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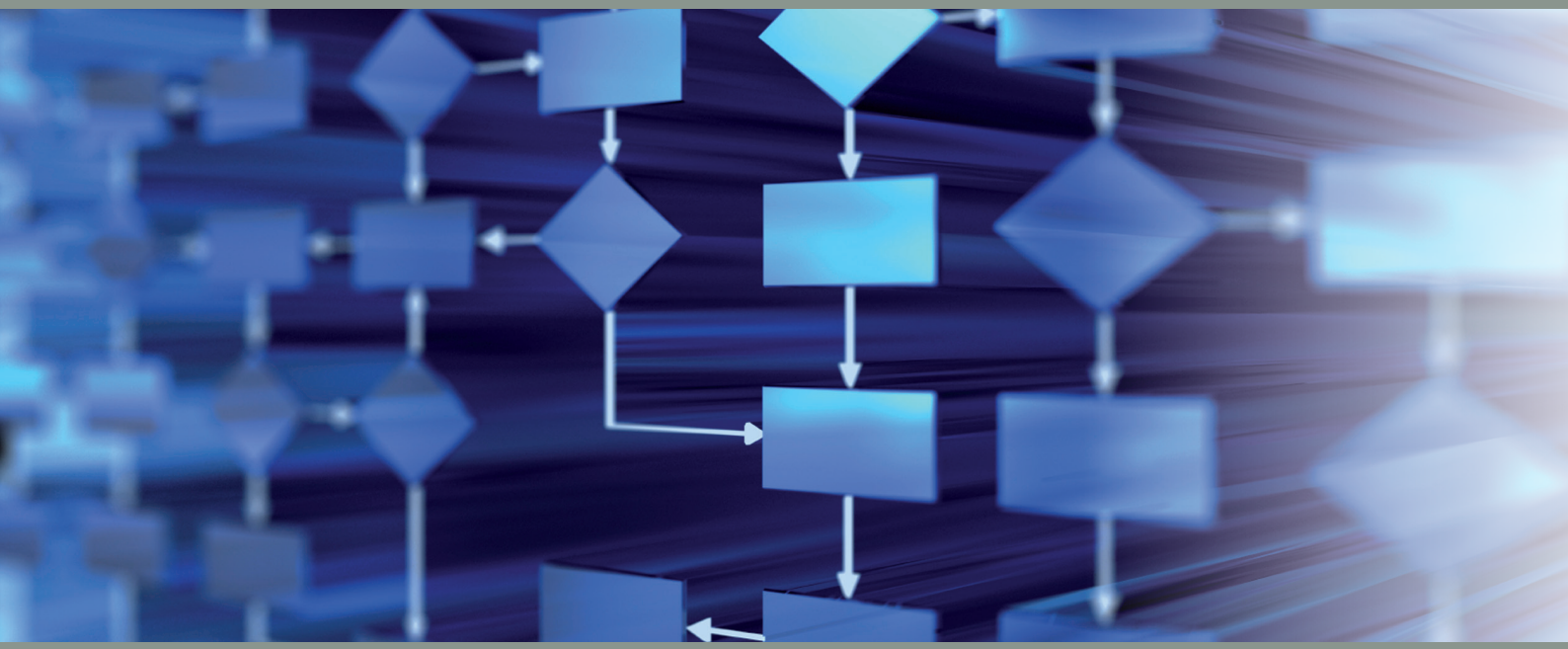

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Abstract

From 2006 to 2015, Polish health related patenting activities increased by an average of 13 percent annually, adding up to 3,463 health related patent and utility model applications worldwide and becoming the top Central Eastern European economy. Still, Poland only accounted for 2.7 percent of the European Union and had a low relative specialization on health related technologies within the EU zone. Moreover, most Polish patenting remains only national.

A limited number of higher education applicants accounted for 42 percent of patents and utility models, with a clear specialization in pharmaceutical technologies. Most private applicants were small and medium-sized enterprises, which specialized in medtech together with individual applicants. The innovative activity is concentrated in the provinces of Masovia, Lower Silesia and Silesia. In Masovia, business and public research organizations were more active, whereas higher education institutes dominated in Lower Silesia. In the Silesia province, the most innovative were business enterprises and higher education institutes. The five largest Polish cities – Warsaw, Wrocław, Lodz, Krakow and Poznan – accounted for 41 percent of all inventors.

Polish health related innovation is a collaborative – both co-patenting (15 percent) and co-inventing (75 percent) – although mostly domestic effort (95 percent). In medtech, business enterprises were more internationally oriented, while the same held true for higher education institutes and PROs in pharmaceutical technologies.

Poland's pharmaceutical specialization is on non-biological preparations (42 percent) and new chemical compounds (31 percent). Firms specialize in non-biological preparations and universities in new chemical compounds. Poland's medtech specialization is in diagnosis and surgery (subclass A61B, 34 percent) and prostheses, stents and orthopedic (subclass A61F, 18 percent).

Disclaimer and Acknowledgements

The views expressed in this paper are those of the authors, and do not necessarily reflect the views of the World Intellectual Property Organization or its member states.

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1 Introduction

In recent decades, advances in technology and institutions have revolutionized the health sector. Scientific breakthroughs in the field of life sciences have transformed the processes of drug development increasing the variety and volume of medicines supplied. However, the increasingly complex pathologies and approval requirements are often cited as reasons behind the cost increase for producing new medicines. Governments have responded with cost containment policies, intellectual property (IP) legislation, and increasing openness of domestic markets to foreign competition. All these factors have influenced patterns of industrial competition and the evolution of the healthcare industry structure (Gambardella, 1995; Gambardella *et al.*, 2000).

Healthcare is consuming an escalating share of income and investment in low-, mid- and high-income countries. Broadly defined IP, and patents in particular, are used intensively in the health sector (Cohen *et al.*, 2000; Silberston & Taylor, 1973). This is not limited to developed economies; it is also the case with emerging and developing ones (López, 2009). The challenges this sector is facing – including lack of capacity to transfer technology and IP protection – directly affect the downstream diffusion of knowledge.

Healthcare is a sectoral system of innovation with key stakeholders that are diverse in their innovative nature and hence have different incentives for making use of IP (Malerba, 1996, 2002). The characteristic stakeholders are the foreign and incumbent firms highly specialized in pharmaceuticals and biotechnologies, collectively referred to herein as "pharma" (Scherer, 2001). Firms developing medical devices and software technologies constitute another key segment of the health sector. These firms, specialized in medical technologies, referred to herein as "medtech", are part of a strong knowledge-driven industry involving several global leaders. It is also a very innovative sector characterized by a high density of inventors and innovators, as well as a high degree of innovativeness among the main consumers, which include medical schools and hospitals (Rosenberg and Gelijns, 1994; Gelijns and Rosenberg, 1995a, 1995b). In particular, medical devices, bioinformatics and telemedicine innovations rely heavily on the transfer of capabilities already generated outside the healthcare sector, making it not only inherently interdisciplinary but also outward looking by nature (Rosenberg *et al.*, 1995).

Firms in both the pharma and medtech industries interact with various other upstream and downstream stakeholders – such as hospitals and medical schools – to innovate (Powell *et al.*, 1996). Describing the use of IP by these stakeholders plays an important role in better understanding the innovative activities in the healthcare sector and each stage of the value chain. Effective patent protection of new healthcare technologies is crucial for both research and market oriented firms. Each stakeholder may have different incentives to make use of IP instruments, particularly in terms of securing the appropriation of their innovation and the knowledge sharing involved in the process.

This paper seeks to shed light on some of the issues related to the use of IP in the health sector in the context of a transition economy, such as Poland. It analyzes how the pharma and medtech industries in Poland make use of the IP system. In doing so, it will identify areas of excellence in innovation within the health sector, with the potential to support growth in the Polish economy.

As such, the key objectives of this report are: (i) to evaluate the scale and intensity of patenting activity in the healthcare sector in Poland, including as benchmarked against other EU countries; (ii) to identify and characterize Polish applicants patenting in Poland and abroad, including the level of collaboration; and, (iii) to identify technological specializations for inventions filed by Polish applicants.

2 IP legal framework in Poland

In Poland, issues concerning industrial property – including patent and utility model laws – are regulated under the Industrial Property Law Act of June 30, 2000.[1] This act has been harmonized with the law of the European Union (EU), in particular with respect to the European Patent Convention (EPC) of October 5, 1973.[2]

As in the rest of the EU, patents in Poland are exclusive rights granted with respect to inventions that are new, inventive and industrially applicable. This exclusivity means that the patent owner has an absolute right to commercially use the claimed invention throughout the territory for which the patent was granted, by stopping others from making, using, offering for sale, selling, and importing the claimed invention. Patents are generally granted for a maximum of 20 years.

In the pharma technologies, inventions are usually related to chemical compounds, biomolecules or medicinal formulations intended for the treatment or diagnosis of medical conditions by pharmacological, immunological or metabolic means. They also relate to processes for the manufacture of these products, as well as to various diagnostic methods based on the analysis of biological material.

In the area of medtech, the vast majority of claimed inventions pertain to medical devices that include various instruments, apparatus, appliances, materials or other articles intended to be used for treatment, prevention, monitoring, and diagnosis of human and animal diseases. For the purposes of analyses in this study, the broader term “medical technologies*”* is used instead of “medical devices”.

In the case of patents for medicines, the maximum protection time of 20 years can be extended by obtaining a Supplementary Protection Certificate (SPC).[3] The purpose of the SPC is to compensate the patent owner for the time that passes between the patent's filing date and the date the product is authorized for sale. The SPC is granted for medicinal products within the scope of the authorization and within the limits of the granted patent for a maximum period of five years. This term can be extended by six months if the medicinal product is suitable for children.[4]

Another form of protection for innovations is via the utility model: a special form of patent, sometimes referred to as a "petty patent". Like patents, utility models provide the right to exclusive use of the claimed innovation for a fixed period. However, the protection provided by utility models is not as strong as in the case of patents because the terms and conditions for granting a utility model are less stringent, and the maximum duration of protection is much shorter than for regular patents (10 years).

In Poland, a utility model may only relate to a specific, three-dimensional object defined by its technical characteristics, such as shape, construction or durable assembly. For a utility model to be valid in Poland, the invention claimed must be novel and useful. Thus, processes of manufacture, diagnostic methods, compounds, and medical uses are not

[1] The Act of 30 June 2000, Industrial property law (Journal of Laws of 2017, item 776)
[2] Convention on the grant of European patents of 5 October 1973 text as amended by the act revising Article 63 EPC of 17 December 1991 and by decisions of the Administrative Council of the European Patent Organization of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996, 10 December 1998 and 27 October 2005 and comprising the provisionally applicable provisions of the act revising the EPC of 29 November 2000
[3] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products
[4] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for pediatric use and amending Regulations

eligible for utility model protection. For the same reason, utility models are more popular in the medtech sector, where the shape or construction of a particular medical device may constitute an innovative technological idea. This innovation may be too incremental to meet the patentability requirements of a full patent but sufficient for utility model protection.

In Poland, inventors can acquire patent protection either by submitting a national patent application to the Polish Patent Office (PPO) or by validating a European patent (EP) granted by the European Patent Office (EPO). In the first case, an application can be filed directly to the PPO or alternatively as a national/regional phase of an international application filed via the Patent Cooperation Treaty (PCT). The PCT national phase or the EP validation require translation into the Polish language.

3 Methodology

The aim of the study is to provide in-depth analysis of patent activities in the Polish healthcare sector in order to assess the level of innovation in that field. Studying the pace of patenting and seeking the interdependencies within classes and groups of patents can help uncover the directions and dynamics of technological changes within the sector.

As part of the research work carried out, the following issues were analyzed:

- How do health sector applicants use the patent system in Poland and other EU countries?
- Who are the national stakeholders active in the health sector?
- What main trends and differences can be observed between academic and business sector applicants?
- Where does healthcare patenting activity occur in Poland?
- What is the degree of national and international collaboration among Polish inventors and applicants?
- What technological specializations are observed within the pharma and medtech industries in Poland?
- Which markets do Polish healthcare innovators seek protection in?
- Is Poland an attractive market for foreign patent holders?

In order to answer these questions, this study makes use of various data fields found within patent documents for describing the main directions of the research being carried out, the inventive activities, as well as the innovative and competitive potential of economies. This is based on patent activity being a well-established measures of innovation activity and reflecting, at least partially, the technological dynamics of companies and other stakeholders of a country or a region (OECD, 2009).

This study focuses mainly on Polish patent and utility model applications for healthcare technologies filed in Poland and abroad. Due to the small number of utility model applications in Poland, if not indicated otherwise, they were analyzed together with patent applications and collectively referred to as applications or filings. This analysis took into consideration the applications with a priority date between January 1, 2006 and December 31, 2015.

The main sources of data used in the study were the PPO's internal database (SOPRANO)[5] and the EPO's database (PATSTAT)[6]. The analyses relating to the activity of Polish and foreign applicants in Poland were conducted using the SOPRANO database. The analyses of the worldwide patent activity of Polish applicants compared to other European applicants and those regarding EP validations in Poland and other EU countries by foreign applicants were conducted using the PATSTAT database. In particular, we made use of PATSTAT Global, which contains bibliographical data relating to more than 100 million patent documents from most industrialized countries and several developing ones. This data is complemented by the PATSTAT EP Register, which contains bibliographic and legal status data on published European and Euro-PCT patent applications.

This study makes use of the International Patent Classification (IPC) symbols allocated to patent documents to identify patent applications concerning healthcare technologies. The full list of selected IPC symbols and the search methodology employed is described in table A.1 in the Annex. All applications included in the study were divided into two groups: pharma inventions and medtech inventions. Applications with IPC symbols for both fields were treated as belonging to medtech.

The applications classified in A61K or A61P were regarded as pharma inventions. Filings containing IPC codes only for the compounds or biomolecules per se (e.g. C07D or C07K alone) were not included in the study, as it was determined that they did not directly concern pharmaceutical applications. In the pharma field, we also included patent applications pertaining to the analysis of biological material (e.g. blood, urine) for diagnostic purposes, which are classified in G01N33/48 or G01N33/50 and their subgroups. For a more complete picture of diagnostic methods, the applications classified in C12N and C12Q that have the keyword "diagnos*" in the abstract were also recognized as falling within pharma.

Additionally, based on the methodology developed by the authors, five specific technological specializations were distinguished in the pharma field: (a) new biologics, (b) biological preparations, (c) new chemicals, (d) non-biological preparations, and (e) diagnostics. Owing to the fact that one application may have several IPC symbols assigned, ranked according to the complexity of a given technical problem (from the most to the least complex), the main IPC symbol assigned to it in the first instance was used to determine a specific technological specialization. The definitions of individual pharmaceutical specializations and the IPC symbols used to define them can be found in table A.2 in the Annex.

To identify inventions in the field of medtech, the IPC symbols indicated in the WIPO technology concordance table – which links the IPC symbols with 35 fields of technology – were used (Schmoch, 2008). Applications in the following subclasses were included: A61B, A61C, A61F, A61G, A61H, A61J, A61L, A61M, A61N, and H05G. Subsequently, applications with IPC symbols not relating directly to healthcare were excluded (see table A.1. in the Annex).

However, due to a vast variety of medtech innovations in relevant IPC classes, the authors of this working paper refrained from applying the similar methodology to select specializations. Instead, it has been assumed that each of the 10 aforementioned subclasses constitutes a technological specialization. Please refer to table A.3 in the annex for a detailed description of each IPC subclass.

The analysis of the technological specialization was carried out using a Relative Specialization Index (RSI), which is calculated by comparing the share of applications

[5] The database legal status of 13 November, 2017.
[6] PATSTAT Online Autumn edition, 2017.

originating from each country in a given technology area to the share of the total number of applications originating from that country in all technology areas[7]. The index is equal to zero when the participation of a given country in a given technology area is equal to the share of all applications filed in all technical fields. If the index is positive, a specialization is observed[8].

We have grouped the entities filing the IP rights applications into five categories: higher education institutes (HEI); public research organizations (PROs), which include research institutes and scientific units of the Polish Academy of Sciences; individuals (IND); foreign entities (Non-residents); and business enterprises (BES), which include all entities not belonging to the previous categories.

Applications were assigned to a given country according to the unique countries of residence of the applicants. This means that all applications with at least one applicant residing in Poland were considered domestic (Polish) applications. This also means that applications with two or more applicants originating from different countries were counted as one application from each of these unique countries, irrespective of the number of applicants. The same applies to other features, such as the type of entity or the legal form that may differentiate jointly submitting entities.

It is worth noting that this methodological approach results in the sum of applications from all countries or from all entity groupings being larger than the sum of all unique applications within a respective database. The features of the domestic applicants, such as the legal form, the form of ownership, the declared number of employees and the type of prevailing activity (PKD) analyzed in the subchapter were determined based on data from the National Official Business Register (REGON). For 51 entities (8 percent), the above features could not be determined due to the deletion of these entities from the register. The exception is the legal form, which was assigned to 32 missing entities.

4 Results

This section explores in detail how the healthcare industry in Poland makes use of the IP system. It presents the main features characterizing this phenomenon and compares them with current trends in the EU. The main national stakeholders of the patent system active in the healthcare technologies were also identified and the most important differences between them were identified and presented in a geographical context, thus identifying the main clusters and their specializations. In addition, the level of collaboration between stakeholders filing healthcare applications in Poland was analyzed, and the patent strategies applied by these entities were described.

4.1 Recent trends in health industry use of the patent system in Poland and the EU

We identified 126,986 IP rights applications in PATSTAT as healthcare technologies filed worldwide by entities from EU countries from 2006 to 2015. Of these, 92 percent were

[7] The RSI formula is $RSI = \log10\left(\frac{n_i/n_{total}}{N_i/N_{total}}\right)$, where n_i is the number of IP rights applications in healthcare technology from a given country, n_{total} is the total number of applications in healthcare technology, N_i is the total number of applications in all technologies from a given country and N_{total} is the total number of applications in all countries and all technologies.

[8] A patent analytics study on the Australian Pharmaceutical Industry, 2015 r.,p.12, available at: https://www.ipaustralia.gov.au/sites/g/files/net856/f/patent_analytics_study_on_the_australian_pharmaceutical_industry.pdf [retrieved 2 August 2018]

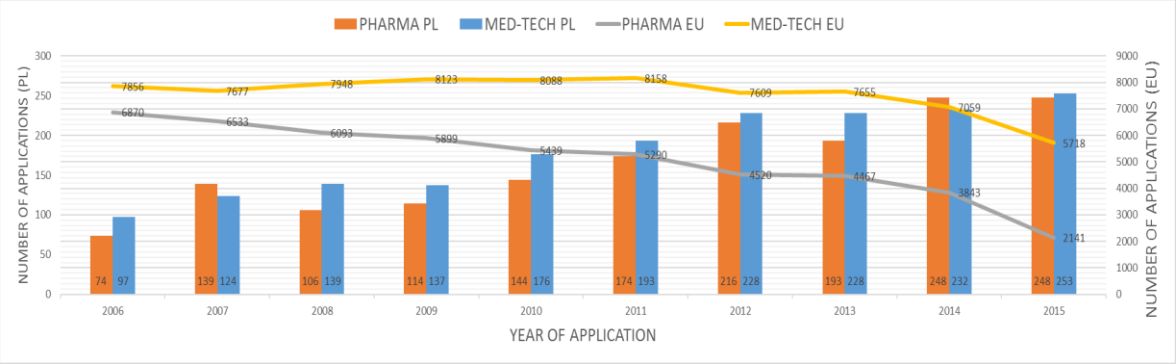
patent applications and 8 percent were utility model applications. Of the total number of applications, 41 percent related to pharma and 59 percent to medtech.

The total number of applications from EU countries presented above also includes 3,463 applications filed by entities from Poland, of which 1,807 (52 percent) related to medtech and 1, 656 (48 percent) to pharma. Over the analyzed period, the annual number of the applications increased from 171 to 501, which represents an average annual growth of 13 percent. (Figure 1).

The aforementioned values refer to the number of simple patent families[9] to avoid multiple counting of the same technology applications (based on the same priority) seeking protection simultaneously in other patent offices.

In total, from 2006 to 2015, the PPO received 3,275 healthcare technologies applications from domestic and foreign entities. Of this, Polish applicants submitted 3,209 applications: 1,683 in medtech and 1,518 in pharma (53 percent and 47 percent respectively).

Figure 1: EU and Polish healthcare technologies filed worldwide by year 2006-2015.



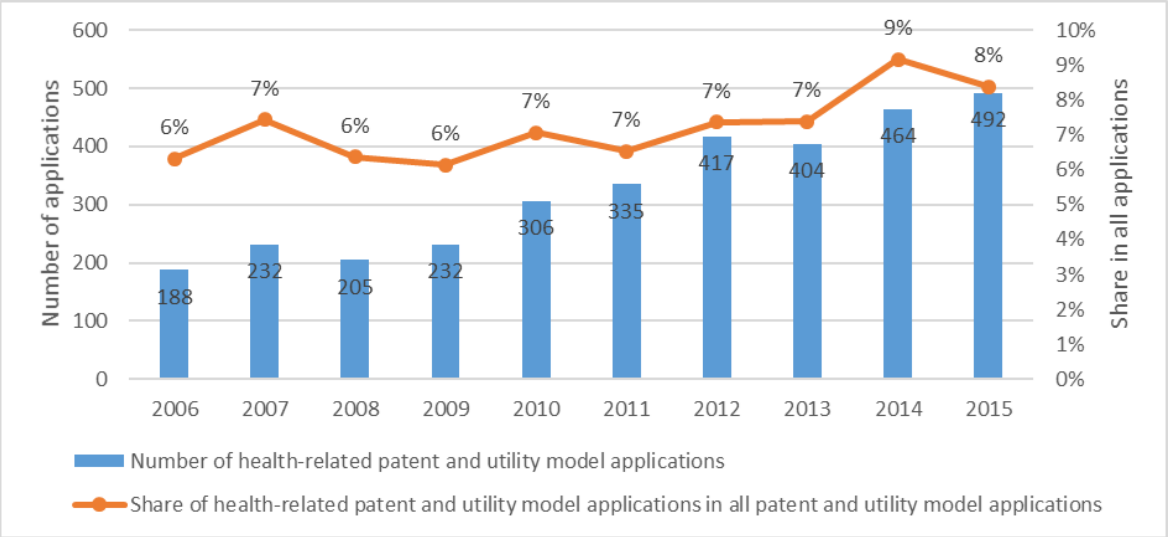
Source: PATSTAT Online Autumn edition, 2017. Notes: DOCDB simple patent families count; data for the years 2014 and 2015 are incomplete.

Over this decade, the annual number of the healthcare technologies filed at the PPO increased from 188 to 492, which represents an average annual growth of 11 percent (Figure 2). This increase was slightly higher than the increase in the total number of applications in Poland during this period. As a result, the share of healthcare applications in the total number of applications in Poland increased from 6 percent to 8 percent.

Such a strong positive trend differs significantly from the trend for the EU as a whole. Since 2011, there has been a drop in IP rights applications originating from the EU in the medtech field. In the case of pharma, applications decreased throughout the whole period considered (Figure 1).

[9] DOCDB simple patent family is a collection of patent documents that are considered to cover a single invention. The technical content covered by the applications is considered identical. Members of a simple patent family all have exactly the same priorities.

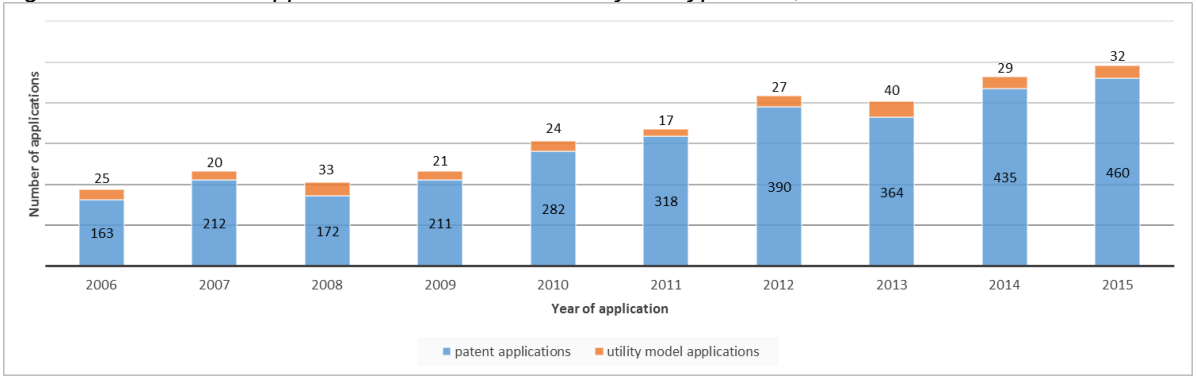
Figure 2: Healthcare applications filed at the PPO, 2006-2015.



Source: SOPRANO database.

Out of 3,463 healthcare technology applications filed by Polish entities worldwide, only 270 made use of utility model protection. The utility models also represented a small share of healthcare technologies filed at the PPO (Figure 3). The share was 8 percent on average, but it fluctuated noticeably throughout the period. This share peaked in 2006 and 2008 reaching 13 percent and 16 percent respectively; in turn, it only amounted to 5 percent of all applications in 2011.

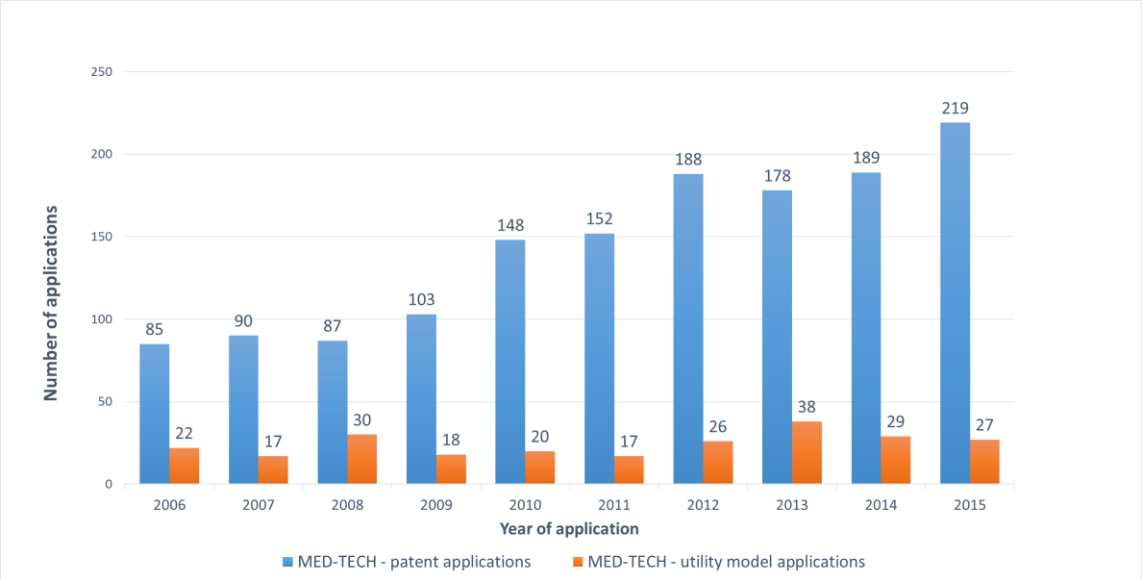
Figure 3: Healthcare applications filed at the PPO by the type of IP, 2006-2015.



