Public Policies and patents for breast cancer in Brazil, India and Australia

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Abstract

This article illustrates that public policies to facilitate access to medicines, research investments, and selfawareness for breast cancer are the way to change the scenario of breast cancer in Brazil, India and Australia. The motivation was due to the fact that the literature reports breast cancer as a public health problem due to high incidence and mortality rates, whether the country is developed or not. The method adopted was the review study based on the data analysis on public policies and patents for breast cancer in Brazil, India and Australia available in official websites, INPI, Espacenet and Patentscope databases, journals and international newspapers Specialized and physical literature related to the theme. The descriptors used were cancer, breast, breast cancer, breast cancer and Australia, cancer patents, breast cancer and India. The following inclusion criteria used were year and period of publication, availability of the article in full and the intersection between the descriptors. The research concluded that there is an urgent need to prioritize public health with more investment in breast cancer research and awareness programs on the importance of early detection in those countries, primarily in India.

Keywords: Public policies, breast cancer, patents.

1. Introduction

As populations age, expectations for survival and quality of life become higher as societies increasingly take control of health problems related to infectious diseases. The high cost of medicines is one of the factors contributing to rising pharmaceutical expenditures [1] and difficulty accessing medicines. "*The end consumers of prescribed pharmaceuticals (patients) are virtually powerless to negociate prices - in part because they often simply cannot 'walk away from a deal'*. " (Introduction [2]) In this sense, the public demand for access to effective treatment of breast cancer has been a source of pressure for the companies that produce drugs for this therapy, for those who finance health care, for those who provide such care, for regulatory agencies responsible for controlling the licensing and use of pharmaceuticals.

Intellectual property rights favored research on pharmaceutical products and processes with the signing of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1964, and gradual adoption by the member countries of the World Trade Organization (WTO). The intellectual property

regime and the access to medicines, however, have not converged in a beneficial way when it comes to public health policies, especially in the diagnosis of malignant diseases, such as breast cancer. "Moreover, public and private insurers often operate in a context of intense pressure from stakeholders, pharmaceutical industry and consumer organizations to provide funding for new medicines." [1]

Surgery is one of the main forms of treatment of breast cancer. Chemotherapy and radiotherapy are also therapy modalities to be used in isolation or together, depending on the patient diagnosis. However, they are very expensive and the approval, licensing and supply of oncology drugs are not optimized and relaxed. As the number of people affected by breast cancer in the last decades has risen. There is a need to recognize that public policy and all those involved in this process have to develop a robust and rapid approach for breast cancer patients. Recent World Health Organization (WHO) [3] research shows breast cancer has been the third leading cause of cancer deaths in women.

According to estimates by the National Cancer Institute (INCA) [4], Brazil presented statistics of more than 57 thousand new cases of breast cancer in 2016. In India, official statistics report that breast cancer is the most common cancer in most cities and the second most common in rural areas. In Australia more than 15,000 women were diagnosed with breast cancer in 2016, according to government website indicators in 2017.

This article discusses the urgency of ensuring the continuity and vigor of programs that help research against breast cancer in voluntary financing industries, academies and settings. But also, the management of procedures that regulate in a way that protects the rights of the public interest and do not prevent early access to therapies that, for the patient, may be the only safe way to try healing.

2. Methodology

The research methodology adopted in this study was the review study based on the data analysis [5,6] on public policies and patents for breast cancer in Brazil, India and Australia available in official websites, Instituto Nacional da Propriedade Industrial (INPI), Espacenet and Patentscope databases, specialized journals and international newspapers and physical literature related to the theme. The descriptors used were "cancer", "breast", "breast cancer", "br

3. Breast cancer

Health literature reports that cancer happens when cells in the body change and grow out of control and most of these cells form a lump or mass called a tumor. It can be detected through screening exams such as mammography or when the woman perceives a lump.

As the most common cancer diagnosed among women worldwide, breast cancer is a disease of considerable public health importance [7]. The risk of breast cancer increases with age and there are 999 000 new cases of breast cancer each year (about 22% of cancers in women) and 375 000 deaths [8].

According to World Cancer Research Fund International statistics (2016) [9] nearly 1.7 million new cases diagnosed in 2012 (second most common cancer overall). This represents about 12% of all new cancer cases and 25% of all cancers in women. The literature points out that detecting cancer at an early stage reduces the financial impact: not only is the cost of treatment smaller, but people can continue to work and support their families if they have treatment.

