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Cancer patent scenario in Brazil: Analysis of competitive advantages

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ABSTRACT

The present study describes the geographical and sectorial profile of chemical and biotechnological patents, regarding prevention, diagnosis, and treatment for the most frequent cancer types in Brazil that are currently registered in the Brazilian National Institute of Industrial Property – INPI, from 1998 until 2013. The steps taken to generate competitive advantage in the Brazilian oncological drug market are discussed and an analytic sectional survey was performed using the INPI database. In addition, a literature review on technology and scientific development was conducted using the Porter's Diamond of National Advantage model. From 503 requests for patents, 41.4% corresponded to breast cancer, 13.7% lung cancer, 38.6% prostate, and 6.4% cervical cancer. Regarding the sectors and countries involved, the vast majority (74.4%) came from the pharmaceutical industry: mainly from the USA and Switzerland. According to the analysis and the Porter Diamond Model, we concluded that Brazil is uncompetitive in cancer R&DI.

1. Introduction

Technological innovations in health have been a recurring theme for debate at government and civil society levels, according to the impacts produced in the life quality of populations and the economy of many countries. Amongst the innovations that stand out, are those geared towards prevention and cancer control [2,3].[1] Moreover, countries from the European Union, United States, and Canada present as a priority the development of policies aimed toward cost management; keeping in mind the financial commitment they have with technology, innovation, expensive medical-hospital care, and ambulatory treatment with oncological medication [1]. The growing economic and intellectual capital investment in this segment is not limited to developed countries, because countries with medium to low-income also face the same challenges. The challenges faced, are due to the continuous global increase in the cancer incidence and the centralized high costs: primarily in drug therapies [1,2].

For medication development within the pharmaceutical sector, it is not only necessary to comply with the four stages of discovery and development (Research stages and Development – R&D) [1,2], production, and marketing of new products, but it is also equally important to promote them. Amongst the initial stages, one can find the patent request stage. The possibility to carry out all the phases are centralized in the developed countries, which possess encouraging units to R&D industrial capacity and the domain of productive activities. In other words, they present a triad of attributes that enables a competitive advantage over other countries.

A competitive advantage, according to Professor Michael Porter from Harvard University, emerges from the concept of what a company is capable of creating for its consumers [4]. It relates to the business' capacity (country) to innovate goods and services, improve the production processes and organizational management in order to become competitive in front of the world's best competitors. Within this context, the development and registration of chemical and biotechnological patents registries in cancer constitutes a competitive advantage for public and private companies and invention shareholders for their country of origin, as it ensures a temporary monopoly. The patent, evolving into a special product (innovation), can render more profit, and in some cases, political capital that exerts influence in the civil society for adhesion to new health technology and practices at a national and international level.

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[1] Brasil. Lei Federal n° 10.973, de 2 de dezembro de 2004. Dispõe sobre incentivos à inovação e à pesquisa científica e tecnológica no ambiente produtivo e dá outras providências . *Diário Oficial da União*.13 de Abr. 2014. p.2.

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2213-5383/

In Brazil, incentive measures have been taken for scientific and technological research and the industrial capacity for the productive medication chain in order to minimize the trade deficit in healthcare that includes the importation of oncology drugs [1,5]. This deficit results from non-servicing on the behalf of the national industry production to the demand of health services, proven by the increase in expenses with imported products, surpassing $1.7 billion USD in 2005 to $3.7 billion USD in 2011 [6].

Based on the assumption that technological innovations are a differential factor in the competiveness between companies and countries and considering chemical and biotechnological-based patents in cancer as indicators of the collective efforts in favour of a better quality of healthcare linked to the an increase in the economical development, the objective of this study was to characterize the geographical and sectorial profiles of chemical and biotechnological-based patents. This was performed in relation to prevention, diagnosis, and treatments for the most incidental cancers in Brazil (breast, lung, prostate, and cervical cancer[2] that were placed in the INPI between 1998 and 2013. Additionally, this study discusses Brazil's features for competitive advantage attainment in the production area of new oncological agents. This article is the first in Brazil describing the current framework of the national production of new technology geared towards prevention and explains the dynamics of the national features that favour or inhibit scientific or technological production. Furthermore, this work gives realistic notions of what can be improved in Brazil in order to increase competiveness within the oncological production area.