Source: SOPRANO database.

The creators of utility models filed at the PPO from 2006 to 2015 constituted only 6 percent of all national creators. It is also worth noting that basically all healthcare utility models applications submitted at the PPO by domestic entities relate to medtech, and their number is still relatively low (Figure 4). In light of this, patent and utility models applications will be presented together on subsequent charts.

Figure 4: Patent and utility model applications filed at the PPO by domestic entities in medtech, 2006-2015.

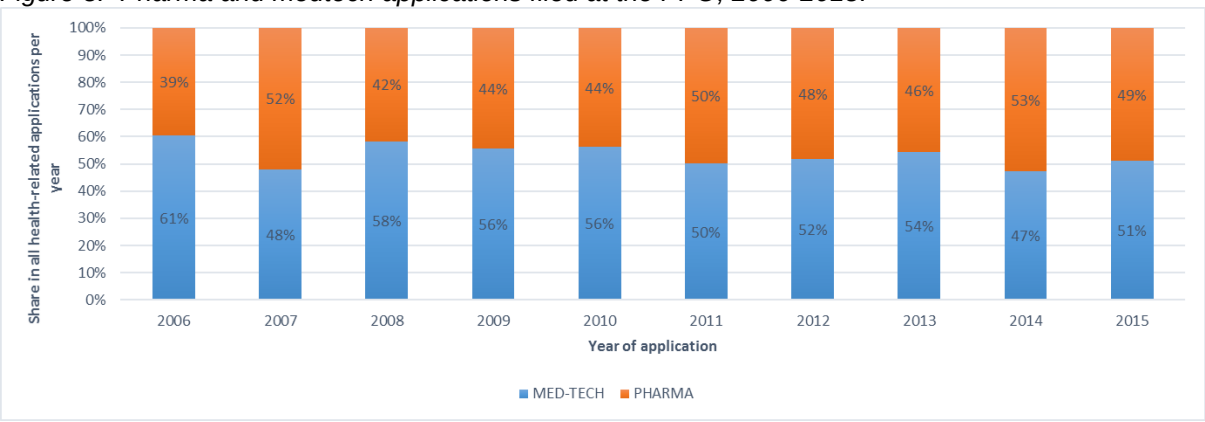


Source: SOPRANO database.

Over the analyzed period, the overall number of IP rights applications in pharma and medtech was relatively stable (Figure 5). This is quite remarkable as medtech R&D expenditures are much lower than those observed in pharma industries (Wisła and Sierotowicz, 2018).

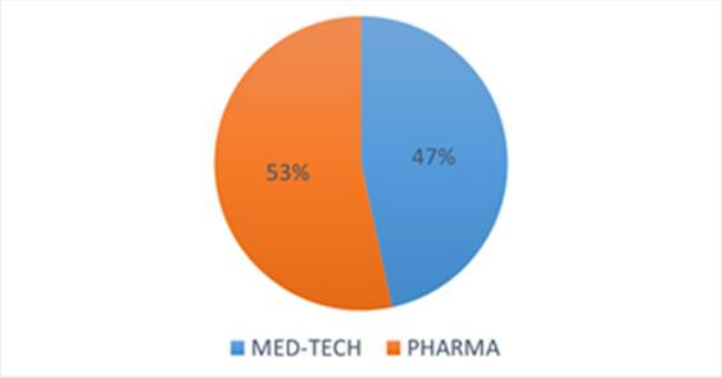
Taking into account the number of applications from all years, the share of applications in medtech amounted to 53 percent and in pharma to 47 percent. A similar proportion can be observed by analyzing the number of creators of national healthcare technologies according to particular technical fields (Figure 6).

Figure 5: Pharma and medtech applications filed at the PPO, 2006-2015.



Source: SOPRANO database.

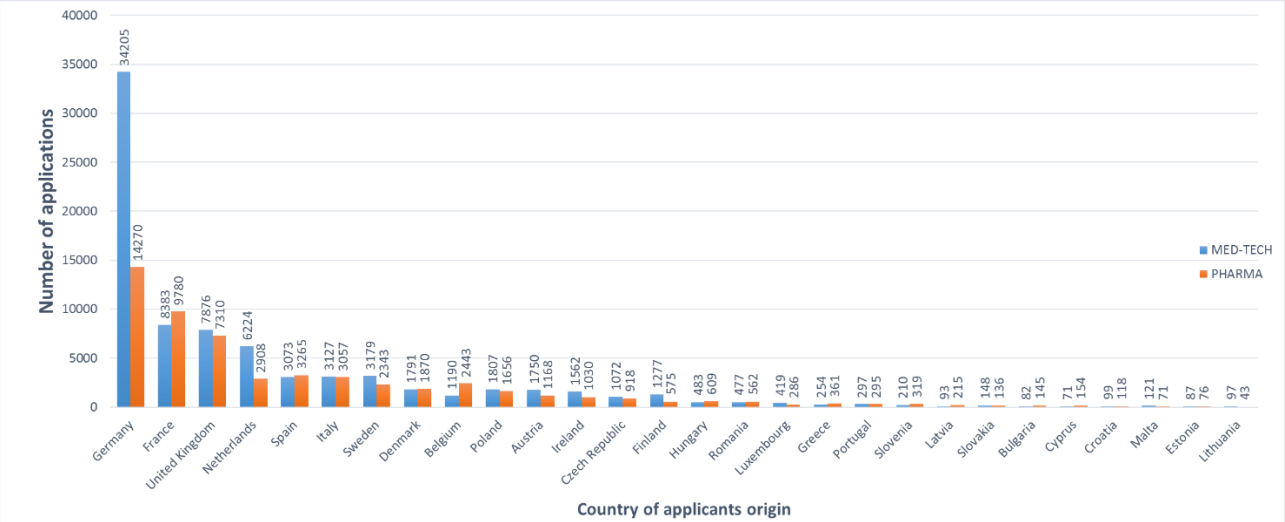
Figure 6: Domestic inventors of healthcare applications by field, 2006-2015.



Source: SOPRANO database.

Among the EU applicants, Germany, France and United Kingdom filed the largest number of applications in the field of healthcare technologies in the period covered (Figure 7). The domination of these countries is not accidental, because it is also observed when comparing the total number of applications in all fields of technology. It is worth emphasizing that the number of applications from Germany in the field of medtech was greater than the sum of this type of applications from the remaining seven top filing countries. Moreover, many EU economies, as well as the EU as whole, had more medtech patent filings than pharma ones. This is the case with Germany, the United Kingdom, the Netherlands, Italy and Sweden, among others (Figure 7).

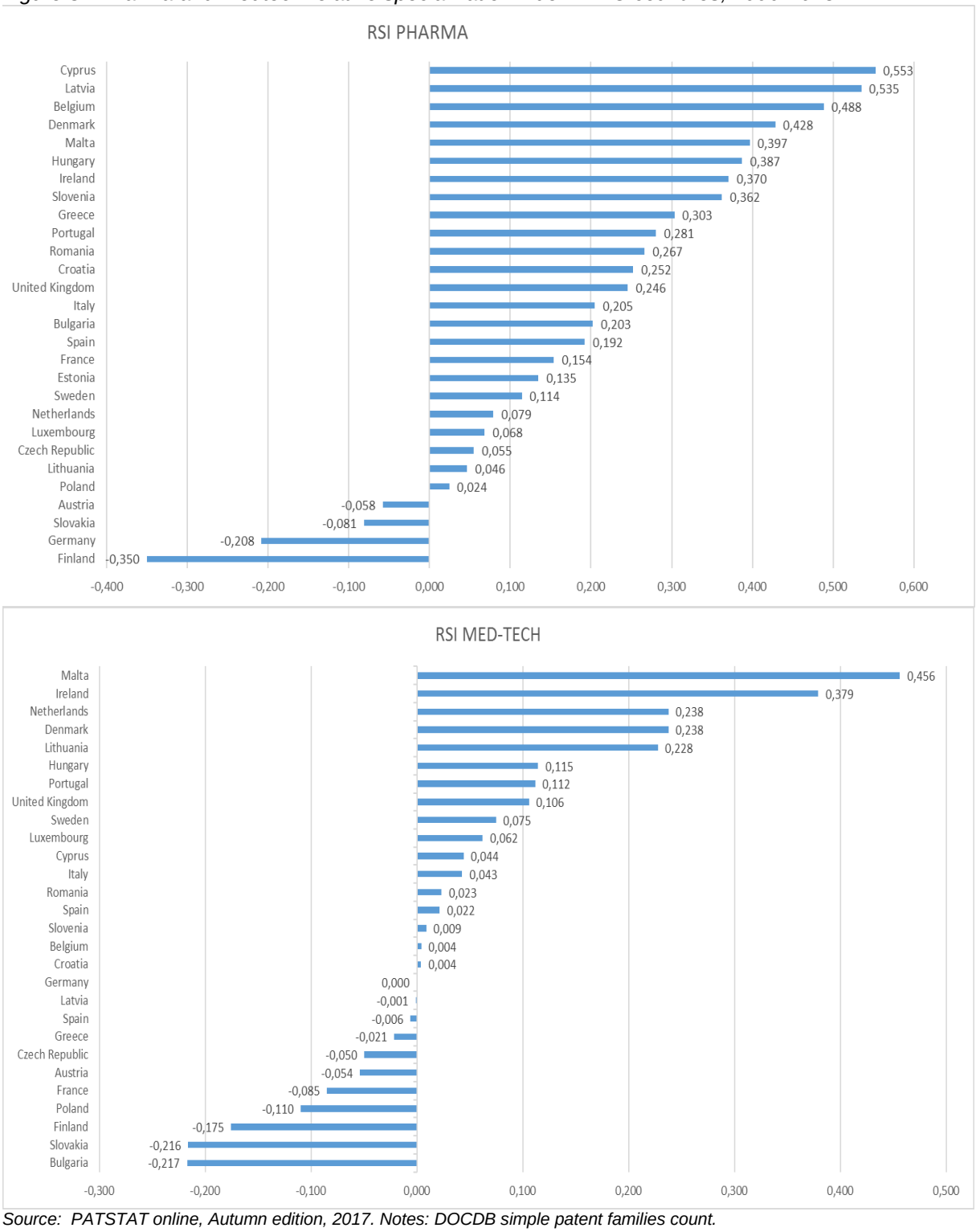
Figure 7: Pharma and medtech filed worldwide by EU country, 2006-2015.



Source: PATSTAT Online Autumn edition, 2017. Notes: DOCDB simple patent families count.

Poland accounted for 2.7 percent of the total healthcare technologies in the entire EU area (Figure 7). Among EU countries, Poland ranked 10th, just below Belgium and higher than Austria, Ireland and all other Central Eastern European (CEE) countries. However, Poland has a low relative specialization index (RSI) for healthcare technologies when compared to other EU economies (Figure 8). Poland is among the least specialized EU countries in pharma and has a negative RSI in medtech. Denmark – which had almost the same number of applications as Poland – was in the fourth place in both fields. Germany, the largest origin for pharma technologies, has the second lowest level of specialization, with a highly negative RSI in this field.

Figure 8: Pharma and medtech relative specialization index in EU countries, 2006-2015.



Source: PATSTAT online, Autumn edition, 2017. Notes: DOCDB simple patent families count.

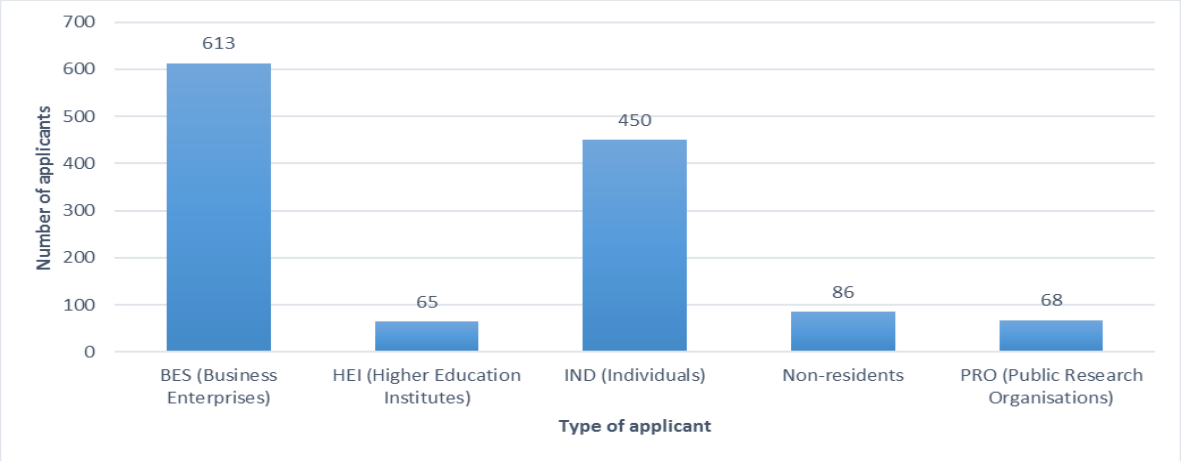
4.2 Who uses the patent system in Poland?

From 2006 to 2015, 1,282 domestic and foreign health sector entities filed for patent and utility model protection (IP protection) at the PPO. On average, these applicants filed 2.5 applications per decade. It is worth noting that some of these applications were filed by several co-applicants.

Most of these applicants were resident business enterprises and individuals (Figure 9). The academic sector includes 65 domestic higher education institutes, 44 research institutes and 24 scientific institutes of the Polish Academy of Sciences (referred to collectively herein as PROs). Only 86 applicants were foreign entities, but this figure excludes those foreign applicants filing in Poland through EP validations.[10]

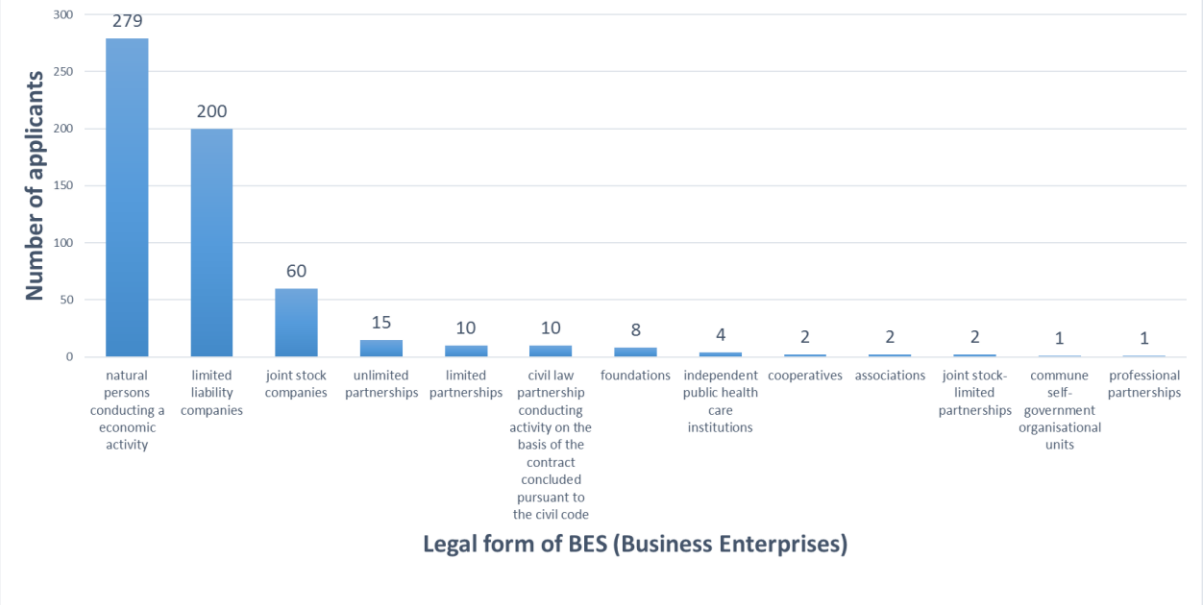
In terms of the country of origin, the applicants were an extremely homogenous group, as 93.3 percent of them were based in Poland. However, the low percentage of foreign entities filing directly and via PCT route at the PPO does not mean that Poland is not an attractive area for them in the context of maintaining protection of their exclusive rights. Rather, it results from the fact that, since Poland's accession to the European Patent Convention in 2004, most foreign applicants have applied for patent protection in Poland via the European procedure or the Euro-PCT route (Table 6).

Figure 9: Number of healthcare technologies applicants by type of entity, 2006-2015.



Source: SOPRANO database.

Figure 10: Business enterprises filing for healthcare technologies by type of business, 2006-2015.



Source: SOPRANO database and REGON.

[10] Analysis of the European Patents validations were described 4.8.

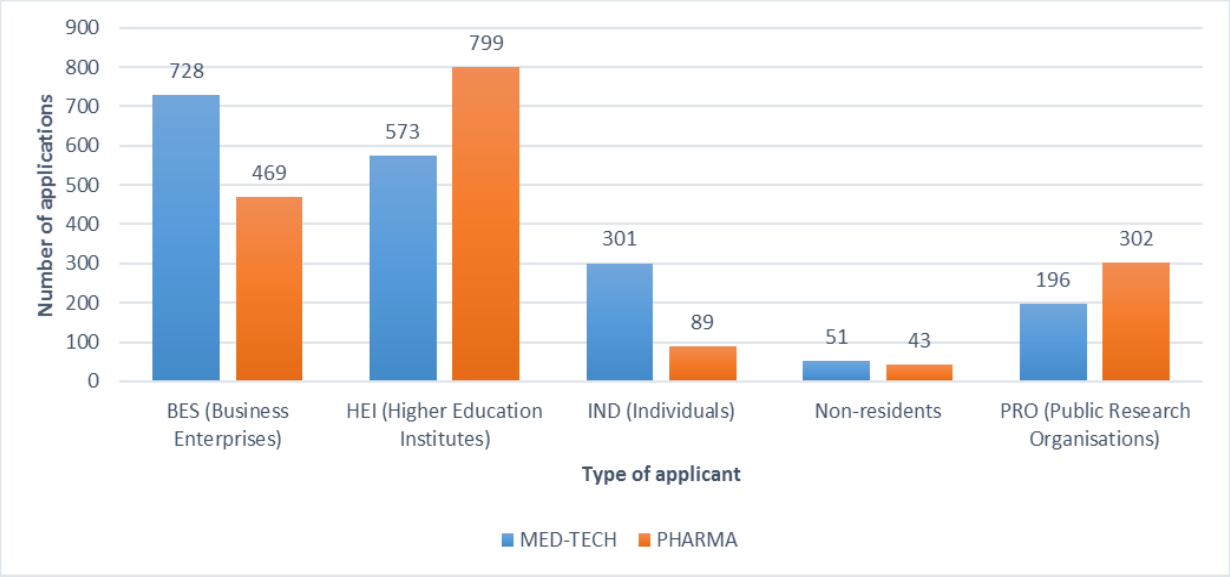
The business sector is the most represented group of domestic entities filing healthcare technologies at the PPO from 2006 to 2015. Figure 10 shows business enterprise applicants by the type of business. Out of the 613 registered businesses, 279 were individuals or sole operators conducting economic activity (46 percent), 200 were limited liability companies (33 percent), and 60 were joint-stock companies (10 percent). The sum of sole business operators and individual applicants for IP rights in general produces a total of 729 applicants (57 percent) filing as individuals, either as a registered business in their own name or not (Figure 9 and Figure 10).

As for the number of healthcare applications, higher education institutes – the least numerous category of entities – account for the largest share of applications (42 percent). Moreover, academic entities seem relatively more specialized in pharma technologies than in medtech. Academic entities filed almost twice as many pharma applications as individuals and business enterprises in total (Figure 12). However, there are also differences within academic institutions. PROs belonging to the Polish Academy of Sciences structure are more specialized in pharma technologies than those outside it.

Domestic business enterprises show the highest activity in the field of medtech. Together with Polish individuals, they filed 60 percent of all medtech applications at the PPO. The relatively small share of applications belonging to the large group of individual applicants indicates that these are applications with several applicants (Figure 9 and Figure 11).

Utility models applications accounted for 11 percent of applications from the business sector: 16 percent of these applications were from individuals and 22 percent from non-residents. By contrast, only 3 percent of applications from the science sector were for utility models.

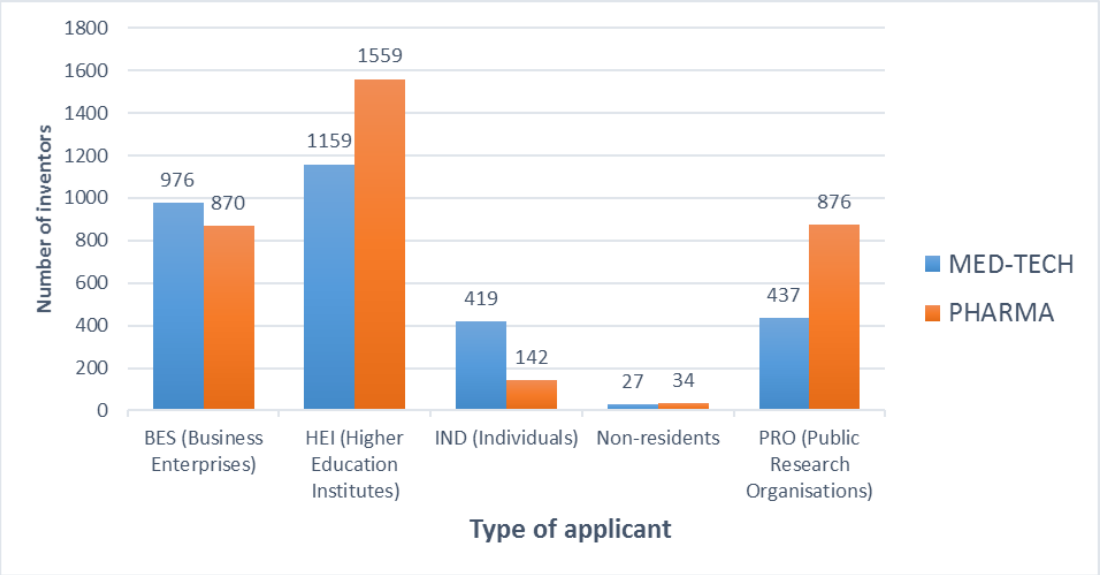
Figure 11: Pharma and medtech applications by type of entity, 2006-2015.



Source: SOPRANO database.

Most national inventors worked on technologies filed by higher education institutes (Figure 12). Thus, one national inventor working for the university accounted for an average of 0.52 applications filed in the PPO. In the case of other types of domestic entities, this ratio was 0.65 for business enterprises, 0.70 for individuals, and 0.39 for PROs. For comparison, this indicator for Polish inventors working for foreign entities amounted to 0.44 applications per person, while it amounted to 0.61 on average for all applications (Figure 11 and Figure 12).

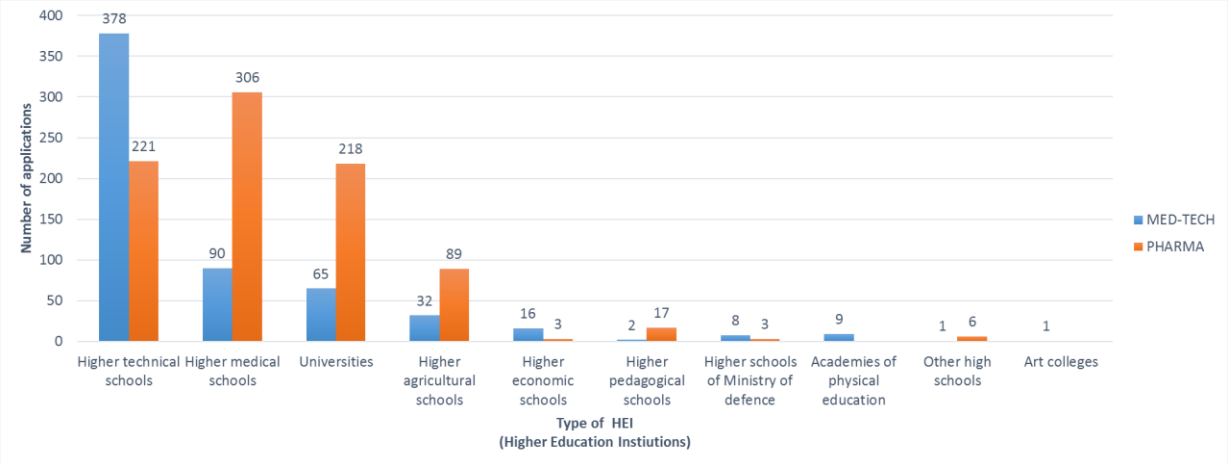
Figure 12: Number of inventors in pharma and medtech by type of entity, 2006-2015.



Source: SOPRANO database.

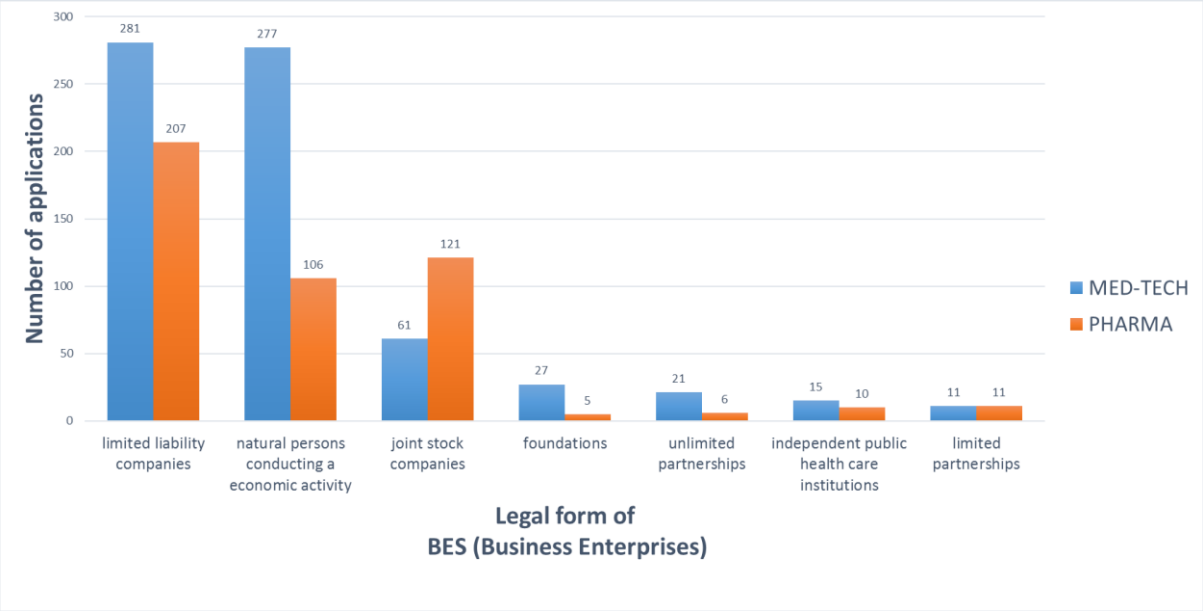
A significant portion of applications in the field of medtech from higher education institutes resulted from research and development carried out in higher technical schools (Figure 13). Medical universities were at the forefront in patenting of drugs. A significant part of pharma applications also came from other universities, including the Jagiellonian University with Collegium Medicum, which plays the role of a typical medical school. It is interesting that higher economic schools and physical education academies have also been involved in the development of medical technologies. An interesting case is the Social Academy of Sciences in Łódź, which filed eight patent and eight utility models applications in the field of medtech during the analyzed period.