Currently there is not sufficient knowledge on the causes of breast cancer therefore, early detection of the disease remains the cornerstone of breast cancer control [10]. Experts believe that life expectancy is a strong factor in explaining much higher rates of breast cancer in developed countries than in developing countries. Ferlay [7] declared that "the number of established and hypothesized risk factors for breast cancer exceeds that of any other cancer resulting in a rich, but complicated and often conflicting literature on the epidemiology of this disease." They also considered that women in poor countries have short lives than there from rich countries and have different lifestyles and eating habits that are thought to contribute to the incidence of this type of cancer.

4. Public policies and patents for breast cancer treatment

One of the largest global industries is the Pharmaceutical Industry. The continuous innovation of new drugs to which it is associated demands to be aware of the constant regulatory and technical aspects associated to the process of this production. It also needs to consider ethical and economic issues that pervade security, quality, profits, patent rights, and protection. [11].

The variance in technical requirements from country to country made it necessary to duplicate many timeconsuming and expensive test procedures in order to release new medicines in the international market. This resultant increase in cost of research and health care made it necessary to rationalize and harmonize regulation, so as to make safe and efficacious new treatments available to patients in the minimum amount of time [12].

Cancer imposes a major disease burden worldwide, with considerable geographic variations in incidence; mortality; survival [8]. These many facets and the currently global trend toward the development require updated public policies. Policies that allow access to medicines, but also enable and stimulate research. These aspects of breast cancer screening policy and practice have been subject for "*debate about whether or not the benefits of breast cancer screening outweigh the harms amongst certain population groups, and the level of information detail to provide for women*" [13].

Information on symptoms and forms of breast cancer, and guidelines for treatment are available on the National Comprehensive Cancer Network (NCCN) [14]. WHO promotes comprehensive breast cancer control programs as part of national cancer control plans [3]. In doing so, for low-and middle-income countries, awareness of early signs and symptoms is recommended as well as screening for clinical breast examination in demonstration areas, because good health infrastructure is needed in a country so that it can pay for a long-term program such as Mammography screening, still very expensive.

4.1 Patent application from Brazil, India and Australia in the searched databases

The search took place on June 10, 2017. The INPI database [15] was the first search about Brazil patent applicance. The words "breast cancer" found no results. When they were writen in portuguese *câncer de mama* or *câncer mama* to filter titles, 125 patent applications from Brazil were found for this purpose from March 22, 1988 to November 03, 2015. Inserting them as a filter on the *basic search* option, 236 were found for the period from September 13, 1994 to November 03, 2015, the most recent request. Search in the Patentscope database [16] found no results in the worldwide data base for "breast cancer AND Brazil" in the title or abstract as well in the Espacenet data base [17].

In the Patentscope database, the terms "breast cancer AND India" were used to filter titles on the *simple search* and 03 Indian patent applications were found for this purpose between June 29, 2011 and December 17, 2015. All the applications contained breast cancer in the abstract and none in the title. At the Espacenet database, the terms "breast cancer AND India" were used to filter on the *smart search* icon and 02 Indian patent applications for this purpose were found between September 12, 2010 and April 16, 2016. All the applications contained breast cancer in the abstract and none in the title.

Australia was the last country searched. In the Patentscope database, the terms "breast cancer AND Australia" were used as filter on the *simple search* and 14 Australian patent applications were found for this purpose between March13, 1997 and April 27, 2017. Four applications contained breast cancer in the title and 10 in the abstract. At the Espacenet database, the terms "breast cancer AND Australia" were used as filter on the *smart search* icon and 05 Australian patent applications for this purpose were found between November 07, 2006 and February 23, 2017. Two of these applications contained breast cancer in the title and 03 in the abstract. Figure 1 shows the result of patent applications in the searched databases. Figure 2 shows the start and last patent application date found in the countries concerned for this article.

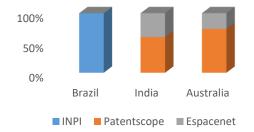


Figure 1. Patent application Source: Research results (2017) prepared by the authors

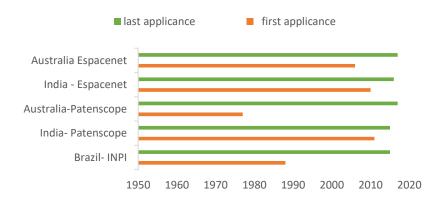


Figure 2. First and last year applicance Source: Research results (2017) prepared by the authors

4.2 Public policies for breast cancer in Brazil

According to [18] the breast tumor was responsable for the 18 thousand women deaths in 2015, in Brazil. It is the third cancer mortality for women, although there are early detection and treatment methods available for breast cancer even in district health centers.

However, data in literature show that, in the public service, there are delays between the first symptoms of the disease and the diagnosis, between the diagnosis and the first treatment, and between the various phases of the treatment.

