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Ten years of the genomic era in Brazil: Impacts on technological development assessed by scientific production and patent analysis

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A B S T R A C T

Over ten years ago Brazil entered the era of genome projects with the launch of its first sequencing effort. Since then, a series of projects have been undertaken in the country, greatly contributing to the formation of scientific research networks, related infrastructure and specialized labor. Today, Brazil's competence in this area is internationally recognized and it is one of the main countries in the number of genomes sequenced. This article examines the effects of these genome initiatives on Brazilian technological innovation, through a broad bibliometric review, comprising the analysis of academic and patent publications, which revealed that the development of technology has not kept pace with scientific output.

1. Introduction

The history of genome projects started a scant thirty years ago, when Sanger and his collaborators in 1977 revealed the first complete DNA genome, from the bacteriophage ΦX174. This sequencing work, employing an extremely laborious manual technique, allowed the identification of the 5386 nucleotides of this phage. Only eighteen years later, now with the help of automated sequencing technologies and computerized assembly methods, it was possible to decipher the entire genome of a cellular organism – the 1,830,137 nucleotides of *Haemophilus influenzae* Rd. Since then, the number of projects around the world has grown immensely, initiating what has been called the "genome era" [1].

Brazil's participation in genomics began in 1997 with the project to sequence the complete genome of the bacteria *Xylella fastidiosa*. Financed largely by FAPESP (Fundação de Amparo à Pesquisa do Estado de São Paulo), the governmental agency responsible for the support of scientific research in the state of São Paulo, the project's aim was to foster a new research area in the country, considered strategic and highly competitive internationally [2,3].

The result of this pioneering effort, published in Nature in 2000 [4], represented a landmark for Brazilian science, since *Xylella fastidiosa*,[1] which is the etiologic agent of citrus variegated chlorosis (CVC), was the first phytopathogenic organism to be sequenced and annotated [2]. With this, Brazil entered the select group of countries that had sequenced the entire genome of an organism.

The success of this groundbreaking initiative triggered a series of genome projects in the country, leading to the formation of virtual research networks, the development of related technology and the hiring/training of specialized staff in various national research centers. This has enabled the country's scientific community to gain notable experience in large-scale sequencing, genome analysis and bioinformatics [2,5].

Today, just over ten years after the launch of its first genome project, Brazil is among the leading countries in number of genomes sequenced, according to international statistics (GOLD[2]), and its competence in the area is recognized and respected worldwide.

Since these initial sequencing efforts, which have generated a huge amount of data, the scientific community has also begun to concentrate on deciphering this information, in an attempt to understand the functions of the genes identified and to learn how to interfere in the biological processes for the benefit of society. In view of this scenario, it is important to analyze how the investments and efforts into genomics have contributed to Brazil's scientific, technological and innovative progress.

Bibliometric indicators have been widely adopted for benchmarking and assessing science and technology. Scientific publication related indicators have served mostly in mapping scientific

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[1] *Xylella Fastidiosa* is the phytopathogen (bacteria) that causes citrus variegated chlorosis (CVC), a disease that primarily affects oranges and results in significant economic loss to the state of São Paulo [5].

[2] GOLD – Genomes On Line Databases, available at http://www.genomesonline.org/gold_statistics.htm (consulted in October 2009).

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efforts, while patent related indicators have been applied for assessing technological activity [6,7]. Therefore, the goal of this paper is to analyze the country's scientific and technological performance in the genomic area through the use of these indicators, derived from Brazilian scientific publications and patent applications filed by residents with the Brazilian patent and trademark office (INPI – Instituto Nacional da Propriedade Industrial).

According to many authors, this type of analysis is a way to reveal the research and development (R&D) potential and technology flow dynamics in a country, and is also considered indispensable for the formulation of public and private policies and strategies [6–11]. In addition, we also performed a mapping of local competencies in science, technology and innovation (ST&I) in the genomic field.

