A Reference Framework of mHealth Patents for Innovative Services

Massimo Barbieri[1] and Giuseppe Andreoni[2(✉)]

[1] Politecnico di Milano – Technology Transfer Office, P.zza L. Da Vinci 32, 20133 Milan, Italy
massimo.barbieri@polimi.it
[2] Dip. di Design, Politecnico di Milano, via G. Durando 38/A, 20158 Milan, Italy
giuseppe.andreoni@polimi.it

Abstract. mHealth is an emerging and rapidly developing field with huge exploitation expectancies both in improving life quality of patients and in market opportunities. Patents and innovations in mHealth represents a priority for companies to enter and exploit their know-how and market requests. This paper focuses on the analysis of the Intellectual Property Rights in the field of mHealth systems to draw a reference knowledge framework of the mHealth scenario. An up-to-date detailed categorization, the geographical distribution and the identification of top players in mHealth is presented.

Keywords: mHealth · IPR · Patent · Distribution · Companies · Exploitation

1 Introduction

In 2011 WHO stated that the use of mobile and wireless technologies to support the achievement of health objectives has the potential to transform the face of health service delivery across the globe. Mobile health (mHealth) covers "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices [1]. Fourteen categories of mHealth services were identified by the WHO report: health call centres, emergency toll-free telephone services, managing emergencies and disasters, mobile telemedicine, appointment reminders, community mobilization and health promotion, treatment compliance, mobile patient records, information access, patient monitoring, health surveys and data collection, surveillance, health awareness raising, and decision support systems [1].

Also EU in its "Green Paper on mHealth" recognizes how mHealth is an emerging and rapidly developing field which has the potential to play a part in the transformation of healthcare and increase its quality and efficiency [2]. mHealth solutions cover various technological solutions, that among others measure vital signs such as heart rate, blood glucose level, blood pressure, body temperature and brain activities. Prominent examples of apps are communication, information and motivation tools, such as medication reminders or tools offering fitness and dietary recommendations. This means a huge market potential to be exploited through a widespread category of systems or devices

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or software applications (or "apps"), that are considered to be a medical device according to the specific and corresponding regulation regulations [3, 4].

mHealth products are portable devices (such as smartphones or tablets), which use software applications (or "apps") for health monitoring purpose, prevention and detection of diseases and basic diagnosis [5]. mHealth apps are rapidly growing and evolving thanks to cloud computing and 4G technologies and are available in every area of healthcare such as physical activity, anti-obesity, diabetes and asthma self-management [6]. According to IMS Institute for healthcare informatics, more than 165,000 m-Health apps are available [7] and at the 2010 more than 200 million mHealth apps were downloaded [8].

New generation mobile/smartphones are equipped with embedded and advanced sensors such as accelerometers, gyroscopes, GPS, microphones (that can be used as stethoscopes to detect heart rate) and cameras. Techniques like ultrasound, fluorescence imaging and even a combination of imaging cytometry and fluorescent microscopy were developed using a smartphone. The computing capacity of smartphone/tablet PC is getting more and more high, as well as the quality of their components. Software platforms (iOS or Android or Windows), network protocol systems (3G, 4G, 5G), battery life of smartphones and graphical user interfaces (GUI) are the critical points to be faced and solved.

Innovation in the field of mHealth devices is rapidly growing and patents could be an indicator of these innovative activities. The purpose of this study is to evaluate the technology progress of mHealth devices and to analyze the patent data in more detailed way. For this reason this paper focuses on the analysis of the Intellectual Property Rights (IPR) in the field of mHealth systems to draw a reference knowledge framework of the mHealth scenario.

2 Materials and Methods

Patent searches can be carried out by means of keywords, classification symbols or a combination of both methods. Sometimes keyword searching is not effective because it's subjective and limited to the language used [9, 10]. These drawbacks can be overcome by using a classification tool. The patent classification systems are a language independent tools that help to retrieve patent information. The most worldwide used systems are IPC (*International Patent Classification*) and CPC (*Cooperative Patent Classification*). The IPC is used by more than 100 national and regional patent offices. It's a hierarchical classification system, revised annually, consisting of eight sections, which are divided into around 70,000 sub-divisions called classes, subclasses and groups. CPC is based on IPC and ECLA (the former **E**uropean **Cla**ssification). It's more frequently updated than IPC and has more detailed sub-divisions (around 200,000), useful for faster moving technology fields classification [11].

All patent searches were performed using Orbit database [12], which is a fee based patent database with a good data coverage.

3 Results

A search with the keywords ("mHealth" or "mobile health") in the "title/abstract/claims/concepts/object of invention" search field showed 740 results. We performed a statistical analysis in order to retrieve the main IPC/CPC codes, as reported in Table 1. Patent applications relating medical information are generally classified in the generic subgroup G06F 19/00 of IPC.

Table 1. Results of the quick search.

