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New Regulations on Medical Devices in Europe: Are They an Opportunity for Growth?

Petra Maresova and Ladislav Hajek
Department of Economy, Faculty of Informatics and Management, University of Hradec Kralove, Rokitanskeho 62, 500 03 Hradec Kralove, Czech Republic;
Ondrej Krejcar and Kamil Kuca
Center for Basic and Applied Research, University of Hradec Kralove, Rokitanskeho 62, 500 03 Hradec Kralove, Czech Republic;
Michael Storek
Admirx, Inc., Cambridge, MA 02139, USA;

A B S T R A C T

Increasing demand for modern treatments and significant profit margins are strong incentives for investors and producers. However, the production and use of medical devices is subject to a number of laws, regulations, strict standards, and certification processes. Therefore, the aim of this paper is to analyze patent activity based on the example of the selected country (Czech Republic), compare it with selected foreign countries, and discuss the development of this industry in the context of new medical device regulation (MDR) implementation. The paper is based on the theoretical concept of the relationship between regulation and innovation. The main challenge in the implementation of the new medical device regulations lies in the area of innovation. This is because most innovative research in the medical device sector is undertaken by small to medium enterprises (SMEs) rather than by large companies. SMEs are more vulnerable than big companies when it comes to development because the accompanying administrative costs can be so high that it may force the company to leave the market. Given that the main reason for the existence of economic regulations are various forms of market failure, which occurs when market mechanisms do not lead to results that benefit society, any attempts to redress this situation should naturally lead to greater benefits for society and hence benefits for the given industry as well.

A R T I C L E I N F O

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medical device industry; innovation; patent analysis; regulatory; market potential

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1. INTRODUCTION

The current driver of developed and developing economies is innovation (Jaskyte Bahr2019). The area of health care and medical devices is important in relation to quality of life (Parisio et al.2020; Velenturf et al.2019;Zhang et al.2018).

In general, the medical device industry includes products such as therapeutic and surgical devices, patient monitoring, and diagnostic and medical imaging devices. It is a very heterogeneous area in terms of production and markets, spilling over into different fields of manufacturing and healthcare services (Medical Devices in the EU: A Global Leader in Safety, Availability and Innovation2015). Increasing demand for modern treatments and significant profit margins are strong incentives for investors and producers (Yamaue2017;World Intellectual Property Organization et al.n.d.). However, the production and use of medical devices is subject to a number of laws, regulations, strict standards, and certification processes. Therefore, the development and manufacturing of medical devices have to take into account the macroeconomic framework with specific factors in terms of their production and use.

According to the International Trade Administration (ITA) for global medical devices, sales are estimated to increase by 6.4% annually from 2016 to 2020, reaching nearly US$440 billion. While the United States is projected to remain the world's largest medical device market, the Asia/Pacific and Western Europe markets are expected to expand at a faster pace over the next several years (Five Trends to Watch in the Medical Device Industryn.d.) (ITA 2017). Demographic shifts underlie the long-term market opportunity for medical device manufacturers. Aging populations and technological developments will bolster industry growth. The elderly account for nearly one third of total healthcare consumption. According to United Nations projections, the global elderly population will rise from approximately 610 million (8.3% of the world population) in 2015 to 1.8 billion (17.8% of the world population) in 2060. Europe's elderly are projected to reach nearly 29% of the population by 2060, making it the world's oldest region (World Population Prospects-Population Division-United Nationsn.d.). These facts indicate that there exists a potential for market growth in the area of innovative solutions for medical devices.

On the other hand, medical company innovation depends on national health systems, clinical trials, approvals, regulated prices, and a number of other factors which can be included into framework conditions, making the health sector very unique. At the aggregate level, many types of regulations are either neutral, and thus have no direct effect on innovation, or are more often perceived as a driver rather than a barrier. While a regulation on its own can be sound, it rarely works alone, but is rather linked to other regulations. This lack of regulatory alignment seems to be the main barrier and can be addressed in particular when it comes to new regulations.

According to the Porter hypothesis, strict environmental regulation triggers the invention and introduction of cleaner technologies and environmental improvements—the innovation effect—making production processes and products more efficient. The cost savings can compensate not only the compliance costs directly attributed to new regulations, but the innovation costs as well. Firms are able to take advantage of innovation through learning curve effects or patenting, and gain a dominant competitive position compared to companies in countries where regulation was introduced later.

A significant change in legislation will affect European medical device manufacturers starting from May 2020. It is the new Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA Relevance)2017).

When it comes to implementing medical device regulations, the main challenge lies in the area of innovation. Most of the innovative research in the sector of medical devices is undertaken not by large companies but rather by small to medium enterprises (SMEs) which are based on the collaboration of healthcare professionals and small local companies or university labs. Out of the 25,000 MedTech companies in Europe as many as 95 percent qualify as SMEs (EUCOMED Medical Technology 2013) (Bernasconi2017). It is SMEs rather than large companies that are most vulnerable to forced market exit because of the high administrative costs of development.

In the light of the fact that countries of the European Union face the impending challenge of new legislative regulations on medical devices with serious concerns, the aim of this paper is twofold. The first aim is to analyze the current conditions of patent activity in a selected European country where there has been no change in the relevant legislation since 1994. The second is to examine the development of the situation in the United States, where there have been updates to legislative regulations as of 2002 and 2003. In many respects, the changes in legislation introduced in the United States overlap with those that are to be implemented in the EU. Hence, based on an analysis of the development in the United States, possible implications of the new regulations in the EU can be derived and discussed.

The rest of the article is organized as follows. Theoretical background provides on overview of current situation in the medical device industry and specifics linking medical device industry and regulations. Section3 deals with methodology and objectives. Section4 presents the results and analyses patent activity in the national and international context. The discussion and conclusion with policy implications are described in the final parts of the paper.