Faced with the demand and insufficient infrastructure of the Unified Health System to meet the growing demand of breast cancer patients, the Brazilian government, through the Ministry of Health, approved the Ordinance number 3.276 in 2007 [19]. It contains the following text:

II- Health institutions that are willing, in close cooperation with SUS managers, to provide support services for the institutional development of the Unified Health System - SUS in the areas of evaluation studies and incorporation of technologies, human resources training, research of Public health interest and development of techniques and management operation in health services. (Art. 2nd) [authors' translation]

The Israelita Albert Einstein Hospital adopted this procedure, but, according to [20] expenditures related to the diagnosis and treatment of patients with breast cancer originating from SUS demonstrate the imposition of planning that allow public-private partnerships For this type of therapy. Public policies and regulatory arrangements for access to medicines that prioritize care priorities and prevent patients from deleterious effects on the prognosis due to delays or frequent locomotion between public and private institutions to comply with all treatment steps.

In Brazil, the reference bodies for breast cancer are the Brazilian Federation of Gynecology and Obstetrics Associations (FEBRASGO), National Institute of Cancer (INCA, the Brazilian Society of Mastology (SBM), the Brazilian Medical Association (AMB), and the Federal Council of Medicine (CFM).

Brazil directs its public policies for screening and early detection of breast cancer. To this end, it created the Law 11.664 [21] dated April 29, 2008, in which SUS guarantees to all Brazilians free access to

mammography from the age of 40 and the health professional can request diagnostic mammography, when there is some suspicion or history of breast cancer regardless of the age of the patient.

For the screening of this type of cancer, the Brazilian Ministry of Health determines the biennial mammogram for women between 50 and 69 years old as a strategy, which is challenged by health professionals who deal with women affected by malignant breast tumors. These health professionals claim there is a need for annual mammography for this age group. INCA has carried out campaigns to clarify the risk factors, the most frequent signs and symptoms, the importance of self-examination and the imperative of the immediate search of health services by identifying any of these abnormalities in the female breast. However, Avellar [22] "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".

Country	Brazil			
Breast cancer incidence,	Incidence 56,20			
mortality and Survival rate	Mortality 13%			
per 100,000 women, 2016-	Survival rate 87%			
2020 (INCA, 2015)				
Specific breast cancer	National Plan for the Prevention, Diagnosis and Treatment of Uterine			
public policies	and Breast Cancer,			
	Action Plan for the Control of Cervical and Breast Cancers - 2005-			
	2007			
	National Policy on Cancer Care			
	Breast Cancer Information Systems.			
Strategies for early detection	Self-awareness campaigns and Mammography in public hospitals			
	and private partner entities			
Available public treatment	Organized participation. Assigned seats in state and municipal			
and Social participation	councils.			
	Health professionals, self- awareness campaigns, mammography,			
	chemotherapy treatment and radiology			
Entities engaged in the fight	Brazilian Federation of Gynecology and Obstetrics Associations			
against breast cancer	(FEBRASGO)			
	National Institute of Cancer (INCA)			
	Brazilian Society of Mastology (SBM)			
	Brazilian Medical Association (AMB)			
	Federal Council of Medicine (CFM)			

Table 1. Summary of basic epidemiological data and policy results in Brazil

Source: Authors'elaboration. Research results from secondary data (2017).

4.3 Public policies for breast cancer in India

Breast cancer in India is responsible for about 70,000 deaths in India every year [23]. Owing to the lack of awareness of this disease and in absence of breast cancers screening program, the majority of breast cancer are diagnosed at a relatively advanced stage [24].

The government of India crated the National Cancer Control Programme (NCCP) in 1975-76. October is breast cancer awareness month, an annual campaign to educate people about breast cancer supported by the National Health Portal (NHP) [25]. It also provides nationwide cancer statistics of India by the National Cancer Registry Programme (NCRP). But, according to [23] "early detection screening for breast cancer is still not a priority as the emphasis remains on treatment of cancer and strengthening of tertiary cancer hospitals, rather than prevention via screening or early detection of cancer."

Although the specific studies conducted on time trends in India have reported statistically significant increases for female breast cancer [26], lack of access to a well-organized and well-regulated cancer care systems further complicates the situation [27]. The care of women programs are concentrated in the cities and financial constraints become a barrier to women' care beyond gender inequality, stigma, fear, illiteracy and lack of awareness. Thus, diagnosis in advanced stages of the disease contributes to the /high mortality rate of women with breast cancer [28].

India tries to make the price of cheap breast cancer drugs cheaper and by reducing support for intellectual property India is undermining incentives for drug development and foreign investment that will allow for growth but drug makers are reluctant to cut prices in middle-income countries [29]. There have been some studies in pathology of breast cancer, reported from India. However, most have been descriptive reports about the types of carcinoma and more recently, receptor expression pattern [30].