CPC codes	Definition	No. of inventions
G06F-019/3+	Medical informatics	107
A61B-005/00	Detecting, measuring or recording for diagnostic purposes	128
G06Q-050/22	Health care	98

A more precise and specific search was carried out using a quite complex query, which gave 6,550 results. The parameters of the query were: [(m_health OR (mobile 1w health) OR smartphone? OR (tablet 1w pc) OR PDA OR personal_digital_assistant OR phablet)/TI/AB/IW/CLMS/KEYW/OBJ AND (G06F-019/3+ OR G06Q-050/22 OR A61B-005+)/IPC/CPC]. The distribution of search results by publication years is shown in Fig. 1 below.

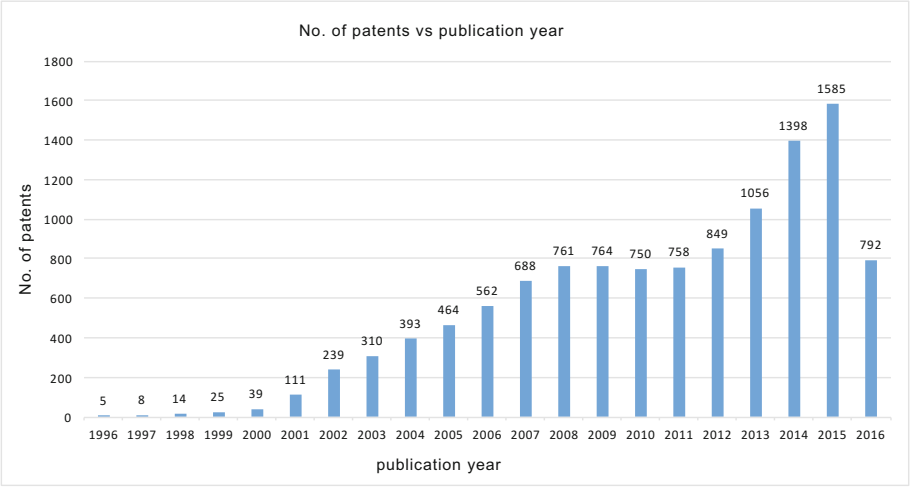

Fig. 1. The evolution of patent number in the last 20 years by publication year.

Since patent applications are published 18 months after the filing date, it could be said that the number of patent applications grew rapidly from 2011, reaching its peak in

2013. The distribution of search results by Priority country reveals that most of inventions are generated in the United States of America (Fig. 2). The main patent applicants are reported in the Fig. 3 below.

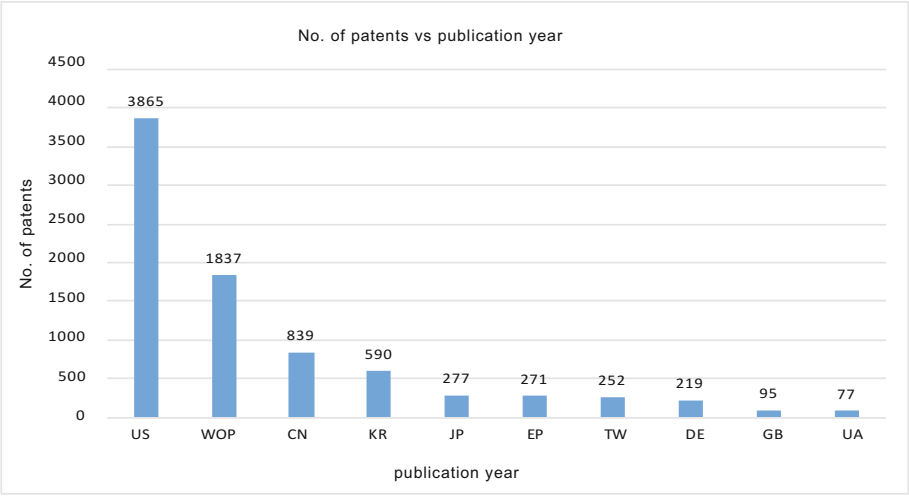

Fig. 2. The distribution of search results by priority country.