2. THEORETICAL BACKGROUND

2.1. Specific Features of the Medical Device Industry

The production and usage of medical devices differs in many ways from those of other manufacturing industries, and also the pharmaceutical industry. Over the past 25 years there has been an acceleration in the development of new medical devices stimulated by the rapid development of scientific and technical knowledge. Based on the analysis of current developments, we can formulate some specific features of the medical devices industry compared to other sectors of the national economy.

Developing new products and procedures is risky and usually more resource intensive compared to some other sectors of the economy. However, barriers to entry in the form of existing regulations provide a measure of relief from competition, especially for newly developed products.

Government regulations restrain conditions for competition in which firms may realize an acceptable level of returns on their investments. Regulations determine medical device design and development, preclinical and clinical testing, premarket approval, registration, manufacturing, storage, advertising and promotions, sales and distribution, export and import, and post market control.

The potential users of new medical devices, that is, the physician-researchers, play an important role during the development process. They may also be crucial to the invention of medical device prototypes. They identify the clinical need for a new device or for improvements in existing devices and they are, in many cases, the designers or builders of the original prototype. Accordingly, close interactions between clinicians and the industry are important for the development of medical devices (Gelijns and Institute of Medicine (US) Committee on Technological Innovation in Medicine1989).

Medical devices are a much more heterogeneous group of products than drugs in terms of design, use, and purpose. There are approximately 1700 different types of medical devices and 50,000 separate products. There is much more variety in the types of firms that invent and develop medical devices than is the case with drugs.

The industry is characterized by a large number of small firms. Large companies, however, dominate the industry in terms of sales. Small firms and even individuals produce most of the innovations in the early stages of developing a new class of medical devices, whereas larger firms play an especially important role later on in the development process (sometimes through the acquisition of small firms).

The export of medical devices assumes a high level of expertise of product distributors who are able to communicate with local medical institutions to implement these devices and obtain the required certificates in the country.

The industry and its products bring high added value, which is related to the requirements for a high level of qualification. Evaluations of the effectiveness of medical device production due to specifics must be comprehensive and multi-criteria-based. The key performance indicators (KPIs), for example the value added per employee value added in relation to cost, value added in relation to investments and its correlation analysis show that the industrial sector which may be classified as unimportant at first glance may be the most efficient (Hedvicˇáková and Král2019).

Producers have to take into consideration user expectations and user experience (UX)—in other words user comfort and convenience in order to create user-friendly devices. Businesses can gain a competitive advantage when taking both medical and patients' usability needs and preferences into consideration.

Medical device purchasing decisions tend to be largely disconnected from price because device manufacturers receive payments from insurers who usually reimburse healthcare providers.

The medical device industry faces increasing healthcare costs on a global scale. The focus on cost-cutting and efficiency can lower reimbursement rates and reduce procedure volume. The purpose is the transition of the healthcare delivery from fee-for-service (FFS) to value models leading to fewer hospital admissions and procedures. A number of countries have instituted price ceilings on certain medical procedures, forcing down product prices.

The consumers (patients) are removed from interactions with manufacturers, because the primary customers of medical device companies are physicians (product approval committees at hospitals) who select the appropriate equipment for patients.

Most countries are moving away from a cost-based essentially open-ended reimbursement system towards a prospective payment system (PPS) for hospitals based on diagnosis-related groups (DRGs). Under PPS hospitals there is a strong financial incentive to provide the least resource-intensive treatment. There is little incentive for hospitals to use technologies that have long-term benefits even though they may ultimately have a greater impact on the efficiency of the system as a whole.

There are some new structural factors that influence strong demand for medical devices. The main factor is an aging population, driven by declining fertility rates and increasing life expectancy.

2.2. Linking Innovation and Regulation

The link between regulation and innovation is complex and any direct causality is hard to detect. The complexity of the relationship between regulation and innovation emanates from the fact that changes in the regulatory framework do not always trigger changes in innovation in an immediate and direct way. Such changes in innovation will sometimes occur in the course of indirect changes in competition, skills, investment or entrepreneurial activities. According to Ashford (2000) a strong form of the Porter hypothesis, referring in

particular to environmental regulation, illustrates that stringent regulation can dramatically stimulate innovation via the replacement of dominant technologies by new firms or entrants. The health sector is associated with barriers related to product safety regulation, environmental protection and labelling. There are barriers due to regulation, but regulation can be also a stimulus for innovation.

To understand innovation in health, it is important to bear in mind that the nature of the EU's regulatory capacities in this field are quite limited in scope compared to other sectors. The EU's strategic direction in the field of health is primarily elaborated in the EU Health Strategy. One of its four principles is supporting dynamic health systems and new technologies. Medical devices are seen as a key source of innovation in healthcare and the medical device industry is considered to be one of the most innovative sectors in Europe. Other areas of legislation that have an impact in the health sector include patents, patients' rights in cross-border healthcare, etc. Healthcare has high potential for innovation and growth and the European Commission has identified a number of innovation challenges affecting the healthcare sector in the EU.

The United States' dominance in this area and the increasing presence of emerging players such as China are ongoing challenges for the EU. Although medical technology is the leading technological field in terms of patent applications and patents granted in the EU, the sector is dominated by globally operating companies. The United States accounts for almost half of all health-related patents in the world, for both medical technologies and pharmaceutical products. In this area, several regulations seem to have had an impact on innovation, although it has not been possible to establish clear direct links. For example the medical technologies/medical devices market in the EU is considered to be highly innovative, and yet the current legislation is being revised to address safety concerns and disparities in the EU market. Although one of the objectives of the proposed policy options was to amend medical device regulation aims at driving innovation, it remains to be seen how this is implemented. The Clinical Trials Regulation, identified as a barrier to innovation has recently been reviewed. The survey data analyzed for this sectoral study showed that the net impact of EU legislation is perceived as positive.