2. Methods

Analytical cross-sectional study of record requests for chemical and biotechnological-based patents related to prevention, diagnosis, and treatment for breast, prostate, lung, and cervical cancers placed in INPI, between 01/01/1998 and 12/31/2013. The search for identifying patent request records was performed in the INPI database (PPI System-Research in Industrial Property): available at: https://gru.inpi.gov.br/pPI/.

The search protocols were elaborated for each topography studied: breast, lung, prostate and the cervix, in accordance to a conceptual analysis with a sensitive application for relationships between simple and compound terms in the subject area presented in all of the strategies, including the use of controlled subject description vocabulary. Furthermore, this vocabulary is present in the Mesh/Medline, DeCs/BVS, and other terms that are not covered by subject descriptors. The search strategies were combined with the Boolean operators "OR" for addition and "AND" for the relationship between terms. In the initial search, 566 distinct applications were recovered. Out of these applications, 503 were selected in accordance to the research eligibility criteria (chemical and biotechnological-based patents).

Afterwards, the data collected was tabulated into electronic spreadsheets from the Microsoft Excel program, and analysed through descriptive statistics. A detailed method is shown below, to make the results' reproducibility feasible:

(a) Breast – Summary'("cancer* OR neoplas* OR tumor* OR carcino* OR onco* OR anticancer* OR antineoplas*) AND (mama OR breast OR seio OR peito)' \Deposit date: '01/01/1998′ to '12/31/2013′ (b) Prostate Summary: '(cancer* OR neoplas* OR tumor* OR carcino* OR onco* OR anticancer* OR antineoplas*) AND (prostat*)' \Deposit date: '01/01/1998 to "12/31/2013" (c) Lung – Summary (a) ' ("cancer* OR neoplas* OR tumor* OR carcino* OR onco* OR anticancer* OR antineoplas*) AND (pulmão OR lung)'\Deposit date: '01/01/1998'a '12/31/2013′. Data collection date: November 26, 2015.

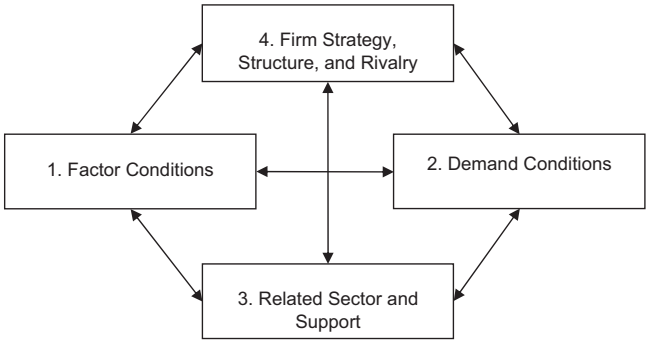

Fig. 1. Porter's competitive diamond model [4].

For the qualitative analysis of the results, we sought to identify conceptual themes that made the content categorization possible: according to the content analysis [7,8], method with the objective of establishing internal relationships with the determining attributes from the Porter's Competitive Diamond summarised in Fig. 1.

The four determining attributes from the Porter Diamond model are perceived in this study as areas that act in an intertwined fashion, which seek to optimize the spawning of new scientific knowledge and technological innovations, as means to create competitive advantages for companies and their country of origin. The following phase consisted in identifying, differentiating, and grouping of thematic contents of chemical and biotechnological-base for prevention, diagnosis, and treatment for the cancers selected for this study. In this stage, three researchers classified the patents as "blind," without one being aware of the classification of the other one, serving as a way to avoid evaluation errors. The competitive advantages were discussed in the area of research, development, and innovation (R&DI) in cancer in Brazil, through collating between the object analysis and scientific literature regarding technological innovations [2,3,5,6,9] and competitive analysis [4,10,11].