2. Methodology

2.1. Indicators of scientific activity

To analyze Brazilian scientific production in the genomic area, we carried out a search of the works published by Brazilian authors over an eleven-year period (1997–2007). The data were obtained from the Web of Science database (ISI-Thomson Group): SCI-Expanded (Science Citation Index Expanded) and SSCI (Social Sciences Citation Index). We chose these sources for their comprehensive and multidisciplinary nature, since they index documents in the most diverse areas of knowledge [12,13]. Our search strategy was based on Boolean logic, so we could not use databases that do not accept Boolean operators. SciFinder was not used since it uses the Chemical Abstract Service (CAS), which is more focused on the chemistry area.

The research strategy was based on keywords, a method already employed by many authors previously [7,9,14]. We sought the occurrence of keywords related to the genomic area in the titles, abstracts and keyword fields of scientific works, first in August 2007 and then in July 2009, to update our data.

We chose the keywords based on the works of CAULFIELD [15], OECD [16], CAMPBELL [17] and NUFFIELD COUNCIL ON BIOETHICS [18], which show the main themes associated with patent applications in the genetic area filed before patent offices such as the USPTO and EPO. Based on these publications and according to the aims of this work, we chose the following terms in 'or' relationship: DNA; "DEOXYRIBONUCLEIC ACID"; RNA; "RIBONUCLEIC ACID"; cDNA; EST; "EXPRESSED SEQUENCE TAG"; NUCLEIC; GENOME; GENE; GENIC; and GENOMIC.

2.2. Indicators of technological activity

To quantify and evaluate the patent applications filed by Brazilians or companies headquartered in Brazil (resident nationals) with the INPI, we undertook a search of its patent database.[3]

The approach for the search and recovery of documents was slightly different than that used for scientific publications. In this step of the work, in addition to searching for keywords in patent application summaries, we also searched in the technological field of the invention, using the International Patent Classification (IPC[4]) [19,20]. Furthermore, the time interval analyzed was shorter than that for scientific activity, going from 1997 (the year the current Industrial Property Law entered into force) until 2006, since patent applications must be kept in confidence for eighteen-months. Because of this, some applications filed in 2007 and 2008 were not available for public consultation at time of our initial research in October 2007. Therefore, as with the scientific indicators, we updated our data in July 2009.

Again, we searched for the keywords in the summaries of patents based on the works of CAULFIELD [15], OECD [16], CAMPBELL [17] and NUFFIELD COUNCIL ON BIOETHICS [18], which show the main terms associated with genetic invention patent applications filed with patent offices such as the USPTO and EPO. Based on these publications and according to our study aims, we chose the following keyword terms in 'or' relationship: DNA; "DEOXYRIBONUCLEIC ACID"; RNA; "RIBONUCLEIC ACID"; cDNA; EST; "EXPRESSED SEQUENCE TAG"; NUCLEIC; GENOME; GENE; GENIC; and GENOMIC.

Since all patent applications are classified according to their technological field, in the search by international classification of the application we chose group C07H 21, which is related to the area of genomic technology. This group contains applications that refer to compounds containing two or more mononucleotide units having separate phosphate or polyphosphate groups linked by saccharide radicals of nucleoside groups, e.g. nucleic acids.

All the patent applications found with the described search strategies were analyzed individually, allowing exclusion of duplicates.

Another important issue is the fact that the INPI database has limitations, which could have influenced the results obtained in the searches. The main ones are listed below:

- Only patent documents published from August 1, 2006 are available for consultation in their entirety.
- For documents published between 1982 and 1999, only the cover sheet is available. However, there are documents in which some of the information on the cover sheet is incomplete, such as the name of the applicant and the abstract.
- Delays in the INPI's administrative procedures mean some applications are published after the eighteen-month deadline from the filing or priority date.
- The INPI has a backlog of patent applications still not analyzed, which affected the number of applications examined in this study.

2.3. Mapping of competencies

To identify Brazilian CT&I competencies (research specialists and groups) in the genomic area, we searched the Portal Inovação[5], which relies on the information from the Plataforma Lattes[6] database.

This portal, launched in October 2005, offers a set of indicators and permits searches by competencies and opportunities for technical and scientific cooperation [21]. Companies, specialists, R&D groups and science, technology and innovation institutions are among the main actors of the portal.

The search for competencies in the genome area was done in November 2007, using the search words GENÔMICA and GENOMA.

[3] Brazilian Patent and Trademark Office database, available at http://www.inpi.gov.br.