While regulations provide the main framework conditions, their effects on innovation processes vary over time and with the development of industries, technologies, processes and products. If a technical standard helps to establish a new market, after some time or some years it can become outdated and a barrier to new developments. When regulations are designed, they serve specific purposes, such as consumer health and wellbeing, market access and competition, or environmental protection and sustainability aspects (Porter and Linde1995;Wagner 2004).

The European Commission Report (Bernasconi2017) provided a conceptual framework to analyze patent activity and discuss the development of the medical device industry in the context of current legislative conditions and regulations. This report evaluated the impacts of EU regulatory barriers on innovation, including the health sector, its regulatory framework, innovation drivers and barriers. Regulatory barriers to innovation were identified for the whole economy as well as within the health sector. Regulatory factors act as drivers in Italy and Romania. A neutral effect tends to be asserted by respondents from the Czech Republic, Denmark, Finland, Germany, the Netherlands and the United Kingdom. Manufacturers associate barriers with product safety regulation, environmental protection and labelling. According to the survey responses, regulation has neutral effects for the majority of respondents. While barriers from regulation have been identified, its positive and driving role predominates, and it not only hampers but also fosters innovation to a large extent. Nevertheless, regulation can become outdated, irrelevant and, thus, an unnecessary burden.

The term regulation is defined by the OECD as "the diverse set of instruments by which governments set requirements on enterprises and citizens. Regulations include laws, formal and informal orders and subordinate rules issued by all levels of government, and rules issued by non-governmental or self-regulatory bodies to whom governments have delegated regulatory powers". (OECD.Org-OECDn.d.) The EU di fferentiates three types of formal and informal legal provisions: legislative proposals, such as regulations, directives and decisions; non-legislative initiatives, which comprise soft regulation such as recommendations; and voluntary agreements (self-regulation or co-regulation) and technical standards. Regulations are accompanied by a number of administrative procedures including inspections and tests.

2.3. Medical Device Market Regulations

Considering the complexity and specificity of the development of medical devices, the legislative context and knowledge of its complexity is essential. Medical device manufacturers face a single regulatory body across the EU (Czech Republic—Overview of Device Industry and Healthcare Statistics 2014). To be allowed on the market, a medical device must meet the requirements set by the EU Medical Devices Directive. Devices must receive a Conformité Européenne (CE) marking certificate before they can be sold on the market. This CE marking verifies that a device meets all regulatory requirements, including EU safety standards. A set of different directives applies to different types of devices, potentially increasing the complexity and cost of compliance.

European legislation ensures the safety and efficiency of medical devices in the European market (Kramer et al.2014;De Maria et al.2018). Two new European regulations are replacing three existing directives in the years

up to 2022. They will establish a modernized EU legislative framework to ensure better protection of public health and patient safety.

Medical devices within the EU are currently regulated by three directives:

(a) Active Implantable Medical Devices (AIMDD), (EUR-Lex. 1990) (EUR-Lex-01990L0385-20071011- EN-EUR-Lexn.d.)

(b) Medical Devices (MDD), (EUR-Lex. 1993)

(c) In vitro Diagnostic Medical Devices (IVDMD), (EUR-Lex. 1998).

On 5 April 2017, two new regulations on medical devices and in vitro diagnostic medical devices were adopted. They entered into force in 2017 and replaced previous directives. The new regulations will be fully applicable in May 2020 for medical devices and May 2022 for in vitro diagnostic medical devices (EUCOMED-Medical Technology2013).

The new regulations contain a series of improvements to modernize the current system. Among them are stricter ex-ante control for high-risk devices reinforcement of the criteria for designation and processes for oversight of notified bodies a new risk classification system for in vitro diagnostic medical devices improved transparency through a comprehensive EU database on medical devices strengthening of post-market surveillance requirements for manufacturers etc.

In medical device evaluations a distinction needs to be made between diagnostic and treatment devices. Criteria for diagnostic technology evaluations can be divided into four groups:

(d) Technical capacity

(e) Diagnostic accuracy

(f) Diagnostic and therapeutic impact

(g) Patient outcomes

Evaluations provide information on technical and diagnostic devices, and possibly on its risks and complications. The main measures of diagnostic performance are sensitivity (ability of a test to detect disease when it is present) and specificity (ability of a test to correctly exclude disease when it is absent). On the basis of the results of clinical investigations a device may be approved for the market. Information on effectiveness can be provided by experimental or observational studies. An advantage of using modern observational databases (Database| Definition Types & Factsn.d.) is that they represent continuous monitoring of the use of devices in practice, as well as their outcomes (Gelijns and Institute of Medicine (US) Committee on Technological Innovation in Medicine1989).

3. METHODOLOGY AND OBJECTIVES

3.1. Design of the Study

The aim of this article was to comprehensively describe and analyze the issues of production and implementation of medical devices from the perspective of patent activity governmental and supranational institutions, legal regulations, standards, and the certification process, along with major impacts and requirements for companies. Patent analysis was conducted on the example of the Czech Republic as an EU member state which is at the same time rather weak in this segment hence there are concerns about the future development of SMEs. Furthermore patent activity in the United States was examined, both before and after the introduction of new medical device regulations in 2003. The current USA legislation shares many points with the upcoming EU legislation; therefore, based on an analysis of the situation in the USA, it is possible to infer and discuss possible impacts of the new legislation on the European market.

3.2. Data Analysis

The study was based on statistical surveys and reports of international organizations such as Eurostat, European Commission, Organization for Economic Cooperation and Development (OECD), World Health Organization (WHO), National Centre for Biotechnology Information (NCBI), etc., but also on Czech information sources such as the Czech Statistical Office (CZSO), Czech Republic's Ministry of Health, Institute of Health Information, and the Association of Manufacturers and Suppliers of Medical Devices (AVDZ).

