European share of patent filings going down from 24.2% to 9.3%, and the US share increasing to 60.3%. As with the inhaler space, WIPO (representing PCT filings) remains significant in the wireless dataset.

Table 16 Number of general auto-injector patents by country

Patent authority	Number	% of total
US PTO	338	24.2%
European Patents (EPO & National)	337	24.2%
WIPO	308	22.1%
China	115	8.2%
Canada	68	4.9%
Japan	63	4.5%
Australia	60	4.3%
South Korea	34	2.4%
Other	71	5.0%

Table 17 Number of wireless-related auto-injector patents by country

Patent authority	Number	% of total
US PTO	129	60.3%
WIPO	65	30.4%
European Patents (EPO & National)	20	9.3%
Japan	0	0.0%
China	0	0.0%
South Korea	0	0.0%
Other	0	0.0%

Turning to the location of assignees (see Table 18), patents filed by UK-based assignees are once again ranked second (with 140 patents) behind the USA (with 416 patents). These relative positions are the same for the number of patents in the last 5 years. When turning to wireless-related patents, UK-based assignees are now ranked *tenth*, with Denmark second and Switzerland third. Given the relatively small numbers in the dataset it is difficult to read too much into the particular ranking, but what is evident is the rapidly growing overall share of patents by US assignees, again showing that, at least in terms of patent ownership, market share in wireless-related medical device technologies may be going to the US economy.

Table 18 Location of assignees: auto-injector patents

General patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	416	153
United Kingdom	140	103
Germany	95	80
Switzerland	77	51
France	59	37
China	56	20
Denmark	41	23
Sweden	37	18
Netherlands	27	6
Republic of Korea	22	5
Israel	17	11
Japan	12	4
Italy	11	9
Canada	10	3
Belgium	8	8
Bermuda	8	8
Austria	7	2
Ireland	5	0
Spain	5	1
Luxembourg	4	0

Wireless-related patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	138	71
Denmark	16	6
Switzerland	7	5
Sweden	6	0
Israel	6	4
Germany	5	5
Japan	5	3
Republic of Korea	4	2
Canada	4	1
United Kingdom	3	2
Ireland	2	2
Japan	1	0
Spain	1	0

4.4 Heart rate monitors

Heart rate monitoring/measuring devices are one of the most basic functions both in the hospital and at home. It is by its very nature an activity that requires some electronic elements for the measurement, recording and display of information. It is therefore also one of the earliest spaces where wireless technology has been applied. Given the relative simplicity of the measuring function (from a clinical perspective), there are relatively few regulatory barriers to entry in this space. It is also a device type that can be used in leisure and sports activities, as well as being integrated into everyday personal and wearable devices such as watches, MP3 players or mobile phones.

Timeline: evolution of patent filings of 'pure' devices and wireless-related device patents

Figure 10 shows the increase in the cumulative number of patents in the general heart rate monitor space, as well as the cumulative increase in patents relating to heart rate monitor and wireless communication, while Figure 11 shows the annual number of applications. Compared to the other spaces, the level of patenting in wireless-related patents is highest, at 89% of the total space. This may reflect the ease of measurement and consequently data integration, as well as the lack of many/complex regulatory requirements (such as those

around glucose measurements or drug delivery devices). Again, it is apparent that the patenting in the wireless-related patent accelerates after 2000, but the penetration of wireless starts at an earlier stage. It is also striking that in recent years the *majority* of patent filings in this space are related to wireless technologies. Possible reasons for this shift may relate to increased reliance on treatment at home, as well as the increased use of such devices in sports training and leisure activities.

Figure 10 Heart rate monitor and wireless-related heart rate monitor patents: cumulative number of applications

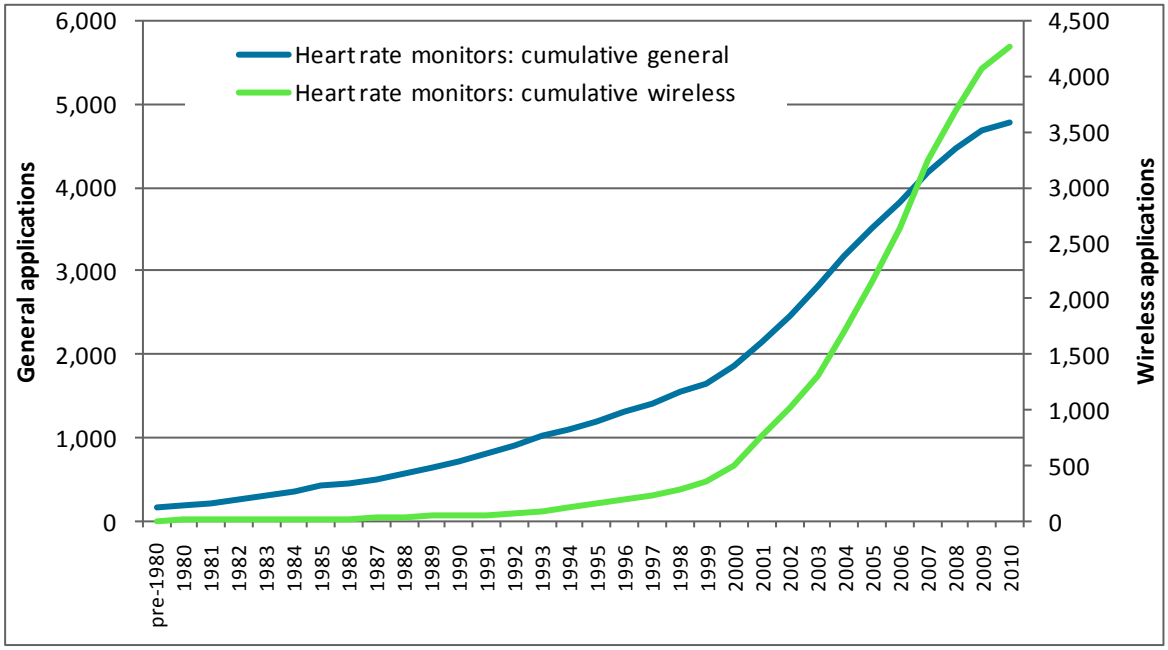
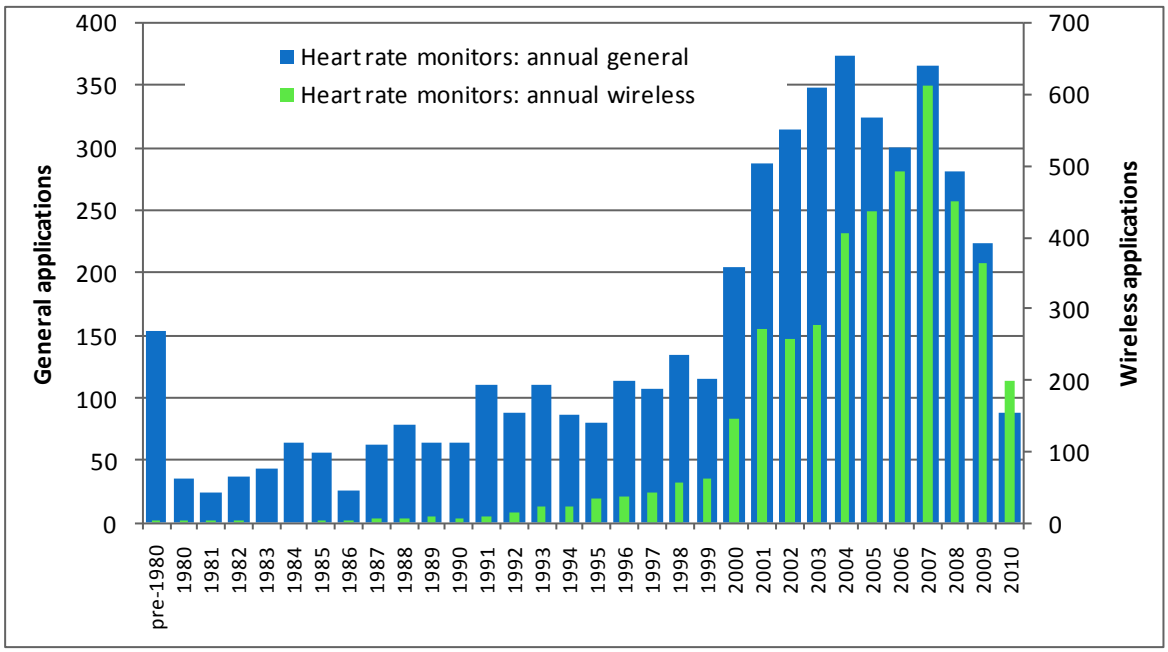


Figure 11 Heart rate monitor and wireless-related heart rate monitor patents: annual number of applications



Key players and market structure

As shown in Table 19, Medtronic is the highest-ranking healthcare sector company in this space. However, there is a very different composition of the top assignees in this dataset, compared to the drug delivery spaces, with a large presence of non-pharmaceutical companies such as Phillips, GE, Toshiba, Sharp, HP, Qualcomm and others. This is probably related to the greater level of simplicity of this space from a non-pharmaceutical perspective, as there is no 'body intrusion', and to the fact that there are fairly few clinical requirements around heart rate measurement. It is also notable that watch companies (such as Casio) have entered this space, as the wearable watch/device platform expands beyond the 'time-keeping' function to other fields.[7]

[7] Note that, given the very high proportion of wireless-related patents in the overall heart rate monitoring dataset (at 89%), there is a large overlap between the top assignees in general and wireless-related patents

Table 19 Top assignees of general and wireless-related heart rate monitor patents related to wireless

General patents			
Index	**Assignees**	**Number of patents**	**Percentage of patents filed in last 5 years**
1	Koninklijke Phillips Electronics NV	178	72%
2	Cardiac Pacemakers	151	64%
3	Medtronic Inc.	102	42%
4	General Electric	97	61%
5	Colin Corp.	84	1%
6	Toshiba	81	42%
7	Omron Corp.	79	52%
8	Polar Electro Oy.	68	31%
9	Pacesetter Inc.	54	37%
10	Sharp	50	4%
10	Fukuda Denshi Co. Ltd	50	14%
12	Hewlett-Packard Company	46	2%
13	Hitachi Medical Corp.	39	18%
14	Terumo Corp.	38	8%
15	NEC Corp.	34	0%
16	Siemens	33	33%
17	Matsushita Electric	27	41%
18	Casio Computer Co. Ltd	26	0%
19	Seiko Epson Corp.	24	42%
20	Qualcomm Inc.	21	100%

Wireless-related patents		
Index	**Assignees**	**Number of patents**
1	Koninklijke Phillips Electronics NV	157
2	Medtronic Inc.	124
3	Qualcomm inc.	120
4	Cardiac Pacemakers	109
5	Intel Corp.	97
6	Polar Electro Oy.	67
7	General Electric	66
8	Motorola Inc.	56
9	Sotera Wireless Inc.	45
10	Corventis Inc.	35
11	Nike Inc.	29
12	Searete LLC	28
13	Hewlett-Packard Company	26
14	Nokia	25
15	International Business Machines Corp.	23
16	Welch Allyn Inc.	22
17	Nellcor Inc.	20
18	Baxter Int.	18
18	Pacesetter Inc.	18
18	Univ North Carolina	18

Geography of patent filings and assignee location

It is immediately apparent from Table 20 that the distribution of patent filings for heart rate monitors is significantly different from that for drug delivery devices, with the US PTO share of 47.2%. The share of European-filed patents *as a whole* is similar to that of Japan (13.9% and 12.6%, respectively). Given that it is the space with the highest wireless penetration, it is not surprising that the US patent filings also lead in the wireless-related heart rate device dataset (65.5%), while European patent filings amount to only 7.1% of the total. It is interesting that the share of Japan drops significantly to just 0.2%, on a par with China.

Table 20 Number of general heart rate monitor patents by country

Patent authority	Number	% of total
US PTO	2,254	47.2%
WIPO	828	17.4%
European Patents (EPO & National)	661	13.9%
Japan	603	12.6%
China	261	5.5%
Canada	68	1.4%
South Korea	31	0.6%
Australia	20	0.4%
Other	45	1.0%

Table 21 Number of wireless-related heart rate monitor patents by country

Patent authority	Number	% of total
US PTO	2,791	65.5%
WIPO	1,120	26.3%
European Patents (EPO & National)	303	7.1%
China	22	0.5%
Japan	9	0.2%
South Korea	1	0.0%
Other	15	0.0%

Turning to the location of assignees (see Table 22), the UK remains fifth in the general dataset both for all time and in the last 5 years in terms of patent filings by UK-based assignees. It is worth noting that in the overall dataset Japan and China comes second and third, respectively, perhaps reflecting their different focus areas within the electronics industry. However, when we look at developments over the last 5 years, the Netherlands comes second after US-based assignees. This latter development may be related to the entry of Phillips in the personal care medical devices space. The strong position of the Netherlands as an assignee location remains when considering the wireless-related patents. In addition, Israel-based assignees come third here (from sixth in the general space), probably due to the high number of medical devices start-ups in Israel. Finland-based assignees also account for around 100 patents in the wireless-related heart rate monitors, probably due to Nokia's entry in this space.

Table 22 Location of assignees: heart rate monitor patents

General patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	1,890	540
Japan	344	98
China	221	98
Netherlands	164	102
United Kingdom	113	42
Israel	109	26
Germany	105	31
Finland	81	29
Republic of Korea	64	33
Canada	51	18
Sweden	50	25
Australia	48	16
Switzerland	47	26
France	42	14
Italy	38	10
Taiwan, Province of China	24	9
Russian Federation	16	5
Romania	13	6
Hungary	12	1
Cayman Islands	11	8

Wireless-related patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	2,654	1186
Netherlands	149	102
Israel	130	41
Finland	100	41
Germany	96	42
Japan	87	33
United Kingdom	82	40
Canada	66	26
Switzerland	50	32
Sweden	40	25
Republic of Korea	39	20
China	34	23
Australia	32	19
Taiwan, Province of China	29	14
Italy	27	16
Denmark	23	9
France	14	8
Cayman Islands	13	10
Ireland	10	8
Portugal	10	10

4.5 Blood pressure monitors

The blood pressure monitoring devices space is fairly mature. Given the relatively low regulatory barriers to entry, there is a diverse set of actors in this space. Also, because of the fairly widespread use of these devices (in hospitals, by practitioners and at home), it is a fairly developed industry.

Timeline: evolution of patent filings of 'pure' devices and wireless-related device patents

Figure 12 shows the increase in the cumulative number of patents in the general heart rate monitor space, as well as the cumulative increase in patents relating to heart rate monitor and wireless communication, while Figure 13 shows the annual number of applications. The timeline of development of this space reflects the fairly 'mass' nature of this market, with a steady increase of patents through the 1980s, 1990s and 2000s, reaching close to 6,000 patents in recent years. The wireless component has been growing since 2000, and has exceeded 2,500 patents, which represents a 44% penetration of wireless technology, the third largest in our study, after heart rate monitors and blood glucose monitors.