Figure 13: Pharma and medtech by academic entity type, 2006-2015.



Source: SOPRANO database.

Figure 14: Pharma and medtech by business enterprise entity legal form, 2006-2015.

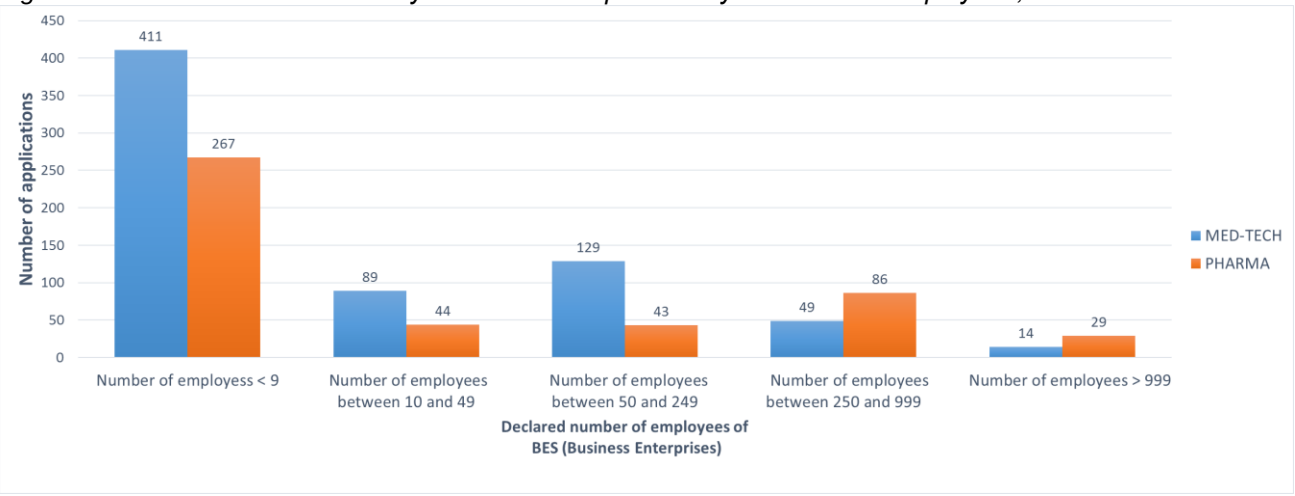


Source: SOPRANO database. Notes: The figure presents the types of the legal form to which 20 and more applications can be assigned.

Companies and individuals are more specialized in medtech than pharma. Sole operators, limited liability companies and joint-stock companies account for about 90 percent of the technologies filed by business enterprises. Sole operators field a significant share of applications, out of which 25 percent were medical or dental practitioners. Both individuals and limited liability companies specialized in the field of medtech while joint-stock companies specialized in the pharma field, which may be attributed to the higher costs of research activities in this field (Figure 14).

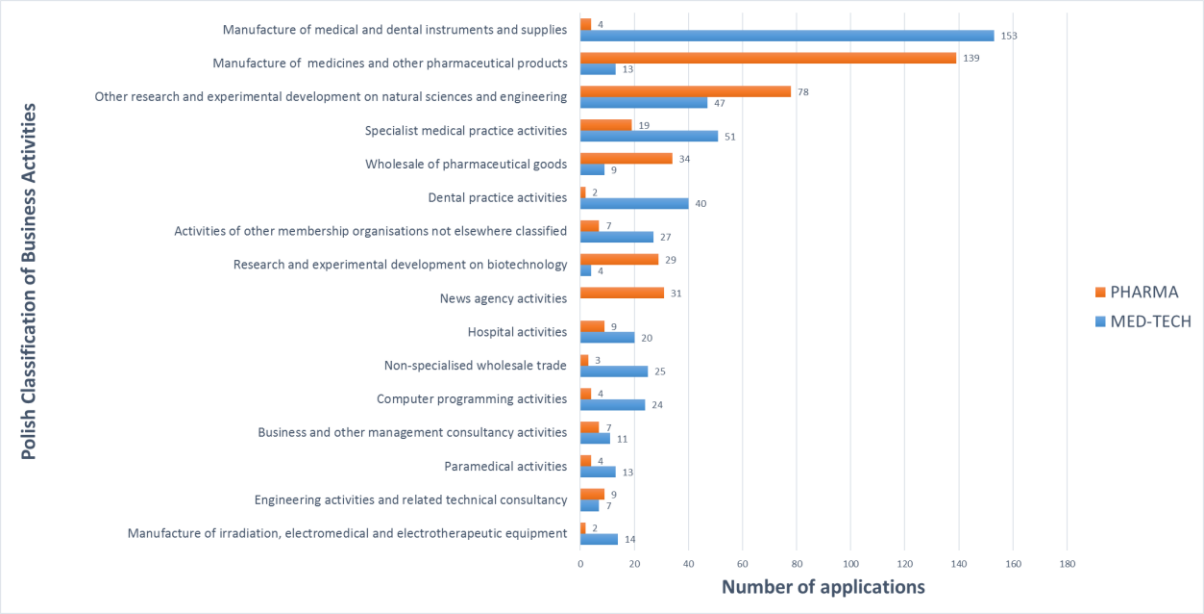
Microenterprises – i.e. companies with less than 10 employees – accounted for 57 percent of the applications filed by business enterprises. Micro, small and medium enterprises – i.e. entities employing up to 250 staff – were the dominant group of applicants who filed over 80 percent of applications in this sector. (Figure 15).

Figure 15: Pharma and medtech by business enterprise entity's number of employees, 2006-2015.



Source: SOPRANO database and National Official Business Register REGON.

Figure 16: Pharma and medtech by business enterprise industry, 2006-2015.



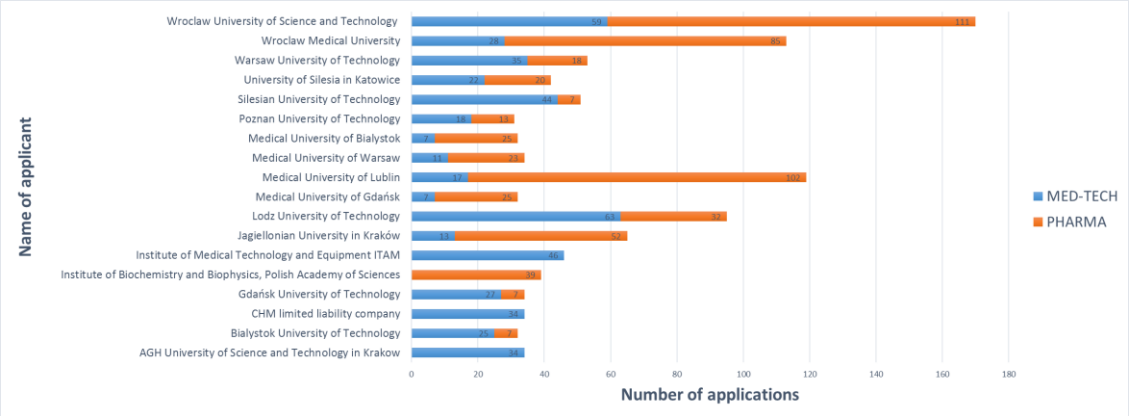
Source: SOPRANO data base and National Official Business Register REGON. Notes: classification into industries follow PKD[11].The figure presents PKD to which more than 15 applications can be assigned.

In relation to the industry of the applicants, we observe that the most represented industries were those related broadly to the health sector, such as: manufacture of medical and dental instruments and supplies (PKD 3250Z), manufacture of medicines and other pharma products (PKD 2120Z), other research and experimental development on natural sciences and engineering (PKD 7219Z), and specialist medical practice activities (PKD 8622Z). These industries filed more than 40 percent of applications from business enterprises (Figure 16). These applicants also included economic entities defining their dominant activity as, for example, news agency activities (PKD 6391Z) or non-specialized wholesale trade (4690Z).

HEIs account for most of the top filing resident entities from 2006 to 2015 (Figure 17). The three most active HEI applicants were the Wrocław University of Science and Technology, the Medical University in Lublin and the Wrocław Medical University. In contrast to other entity types, top filing HEI often contribute to both pharma and medtech, although with a disposition towards pharma. The first ranked non-HEI applicant is a PRO, the Institute of Medical Technology and Equipment (ITAM), which ranked ninth. The first ranked business company is CHM LLC (15th). CHM LLC is also the only entity in this top filing group filing more utility model applications than patents. The other applicants listed in the ranking file for utility model protection only rarely.

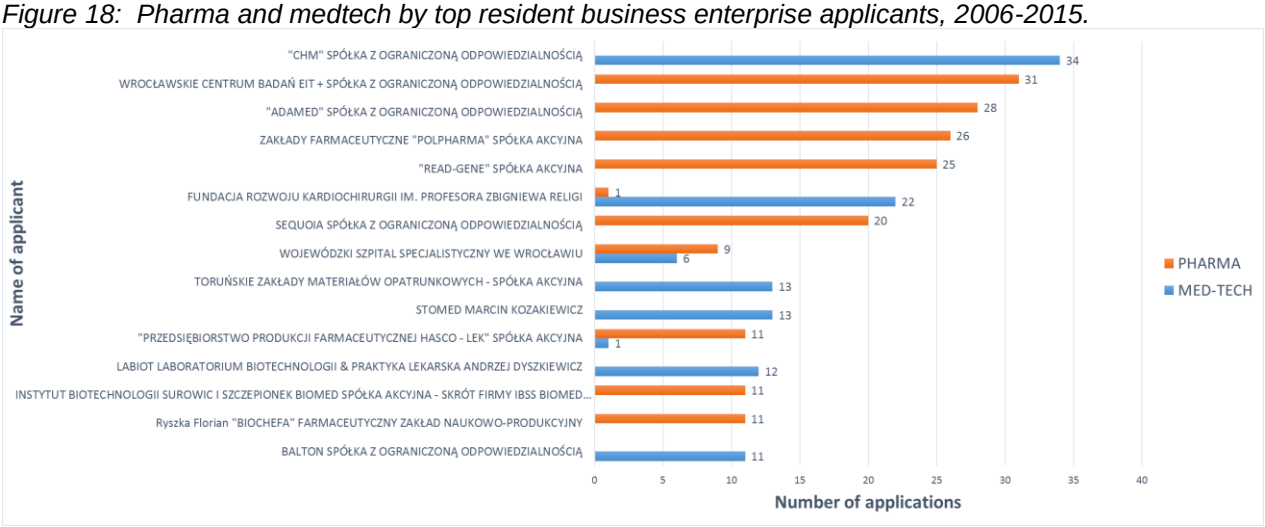
[11] PKD is a classification which hierarchically systemizes division of the kinds of social-economic activities that are carried out by economic units.
https://stat.gov.pl/en/metainformations/classifications/#Polish%20Classification%20of%20Activities%20%28PKD%29

Figure 17: Pharma and medtech by top applicants, 2006-2015.



Source: SOPRANO database. Notes: The ranking includes entities that filed more than 30 patent and utility model applications in the health sector at the PPO in 2006-2015.

Figure 18: Pharma and medtech by top resident business enterprise applicants, 2006-2015.



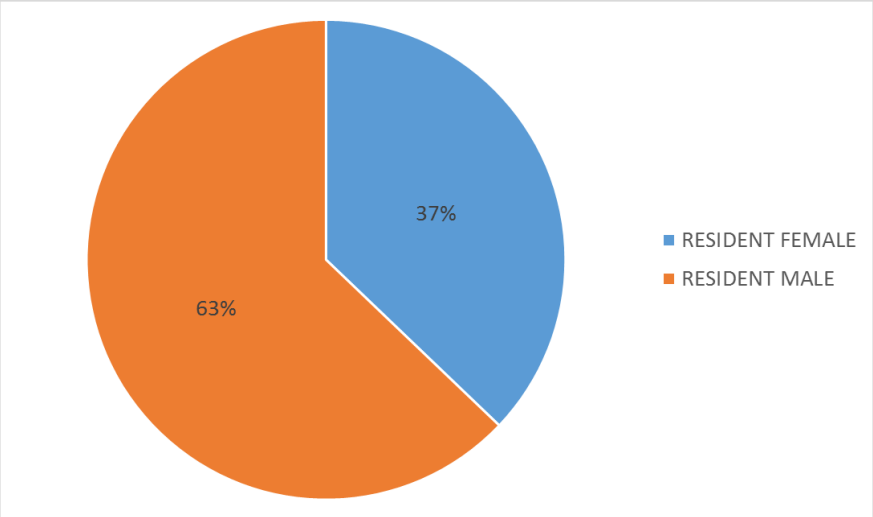
Source: SOPRANO database. Notes: The ranking includes resident business enterprise applicants that filed more than 10 patent and utility model applications in the health sector at the PPO in 2006-2015.

The Wrocław Research Center EIT+ LLC (WRC EIT+) follows CHM LLC.[12] In most other cases of business enterprise entities, applicants had filed applications only in one field. The only exceptions were the Foundation of Cardiac Surgery Development, Professor Zbigniew Religa, the Provincial Specialist Hospital in Wrocław, and the Pharma Production Company Hasco-Lek S.A. (Figure 18).

Finally, a gender analysis of inventors was also carried out. Gender was identified based on the inventors' names. The share of men among active inventors in the health sector was 26 percentage points higher than the share of women inventors (Figure 19). Throughout the 10 years, the higher share of male inventors persists. However, there is a slight increase observed in total female inventors. The largest difference between the share of women and men in the analyzed years was in 2009 (Figure 20).

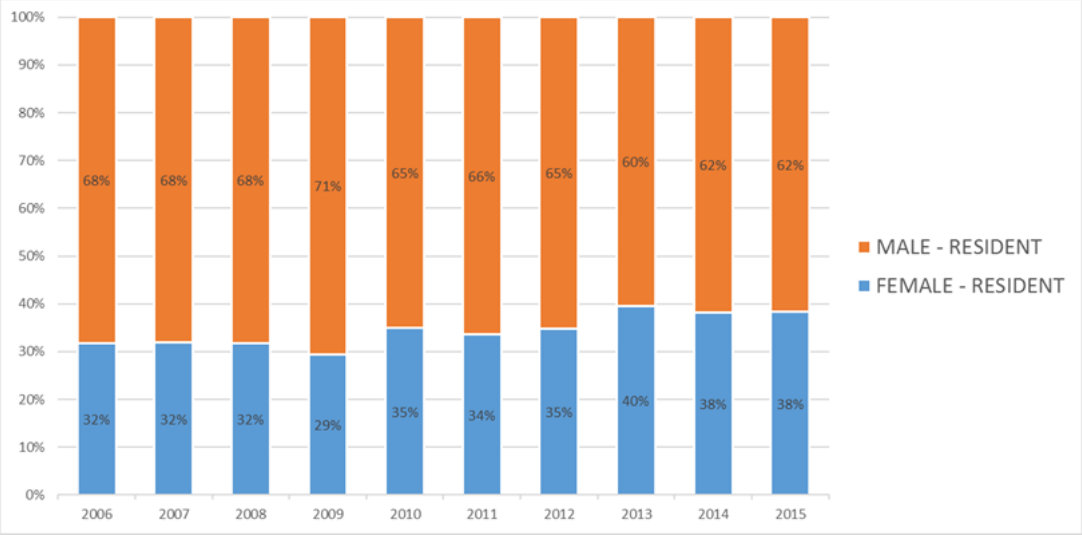
[12] WRC EIT+ is an example of effective collaboration between the scientific community and local government. WRC EIT + combines the features of an enterprise and a research institute with the aim of supporting the Polish economy through the development of new technologies and conducting interdisciplinary scientific research.(www.eitplus.pl)

Figure 19: Domestic inventors in the health sector by gender, 2006-2015.



Source: SOPRANO database.

Figure 20: Domestic inventors in the health sector by gender by year, 2006-2015.



Source: SOPRANO database.

4.3 Where are the healthcare technological clusters in Poland?

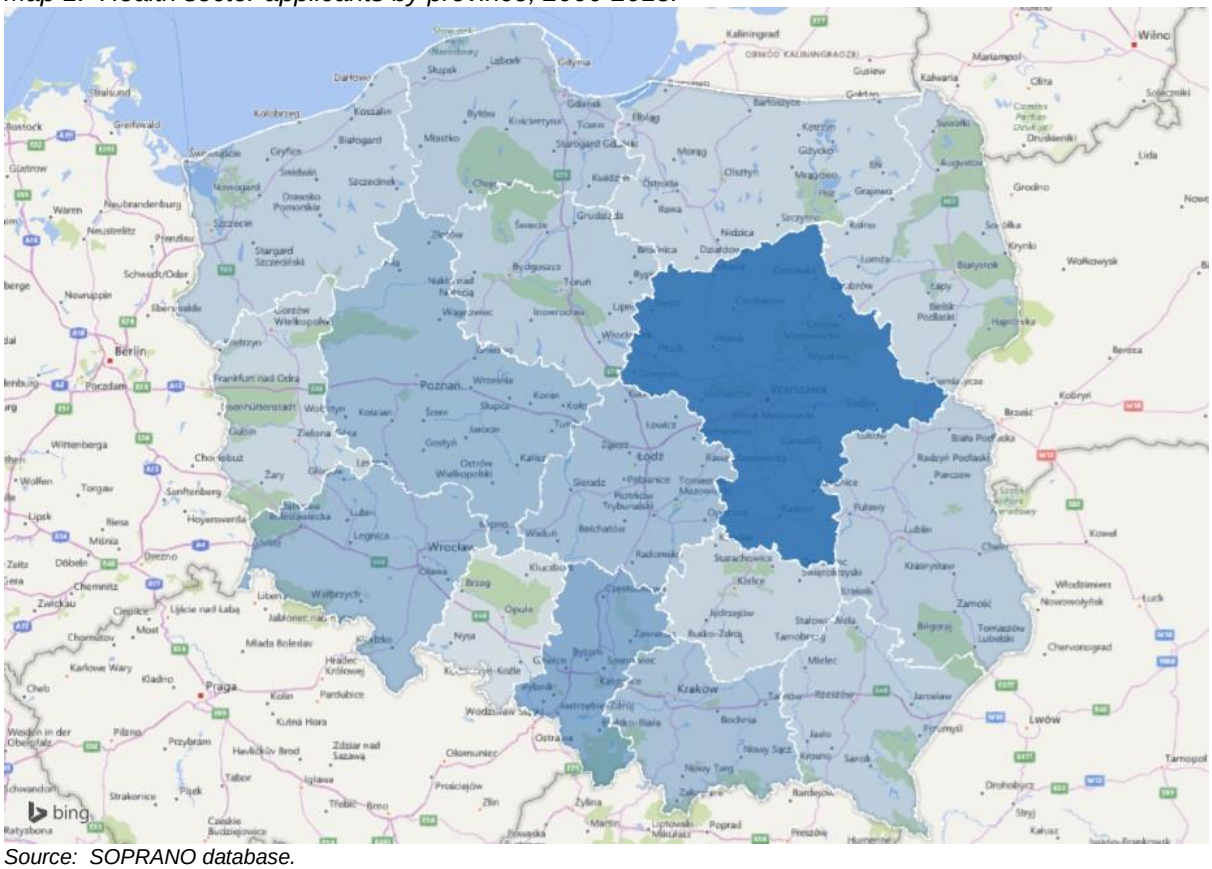
In terms of location, the Masovia Province had the largest concentration of domestic entities (27 percent) filing for healthcare technologies (Map 1). More than 100 applicants each were observed in the Silesia (160), Greater Poland (110) and Lower Silesia (104) Provinces. This should not come as a surprise as these are the regions with the largest numbers of registered national economy entities.

Taking into account the number of applications filed by these entities, it is worth noting that two Provinces dominated, namely Masovia and Lower Silesia. In the case of both provinces, pharma applications prevailed. A large number of applications also came from the Silesia Province, which like most of the provinces, specialized in medtech. The least active applicants were from the Opole Province. Such a geographical distribution of applications is probably a consequence of the fact that the most active applicants have their headquarters in the dominant provinces, both from the science and the economic sector (Map 2).

In the case of the Masovia Province, the most active were entities from the business sector as well as research institutes and scientific units of the Polish Academy of Sciences. By contrast, in Lower Silesia and Lesser Poland, the highest number of applications came from HEIs. While business sector and HEIs applicants stand out in the Silesia Province.

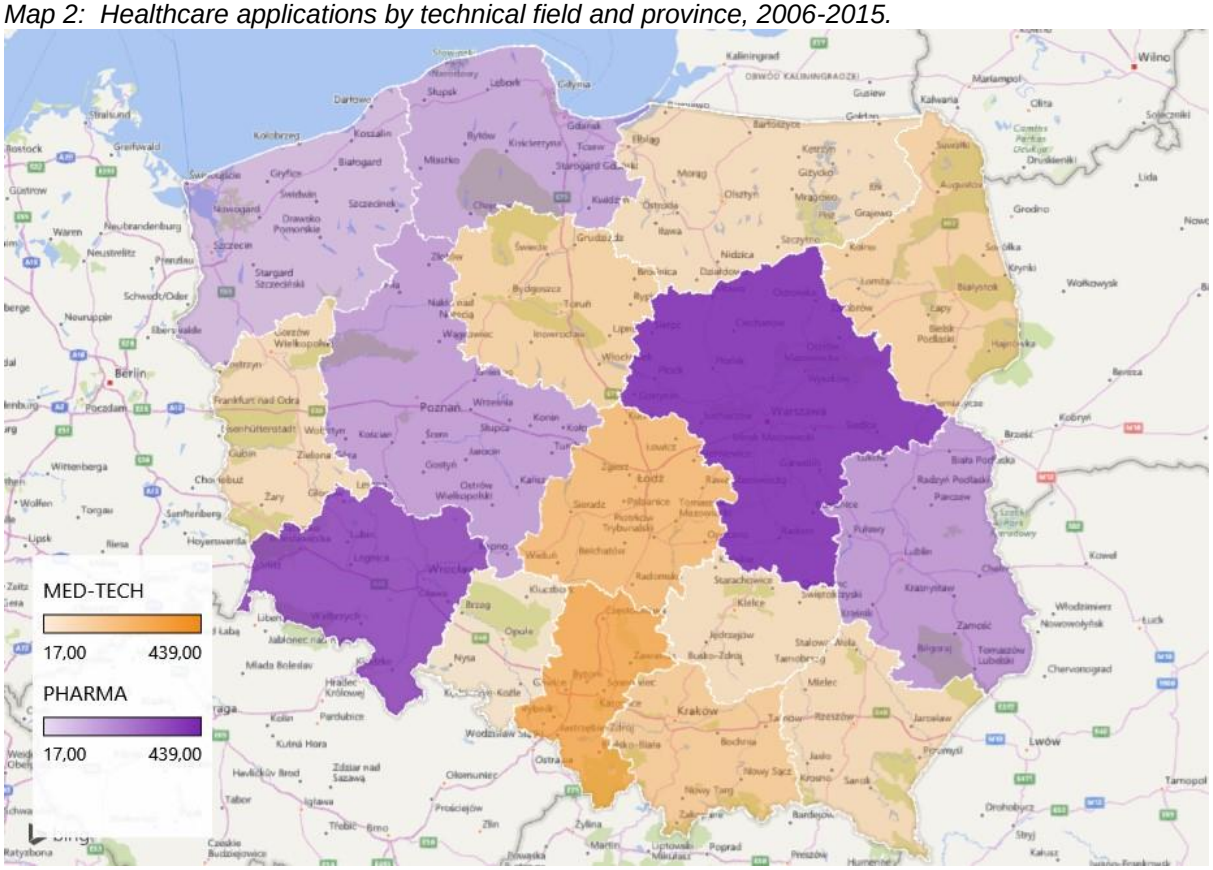
As in the case of the most active applicants (Map 3), the majority of domestic inventors came from the major urban centers, such as Warsaw (867 inventors), Wrocław (516), Lodz (340), Krakow (253) and Poznan (219). In total, 41 percent of all domestic inventors have their place of residence in one of these five cities. Out of urban centers that are not provincial cities, Gliwice (57 inventors) and Zabrze (47 inventors) stand out, consistent with observations made as to the number of applications.

Map 1: Health sector applicants by province, 2006-2015.



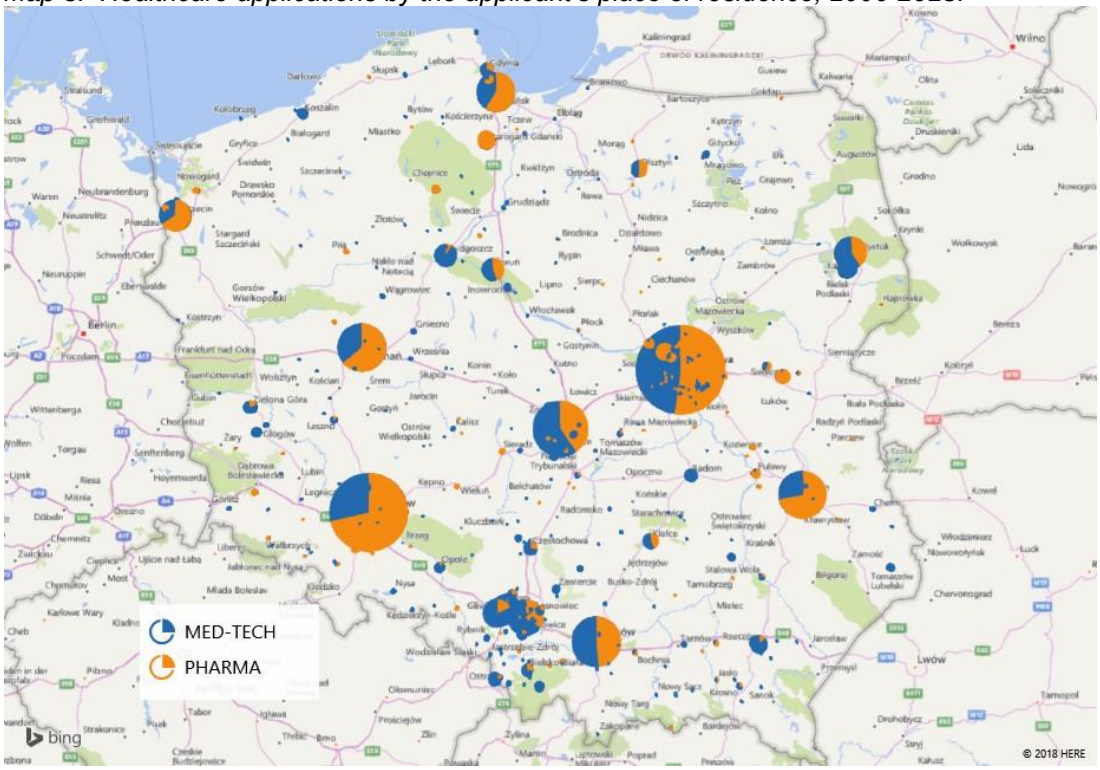
Source: SOPRANO database.