In addition, the study settled the approach to the organizational [12] cultural framework for result analysis by considering that people who worked in companies (public and private) are held inside of a cultural organizational pattern, associated with the socioeconomic and cultural reality formed in the country, hence favouring or inhibiting scientific and technological production.

3. Results

3.1. Patent requests in Brazil and intervention areas

Five hundred and three requests for patents of chemical and biotechnological-base were registered in the INPI, driven by prevention, diagnosis, and treatment for the following cancers: breast 41,4% (208), prostate 38,6% (194), lung 13,7% (69), and cervical 6,4% (32). Likewise, it is worth highlighting that the same request can refer to more than one type of tumours and interventions in healthcare. As can be seen in Fig. 2A, the greatest number of patent requests was from treatment areas (68,4%) followed by prevention (16,7%) and Diagnostic (14,8%). Fig. 2B shows that 74,4% (374) of the total requests belong to the pharmaceutical industry sector, whereas 14,3% (72) came from universities and only 1% (5) from

[2] Instituto Nacional de Câncer José Alencar Gomes da Silva. Coordenação de Prevenção e Vigilância. Estimativa 2014: Incidência de Câncer no Brasil. Rio de Janeiro: INCA; 2014 [citado março 2014]. Disponível em: http://www.inca.gov.br/estimativa/2014/estimativa-24012014.pdf.

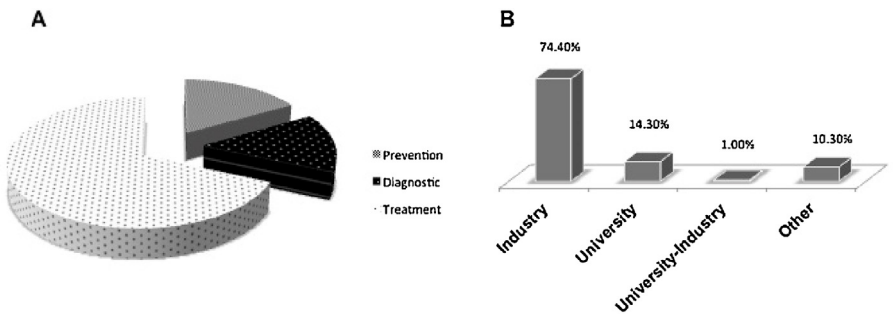

Fig. 2. Patent requests in cancer for the intervention area in healthcare in Brazil.

Table 1
Geographical and sectorial profile in the patent area in Brazil, 1998–2013.

[a]Countries	Industry		University		University Industry		Other		Total	
	n	%	n	%	n	%	n	%	n	%
United States	171	72,5%	40	16,9%	3	1,3%	22	9,3%	236	46,9
Switzerland	72	100%	–		–	–	–	–	72	14,3
Brazil	3	6,3%	23	47,9%	–	–	22	45,8%	48	9,5
Germany	30	96,8%	1	3,2%	–	–	–	–	31	6,2
Japan	17	94,4%	–	–	1	5,6%	–	–	18	3,6
Canada	15	88,2%	2	11,8%	–	–	–	–	17	3,4
France	12	70,6%	–	–	1	5,9%	4	23,5%	17	3,4
United Klingdom	8	72,7%	3	27,3%	–	–	–	–	11	2,2
Sweden	7	87,5%	–	–	–	–	1	12,5%	8	1,6
Denmark	6	100%	–	–	–	–	–	–	6	1,2
Spain	5	83,3%	–	–	–	–	1	16,7%	6	1,2
Belgium	4	80,0%	1	20,0%	–	–	–	–	5	1

[a] Countries with less than 1% of requests were omitted from this table. Source: INPI Patent Registry, 2015.

