Available online at www.sciencedirect.com
ScienceDirect
Biotechnology Advances 25 (2007) 57–74
BIOTECHNOLOGY ADVANCES
www.elsevier.com/locate/biotechadv

Research review paper

Synergy between Competitive Intelligence (CI), Knowledge Management (KM) and Technological Foresight (TF) as a strategic model of prospecting — The use of biotechnology in the development of drugs against breast cancer ☆

Claudia Canongia

National Institute for Metrology, Standardization and Industrial Quality (INMETRO), Brazil

Received 21 August 2006; received in revised form 4 October 2006; accepted 12 October 2006
Available online 19 October 2006

Abstract

The aim of this paper is to demonstrate the synergy between Competitive Intelligence, Knowledge Management and Technological Foresight, and to emphasize the proposal of a strategic model of data prospecting as a mechanism to support decision-making in regard to three approaches for sustainable development and innovation: technological, social and economic. The use of biotechnology in the development of drugs against breast cancer is the case study. The article shows the results of data and text mining in specialized medical and patent databases, identifying the most frequently cited drugs, as well as the authors of research, and the inventors of new technology at the beginning of the 21st century. In addition, the study includes reference to Brazilian competence in breast cancer area, the international trends in drugs for treatment of this cancer, leading international institutions and Brazilian competencies. A framework is presented, which could serve as a guide and support for the decision-making process.

Keywords: Strategic model of prospecting; Competitive Intelligence; Knowledge Management; Technological Foresight; Breast cancer drugs; Biotechnology; Health sector; Brazil

Contents

1. Introduction . . . 58
2. Knowledge era: the challenge of gloCalization . . . 58
3. Why intensive sectors in R&D? . . . 59
4. The model of a prospecting strategy for R&D-intensive sectors . . . 61

☆ This paper is part of the doctoral thesis of Claudia Canongia. The supervisors were Adelaide Antunes DSc, titular professor of the School of Chemistry (EQ/UFRJ) and Maria de Nazaré Freitas Pereira PhD, expert in the Information Society area.

E-mail address: ccanongia@inmetro.gov.br.

0734-9750/$ - see front matter © 2006 Elsevier Inc. All rights reserved.
doi:10.1016/j.biotechadv.2006.10.001

5. Application of the strategic model of trends and prospecting: the use of biotechnology in the development of drugs against breast cancer — a vision of the potentialities and opportunities for Brazil . . . 62
5.1. Model: previous phase A . . . 62
5.2. Model: previous phase B . . . 62
5.3. Phase 1 model: R&D and technology trends; Brazilian competencies in biotechnology and breast cancer . . . 63
5.3.1. R&D trends . . . 64
5.3.2. Technological trends . . . 64
5.3.3. Identification of Brazilian competencies — the local view . . . 67
5.4. Phase 2 model: content analysis . . . 67
5.4.1. Analysis of R&D trends (articles) . . . 67
5.4.2. Analysis of R&D trends (patents) . . . 67
5.4.3. Analysis of Brazilian competencies (Lattes CVs and directories) . . . 69
5.5. Phase model 3: interviews: validation and new input from stakeholders . . . 70
5.6. Phase model 4: global analysis: applying the SWOT[32] matrix . . . 71
5.6.1. Opportunities . . . 71
5.6.2. Strengths . . . 71
5.6.3. Threats . . . 71
5.6.4. Weaknesses . . . 72
5.7. Phase model 5: recommendations . . . 72
6. Final considerations . . . 73
References . . . 73

1. Introduction

Knowledge Economy has shown that understanding innovation consists of a process of searching and learning dependent on interactions and specific situations is a complex approach and a challenge to the future, mainly considering the exigencies of a globalized market. The economic success of any country, region or place increasingly depends on its capacity to specialize in activities which allow it to establish effective and dynamic competitive advantages, based on local competencies and capacities to learn, in the sense of creating an environment of transformation and progress, as well as the capacity to cooperate, which has become key in innovation.

In this context, to understand the synergy between CI, KM and TF and the application of these methodologies is important in building a vision of the complex relationship of a given sector, with the goal of generating value-added information about technological, social and market trends and thus feeding the cycle of the creation of new wisdom, emphasizing the need to prioritize action in the short, medium and long terms. (Canongia et al., 2006).