[4] IPC – International Patent Classification – is a classification utilized globally to index documents on patents of invention and utility models. The IPC was established in 1971 by the Strasbourg Agreement of the World Intellectual Property Organization (WIPO). It is divided into eight main sections, which are in turn subdivided into classes, subclasses, groups and subgroups. To keep up with the evolution of technology, the IPC is revised and updated periodically, when a committee of experts gathers to evaluate and improve the system. Available at http://www.wipo.int/classifications/ipc/ipc8/?lang=en.

[5] Portal Inovação of the Brazilian Ministry of Science and Technology (Ministério da Ciência e Tecnologia – MCT), available at: http://www.portalinovacao.mct.gov.br.

[6] Plataforma Lattes is a set of databases containing résumés of researchers and the names of institutions in the area of science and technology, integrated in a single information system, whose importance nowadays not only extends to the operational activities to foster science and technology of the National Research Council (CNPq), but also similar actions of other federal and state government entities. Available at: http://lattes.cnpq.br/index.htm.

Table 1
Top countries with Genome Projects.

Country	Sep/09	Jan/08	Jan/07	Jan/06	Jan/05
United States	4446	2555	1683	883	531
United Kingdom	302	202	116	52	45
Japan	180	146	83	56	47
France	177	136	122	79	38
International Consortium[a]	103	97	90	42	36
Germany	140	89	76	61	54
Canada	87	73	53	12	6
China	79	40	26	16	9
Brazil	37	35	31	18	14

[a] According to GOLD, International Consortium is a generic name, denoting any group from collaborators across the world.
Source: GOLD database, authors' elaboration

3. Results

3.1. Profile of Brazilian scientific publications in the genomic area

The success of Brazil in genomics is illustrated by the statistics of the Genome On Line Database (GOLD). GOLD was created in 1997 with the aim of monitoring genome-sequencing projects worldwide and providing the scientific community with a single centralized database integrating diverse information related to those projects [22].

The database also provides readily available graphical overviews for specific data types. These are provided through the "Gold Statistics" link, available at the home page of the database, and include the following data types: published complete genomes; ongoing genomes projects; project relevance; top sequencing centers; genome projects according to phylogenetic groups; major sequencing centers; top countries with genome projects; and top funding agencies [22,23].

Recent statistics from GOLD show that Brazil currently occupies ninth place among countries with genome-sequencing projects, with a total of 37 projects, behind only of the United States, United Kingdom, Japan, France, International Consortium, Germany, Canada and China (Table 1) [http://genomesonline.org/gold_statistics.htm].

This success is also reflected in the total number of scientific works published by Brazilians in the genomic field. During the eleven-year study period (1997–2007), there were 13,760 scientific works published, a much greater number than in the previous ten years (1987–1996), which amounted to 1937 publications.

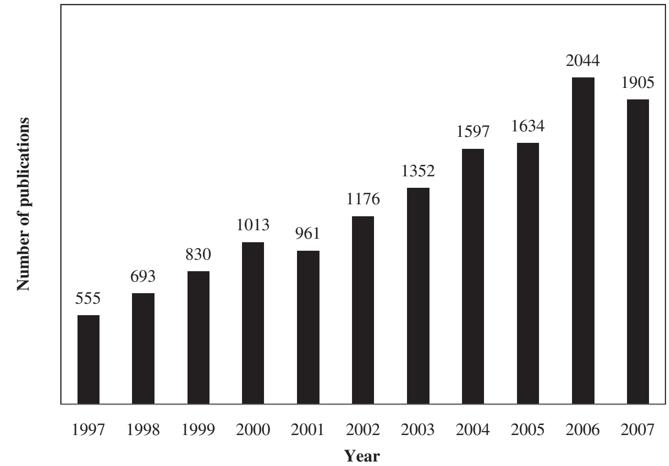

Fig. 1. Brazilian publication outputs in the genomic field during 1997–2007 (Source: Web of Science databases, authors' elaboration).

Fig. 1 shows the yearly evolution of the total number of Brazilian works published in the period. In 1997, the year of the first Brazilian genome project, there were only 554 works published, while in 2007 this number had risen to 1905. These data demonstrate that the investments and efforts made during these eleven-years of genome research stimulated national scientific output in the area.