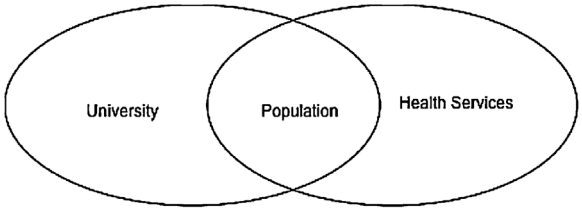

Fig. 3. Current induction model for competitive advantages in the brazilian cancer patent area. Adapted from Gadelha et al. [9].

the cooperation university- pharmaceutical industry. Other sectors corresponded to 10,3% (52).

3.2. Countries and sectors involved in the patent request process in Brazil

The next analysis was the stratification of patent requests according to different countries and sectors. Table 1 presents the countries, public, private sectors with patent requests of chemical, and biotechnological-base for prevention, diagnosis, and treatment for breast, prostate, lung, and cervical cancer in the Brazilian INPI office between 1998 until 2013.

The results shown in Table 1 indicates that the industrial sector of R&D in cancer belonging to the United States and Switzerland, accounts for the vast majority of the request registries for patent protection in the Brazilian office (503 requests). Brazil comes in third place (9.5%), with the university sector accounting for the majority of the patent request registries (47.9% of 48 requests made). With the content analysis method, it was possible to identify three thematic subcategories in the patent request registry that exercises intense relationships with the determining features from the Competitive Diamond. Fig. 3 systemic approach illustrates the national environment in R&DI in chemical and a biotechnological-base in cancer. The national industry does not appear as a competitive advantage inductor because of the 6.3% (Table 1) representation of the total patent request registries in the field. In fifteen years, only three requests were presented.

Regarding the countries' frequency of appearance in the patent request registries (Table 2), 10.1% of them indicated Brazil. The United States continues to be the country that receives more priority, with 65.9%, yet relativized in function of the majority of these registries being from the United States. The United States' pre-

Table 2
Indication of priority countries, 1998–2013.

Countries	N° [a]	%[b]
United States	333	65,9%
Brazil	51	10,1%
United Kingdom	20	4,0%
Japan	20	4,0%
Germany	16	3,2%
France	9	1,8%
Spain	5	1,0%
Australia	4	0,8%
Sweden	4	0,8%
Taiwan	4	0,8%
Canada	3	0,6%
Cuba	3	0,6%
Denmark	3	0,6%
China	2	0,4%
Italy	2	0,4%
Finland	1	0,2%
India	1	0,2%
New Zealand	1	0,2%
European Patent Organization	19	3,8%
International Patent Institute	1	0,2%
Not informed	7	1,4%

[a] In four cases, there were two priority countries: United States/The European Patent Organization (two cases); United States/Australia; United States/France.
[b] 503 placements.

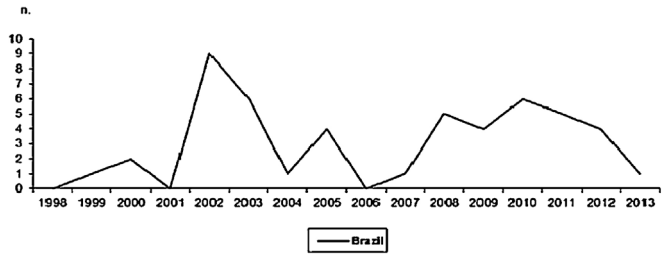

Fig. 4. National patent productions of chemical and biotechnological-base in cancer over time in years.
Source: INPI Patent Registry, 2015

dominance, *prima facie* continues to appear when researched in international patent request databases, for example: World Intellectual Property Organization (WIPO) and the European Patent Office (Espacenet). It is relevant to point out that during this study period, four foreign patent request registries prioritized Brazil.

3.3. National production of chemical and biotechnological- base patents as of 1998

The national production of chemical and biotechnological-base patents was also investigated over a time period starting from the year 1998. The results from Fig. 4 indicate that Brazil presents a low-productivity and inconsistency in the area of chemical and biotechnological patents for prevention, diagnosis, and treatment for the cancers indicated in the study. Between 1998 and 2013, the national entities registered 48 requests in the Brazilian office, against 454 from other countries; a fact that demonstrates a low-performance far from desired and a recent decline in patent requests. This reveals a productivity abyss when we compare Brazil to other countries in the area of chemical and biotechnological-based patents.