Figure 12 Blood pressure monitor and wireless-related blood pressure monitor patents: cumulative number of applications

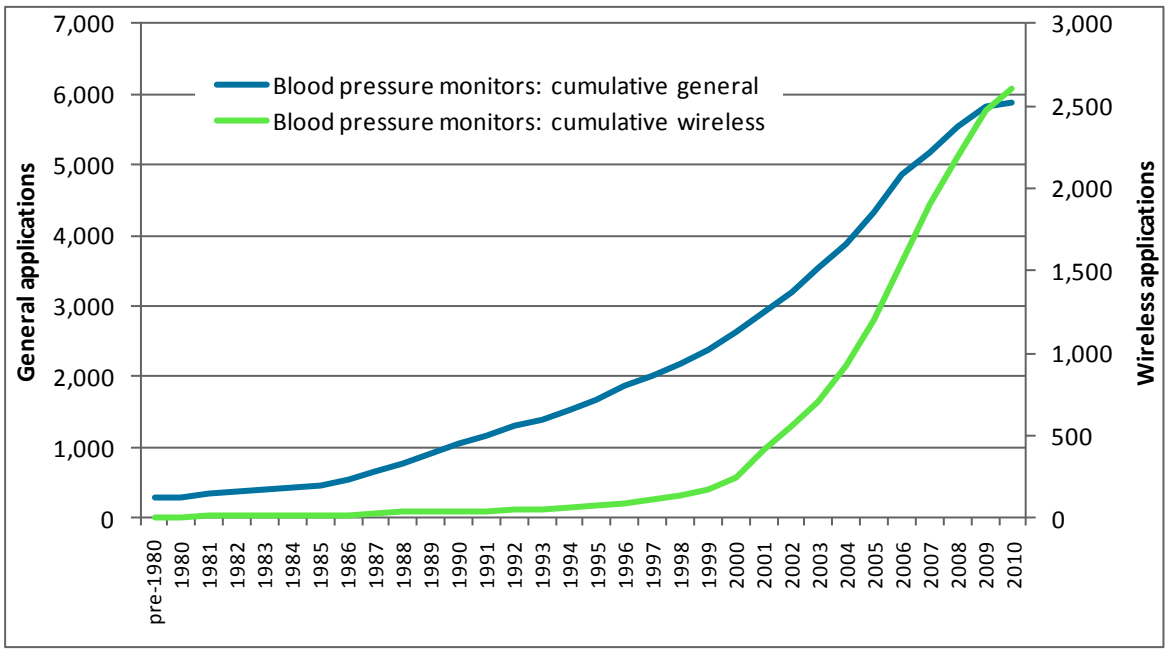
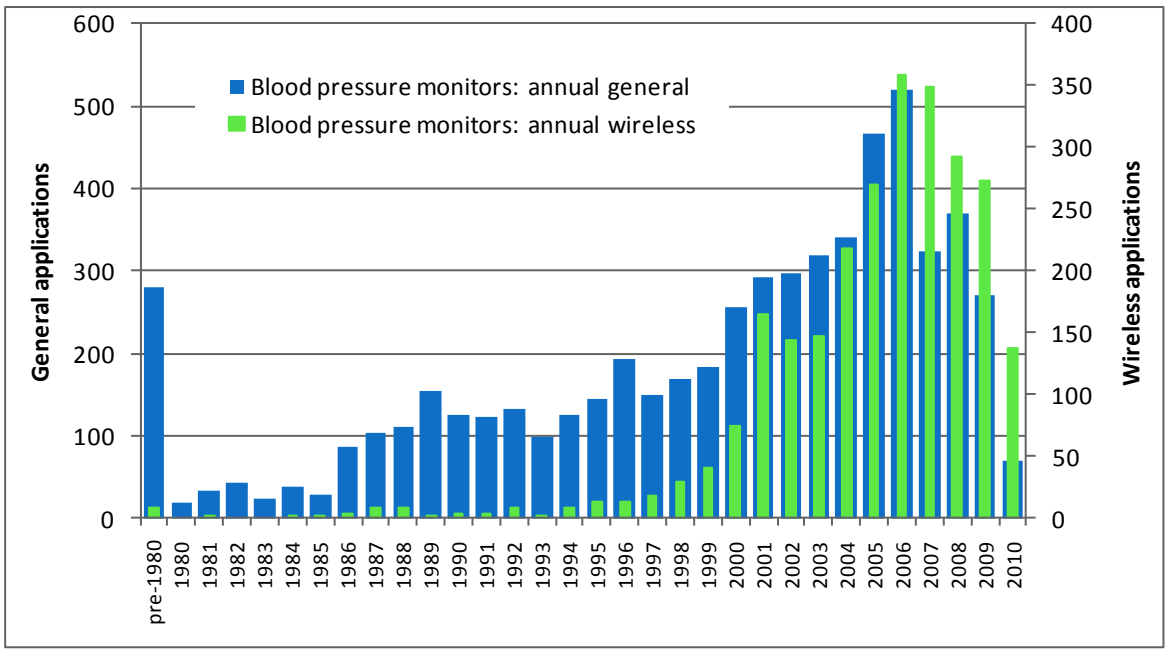


Figure 13 Blood pressure monitor and wireless-related blood pressure monitor patents: annual number of applications



Key players and market structure

As with the heart rate monitors space, in blood pressure devices there is also a strong presence of electronics companies (Matsushita, General Electric, Phillips, Seiko and Samsung) in the top 20 (see Table 23). This is unsurprising given the large percentage of patents that refer to wireless communication compared to the total number of patents

relating to the devices. In the wireless-related dataset, there is the additional entry of companies such as IBM, Nokia, Qualcomm and Intel.

Table 23 Top assignees of general and wireless-related blood pressure monitor patents related to wireless

General patents			
Index	**Assignees**	**Number of patents**	**Percentage of patents filed in last 5 years**
1	Omron Corp.	717	57%
2	Colin Corp.	449	0%
3	Terumo Corp.	249	40%
4	Matsushita Electric	186	23%
5	Citizen Watch Co. Ltd	98	56%
6	Nippon Telegraph & Telephone	80	98%
7	Critikon Inc.	69	3%
8	General Electric	68	85%
9	Microlife Corp.	57	46%
10	Welch Allyn Inc.	51	53%
10	Spacelabs Inc.	50	2%
12	Healthstats Int. Ltd	49	53%
13	Phillips Electronics NV	44	89%
14	Health & Life Co. Ltd	44	80%
15	Sotera Wireless Inc.	36	92%
16	Seiko Epson Corp.	35	14%
17	Medwave Inc.	35	17%
18	Medtronic Inc.	34	41%
19	Braun Gmbh	33	30%
20	Samsung	31	68%

Wireless-related patents		
Index	**Assignees**	**Number of patents**
1	Intel Corp.	129
2	Phillips Electronics NV	75
3	Sotera Wireless Inc.	63
4	Medtronic Inc.	55
5	Welch Allyn Inc.	37
6	Cardiac Pacemakers	35
7	General Electric	28
8	Searete LLC	23
9	International Business Machines Corp.	22
10	Health Hero Network Inc.	21
11	Nellcor Inc.	19
11	Hill-Rom Inc.	19
13	Nokia	18
14	Omron Corp.	17
15	Bodymedia Inc.	16
15	Corventis Inc.	16
17	Microlife Corp.	15
17	Qualcomm Inc.	15
19	Colin Corp.	13
19	Abreu Marcio Marc	13

Geography of patent filings and assignee location

As shown in Table 24, the European market share of patent filings (31.8%) is higher than in the heart rate monitoring space, but behind that in drug delivery devices. However, Japan and China also account for substantial proportion of the space, with 18.5% and 11.6% respectively. Turning to wireless-related patents (see Table 25), this shows a familiar pattern, with US PTO filed patents accounting for 66.9% of the total, followed by European-filed patents at 6.6% and very low rates for China and Japan.

Table 24 Number of general blood pressure monitor patents by country

Patent authority	Number	% of total
US PTO	1,873	31.8%
European Patents (EPO & National)	1,129	19.2%
Japan	1,087	18.5%
China	683	11.6%
WIPO	609	10.3%
South Korea	164	2.8%
Canada	117	2.0%
Australia	80	1.4%
Other	149	2.5%

Table 25 Number of wireless-related blood pressure monitor patents by country

Patent authority	Number	% of total
US PTO	1,744	66.9%
WIPO	654	25.1%
European Patents (EPO & National)	171	6.6%
China	31	1.2%
South Korea	2	0.1%
Japan	1	0.0%
Other	4	0.1%

Turning to assignee locations (see Table 26), in the general dataset the geography patterns observed above for the patent filings are mirrored closely, with the USA followed by Japan, China and Germany. In the last 5 years, however, Japanese-based assignees have overtaken the USA, with China coming third. Nevertheless, when looking at the wireless space, US-based assignees remain leaders by a large margin.

Table 26 Location of assignees: blood pressure monitor patents

General patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	1,296	369
Japan	1,080	373
China	465	237
Germany	152	50
Taiwan, Province of China	105	39
Republic of Korea	103	49
Switzerland	88	48
United Kingdom	87	29
Netherlands	59	37
Canada	55	6
Singapore	43	18
Israel	39	16
France	28	7
Australia	24	7
Russian Federation	23	10
Ireland	21	21
Hong Kong	19	13
Finland	18	2
Denmark	12	6
Hungary	12	3

Wireless-related patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	1,481	707
Japan	98	51
Netherlands	69	50
Israel	58	24
Switzerland	52	27
Germany	48	21
Canada	41	15
Taiwan, Province of China	41	29
China	35	22
Ireland	26	22
United Kingdom	25	8
Finland	19	8
Sweden	19	10
Republic of Korea	15	12
Australia	12	8
Denmark	12	9
Singapore	10	5
Italy	9	7
Virgin Islands (British)	9	3
Brazil	5	5
Croatia	5	0
India	5	3
Spain	5	4
Hong Kong	5	2

4.6 Blood glucose measurement devices

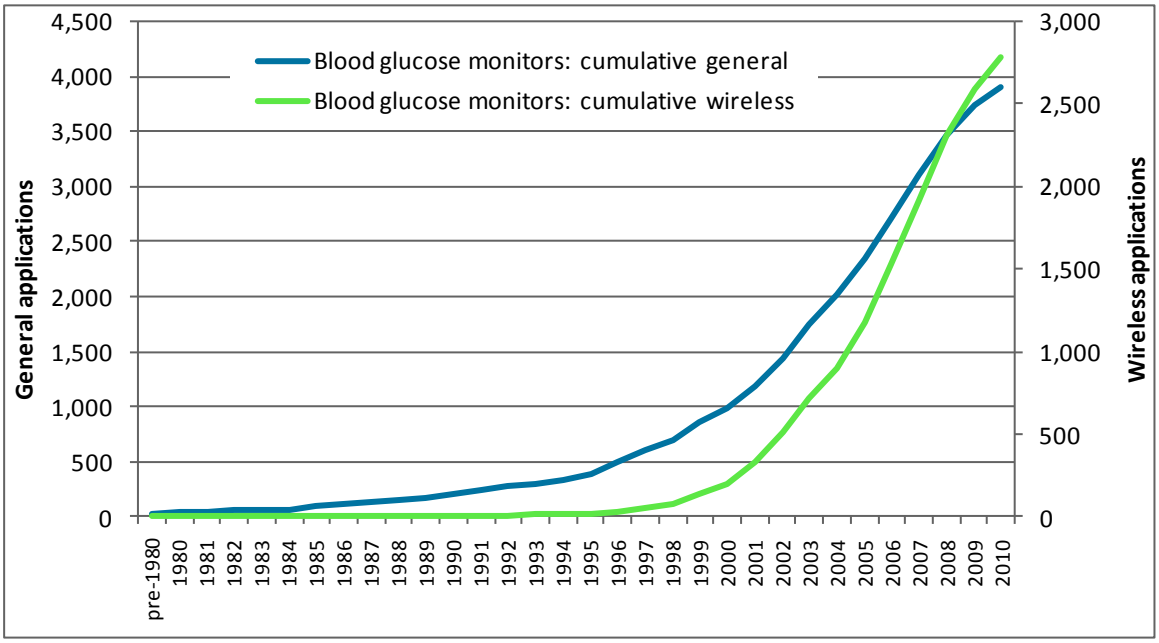
Blood glucose measurement devices are related to the treatment of diabetes patients. Until recently, the predominant business model was proprietary systems developed and serviced by several major pharmaceutical and medical device companies. Monetisation has frequently been through proprietary systems around the testing strips, while connectivity until a few years ago was primarily through cabling and paired devices for doctor data monitoring and analysis. The global market for blood glucose monitors and strips is forecast to reach USD18 billion by 2015. Key factors driving market growth include an increasing diabetic population (particularly in key emerging markets such as China), growing patient awareness, technological advancements and increasing numbers of patients adopting blood

glucose self-monitoring. In addition, the affordable cost of blood glucose test strips and an increase in daily monitoring are also expected to contribute to market growth.[8] Many of these factors are likely to contribute to increased demand for interconnectivity with personal devices and remote transmission of data to health practitioners.

Timeline: evolution of patent filings of 'pure' devices and wireless-related device patents

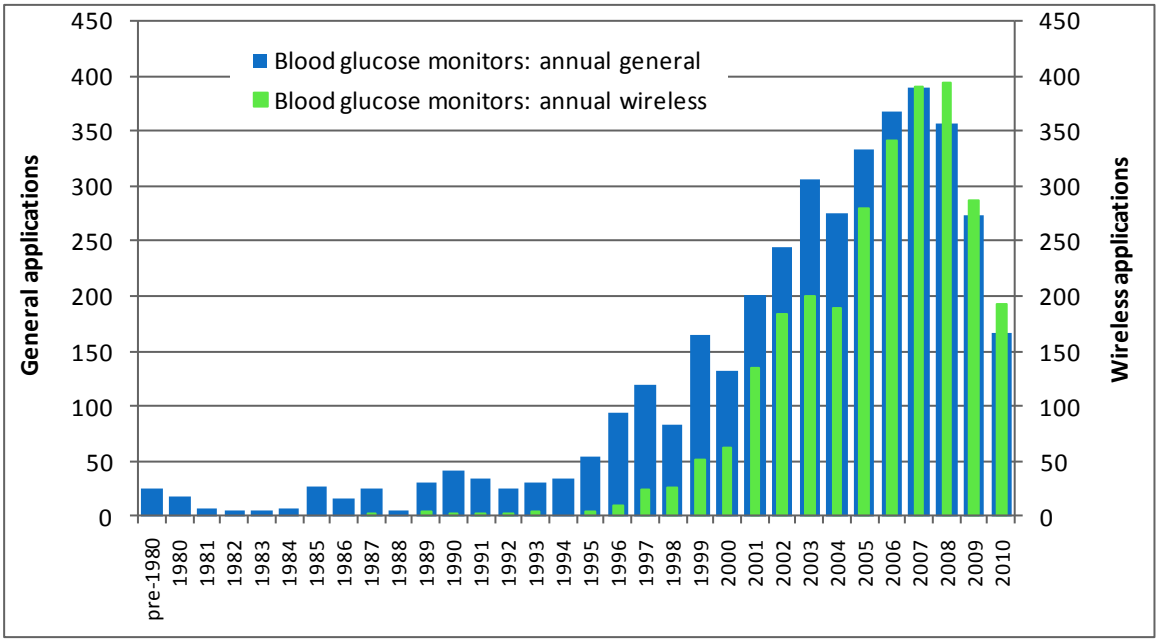
Figure 14 shows the increase in the cumulative number of patents in the general blood glucose monitoring space, as well as the cumulative increase in patents relating to heart rate monitor and wireless communication. The penetration of wireless into the devices space has reached 71% of the patents. However, it may be that the actual market share of wireless-enabled devices is much lower, as there are likely to be greater delays due to regulatory requirements, in comparison to the other monitoring device types. Nevertheless, the expectation by industry participants is that the space will be transformed through increased market penetration of wireless devices, and most importantly through their integration in healthcare information systems

Figure 14 Blood glucose monitor and wireless-related blood glucose monitor patents: cumulative number of applications



[8] http://www.companiesandmarkets.com/Market-Report/blood-glucose-meters-and-strips-a-global-strategic-business-report-450111.asp

Figure 15 Blood glucose monitor and wireless-related blood glucose monitor patents: annual number of applications



Key players and market structure

What is striking about the blood glucose monitoring space is that whereas the percentage of wireless is quite high (at 71%), the incumbent companies still play a large role, as shown in Table 27. The overall IP ownership concentration (number of patents held by top ten assignees as % of total) is 38%, the third highest in the five spaces studied here. In the wireless-related dataset, the IP ownership concentration increases to 46%, on a par with that of auto-injectors.

