

Committee on Development and Intellectual Property (CDIP)

Twenty-Second Session
Geneva, November 19 to 23, 2018

SUMMARY OF THE STUDY ON INTELLECTUAL PROPERTY IN THE HEALTH SECTOR INNOVATION SYSTEM IN POLAND

prepared by the Secretariat

1. The Annex to this document contains a Summary of the Study on Intellectual Property in the Health Sector Innovation System in Poland prepared under the project on Intellectual Property and Socio Economic Development – Phase II (CDIP/14/7). The Study has been prepared under the coordination of the WIPO Secretariat in collaboration with the Patent Office of the Republic of Poland (PPO).

2. *The CDIP is invited to take note of the information contained in the Annex to the present document.*

[Annex follows]

Intellectual property in the health sector innovation system in Poland

In 2015, the Polish Government requested the World Intellectual Property Organization (WIPO) to conduct economic study work in Poland under the second phase of the CDIP project on intellectual property (IP) and socio-economic development (CDIP/14/7).

Bilateral consultations and the policy needs of the Polish Government set the focus of the country study as the role of IP in the innovation ecosystem of the broadly defined health sector.¹ Accordingly, the PPO organized a workshop involving key stakeholders from the health sector, including amongst others the Ministry of Health, the Ministry of Economy, the Central Statistical Office of Poland, the Ministry of Science and Higher Education, the Polish Academy of Sciences, the University of Warsaw, the Jagiellonian University, and industry representatives.

The background research and fact finding missions showed that Poland seemed to have an active and growing scientific community in the life sciences field, partly due to substantial support from European Union structural funds. There are subfields where Poland seemed to have innovation potential, such as upstream biotechnology research in certain medical fields, personalized medicine, telemedicine, generic medicines, and the conduct of clinical trials. However, most R&D still relies on public funding which may explain partially the limited success of technology transfer offices in commercializing academic inventions, notwithstanding a considerable number of patent filings and the creation of numerous technology transfer institutions.

The country study explored in further depth these and related matters by providing the first landscape on innovation and IP use in the health sector of Poland.

The study was conducted from May, 2016 to August, 2018, in collaboration with the PPO and other Polish governments agencies. This document summarizes the implementation and main outcomes of the study.

Objectives

The study's main objective was to support evidence-based innovation and IP policymaking in the health sector of Poland. The study mapped the recent innovation and use of IP trends in the health-related innovation system in Poland, as well as the potential for growth in the scope and variety of IP protection. It explored qualitatively the usefulness and limitations of IP in the Polish health sector, outlining the existence of health innovations not protected by patents and presenting good practices in IPR management.

Among others, the study was guided by the following research questions:

1. What are the factors influencing innovation performance in Poland's health sector?
2. What is the relevance of the IP system for this sector?
3. What are the reasons for different approaches to patenting by different science and industry stakeholders?
4. What are alternative methods of protecting health-related innovations?
5. What are examples of best practices in IPR management in the health sector and patenting strategies of industry participants?

¹ In initial consultations, the Government also expressed an interest in including the energy sector in the study, but it subsequently dropped this interest.

Coordination and execution

The study implementation required coordination between the Economics and Statistics Division of WIPO and the PPO. Local consultants and PPO staff implemented the technical and analytical components of the study work under the supervision of WIPO's Economics and Statistics Division (ESD) and the PPO. WIPO and the PPO provided substantive inputs based on their IP international and national expertise. Additionally, the project relied on the expertise of various stakeholders in the Polish government, academia and private sector, which provided inputs to the qualitative survey component, commented on the study work in a technical workshop and acted as reviewers.

Methodological design

The implementation of the study was divided into three main components: (1) a statistical analysis of innovation in the Polish pharmaceutical and medical technology industries; (2) a patent mapping of the Polish pharmaceutical and medical technology industries; and (3) a qualitative assessment of those industries' innovation potential.

Each component had a specific methodological strategy, which is summarized as follows.