4. Discussion

The results presented show that Brazil is an attractive country in the cancer area of R&D worldwide, primarily for countries from the European Union, the United States, and Canada (Fig. 2A and B, Tables 1 and 2). The interest in some ways could be related to the growing internal consumer's demand for new oncological medication via governmental programs[3,4] and improvement in treatment quality. Other reasons could be the increase in early detection methods [13] and judicial action, without forgetting the growing wedge of supplementary health [15],[5] and the dispute of the international commercial centres which can equally be contributors to the growing consumer's demand [14]. In addition, said interest could also be due to a lower internal patent deposit even with a growing national demand, making Brazil an interesting polo with little internal competiveness.

In the scope of competitive advantages in the R&DI market in cancer in Brazil, the study identifies and validates the hypothesis that the country suffers some structural obstacles and also difficulties in the innovation management in order to be competitive in this area [2,3,5,6]. To further explain, competitive advantages will be discussed through a careful analysis and comparison of our results with the scientific literature regarding technological innovation and analysis of competitiveness (according to the four determining attributes from the Porter Diamond model), as follows:

Factor conditions [4] – conditions that affect the competitiveness in industry. This determinant establishes a connection with the health economic field studies, by considering the productive sector of goods and services in health, the location that creates conditions for the country to promote economic and social development in various areas, and sectors within the society [2,3,5,6]. Some studies on factor conditions indicate that Brazil suffers from structural bottlenecks, in terms of innovative dynamism; for example, the existing breakdown amongst high degree of scientific training and the limited existing innovative capacity in the productive base in healthcare. Table 1 data analysis shows that national industries, with a few exceptions, do not present production in research activity and scientific/technological development in cancer; as the national universities indicate present scientific productivity in this area, totalling 47.9% of the patent requests in the country.

These results, on a large-scale show; for example the construction of a national profile of technological innovation, sustained by the classical economic theory of the fifties up until the eighties: basic research → applied-research → development → commercialization. In other words, the national industry would only relate to the production and commercialization phases, without an interaction with that produced within the universities [16]. Additionally, the data revealed the low investments from the Brazilian industrial sector in R&DI and oncology, headed in the opposite direction of the current competitive success model—The interactive Model of Innovation (collective learning process) defended by the Kline & Rosenberg precursors from the eighties, also followed by other authors [17,18,19].

The demand conditions [4] – relates to studies regarding qualified clients [4,11,20,21] as decisive for the competitive advantage creation, because they offer companies, well in advance, the new consumption trends of today's society. In other words, production is determined by the consumer's needs. This is considered a competitive advantage source, while forcing companies to innovate quickly and elevate the national production's quality standards. In the Brazilian healthcare service scope, the qualified client would be represented mainly by governmental agencies and their regulatory sectors, and the public and private medical/hospital service provisions [5,21]. These entities formed by specialized professionals, evaluate and provide recommendations that can anticipate or even shape global and local trends [4].

Either way, the political values, from and ideological and/or economic perspective can impose needs that asides from not constituting in competitive advantages in local or international environments, which do not correspond to the local nosological profile. The result analysis (Table 2) compliment pieces of information present in previous studies [5,6,9] that showed that Brazil is not amongst the priority countries for development of new biotechnological and chemical-base compounds, geared toward prevention, diagnosis, and cancer treatment cited in this study. Nevertheless it is geared toward the commercial center, considering that the patent request in the countries of interest complicates the entry of traditional competition and newcomers. This suggests that technological innovations incorporated by the healthcare sector are not designated to only assist the national needs.