Table 27 Top assignees of general and wireless-related blood glucose monitor patents related to wireless

General patents			
Index	**Assignees**	**Number of patents**	**Percentage of patents filed in last 5 years**
1	Roche Diagnostics Gmbh	263	92%
2	Lifescan Inc.	190	41%
3	Medtronic Inc.	163	66%
4	Abbott Laboratories	146	89%
5	Health Hero Network Inc.	71	59%
6	Bayer Inc.	65	40%
7	Novo Nordisk AS	55	62%
8	Terumo Corp.	44	61%
9	Matsushita Electric	42	31%
10	Cygnus Inc.	38	0%
10	Becton Dickinson Co.	38	45%
12	Futrex Inc.	30	0%
13	Arkray Inc.	29	55%
14	Masimo Corp.	28	18%
15	Sensys Medical Inc.	26	27%
16	Optiscan Biomedical Corp.	26	19%
17	Sysmex Corp.	26	88%
18	Univ Virginia Commonwealth	25	72%
19	Dexcom Inc.	24	96%
20	Therasense Inc.	21	43%

Wireless-related patents		
Index	**Assignees**	**Number of patents**
1	Medtronic Inc.	174
2	Roche Diagnostics Gmbh	170
2	Abbott Laboratories	170
4	Health Hero Network Inc.	53
5	Novo Nordisk AS	52
6	Lifescan Inc.	49
7	Dexcom Inc.	46
8	Pelikan	31
9	Nokia	30
10	Searete LLC	29
11	Cardiac Pacemakers	28
12	Koninklijke Phillips Electronics NV	23
13	Therasense Inc.	20
14	Greatbatch Ltd	19
15	Expanse Networks Inc.	18
16	Smiths Medical ASD Inc.	17
17	Qualcomm Inc.	15
18	Samsung	14
18	Bodymedia Inc.	14
18	Abreu Marcio Marc	14

Geography of patent filings and assignee location

Patents filed with the US PTO dominate this space, with 44.6% of total filings, followed by European-filed patents at 13.3% and Japan at 5.9% (see Table 28). WIPO filings (representing PCT filings) represent 23.4% of the total. Looking at the wireless-related dataset (see Table 29), the dominance of US patent filings is even more pronounced, standing at 66%, followed by European filings at 6%, and most of the rest composed of WIPO filings.

Table 28 Number of general blood glucose monitor patents by country

Patent authority	Number	% of total
US PTO	1,739	44.6%
WIPO	913	23.4%
European Patents (EPO & National)	520	13.3%
Japan	229	5.9%
China	181	4.6%
Canada	156	4.0%
South Korea	63	1.6%
Australia	33	0.8%
Other	66	1.7%

Table 29 Number of wireless-related blood glucose monitor patents by country

Patent authority	Number	% of total
US PTO	1,846	66.2%
WIPO	747	26.8%
European Patents (EPO & National)	166	6.0%
China	18	0.6%
South Korea	4	0.1%
Japan	2	0.1%
Other	1	0.0%

Turning to the geographic location of assignees, US-based assignees are by far the leader in both the general and wireless-related datasets. Japan, Germany, Switzerland, China and Korea all have similar quantum of patents, ranging between 115 for Korea and 219 for Japan. The composition of the top five patent assignee countries remains the same if we only look at the last 5 years, with UK-based assignees coming seventh in both cases. When we look at the wireless-related dataset, it is interesting that Denmark and Israel come ahead of the Asian countries.

Table 30 Location of assignees: blood glucose monitor patents

General patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	2,130	746
Japan	219	119
Germany	202	109
Switzerland	156	112
China	119	67
Republic of Korea	115	57
United Kingdom	96	41
Denmark	90	32
Israel	78	25
Canada	42	10
Australia	35	13
Taiwan, Province of China	27	11
Netherlands	24	19
Sweden	22	9
Netherlands Antilles	19	2
Finland	14	7
Luxembourg	12	1
Barbados	10	0
France	9	5
Italy	7	4

Wireless-related patents		
Country of assignee	**Total number of patents**	**Total in last 5 years**
USA	1,792	856
Switzerland	111	79
Germany	99	71
Denmark	91	33
Israel	80	24
United Kingdom	64	35
Japan	57	28
Republic of Korea	42	23
Canada	41	12
Finland	30	10
Netherlands	25	16
Taiwan, Province of China	21	15
Netherlands Antilles	17	2
Australia	15	6
China	15	11
Sweden	9	8
New Zealand	7	7
Italy	6	3
Luxembourg	6	0
Bermuda	5	5

4.7 Patent landscaping research limitations

It is important to note several research limitations, due both to the project limitations and to general patent landscaping techniques used. Firstly, given the time and resource constraints of this project, we focused on performing 'rapid' and indicative patent landscaping. We expect that a 'commercial' grade patent landscaping report would uncover larger number of patents under all categories. Secondly, we did not build an independent dataset around telecoms and wireless standards more broadly, which we expect would be a dataset of substantial size and complexity. Nevertheless, as the interview results suggest, most of the interoperability technology taken as a given by medical devices will come from the telecoms wireless space. Thirdly, the patent search algorithms were in English, and this may introduce an Anglo-Saxon bias in terms of patents identified.

Possible future research could extend the current methodology to develop, possibly in collaboration with standards bodies and patent offices, a patent landscape map of technology standard essential IPRs and patent pools.

5 Interview results: interview evidence analysis

5.1 The respondents

In total, we conducted eight interviews encompassing a range of organisations and industries. We originally approached a total of 26 individuals from 23 organisations: retired and current executives from global pharmaceuticals, telecoms and software multinational companies, law firms in the IP and standards space, standards organisations and SMEs in the medical devices space.

Table 31 summarises the respondent's organisation and position (or most recent career position). Several consultancies were approached because their principal was a former senior executive in a major global corporation in either healthcare or telecoms. Their answers provided insights into corporate perspectives on this space, as well as capturing the views of independent experts. Most of the respondents requested anonymity, so we have coded their answers as indicated in Table 31.

Table 31 Summary of interview respondent roles and organisations

Type of organisation	Respondent's position	Interview code
Engineering consultancy	Managing director	Engineering Consultancy
European law firm	Partner focusing on IP and anti-trust	Law Firm 1
R&D consultancy	Former R&D manager of a global pharmaceutical	R&D Consultancy
IP consultancy	Former R&D manager of telecoms multinational	IP Consultancy
SME – medical devices	Serial entrepreneur, founder	SME
Standards body	IP expert at standards body	Standards Body
Telehealth corporation	Group product director	Telehealth Corporation
UK law firm	Partner focusing on standards	Law Firm 2

The following discussion categorises the responses under the following headings:

- patent thickets
- technology standards
- the impact of the introduction of standards in an industry characterised by patent thickets
- the role of policy and policy options
- the UK economy and policy implications and suggestions

5.2 Responses related to patent thickets

Growth of patent thickets

A core theme that we explored through all the interviews was related to the nature of patent thickets and their potential impact on different players. There was broad agreement

that the medical devices space as a whole is not yet particularly crowded, but that the rate of patenting is now increasing and it is probable that it will become crowded:

> "Competitors are patenting 'hugely' in the medical devices field … While it is unclear to what extent it is crowded overall, patents are indeed very important for our company's strategy with regard to attracting investors and also engaging with corporate partners." (SME)

> "In the health space there is very active patenting. Patents tend to emerge in a mature space (market) but Telehealth is a relatively new area so it is not yet crowded with patents. But when it does become mature, it is expected that there will be a lot more patents." (IP Consultancy)

> "The pharma and healthcare spaces are not too crowded in terms of patenting, especially when compared to sectors like semiconductors and mobile phones. The medical devices patent space is a good performer [in terms of patenting] compared to other healthcare spaces." (Law Firm 1)

> "It is very difficult to know whether or not one is likely to infringe when designing a product in the Telehealth space. The effort required to assess is often too difficult [resource consuming] … From the mobile communications perspective – yes there is overcrowding and lots of overlaps." (Engineering Consultancy)

For one of the law firms, the formation of patent thickets is the natural outcome of high rates of innovation and the growth in importance of a market:

> "The irony is that patent clusters occur most densely in biz segments that are most dynamic, such as new semiconductors every couple of years … But the growing number of patents is not an issue in itself, as it is the result of a dynamic underlying industry." (Law Firm 1)

The formation of patent thickets can also be related to the evolution of technologies and cumulative technological change:

> "Patents and the patent system are assisting with incremental innovations. Very rarely, if ever, you will have a radical innovation/disruptive innovation captured in a single patent." (Law Firm 2)

> "In medical devices in particular, innovation involves building on cumulative technologies, so one continues to design similar devices but to differentiate them from others, and for the purposes of patentability, the claims and scope are tightened and narrowed – a typical patent game. As a result, the number of patents in this space grows and developers also need more and more patents." (SME)

Hence, a broad increase in innovation in a technology area will be associated with an increase in patent numbers in what could appear to be lots of very similar patents, based around incremental innovations. Yet these patents are the result of the patent portfolio strategies of corporate and SME IP managers.

It is worth exploring in future research the interplay between the uncertainty around patent validity in a highly crowded patent space, and the likely uses of patents. For instance, even if inventors do not anticipate to actively pursue infringers, there may be brand or signalling value of a patent. In line with this, a corporate respondent felt that the value of patents lies in several dimensions:

> "[In addition to protection] patents are also important because they help to differentiate products, and allow cross-licensing. Through patents, one can ensure innovative solutions/products. In comparison to patents, trademarks and registered designs are less important for our company." (Telehealth Corporation)

Patent thickets in medical devices and Telehealth

As far as the Telehealth space in particular is concerned, there were several opinions expressed. In comparison to medical devices or broadly related telecoms patents, there are as yet relatively few patents specifically in the Telehealth space. As it stands, and in particular with respect to wireless standards on interoperability, medical devices telehealth-related patents are building on patented technologies and standards from the telecoms space. However, as the space matures and novel user needs are discovered, the patenting levels in Telehealth are expected to increase.

At the same time, medical device inventors focusing on Telehealth applications arrive into a space that is *already* characterised as a patent thicket, albeit one frequently governed by standards (such as through ETSI).

> "If we take as concept an inhaler storing data, which then transmits data to a mobile phone by wireless link … As this is based on communications protocols from elsewhere, there may be difficulty in patenting this invention, or there may be overlaps with pre-existing patents in the telecoms field." (Law Firm 2)

> "Since a monitoring device is presumably either licensable or proprietary and is already transmitting data, then the issue of standardisation in interoperable medical devices should not present itself. Instead, if there is any issue with standardisation, then the rules of the IT and telecoms sectors will prevail. As for innovation and competition, and if the rules of IT and telecoms sectors do not pose a problem, there will probably be many opportunities for innovation and competition." (R&D Consultancy)

Despite the fact that, as stated above, there are relatively few patents specifically in the Telehealth space, for some particular device areas (such as glucose monitors) there does already appear to be some heavy concentrations of patents:

> "There are already thousands of glucose monitors in the market transmitting data, but is this a new innovation? Maybe if there is a novel way on what can be done with the glucose data on an individual and aggregate level, for instance, UK-wide uses of glucose level data, then this could be considered innovative and perhaps patentable and possibly create a new niche/service." (Law Firm 2)

Perceptions of barriers arising from patent thickets

The different respondents maintain significantly different perceptions of barriers to innovation or competition. The SME respondent emphasised a patent-thicket-related barrier concerned with low-quality patents:

> "If you cannot innovate into the [medical devices] space you cannot enter. More small companies are squeezed out and the space becomes mature – no more innovation in the space … In particular, where there are many bad [low-quality] patents present in a thicket, these can become part of the prior art selection by patent examiners. Smaller companies are less likely to ignore these bad patents due to fear of litigation." (SME)

A medical-devices and standards-focused patent lawyer gave a somewhat surprising interpretation of patent thickets. From the patent lawyer, the biggest barrier to inventors in the emerging telemedicine patent thicket is related to differing patent rules between the UK/EU and USA, rather than to the existence of patent thickets per se:

> "There is a perception of a barrier to inventors around the patenting of methods relating to medical devices used for the treatment of humans. For instance, the structure of a bent catheter may be very similar to another patented catheter product … But it may be the way in which it is rotated/inserted inside the vein that is novel … But as soon as the EPO sees that it is a 'method', the patent application will not go through." (Law Firm 2)

The R&D Consultancy respondent challenged this view:

"Surely an inventor will try his/her best in both jurisdictions and will not be put off by uncertainty in one of these. The technology in question may have a small but different structural distinction – a patent attorney would try all types of claims... In any case, if it is the same as the prior art, you may have difficulty in policing your 'method' patent in any case" (R&D Consultancy)

There has been a massive growth in medical device patents, but a lot of this has been focused in the USA, where software and method patents are allowed (Law Firm 2). Consequently, UK SMEs may pursue a different IP strategy to a US SME in the medical devices space; and both of these are likely to differ from a global corporation in their strategy.

One of the law firms, however, felt that patent thickets do not give rise to any problems that the market could not resolve itself:

> "The real issue is not whether there is a cluster of patents, but whether there is a 'gateway technology' … So you need to understand if there is a blocking patent family in a particular space. Industry participants will find a solution in the event there are overlapping patents or a gateway technology that everyone needs to access. I do not think there is such a mythical gateway technology in the medical devices space." (Law Firm 1)

> "My wife has not been shot, there is not a problem … Patenting in healthcare is discrete and finite … the market makes its own solution – if there is a big enough problem, the relevant patent holders will cross-license … if there is a mythical gateway technology for med devices, then everyone would realise it and cross-license." (Law Firm 1)

Patent thickets, market structure and participant reactions

The market participant reaction can largely be related to the type of players in the medical devices space. Traditionally, there have been two types of players in this space: the large multi-billion dollar organisations with multi-product portfolios; and SMEs that develop one or several device types. It is worth noting that new technology players do not necessarily mean new technology. Instead, new technology players could be those that use existing technology in a new or novel way, or that introduce the technology into an existing focus space. Such new applications can be disruptive as they could be expensive or present new competitive pressures.

According to one of the law firms, in a patent thicket environment:

> "Large companies will try to control their markets by having proprietary elements and proprietary consumables (accessories, peripherals). Such an example can be seen with printer manufacturers, who are giving away printers for free, but are making their money on consumables, such as printer cartridges. In the medical devices sector, the same business model exists, for instance in the glucose meter space, where the technology owners give away [for free or very cheaply] the glucose monitor but charge for testing strips." (Law Firm 2)

However, what is interesting is that elements of this proprietary strategy can survive even if the companies engage with a standards environment: for instance an Apple device will use WiFi/Bluetooth standards, while also keeping a proprietary space, such as the Apps Development environment.

We have already cited the opinion of Law Firm 1 that industry participants will find a solution in the event that there are overlapping patents or a 'gateway technology' that everyone needs to access. The SME respondent described how, at a company IP and R&D management level, companies will:

> "… do validity searches and design around perceived overlapping patents, … file more patents by narrowing the scope and tightening the claims … The possibility of inventing something totally new in devices is rare, and so it will be likely that overlapping patents will be identified." (SME)

The SME respondent also expressed concern that if patenting examiners make it more difficult for SMEs to patent in a patent thicket, they may lose out to the generics companies that have economies of scale:

> "So unless examiners recognise what is innovation/novelty and grant patents to SMEs, innovations from them may suffer or be suffocated … The bad patents in the medical sector are well known. Smaller companies are less likely to ignore these bad patents due to fear of litigation." (SMEs)

Of course, even if SMEs have a strong patent portfolio, this becomes meaningful as a tool for protecting against copying "if they have access to affordable patent litigation" (R&D Consultancy).