Map 2: Healthcare applications by technical field and province, 2006-2015.



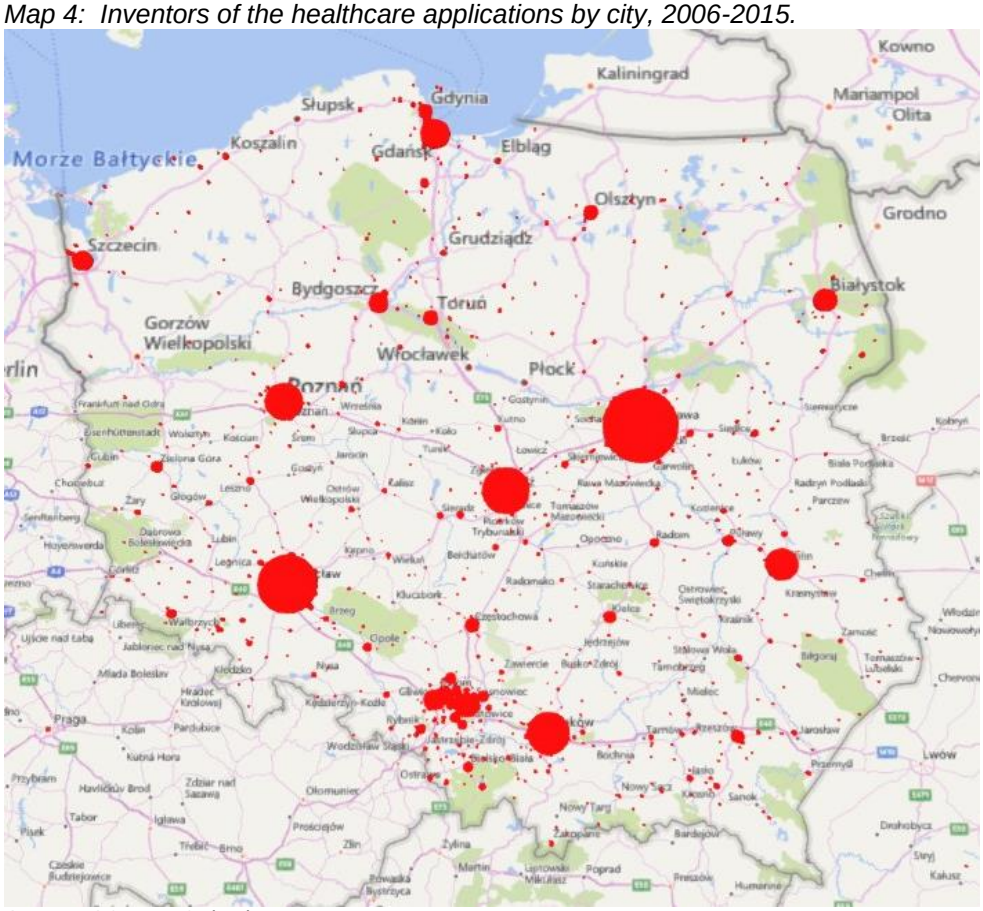
Source: SOPRANO database. Notes: Color indicates the dominant specialization and its intensity the number of applications.

Map 3: Healthcare applications by the applicant's place of residence, 2006-2015.



Source: SOPRANO database.

Map 4: Inventors of the healthcare applications by city, 2006-2015.



Source: SOPRANO database.

4.4 Collaboration for innovation

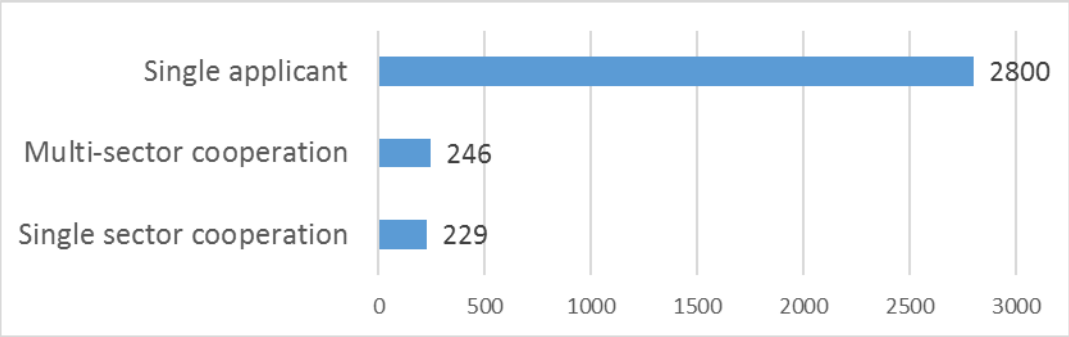
4.4.1 Collaboration between applicants

The first step in defining the process of collaboration in the health sector was identification of applications for IP rights filed by at least two applicants at the PPO in the years 2006 to 2015. These applications were analyzed with respect to their frequency as well as the number and the type of co-applicants.

This approach makes it possible, among other things, to track the development of business relations that contribute to the creation of technology clusters and dissemination of knowledge, and also helps to assess the level of interest in foreign expansion or investment.

Based on the analysis of 3,275 applications for IP rights filed at the PPO, it was established that 475 (15 percent) were filed by at least two applicants. It can be assumed that these applications were the result of collaboration between those entities. At the same time, we can see that there was no dominating model of collaboration, as there were 229 applications filed jointly by entities of the same type, which represents 48 percent of the total number of applications with multiple applicants. In the case of the remaining 52 percent of applications, we observe collaboration among entities from various categories (Figure 21).

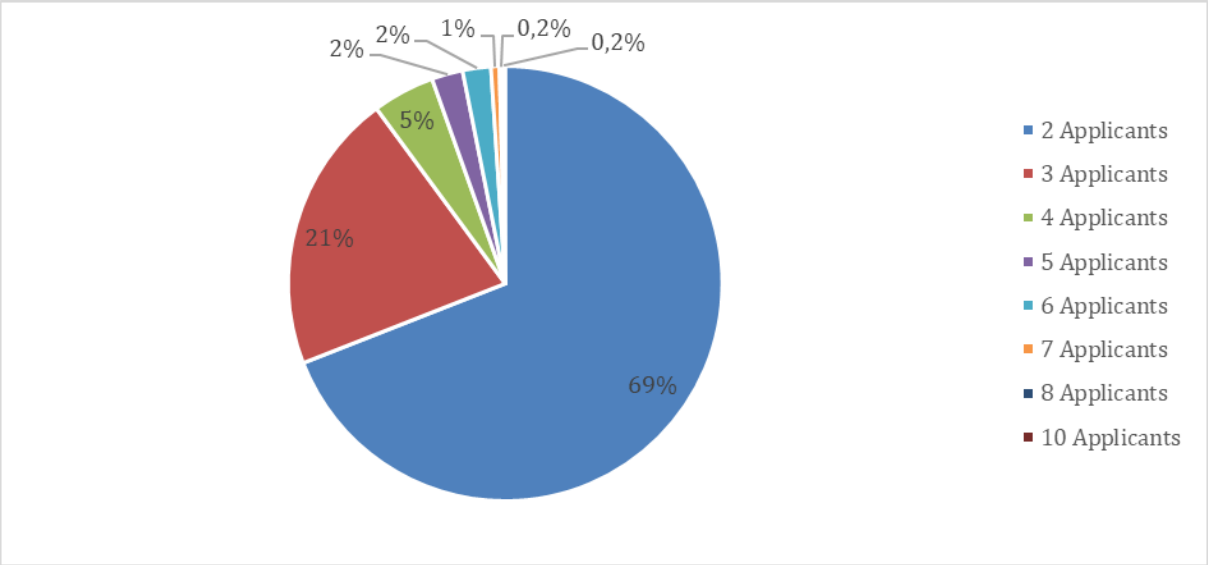
Figure 21: Healthcare applications filed at the PPO by type of collaboration, 2006-2015.



Source: SOPRANO database.

As for the analysis of the number of co-applicants, collaboration between two (69 percent) or three (21 percent) applicants is most common. The remaining 10 percent are cases of collaboration between more than three applicants. There was one application filed jointly by eight applicants (seven individuals and one business entity) as well as one application filed jointly by 10 applicants (nine individuals as creators and a university).

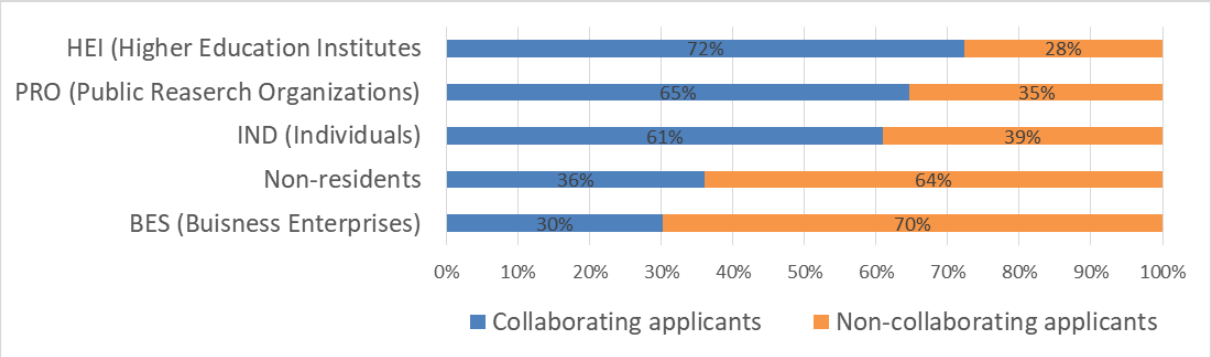
Figure 22: Healthcare applications filed at the PPO by the number of applicants, 2006-2015.



Source: SOPRANO database.

Out of all 1,282 entities which filed their applications between 2006 and 2015, 583 of them filed jointly with another applicant. Of higher education institutes, 72 percent of them were collaborating (47 entities). Of PROs, 65 percent were collaborating (44 entities). In the case of individuals, 61 percent were collaborating (274 persons). At the same time, just 30 percent (187) of business enterprises filed jointly with other entities. In the case of foreign entities filing at the PPO, 36 percent (31) entities were collaborating (Figure 22).

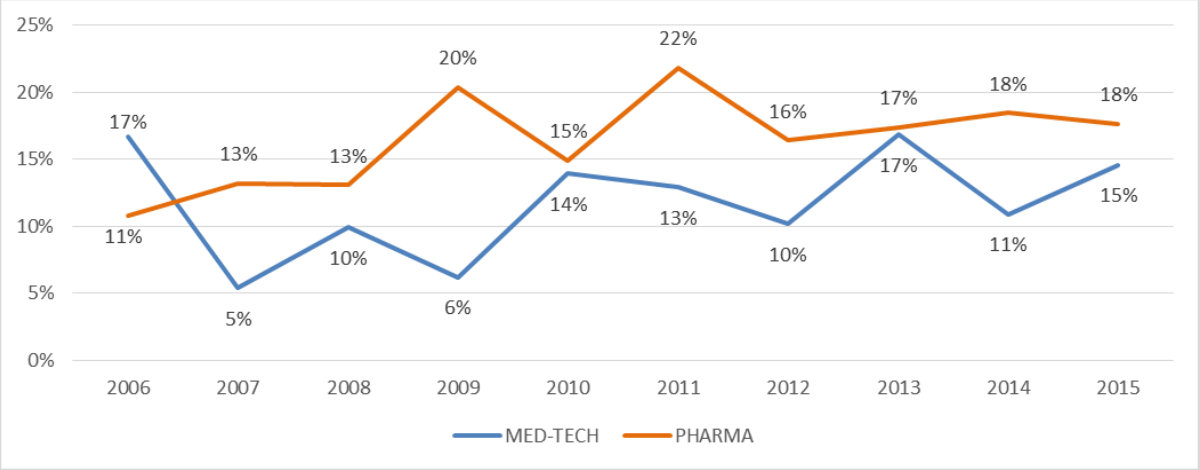
Figure 23: Collaborating applicants in the health sector by type of applicant, 2006-2015.



Source: SOPRANO database.

In the pharma sector, the average percentage of applications resulting from collaboration between several entities in this period was 16 percent; while in the case of medtech, it was 12 percent. The higher percentage of collaboration for pharma may follow from the technological advancement of the applications, as well as high cost of invention development process in pharma (Figure 24).

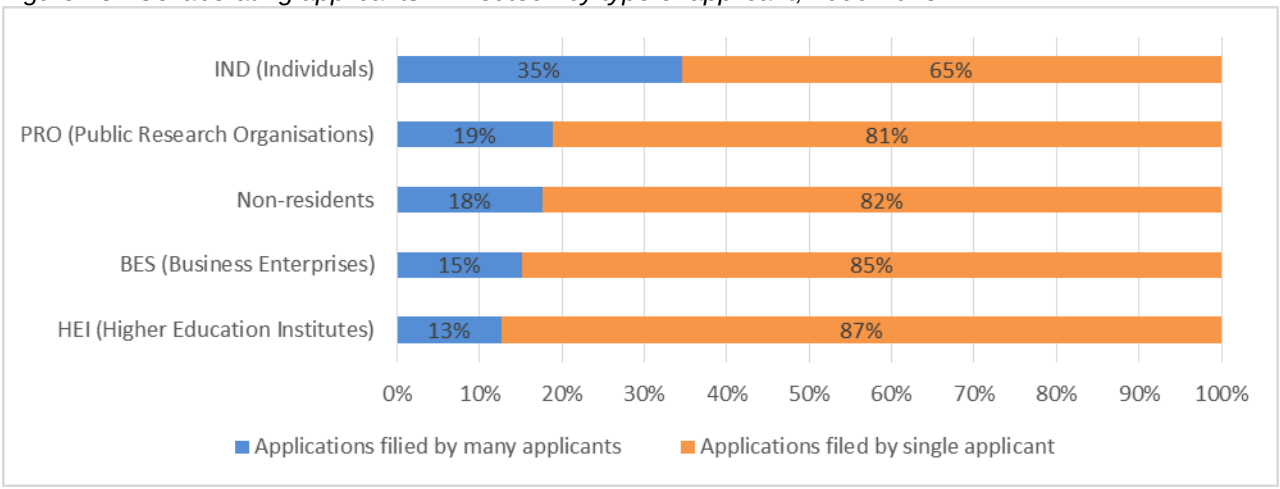
Figure 24: Health sector applications filed at the PPO jointly by several applicants, 2006-2015.



Source: SOPRANO database.

In the case of medtech, the share of applications filed by several applicants, for particular types of entities, was about 20 percent; in the case of individuals, the percentage was the highest, amounting to 35 percent. For HEIs, the share was the lowest at just 13 percent (Figure 25).

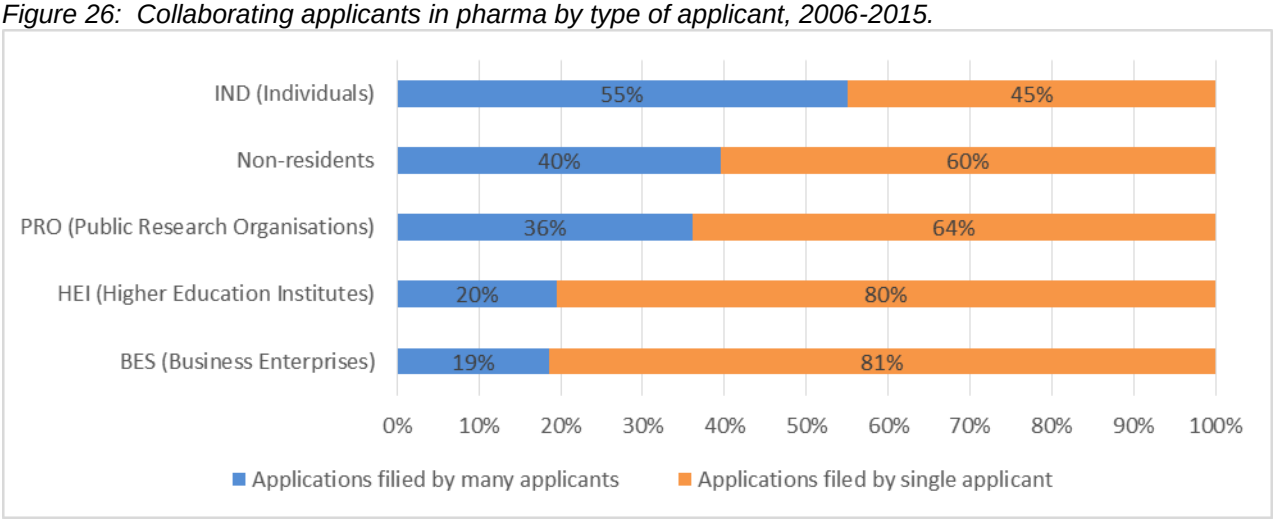
Figure 25: Collaborating applicants in medtech by type of applicant, 2006-2015.



Source: SOPRANO database.

The case of applications from pharma is slightly different. The share of applications resulting from collaboration among entities was about 35 percent. Collaboration was most prevalent among individuals, then among foreign entities, and PROs. The smallest number of applications resulting from collaboration was from higher education institutes and business enterprises. (Figure 26)

Figure 26: Collaborating applicants in pharma by type of applicant, 2006-2015.



Source: SOPRANO database.

In the ranking of entities that filed at least 10 applications in collaboration with other applicants, higher education institutes and PROs – i.e. the academic sector – are prominent. The most active entity out of business enterprises filed eight applications jointly with other applicants. In the case of other types of entities, the number of applications resulting from collaboration was not more than six applications for individuals and not more than two for foreign entities (Table 1).

Table 1: Top applicants that filed in collaboration with other applicants, 2006-2015.

Name of Applicant	Number of Applications
Medical University of Lublin	43
Wrocław Medical University	32
Medical University of Bialystok	21
Ludwik Hirszfeld Institute of Immunology and Experimental Therapy, Polish Academy of Sciences	19
Lodz University of Technology	18
Institute of Biochemistry and Biophysics, Polish Academy of Sciences	17
Wrocław University of Science and Technology	16
Jagiellonian University in Kraków	16
Wiitold Chodźko Institute of Rural Health in Lublin	15
Medical University of Warsaw	14
University of Lodz	12
Institute of Medical Technology and Equipment (ITAM)	11
Maria Curie-Skłodowska University	10
Medical University of Gdańsk	10

Source: SOPRANO database. Notes: The list includes entities that filed at least 10 applications.

Presented below is a collaboration matrix that shows the intensity of collaboration among particular types of entities. The analysis of the matrix data points to a low level of collaboration among higher education institutes, PROs and individuals. However, a high level of collaboration can be observed within the academic sector between higher education institutes and PROs. Business enterprises collaborated with all types of entities on a similar scale, though there is a slightly higher number of applications filed jointly with individuals.

Table 2: Collaboration matrix by type of applicant, 2006-2015.

	Individuals	Business Enterprises	HEIs	PROs	Non-residents
Individuals	61	69	20	6	10
Business Enterprises	69	51	53	44	9
Higher Education Institutes	20	53	77	89	8
PROs	6	44	89	34	2
Non-residents	10	9	8	2	6

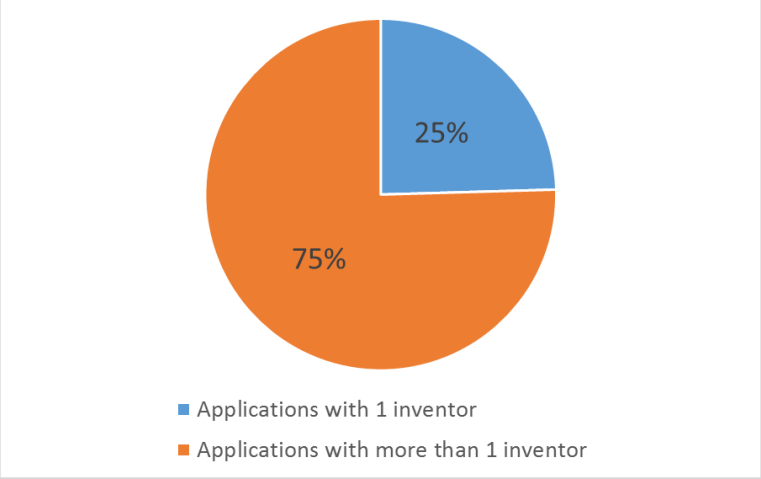
Source: SOPRANO database.

Collaboration between Polish and foreign applicants was minor, comprising of just 20 co-applications. These applications showed collaboration with entities from the United States of America (5 co-applications), Canada (2), Germany (2), Russia (2), Ukraine (2), Moldova (1), France (1), Denmark (1), Ireland (1), Switzerland (1), Italy (1), and United Kingdom (1). That was mainly collaboration with foreign individuals, in addition to three cases of collaboration with foreign universities, and three cases of collaboration with foreign research institutes.

4.4.2 Collaboration between inventors

Approximately three quarters of health sector applications filed at the PPO were the result of a research team of at least two inventors (Figure 27). These collaborative efforts can occur within the same entity or across organizations, and can include foreign collaborative ties. These collaborative inventions – particularly when they include different organizations – can be interpreted as a form of knowledge transfer.

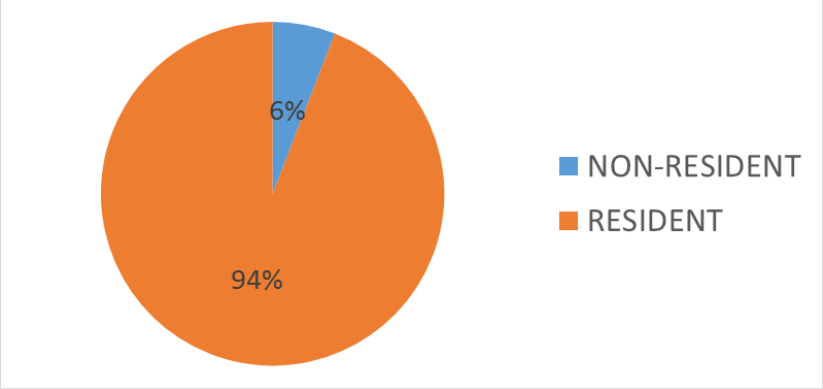
Figure 27: Healthcare technologies by research team size, 2006-2015.



Source: SOPRANO database.

Most healthcare technologies developed by national applicants were the result of research carried out without international collaboration. Only 6 percent of inventors listed in the applications filed at the PPO had their place of residence outside of Poland (Figure 28).

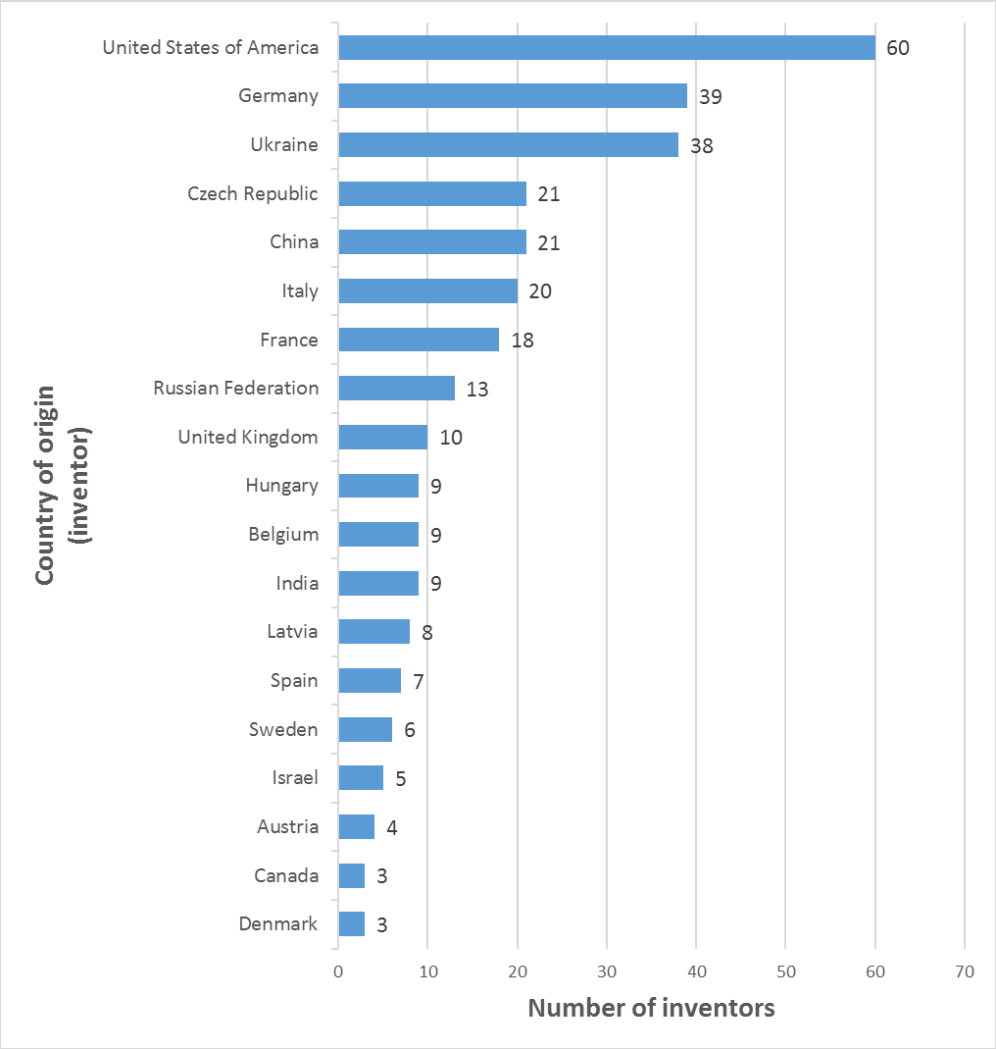
Figure 28: Inventors of healthcare technologies by place of residence, 2006-2015.



Source: SOPRANO database

There are representatives of 37 different countries among the few foreign inventors. There are more than two inventors in 19 of these countries. Foreign inventors originated mostly from the United States, Germany and Ukraine.

Figure 29: Inventors of healthcare technologies by country of residence, 2006-2015.

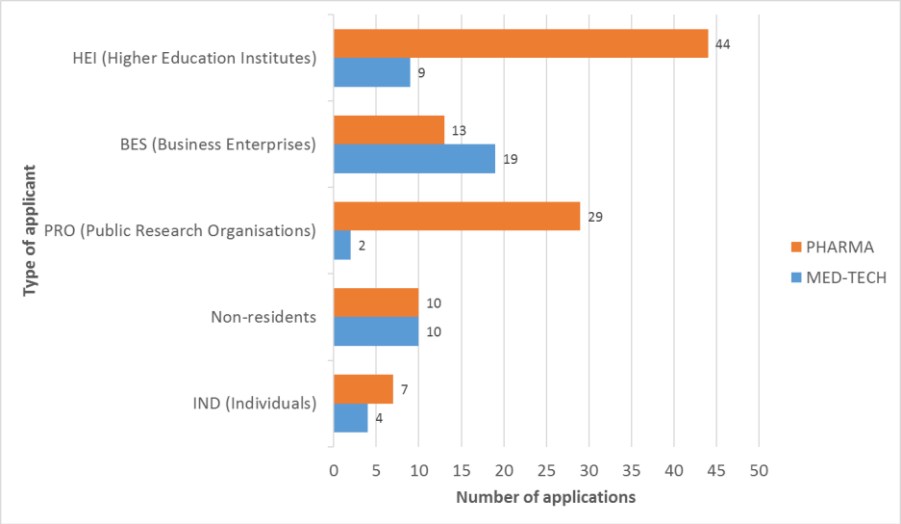


Source: SOPRANO database. The list includes countries in which more than two inventors have their place of residence.