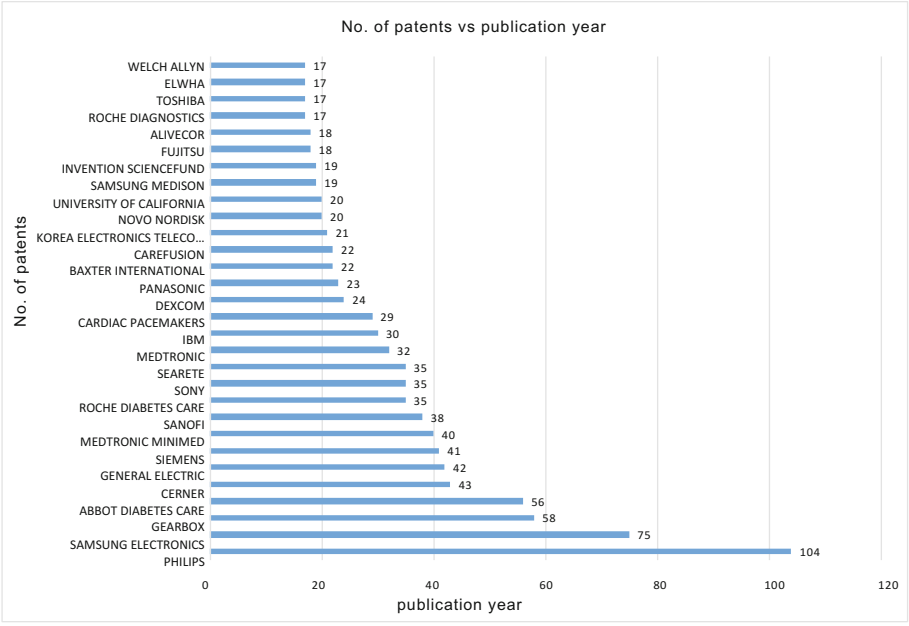

Fig. 3. List of top applicants.

A deeper analysis was performed on each relevant CPC code, using the same keywords (see Table 2, where in bold are evidenced the most populated fields).

Table 2. List of relevant CPC codes and the corresponding number of inventions.

CPC codes	Definition	No. of inventions
G06F-019/3+	Medical informatics	107
G06F19/30	Medical informatics	30
G06F19/32	Medical data management	10
G06F19/321	Management of medical image data	156
G06F19/322	**Management of patient personal data**	**583**
G06F19/323	on a portable record carrier	119
G06F19/324	Management of patient independent data	93
G06F19/325	Medical practices	73
G06F19/326	Medication information	76
G06F19/327	Management of hospital data	298
G06F19/328	Health insurance management	159
G06F19/34	Computer-assisted medical diagnosis or treatment	43
G06F19/3406	Local monitoring or local control of medical devices	482
G06F19/3412	Medical equipment management	93
G06F19/3418	**Telemedicine**	**819**
G06F19/3425	Consulting other medical practitioners	87
G06F19/3431	Calculating a health index for the patient	106
G06F19/3437	Medical simulation or modelling	90
G06F19/3443	Medical data mining	100
G06F19/345	Medical expert systems, neural networks or other automated diagnosis	312
G06F19/3456	Computer-assisted prescription or delivery of medication	347
G06F19/3462	Computer-assisted distribution of medication from dispensers	132
G06F19/3468	Computer-assisted delivery of medication via infusion or injection	147
G06F19/3475	Computer-assisted prescription or delivery of diets	168
G06F19/3481	Computer-assisted prescription or delivery of treatment by physical action	371
G06F19/3487	Medical report generation	229
G06F19/3493	Computer-assisted epidemiological alert systems	25
G06F19/36	Computer-assisted acquisition of medical data	19
G06F19/363	Manual data input	192
G06F19/366	Acquisition of data related to laboratory tests	58
G06Q50/22	**Health care**	**1,736**

Narrowing the second search query with a priority date starting from 2013 and G06F19/3+ sub-divisions, the search gave 926 results, and telemedicine and the management of patient personal data are the technical fields with more inventions.

4 Discussion

Data of publication year indicate the presence of different mHealth epochs: until 2001 there a few experiences and innovations probably due to the immaturity of technologies related to this field; with the diffusion of communication technologies, from 2002 to 2008 an increasing number of applications/inventions have been achieved. Another stability period started and lasted up to 2011, and since 2012 with the rapid introduction and global spreading of smartphone and related apps a new rapid development era is in progress.

About Top players data demonstrates that multinational biomedical companies cover the first position of ranking, but it is interesting to note the presence of big software developers and also one university.

Concerning the methodology, a big difference is noticeable in the results coming from other research engine or sources: using the search query "m-health or mobile health" Scopus provided 1.059 results, while Espacenet only 645 if analyzing the full text (57 if only in the title, or 106 including title and summary). This means that general data could be obtained by these sources, but the detail level provided by specific database is more relevant.

The technical fields in which innovation is more marked are: 1. Telemedicine; 2. Management of patient personal data (e.g. patient records); 3. Local monitoring of medical devices (e.g. graphical user interfaces); 4. Computer assisted prescriptions (e.g. prescription filling or compliance checking); 5. Medical expert systems (e.g. medical decision support systems).

5 Conclusion

This short IPR analysis demonstrated that mHealth is in the big expansion period. Technology is mature and related inventions start covering all the opportunities. A saturation and real discrimination of IPR is expected in the near future.

According to the responses to a European Commission public consultation, privacy and security, patient safety, a clear legal framework and better evidence on cost-effectiveness are all required to help mobile Health care ("mHealth") flourish in Europe [2].

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