In addition to describing the current state through patent activity, a cluster analysis method was utilized.

Patent searching was done from 20 to 23 November 2019 using Espacenet (Espacenet–Patent Searchn.d.) and the PatentInspiration database (Search and Analyze Patents-PatentInspirationn.d.). Searching was done using the following strict criteria:

20-year window: Publication date 1/1/1999–31/12/2019

Czech applicant: [CZ] in Applicant

'medical' AND 'device' in Title, Abstract OR Claims

A basic search strictly using the term 'medical device' resulted in 85 patent applications. This set unfortunately did not cover all patents from Czech applicants, as there are several well-known companies which were not covered. Thus, we updated our search with other meanings using the stemming option in PatentInspiration DB. Stemming is a search system feature which attempts to reduce a given search term to its basic root meaning. With this option, we generated 97 patent applications, where several companies were still not presented. For this reason, we changed our search string from strictly 'medical device' to several other strings which cover a wider area and contain the meaning of 'medical device'. 'Stemming' was also an option used. As a result, an enhanced set of strings was used as follows:

> "medical device" OR "implantable device" OR "catheter" OR "cardiovascular device" OR "stent" OR "surgical device" OR "therapeutic patch" OR "medical instrument" OR "cardiovascular stent" OR "endovascular stent graft" OR implant OR "aneurysmal repair device" OR "catheter assembly" OR "bioabsorbable stent" OR "implantable structures" OR "luminal prosthesis" OR "gastrointestinal (GI) stents" OR "implant device" OR "plaque-trapping device" OR "intra-luminal device" OR "leadless cardiac pacemaker" OR "medical assembly" OR "implantable assembly" OR "flexible biodegradable material" OR "bioresorbable stent" OR "cardiac lead system" OR "non-implantable device" OR "electronic pill" OR "spine jack" OR "cannula" OR "implantable medical apparatus".

PatentInspiration returned 357 patents, where a significant update of covered companies is shown in Table1.

Table 1. Technological areas mentioned in patent applications.

	Basic (Medical Device)	**Stemming (Medical Device)**	**Enhanced Medical Device (MD) and Stemming**
Electrical engineering			
Electrical machinery, apparatus, energy	7	7	6
Telecommunications	5	5	5
Digital Communication	1	1	
Basic Communication processes	2	2	2
Computer technology	10	10	8
IT methods for management	2	2	3
Semiconductors			2
Instruments			
Analysis of biological materials			9
Control	4	4	3
Medical technology	62	71	300
Chemistry			
Organic fine chemistry	3	4	6
Biotechnology		1	9
Pharmaceuticals	5	9	27
Macromolecular chemistry, polymers	3	7	23
Materials, metallurgy	1	1	12
Surface technology, coating	5	5	11
Environmental technology	2	2	

Table 1. Cont.

	Basic (Medical Device)	Stemming (Medical Device)	Enhanced Medical Device (MD) and Stemming
Micro-structural and nano-technology			6
Mechanical engineering			
Engines, pumps, turbines	1	1	
Textile and paper machines	1	1	7
Other special machines	2	3	14
Mechanical elements		3	3
Other fields			
Furniture, games	4	4	4
TOTAL	85	97	359
Data quality (used patents)	98.82%	98.97%	96.66%

Table1 summarizes the coverage of medical device patent application for the last 20 years in the Czech Republic. The most covered technological area is medical technology, where almost 84% of all patents from our patent pool were targeted. The next most used technological area is represented by 94 patents in total for chemistry while there are 27 patents in pharmaceuticals and 23 patents in macromolecular chemistry and polymers. These basic characteristics and technology indicators correspond with the prediction; thus, the methodology for the search strategy can be evaluated as approved or confirmed.

4. RESULTS: PATENT ACTIVITY IN THE MEDICAL DEVICE MARKET

4.1. International Context

To illustrate the situation and compare and evaluate the patent activity of this industry in Europe, the values are compared within selected countries of Eastern and Western Europe, where IPC code patent activity was compared to one million inhabitants. The results clearly show a fundamental difference between Western and Eastern European countries, where the Czech Republic is an EU country with lower patent activity. Even after recalculation, the greatest force in Germany is in this direction (Table2).

In terms of future developments and changes in legislative conditions, concerns are voiced to a more or less equal extent across all the EU countries. The new regulations bring about new expenses on the certification process, which is a challenge that many SMEs are not ready for, as a result of which they might not be able to comply with the new legislation.

Table 2. Patents in the period 1 January 1999–2019; patents compared internationally between Western and Eastern European countries.

	CZ (10.6 Million People)			PL (38 Million People)			AT (8.8 Million People)			DE (82.8 Million People)		
	patents	%	Patent/1 Million Population	patents	%	Patent/1 Million Population	patents	%	Patent/1 Million Population	patents	%	Patent/1 Million Population
total	359		33.87	615		16.18	3290		373.86	39,896		481.84
granted	208		19.62	264		6.95	1671		189.89	18,678		225.58
A61F2/00	114	21	10.75	164	18	4.32	360	8	40.91	7372	14	89.03
A61B17/00	16	3	1.51	88	10	2.32	262	5	29.77	4618	9	55.77
A61L27/00	51	10	4.81	106	12	2.79				2364	4	28.55
A61B5/00	20	4	1.89	35	4	0.92	199	4	22.61	3545	7	42.81
A61N1/00							927	19	105.34			
A61M25/00	30	6	2.83	41	5	1.08				2303	4	27.81
A61C8/00	26	5	2.45	51	6	1.34						
H01L21/00							286	6	32.50	2146	4	25.92
H04R25/00							412	9	46.82			
A61L31/00	17	3	1.60	33	4	0.87						
A61F11/00							269	6	30.57			
H01L29/00							259	5	29.43			
A61M5/00										2388	4	28.84
A61C1/00							174	4	19.77			