In this feature, the level of the country's schooling emerges as an indicator of competitive advantage spawning [4,11,20]. Under this approach, the combining of operating entities and educated citizens will enhance opportunities for public and private entities

[3] Brasil. Portal Brasil Saúde. R$ 35 bilhões serão investidos na aquisição de medicamentos até 2016. [Internet]. 2015.[citado 2015 jul]. Disponível em http://www.brasil.gov.br/saude/2013/04/r-35-bilhoes-serao-repassados-*para*-a-aquisicao-de-medicamentos-ate-2016

[4] Associação Brasileira de Desenvolvimento Industrial. Governo investe na produção local de biofármacos para economizar na importação. [Internet]. 2015. [citado 2015 jul.] Disponível em http://www.abdi.com.br/Paginas/noticia_detalhe.aspx?i=3586

[5] Souza RML. O mercado de saúde suplementar no Brasil: regulação e resultados econômicos dos planos privados de saúde. 8 ª Jornada de Estudos de Regulação – IPEA. [Internet] 2015. [citado jul 2015] Disponivel em: https://web.bndes.gov.br/bib/jspui/handle/1408/3722. Citado em julho de 2015.

of their country, as means to produce technological innovations geared toward new and legitimate needs and local trends, with search and claims activities (listening to clients and evaluating the scenario). Through this path, the requirement for competitive advantage spawning would be to expand investments in education and evaluate the level of teaching quality in the country. Furthermore, the present analysis suggest considering the constituted reality of each productive area of also, the country, because they are not homogeneous and they are in constant transformation.

The related and supporting industries – indicates the local production of equipment and input for the scientific research need at a worldwide level with a vision to meet domestic enterprises with quality, swiftness, and low-costs [4,11]. It is equally important for providers to be located in the same region to incentivize the technical corporation exchange and accelerate the information transfer and innovation flow. The Brazilian refund anticipation loans can provide the cooperation, collective learning, tacit knowledge, and the innovative capacity of companies and also, local institutions, to increase sustainable competiveness [22].

Considering these assumptions, the result (Table 1) can be interpreted as an absence of integrated actions between the research teaching areas and the industrial areas, in the Brazilian innovation process. As a response, integration initiatives were performed in the framework of the Brazilian Ministry of Health and institutions, such as *Redes Nacionais de Pesquisa Clínicas* (National Network for cancer research –RNPC),[6,7] and the *Rede Nacional de Desenvolvimento e Inovação de Fármacos Anticâncer* (National Network to develop anti-cancer medication- REDEFAC).[8] The intention behind these network's creation was to acquire and develop *know-how* specifics about spawning and the production of new oncological technology, and at the same time, standardize procedures, structure research centres, and to share knowledge among researches and healthcare professionals. In the light of the interactive system of innovation, the formation of these networks would constitute a strategy for enhancing and fortifying the inter-sectorial model of production from the R&DI in cancer, involving concurrently the academic and industrial field and health service provision, differently to the present model seen in Table 1. Therefore, this is a matter of encouragement between the healthcare, economy, and industrial sectors 2. Under the formation of these networks, in the context of organizational culture, it stands out the construction of values from interorganizational relationships [12].

Firm strategy, structure, and rivalry [4] – this determinant indicate that competitive strategies adopted by companies suffer from influence, especially from the local political context and from variables from the world stage [4,11]. They defend the hypothesis that the management system should emanate practices from developed management in the organizations of the country, and not the integral reproduction/application of universal models. In addition, they emphasize the need to enhance economic capital to develop the infrastructure, just like specialized professionals as a determining condition of the process to achieve competitive advantages in the national and international environment. The analysis from this feature indicates that the investment in the R&DI shows a high degree of risks, meanwhile the returns on the capital invested can be sometimes moderated or none.

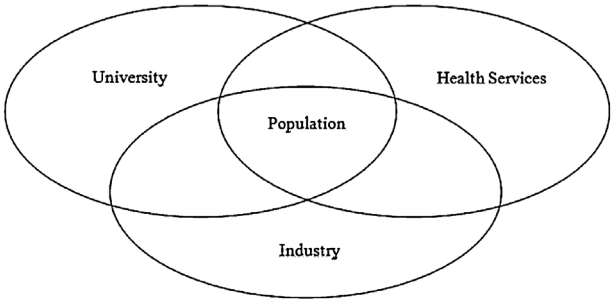

Fig. 5. Inducer model expected at a national level for competitive advantage related to cancer in Brazil.