A respondent from the Telehealth sector felt that whereas currently there are no major barriers at play, this could change rapidly as the Telehealth market matures. It is also notable that the potential impact of a patent thicket on market behaviour can be related to IP strategy choices by key players (which can differ between sectors and over time).

> "There is no concern with overlapping patents in Telehealth at the moment because it is relatively new. There is a sense that patentees don't tend to enforce patents in emerging areas but wait until the market in this area matures. However, for the future, if there are many overlapping patents, then the effects will depend on who owns these patents, what the patents are about and how they enforce them." (Telehealth Corporation)

The SME respondent noted that for an SME that is seeking to enter a new market niche with 'cross-over technology' there are two forms of threats: commercial threats and patent threats, and each of these comes from different locations. The commercial threat comes from competitors that are not in the field of medical devices patents, but are big players in the general healthcare sector. The patent threat comes from medical device patent holders

that are located in different countries but are not necessarily in the market niche of the respondent.

The importance of leading players' IP strategy can be illustrated by looking at the evolving IP strategy of a telecoms multinational (referred to in the box as 'the Company'), the IP strategy of which has changed significantly several times, partly in reaction to the evolving nature of its patent landscape and market environment.

A telecoms multinational's evolving IP strategy

The Company's IP strategy has changed dramatically since the late 1980s. It has gone through several different phases.

Before late 1980s: The Company thought, like other EU companies, patents are for 'American lawyers', and not a European consideration. However, in the late 1980s the Company started exporting to the USA. Motorola blocked the Company entry on the back of patent infringement, and tough litigation battles followed - but with hindsight it was probably one of best things that happened as it forced the Company to mature its IP strategy. The Company's senior management realised that IP was beginning to be a serious issue and that they needed to invest in IP and develop a strategy for it.

Early 1990s: The Company's strategy was to build its IP portfolio in order to have negotiation leverage. This continued until the late 1990s, by which time it had developed its portfolio of 45-50,000 patents from zero in ten years.

Mid-1990s: The Company's main strategy was cross-licensing. In that time, rarely if ever did IP stop any R&D work: "all the patent holders looked like you – big telecoms companies."

In the 2000s: Cross-licensing strategy works 'if the guys across the table look like you; but it doesn't work if the guys across the table aren't afraid of your weapons." So cross-licensing was not the only the only strategy. The telecoms industry was beginning to be confronted by horizontal players, operators wanting to develop technology, new entrants from China and Taiwan who hadn't invested in technology in 1990s and individual innovators. Furthermore, the economic climate was changing, including a trend of increased patent litigation. So the key question for the company was, "what should it do with its patent portfolio?" Towards the late 2000s, there was management pressure to start exploiting this huge IP portfolio. IP strategy became a lot more complex, more sophisticated and more careful with cross-licensing. The company started to grow areas where its IP portfolio was weak; to put less effort into IP rich areas; to participate in patent pools (e.g. MPEG, etc.); and to undertake more targeted licensing. Freedom of action was no longer the only reason to build a patent portfolio. The company became more assertive in terms of its patent litigation. It had a very strong position regarding standards: this has remained constant over the period, but the number and diversity of standards has increased dramatically (e.g. growth in numbers of non-cellular standards), and so much more work had to be done to follow and deal with such standards.

5.3 Responses related to technology standards

This section discusses the respondents' attitudes to standards, initially in general terms (with specific reference to the telecoms sector) and then specifically for the Telehealth sector. Section 5.4 then discusses the Telehealth sector in more detail.

Formation of standards

Standards "give people something to aim at" and this promotes the need to be innovative to enter the game. Standards will always provide a stimulus, but they may also give rise to restrictions. For example, if the standard uses a disproportionate number of patents from a small number of players, this could raise an antitrust issue; if manufacturing of the device or the components is in a small number of hands, then standards can result in anti-competitive behaviour. (Standards Body, IP Consultancy)

A number of the respondents have a very positive attitude to the formation of standards:

> "We are interested in seeking and contributing to standardisation because standards are important for ensuring the level of quality, reliability and consistency of performance. Without standards, the risk of unreliability and quality is increased. Interoperability is currently enabled through existing standards." (Telehealth Corporation)

> "Telecoms and interoperability are an enabling technology for medical devices, so overall they should facilitate further innovation in the space … The advantage of standards is that you do not have hundreds of different manufacturers making their protocols … Without the standards, you would have each company trying to develop their own system … Standards will not be affected if these products transmit data via the telecoms infrastructure as there are already standards and protocols for such transmission." (Law Firm 2)

For SMEs, the key positive effects of standards are related to the "clear remit of what can be done", as well as fast implementation and the promotion of competition by making products and services compatible through a common standardised platform. Applications can be harmonised in a market on the back of a standard, such as what happened through the dissemination of the USB port.

> "Standards are a good thing, they allow more people to participate so there are multiple sources of supply … However, standards can be very slow moving, which does not fit well with SMEs/innovation … Also, SMEs are worried about their best ideas being taken, being redeveloped by big companies and re-launched without recompense to the SME." (Engineering Consultancy)

At least in the early stages of a standard's creation, large companies can play a dominant role:

> "Big companies want standards because they have a leading role in the creation of standards and standards are written in a way to benefit the big players. Standards are written with big players in mind. For instance, in mobile telephony, there was intense lobbying by big players for the encryption standard for multimedia application. This was then written into the standard. So companies have to comply with the encryption standard if they want to provide this application. So what happens, then, is that to use this encryption a company is tied to one or more of the companies that own this encryption." (Telehealth Corporation)

> "Big companies like standards because they offer certainty... Business loves certainty, as it facilitates investment" (R&D Consultancy)

At the same time, the processes of a standards body (such as ETSI) can facilitate access by SMEs to multinationals, and provide them with influence they would not have under a proprietary standard (or 'no standard') environment:

> "A standards body helps a lot for the SMEs – it gives them a platform to have access to the big multinationals, where they can meet and discuss topics. If you look at how standards processes are deliberated, it is done on a consensus basis … SMEs are approaching and meeting multinationals, so they have significant power. SMEs also have the possibility to group together and push multinationals' position." (Standards Body)

Standards and patent thickets

In a lot of literature we surveyed, the general view seemed to be that standards are a *response* to a patent thicket. Yet in some cases a patent thicket may evolve *after* the establishment of an industry standard, at least in part due to the clearer 'rules of the game'. For instance in the case of ETSI:

> "The standards provide for all the companies clarity on which basis they can develop further products. This in turn may have led to higher patenting rates, reflecting accelerated innovation...The increase in patent applications in the telecoms sector was after the telecoms standards were established; it may be also because then it was the birth of telecoms itself; as the telecoms sector increased in success, it was in parallel with ETSI's own success." (Standards Body)

> "At the time of the formation of ETSI, IP was not a major topic at all. The key drivers were client needs and the search for increased market access through interoperability. But as the sector matured and the value of technology ownership became clearer, there was a drastic increase in patent applications in the telecoms space." (Standards Body)

At the same time, when faced by a complex patent environment, patent holders may also use other forms of IP. According to the engineering consultancy respondent, they may rely on trade secrets over and above their patent portfolio, but in addition will focus on putting forward high-quality patent filings to ensure that their patents are granted and defensible. In addition, where a company's strategy may involve attraction of external investment, it may focus on acquiring large numbers of patents in order to be attractive to such investors.

Standards and innovation

A well-run standards body can influence innovation by establishing linkages between key players and focusing discussions around key technology areas:

> "Standardisation through a standards body means that there's a lot of discussion about technology between companies, discussion about which technology should be chosen, its relative advantages. That automatically triggers a demand that companies should be innovative, as they will need to convince others through deliberation processes that their technology is the best solution … A technical committee meeting can see up to 200 engineers sitting in one room. That is a huge push for innovation and opportunity for exchange of new ideas and new technology." (Standards Body)

> "Standards facilitate innovation, as companies can be more secure in the interoperability of their technology and that there is a market out there for the product. The ability of companies to show/make other companies aware that they have essential IPR puts them in a better position in cross-licensing discussions." (Standards Body)

> "Standards have given companies a framework for innovation. Smaller companies can innovate more freely as it provides more certainty regarding the success of their product." (Standards Body)

While for SMEs there are many advantages for participating in technology standards, there are also potentially high costs and disadvantages.

> "It can be costly to follow the developments in multiple standards. Moreover, as many of the benefits are captured by companies that participate in the governance bodies, SMEs will be unable to dedicate as many resources to participation as large corporations may. In particular, if they want to contribute essential IPRs to a forum, they would need to compete and convince often much larger players." (Standards Body)

Ultimately, the formation of a standard (and the related governance structures) can never be a perfect solution, but it may be a very effective one for the market participants as it gives them a degree of certainty while still leaving room for innovation:

> "Standardisation is always a compromise. The advantage is that once a group of companies/members in a standards body have decided to agree on a technical platform/solution, they have certainty about how the companies will work in the future. It provides minimum requirements that they need to follow. It provides lots of room for innovation, but still enables them to be successful in the market … Standardisation gives clarity for the companies that they will at least be sure that a certain direction will mean that revenue is possible." (Standards Body)

In the absence of such standards, it is also possible to address such concerns by patent pooling or compulsory licensing.

What standards are most appropriate for the Telehealth sector

There is a fair degree of uncertainty regarding the type of standards that will emerge, whether formal, regulatory, open source or proprietary:

> "If we have developed a technology which is successful and has the potential to become a standard, then the question is whether to follow a proprietary approach, or throw into a standards body like ETSI. Is it better to be proprietary or to be part of a standard? The risk of pushing it through a standards body is that you give away good ideas, open the door to more competition and more fragmentation. Standards bodies are not necessarily friendly to SMEs, as they are based around the largest companies. Even standards meetings around the world, lasting a week, are a barrier to SMEs." (Engineering Consultancy)

According to the respondents, the most appropriate type of standards and governance mechanism depends on the kind of innovation, product, services, business model innovation and processes that are involved:

> "If it is a radical product innovation [brand new product], then de facto standards may be the optimal solution for further innovation … If the product is part of a bigger system, then in that case formal standards are very important for further innovation and competition … If it's a service innovation, for instance a web-based service that has to be interoperable, then some standards are very important; but the actual workings of the service should not be controlled or 'standardised', for instance eBay." (IP Consultancy)

> "Open standards (such as Symbian) will be very appropriate, especially as phones become more like computers. There are also a number of national standards (pushed by governments), in particular in China and South Korea, which may be part of industrial policy, where these governments may perceive a large enough domestic market to have its own/proprietary standard. But it is not only national champions that help with such standards, some of the global players are also involved, and have integrated their IP into these … But such

> 'national standards' may also make it more difficult for domestic firms to compete, as they have to serve both domestic and international markets, and may be unable to build economies of scale … We have often wondered why the Japanese companies did not play a major role in the global telecoms industry, and one interpretation is that this is related to a proliferation of national-level standards." (IP Consultancy)

This respondent also felt that while there are no current standards per se for the Telehealth sector, the most appropriate form for emerging standards should be formal, regulatory and/or open source:

> "Ad hoc, proprietary and de facto standards will not serve the sector well because of the diversity of applications, although this is likely to be preferred by SMEs, who want to protect their innovation. Ad hoc, proprietary standards will fragment the sector and make such applications cost ineffective for the procurer … For wide take-up of the application, the developer also has to make sure that its IP is licensed to ensure such interoperability as well as licensing appropriate technology. So to ensure that these concerns are addressed, formal standards are the best solution." (IP Consultancy)

5.4 Impact of the introduction of standards in an industry characterised by patent thickets

Effect of standards on market dynamics

As shown in the literature review section, many contributors saw technology standards as a direct response to patent thickets. We put this point to respondents, and explored how the introduction of technology standards affects the market dynamics and business models.

> "Once a standard has been set up there is less of an issue regarding patents on that topic. The arguments tend to be related to peripheral issues." (Standards Body)

For example, recent developments in the Smartphone market show that most of the patent litigation issues are around very important but non-standards-related issues, such as touch-screen-related patents.

Respondents expect that the Telehealth sector will be more like the ICT space, with large company patent portfolios (and overall numbers) and different patent owners, and that it will therefore be unlikely for any player to have exclusivity in this space. However, there are also expected to be significant differences in the emerging business models of the Telehealth space, when compared to ICT:

> "The key question is how do you sell a healthcare app on a mobile device? For instance, a technologically simple application to monitor the times a patient

> takes his medicine poses big challenges for selling and distributing it." (IP Consultancy)
>
> "The presence of many new entrants has given rise to a very complex business model in Telehealth. In the telecoms industry, there's a great similarity in business models across countries. In healthcare, there are great differences from country to country, exacerbated by very complex distribution channels and buying/purchasing models from country to country. For instance, in the UK, will it be the NHS or the GP/surgeries (given intended changes in the NHS by the coalition government) and in Europe (the Netherlands), the insurance companies?" (IP Consultancy)

Given the fragmented nature of the market, the incentives for players to keep systems proprietary (rather than enter into a standard) are higher, as it is more difficult to capture economies of scale:

> "If a Telehealth developer wants to sell a phone-based application in a certain region in the UK, it does not make business sense for the developer to force the client to buy from one vendor or one type of phone. Instead, the developer wants the application to work on multiple platforms in order that it is cost effective for the purchaser. Also, there is a need for backend infrastructure (hosting) to support the applications." (IP Consultancy)

The type of standard established, its governance mechanisms and participants will all impact the business models adopted:

> "Standards are generally good for innovation and competition but an important aspect of standards is that they lead to different business models. And it is the business model that is eventually adopted that matters regarding competition and innovation." (Law Firm 2)

There are also factors that make it difficult for SMEs to compete in a complex standards environment:

> "Standards could be a barrier to entry because of the upfront financial investment in the production of these standard-compliant products. Also getting product approval in this focus space can also be expensive. Large corporations have invested a lot into R&D, therefore it is important for to innovate up to a point where they know their platform is the best and the one that will be adopted by the standardising body." (Telehealth Corporation)

However, a former senior R&D executive from the pharmaceutical industry has not observed any tangible effect of new technology players in this sector:

> "As far as the respiratory medical device space goes, there is nothing to prevent entry of new companies apart from the usual costs of entering into a new

> market sector, R&D, innovation, marketing, knowledge acquisition, etc., or setting up a new company … And there is scope for further innovation in the respiratory medical device area, especially around portability and functionality." (R&D consultancy)

There may also sometimes be a lack of clarity in the objectives of standards membership by a major multinational:

> "Big players are always involved in big forums because they have deep pockets but the question is what is their focus? How can they 'translate' their membership into good solutions? Sometimes it seems they are interested in translating their membership into quick profits!" (Telehealth Corporation)

It is apparent that under a multiple-standards environment (such as that characterised by the Smartphone industry), there will be duplication of R&D efforts as well:

> "A key starting question for Smartphone apps developers is always whether the solution can be deployed on a mobile/Smartphone using (at least) Symbian, Apple, Microsoft, Google Android platforms." (IP Consultancy)

In the UK specifically, there may also be a gap in awareness about how IP can and is being used to support innovation and market entry:

> "Too many SMEs (and universities) do not know much about IP management and strategy and 'how the game is played'. For instance, they are surprised that maintaining a patent is expensive. Government should raise awareness of the importance of these issues [IP management and strategy] so that these organisations will know what to do with their IP, to manage it properly and use it strategically." (IP Consultancy)

> "Insurance schemes should be investigated to cover patent litigation costs." (Engineering Consultancy)

Enforcement of IPRs under a standards regime

A key element of enforcement under a standards regime is that participants must be confident that they will get a fair share of the royalties collected on their behalf by a standards body. However, the setting and implementation of a royalties mechanism can be complex:

> "Due to competition laws, royalties should not be set by technical bodies (such as a standards committee). Technical bodies are governed by engineers, and they will focus primarily on ensuring that standards work *technically*. It is also difficult for companies to pre-agree on royalties, as that would delay the work of the technical body, and may amount to collusion if it is only several players contributing essential IPRs … In effect, the participants negotiate *ex post* under

> the FRAND [fair, reasonable and non-discriminatory] or other agreed principles." (Standards Body)

The establishment of royalty rates under a standards regime can be particularly challenging. FRAND rates cannot be specified upfront because of competition law considerations. Because standards organisations may be focused on building a consensus around technology, they rely primarily on self-reporting. This may be open to abuse:

> "If you have hundreds of participants, then it is difficult to monitor and coordinate the essential IPR declarations." (IP Consultancy)

Identifying essential IPRs upfront is very important for technology standards:

> "There is a danger that if you leave out some patents from a standard, they could come back as a 'patent troll'." (IP Consultancy)

For SMEs, enforcements can be prohibitively expensive. A patent pool and/or a standards body can provide an important channel through which a low-cost mechanism for royalties collection can be established:

> "Essential patents are very important in the telecoms space, e.g. they underpin a standard. These patents are valuable enough to assert." (Engineering Consultancy)

> "Enforcement of IPRs via patent pools can give advantages to companies that are contributing IPRs to the patent pools; patent owners can also market it via patent pool; gives transparency as to who owns what." (Standards Body)

There is some support by respondents to the idea that the presence of an industry body (especially if backed by a patent pool) can reduce the likelihood of patent litigation. At the very least, it would appear that SMEs can 'free ride' on large players' ability and willingness to litigate to defend essential IPRs behind a standard:

> "For instance, if the members of a standard organisation all have the opinion that a patent [that is claimed to be the focus of an infringement] is not valid/not infringing, this can have a positive effect on all those companies that are participating … If smaller companies see that bigger companies are winning, they will continue to invest." (Standards Body)

This was seen as particularly important as a defence against 'non-practising patent entities' (also known as 'patent trolls'), where SMEs would have little ability to oppose an infringement lawsuit outside a standards body.