However, an evaluation of the number of publications involving organisms sequenced in the Brazilian projects showed that only about 15% of the works involved organisms sequenced in Brazil.

The data gathered also showed that the majority of works published by Brazilian authors in the genome area come from public universities linked to the federal and various state governments of the main states of the southeast (São Paulo, Minas Gerais and Rio de Janeiro) and south (Rio Grande do Sul) of the country.

A detailed analysis of the academic works found in the searches also showed that even though Brazil's official language is Portuguese, 98% of the works were published in English, revealing that the target public was the international scientific community. Besides this, the great majority of the published documents found (91%) were scientific articles, while 4% were in the annals of congresses and other events, 4% were reviews and 1% consisted of other types of documents.

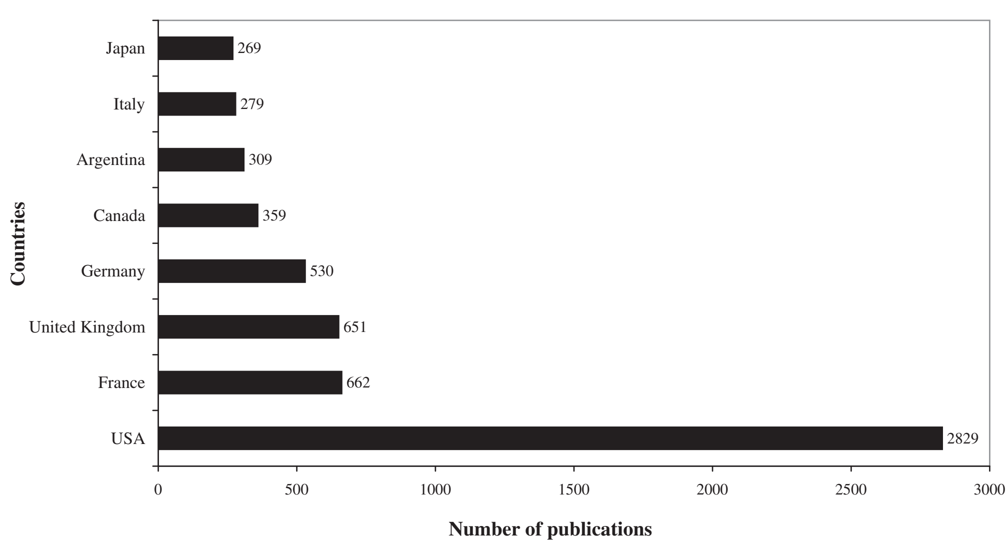

Fig. 2. Main collaborator countries to Brazilian authors in genomic field from 1997 to 2007 (Source: Web of Science databases, authors' elaboration).

Table 2
Statistics of Brazilian patent applications filed in INPI from 1997 to 2006.

Year	Total of patent applications filed in INPI	Total of patent applications filed by residents in Brazil	Patent applications in genomics filed by residents	Patent applications in genomics filed by non-residents
1997	19,443	5878	12	370
1998	18,919	5292	4	283
1999	20,883	6106	4	306
2000	20,605	6222	18	337
2001	20,679	6705	4	273
2002	19,541	6832	13	273
2003	21,278	7195	16	294
2004	22,860	7484	19	376
2005	24,043	7107	22	362
2006	24,160	6919	18	141
Total	212,411	65,740	130	3015

Source: INPI's database and INPI's statistics – authors' elaboration (available at: http://www.inpi.gov.br/menu-esquerdo/instituto/estatisticas-new-version).

Another interesting point was related to international scientific collaboration. Around 40% of Brazilian publications in genomics were co-authored with foreign authors (Fig. 2). Of the eight countries listed – Japan, Italy, Argentina, Canada, Germany, England, France and the United States – according to the GOLD[2] only two, Argentina and Italy, are not among the main countries in genome projects. This indicates that the Brazilian scientific community has been interacting with researchers from countries with more experience in genome research. On the other hand, the partnerships with Argentina and Italian researchers suggest that Brazil is also playing a reference role in the development and dissemination of this technology.