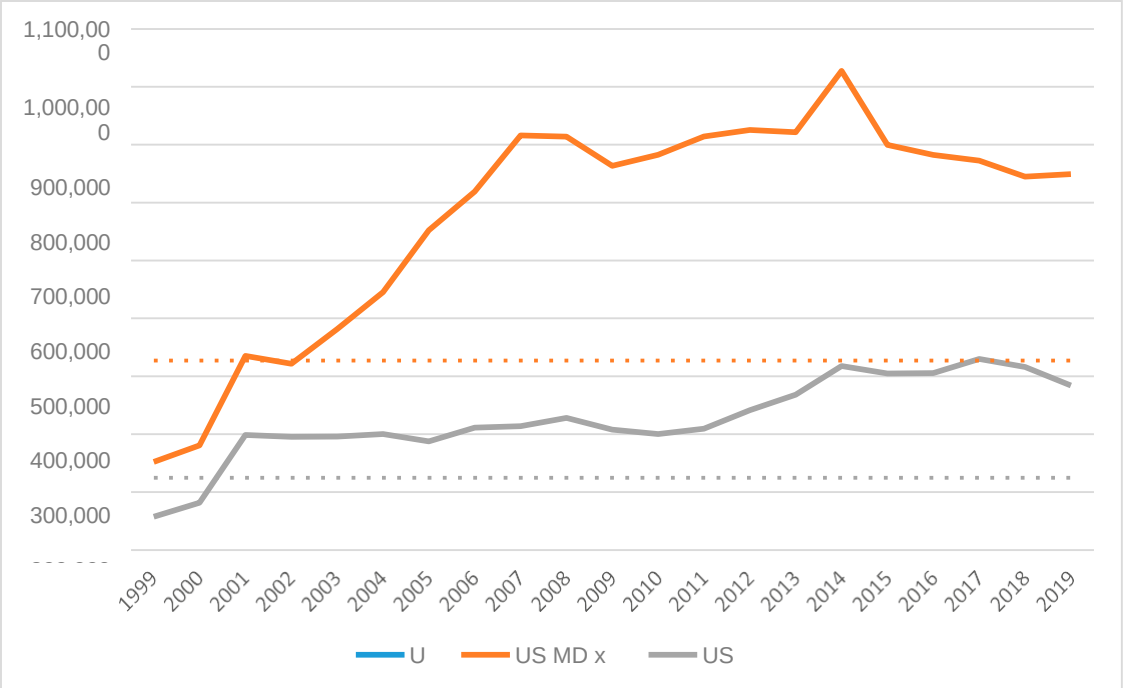
4.2. The United States Context

The United States is the world leader in the medical device market. The most recent legislation changes in the United States took place in 2002 and 2003. The body responsible for regulating companies that manufacture, import, and sell medical devices in the United States is the FDA's Center for Devices and Radiological Health (CDRH). There are three classes of medical device: Class I, II, and III. The higher the class, the stricter the regulatory control. Each device type falls into one of the three classes according to the general device classification criteria set out in the regulation. As to the requirements for each class, Class I devices typically do not require Premarket Notification 510(k), Class II devices do require Premarket Notification 510(k), while Class III devices typically require Premarket Approval. The Medical Device User Fee and Modernization Act of 2002 came into force on 26 October 2002. According to this regulation, the FDA is entitled to charge companies for medical device Premarket Notification 510(k) reviews. Small companies, however, may be eligible for a reduced fee. The payment of the fee is obligatory, regardless of the FDA's decision of whether the device will be approved. The application fee applies to Traditional, Abbreviated, and Special 510(k)s. Devices that do not qualify for Class I or II are, as a rule, high-risk devices that may cause injury or illness. Such devices require PMA and must be submitted to the 510(k) process. This process is more rigorous and requires the evidence of clinical data. Starting with the fiscal year 2003 (1 October 1 2002 through 30 September 2003), medical device user fees are collected for original PMAs and certain types of PMA supplements. As with PMNs, small companies may qualify for reduced or waived fees (Center for Devices and Radiological Health2019).

Some of the legislation changes about to come into force in the EU have already been implemented in the United States by the FDA. Research of the patent application activity in the United States after the introduction of the new regulations brings the following results.

Figure1 illustrates the development of patent application activity in the USA overall and in the segment of medical devices for comparison. The data show that around 2003 there was a growth in patent activity (for convenience, when comparing the development within one figure, values for the medical device market are multiplied by fifty). Considering that the research does not cover all possible causes and economic and technological changes, a clear positive correlation between the new legislation and further market development cannot be confirmed. However, it can be confirmed that the new regulations protecting the patients did not result in decreasing innovation activity of companies in the market.

Figure 1. Development of patent application activity in the United States overall and compared with the medical device industry.