Only 118 healthcare applications filed at the PPO resulted from the work of international research teams, i.e. teams of Polish and foreign residents.

Polish academic applicants – both higher education institutes and PROs – have more internationally developed applications for pharma technologies (Figure 30). Business enterprise applicants had higher amounts of such applications for medtech. It is worth noting that most of the applications for inventions and utility models developed within international research teams were filed in the pharma field.

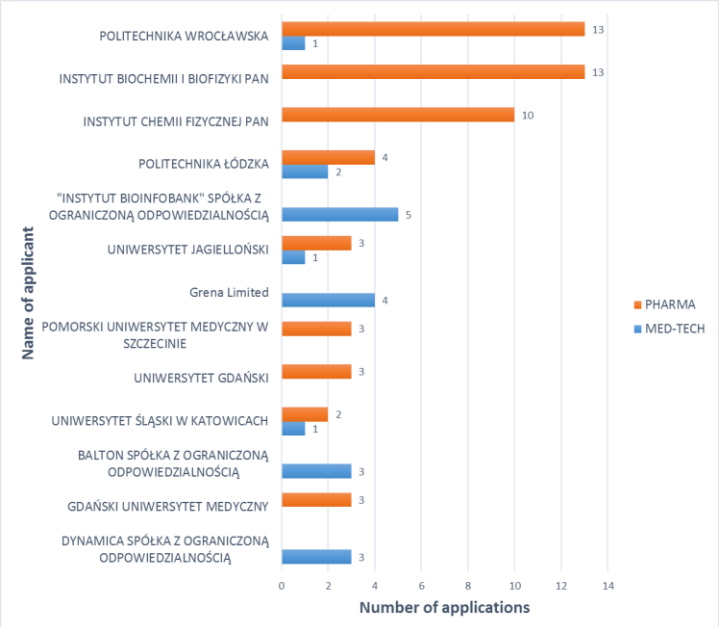
Figure 30: Internationally co-developed pharma and medtech by type of applicant, 2006-2015.



Source: SOPRANO database.

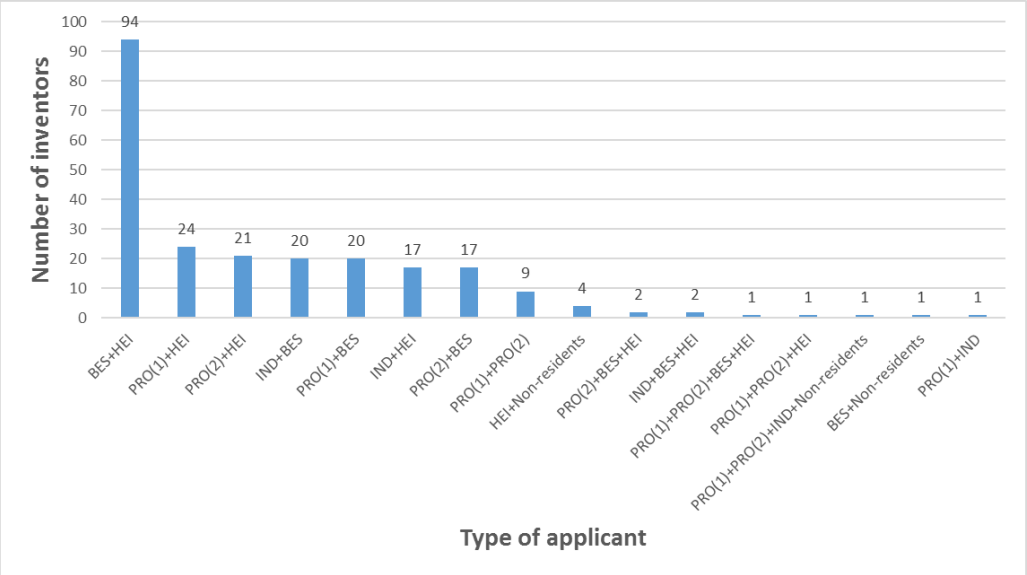
It is not surprising that the top ranking entities in terms of international collaboration in the field of healthcare technologies are academic institutions (Figure 31). The top entity is the Wrocław University of Science and Technology, which is followed by two scientific institutes of the Polish Academy of Sciences: the Institute of Biochemistry and Biophysics and the Institute of Physical Chemistry. It is worth emphasizing that among these, there are also four enterprises, one of which is based abroad (Grena Limited).

Figure 31: Top applicants internationally co-developing pharma and medtech, 2006-2015.



Source: SOPRANO database. The list includes entities that filed more than two applications.

Figure 32: Inventors collaborating with different types of entities, 2006-2015.[13]



Source: SOPRANO database.

Collaboration between the same inventors and different types of entities was also not a frequent phenomenon in the analyzed period. Only 235 national inventors undertook collaboration with inventors from other organizations, which represents only 5 percent out of 4,674 analyzed inventors (Figure 32). The most represented group were inventors working for both higher education institutes and business enterprises, comprising 94 inventors. The next groups were inventors active within the broadly understood science sector – i.e. collaborating with both higher education institutes and PROs – 24 inventors, or both with higher education institutes and scientific units of the Polish Academy of Sciences – 21 inventors, or within the same PROs – 9 inventors. In turn, there were 37 inventors collaborating with both PROs and the business sector. Only a few inventors worked for more than two types of filing entities.

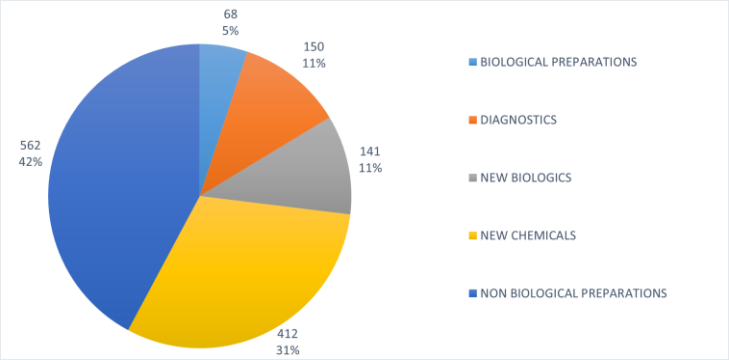
4.5 Specialization within pharma and medtech

4.5.1 Specialization within pharma

Five specializations were distinguished within the 1,333 applications filed at the PPO by Polish entities in the field of pharma technologies. The definitions of the specific pharma specializations and the IPC symbols used to define them can be found in table A.2 in the Annex. Two dominating specializations can be identified, within which Polish entities filed the highest number of applications during the analyzed period. The first is *non-biological preparations* which covered 42 percent of applications. The second is *new chemical compounds* with 412 applications constituting 31 percent of the total. The least numerous specialization in the pharma field was *biological preparations*, with 5 percent of applications (Figure 33).

[13] Applications with one type of applicant were analyzed because, in the case of applications filed by applicants representing several types of applicants, it cannot be determined specifically with whom an inventor collaborated.

Figure 33: Specializations within pharma technologies, 2006-2015.



Source: SOPRANO database.

4.5.1.1 New biologics

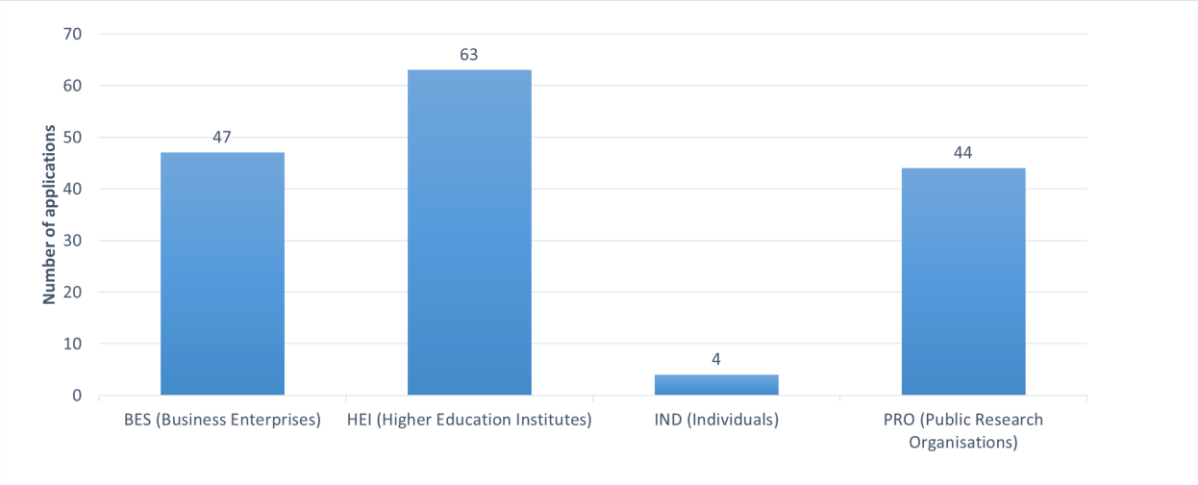
New biologics covers new peptides, proteins, antigens, antibodies, genes, cells, enzymes, microorganisms that have therapeutic properties, as well as compounds, mainly organic, obtained by biotechnological methods (involving microorganisms or enzymes) with therapeutic properties. For this specialization, the average number of applications in the analyzed period was 14 per year, with the lowest number filed at the PPO in 2008 and the highest number filed in 2014 (Figure 34). In total, within the specialization *new biologics* in the examined period, 141 applications were filed at the PPO, which constitutes 4 percent of applications from the health sector filed by domestic entities.

Figure 34: New biologics, 2006-2015.

Source: SOPRANO database.

The share of applications from various types of entities within this specialization is very similar to that which characterizes the entire field of pharma, i.e. with the dominance of higher education institutes and the smallest percentage of applications from individuals (Figure 35).

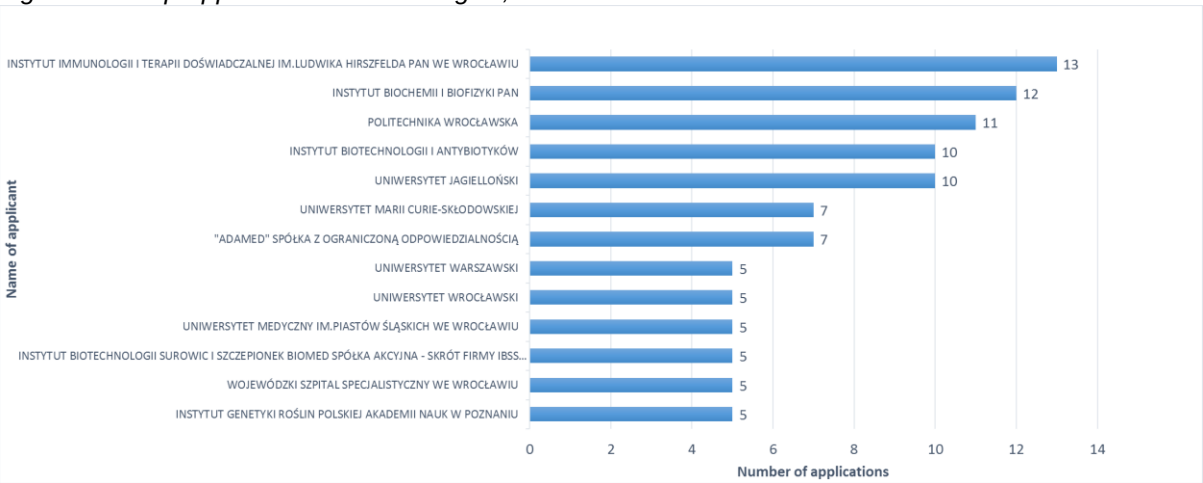
Figure 35: New biologics by applicant type, 2006-2015.



Source: SOPRANO database.

The top applicants are mostly PROs and higher education institutes. The highest number of applications from the business sector were filed by Adamed Ltd., IBSS "Biomed" S.A. and the Provincial Specialist Hospital in Wrocław (Figure 36).

Figure 36: Top applicants in new biologics, 2006-2015.

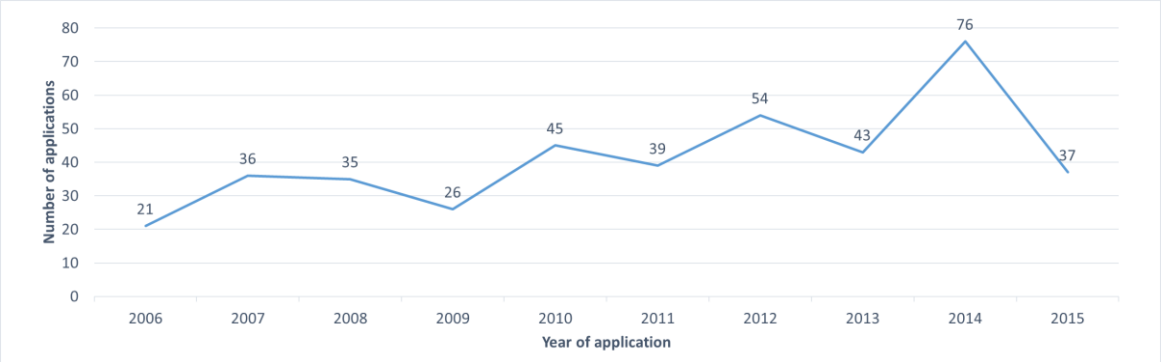


Source: SOPRANO database. Notes: The list includes entities that filed more than four applications.

4.5.1.2 New chemicals

The specialization of *new chemicals* covers new organic compounds which have therapeutic properties. For this specialization, the average number of applications was 41 per year, with the lowest number of applications filed at the PPO in 2006 and the highest number of applications filed in 2014 (Figure 37). In the analyzed period, the PPO received 412 applications within the specialization *new chemicals*, which constitutes 13 percent of applications in the health sector filed by domestic entities.

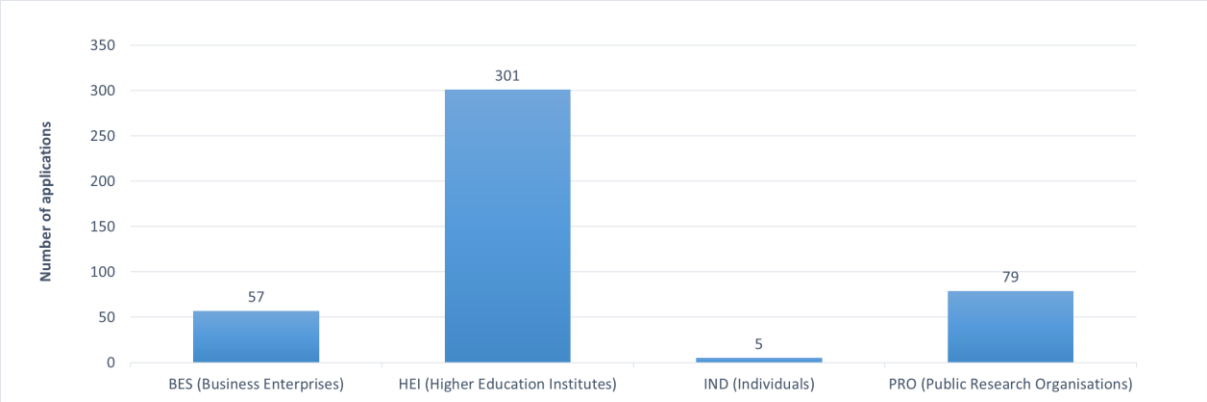
Figure 37: New chemicals, 2006-2015.



Source: SOPRANO database.

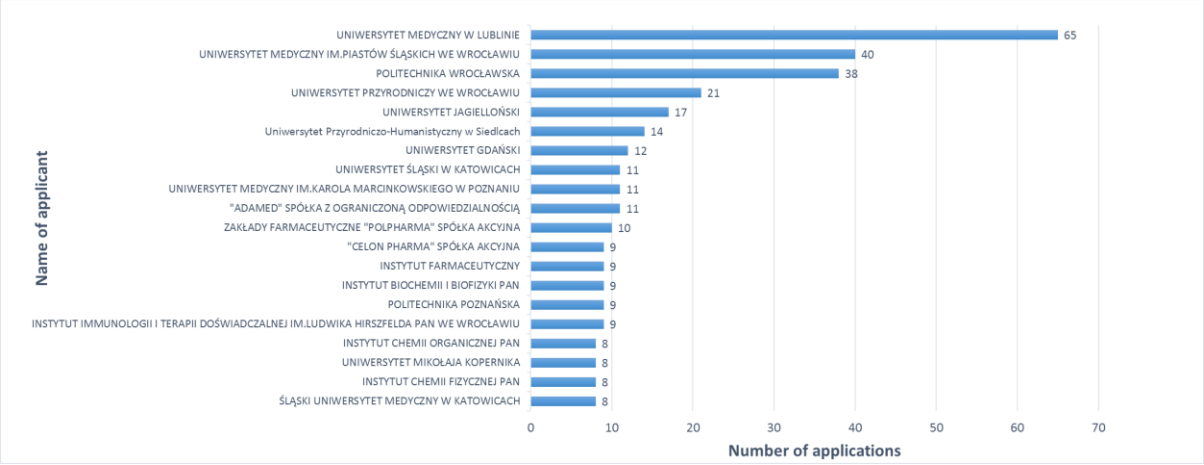
For this specialization, higher education institutes had the biggest advantage over other groups. In total, the science sector entities filed 92 percent of all applications within this specialization (Figure 38). The dominance of higher education institutes with regard to this specialization is also visible in the ranking of top applicants. Out of the 20 entities that filed more than seven applications, the top 11 are higher education institutes. The business sector is represented in this ranking by the following companies: Adamed Ltd., Polpharma S.A. Pharma Works and Celon Pharma S.A. (Figure 39).

Figure 38: New chemicals by applicant type, 2006-2015.



Source: SOPRANO database.

Figure 39: Top applicants in new chemicals, 2006-2015.

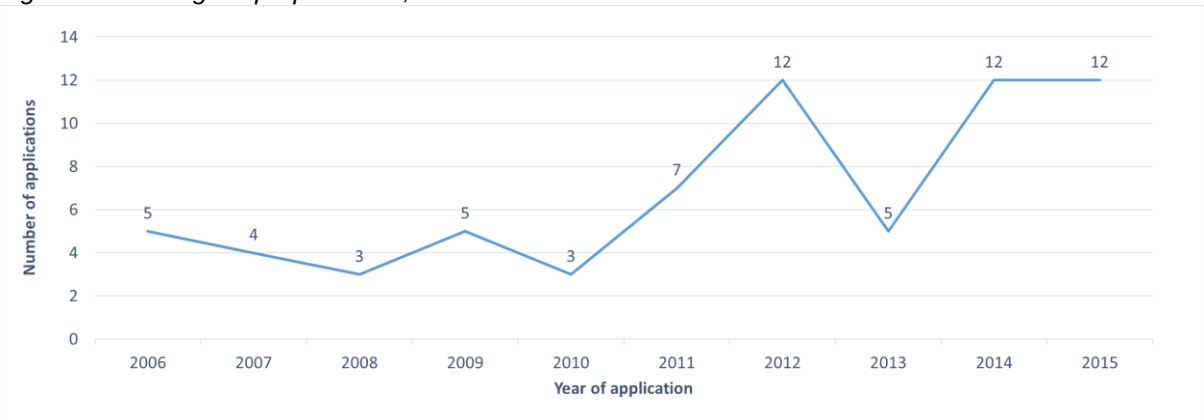


Source: SOPRANO database. Notes: The list includes entities that filed more than seven applications.

4.5.1.3 Biological preparations

The specialization of *biological preparations* entails medical preparations, such as pharma compositions or vaccines, containing peptides, proteins, antigens, antibodies and genes, as well as new medical applications of biological substances with other established uses. In the analyzed period the average number of applications for this specialization was seven per year, with the lowest number filed at the PPO in 2008 and 2010, and the highest in 2012, 2014 and 2015 (Figure 40). The PPO received 68 applications in total, which is the lowest number for all pharma specializations. They constituted 2 percent of applications from the health sector filed by domestic entities.

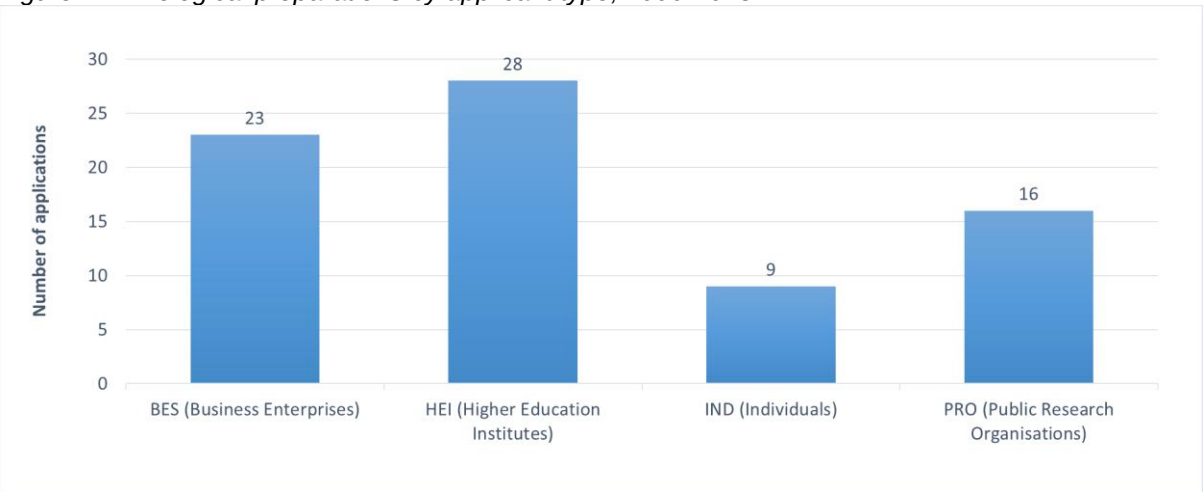
Figure 40: Biological preparations, 2006-2015



Source: SOPRANO database.

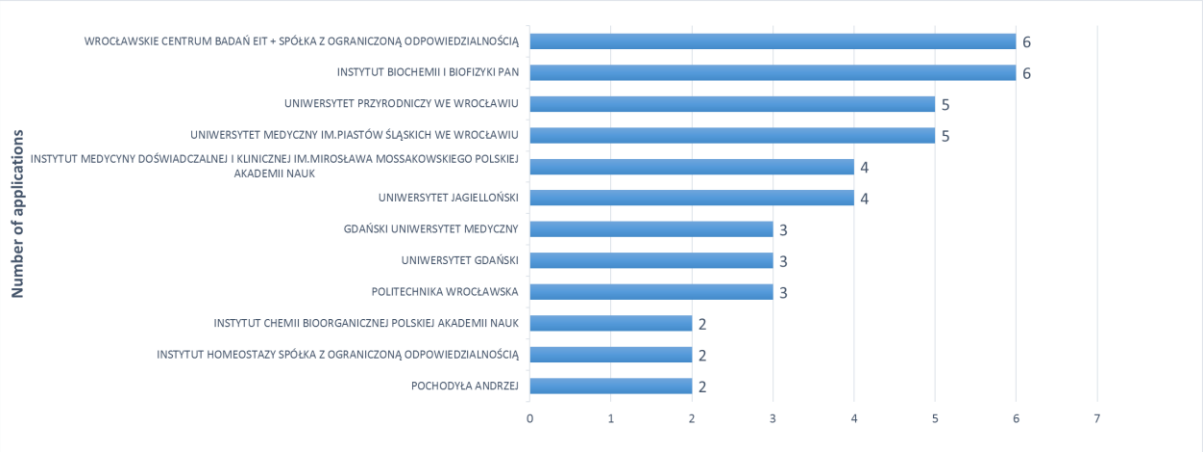
Entities from the science sector – namely higher education institutes (28) and PROs (16) – filed most of these applications, although the share of applications from business enterprises was relatively high and amounted to 34 percent of the total (Figure 41). High activity from business enterprises within the *biological preparations* specialization is reinforced by the shared top ranking of the company Wrocław Research Centre EIT+ Ltd. and the PAN Research Center (Institute of Biochemistry and Biophysics Polish Academy of Sciences), (Figure 42).

Figure 41: Biological preparations by applicant type, 2006-2015.



Source: SOPRANO database.

Figure 42: Top applicants in biological preparations, 2006-2015.

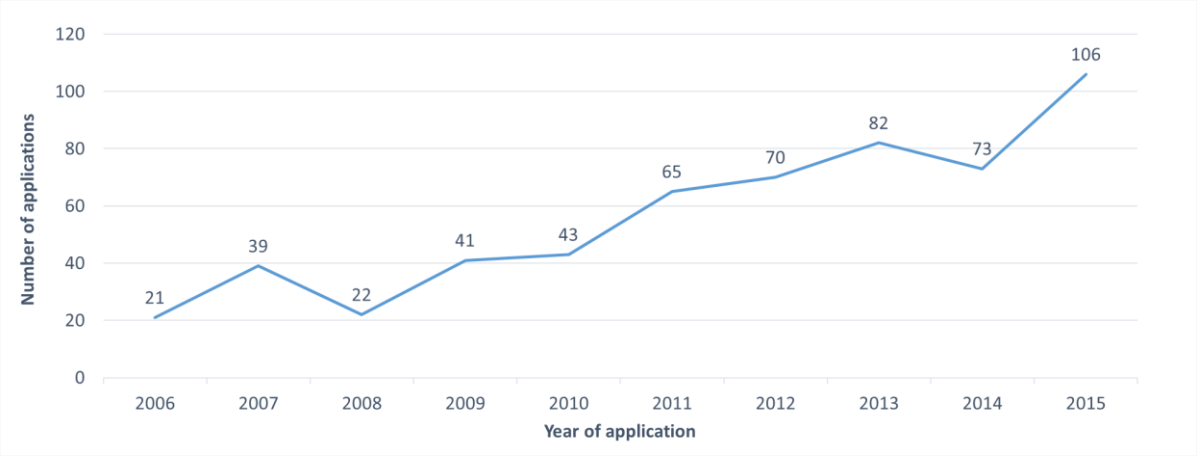


Source: SOPRANO database. Notes: The list includes entities which filed more than one application.

4.5.1.4 Non-biological preparations

The specialization of *non-biological preparations* covers medical preparations containing various compounds of non-biological origin, including organic, inorganic and plant compounds, as well as new medical applications of these substances. For this specialization the average number of applications in the examined period was 56 per year, with the lowest number of applications filed at the PPO in 2006, and the highest in 2015 (Figure 43). In total, the PPO received 562 applications within this specialization, which is the highest number for all pharma specializations. They constituted 18 percent of applications from the health sector filed by domestic entities.