Standards and Telehealth

In the general health sector, there are many regulations that do not exist in the telecoms or ICT sectors, for example for types of medicine and their uses, clinical trials and certification.

So in the medical devices sector it may not only be a question of standards but a 'regulatory multiplicity' problem. However, in medical devices (applications) that do not have to deal with types of medicines/drugs, the regulatory issue may not be as important as standards will be. The market dynamics in these different niche areas are therefore likely to be quite different.

In the medical devices space, the multiplication of standards and regulatory requirements can slow down innovation significantly:

> "While technology standards are generally a good thing, they may also create obstacles for SMEs. The SMEs know what technology they are developing and how it works. So to be compliant with the standards they have to spend a lot of time and resources … If a standard aids the consumer then that is great, but it is always an obstacle to design up the standards. If the SME did not have regulations and standards to comply with, the development time would have been reduced from 8 to 3 or 4 years. Instead, only 20% of time has gone into actual innovation that makes the product work; the balance is in clearing the regulations and standards." (SME)

That is why, for SMEs:

> "If the technology they are developing is beyond the scope of the standards, then the SME ignores the standards and develops a product that fits the market." (SME)

The emerging Telehealth space is also going to be impacted by the side effects of convergence in the telecoms space:

> "With the increasing convergence between telecoms and the Internet, there's a confusion of norms and culture. For example, Internet companies take the Net Neutrality principle as a given, and are also much faster/more radical in their innovation, less bound by rule-making norms. By contrast, telecoms companies have evolved in a different environment, more prone to rules following (e.g. through standards bodies) … This may make coordination more problematic, and the creation of formal standards difficult." (IP Consultancy)

5.5 Policy role/policy options

Adapting the IP regime: patent rules, quality of patents and patent examiner expertise

For a law firm respondent, a key UK and EU problem in the Telehealth and medical devices area relates to the difficulty in patenting software and to patents related to business methods:

> "Given that EPO and UK IPO will not allow you to define patent in terms of how [the device] is being used, that causes the biggest problem for companies

> operating in this space … The main issue for medical device innovators/players in the UK is that they cannot patent a 'method' for using their device. The biggest problem is that lots of medical devices are very similar in structure … What's new is how the medical device is being used … I explain to my clients that the reason the EPO/UK IPO will not allow this is so that people do not go suing doctors and nurses for using their devices … The inventors' answers are: 'we just want to be able to differentiate our products from others'." (Law Firm 2)

There is a similar consideration around software patents:

> "As the Telehealth space evolves, an increasing amount of value will be derived from software and databases. Yet there is ambiguity in the UK and EU around patents for software … Many court cases and rules allow for software patents, but there are differences between patent examiners as to how easily they grant software patents. There is a need for uniformity of practice." (Law Firm 2)

A related problem is that of patent infringement in the healthcare sector. It may be that patent examiners are concerned that a drastic increase in the number of patents in the medical devices field could potentially open up medical practitioners to infringement claims and patent hold-ups. A law firm respondent suggested a change in patent infringement rules that would probably be acceptable to most of the market and could address this problem:

> "You could make healthcare practitioners exempt from infringement claims so that there is no threat to the actual use of medical devices/products on the market on the basis of IP infringement. This would be something that the technology/IP owners can fight out without affecting the practitioners directly." (Law Firm 2)

A key problem that several respondents mentioned was related to the quality of patent examinations, both in the UK IPO, but also under PCT.

> "The problem is not overlapping patents … the problem is with PCT examiners who are very zealous in deciding that applications are overlapping, without giving any explanation as to why an application is overlapping. For example PCT examiners have been known to indicate 'x' signifying 'overlapping' against 1-36 claims of a PCT application. This is a highly unlikely situation where all 36 claims are overlapping! It is much harder to understand the differences in the field than to see the similarities. Examiners could be lazy and not scrutinise what the claims are that show the differences from the prior art. Yet it is the duty of examiners to interpret applications correctly." (SME)

It is also not unusual, according to the same respondent (but referring to the experience of peers in the field) that the search reports from the UK IPO differ from those under PCT. Some specific policy suggestions by the SME respondent are to:

- consider harmonisation between the PCT and the IPO and reduce costs, time and 'headaches' for SMEs, especially as it costs thousands of pounds to prepare the PCT application and the PCT process takes about 18 months
- allow requests for a second examination at the PCT, but which is currently not permitted
- encourage the UK IPO to treat requests for re-examination (which is allowed) with "less disdain". Very often one encounters "a grumpy examiner" at the IPO when requesting a re-examination. Re-examinations can really help SMEs.

Another respondent, sympathetic of the pressures on examiners, suggested that one way to accelerate and increase the accuracy of the examination process would be to use peer identification of prior art (but not peer examination):

> "The important thing is to make it harder to get low quality patents, more invalidation sooner." (Engineering Consultancy).

The standards body respondent suggested that the practice of collaboration between telecoms standards bodies such as ETSI and patent authorities be extended more broadly.

> "For a standards body, it is very important that there is transparency to the patenting process and patent office decisions … It is important to have transparency during the standardisation process regarding the different patents in a space, so that the members are obliged to make IPR declarations, and so that the standards body can take a decision around contributing IPRs, and avoid conflicts … Consequently, some standards bodies have provided patent offices with access to relevant documents when considering patent applications." (Standards Body)

> "Patent authorities need to improve their [patent examination] capabilities … And standards bodies can give access to documents so that [patent authorities] can do their work properly." (Standards Body)

Hence, patent authorities can benefit from the topical libraries developed around specific patents that are related to standards. This can provide greater transparency and assist faster examination around patents related to essential IPRs or related in other ways to a standard.

Avoiding 'standards thickets'

A repeated theme in the interviews was that while, overall, respondents felt positive about the role of standards, they were also mindful of a proliferation of standards and standards

bodies. There may also be a tendency by industry players to develop new standards consortia/focus areas:

> "There are lots of new forums that are coming close to standards making established by various players … For established industry standards organisations it is not always very positive, as there is duplication. But industry favours the opening up of a new consortium to push certain things forward … if you open up your own body you can select the starting members, usually coming from one area, focused on one solution … It is politically and technically easier to achieve new objectives in a smaller group." (Standards Body)

Several respondents pointed to the danger of too many standards, or a 'standards thicket' as one respondent put it. In the medical space in particular, the importance of telecoms standards only adds to the regulatory and standard requirements for SMEs related to clinical trials and healthcare regulations:

> "Standards are important for harmonisation of products. Currently, the standards in the medical sector are just about at the right balance. But there mustn't be a temptation to introduce more standards. Overall good experience with standards, but wary of over-standardisation." (SME)

> "Key measures to support innovation and competition in the UK market: (1) need for formal or open source standards; (2) streamline procurement process to make distribution/selling easier; and (3) no over-regulation." (IP Consultancy)

6 Results and analysis

6.1 Waiting for the thicket to grow: the coming Telehealth patents thicket

Currently, the Telehealth space is primarily the result of the overlap and convergence of the medical devices and telecoms spaces. In both these sectors there are large pre-existing concentrations of IP. Both the telecoms and healthcare industry participants have evolved over time IP strategies that are able to deal with large volumes of patents in their space, and the challenges in navigating such a space discussed in earlier sections. In medical devices such solutions have primarily related to product licensing and invent-around solutions; and in the telecom space primarily around patent pools and technology standards. Currently, many of the relevant patents to interoperability standards are taken as a given by medical device companies, and these are primarily accessed through open standards and industry standards in the telecom space. However, there is an expectation in the industry that as the space matures and market size increases there will be a rapid growth in patents. There are many factors in the Telehealth space that are consistent with the drivers behind patent thickets identified in other industries:

- growing market size
- low quality of patents around some medical devices
- overlapping scope of patent applications
- strategic patenting to grow patent portfolios
- complex and multi-component technologies
- important gateway patents and essential IPR
- patenting ever narrower/incremental invention claims
- increased complexity of patent applications
- patent race between major players in an industry
- ‘land grab’/’gold rush’ in a rapidly emerging new domain
- convergence with patent portfolios from different domains contending for new space
- lack of common definitions and knowledge in a new space resulting in multiple overlapping patent applications.

From an industry actor’s perspective, the development of a patent thicket can lead to a number of effects/reactions in an industry, such as:

- cross-licensing between key patent players
- patent litigation holdup
- high transaction costs, information gathering costs, negotiation costs
- increased infringement risk and uncertainty – leading to R&D duplication for invent around
- strategic patenting – boosting patent portfolio to improve negotiation position
- vertical monopolies

- patent thicket 'share' could become a source of competitive advantage

If indeed we are seeing the initial stages of a Telehealth patent thicket developing, there are two factors specific to this space that may be particularly significant in terms of market dynamics we can expect:

- Overlap of technology systems: the Telehealth space is the result of a convergence of two previously separated industries, each with a large patent concentration. There may already be a number of patents with overlapping claims each granted in a different domain area.
- Gateway patents: the gateway patents related to wireless communications are already part of various telecoms industry standards arrangements. However, future evolution of the Telehealth space may result in further gateway patents, e.g., around interconnectivity of electronic records.

6.2 Standards

The literature review and interviews identified a range of *de jure* and *de facto* standard arrangements, ranging from proprietary standards, to industry body and patent pool based standards, as well as regulatory-imposed standards arrangements. The precise effect of standardisation on an industry will depend on the type of standards arrangement chosen, as well as on pre-existing industry conditions, and on post-standard behaviour of key industry actors. Moreover, it is possible that larger industrial actors subscribe to several strategies at once at different parts of their value chain, by, for instance, combining an aggressive patent protection strategy in some products with active participation in open and industry standard bodies in other locations.

We identified a number of factors that can contribute to the emergence of a standard, and these could ostensibly be used by policy makers and industry players to identify technology areas that may be ripe for standardisation.

Table 32 Key factors behind the emergence of standards

Key indicators	Industry examples
Increasing patent complexity and litigation trends	**Semiconductor industry:** increasing number of patent cross-references, slow-down in patenting rates
Increasing speed of product life cycle	**Telecoms:** 1.5–2 years product life cycle – much shorter than the patent life-cycle
Increased heterogeneity of client/user types	**Telecoms:** complex matrix of user capabilities/needs/tastes
Fragmentation of market by geography and local conditions	**Telecoms:** spread of GSM/3G standard globally allows access of large number of market niches; complex combination of service providers/ manufacturers/ content providers/ application developers serving unique niches
Increased complexity of technology platforms	**Semiconductors:** rapid speed of development and user demand led to increasing complexity; equipment manufacturing increasingly done by third parties
Increasing user autonomy (vis-à-vis distributor)	**Telecoms:** Increasing choices and number of segments give operators key role – but also lead manufacturers to interact directly with users
Major external threat: big player from another industry entering your space	**Telecoms:** Non-traditional entrants into the telecom space contributed to major telecom players supporting Symbian standard
Major markets identified, but cannot be reached under current business model	**Telecoms:** Entry of Apple Smartphone and Google Android – Symbian Foundation and royalty-free licensing

Source: CambridgeIP research

Within the Telehealth space, it appears that actors are taking as a given the standards and standard practices from the telecoms space. Consequently, standards bodies such as ETSI and Continua Alliance can be quite important in helping telecoms technology migrate and be 'translated' into a healthcare context. At the same time, a number of healthcare sector factors may be putting barriers on standardisation. These include country-level regulatory requirements, information system requirements that differ between different countries' healthcare systems (and *within* countries), and, generally, the strict regulatory requirements for the licensing of a medical device. At any rate, it is to be expected that as the space matures further, the complexity of technologies and applications evolves (and as the patent space becomes more populated), the need for telehealth-specific standards will increase. Broadly, this can be expected to be a positive development for innovation and market competition. In Table 33, we identify the key positive and negative impacts on innovation that are likely to emerge from a standardisation effort in this space. For simplicity, we limited the analysis to formal standards, which would exclude, for instance, proprietary *de facto* standards, and would be consistent with the effects of an industry standards body.

Table 33 Impacts of standards on innovation

Positive effects of formal standards on innovation	• Decreased likelihood of patent litigation (around essential IPRs) – frees up more resources for R&D • Provides a wide base of third-party technology on which future technologies can be built • A standard-setting body can become the hub of a knowledge network, accelerating innovation in a space, facilitating coordination • Help a technology gain acceptance more widely • Provides SMEs with a platform for collaboration and marketing of their products • Some level of certainty of return on investment (for companies whose IP is included in a patent pool –backed standard) • Provides SMEs with a channel for influence • A standard implemented *before* a major patent thicket evolves can alleviate many of the problems related to patent thickets • Market creation (new products) or increased market access leading to increased revenues • Accelerated technology diffusion • Interoperability rules will lower the costs of designing and producing the products • Improved quality or reliability
Negative effects of formal standards on innovation	• Lock-in to legacy systems • Potential for patent holdup due to essential IPRs that have not been declared prior to a standard • Adoption of standards by smaller firms may be costly and thus could plausibly be a barrier to entry for these small companies • Uncertainty of cumulative royalty burden may discourage new entrants • Danger of dominance by big players • Slow to adapt to new technologies/opportunities

The impact of standards on innovation and market acceleration is also related to the various effects on the levels of competition in an industry (summarised in Table 34). It is worth noting that there is by now a fairly developed body of best practice around the management and regulation of technology standards that allow the mitigation, if not elimination, of some of the anti-competitive effects of standards (and patent pools behind these). There is perhaps a relatively little researched area comparing the trade-offs and effects *ex ante* and *ex post* of the establishment of standards. For instance, in the case of ETSI it is likely that at the outset it would have been large incumbents setting up the standard body that benefitted most from the establishment of a market for their technologies. But over time, and as the body evolved, the benefits were dispersed more widely through an international group of participants, many of which were SMEs. In addition, the dynamic nature of these industries means that corporate strategies can change quite frequently, and with that so would their role in standards bodies and by extension in patent pools.