4.3. The Czech Republic situation

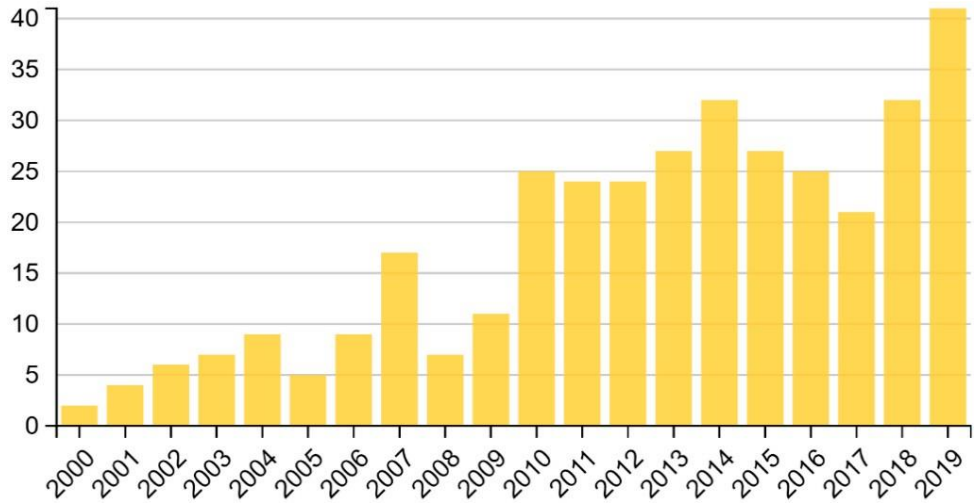
The Czech Republic (CR) is an important manufacturer of medical devices in Europe (The Largest Presentation of Czech Medical Technology in Britain in Recent Yearsn.d.). This is an extremely important

segment of the industry, built on strong traditions in the development and production of healthcare, which has high added value and also a positive effect on highly skilled employment. At the same time, it has a positive impact on the Czech Republic's trade balance. One of the largest production lines in the world where high-standard hospital beds are made is in the Czech Republic.A Czech microscope manufacturer has also achieved global success (Marešová and Kucˇa2014 Marešová et al. 2015). Most healthcare manufacturers are strongly export-oriented with regard to the small Czech market which exports their products worldwide.

At the same time, the Czech Republic belongs to the groups of countries of the former Eastern Bloc, which are still subject to lower levels of economic development than, for example, Germany or Switzerland.

The most indicative characteristic for patent activity in a given area or patent pool can be seen as patent application activity during the past 20 years, as shown in Figure2. It is evident that the patenting trend is significantly increasing, whereas 20 years ago only two to six patents were submitted to the patent authority; in 2018, more than 30 patent applications were filed, which represents five times more in comparison to earlier millennial years.

Figure 2. Patent application activity for the last 20 years in the Czech Republic in the medical devices sector.



Another important characteristic that can provide an overview of the patent pool area is the International Patent Classification (IPC) code map. The map is based on the definition of IPC codes by the World Intellectual Property Organization (WIPO). The most covered codes lie in human necessities (hereafter referred to as A), while the other areas do not cover more than 2% of patent applications in our patent pool. From the A category, most patents fall in A61 codes, which is represented by medical or veterinary science and hygiene. One hundred and fourteen patents are categorized into A61F2 (filters implantable into blood vessels), where mostly stents are located. In this category, the leading applicant is Ella CS Company (Hradec Kralove, Czech Republic), with 36 patent applications, followed by Beznoska s.r.o. The next largest category is A61L27 (materials for prostheses or for coating prostheses), with 51 patents, as shown in Figure3. This category is most often occupied by Medicem Institute s. r. o. (Medicem s. r. on.d.), with six patents, and the University of Chemistry and Technology Prague and Beznoska s.r.o., with five patents each.

Figure 3. The most used International Patent Classification (IPC) codes for patents submitted by applicants from the Czech Republic in the medical devices area.

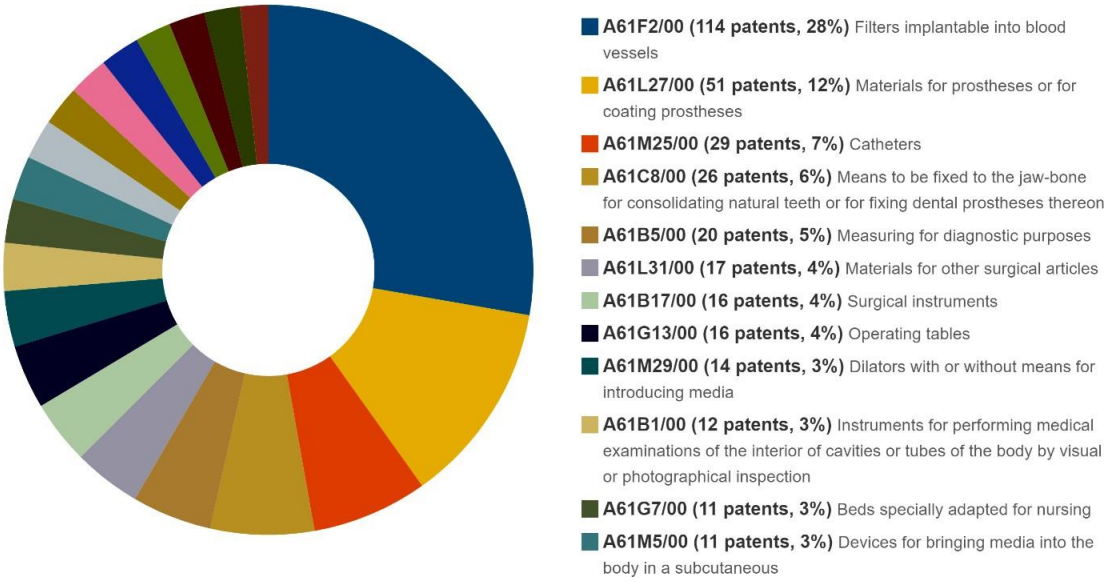
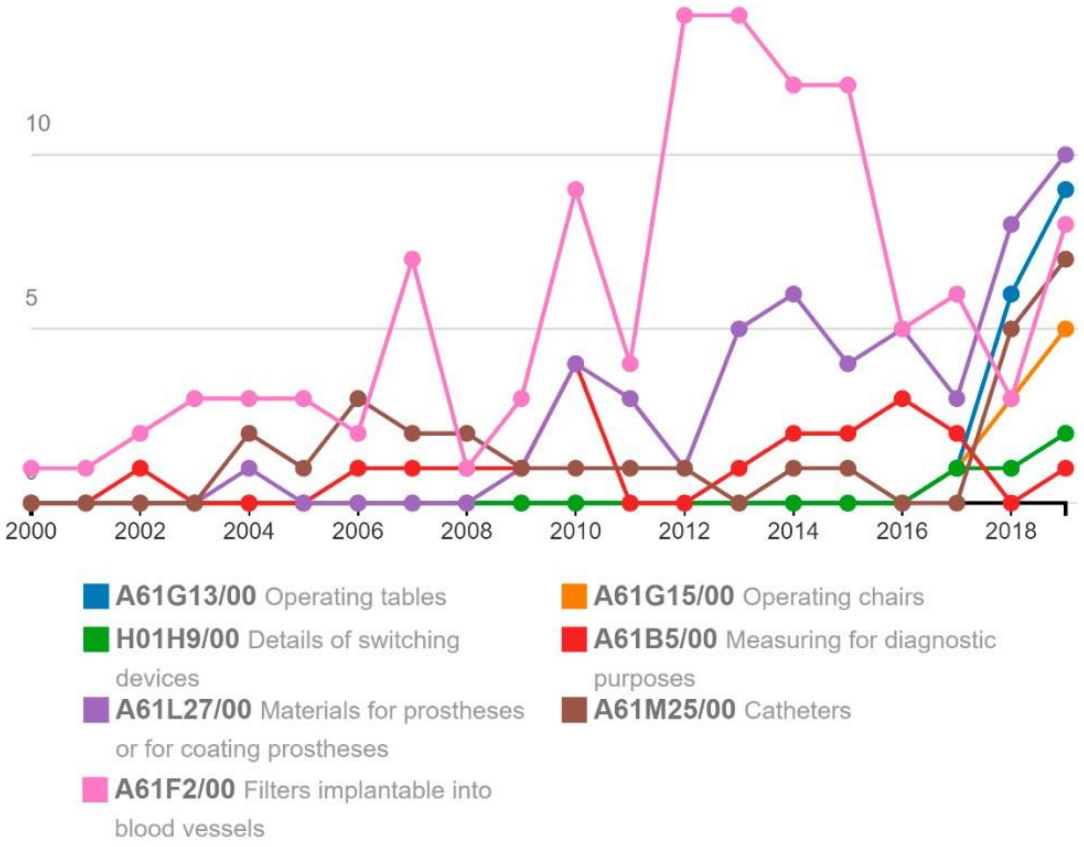