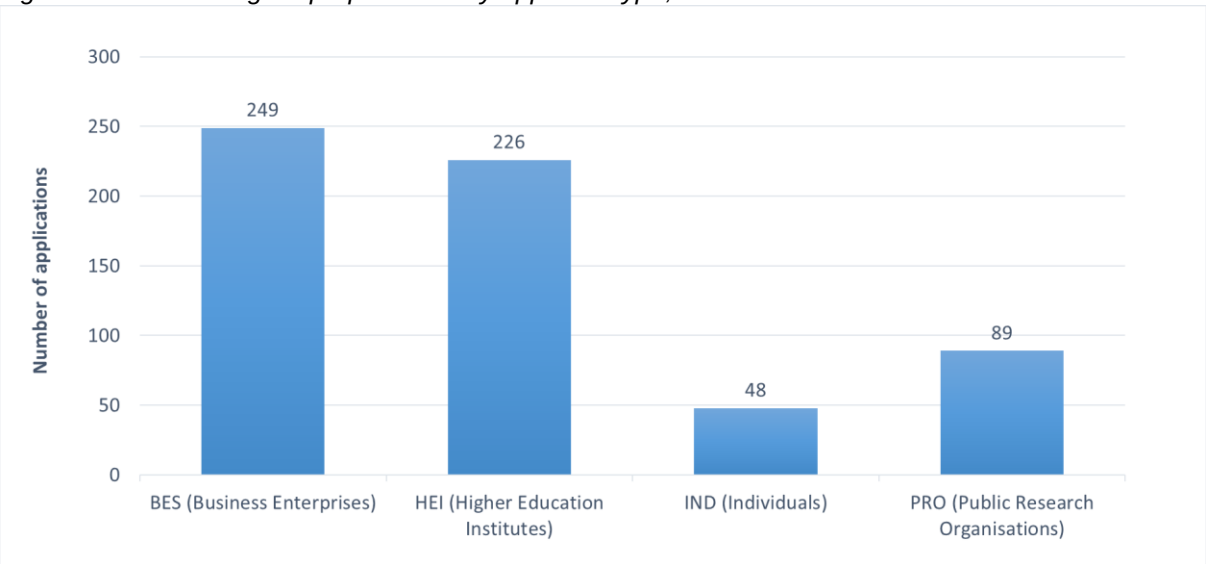
Figure 43: Non-biological preparations, 2006-2015.



Source: SOPRANO database.

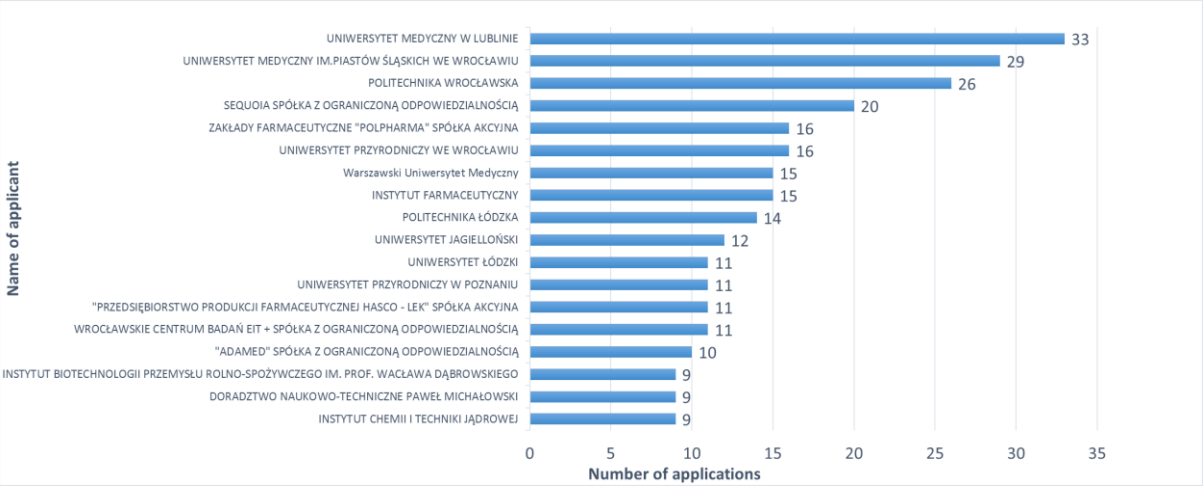
This is the only specialization within which the largest number of applications was filed by business enterprises. However, the combined number of applications from the science sector entities (higher education institutes and PROs) was higher. Nevertheless, the science sector cannot be considered dominant, as is the case with other pharma specializations (Figure 44). Among the 18 top applicants within the *non-biological preparations* specialization, six entities are classed as business enterprises. In this group, the highest number of applications (20) were filed by Sequoia Ltd., which ranked fourth behind the Medical University of Lublin, Wrocław Medical University and Wrocław University of Science and Technology (Figure 45).

Figure 44: Non-biological preparations by applicant type, 2006-2015.



Source: SOPRANO database. Notes: The number of applications shown here does not amount to the total number of applications filed, because some were filed jointly by entities belonging to different categories (type of entity).

Figure 45: Top applicants in non-biological preparations, 2006-2015.

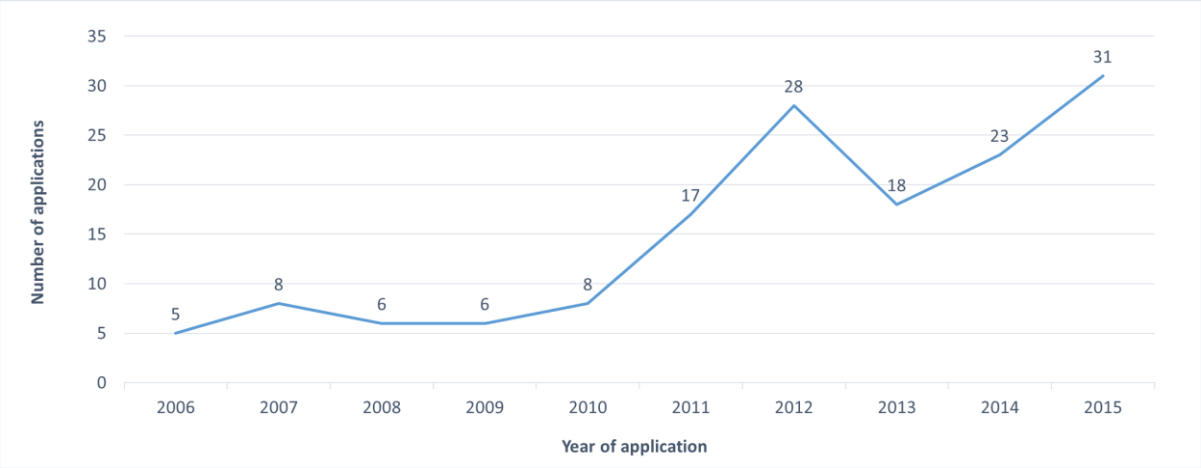


Source: SOPRANO database. Notes: The list includes entities that have filed more than eight applications.

4.5.1.5 Diagnostics

The specialization of *diagnostics* covers analytical methods involving the examination or analysis of biological material (e.g. blood, urine) using, among other things, nucleic acids, enzymes, microbes, antibodies, proteins and other substances occurring in this material. In the case of this specialization, the average number of applications was 15 per year, with the lowest number received by the PPO in 2006, and the highest in 2015 (Figure 46). During the analyzed period, the PPO received a total of 150 applications with this specialization, which constituted 5 percent of applications from the health sector filed by domestic entities.

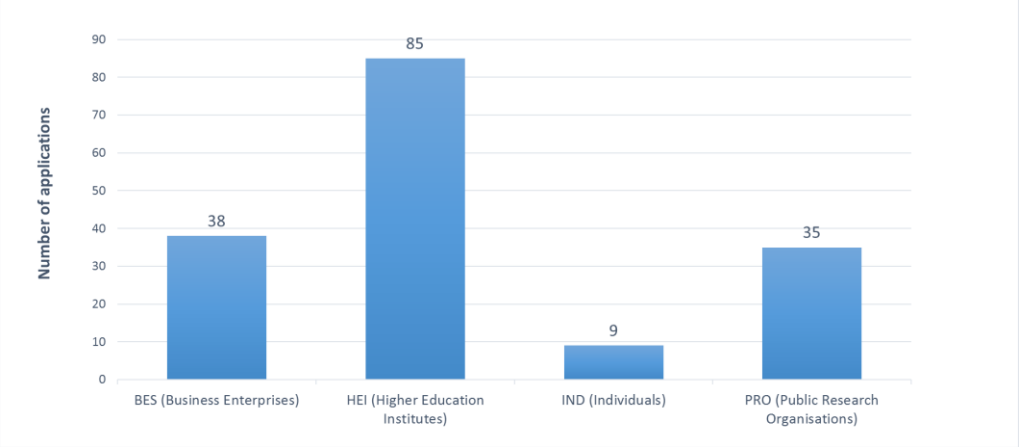
Figure 46: Diagnostics, 2006-2015.



Source: SOPRANO database.

As in other specializations apart from *non-biological preparations*, higher education institutes and PROs filed the highest number of applications within the *diagnostics* specialization. In total, the share of applications from the entire sector was 69 percent (Figure 47).

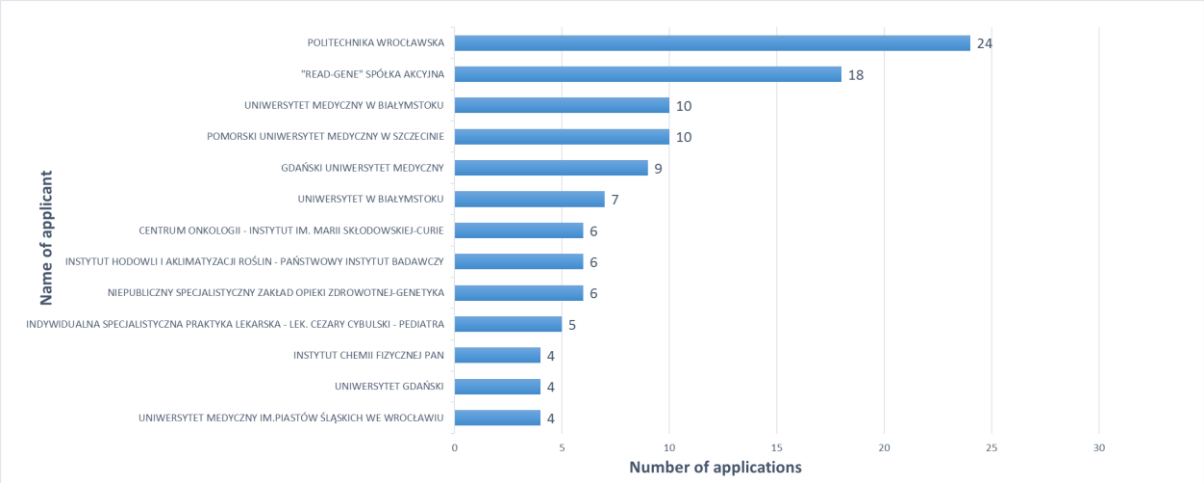
Figure 47: Diagnostics by applicant type, 2006-2015.



Source: SOPRANO database.

Although only one quarter of the applications were owned by entities from the business sector, one of the companies was the second most active domestic entity in this specialization. This company is Read-Gene S.A., which filed 18 applications in the analyzed period. Only Wrocław University of Science and Technology had more applications (24). Besides Read-Gene S.A., the ranking also includes two entities that are not scientific institutions, namely Non-Public Specialist Health Care Centre-Genetics and a sole business operator (Figure 48).

Figure 48: Top applicants in diagnostics, 2006-2015.



Source: SOPRANO database. Notes: The list includes entities which have filed more than three applications.

4.5.2 Specialization within medtech

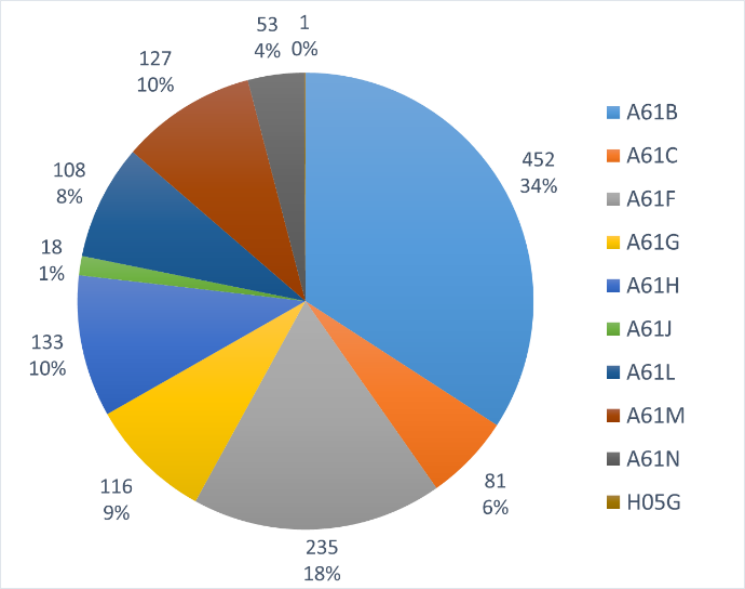
This study identified 1,324 medtech applications and assigned them to ten specializations identified by IPC subclasses (Figure 49). The descriptions of specific IPC subclasses used to define medical technologies specializations are listed in Table A.3 in the Annex.

As shown in Figure 49, the highest number of medtech applications were filed in subclasses A61B (452 applications, 34 percent) and A61F (235 applications, 18 percent). Taking into account the number of applications, these are two key specializations in the field of medtech. Subclass A61B refers to: diagnosis; surgery; and identification. Subclass A61F relates to: filters implantable into blood vessels; prostheses; devices providing patency to, or preventing collapsing of, tubular structures of the body (e.g. stents); orthopedic, nursing or contraceptive devices; fomentation; treatment or protection of eyes or ears; bandages, dressings or absorbent pads; and first-aid kits.

Subclasses A61H, A61G, A61M and A61L follow in relevance, with applications ranging from 108 to 133 (about 8 to 10 percent). A61H refers to: physical therapy apparatus; artificial respiration; massage; and bathing devices for special therapeutic or hygienic purposes or specific parts of the body. A61G relates to: transport; personal conveyances; accommodation specially adapted for patients or disabled persons; operating tables or chairs; and chairs for dentistry. A61M concerns; devices for introducing media into, or onto, the body; devices for transducing body media or for taking media from the body; and devices for producing or ending sleep or stupor. A61L includes: methods or apparatus for sterilizing materials or objects in general; chemical aspects of bandages, dressings, absorbent pads, or surgical articles; and materials for bandages, dressings, absorbent pads, or surgical articles.

Subclasses A61J (18 applications, 1 percent) and H05G (one application, less than 1 percent) have the lowest shares of medtech applications filed by domestic entities. A61J relates to: containers specially adapted for medical or pharma purposes; devices or methods specially adapted for bringing pharma products into particular physical or administering forms; devices for administering food or medicines orally; baby comforters; and devices for receiving spittle. Subclass H05G concerns X-ray techniques (Figure 49).

Figure 49: Specialization within medtech, 2006-2015.



Source: SOPRANO database.

The top applicants in the A61B subclass were CHM Ltd. (31 applications), the Institute of Medical Technology and Equipment ITAM (25), Wrocław University of Science and Technology (21), Gdansk University of Technology (17), University of Silesia in Katowice (13), Lodz University of Technology (12), Wrocław Medical University (12), Professor Zbigniew Religa's Cardiac Surgery Development Foundation (10) and University of Warmia and Mazury in Olsztyn (10).

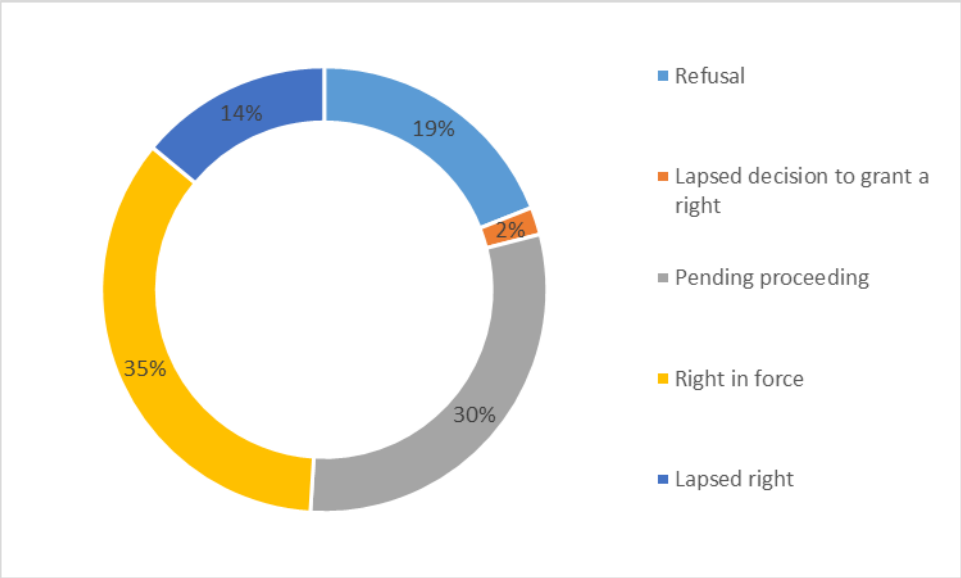
4.6 Management of IP in the health sector

An examination of IP rights can be carried out by analyzing their use by the entities to which they were granted. These rights are mainly used by entities for protecting their solutions in the domestic market as well as in target foreign markets. It is important to determine how long the entities maintain their rights, i.e. whether they pay fees for subsequent protection periods. Entities may also commercialize solutions protected by exclusive rights by selling them or licensing them.

Information on the number of maintenance fees paid by an entity is indicative of its determination to pay the costs of maintaining an exclusive right in force. In accordance with Polish legislation, exclusive rights are granted for inventions or utility models that meet the conditions of patentability and obtain the PPO's decision on granting the right, under the condition that the fee for the first three years of protection is paid. Thus, among other things, the payment of the fee is required to obtain an exclusive right and enforce it with retroactive effect, i.e. from the filing date. Failure to pay this fee results in discontinuance of a granting proceeding. If a granting proceeding lasts longer than three years, the entitled entity should also pay fees for the subsequent years of protection. Otherwise, the exclusive right shall lapse in accordance with Article 90 of the Act of 30 June 2000.

As of the day the data was retrieved from the SOPRANO database, 1,578 out of 3,201 (49 percent) healthcare applications filed at the PPO by domestic entities between 2006 and 2015 resulted in a granted IP right. The remaining 51 percent constituted applications that were still being processed or had been refused (Figure 50).

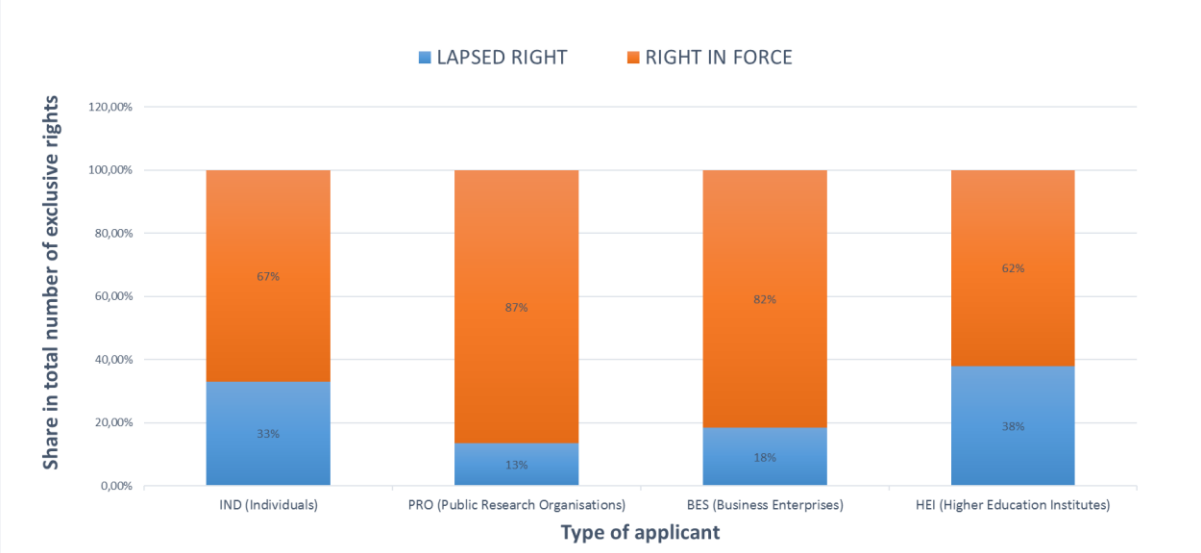
Figure 50: Legal status of healthcare applications filed at the PPO, 2006-2015.



Source: SOPRANO database. Notes: This is the application status as of November 13, 2017. Applications which resulted in a granted exclusive right had the status of Right in force or the Lapsed right (due to the lack of payment for protection or by law).

Out of the 1,578 applications that were granted an IP right, 71 percent (1,113) were still in force on the day of data retrieval, while 29 percent (465) had the status of lapsed rights. The highest percentage of lapsed rights included rights granted to higher education institutes (38 percent) and individuals (33 percent), while the smallest rate of lapsed rights were those granted to PROs (13 percent) (Figure 51).

Figure 51: Legal status of IP rights granted by the PPO, based on applications filed at the PPO, 2006-2015.



Source: SOPRANO database.

The analysis of the duration of maintaining protection in force by various groups of entities was carried out on the set of lapsed rights, because only then the whole protection period from filing an application to the lapse of a right is known. For all types of entities, the lapse of rights occurred most often after the first three years of protection, whereas for higher education institutes, such cases accounted for as much as 50 percent. Comparing entities in each sector, the percentage of lapsed rights after the first period of protection was 37 percent, 38 percent for PROs and 26 percent for individuals. The period of protection

exceeded five years in only a few cases. Entities from the business sector and PROs held the highest percentage of rights maintained for five years or more, at about 41 percent (

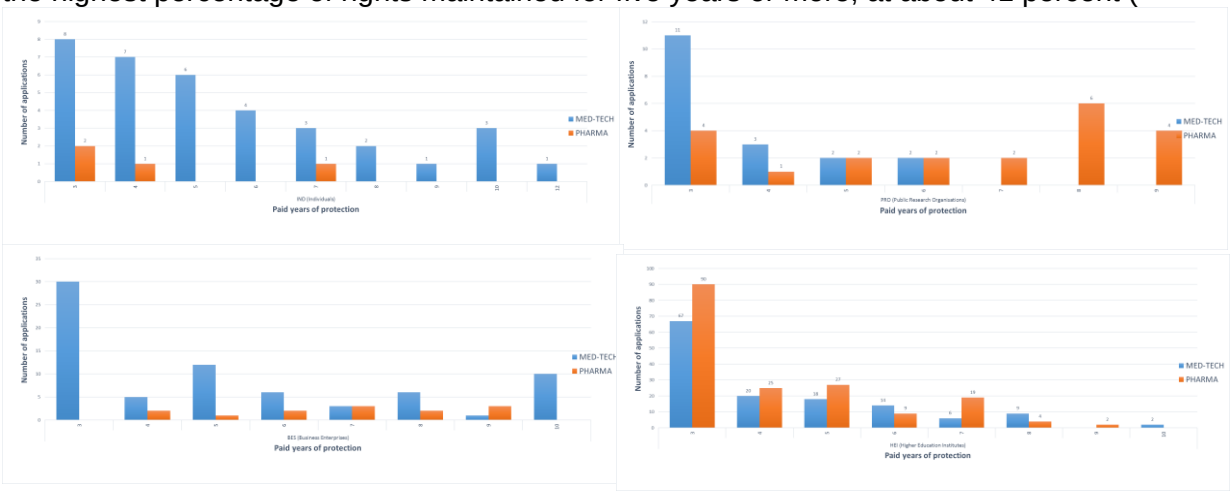


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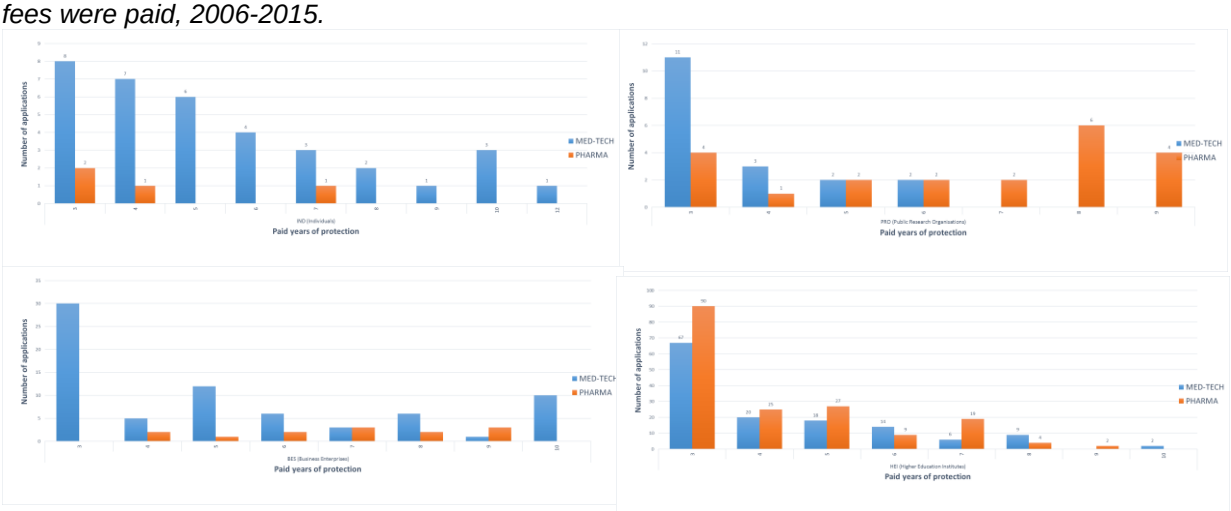
Figure 52: Healthcare applications filed at the PPO by the number of years for which maintenance fees were paid, 2006-2015.