Moreover, as Salicrup and Fedorkova (2006) emphasizes, biotechnology will be a key driver of sustainable growth and development, and some developing economies with enormous human capital, such as India, China, Brazil, and Korea, have been able to demonstrate their capabilities and accomplishments through several biotechnology R&D activities.

2. Knowledge era: the challenge of gloCalization

In the current era success is defined by the way in which innovation is managed and valued, as this factor is currently considered dominant for local economic development and for patterns of both local and global competition. Local specific capacities are strengthened, leading to global dynamics which retrofeed local dynamics – *gloCalization* – think globally, act locally. (Humbert, 2005). The management of innovation is thus essential, and will increasingly be a challenge in the years to come, especially for emerging economies. The existence of national, regional and local systems of innovation (SIs) is essential for the retrofeeding of the capacity for innovation at three levels: macro (political, social, economic, environmental), meso (sectoral/industrial) and micro (organizational).

The aggregation in the value chain which moves from information to decision-making finds itself strongly dependent on the process of macro-coordination and involves continuous monitoring of activity, an essential for improvement in formulating strategies. The value of results is expressed in the fact that decisions based on higher value-added information make possible the construction of knowledge bases

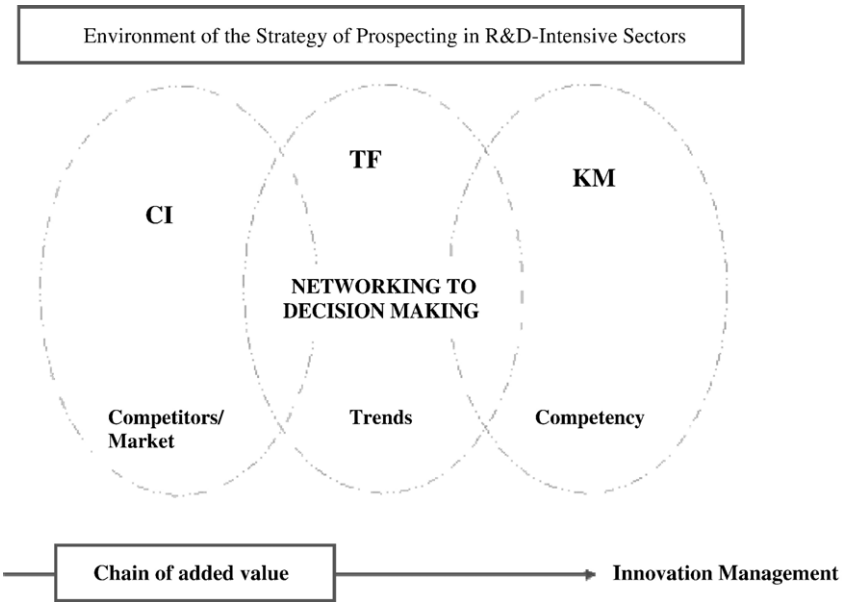

Fig. 1. Environment of the Strategy of Prospecting in Intensive Sectors in R&D: integrating CI, KM and TF. Source: adapted from Canogia et al., (2004a).

for the creation of a future which will guarantee competitiveness and sustained development (FOREN, 2001).

In the sectoral analysis, with regard to the knowledge dimension, the virtuous cycle of innovation is strongly connected to the process of socio-technical transformation and growth, which progress from technological learning, passing through absorption, adaptation and the production of new goods and services. The adoption of management models capable of promoting synergy between the activities of science and technology and economic and social development is the current challenge.

Within this new competitive paradigm, the salient features are the demands for excellence in products and services, and increases in differentiation, flexibility, speed, cost rationalization and innovation. Meeting these demands calls for new management models, and it is here that the importance of approaches such as Competitive Intelligence, Knowledge Management and Technological Foresight becomes evident. In this regard, a macro vision of the model proposed in this study is presented in Fig. 1.

According to Georghiu (2001), some of the activities undertaken in Foresight, while initially focused on technology, end up producing recommendations which address the infrastructure of national systems of innovation.