3.2. *Profile of the patent activity in genome technology in Brazil*

Table 2 shows that during the interval from 1997 to 2006, 212,411 patent applications related to all areas of technology were filed with the Brazilian PTO (INPI). About 30% (65,740) of these applications were filed by national residents (http://www.inpi.gov.br/menu-esquerdo/instituto/estatisticas-new-version, accessed in July 2009).

The data from the INPI base showed that 130 patent applications (approximately 0.2% of all national filings) were related to inventions in the genome area (Table 2). During the entire period analyzed, the years that stand out for number of filings were 2005 and 2004, with 22 and 19 applications, respectively.

Slightly more than 10% of the genomic patent applications showed some type of relation to one of the target organisms of sequencing efforts in the country. The first applications with this relation were filed in 2000.

Because the original search only gathered data on the number of patent applications published, not their status, we also checked the current situation of these applications. Table 3 shows that 8% of the applications were withdrawn or abandoned 7% are undergoing technical examination, 4% have been analyzed and decided (granted or rejected) and 81% have not yet been examined.

We also analyzed the patent applications found regarding the applicants' profile, as shown in Table 4. The applicants can be grouped into four categories: 1 – public sector, including public universities, governmental funding agencies and public research companies/institutes, which together filed 60% of the patent applications; 2 – private sector, composed of private universities and companies, responsible for 12% of the applications; 3 – inventors (individual applicants) who filed 6% of the applications; and 4 – partnerships, designated by co-ownership of the application, which accounted for 22% of the applications and include joint ventures between categories.

The profile of these partnerships is shown in Fig. 3, which demonstrates that the main type of joint ownership is between public sector institutions, accounting for sixteen applications, seven of them between public universities and governmental funding agencies. This is followed by partnerships between the public and private sectors, with seven applications, of which four are between governmental funding agencies and private firms.

Another noteworthy figure is the interaction with inventors, who appear as co-owners of applications together with public universities (three applications) and private companies (two applications). Additionally, we found a single application with two private institution co-owners.

3.3. *Profile of Brazilian competencies in the genome area*

Our intent in mapping Brazilian competencies in the genomic area was to reveal the profile of the research groups and specialists. This showed that there are 1282 research groups, distributed in 25 states (including the Federal District). Fig. 4 shows the distribution of these groups by region of the country. This analysis demonstrated that 56% of the research groups are in states in the southeastern region, with the standouts being São Paulo (410 groups), Rio de Janeiro (173 groups) and Minas Gerais (130 groups). Another 20% of the groups are in the southern region, led by Rio Grande do Sul (125 groups) and Paraná (101 groups). The northeastern region collects 13% of the groups, led by Bahia (55 groups) and Pernambuco (39 groups), while the midwestern and northern regions account for 8% and 3% of the groups, respectively.

Table 3
Status of Brazilian patent applications in genomics filed by residents.

Application status	Number of patent applications	(%)
Withdrawn	5	4
Abandoned	5	4
Under examination	9	7
Granted	3	2
Denied	3	2
To be examined	105	81
Total	130	100

Source: INPI's database; authors' elaboration.

Table 4
Resident applicants of Brazilian patent applications in genomics.

Applicants	Number of patent applications	(%)
Public Universities	40	31
Private Universities	1	1
Public Institutions	20	15
Private Companies	14	11
Inventors (individual applicant)	8	6
Government Funding Agencies	18	14
Partnerships	29	22
Total	130	100

Source: INPI's database; authors' elaboration.

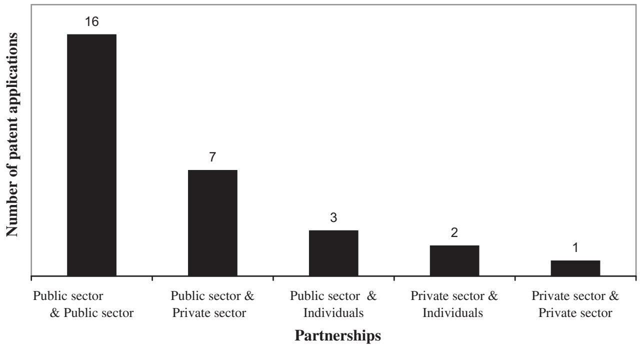

Fig. 3. Partnerships in Brazilian patent applications (Source: INPI's database, authors' elaboration).