Table 34 Market structure and competitive effects of standards and patent pools

Possible pro-competitive effects	Possible anti-competitive effects
• Facilitate equal access to licences for all potential licensees • Speed up access to technology • Integrate complementary technologies • Reduce transaction costs for both licensees and licensors • Possible clear blocking positions • Avoid costly infringement litigation • Potentially reduce the cumulative licence fee • Protect against patent holder strategies such as bundling essential IPRs with non-essential ones • Non-discriminatory and equal access to all potential licensees (*if* agreed in the portfolio licence conditions) • A valuable source of information to would-be licensees about essential IPRs • Decreased switching costs between alternative suppliers	• Restrict competition between the licensors that participate in the pool, which may result in price-fixing and increased prices • Possibly force licensees to purchase patents that they normally would not have selected • Non-participating firms that hold patents that are substitutes to patents included in the pool may be locked-out of a market • Limit competition in downstream products incorporating the pooled patents, or in markets for complementary goods • Remove incentives for further innovative behaviour • Lock-in to an inferior technology • Dominance by large players at early stages of Standard/Pool formation • Standard setting process can facilitate oligopolistic collusion • Risk of a patent holdup by essential IPR holders outside of a standard

6.3 Market entry and reaction strategy within the medical devices space

From our patent landscaping research we found that:

- the penetration rates of wireless into medical devices differs significantly. Much of that difference is probably attributable to barriers to entry into the respective markets due to regulatory and clinical requirements. However, the penetration for all spaces has been increasing in recent years, opening possibilities for multi-device integration across healthcare systems.
- IP ownership concentration as measured by the top 10 assignees' patents as a percentage of the total number of patents ranges between 28% for heart monitoring devices to 46% for wireless-enabled auto-injectors and blood glucose monitors. Also, IP ownership concentration is higher for wireless-enabled devices, possibly indicating an early entrant market penetration advantage. It is also notable that the IP ownership concentration is lowest for heart rate monitoring devices, which is the industry with the lowest regulatory barriers to entry and is also used in multiple contexts.

These findings suggest that the medical devices value chain may already be changing as a result of the increased penetration of Telehealth. The interoperability between devices and communications protocols in effect increases the 'size' of the technology system/product and associated services that are, or could, be provided to final users and buyers. The way in which this system evolves, where value resides and how it migrates will depend on the

ways in which the new ecosystem evolves. The types of standards that will govern interconnectivity and overlaps between different ecosystems will therefore play a critical role in terms of how the Telehealth industry evolves. For instance, if the traditional components of medical devices become increasingly commoditised (e.g., through patent expiries and entry of generic manufacturers), it is possible that value will be increasingly captured in the data transmission activities (e.g., through monetisation of 'transmission events'), as well as in data fusion and analysis (e.g., premium pricing for multi-sensor diagnostics). It is therefore important to explore the potential market entry modes and strategies of the different actor types in the emerging Telehealth space.

Large pharmaceutical and medical device companies

As the Telehealth market develops, it is apparent that the number of players (and industry perspectives they come from) will multiply. In some areas this is likely to be accompanied by multiple standards around data communication and information systems. It is as yet unclear how the incumbents in the healthcare and medical devices space will evolve their strategies. For the large corporations in the healthcare/medical devices space, there are several broad strategic options, which include:

- wait and see – learn from others' mistakes
- protect current niches and experiment with new ones
- protect current niches and migrate into new areas
- new horizons: lead and redefine the market place
- partner with major telecoms providers to build a new ecosystem
- withdraw from devices space, and focus on clinical information systems

Each incumbent is likely to follow a different iteration on these broad strategic options, and these may even differ within the device spaces they are looking at. However, the choices they make will have an impact on their R&D, collaboration and IP strategies, and are likely to affect significantly the current layout of the value chain in these industries. For example, a decision to withdraw from the devices design space and focus on partnering/open innovation solutions could lead to the shut-down of device R&D facilities and a greater focus on corporate venturing and strategic licensing as a way of developing novel products. A protect-and-migrate strategy could be accompanied by heavy patent litigation to protect existing 'gems' in the patent portfolio, combined with R&D investment in new areas that could enable vertically integrated solutions. Needless to say, the type of standards arrangements will affect corporate strategies, and will themselves be the result of corporate strategy choices (e.g., a partnership with Apple or Microsoft will lead to different systems architectures and locations of new IP).

SME incumbents

For most of the smaller players in the medical devices industry, it is likely that the 'rules of the game' will be taken from what the telecoms sector brings. They are unlikely to be able to engage throughout the telecoms system. They are most likely to take from telecoms, as

a given, standards, platforms, interconnections and are likely to pay royalties/license in. The different partnering options open include:

- grand alliance with big medical devices companies – within their ecosystems, etc.
- enter an alliance/ecosystem of a big telecoms player - they provide the medical gear, big telecoms company provides ecosystem, all others interconnect
- collaborate with other SMEs - get bits of kit/technology where needed, and interconnect through standard/open standard

New entrants from telecoms

It is evident that entrants from the telecoms industry have a comparative advantage in terms of their technology, patenting and market position in the telecoms space. They face particularly strong barriers to entry in areas where there are particularly strong regulatory pressures, such as clinical trials and country-level healthcare authorities licensing, as well as in terms of routes to market into local healthcare purchasing bodies. It is therefore most likely that new entrants would, at least initially, focus on areas with lower levels of regulation. This hypothesis was borne out by our patent landscaping results, which showed the highest level of penetration by wireless technology and non-healthcare companies in the relatively regulation-free blood pressure and heart rate monitoring markets. But as wireless technology enters more 'difficult' spaces such as drug delivery devices, or patient compliance monitoring, it is likely that they will seek collaborations and possibly use M&A to acquire the necessary capabilities rapidly. One additional source of advantage could be in their large patent portfolios in the telecoms and software space, which provide a 'currency' in case a patent thicket develops and they must defend themselves against incumbents.

6.4 Implications for the UK

Telehealth as an opportunity for UK plc

Telehealth seems to be a unique emerging area in the UK. UK industry enjoys a strong position internationally in medical devices and wireless, and there is a relatively concentrated healthcare purchasing system in the UK. Our patent landscaping and interviews identified significant capabilities by UK-based patent assignees in several medical device areas. A large proportion of this capacity is in SMEs, including medical device specialists and engineering consultancies. This is complemented by the co-location of R&D operations of major pharmaceutical companies. It is also well known that the UK has a traditional strength in wireless and telecoms, currently through players such as Cambridge Silicon Radio, ARM, BT, Vodafone and many start-ups. In addition, the procurement structure of the UK's healthcare system means that the UK is one of the largest consolidated healthcare services markets internationally. The combination of these factors suggests that Telehealth provides a unique opportunity for UK industry to build global leadership.

However, we have also observed that over the last few years the position of UK inventors as sources of patent applications has declined significantly across most of the devices. In addition, Europe as a whole falls behind USA in terms of the number of patents filed in medical devices, as well as the position of its companies in Telehealth.

Software and method patents

In the earlier sections, it was evident that the UK and other EU countries have drastically lower shares of patents filed in wireless-related medical devices, compared to the 'general devices' spaces. This was true of every device technology space, and in some areas EU leadership was reversed. In addition, the analysis of patents by assignee origin showed that whereas the UK came second globally in devices overall, when it came to wireless-related patents, its position dropped significantly. This is despite the fact that many telecoms standards (such as Bluetooth) originate in the UK.

Under the current patenting rules and practices by UK IPO and EPO, UK (and EU) SMEs may be at a disadvantage with respect to access in the US/North American healthcare market due to the lower ability (perceived or actual) to patent software and method-related inventions in the EU. While this may not affect their ability to operate in the UK and EU markets, it will affect their ability to (a) enter and operate in the US market; and (b) engage with multinationals, especially where they are competing against US companies that may have a strong IP portfolios, and whose products/technologies are likely to be integrated in technology platforms that will have global (and US) usage. In other words, SMEs' ability to access the world's largest healthcare market may be limited, on the back of a lower patent portfolio. While a larger company with more resources will be able to pursue a selective patenting strategy (e.g., filing different types of patents in the USA and EU), for smaller companies this differential strategy may be too expensive. This may also limit the ability of the companies to raise growth/venture capital finance. Finally, they may be less able to protect entry to the UK and EU markets, as their technologies will have a lower level of patent protection compared to that of companies with a strong US patent portfolio. While in principle the global playing field should be the same for US and EU SMEs, US-based SMEs have the advantage of developing their products on home turf which is more favorable for IP protection.

SMEs and Telehealth

A core differentiator of SMEs in the medical devices space is their ability to develop and commercialise innovative design models. Due to regulatory burdens, frequently the most feasible strategy for them is to commercialise their devices through partnerships, licensing-out or outright sale of their products to big medical devices players (frequently, big pharmaceutical companies). In addition, the USA tends to be a key market for their devices.

Our interviews uncovered various barriers that SMEs face both in a patent thicket and in a standards context. One particular area of concern appears to be around perceived or actual difficulties in working with patent examiner practices around software and method patents.

While large corporate IP departments would be able to dedicate resources to handle the issues identified earlier, for SMEs such problems could amount to insurmountable barriers given limited financial and organisational resources. In particular, whereas an EU corporation can have a differentiated *global* patenting strategy that takes into account different patent rules in different locations, SMEs may often have only the resources for several filings at most. For US SMEs, the ability to patent in the US around software and method patents puts them in a strong position when seeking collaboration or licensing deals with corporate clients. By contrast, for EU SMEs, if they are unable to patent in the EU, they would have to find additional resources to patent in the US *and* seek to access the US market.

These claims are consistent with the findings from the patent landscaping exercise, where the geographic filing patterns are broadly replicated in terms of assignee location patterns. Looking at US- versus EU-filed patents, we found that whereas in the overall medical devices dataset EU-filed patents accounted for 21.6% of the total (compared to 33.2% for the US PTO), in wireless-related patents for medical devices EU-filed patents account for only 7.5% (compared to 64.5% for US PTO). A similar drop is apparent when comparing patents originating from US and UK assignees in medical devices patents in general compared to wireless-related patents.

SMEs fear that if they are unable to patent around their inventions then their business models may be unsustainable as their position with respect to multinational partners and/or US market entry will be weaker. At the same time, generic manufacturers, which have both cost and economies of scale advantages, may be able to take such non-patented novel designs.

UK and EU market for Telehealth

While the UK healthcare market is currently one of the largest in the EU and internationally, some respondents felt that currently procurement practices are most likely to favour 'local' and proprietary solutions, and avoid standardisation. By contrast, a consolidation of the UK (and possibly EU) healthcare markets in terms of purchasing requirements could help to build economies of scale for medical devices manufacturers, which could, in turn, help global players from the UK and EU to emerge. This would be similar to the experience of the telecoms industry, where ETSI was setup in the 1980s in part in order to enable the synchronisation of telecoms equipment procurement in various EU states, thus giving rise to lower costs and higher competition through improved interoperability.

At the same time, the current healthcare services (and Telehealth) market structure was seen by respondents as promoting a proprietary standards structure or a fragmented market. The absence of a long-term Telehealth strategy (in terms of purchasing) would make it difficult for UK operators to scale globally so it becomes important for smaller players to dominate local/national economy. As one respondent put it, "the UK government needs to learn to play the China game", by using its domestic market-making

power to help promote the development of UK globally-scalable technologies, and with them UK businesses that can have a global reach and impact.

6.5 Emerging policy options

We used the interviews, literature review, patent landscaping results and team analysis sessions to generate several policy options which may be appropriate in the context of a growing patent thicket in the Telehealth space, but also as a way to assist the retention and growth of R&D capacity in the UK in this field. Needless to say, most of these suggested policies are likely to have an impact beyond the Telehealth space, and may be appropriate for further investigation.

Table 35 Key policy options

It.	Policy option	Anticipated effect
1	Facilitate emergence of industry standards	Assist private sector in coordinating and accelerating the development of industry standards
2	Collaboration, monitoring and information exchange between Patent Offices and Standards Body	Speed-up patent examinations, and ensure essential IPR patents are revealed early on; better resource uses by patent examiners
3	Establish topical libraries of patents around standards	Improve transparency for SMEs and reduce information gathering and transaction costs
4	Patent offices to assist in identifying essential IPRs	Assist standards organisations with identifying essential IPRs, especially around new applications, and close to the time of establishing a new standard
5	Awareness programs for IP usage for SMEs	Additional awareness programs for SMEs about how to engage with standards bodies and in complex/patent thicket spaces
6	IPC Codes for Telehealth	Establish Telehealth-specific IPC codes to facilitate patent classification and searching (in line with similar practices in nanotech and cleantech)
7	Clarify rules around method and software patenting	Facilitate patenting strategy for companies in the Telehealth space. It would require EU harmonization.
8	Patent Infringement rules clarification	Clarifying an exemption of healthcare practitioners from patent infringement rules may facilitate the road to patenting in medical devices, as the infringement issue will be dealt by and between companies (without direct impact on users)
9	Improve quality of patents in medical devices space	Improved quality of patents will lead to lower levels of uncertainty in patenting strategy
10	Better matching of examiner expertise to the patenting domain	Assist and speed up patent examination, and limit iterations between company and examiner
11	Export support of IP licensing	Support the export of IP intensive services, including licensing-out, through organisations such as the ECGD
12	Investigate patent infringement insurance schemes	Decrease IP risk for SMEs, increase certainty

7 Overall conclusions and implications for IP review

The Review of Intellectual Property and Growth (the Review) aims to "… develop proposals on how the UK's IP frameworks can further promote entrepreneurialism, economic growth and social and commercial innovation". In this section, we consider the policy implications for key Review topics that arise from analysis of interviews and from the IP Landscape conducted by CambridgeIP. We have additionally identified a range of opportunities for the UK arising from UK strengths in the IP Landscape focus space of medical devices and Telehealth, and the UK's market structure.

We note that the relatively large proportion of UK-based SMEs and the global nature of markets and competition in the focus space suggest that policy makers should consider how to support international IP generation and IP exploitation by UK-based SMEs. Table 36 below summarises SME-focused considerations.

Opportunity – UK capabilities: Telehealth provides a unique opportunity for UK industry to build global leadership. Significant capabilities by UK-based patent assignees in several medical device areas and in wireless technologies

Policy response: standard setting to establish a mass market and mark of quality internally and internationally for UK-developed technologies; support to UK-based SMEs in the development and deployment of international IPR strategies; review public procurement practices in the NHS and elsewhere

Recommendations: work with other public sector institutions to develop a coordinated Telehealth technology and procurement strategy. This may include identifying UK leaders in medical devices, telecoms and wireless, and policy stakeholders such as NHS, UK IPO, and UKTI and ECGD. An outcome could be to identify overlapping areas between NHS procurement priorities, UK IPO insights about UK patent positioning, and UKTI/ECGD policy tools for stimulating licensing exports.

Problem - thickets: rapid patent proliferation in certain complex 'cross-disciplinary' and 'cumulative' technology spaces – increased transaction costs, hold-up and vertical monopoly.

Note: The Telehealth space may see a relatively high intensity patent as it is the result of a convergence of two previously separated industries, each with a large patent concentration.