Country	India			
Breast cancer incidence,	Incidence 70,00			
mortality and Survival rate	Mortality 48,5%			
per 100,000 women, 2016	Survival rate 51,5%			
(NHP . National Health				
Portal.India, 2016)				
Specific breast cancer public	National Cancer Control Programme (NCCP)			
policies	National Cancer Registry Programme (NCRP).			
Strategies for early detection	Self-awareness campaigns			
	Mammography at the NCCP and NCRP centers in the cities but not so			
	easy to use.			
Available public treatment	Mammography, chemotherapy treatment and radiology after diagnosis			
and Social participation	and usually late, as well as only in the cities where there is a center of			
	the both related cancer programs.			
Entities engaged in the fight	Karnataka State Cancer Registry Programme			
against breast cancer	Hospital Based Cancer Registry in Regional Cancer Centres			

Table 2. Summary	of basic	epidemio	logical data	and policy	results in India
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Source: Authors'elaboration. Research results from secondary data (2017).

4.4 Public policies for breast cancer in Australia

Cancer is a leading cause of death in Australia – more than 44,000 people died from cancer in 2013. Cancer accounted for about 3 in 10 deaths in Australia [31]. And breast cancer is the second largest cause of cancer death in Australian women after lung cancer. It is the most common cancer diagnosed in Australian women (apart from non-melanoma skin cancer [32].

The risk of being diagnosed with breast cancer by age 85 is 1 in 8 for women and 1 in 838 for men, according to the official data. For this reason, the Australian government created breast cancer control programs and policies such as BreastScreen Australia, which aims to continue to reduce deaths from breast cancer through early detection of the disease [33].

Australian public policy also includes the Clinical Oncology Society of Australia (COSA), the Clinical Oncological Society of Australia, and the Medical Oncology Group of Australia. Screening programs for early detection recommend that even if 40-49 year-old women do not have the symptoms, they can have the mammogram for free and encourage women aged 50-74 to have a mammogram every two years for free through BreastScreen Australia programme.

Besides that, supportive care can include allied health services, such as psychosocial support (often referred to as psycho-oncology); the supportive care spectrum also includes travel and accommodation support and other forms of financial assistance for people living with cancer and their families [32]. "*Priority-setting processes for the subsidy of health technologies in Australia incorporate, either explicity or implicity, a range of social values related to both the process and the content of decision- making*" (p7 [34]) as also "*have been innovators in placing a strong and explicit emphasis on value for money as a decision criterion*" (p5 [34]).

Australian Breast Cancer Research supports research on breast cancer, from prevention to treatment and from treatment to cure. The goal is to transform laboratory discoveries into therapies as quickly as possible.

Country	Australia			
Breast cancer incidence,	Incidence 61,00			
mortality and Survival rate	Mortality 6,5%			
per 100,000 women, 2016	Survival rate 90,0%			
(Australian Government)				
Specific breast cancer public	Clinical Oncology Society of Australia (COSA)			
policies	BreastScreen Australia			
	Clinical Oncological Society of Australia			
	Medical Oncology Group of Australia			
Strategies for early detection	Self-awareness campaigns			

Table 3. Summary of basic epidemiological data and policy results in Australia

	Mammography at the NCCP and NCRP centers in the cities but not so		
	easy to use.		
Available public treatment	Screening mammogram		
and Social participation	The most commonly used treatment modalities		
	are surgery, chemotherapy and radiotherapy.		
Entities engaged in the fight	Karnataka State Cancer Registry Programme		
against breast cancer	Hospital Based Cancer Registry in Regional Cancer Centres		

Source: Authors'elaboration. Research results from secondary data (2017).

5. Conclusion

Literature brings breast cancer as a public health problem due to high incidence and mortality rates, whether the country is developed or not. Early detection ensures greater efficacy in treatment and enables cure or survival. Public policies that facilitate access to medicines, research investments, and self-awareness are the way to change the scenario of breast cancer in Brazil, India and Australia. It is urgent to prioritize public health with more investment in breast cancer research and awareness programs on the importance of early detection, primarily in India.

According to the literature, the overall financial commitment to cancer prevention research is around 4%. Faced with the fact that breast cancer is the most common malignant tumor in women, there is very little knowledge of how to prevent it.

Early detection programs created in Brazil and Australia have prevented marked mortality from those diagnosed with breast cancer. Australian and Brazilian women join the programs and do self-examination. Indian women have encountered varying difficulties in understanding that late breast cancer diagnosis makes satisfactory treatment almost impossible.

Additional studies on the incidence, prevention, and control of breast cancer in Brazil, India, and Australia are necessary and unavoidable in the face of increasing rates of women affected by this disease.

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