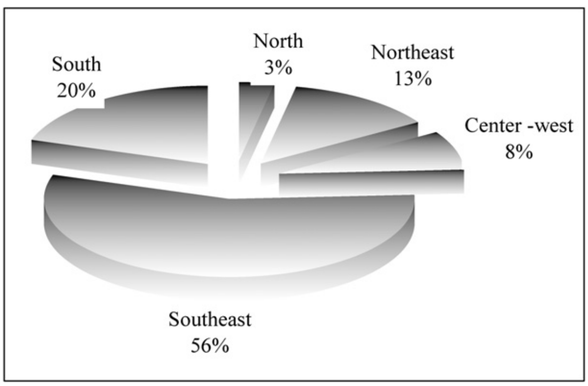

Fig. 4. Geographical distribution of genomic research groups in Brazil (Source: Portal Inovação, authors' elaboration).

The distribution of human resources involved in genomic research followed the same pattern as that for research groups. The 3356 specialists encountered work in 27 states, distributed as follows: 58% in the southeast; 18% in the south; 11% in the northeast; 9% in the midwest; and 4% in the north (Fig. 5). The state of São Paulo has the highest concentration of specialists in the genomic field, one-third of the national total.

However, we must point out that a single specialist can be involved in more than one research group. This explains the high number of groups in relation to researchers.

We also analyzed the researchers as to their academic credentials (degree level). Table 5 shows that 85% of them have postgraduate degrees (master or doctorate), indicating that Brazil has a considerable contingent of highly qualified researchers in the genomic field.

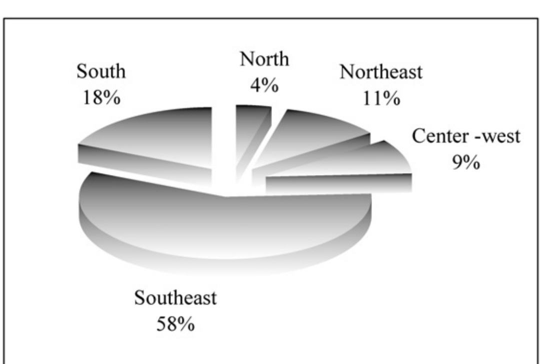

Fig. 5. Geographical distribution of Brazilian experts in genomics (Source: Portal Inovação, authors' elaboration).

Table 5
Distribution of experts in genomics by scholar degree.

Degree	%
Ph.D.	64
M.Sc.	21
B.Sc.	12
Technician	3

Source: Portal Inovação, authors' elaboration.

We should also mention that we did not find any private company listed at the "Portal Inovação" engaged in technical–scientific activity in the genomic field. However, this does not mean there are no Brazilian companies active in this sector, since we found, in the study of patent activity, that there are private companies as patent assignees in Brazil. So, it is important to emphasize that registration in the "Portal Inovação" database is voluntary, which may explain the results mentioned above.

4. Discussion and conclusions

This work has demonstrated how the investments and other efforts of the federal and state governments in Brazil have influenced the generation/diffusion of knowledge and development of innovations in the genomic area.

The data gathered show that the strategic policy of financing various genome-sequencing projects not only has helped foster research in the area, but also has concentrated most of this research in public sector institutions. This has led to the creation of infrastructure staffed by highly qualified human resources. The result, as seen, has been a substantial increase in Brazil's scientific production in the segment.

Besides this, the study shows that the national distribution of researchers and research groups in the genomic area is skewed to the southeastern region, where over 50% are concentrated. Within this region, the state of São Paulo has the greatest number of groups and researchers.

The reason the state of São Paulo stands out so much in the genomic field goes back to the start of the genomic era in Brazil. In 1997, when the São Paulo State Research Support Foundation (FAPESP) launched the first project in the country to sequence the genome of an organism, a virtual network was also implemented in the state by the Organization for Nucleotide Sequencing and Analysis (ONSA) – The Virtual Genomics Institute. The objective of this network was to facilitate the participation of as many research laboratories as possible in the state. These laboratories also received equipment and staff training in all steps of the methodology, greatly stimulating the formation of research groups and specialized laboratory staff [2,5,24].