Figure4shows trends of patent applications from the last year for applicants in the Czech Republic. The trend grew to 10 and eight patents for 2019 and 2018, respectively, for A61L27. This category is continuously increasing and is covered by many companies, as mentioned. In the last three years, there has also been an interesting growth of A61G13—operating tables—with 16 patents, where the lone applicant is Borcad Medical a. s. Most of these patents are submitted by a family together with a world or European patent, and in several cases a Chinese patent application is included. This indicates an export orientation of companies to the entire world. There are also patents for medical devices for leg support.

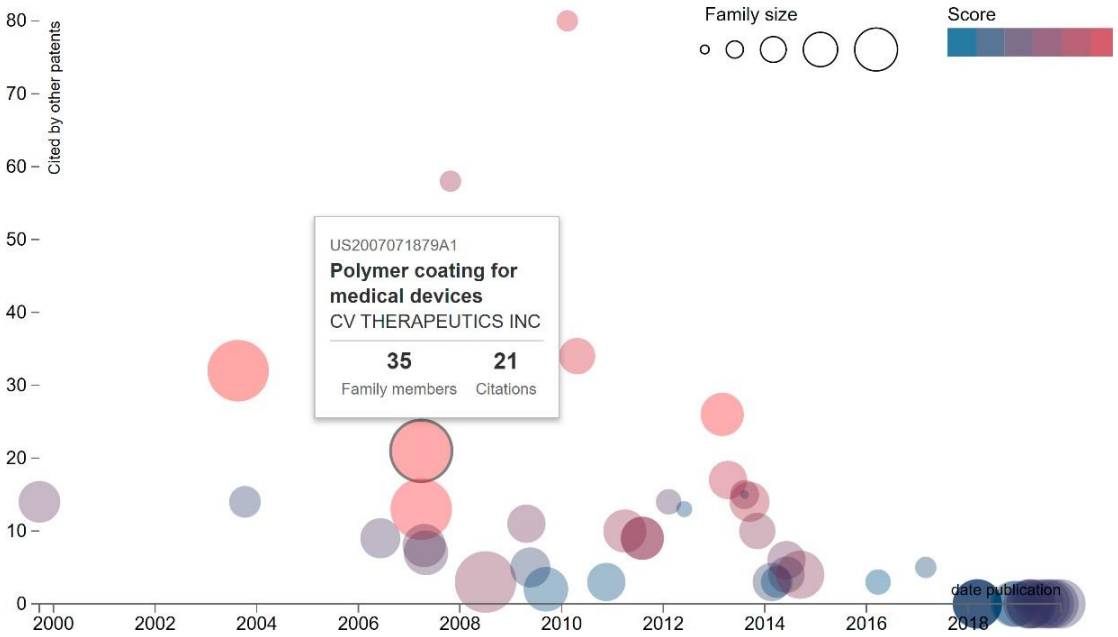
Figure 4. IPC code evolution for patents submitted by applicants from the Czech Republic for medical devices area showing patenting trends from 2000 to 2018.



The same company is also represented by the orange-colored category (A61G15), with five patents in 2019, again for medical devices for leg support.