Policy response options: sector-specific mechanisms to address patent thickets and potential conflicts arising from thickets, including:

- cross-licensing regimes
- patent pooling
- assist the private sector in accelerating/coordinating the development of technology standards

- insurance schemes for patent infringement to facilitate entry in the US/other markets

Recommendation: in-depth study of technology-market spaces to identify patent thickets and areas ripe for standardisation in other sectors (e.g. cleantech) and inform sector-specific policies to address these (e.g. identifying the most appropriate standardisation mechanisms). In addition to existing IP practices and patent concentrations, industry supply chains, existing innovation/R&D networks and technology trends will all require consideration.

Problem - thickets: uncertainty created by grant of overlapping patent rights especially in early stage technology spaces

Policy response options: encourage greater quality of patent examination and patents

Recommendations: investigate options to improve patent examiner exposure to emerging early stage technology spaces; seek to improve international cooperation between patent offices to arrive at agreed definitions and avoid unintended overlaps; monitor key patent spaces to identify overlapping patent grants at an early stage; investigate "open examination" models, such as sharing essential IPR libraries held by standards bodies.

Problem – 'blocking' and 'gateway' patents: granted patents covering aspects of a technology space that may block future innovation.

Policy response options: research licences, public purchase of IP rights, inclusion of essential IPRs in patent pools and standards regimes, and compulsory licenses as a last resort

Recommendations: case-by-case consideration of blocking patents; patent landscaping in collaboration with standards bodies to identify potential gateway and blocking patents around emerging standards areas; monitoring of technology-market spaces to identify blocking patents at an early stage

Problem – patent trolls or 'non practising patent entities': increase in actual and perceived threat of patent litigation, may discourage R&D activity within a technology space

Policy response: encourage the establishment of industry bodies and voluntary patent pools to reduce the likelihood of patent litigation; establish insurance schemes; consider infringement exemptions for healthcare practitioners;

Recommendations: identification of significant non-practising patent entities in core technology-market areas through analysis of patent ownership and litigation trends; detailed patent landscaping and R&D network analysis in areas of concern; maintain a database of non-practicing patent entities, with contribution by industry

Problem – differing patent examination and grant procedures and standards internationally

Policy response: continue to seek international harmonisation of patent examination, grant procedures and standards (along the lines of the Patent Prosecution Highway); clarification of rules in relation to software and business method patents in the UK and EU

Recommendations: awareness-raising in relation to implications of different rules to enable UK-based innovators to select most appropriate patent systems

Problem – UK SMEs may be falling behind in terms of R&D and market share in traditional areas of strength, including pharma/medical devices.

Policy response: as this is a fairly large area, we have systematised our recommendations in the table below.

Table 36 SME-specific considerations in relation to problem areas identified

Problem area identified	SME-specific challenges	SME-related policy options identified
Patent application process	Cost and complexity of obtaining patents too high for many SMEs	Expedited patent examination procedures in select technology-market areas (e.g. Fast track for green patent applications) Awareness and training schemes for SMEs around patent application processes
Participation in patent pools and standards regimes	Too costly and too complex for many SMES SMEs often not involved in establishing the 'ground rules' SME information on IP rights relevant to patent pools and standards regimes often incomplete	Improved information and training for SMEs around patent pools and standards regimes Encourage SME's to 'club together' and aggregate their participation in regimes and pools, especially in establishment phases Establish topical libraries of patents around standards
Protection of software and business methods generated in the UK	Under the current patenting rules and practices by UK IPO and EPO, UK (and EU), UK-based SMEs may be at a disadvantage with respect to access in the US/North American healthcare market, due to the lower ability (perceived or actual) to patent software and method-related inventions in the EU.	Facilitate software and business method patent filings by UK SMEs in the USA; education of UK SMEs around the risks and different strategy options available around international patent prosecution and protection strategies
Export of UK generated IP	Many SMEs simply do not consider international IP markets and IP exploitation channels in their business strategies and plans Too costly for many SMEs UK (and Europe) patents do not readily enable coverage of software and business methods: impacting SME ability to enter and operate in USA market and compete with multi-nationals	Awareness programmes around IP usage for SMEs International patent landscaping exercises to inform awareness of SMEs about global IP opportunities and IP competition in key technology spaces SME participation in patent pools and standards, providing an important channel through for royalties collection Facilitate software and business method patent filings by UK SMEs in the USA Use UKTI and ECGD to support IP licensing exports
Understanding freedom to operate	Closely associated with rapid patent proliferation and patent thickets: high volume, complex and inter-related IP Landscape spaces are difficult for SMEs to navigate	IP Landscapes in key areas of national strength Support towards SME IP Landscape research costs Awareness programs and training for SMEs Encourage SME pooling of knowledge and resources

Understanding ability to operate	Product deployment within complex IP Landscapes is further complicated by variety of interoperability standard types and regulation of end-user spaces (e.g. Health)	Support towards SME engagement of interoperability and industry experts
IPR enforcement	Too costly and complex for many SMEs	Investigate patent infringement insurance schemes A patent pool and/or a standards body can provide an important channel for a low-cost mechanism for IPR enforcement and royalties collection
IP exploitation	Lack of SME expertise Too costly for SMEs SME lack of economies of scale, when compared to major incumbents	SME and industry-specific IP export support programmes Develop IP Landscapes and patent libraries as a resource for SMEs Development of licence and collaboration template agreements Support the export of IP-intensive services, including licensing-out, through organisations such as the ECGD
UK market structure	Fragmented market with much internal competition, growing diversity of players, including many SMEs	Establish standards to consolidate the UK market In medical device spaces: consider revision of NHS purchasing rules to facilitate SME access to this major consolidated market
Large number of international competitors	Geographically fragmented international market with much international competition	Establish standards to create international mass market for UK generated technologies

Opportunity – UK's Telehealth leadership

Key research findings from our IP Landscape research in this project surround the significant capabilities of UK-based patent assignees in several medical device areas and in wireless technologies. The procurement structure of the UK's healthcare system means that the UK is one of the largest consolidated healthcare services markets internationally. *Our conclusion is that the rapidly growing Telehealth space provides a unique opportunity for UK industry to build global leadership.*

Important considerations for policymakers in relation to the Telehealth space include that:

- the Telehealth space results from the convergence of two previously separate and patent intensive industries – medical devices and telecoms. IP practices, regulatory environment and corporate strategies in these two industries differ in several key respects.

- there is a wide diversity of types of Telehealth market participants in the UK, including a relatively large proportion of UK based SMEs holding valuable IP.

- as with most modern high-technology spaces, markets, competition and consequently IPR considerations are global.

Policy response options:

- Standard setting to establish a mass market and mark of quality internally and internationally for UK-developed technologies
- Review public procurement practices in the NHS and elsewhere to create a unified internal market for the development and deployment of IPRs
- Support to UK based SMEs in the development and deployment of international IPR strategies in the Telehealth space
- Further research into the technology-market space, including IP Landscapes and technology landscapes, to identify UK leaders, unpatented UK developments, UK centres of excellence and to better understand the global competitive environment in particular sub-sectors.

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9 Appendix A Interview Questionnaire

Available on request

10 Appendix B Methodology

Our methodology was based on several parallel tracks.

- Literature and previous research survey
- Patent Mapping of the sub-sector(s) – inhalers, medical diagnostics and stem cells research which are notable in the creation of patent thickets/portfolios.
- Conducting an interview program with selected companies, which will be identified from the above sectoral map(s).
- Analysis and Interpretation, using patent mapping, interview and industry literature data

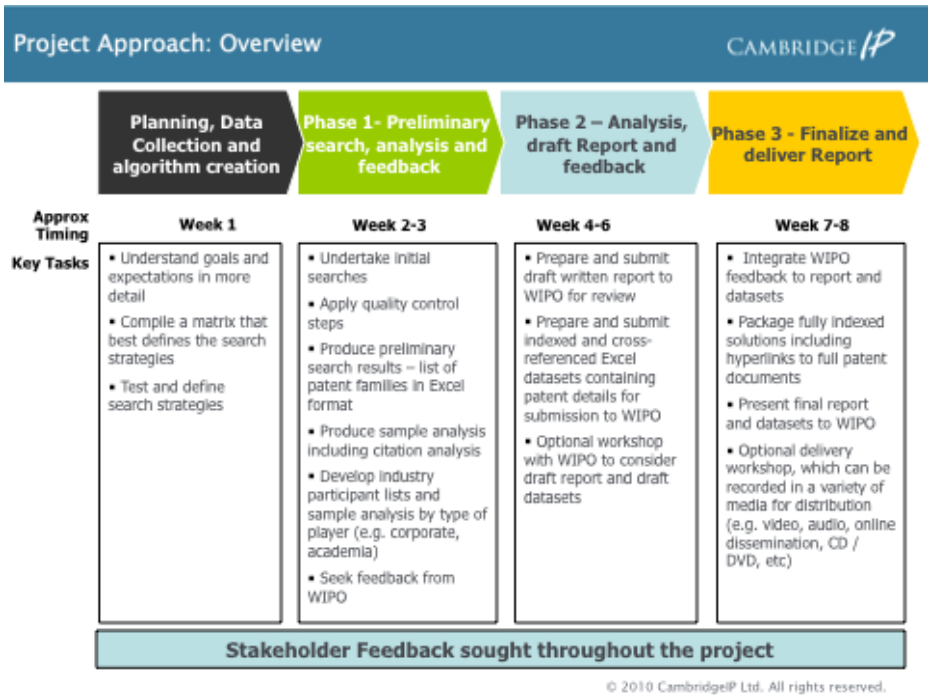
We provide brief information on the patent landscaping and interview modules of the project.

10.1 IP Landscape® production process

Patent landscaping can be a complex and iterative process. Without some degree of automation, it can lead to excessive costs, long time-scales and a higher risk and incidence of human errors. CambridgeIP has sought to address these problems by introducing automated or decision-support information systems that vastly accelerate the process of patent landscaping. In the process we have also developed some novel analytics which we believe are an industry-first.

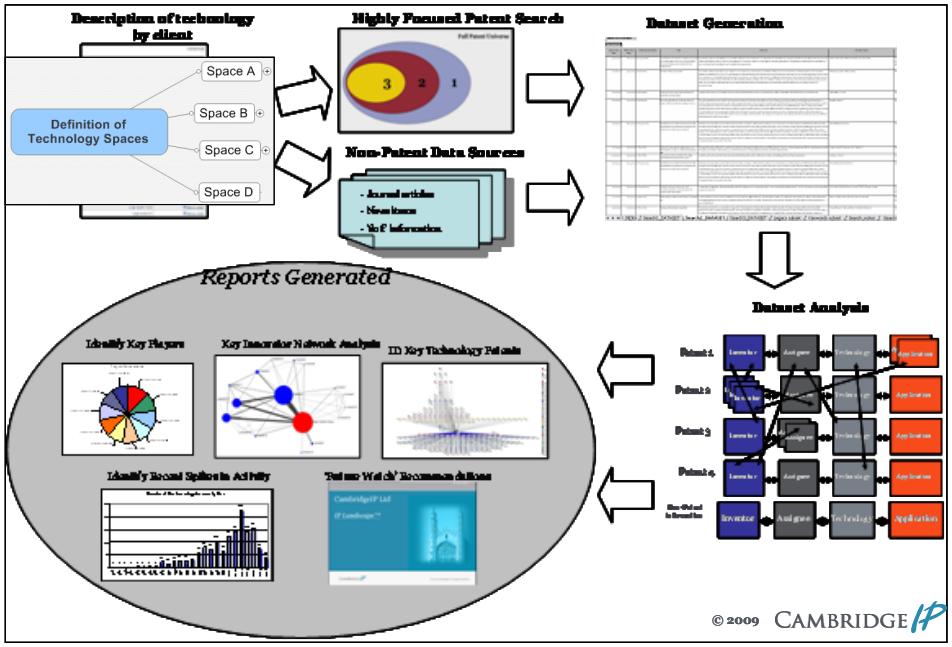
Our process and timeline for the patent mapping part of the project is summarized below:

Figure 16: Patent Mapping Timeline



Additional detail on our process for IP Landscape® production is provided in the illustration below:

Figure 17: IP Landscape Production Process



Quality controls and data cleaning: There are a number of quality control steps that we undertake prior to conducting any analysis. These steps ensure that the data is of sufficiently high-grade to allow deep-level analysis. Our rigorous data cleaning, quality control and dataset completion allows our subsequent analysis of relationships within the dataset can be conducted with confidence.

Data analysis: We have developed a proprietary system for conducting analyses. This is a modular system, to which we are continuously adding new functionalities and analyses. The result is our ability to perform analyses that would usually take an operator many hours to perform using spreadsheet driven processes to become a 4-5 click process. We have also developed a rapid prototyping methodology that enables us rapidly to develop highly customized analyses meeting the specific needs of a client.

Integration of special data sources to our process and results: We have the capability of integrating highly customized and client-specific data into our core analysis process. Consequently, clients can benefit from high turnaround times associated with a mass data application, with the benefit of a high level of specificity to the client's needs. The following are some examples of data sources that we integrate:

- Journal articles and conference proceedings
- Industry licensing and collaboration datasets
- Government funding and support schemes
- Organizational unit-level R&D expenditure and/or bibliometric production

We do not anticipate performing integration with non-patent data for this project. However, this could be conducted as follow-on work in future project, should the client need this.

Patent data coverage

CambridgeIP has as standard country and time coverage of the underlying patent databases:

- INPADOC (patent family documents from 71 patent offices worldwide and legal status information from 42 patent offices worldwide): 1968-present
- WIPO PCT Publications: 1978-present
- European (Granted): 1980-present
- European (Applications): 1979-present
- US (Granted): 1971-present
- US (Applications): March 2001-present
- Abstracts of Japan: October 1976-present
- German (Granted): 1968-present
- German (Applications):1968-present

CambridgeIP database enhancement: In this project, we propose to use Thomson Delphion as a primary service provider for patent data, subsequently improving data coverage by access to other patent data service providers (including Boliven.com, ESPACNET and US PTO) to plug automatically any 'gaps' in the data identified.

10.2 Interviews

We conducted eight interviews encompassing a range of organisations and industries. We originally approached a total of 26 individuals from 23 organisations: retired and current executives from global pharmaceuticals, telecoms and software multinational companies, law firms in the IP and standards space, standards organisations and SMEs in the medical devices space.

Table 31 summarises the respondent's organisation and position (or most recent career position). Several consultancies were approached because their principal was a former senior executive in a major global corporation in either healthcare or telecoms. Their answers provided insights into corporate perspectives on this space, as well as capturing the views of independent experts. Most of the respondents requested anonymity, so we have coded their answers as indicated in Table 31.

Table 37 Summary of interview respondent roles and organisations

Type of organisation	Respondent's position	Interview code
Engineering consultancy	Managing director	Engineering Consultancy
European law firm	Partner focusing on IP and anti-trust	Law Firm 1
R&D consultancy	Former R&D manager of a global pharmaceutical	R&D Consultancy
IP consultancy	Former R&D manager of telecoms multinational	IP Consultancy
SME – medical devices	Serial entrepreneur, founder	SME
Standards body	IP expert at standards body	Standards Body
Telehealth corporation	Group product director	Telehealth Corporation
UK law firm	Partner focusing on standards	Law Firm 2

We interviewees them with a preview of a questionnaire (attached in Appendix A), which focused on several key questions:

- Patenting strategy around complex technologies
- Regulatory/policy impact on thicket/portfolio creation
- Market participant reactions to thicket/portfolio formations
- Effect on industry structure of patent thicket/portfolio '
- Companies' strategy for dealing with thickets/portfolios
- Formation of patent pool + standard in response to thickets/portfolios
- Effect of entry of external players into an industry (e.g. telecoms into healthcare)
- Other important factors related to patent thickets, standards and their impact on behaviour which we may identify in the research
- Policy suggestions

In conducting the interviews we took into account any early data available from the patent mapping modules, as well as industry literature on industry developments. If appropriate we may also seek feedback from UK IPO. As a cost measure, the questionnaires will be mostly administered through telephone interviews. We will be using our respective professional networks to gain access to appropriate respondents, and hence do not anticipate having problems with access.