1 - Innovation in the Polish health industries

The analysis focused on selected economic aspects of the pharmaceutical and medical technologies industries, with particular regard to its innovativeness and evolution. It relied on sound descriptive statistics and appropriately sourced data. The study documented statistically the evolution of these two industries and their innovativeness. It compared the main indicators whenever possible with those from other European Union (EU) countries. The analysis also relied on detailed firm-level innovation data to describe innovation activities, financing sources, cooperation, knowledge sources, and hampering factors.

The main sources of the analysis were Central Statistical Office of Poland, Eurostat, industry annual reports and the existing scientific and technical literature.

2- Patent mapping of health related technologies

The analysis focused on the patent and utility model filing trends in Poland and from Polish applicants abroad. It relied on commonly used patent analytics metrics and indicators, drawing on the patent examination and IP statistics expertise of the PPO and WIPO ESD teams. The concepts and definitions used in the analysis followed and adapted the main definitions of the current scientific and IP related literature.

The baseline data sources were patent and utility model applications filed at the PPO by Polish residents and non-residents, those filed at EPO and validated in Poland by Polish residents and non-residents, and those filed abroad by Polish residents.

3- Qualitative assessment of the Polish health industries

The qualitative assessment of the Polish pharmaceutical and medical technology industries was based on an in-depth analysis of more than 40 interviews conducted with main local stakeholders in these industries. The analysis focused on the impact of patent protection on the conditions for innovation in the Polish pharma and medtech industry in light of the experience of Polish entrepreneurs.

A senior local consultant and the PPO jointly developed a detailed interview script to capture the qualitative information and established the interviewee sample. The PPO coordinated the field exercise, which was executed by local junior consultants specially engaged and trained for this purpose. A senior local consultant conducted the final analysis with the supervision of the PPO and WIPO ESD teams.

Implementation timeline and main activities

Initial discussions on the country study started in 2015, which resulted in a fact-finding mission to Warsaw and Krakow in March 2015, after which WIPO-ESD agreed to undertake the country study. The mission was instrumental to establish the feasibility and scope of the study in close discussions with the main relevant Polish government agencies and the academic and private stakeholders. The study work formally started in May 2016 when a research agreement between the PPO and WIPO was signed. The agreement provided for the PPO to execute the local study work, particularly the national qualitative field exercise.

The study work's progress was jointly reviewed in a special workshop held in Krakow in September 2016. The meeting served to review the preliminary results of components 1 and 2, and to discuss the implementation of the fieldwork of component 3. Following the mid-study review, WIPO-ESD and PPO decided to change the strategy for the main analysis of the components due to scheduling conflicts with the senior local consultant. As a consequence, new local consultants assumed the lead analytical role for components 1 and 3, while PPO staff led the analytical work of component 2.

The three components were consolidated into three self-standing but related studies, which were finalized and externally reviewed in July 2018.

Lessons learned

The country study was generally implemented according to the initial scope established during its design. However, there were challenges faced during its implementation that had an impact on the expected timeline. This section explains these challenges and derives takeaways from them.

There were three challenges that had an observable impact on the timeline. The first one concerns the preparation of a technical agreement between WIPO and PPO. This type of agreement provides a clear and useful framework to operate this type of collaboration. However, its preparation and validation required many iterations between not only the technical sides of the involved institutions but also other administrative functions involved in the process. All the time involved in these iterations compound, increasing the likelihood of underestimating their footprint in the overall study timeline.

The second challenge concerns the implementation and execution of fieldwork such as the interviews performed in component 3. This type of empirical exercise typically requires substantive resources and faces considerable uncertainty – e.g. the availability and goodwill of respondents – often delaying the initially established implementation timeline. The PPO

performed a commendable work in coordinating the interviews, training the interviewers and processing the results; however, the task proved very demanding for the local PPO team.