The data analysis (Table 1) suggests that the Brazilian industrial sector lacks economic and human resources to develop research in cancer and space in their organizational structure that entails companies (public and private) to act in the same sector. Competiveness between national companies would have as an outcome the chaining of internal rivalries and the consequent enhancement of creativity [4]. In the case of Brazil, the expected results would be the elevation of new technology production and significant improvements in healthcare services offered to people, apart from the reduction of competitive advantages from protectionist policies [5,6,9]. The systemic approach data (Fig. 3) shows the population as an essential component for new scientific findings and technological findings in healthcare, reinforcing the need for integration and presence of diverse sectors of the satisfying of the achievement attainment fulfilment in the area of cancer patents at a world level.

Regarding Brazil's performance in the area of chemical and biotechnological-base patents in cancer, the results from Fig. 4 makes us aware of the instability in productive activities and a decline in the cycle since 2010. The emerging question is if the political and economic ruptures that exist in the country, the poor level of the population's schooling, or the shortage of qualified human resources would explain the poor performance in this area. Somehow, the results point out the urgent need for investment prioritization in the productive healthcare, chemical and biotechnological-base, electronic and medical/hospital materials area, as well as considering the four determining features of the Porter's Diamond in the implementation of these practices. It is expected, in an ideal competitive advantage model, a possible growing in the national industrialization combined with a close interaction between different sectors such as the ones shown in Fig. 5, which could lead to a greater deposit of national patents.

5. Conclusion

Collectively, this is a substantial study regarding the competitive advantages in the Brazilian cancer Patent Scenario. The innovation area and the theoretical field of health economics are discussed empathizing that the potential for research and innovation in cancer exists in Brazil as one of the paths to decrease the dependency on international pharmaceutical products. That perspective would be easily reached by financial capital investments in infrastructure and human resources capacitation, since innovation, as we know, occurs overall from the generation and transformation of scientific knowledge in new goods and services, and not only through acquisition of new technology. We observed a predominance of international pharmaceutical industries in the Brazilian patent registry requests, which were linked to the country's most incident cancer types. The results also point out for the poor performance of the national industries in patent deposits, showing reduced funding programs in research and also reduced technological innovation in healthcare.

[6] Brasil. Portaria n.794, de 13 de abril de 2011. Institui a Rede Nacional de Pesquisa Clínica (RNPC) em Hospital de Ensino. *Diário Oficial da União*. 22 de dez. 2011.

[7] Brasil. Portaria n.12, de 13 de dezembro de 2011. Institui a Rede Nacional de Pesquisa Clínica em Câncer (RNPCC) e cria seu comitê gestor. *Diário Oficial da União*. 22 de Dez. 2011.

[8] Brasil. Portaria n.30, de 25 de setembro de 2012. Institui a Rede Nacional de Desenvolvimento e Inovação de Fármacos Anticâncer (REDEFAC) e aprova seu regimento interno. *Diário Oficial da União*. 26 de set. 2012.

The data analysis and the application of the Diamond model allowed us to conclude that Brazil is still uncompetitive in R&DI in cancer due to several factors comprising structure nature bottlenecks, the poor conception of technological innovations, the population's level of education and the lack of specialized human resources in detriment of the linear approach to innovation. In order to emerge as competitive among the world's leading countries, some structural changes have to be performed and it is necessary that Brazil's policies, and practices, become in accordance with the interactive innovation model. Furthermore, our careful analysis on the patent registry requests could be used as a tool for the researchers and managers in the healthcare sector in order to develop better strategies in healthcare politics. At last, there is a clear need to improve our population knowledge in R&DI and to better integrate different sectors such as the educational, research, industry and governmental in the Brazilian innovation process.

Disclosure

We acknowledge that there are no known conflicts of interest associated with this publication.

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