Additionally, according to information in the GOLD database, FAPESP also invested substantially in genome projects, financing at least 14 of the 37 national genome projects. This is one more reason why the state of São Paulo is the national leader in genomic research.

We also found that the country's scientific output in the genome area increased significantly over the study period, rising from roughly 2000 publications between 1987 and 1996 to nearly 14,000 between 1997 and 2007.

Nevertheless, the statistics on genomic patent applications in the country by national owners between 1997 and 2006 show that despite the steady growth, the number of these applications was still modest, numbering little more than 100 applications. This corresponds to only around 0.2% of all the patent applications filed by national residents in the study period.

Together these data indicate that although national policies for investments in the genomic area have yielded fruit for the Brazilian scientific community and production, the same cannot be said for technological production. Thus, it appears that only a small part of the scientific knowledge generated is being transformed into products or technological results by the nation's industry, from the data on patent activity.

Even though there are arguments against relying on this form of correlation between basic research and technological development, since data on patent activity are constantly being partly associated with the effort to transform inventions into innovations, there is no denying that data of this nature are relevant when involving new technological creations with commercial perspectives [6,25,26].

Since inventions in the genomic area generally involve potential commercial use and can be revealed/copied by reverse engineering, it is fundamental to obtain patent protection of these inventions [26]. Otherwise, there will be little interest by companies to invest in development of inventions to take them to market [6,27].

In this respect, the results of this work show that both Brazilian scientific and technological production are mainly concentrated in public institutions, since the great majority of published works are by authors associated with the leading public universities (state and federal), and these along with other government institutions also are responsible for almost 90% of patent applications in the genomic area as well. These findings further evidence that Brazilian R&D activities in this area are overwhelmingly concentrated in government universities or other public research institutions instead of the private sector.

Therefore, although these mainly government efforts have been effective in producing groundbreaking research in the country, there has not been sufficient interaction with the private sector. One possible factor may be that Brazilian researchers have insufficient awareness of the industrial property system. So, although these academic institutions are doing a good job in the purely scientific area, they are still relatively unprepared for economic exploitation of the technologies developed [28,29].

However this scenario is expected to change in the next few years, taking into account the entry into force of the Technological Innovation Act (Law 10.973) at the end of 2004. It establishes incentives to innovation and scientific and technological research in the country. This law, implemented in April 2005, allows public funds to be spent on industrial projects and encourages public and private sectors to share staff, funding and facilities, thus increasing technology transfer between universities and industry. It also contains a provision allowing academic institutions to incubate both joint ventures and private companies. However, this law is too recent to have produced perceptible effects so far.

Another aspect that may have contributed to the low patent activity is the fact that filing and maintaining a patent application, besides being a slow bureaucratic process, is also costly. This question particularly affects public universities and research institutions, whose budgets are normally limited.

Another important factor is the restriction on patenting biological material in Brazilian legislation. Article 10 (IX), of the Industrial Property Law establishes that natural living beings and biological materials found in nature, or isolated therefrom, including the genome or germplasm of any natural living thing, may not be the subject matter of patents of invention. Besides this, Article 18 (III), of the same law determines that all or part of any living being is not patentable, except for transgenic microorganisms.

The fact that many inventions growing out of genome research cannot be patented under Brazilian legislation may well be acting to discourage national inventors from using the country's patent system, thus impairing the country's innovative capacity.

Hence there is a need to identify the failings of the system that are contributing to this inability to convert scientific production into inventions that generate patents and innovations in Brazilian industry.

Studies like the present one examining to what extent Brazilians seek patent protection of their inventions in other countries, especially those where patent legislation is less restrictive, can help shed more light on this situation.

Besides this, studies of this nature can investigate how much Brazilian inventors know about and use the patent system globally, demonstrating if there is interest in protecting the technology produced in Brazil in other markets.

Data such as these can contribute to greater use of the Brazilian patent system and/or efforts to improve it, either through changes in legislation or incentives and public policies supporting scientific and technological development. The results shown in this paper may catalyze the nation's innovative potential and make the Brazilian market more attractive to national and foreign investors.

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