The third challenge involves the availability of local consultants with very different skill sets. The original plan of relying on one single lead local consultant to handle all three components did not provide the same degree of skill diversity and time flexibility, compared to the final setting where each component had a different local expert. In particular, skills on IP analytics and statistics seem to be scarce, which resulted in the PPO assuming the patent analysis.

Summary of the economic studies²

1 - Innovation in the Polish health industries

The first paper analyzes economic and innovation aspects of the Polish health industries, namely the pharmaceutical and the medtech industries. The health industries have observed remarkable growth since entering into the EU. While the pharmaceutical industry faces some economic slowdown since 2011, the medtech industry shows substantial dynamism for its small size. The Polish health industry has still much to do to improve its innovation status. However, the observed trend of the innovation dynamics is cause for optimism. Polish firms in the health industries are increasingly innovating and extracting economic results from these innovations.

Generic medicines represent a considerable share of the Polish market of medicines and the price of pharmaceuticals is among the lowest in Europe. The share of public expenditures in the medicine costs incurred by patients in Poland is one of the lowest among the OECD countries. The Polish pharmaceutical industry observed a remarkable growth after joining the EU but has faced a severe slump since 2011. Similar to most CEE countries, Poland has observed an increase in the number of pharmaceutical firms. The entry of smaller companies and the economic downturn correlates to employment reduction, which is also observed in other CEE countries. Still, Poland has the larger pharmaceutical workforce in the region.

The medtech industry has grown steadily since 2011 but it is still a small industry in terms of firms and output. The Polish medtech industry includes approximately 100 large and small business entities manufacturing medical technologies. However, these have been growing at a steady pace, which is also the case for most of the CEE region. Poland has also observed increasing medtech sales, which is partially due to exports and public support through the European Cohesion Policy. Poland also observed the largest increase in medtech employment, which remained stable in most CEE countries. Poland has the largest medtech industry among the CEE countries, but it lags in productivity. In all CEE economies, the manufacturing of medical and dental instruments and supplies is by far the main medtech segment, but Poland had the lowest proportion of firms manufacturing medical equipment.

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Health-related industries are among the top innovation expending sectors in Poland. R&D expenditures represent the largest share of innovation expenditures, followed by investments in capital goods with embedded technology and in marketing related to the launch of new or significantly improved products.

² The full studies will be made available on: http://www.wipo.int/econ_stat/en/economics/studies

The Polish health industry has innovated more than the national average, but it is still far from EU levels. Most of the product and process innovations were new only to the firm and only a quarter were new in Poland. However, these innovations have increasingly contributed to the revenue of the health industry. Within the innovative sales, the larger share relates to innovations that are new to the firm but not the market. The health industry relies on complexity of their products, secrecy and lead-time advantage to maintain or improve competitiveness in their markets. Being a market dominated by generic and branded generics, less than a third relied on trademarks and industrial designs to maintain competitiveness. About a quarter relied on patents, which is in line with few novel product and process innovations being introduced to the Polish market.

2- Patent mapping of the Polish health related technologies

The second paper analysis the recent use of patent and utility model protection in Poland.

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. This represented an average annual growth of 13 percent.

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. 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.

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. Innovative activity is concentrated in the provinces of Masovia, Lower Silesia and Silesia.

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. Non-biological preparations constitutes the only specialization within which the largest number of applications was filed by business enterprises. Poland's medtech specialization is in diagnosis and surgery (34 percent) and prostheses, stents and orthopedic (18 percent).

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 analysis also 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.

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 health related 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.

3- Qualitative assessment of the Polish health industries

The third paper aimed to present the specifics of innovation in the Polish health industry through the prism of the experiences and opinions of a representative group of 42 companies from both the pharmaceutical and medtech sectors. Through analysis of in-depth interviews, it looked at the legal, economic and social mechanisms and phenomena that determine innovation in this sector.