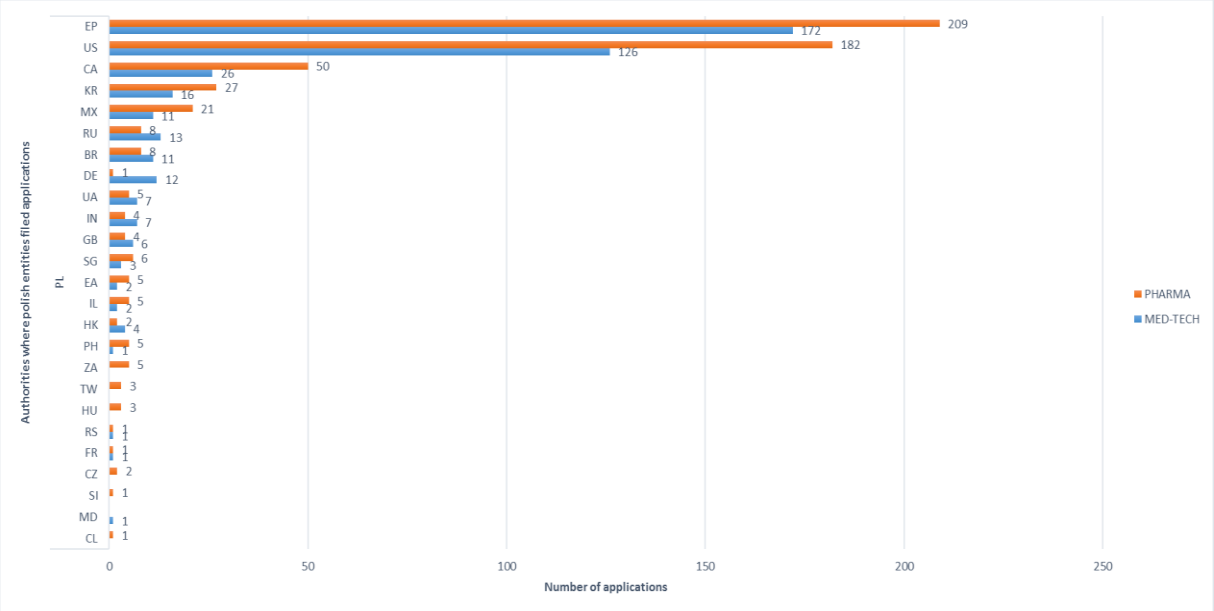


Source: SOPRANO database.

Analysis of the above data shows that – for the most part and especially in the case of higher education institutes – only the first maintenance fee, required to obtain an exclusive right, was paid. Thus, failure to pay a renewal fee resulted in a relatively quick lapse of a patent or right of protection for a utility model. It also means that exclusive rights holders resigned from the potential benefits of maintaining patent protection and were satisfied with obtaining a positive decision from the PPO. Striving to obtain only a positive decision from the PPO, and not the real ability to exercise exclusive rights of protection, may be related to various programs financed from public funds and the parametric assessment of higher education institutes, among other things. The latter may be incentivized by the mere fact of filing applications and obtaining protection. A noticeable decrease in the number of applications filed at the PPO in 2016 and 2017 – a period not covered by this study – may be related to with the fact that calls for proposals in the framework of such projects closed, among other reasons.

In the analyzed period, the activity of Polish applicants was mainly targeted at the domestic market. Out of 4,153 applications filed by Polish entities worldwide,[14] 76 percent were applications filed at the PPO. The remaining 24 percent – of which 57 percent were pharma applications – were mostly applications for inventions and utility models filed at the EPO and United States Patent and Trademark Office (USPTO) (Figure 53). In total, domestic entities filed applications at 25 foreign offices. For comparison, German entities filed applications at 66 different patent offices during the same period. This provides evidence that there is relatively low interest among Polish entities in extending patent protection to foreign markets, which may result from the low competitiveness of inventions seeking protection and high costs of protection of IP abroad, among other things. In addition, the domestic market seems sufficiently large for Polish entities, which have a low internationalization. Otherwise, the number of applications filed in Poland and abroad should be comparable.

Figure 53: Healthcare applications filed worldwide by Polish entities, 2006-2015.



Source: PATSTAT Online Autumn edition, 2017.

Many countries within the CEE region also have a high percentage of applications from their domestic entities filed at their national patent offices, although only Romania (93 percent) did so at a greater frequency than Poland. At the same time, applicants from Western European countries implemented a completely different strategy and filed applications primarily at foreign offices (Table 3).

At the same time, it should be noted that the foreign patent offices most often chosen by Polish entities were also most frequently chosen by applicants from other EU countries. The United States Patent and Trademark Office (USPTO), European Patent Office (EPO), German Patent and Trademark Office (DPMA), Canadian Intellectual Property Office (CIPO) and Korean Intellectual Property Office (KIPO) were the most popular. Thus, it can be concluded that Polish applicants interested in foreign markets, follow the general trend typical for EU countries, and above all, seek protection in Europe and the USA (Figure 54).

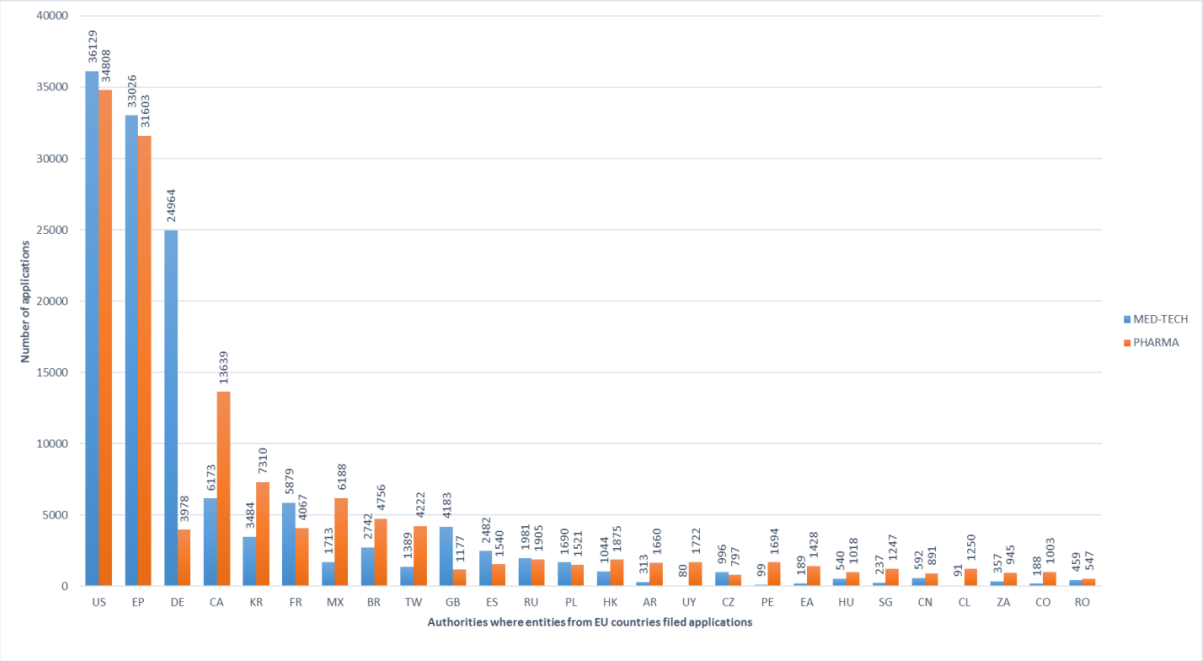
[14] This is the number of all applications filed worldwide, calculated according to individual applications and not according to patent families.

Table 3: Healthcare applications filed by entities from EU countries at their national offices, 2006-2015.

Country of origin of applicants	Share of applications filed in domestic patent office
Romania	93%
Poland	76%
Bulgaria	73%
Czech Republic	69%
Slovakia	64%
Lithuania	62%
Latvia	53%
Croatia	51%
Greece	42%
Hungary	39%
Estonia	33%
Spain	31%
Portugal	31%
Germany	29%
Slovenia	26%
France	22%
Finland	21%
Austria	15%
United Kingdom	14%
Sweden	5%
Ireland	4%
Netherlands	4%
Denmark	3%
Italy	2%
Luxembourg	2%
Belgium	<1%
Cyprus	-
Malta	-

Source: PATSTAT Online Autumn edition, 2017. Notes: If every application filed at a national office were also filed in at least one foreign patent office, the share would amount to at least 50%.

Figure 54: Healthcare applications filed by EU countries by receiving offices, 2006-2015.



Source: PATSTAT Online Autumn edition, 2017.

Among the Polish entities that most frequently filed IP rights applications in the health sector outside Poland were representatives from a diverse range of entities, including higher education institutes and PROs, as well as enterprises and even individuals. Patent and utility model applications filed outside Poland do not indicate the dominance of any one type of entity. Nevertheless, analysis of specific entities shows that the leaders in this group are ADAMED and the Jagiellonian University (Table 4).

Table 4: Top applicants filing outside Poland, 2006-2015.

NAZWA PODMIOTU	LICZBA ZGŁOSZEŃ DOKONANYCH POZA POLSKĄ
ADAMED	77
JAGIELLONIAN UNIVERSITY IN CRACOW	52
L F C CORPORATION	29
WARSZAWSKI UNIWERSYTET MEDYCZNY	25
COPERNICUS	24
HTL-STREFA SPOLKA AKCYJNA	20
INSTYTUT BIOCHEMII I BIOFIZYKI PAN	17
ZAKLADY FARMACEUTYCZNE POLPHARMA	16
FUNDACJA ROZWOJU KARDIOCHIRURGII IM. PROF. ZBIGNIEWA RELIGI	16
SELVITA	15
INSTYTUT BIOCHEMII I BIOFIZYKI POLSKIEJ AKADEMII NAUK	15
POLITECHNIKA LODZKA	14
ADAM MICKIEWICZ UNIVERSITY IN POZNAN	12
AIRWAY MEDIX	12
UNIWERSYTET WARSZAWSKI	11
SICINSKI, RAFAL, R.	11
WROCLAWSKIE CENTRUM BADAN EIT +	11
INSTYTUT BIOTECHNOLOGII I ANTYBIOTYKOW	11

Source: PATSTAT Online Autumn edition 2017. Notes: The list includes only entities that filed more than 10 applications.

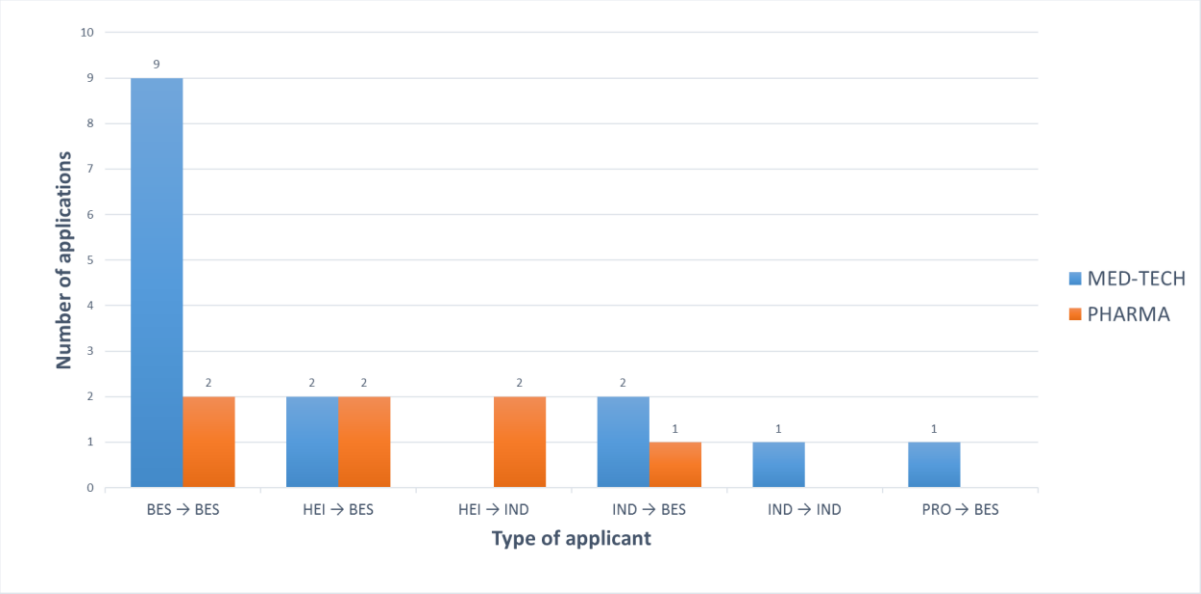
Commercialization is another element of exclusive rights management by an authorized entity. Commercialization should be understood as the sale of results of scientific research, development works or know-how related to these results, or the commissioning of these results or know-how, in particular on the basis of a license agreement, lease or tenancy.[15] In

[15] The legal definition of direct commercialization in accordance with art. 2 para. 1 point 35 of the Act of 27 July 2005 Law on Higher Education (Journal of Laws, 2017, item 2183, with amendments), legal status of 4 June 2018.

the context of IP objects, the most popular commercialization models are sales and licensing.

Based on the PPO data, sale of an exclusive right can be identified by a change of a right holder, which results from assignment of a given right to another entity. Therefore, only applications with exclusive rights were analyzed. The analysis showed that in the case of health applications filed in between 2006 and 2015 by domestic entities, the sale of exclusive rights was rather rare. It concerned only 22 applications, or one percent of applications that were granted an exclusive right. Out of these, 20 were patent applications and two were utility model applications in the field of medtech. The largest number of exclusive rights which changed ownership as a result of sales belonged to business enterprises, and their buyers were other enterprises. In this case, the sales also concerned mostly rights in the field of medtech. On the other hand, the least commercialized rights were those belonging to PROs and individuals (Figure 55).

Figure 55: Exclusive rights that changed ownership, 2006-2015.



Source: SOPRANO database.

Pursuant to the Industrial Property Law license, contracts shall be in writing. In a license contract, restricted exploitation of the invention may be provided for (restricted license). Unless the license contract provides for the restricted exploitation of the invention, the licensee shall have the right to exploit the invention to the same extent as the licensor (full license). The license shall terminate on the lapse of the patent, at the latest. Unless the exclusive exploitation of the invention is reserved in a specific manner in a license contract, the grant of a license to one party shall not prevent other parties from being granted a license, as well as the patent holder from concurrent exploiting of the invention (non-exclusive license). Unless otherwise agreed in the license contract, the licensor shall be required to transfer to the licensee all technical know-how necessary to exploit the invention available at the time of concluding the contract. A patent holder may submit to the PPO a declaration of licenses of the right to exploit the invention (open license).

According to the analysis, licensing is not a popular form of commercialization of exclusive rights among domestic entities. In the case of health sector applications, SOPRANO data include information on only four licenses. However, it should be noted that a patentee is not obliged to inform the PPO about the granting of such a license, therefore the PPO may not have full data on this subject. Licensed patents covered the following solutions:

- PAT.218400 – A vaccine for the treatment of type 1 diabetes in children, the use of a cell sorter and a method for proliferation of Treg cells producing a vaccine for the treatment of type 1 diabetes. The patent was granted to the University of Gdańsk, which granted full, exclusive license to the company POLTREG Ltd.;

- PAT.220414 – Herbs and mineral therapeutic composition. The patent was granted to the company JANUSZ KUREK ALPA – DYSTRYBUCJA, which granted a full and exclusive license to the company NES PHARMA Ryszard Pisklak registered partnership;

- PAT.221223 – Aqueous solution for soaking materials, giving them properties of shielding against low frequency variable electric field in the range of 10^6-10^6 [Hz] and the use of the aqueous solution for soaking materials, giving them properties of shielding against low frequency variable electric field in the range of 10^6-10^6 [Hz]. The patent was granted to a natural person who granted a limited license for an unlimited period to the company SELENA LABS Ltd.;

- PAT.221322 – A device for monitoring rehabilitation exercise performed by patients for rehabilitation of spinal diseases. The patent was granted to the Gdańsk University of Technology, which granted a full, exclusive license to the company TERMA Ltd.

4.7 The most valuable Polish applications in the health sector

To measure the value of applications filed worldwide by Polish entities in the health sector from 2006 through to 2015, the "Patent indicator" methodology, proposed in PATSTAT Online was used. According to this methodology, the value of a given application can be measured using indicators such as the number of forward citations,[16] the number of members in a simple patent family (DOCDB patent family), the number of applicants, the number of inventors, and grants of an exclusive right.

For the purposes of this study, the indicators were weighted[17] and as a result, 997 applications were selected.[18] Out of those, applications that scored more than 40 points were considered to have a special value owing to their innovative potential. In total, 14 such applications were identified, eight from pharma and six from medtech (Table 5).

[16] Forward citations are citations related to patents that cite a given patent.

[17] Weights assigned to individual data used to measure the value of an application: 2 for the number of forward citations, 2 for the number of simple patent family members, -1 for the number of applicants, 0 for the number of inventors and 1 for the information on granting protection. As a result, each application received a certain number of points calculated according to the following formula: 2 * (number of forward citations) + 2 * (number of simple patent family members) -1 * (number of applicants) + 0 * (number of inventors) +1 (in the case of granting protection).

[18] Identification of the most valuable applications was carried out with the assistance of the statistical module available as part of the PATSTAT Online Autumn edition 2017.

Table 5: The most valuable healthcare applications filed worldwide by Polish entities, 2006-2015.

Application number [a] (Polish priority document)	Forward [b] citations	Family members	Title	Applicants	Inventors
PL20100391627 (PL20100391627)	10	24	*Anti-cancer fusion protein*	ADAMED Ltd.	4 [PL]
CA20112811265 (PL20100392396, PL20100392397)	1	32	*Use of a mutant CFTR protein*	Institute of Biochemistry and Biophysics Polish Academy of Sciences	3 [PL] 3 [FR]
CA20112814595 (PL20100393146,PL20110394597)	7	26	*Anti-cancer fusion protein*	ADAMED Ltd.	4 [PL]
US20090996243 (PL20080385388)	27	8	*mRNA Cap analogs*	Kowalska Joanna, Jemielity Jacek, Darzynkiewicz Edward, Rhoads Robert E, Lukaszewicz Maciej, Zuberek Joanna, Board Of Supervisors Of Louisiana State University And Agricultural And Mechanical College	5 [PL] 1 [US]
US20080280282 (without Polish priority)	18	15	*Synthesis and use of anti-reverse phosphorothioate analogs of the messenger RNA Cap*	Jemielity Jacek, Grudzien-Nogalska Ewa M, Kowalska Joanna, Darzynkiewicz Edward, Rhoads Robert E, Board Of Supervisors Of Louisiana State University And Agricultural And Mechanical College, University of Warsaw	3 [PL] 2 [US]
CA20102773242 (PL20090389427)	11	17	*An automatic applicator for liquid pharmaceutical preparations, particularly for insulin*	Copernicus Ltd.	1 [PL]
EP20080162469 (PL20070383243)	23	4	*The system of remote cardiological rehabilitation*	Medicalgorithmics S.A.	3 [PL]
CA20102775785 (PL20090389148)	13	14	*Device for surgical displacement of vertebrae*	LfC Ltd.	3 [PL] 2 [BE]
CA20102767735 (PL20090388694)	6	21	*Indication mechanism for an automatic applicator, particularly for insulin*	Copernicus Ltd.	1 [PL]
CA20092729938 (PL20080385586)	16	10	*New insulin analogues of prolonged activity*	The Institute of Biotechnology and Antibiotics	20 [PL]
EP20090010124 (lack of Polish priority)	12	14	*Vaccine composition comprising 5'-end Cap modified RNA*	Biontech AG;Johannes Gutenberg-Universitaet Mainz; University of Warsaw	2 [DE] 3 [PL]
CA20132863394 (PL20120398051)	14	11	*Injecting device with dose resetting mechanism*	Copernicus Ltd.	1 [PL]
CA20122856480 (PL20110397167)	4	17	*Anti-cancer fusion protein*	ADAMED Ltd.	8 [PL]
PL20110393578 (PL20110393578)	3	17	*Anti-cancer fusion protein*	ADAMED Ltd.	4 [PL]

Source: PATSTAT Online Autumn edition 2017. Notes: (a) the application number in EPODOC format; (b) analysis based on patent families citing patent families.

Noteworthy, two applications in the Polish language (priority documents for a foreign patent family) are on the list of the most valuable applications. It should be noted that one of the key indicators used to measure the value of individual applications was the number of forward citations. Obviously, applications in English – e.g. filed in Canada, the USA and at the EPO – are more often cited than their Polish equivalents.

The individual applications listed in Table 5, grouped by filing entities are described below.

ADAMED Ltd.

In the analyzed period, ADAMED Ltd. filed 105 applications for pharma inventions at the PPO and abroad. Four of these were assessed as particularly valuable. These applications were repeatedly cited in other patent documents and most of their patent family members soon obtained patent protection in many countries, including European patents which were subsequently validated in many EPC countries.

The first is application no. PL20100391627, filed at the PPO in 2010. This application belongs a patent family with 24 members and was cited 10 times. The second application which ranked among the most valuable is no. CA20112814595, filed in Canada in 2011, claiming the priority date of two Polish applications, no. PL20100393146 and no. PL20110394597. This application belongs to a large patent family of 26 members and was cited seven times. The third application which showed high potential for innovation is no. CA20122856480 filed in 2012, also in Canada, claiming the Polish priority document no. PL20110397167. The patent family of this application includes 17 members and has four forward citations. The final noteworthy application is no. PL20110393578, filed in 2011. The 17-member patent family of this application was cited three times.

All of these applications relate to anti-cancer fusion proteins, comprising a fragment of a soluble human TRAIL protein in combination with effector peptide sequences exhibiting anti-cancer properties, such as: proapoptotic, immunostimulatory, inhibiting protein synthesis inside a cell, and anti-angiogenic. In many cases, these proteins exert much stronger effect compared to TRAIL alone; they overcome resistance to TRAIL and also due to the attachment of the effector peptide, they have prolonged half-life and increased retention of protein in the tumor and, as a consequence, increased efficiency.

Institute of Biochemistry and Biophysics of the Polish Academy of Sciences

The Institute of Biochemistry and Biophysics of the Polish Academy of Sciences filed a particularly valuable application: no. CA20112811265, filed in Canada in 2011, claiming two Polish patent documents, no. PL20100392396 and no. PL20100392397. This application belongs to a 32 member family, which was cited by one other patent family. It concerns modulators of the function of the mutant CFTR protein and their use in the treatment of diseases associated with CFTR protein malfunction, caused by the ΔF508 mutation, especially cystic fibrosis.

University of Warsaw

Three applications submitted jointly by Polish and foreign entities deserve attention. Firstly, application no. US20090996243 was filed at the USPTO in 2009 and claimed the priority from application no. PL20080385388. The priority document was filed only by the University of Warsaw, while foreign applications based on this priority were filed by a group of Polish scientists associated with the University of Warsaw together with the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College. The

invention encompassed by this application relates to dinucleotide cap analogs modified at different phosphate positions with boranophosphate or phosphorus-oxide groups. These analogs are useful as reagents in the preparation of capped mRNAs and have enhanced in vitro and in vivo stability. The 8-member family of this application was cited as many as 27 times.

Another application filed by the above-mentioned applicants and the University of Warsaw at the USPTO is application no. US20080280282. It relates to new anti-reverse phosphorothioate RNA cap analogues that are useful in mRNA translation. Despite the fact that this application was filed jointly with scientists from the University of Warsaw, with partial financial support from the Polish government grant no. 2 P04A 006 28 awarded by the Ministry of Science and Higher Education, it does not claim Polish priority, but priority from the US application. The family to which this application belongs includes the European patent no. EP20080771474, which has been validated in many EPC countries, including Poland.

Application no. EP20090010124 is also worth mentioning. It was jointly filed in 2008 at the EPO by the German biopharmaceutical company BioNTech AG, the German university Johannes Gutenberg-Universitaet Mainz and the University of Warsaw. Three authors of this invention originate from Poland and two from Germany. The 14-member patent family of this application, which relates to a vaccine comprising 5'-end Cap modified RNA, was cited 12 times.

Institute of Biology and Antibiotics

Another application classified as being especially valuable in the area of health is the application no. CA20092729938 filed in Canada in 2009 by the Institute of Biotechnology and Antibiotics. It claims Polish priority from application no. PL20080385586. The patent family to which this application belongs was cited 16 times and includes 10 members. The subject of the invention is new biosynthetic analogs of recombinant human insulin of prolonged therapeutical activity, used in the prevention and therapy of diabetes, which are characterized by adequate stability in acidic injection solutions and show the desired biological activity.

COPERNICUS Ltd.

In the analyzed period, Copernicus Ltd. filed 37 applications at the PPO and abroad. All of these applications were medtech applications and three of them were among the most valuable applications in the health sector.

The first is application no. CA20102773242 filed in Canada in 2010, which claims priority from application no. PL20090389427. The patent family of this application includes 17 members and was cited 11 times. The second most valuable application from Copernicus Ltd. is application no. CA20102767735, also filed in Canada in 2010, claiming priority from application no. PL20090388694. The 21-member patent family was cited six times. The third most valuable application from this company is no. CA20132863394, filed in Canada in 2013, which claims priority from Polish application no. PL20120398051. The patent family had 11 members and 14 citations.

All of the above applications relate to an automatic applicator, or components thereof, for liquid pharmaceutical preparations, especially for insulin, in particular for multiple injection application of set doses of a medicine from an exchangeable container, for example for the self-administration of insulin by a diabetic patient. These solutions ensure a capability for the precisely controlled application of the set dose of a medicine, preserving an automatic

application of the medicine without any stress, providing external guidance for the tensioned spring and providing adequate protection against damaging the clutch or the driving arrangement due to excessive rotation of the dose-setting element.

LfC Ltd.

Medtech application no. CA20102775785 was filed in Canada in 2010 and claims priority from application no. PL20090389148. The 14-member patent family of this application was cited 13 times.

The subject of the invention is an implantable device for surgical displacement of vertebrae, used in surgery to remove spondylolisthesis. This device enables operations from both back and front surgical access, depending on the needs and medical indications. At the same time, it ensures decompression of compressed nerve structures, restoration of correct anatomical proportions and final blocking of the whole system, preventing secondary slippage without any additional accompanying elements. This, in turn, decreases the risk related to the necessary collaboration of all the elements of the stabilizing system.

Medicalgorithmics S.A.

Special attention should also be given to application no. EP20080162469, filed at the EPO in 2008 by Medicalgorithmics, a Polish company operating in high-tech industry which specializes in providing systemic and algorithmic solutions in cardiological diagnostics, particularly in the ECG signal analysis. The patent family of this application including four members and was cited as many as 23 times.

This application partly claims priority from Polish application no. PL20070383243 and refers to the ECG monitoring system in non-hospital conditions allowing generation of analytical reports, very similar to the Holter recording, except that the system works in real time and sends the analysis of the patient's results through the internet or mobile network to a physician or monitoring staff who can immediately access the data

4.8 Is Poland an attractive market for entities filing applications in the health sector?

The attractiveness of a given country in the context of IP protection is reflected above all in the number of solutions submitted for protection on its territory by foreign entities. For the purposes of this report, IP rights applications filed by foreign entities in the health sector in EU countries were analyzed. Besides national and PCT applications, validations of European patents[19] were also taken into account because it was assumed that the basic measure of the interest of foreign entities in a given market is the number of validations.

Between 2006 and 2015, the largest number of applications in the health sector were filed at DPMA. In total there were 124,155 national and PCT IP rights applications and validations of European patents.

If the number of foreign applications and validations is taken as a measure of the attractiveness of a given country as a target market where it is worth having protection, next to Germany, the most attractive countries in the EU were the United Kingdom (82,225) and France (79,962).

[19] European patent validation is a translation of a European patent (EP) filed with the PPO in order to ensure the protection of a given EP on the territory of the Republic of Poland.