Lastly, information can be obtained by a combination of family size of patent applications and forward citation count, as shown in Figure5. In general, the further away from the origin of the axes, the more valuable the patent is. This information is supported by many scientific articles that evaluated correspondence of these indicators for patent value and correspondence for company market value. However, there is also another interpretation for company or patent value. If only the number of forward citations is important, then the graph should be interpreted as 'higher is better'. If only the number of family members is, then only the size of the dot is important.

Figure 5. Patent value based on recency, family size, and forward citation size.



1. DISCUSSION

The need for a change in regulations has been emphasized in numerous studies (White and Walters2018) which drew attention to the fact that the current legislation favors the medical device manufacturers at the expense of the patients. Kent and Faulkner(2002) pointed out that the safety of end users is backgrounded while "commercial interests have dominated regulatory policy". They added that in this segment, innovation is faster than legislation, constituting an imbalance that needs to be redressed. Nelkin(1989), among others, expressed concerns about the growing number of medical device recalls and added that, given the increasing pervasiveness of innovative medical devices, the risk for the end user increases as well. Finally Leiter and White(2015), in their recent study, highlighted that "medical devices are increasingly being implanted in human bodies, constituting manufactured risks".

In this respect, the new MDR (EU MDR 2017/745 Gap Assessment and CE Transition Strategy for Medical Device Manufacturers2019) regulations are designed to focus on the safety of the patients first, which also means increased financial costs for the manufacturers.

As the new European legislation comes into effect, 2020 is going to be a challenging year for many companies in the medical device (MD) market. This is the case especially in countries where innovation activity overall is rather low. Such an example is the Czech Republic. An analysis performed on the case of the Czech Republic shows rather low patent activity in the Czech Republic. This has been confirmed by earlier research, where (European Patent Officen.d.) showed that the number of applications filed by companies with the European Patent Office (EPO) in the Czech Republic is more than one order of magnitude lower than rest of EU. This is not only in comparison with countries with high innovation performance, such as Denmark, Germany, or the Netherlands, but also with countries whose innovation performance is not very different from the Czech Republic. Unlike companies in countries with high innovation performance, Czech companies are

more likely to file priority patent applications with the Industrial Property Office, and only a small proportion of them continue with the next successive application. The creation and protection of industrial property has long been a weak point of the national innovation system of the Czech Republic (Inovacni Strategie-Nouvelle Lunen.d. ; Aliabadi et al.2017). While a number of strategic R&D and innovation (R&D&I) documents adopted over the past decade sought to improve this situation, the number of international patent applications under the Patent Cooperation Treaty1 (PCT) and the number of patent applications at the European Patent Office2 (EPO) remains well below the average of research and technology in the Czech Republic taking into account the size of the country. This is where many Czech companies view the new legislation as a threat.

Nevertheless, arguments presented in theoretical studies as well as statistical data of patent application activity in the medical device market in the United States corroborate that changes in regulations do not result in a decline of the industry. The example of the United States shows a rising trend of patent activity in this segment following the introduction of the new regulations and, at the same time, patent activity in the United States is relatively stable across all segments. While this may not be solely the result of the new legislation, it is clear that the change did not cause the medical device market to decline.

2. CONCLUSIONS AND POLICY IMPLICATIONS

The development, production, and use of medical devices is subject to a number of laws, regulatory schemes, strict standards, and certification processes, which focus mainly on safety. Criteria more often include user acceptability, either of the design or the reliability and ease of use in the clinical setting, and the competitive advantages of a new device versus alternative devices. Companies are under increasing market pressure with rapidly changing expectations on medical device usability, applications, and software development. Companies have to apply a faster product development cycle, maintain quality, and remain compliant with industry regulations. Product quality is always one of the main interests of medical device manufacturers. Therefore, significant time and budget must be expended on verification and validation (V&V). Each new product must go through a strict process of quality assessment (QA). Viewed from the perspective of companies in this segment, the conditions for the production of medical devices are demanding, both with respect to implementation and costs. It is, therefore, natural that further strict requirements are a cause for concern. On the other hand, given that the main reason for the existence of economic regulations are various forms of market failure, which occurs when market mechanisms do not lead to results that benefit society, any attempts to redress this situation—which in the case of the medical device market concerns in particular the asymmetry of information—should naturally lead to greater benefits for society, hence also benefits for the given industry.

Policy performance efficiency depends on institutional arrangements, economic structures and international dynamics as well as on socio-economic and infrastructure-related factors for their impact on the economic policy outcomes (Schmitt2012).

The medical device industry is subject to many of the same economic forces that affect all highly innovative industries. Device producers must make reasonable profits, ever vigilant of the commercial strategies and technological advances of competitors. Medical device innovation is influenced by public policy at every stage. Conventional measures of innovation cannot fully express the role and impact of government intervention. Public policies such as regulation, product liability statutes, reimbursement rules, and government funding for basic research have a significant impact on the production and diffusion of new medical devices.

A comprehensive policy analysis is complicated by the diversity of the medical device industry. These policies are intended to influence all stages of the innovation process, and they have different goals. Some promote innovation, others inhibit it. When the government begins to support health services through different programs, political interest could point to support for health services, which had more immediate and direct benefits to constituents than the less direct and long-range research goals. Public policy also has the potential to inhibit innovation in medical devices. Uncertainty is magnified when changes in a number of public policies can alter the incentives to produce or market a product. Various policies have different goals, emanate from different agencies and institutions, involve different decision-making processes, and change at different times, generally without consultation or coordination. Stratification of rules and regulations can lead to redundancy, conflicts, and deleterious interactions (Gelijns and Institute of Medicine (US) Committee on Technological Innovation in Medicine 1989).

The medical device innovation and production environment is formed by many different policies imposed by a variety of institutions. The innovation process is important, but other values, including safety, universal access, and cost controls, must be taken into account.

Conflicts of Interest:

The authors declare that they have no conflict of interest.

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