The interviews point to the following patterns and trends:

- (a) The Polish pharma sector is mostly generic. However, this does not mean that there are not any research-based pharmaceutical companies. A few companies conduct R&D on innovative medicinal products in the area of oncology and immune-oncology. The model of commercialization of their R&D activities assumes that the rights to the examined products and results of the tests done will be sold to big pharma companies. There does not appear to be much promise for Polish innovative medicinal products in the coming years.
- (b) Typically, the generic industry is developing secondary pharmaceutical innovations – i.e. improvements to known medicines or improvements in manufacturing methods. These are medicines intended for the treatment of geriatric conditions, such as neurodegenerative diseases, cancer and cardiovascular diseases.
- (c) Within the pharma sector, the biotechnology and molecular biology subfields are seen to be creating the greatest development opportunities for Polish companies and worthy of governmental support, with regard to both innovative medicines and generic medicines. The main biotechnology companies are working on molecular biology products and technologies, such as isolation or amplification of nucleic acids. As regards biosimilar drugs, their development is more ambitious and demanding in comparison to the production of small molecule generic drugs. Such activities may constitute a good starting point for further development of the potential of the pharma industry in Poland.
- (d) The medtech industry is more diversified in terms of innovation. Innovative medical products and technologies – both breakthroughs and improvements – are patented and introduced to the market. The most groundbreaking innovations include artificial hearts, bone substitutes, traumatological implants and artificial tissues. Other examples of innovation in this sector include neurophysiology diagnostic equipment and devices for an early diagnosis of breast cancer, as well as stents and biodegradable dressings. Many Polish companies are working on highly innovative telemedicine devices and IT solutions for medicine. In the medtech sector, the biggest potential of innovation lies in the following areas: new technologies in diagnostics; tele-medicine and IT in medicine; biomedicine, implants and transplants; medical devices and medical services for an aging population. Due to extraordinarily high costs for the development of original medicinal products, the medtech sector may create more and better chances for breakthrough innovation in Poland.

(e) Firms identify lack of financial support as one of the main barriers to innovation. EU funds are appreciated, but are seen as too focused on basic research instead of implementation and the commercialization of innovations for the market.

(f) Another barrier is the lack of cooperation between sectors, particularly in achieving technology transfer. Companies perceive technology transfer centers as not aligned with the interest of the health industry. Cooperation with the public sector is seen as very difficult, due to the different institutional cultures.

(g) On the grounds of the conducted interviews and given responses, the average knowledge about IP protection in the Polish health industry is still rather weak. While there is a group of companies that have highly specialized and skilled managers in this area, many of the representatives of this sector do not have a full understanding of the role and rules of IP.

(h) For both of the surveyed sectors, patents serve primarily as a defending tool, securing right to an invention against being blocked by others, and only secondarily as a tool for securing exclusivity.

(i) Respondents perceive patents to stimulate innovation in the medtech sector, allowing companies to recoup investment on R&D activities. However, this is seen as perceived to be only partially true in the Polish pharma industry. On the one hand, due to the high costs of commercialization of new medicinal products, the patent system is believed to be a necessary stimulus for innovation, particularly in the research-based pharma sector. On the other, the costs of conducting clinical and pre-clinical trials are so high that they constitute an insurmountable barrier for Polish pharma companies. The basic problem lies in the lack of initial capital and the long waiting time for return on investment, and the uncertainty as to whether investment will indeed yield returns.

(j) Several Polish companies have been struggling to develop new medicines. However, in most of the cases, these companies do not intend to bring their product to the market authorization phase, but they rather sell the invention rights at an advanced R&D phase. In such cases, patents were seen as necessary to recoup the R&D investment.

(k) Some specific health related companies do not make use of patent protection. First, companies producing copies of medicines have no patentable material and therefore no interest in patent protection. Second, and by contrast, innovative companies in the field of molecular biology protect their technologies as trade secrets, due to their short market lifespan. Third, medtech firms specializing in telemedicine find difficult to use patent protection if they cannot relate their innovation to a device.

(l) Firms make use of other IP rights to protect their innovative products and services. These include trademarks, utility models and industrial designs.

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