Poland, with a total number of 13,432 national and PCT applications and validations of European patents, is a leader among the so-called “New Union” (EU28). Besides Hungary, it is also the most popular market in the region for foreign entities. The number of applications and validations of these foreign entities in Hungary was slightly higher, by about 200 (Table 6).

Table 6: Healthcare applications and validations of European patents filed in EU national offices, 2006-2015.

Filing office	Total number of applications and EP validations (domestic and foreign entities)	Total number of applications and EP validations (foreign entities)	Number of EP validated by domestic entities	Number of EP validated by foreign entities	Number of direct applications and PCT national phase entries (foreign entities)	Share of EP validated by foreign entities in total number of applications and EP validated by foreign entities (5:3)	Share of total number of applications and EP validated by foreign entities in total number of applications and EP validatetd in the country (3:2)
1	2	3	4	5	6	7	8
Germany	124155	83922	12230	78858	5064	94,0%	67,6%
France	94391	79962	4809	78718	1244	98,4%	84,7%
United Kingdom	90908	82225	4051	78517	3708	95,5%	90,4%
Italy	55275	52814	2146	52723	91	99,8%	95,5%
Spain	49485	44929	628	44228	701	98,4%	90,8%
Netherlands	36319	34342	1265	33718	624	98,2%	94,6%
Ireland	30012	29228	559	29156	72	99,8%	97,4%
Sweden	26894	24918	1291	24794	124	99,5%	92,7%
Belgium	26740	25742	997	25742	0	100,0%	96,3%
Austria	23572	22050	673	21829	221	99,0%	93,5%
Denmark	21061	20050	753	19948	102	99,5%	95,2%
Finland	15767	14826	159	14762	64	99,6%	94,0%
Portugal	15485	15127	31	15084	43	99,7%	97,7%
Greece	14585	14192	24	14012	180	98,7%	97,3%
Luxembourg	13918	13688	187	13656	32	99,8%	98,3%
Poland	13432	10205	55	10113	92	99,1%	76,0%
Hungary	11223	10431	72	8671	1760	83,1%	92,9%
Czech Republic	10966	9186	35	9081	105	98,9%	83,8%
Cyprus	8481	8470	11	8470	0	100,0%	99,9%
Slovenia	7735	7439	62	6400	1039	86,0%	96,2%
Romania	7332	6334	1	6312	22	99,7%	86,4%
Slovakia	7166	6947	3	6892	55	99,2%	96,9%
Bulgaria	6541	6352	4	6337	15	99,8%	97,1%
Estonia	6081	5993	2	5979	14	99,8%	98,6%
Lithuania	4034	3929	1	3898	31	99,2%	97,4%
Latvia	3520	3293	4	3285	8	99,8%	93,6%
Croatia	1898	1743	1	1695	48	97,2%	91,8%
Malta	1529	1527	2	1527	0	100,0%	99,9%

Source: Calculations based on PATSTAT Online Autumn edition, 2017.

It is worth adding that Poland and Germany are the only countries in the EU where the percentage of healthcare applications and validations from domestic entities was higher than 20 percent, and amounted to 24 and 32 percent respectively. In contrast, in other EU countries, it ranged from 16 percent (Czech Republic) to less than one percent (Cyprus and Malta) (Table 6, col.8).

The vast majority of foreign entities applied for IP rights in the EU by validating a European patent. Only in Hungary and Slovenia, the share of validations in the total number of applications and validations from foreign entities was lower than 90 percent, amounting to 83 and 86 percent respectively. In these countries, foreign entities chose the national or PCT procedure slightly more often (Table 6, col. 7).

The share of validations of European patents from foreign entities in the total number of validations was similar in the EU countries and ranged from 94 to 100 percent. The exception is Germany (87 percent) which means that about 13 percent of European patents validated in this country were owned by German entities.

In total, there were 654,461 validations of 93,699 European patents in the health sector at EU national patent offices. The highest numbers of patents were validated in DPMA (91,088), INPI (83,527) and IPO UK (82,568). In the case of the German office, this means that 97 percent of European patents in the health sector validated in the EU during the analyzed period were validated in this office. In the case of France and the United Kingdom, this percentage was equally high and amounted to almost 90 percent. In Poland, which was the leader among CEE countries, the total number of validations during the period discussed exceeded 10,000, and accounted for 11 percent of all European patents validated in the EU in the health sector (Table 7).

Table 7: Healthcare European patents validated in EU countries, 2006-2015.

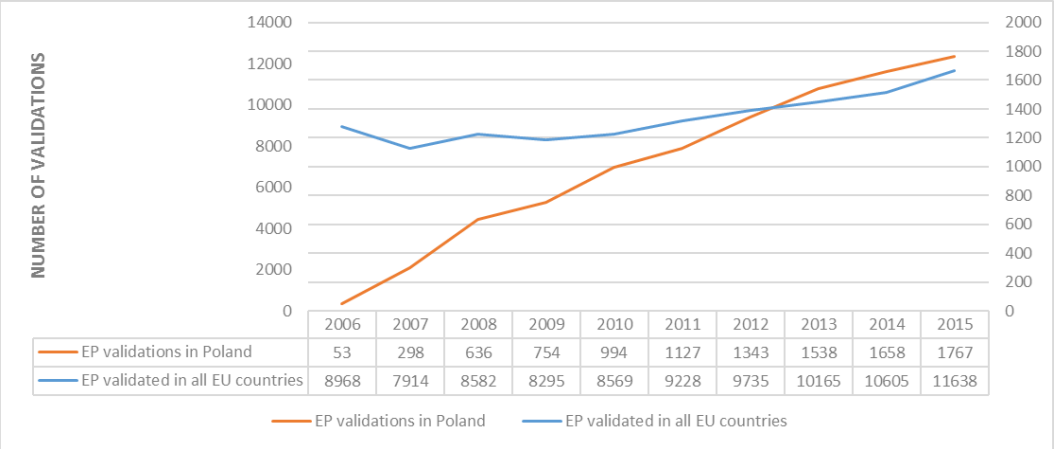
Name of the country of EP validation	Number of EP validations	Share of EP validated in total number of EP validated in all EU countries
Germany	91088	97%
France	83527	89%
United Kingdom	82568	88%
Italy	54869	59%
Spain	44856	48%
Netherlands	34983	37%
Ireland	29715	32%
Belgium	26739	29%
Sweden	26085	28%
Austria	22502	24%
Denmark	20701	22%
Portugal	15115	16%
Finland	14921	16%
Greece	14036	15%
Luxembourg	13843	15%
Poland	10168	11%
Czech Republic	9116	10%
Hungary	8743	9%
Cyprus	8481	9%
Slovakia	6895	7%
Slovenia	6462	7%
Bulgaria	6341	7%
Romania	6313	7%
Estonia	5981	6%
Lithuania	3899	4%
Latvia	3289	4%
Croatia	1696	2%
Malta	1529	2%

Source: Calculations based on PATSTAT Online Autumn edition 2017.

Although the overall number of European patents validated in Poland is not high in comparison to the European leaders, the dynamics have changed substantially over the period. The average annual increase in the number of European patents validated in Poland amounts to 48 percent – from 53 in 2006 to 1,767 in 2015 – while for the entire EU, it was

only percent. This is evidence for ongoing and growing interest in Poland among foreign entities (Figure 56).

Figure 56: European healthcare patents validated in Poland and the EU, 2006-2015.

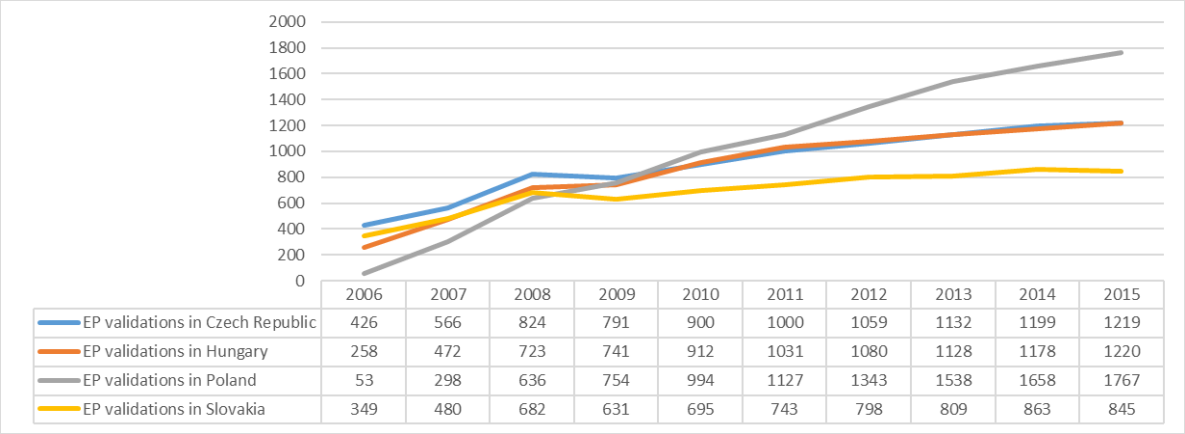


	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
EP validations in Poland	53	298	636	754	994	1127	1343	1538	1658	1767
EP validated in all EU countries	8968	7914	8582	8295	8569	9228	9735	10165	10605	11638

Source: Calculations based on PATSTAT Online Autumn edition, 2017.

At the same time, it is worth noting that while upward trend of validated European patents in the health sector is also characteristic for other countries in the region – such as Hungary, the Czech Republic and Slovakia – it is the most dynamic for Poland (Figure 57).

Figure 57: European healthcare patents validated in Poland and the Visegrad Group countries, 2006-2015.



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
EP validations in Czech Republic	426	566	824	791	900	1000	1059	1132	1199	1219
EP validations in Hungary	258	472	723	741	912	1031	1080	1128	1178	1220
EP validations in Poland	53	298	636	754	994	1127	1343	1538	1658	1767
EP validations in Slovakia	349	480	682	631	695	743	798	809	863	845

Source: Calculations based on PATSTAT Online Autumn edition 2017.

Entities from over 70 countries showed interest in obtaining protection in Poland. The highest number of European patents were validated by Americans (2,494), Germans (1,763), Swiss (1,278), French (756), British (588), Japanese (527) and Italians (455). Considering individual entities, companies such as Novartis (313), Roche (250), Eli Lilly & Company (118), Sanofi (143), Gruenenthal (104), Roche Diagnostics (100) and Janssen Pharmaceutica (100) stand out, as during the period considered they each validated a minimum of 100 European healthcare patents in Poland.

5 Conclusions

Polish health sector entities filed 3,463 applications for IP rights (patent and utility model applications) worldwide from 2006 to 2015, including 3,193 patent applications and 270 utility model applications, of which 1,656 (48 percent) were in pharma and 1,807 (52 percent) were in medtech.[20] This represented an average annual growth of 13 percent. Over the period, Poland accounted for 2.7 percent of the total healthcare technologies in the entire EU area. Among EU countries, it ranked 10th in the EU, ahead of all other Central Eastern European (CEE) countries.

In the analyzed period, the PPO received 3,275 applications, 97 percent of which were filed by domestic entities. At the end of this period, the annual number of applications filed at the PPO was almost three times higher than at the beginning, increasing from 188 to 492 applications per year, representing average annual growth of 11 percent. As a result, the share of healthcare applications in the total number of applications in Poland increased from 6 to 8 percent annually.

For the purposes of the analysis presented in this working paper, entities submitting healthcare applications to the PPO were divided into five categories: higher education institutes (HEI), public research organizations (PRO), individuals (IND), foreign entities and entities of the business sector (BES).

Most of healthcare applications (42 percent) were filed by HEI, which showed the highest activity in pharma. Business enterprises showed the highest activity in medtech. Together with individuals they filed 60 percent of all medtech applications. Micro, small and medium enterprises were the dominant group of applicants among business enterprises and their applications represented over 80 percent of all applications filed by business enterprises.

Taking into account the number of applications filed by Polish entities, Masovia and Lower Silesia provinces dominate regionally and constitute biggest regional health technology clusters in Poland. In the Masovia Province, the most active were entities from the business sector, as well as research institutes and scientific units of the Polish Academy of Sciences. In Lower Silesia and Lesser Poland, the highest number of applications came from higher education institutes.

Out of 1,578 healthcare applications filed by domestic entities at the PPO which obtained an exclusive IP rights, 71 percent (1,113) were still in force on the day of data retrieval, while 29 percent (465) had lapsed. The highest percentage of lapsed rights included rights granted to higher education institutes (38 percent) and individuals (33 percent), while the smallest percentage covered rights granted to PROs (13 percent), which might reveal differences in the applicants' motivations for seeking patents.

The analysis revealed that sale of exclusive rights was rather rare and the least commercialized rights were those belonging to PROs and individuals. As far as the data shows, licensing is also not a popular form of commercialization of exclusive rights used by domestic entities.

Out of 1,282 applicants filing their applications at the PPO between 2006 and 2015, 581 were filing jointly with other applicants: 72 percent of HEIs (47 entities), 65 percent of PROs (44 entities), 61 percent of individuals (274 persons) and just 30 percent of enterprises (187), which shows relatively low-level of stakeholders' collaboration. Top ranking entities in terms of collaborating internationally on healthcare technologies are academic institutions. Business enterprise applicants have a higher number of international co-applications for

[20] Counted by DOCDB patent families

medtech and Polish academic applicants – both HEIs and PROs – are the entities with the most international co-applications for pharma technologies. Approximately three quarters of national healthcare co-applications were the result of a research team effort of at least two inventors. However only five percent of all applications resulted from international inventor collaborations.

Among the most valuable 14 Polish applications filed in the health sector, eight refer to pharma and six to medtech. These applications originated from both business enterprises and the academic sector, while the former own the majority of these applications.

Two dominating specializations can be identified, within which Polish entities filed the highest number of pharma applications during the analyzed period. The first is *non-biological preparations*, accounting for 42 percent of applications. The second is *new chemical compounds,* representing 31 percent of applications. *Non-biological preparations* constitutes the only specialization within which the largest number of applications was filed by business enterprises. Taking into account the number of applications, the key specializations in the field of medtech were in the fields of diagnosis and surgery (34 percent) and stents, orthopedic, nursing or contraceptive devices, treatment or protection of eyes or ears, bandages, dressings or absorbent pads (18 percent).

Out of 4,153 healthcare applications filed by Polish entities worldwide, 76 percent were filed only at the PPO. Relatively low interest of Polish entities in extending patent protection to foreign markets shows that the activity of Polish applicants in the health sector was mainly targeted at the domestic market. The latter, owing to its considerable size, might satisfy their needs but also suggests that the innovative level of the technologies for which protection is sought might not justify broader territorial protection. The remaining 24 percent, out of which more than a half (57 percent) constituted pharma applications, were filed at the European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO). This points to their intended target markets and the considerable innovation potential of the technologies for which patent protection was sought.

When compared to the countries of the so-called “EU15”, Poland is a moderately attractive market for foreign entities. However, with a total number of 13,432 healthcare national and PCT applications and validations of European patents, Poland is the leader in the CEE region. During the analyzed period, the total number of healthcare validations exceeded 10,000 and accounted for 11 percent of all healthcare European patents validated in the EU. The average annual increase in the number of patents validated in Poland amounted to 48 percent, while for the entire EU it was only 3 percent.

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Annex

Tables and Figures

Table A.1: IPC symbols used to identify healthcare technologies

IPC symbols used to identify pharma technologies	IPC symbols used to identify medtech
A61K* (selected symbols: A61K6, A61K9 - A61K51) or A61P* or (G01N 33/48 or G01N 33/49 or G01N 33/5% or G01N 33/6% or G01N 33/7% or G01N 33/8% or G01N 33/9%) or ((C12N or C12Q) and the phrase "diagnos%)" in abstract. ** applications classified in A61K/A61P when co-occurring with A23K or A61D were excluded from the study.*	A61B or A61C or A61F or (A61G1 or A61G3 or A61G5 or A61G7 or A61G9 or A61G10 or A61G11 or A61G12 or A61G13 or A61G15 or A61G99) or A61H or A61J or (A61L12 or A61L15 or A61L17 or A61L24 or A61L26 or A61L27 or A61L28 or A61L29 or A61L31 or A61L33) or A61M or A61N or H05G.

Table A.2: Detailed specializations in pharma

IPC Symbols	Description of detailed specializations
New biologics: new products of biological origin intended for medical purposes.	
C07K	Products such as i.e.: peptides, proteins, antibodies, antigens
C12N	Products such as i.e.: microorganisms, enzymes, cells, tissues, blood components, genes
Biological preparations: **medical preparations containing products of biological origin or the use of these products for medical purposes**	
A61K38	Medicinal preparations containing peptides, proteins, enzymes
A61K39	Medicinal preparations containing antigens or antibodies
A61K48	Medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases; Gene therapy
New Chemicals: **new organic compounds intended for medical purposes**	
C07C	Acyclic or carbocyclic compounds
C07D	Heterocyclic compounds
C07F	Acyclic, carbocyclic, or heterocyclic compounds containing elements other than carbon, hydrogen, halogen, oxygen, nitrogen, sulphur, selenium or tellurium
C07G	Compounds of unknown constitution such as i.e.: alkaloids, antibiotics, vitamins, hormones
C07H	Sugars; Derivatives thereof; Nucleosides; Nucleotides; Nucleic Acids
C07J	Steroids
Nonbiological preparations: **medical preparations containing products of non-biological origin or the use of these products for medical purposes**	
A61K6	Preparations for dentistry
A61K9	Medicinal preparations characterised by special physical form
A61K31	Medicinal preparations containing organic active ingredients
A61K33	Medicinal preparations containing inorganic active ingredients
A61K35	Medicinal preparations containing materials with undetermined constitution
A61K36	Medicinal preparations of undetermined constitution containing

	material from algae, lichens, fungi or plants, , e.g. traditional herbal medicines
A61K41	Medicinal preparations obtained by treating materials with wave energy or particle radiation
A61K45	Preparaty medyczne zawierające składniki czynne nieprzewidziane w grupach A61K 31/00-A61K 41/00
A61K47	Medicinal preparations characterised by the non-active ingredients used, e.g. carriers or inert additives; Targeting or modifying agents chemically bound to the active ingredient
A61K49	Preparations for testing in vivo
A61K50	Electrically conductive preparations for use in therapy or testing in vivo
A61K51	Preparations containing radioactive substances for use in therapy or testing in vivo
A23L	Preparations containing i.e.: food additives such as dietary supplements
***Diagnostics:* analytical methods involving the examination or analysis of biological material (e.g. blood, urine).**	
C12Q	Measuring or testing processes such as i.e.: processes involving micro-organisms, enzymes, nucleic acids
G01N33/48 **(with sub-classes)**	Physical analysis of biological material
G01N33/50 **(with sub-classes)**	Chemical analysis of biological material, e.g. blood, urine; Testing involving biospecific ligand binding methods; Immunological testing

Table A3: Detailed specializations in pharma

IPC Symbols	Description of the detailed specializations
A61B	Diagnosis; Surgery; Identification
A61C	Dentistry; Apparatus or method for oral or dental hygiene
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, dressing or absorbent pads; First-aid kits
A61G	Transport, personal conveyances, or accommodation specially adapted for patients or disabled persons; Operating tables or chairs; Chairs for dentistry;
A61H	Physical therapy apparatus, e.g. devices for locating or stimulating reflex points in the body; Artificial respiration; Massage; Bathing devices for special therapeutic or hygienic purposes or specific parts of the body
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
A61L	Methods or apparatus for sterilising materials or objects in general; Disinfection, sterilisation, or deodorisation of air; Chemical aspects of bandages, dressings, absorbent pads, or surgical articles; Materials for bandages, dressings, absorbent pads, or surgical articles
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
A61N	Electrotherapy; Magnetotherapy; Radiation therapy; Ultrasound therapy
H05G	X-ray technique

Brief description of main applicants

ChM Ltd was established in 1981 by Mikolaj Charkiewicz. Nowadays, the company is an internationally recognized and highly valued producer of specialist implants and instruments for orthopedics and traumatology. It has its own production, marketing and research & development departments, as well as distribution network in the country and abroad. *ChM*® implants are well-known and well-regarded not only in Europe, but also on other continents. The company is based in the town of Lewickie in the Podlaskie Province. (Source: http://chm.eu/o-firmie)

Religa's Cardiac Surgery Development Foundation in Zabrze has existed since 1991. It was created on the initiative of one of the most well-known cardiac surgeons and transplantologists in Poland, Professor Zbigniew Religa. Its activity focuses primarily on scientific research and implementation of modern techniques and technologies in the field of heart treatment in clinical practice. The Foundation also conducts research on the creation of a new model of biological valve created from the cells of the patient, as well as the tissue bank. (Source: http://www.wobit.com.pl/en/frk/).

ADAMED Ltd. is a Polish pharmaceutical and biotechnology company. Its mission is to develop and introduce innovative medicines for key civilization diseases on global markets. For over 20 years, the company has been providing patients with the highest quality medicinal products in many therapeutic groups, including cardiology, psychiatry, pulmonology, gynecology and treatment of urinary tract infections. ADAMED has representative offices in Spain and Ukraine. Currently, the company's products are sold in 22 countries. In 2010, the ADAMED Group was set up, which includes ADAMED, Polfa Pabianice and ADAMED Consumer Healthcare was the company created after the acquisition of Agropharm. ADAMED Consumer Healthcare produces OTC drugs and dietary supplements. In collaboration with the ADAMED R&D department, innovative formulas of dermocosmetics have been developed and patented. ADAMED is a company with 100 percent share of Polish capital. It was established in 1986. (Source: http://przemyslfarmaceutyczny.pl/katalog-firm/firma/grupa-adamed)

IBSS BIOMED S.A. is a Polish biotechnology company operating continuously since 1945. The basis of IBSS BIOMED S.A. activity is the production of probiotics, vaccines, diagnostic preparations, media and indicators. IBSS BIOMED S.A. is one of very few Polish pharmaceutical companies manufacturing innovative medications, including the drug active substance. The creation of new products and the intensive development of the existing ones is carried out through collaboration with Polish research institutions and independent consultants. The company has collaborated with international partners regarding the registration, promotion and distribution of medicinal products for years. (Source: https://www.biomed.pl/Firma/O_firmie)

Provincial Specialist Hospital in Wrocław: In June 2006, the institution received the status of a R&D unit. This meant the acceleration in the development of an interdisciplinary scientific unit called "Integrated Cardiovascular Centre". In December 2010, the only DaVinci surgical robot in Poland started working there. The introduction of the robot to operating procedures allowed the hospital to open a new chapter in the history of Polish

surgery: the first robotic surgery. This event places Poland in the group of the most medically developed countries in the world. (Source: http://wssk.wroc.pl/nasz-szpital/historia)

Polpharma S.A. Pharmaceutical Works is a Polish pharmaceutical company with headquarters in Starogard Gdanski producing medicines that are used in cardiology, gastroenterology and neurology, including popular over-the-counter (OTC) medicines. The main products of Polpharma are generic drugs. The company was established in 1935 as the Polpharma Chemical and Pharmaceutical Plant. From December 1, 1995, the company was transformed into a sole-shareholder company, Polpharma S.A., owned by the State Treasury. It conducts its own R&D works and collaborates with universities and research institutes in Poland and abroad. The company has one of the largest development centers in Central and Eastern Europe, equipped with modern analytical equipment and devices for production in the laboratory and semi-technical scale. The Polpharma Group has a total of seven R&D centers, where it employs over 400 high-class specialists who provide approximately 30-40 solutions per year. (Source: https://www.polpharma.pl/firma/)

Celon Pharma S.A. is an integrated pharmaceutical company which conducts advanced research and manufactures modern drugs. One huge advantage of Celon Pharma S.A. is its strong R&D facilities which allow it to create whole new classes of effective drugs. The R&D department in Celon Pharma S.A. employs over 70 scientists, of whom one in four have PhD titles in molecular biology, pharmacy or chemistry. The firm invests in the development of innovative pharmaceutical products with the potential to treat cancers, neurological diseases, diabetes and other metabolic disorders. Celon Pharma S.A. obtains financial resources for research into new drugs from the sale of generic drugs, as well as from the EU funds. (Source: https://celonpharma.com/o-spolce)

Wrocław Research Centre EIT + Ltd is a research and development organization focused on the development of new technologies by conducting research for the needs and in collaboration with the industry. In order to fulfil this role, the WRC EIT + combines the features of an enterprise and a research institute whose aim is to support the Polish economy through the development of new technologies and conducting interdisciplinary scientific research. It conducts research, as well as R&D projects in the areas of biotechnology, medical diagnostics, material engineering, chemistry, photonics and electronics and nanobioengineering. The Company's registered office is the Pracze Campus in Wrocław. Since April 2017, the company has been subordinated to the Minister of Science and Higher Education. The company was established in 2007 thanks to the involvement of Professor Tadeusz Luty, five universities in Wrocław (University of Economics, Medical University, University of Life Sciences, University of Wrocław, Wrocław University of Technology), authorities of the Wrocław Commune and Marshal's Office of the Lower Silesian Province. The aim of the project was to create a unique didactic and research environment by providing a meeting place for science and business together with modern infrastructure for conducting scientific research. (Source: http://www.eitplus.pl/misja-i-cele/)

Sequoia Ltd is a pharmaceutical company that specializes in the sale of pharmaceutical products to the most vulnerable consumer groups, i.e. babies, children and pregnant women. Among others, the company offers a wide product portfolio in infections and flu, fever, pain, Omega-3 deficiency, protection in antibiotic therapy, wound treatment, gastrointestinal tract protection, allergy, resistance to disease, anemia, and rickets prophylaxis. (Source: https://maspex.com/aktualnosc,spolka-sequoia,257.html)

Pharmaceutical Production Company (PPF) Hasco-Lek S.A. is a leading producer of pharmaceuticals, dietary supplements and medicinal products manufactured in two modern factories located in the capital of Lower Silesia and Siechnice near Wrocław. PPF Hasco-Lek S.A. has been operating in the Polish market since 1984. The portfolio offered by PPF

Hasco-Lek S.A.today comprises about 400 products including Ibum, the leader in Poland in the category of pain relief capsules containing ibuprofen. The company collaborates with many scientific and research centers such as medical universities, universities of natural sciences and universities of technology. The full authorized capital of PPF Hasco-Lek S.A. is a Polish contribution. (Source: http://www.hasco-lek.pl/pl/o-nas/)

Read-Gene is a company operating in the so-called "personalized medicine" industry, which means that each patient is treated individually on the basis of genetic tests. The main segments of the company's activity are chemoprevention, clinical trials and genetic testing. Chemoprevention is the use of natural or synthetic substances to stop, revert or delay the cancer process. Chemoprevention is Read-Gene's main field. Read-Gene offers its services in the area of clinical trials to companies, mainly from the medical, pharmaceutical, chemical and biotechnology branches. Its clinical trials are groundbreaking for the fact that they focus on patients with a defined genetic profile. Read-Gene has an exclusive license agreement concluded with the Pomeranian Medical University in Szczecin for the use of technology protected by intellectual property rights. The company also provides planning consultancy and support services for cancer genetic clinics. (Source: http://www.read-gene.com/pl/informacje/o-read-gene)