11 Appendix C
IPC Code Distribution between Devices and Wireless

Table 38 Top ten IPC codes related to inhalers

		IPC	Description of IPC code
General inhaler space	1	A61M	Devices for introducing media into, or onto, the body; devices for transducing body media or for taking media from the body; devices for producing or ending sleep or stupor
	2	A61K	Preparations for medical, dental, or toilet purposes
	3	B05B	Spraying apparatus; atomising apparatus; nozzles
	4	A61P	Therapeutic activity of chemical compounds or medicinal preparations
	5	B65D	Containers for storage or transport of articles or materials, e.g. bags, barrels, bottles, boxes, cans, cartons, crates, drums, jars, tanks, hoppers, forwarding containers; accessories, closures, or fittings therefor; packaging elements; packages
	6	A61J	Containers specially adapted for medical or pharmaceutical purposes; devices or methods specially adapted for bringing pharmaceutical products into particular physical or administering forms; devices for administering food or medicines orally; baby comforters; devices for receiving spittle
	7	G06M	Counting mechanisms; counting of objects not otherwise provided for
	8	A61B	Diagnosis; surgery; identification
	9	A62B	Devices, apparatus, or methods for life-saving
	10	B05D	Processes for applying liquids or other fluent materials to surfaces, in general
Wireless communication in inhaler space	1	A61M	Devices for introducing media into, or onto, the body; devices for transducing body media or for taking media from the body; devices for producing or ending sleep or stupor
	2	A61K	Preparations for medical, dental, or toilet purposes
	3	A61B	Diagnosis; surgery; identification
	4	A61J	Containers specially adapted for medical or pharmaceutical purposes; devices or methods specially adapted for bringing pharmaceutical products into particular physical or administering forms; devices for administering food or medicines orally; baby comforters; devices for receiving spittle
	5	A61P	Therapeutic activity of chemical compounds or medicinal preparations
	6	G06F	Electric digital data processing
	7	B65D	Containers for storage or transport of articles or materials, e.g. bags, barrels, bottles, boxes, cans, cartons, crates, drums, jars, tanks, hoppers, forwarding containers; accessories, closures, or fittings therefor; packaging elements; packages
	8	B05B	Spraying apparatus; atomising apparatus; nozzles
	9	B67D	Dispensing, delivering, or transferring liquids, not otherwise provided for
	10	G06Q	Data processing systems or methods, specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes; systems or methods specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes, not otherwise provided for

Table 39 Top ten IPC codes related to auto-injectors

		IPC	Description of IPC code
General auto-injector space	1	A61M	Devices for introducing media into, or onto, the body; devices for transducing body media or for taking media from the body; devices for producing or ending sleep or stupor
	2	A61B	Diagnosis; surgery; identification
	3	A61J	Containers specially adapted for medical or pharmaceutical purposes; devices or methods specially adapted for bringing pharmaceutical products into particular physical or administering forms; devices for administering food or medicines orally; baby comforters; devices for receiving spittle
	4	A61K	Preparations for medical, dental, or toilet purposes
	5	H01S	Devices using stimulated emission
	6	A61P	Therapeutic activity of chemical compounds or medicinal preparations
	7	A61N	Electrotherapy; magnetotherapy; radiation therapy; ultrasound therapy
	8	A61F	Filters implantable into blood vessels; prostheses; devices providing patency to, or preventing collapsing of, tubular structures of the body, e.g. stents; orthopaedic, nursing or contraceptive devices; fomentation; treatment or protection of eyes or ears; bandages, dressings or absorbent pads; first-aid kits
	9	G01N	Investigating or analysing materials by determining their chemical or physical properties
	10	A61D	Veterinary instruments, implements, tools, or methods
Wireless communication in auto-injector space	1	A61M	Devices for introducing media into, or onto, the body; devices for transducing body media or for taking media from the body; devices for producing or ending sleep or stupor
	2	A61B	Diagnosis; surgery; identification
	3	G01N	Investigating or analysing materials by determining their chemical or physical properties
	4	H01S	Devices using stimulated emission
	5	G06F	Electric digital data processing
	6	A61N	Electrotherapy; magnetotherapy; radiation therapy; ultrasound therapy
	7	A61K	Preparations for medical, dental, or toilet purposes
	8	A61F	Filters implantable into blood vessels; prostheses; devices providing patency to, or preventing collapsing of, tubular structures of the body, e.g. stents; orthopaedic, nursing or contraceptive devices; fomentation; treatment or protection of eyes or ears; bandages, dressings or absorbent pads; first-aid kits
	9	A61P	Therapeutic activity of chemical compounds or medicinal preparations
	10	A61J	Containers specially adapted for medical or pharmaceutical purposes; devices or methods specially adapted for bringing pharmaceutical products into particular physical or administering forms; devices for administering food or medicines orally; baby comforters; devices for receiving spittle

Table 40 Top ten IPC codes related to heart rate monitors

		IPC	Description of IPC code
General heart rate monitor space	1	A61B	Diagnosis; surgery; identification
	2	A61N	Electrotherapy; magnetotherapy; radiation therapy; ultrasound therapy
	3	G06F	Electric digital data processing
	4	A61M	Devices for introducing media into, or onto, the body; devices for transducing body media or for taking media from the body; devices for producing or ending sleep or stupor
	5	A63B	Apparatus for physical training, gymnastics, swimming, climbing, or fencing; ball games; training equipment
	6	G01S	Radio direction-finding; radio navigation; determining distance or velocity by use of radio waves; locating or presence-detecting by use of the reflection or reradiation of radio waves; analogous arrangements using other waves
	7	G08B	Signalling or calling systems; order telegraphs; alarm systems
	8	G01R	Measuring electric variables; measuring magnetic variables
	9	G06Q	Data processing systems or methods, specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes; systems or methods specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes, not otherwise provided for
	10	G01N	Investigating or analysing materials by determining their chemical or physical properties
Wireless communication in heart rate monitor space	1	A61B	Diagnosis; surgery; identification
	2	A61N	Electrotherapy; magnetotherapy; radiation therapy; ultrasound therapy
	3	G06F	Electric digital data processing
	4	G08B	Signalling or calling systems; order telegraphs; alarm systems
	5	A63B	Apparatus for physical training, gymnastics, swimming, climbing, or fencing; ball games; training equipment
	6	H04L	Transmission of digital information, e.g. telegraphic communication
	7	H04W	Wireless communication networks
	8	A61M	Devices for introducing media into, or onto, the body; devices for transducing body media or for taking media from the body; devices for producing or ending sleep or stupor
	9	H04B	Transmission
	10	G01S	Radio direction-finding; radio navigation; determining distance or velocity by use of radio waves; locating or presence-detecting by use of the reflection or reradiation of radio waves; analogous arrangements using other waves

Table 41 Top ten IPC codes related to blood pressure monitors

		IPC	Description of IPC code
General blood pressure monitor space	1	A61B	Diagnosis; surgery; identification
	2	G06F	Electric digital data processing
	3	A61M	Devices for introducing media into, or onto, the body; devices for transducing body media or for taking media from the body; devices for producing or ending sleep or stupor
	4	G01L	Measuring force, stress, torque, work, mechanical power, mechanical efficiency, or fluid pressure
	5	A61N	Electrotherapy; magnetotherapy; radiation therapy; ultrasound therapy
	6	F16K	Valves; taps; cocks; actuating-floats; devices for venting or aerating
	7	A61G	Transport, personal conveyances, or accommodation specially adapted for patients or disabled persons; operating tables or chairs; chairs for dentistry; funeral devices
	8	G06Q	Data processing systems or methods, specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes; systems or methods specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes, not otherwise provided for
	9	G01N	Investigating or analysing materials by determining their chemical or physical properties
	10	G08B	Signalling or calling systems; order telegraphs; alarm systems
Wireless communication in blood pressure monitor space	1	A61B	Diagnosis; surgery; identification
	2	G06F	Electric digital data processing
	3	H04W	Wireless communication networks
	4	H04L	Transmission of digital information, e.g. telegraphic communication
	5	A61N	Electrotherapy; magnetotherapy; radiation therapy; ultrasound therapy
	6	G08B	Signalling or calling systems; order telegraphs; alarm systems
	7	G06Q	Data processing systems or methods, specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes; systems or methods specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes, not otherwise provided for
	8	A61M	Devices for introducing media into, or onto, the body; devices for transducing body media or for taking media from the body; devices for producing or ending sleep or stupor
	9	H04B	Transmission
	10	H04Q	Selecting

Table 42 Top ten IPC codes related to blood glucose monitors

		IPC	Description of IPC code
General blood glucose monitor space	1	A61B	Diagnosis; surgery; identification
	2	G01N	Investigating or analysing materials by determining their chemical or physical properties
	3	G06F	Electric digital data processing
	4	A61M	Devices for introducing media into, or onto, the body; devices for transducing body media or for taking media from the body; devices for producing or ending sleep or stupor
	5	C12Q	Measuring or testing processes involving enzymes or micro-organisms; compositions or test papers therefor; processes of preparing such compositions; condition-responsive control in microbiological or enzymological processes
	6	A61K	Preparations for medical, dental, or toilet purposes
	7	A61P	Therapeutic activity of chemical compounds or medicinal preparations
	8	A61N	Electrotherapy; magnetotherapy; radiation therapy; ultrasound therapy
	9	G06Q	Data processing systems or methods, specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes; systems or methods specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes, not otherwise provided for
	10	C07K	Peptides
Wireless communication in blood glucose monitor space	1	A61B	Diagnosis; surgery; identification
	2	G06F	Electric digital data processing
	3	G01N	Investigating or analysing materials by determining their chemical or physical properties
	4	A61M	Devices for introducing media into, or onto, the body; devices for transducing body media or for taking media from the body; devices for producing or ending sleep or stupor
	5	G06Q	Data processing systems or methods, specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes; systems or methods specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes, not otherwise provided for
	6	A61N	Electrotherapy; magnetotherapy; radiation therapy; ultrasound therapy
	7	G08B	Signalling or calling systems; order telegraphs; alarm systems
	8	H04L	Transmission of digital information, e.g. telegraphic communication
	9	H04W	Wireless communication networks
	10	H04B	Transmission

12 Appendix D
Example Medical Devices

Sample Medical Devices 1

CAMBRIDGE IP

Device Type	Name	Organisation	Description
Eye Test Device	NETRA (Near-Eye Tool for Refractive Assessment).	MIT's Media Lab; PerfectSight	Tests the patient's eye by utilizing a small plastic device hooked onto the front of a mobile phone's screen. The patient looks into a small lens and then press the handset's arrow keys till sets of parallel green and red lines overlap. After which software integrated in the phone supplies the user with the prescription data.
Oximeter	Smartphone pneumonia diagnostic test	University of Melbourne (part of Microsoft Research Connections)	An oximeter attached to a smartphone measures the oxygen content in red blood cells by measuring the absorption of red and infrared light waves as they pass through a patient's fingertip or ear lobe.
Microscope	Clinical Microscopy for Global Health - Diagnostic Microscope	UC Berkeley Biophysics Group	A mobile phone-mounted light microscope that can take digital images that can then be used to diagnose hematologic and infectious diseases using image analysis software.
Stethoscope	Scope-to-Scope Tele-Ausculation	3M	Using Bluetooth connectivity, the system transfers in real time audio gathered on one Littmann Model 3200 stethoscope to another anywhere in the world.

3M: Scope-to-Scope Ausculation

UC Berkeley: Microscope

MIT; PerfectSight: NETRA

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Sample Medical Devices 2

CAMBRIDGE IP

Device Type	Name	Organisation	Description
Heart Rate Monitor	ecgAnywhere™	Health Frontier	ecgAnywhere™ is a handheld device for that can read and store up 40 ECG reads and transit them via Bluetooth wireless transmission.
	C-AD: ECG Monitoring System	Curvus (subsidiary of WPR Medical)	The C-AD is a fully-integrated, wireless cardiac monitoring system that is able to capture and transmit continuous, real-time ECG readings.
Body Activity Monitoring	Wellcore Personal Emergency Response Medical Alert System	Wellcore	A small personal activity monitor that can automatically detects if the user falls and immediately alerts the Emergency Call Center.
	BodyMedia Personal Monitoring Wristbands	BodyMedia; Sprint	BodyMedia's wristband tracks activity levels which are then stored and analyzed on your phone.
	"Smart Slippers"	AT&T, Texas Instruments	The slippers have pressure sensors in the heels that wirelessly transmits data about the patients movements.

Health Frontier: ecgAnywhere

BodyMedia: Personal Monitoring Bands

Curvus: C-AD ECG Monitoring

Wellcore: Emergency Medical Alert System

AT&T; TX Instruments: Smart Slippers

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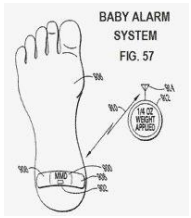
Example Medical Devices 3

CAMBRIDGE IP

Device Type	Name	Organisation	Description
Fetal Monitoring	Fetal heart rate monitor	Edith Cowan University(part of Microsoft Research Connections)	USB connected ultrasound device with smartphone application software to monitor and track heart rate and activity in the womb.
	Monica's AN24™	Alere Health; Monica Healthcare	The device provides the ability to extract key parameters of fetal heart rate and uterine activity traces, which can be transmitted to the coordinating physician.
Baby Monitor	Smart BabyMonitor	Withings	The device monitors your baby and wirelessly transmits the information to the users phone. Your phone can also control functions the Smart BabyMonitor and send alerts when the baby is about to wake up.
	Adhesive Device Monitor	Apple	In-home baby monitoring alarm system that includes a Band Aid-like sensor that would be attached to the child's foot. The device then synchs to the baby's body movement, breathing sounds, pulse or respiratory rate via the sensor. The device also sounds alerts and alarms when the baby's heart rate, respiration or pulse are absent.



Apple: Adhesive Devices Monitor Design

Alere Health & Monica Healthcare

Withings: Smart BabyMonitor

Sample Medical Devices 4

CAMBRIDGE IP

Device Type	Name	Organisation	Description
In Vivo Monitoring Device	SubQore	Cambridge Consultants	SubQore has been designed to be implemented as a custom BiCMOS integrated circuit, optimised for the target application. It is suitable for devices using the Medical Implant Communications Service (MICS)
	Ingestible Event Marker	Novartis AG (licensed tech from Proteus Biomedical)	Ingestible Event Marker (IEM), is a microchip that can be added to pills. When ingested stomach acids activate the microchip, which then sends data such as heart rate, temperature, and body movements to a dermal patch via Bluetooth connectivity.
	Eye Pressure Monitor	University of Michigan	A prototype implantable eye pressure monitor for glaucoma patients that can be integrate with wireless sensor networks.
Test Strip Diagnostic	eSTI² (Electronic self-testing instruments for STIs)	St George's, University of London; UK Medical Research Council	A device is supplied for users to add their samples and then plug into a computer or mobile phone. Software on the phone or computer will analyse the sample, make a diagnosis and recommend a course of action.
	GENTAG Diagnostic Platform	GENTAG	GENTAG technology combines immunoassays with NFC cell phones or PCs for on-the-spot diagnostics and remote monitoring of results. Applications include pathogen detection, trace analysis, women's health, and more.

St. George Univ of London: eSTI2

Cambridge Consultants: SubQore

NovartisAG: Ingestible Event Marker

Univ of MI: Eye Pressure Microchip

GENTAG: Diagnostic Platform

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