3. Why intensive sectors in R&D?

National innovation systems can be understood as the coming together of different agents, with specific functions, who establish amongst themselves a series of coordinated relations in order to attain the objective of meeting the demands of sustained development and competitiveness. If, on the one hand, technical progress increases the capacity for wealth accumulation and income generation, on the other the search for balance between technological progress, competitiveness and social inclusion, the sustainability of nations, governance, and the overcoming of regional inequalities are major challenges to be faced.

According to Nelson (2005, in Cimoli et al., 2006) questions related to governance are currently key in terms of access to markets, and should be given consideration, especially by emerging economies, as an important mechanism for the promotion of competitiveness and welfare, by means of an effective strengthening of the actor network of the national system of innovation. Analysis of R&D-intensive sectors is increasingly a prerequisite for improving competitiveness and economic, social and technological development, as are management models capable of stimulating a holistic perspective and supporting the decision-making process.

The concept of the Sectoral System of Innovation and Production (SSIP), presented by Malerba (2003),

is here considered to be the most adequate for analyses of R&D-intensive sectors, because it offers an integrated and dynamic multidimensional view of those aspects which affect the adoption of technologies and the production of innovation. The SSIP brings together the dimensions of knowledge, the actor network, and of governance. Amongst the advantages of this sectoral approach, the most salient are the analysis of the differences and similarities between sectors, the macro understanding of the factors which define the dynamics of a sector, the identification of factors critical for sectoral innovation and competitiveness, and the collaborative development of recommendations for public policies.

The aim of this article is to present a model of a prospecting strategy for R&D-intensive sectors, in

Table 1
Synergies and complementary points between: IC, GC and Foresight

Approaches	Competitive Intelligence	Knowledge Management	Technological Foresight
1)Vision	Support decision-making process in the medium (up to 2 years) and long (from 2 to 5 years) terms	Support decision-making process in the medium (up to 2 years) and long (from 2 to 5 years) terms	Support decision-making process in the medium (up to 5 years) and long (more than 5 years) terms
2)Objectives	Integrate into strategic planning in the medium and long terms, and foresee opportunities and threats in order to maintain or create competitive advantages.	Integrate into strategic planning in the medium and long terms, and promote appreciation of the value of the internal potential of the organization, of the identification of competencies, and of the generation and circulation of knowledge.	Integrate into strategic planning in the medium and long terms, and indicate innovative trends in technology, processes products and/or services.
3)Principal methods	Based on the gathering, processing and analysis of external and/or internal, formal and/or informal information, and the generation of intelligence.	Based on the gathering, processing and analysis of external and/or internal, formal and/or informal information, and a valuing of knowledge capital.	Based on the gathering, processing and analysis of informal information (opinions), external and/or internal, and construction of a collective vision of the future.
4)Starting point and goals	Attend to critical success factors for organizations (sectoral) in order to better meet market and/or customer demands with new products/services and/or by improving products/services.	Attend to critical success factors for organizations (sectoral) in order to better meet market and/or customer demands with new products/services and/or by improving products/services.	Attend to economic, social, environmental and technological demands, by understanding critical success factors for organizations (sectoral) in order to create the desired future and develop cutting-edge products/services.
5)Techniques	Scenarios; monitoring; modeling and morphological analysis; SWOT matrix; interviews with stakeholders.	Specialist panels; focus groups; brainstorming; communities of practice; monitoring	Delphi; scenarios; modeling and morphological analysis; SWOT matrix; specialist panels; interviews with stakeholders; roadmaps
6)Principal results perceived as an instrument of innovation management	Wealth generation with development of new businesses, markets, products/services, technologies; and value given to network relationships, and increased competitiveness and innovation.	Organizational development and learning, and value given to network relationships, and increased competitiveness and innovation.	Governance of the processes of innovation; and improved negotiation between the different actors in the process of innovation; value given to network relationships, innovation and increased competitiveness.
7)Focus—the main view	Predominance of activities aimed at knowledge and analysis of external movements: whether on the level of policies, laws, the environment, the economy, or on the level of competencies: competitors, partners, clients, suppliers; and of the entry of new products/services and/or substitutes, as well as potential competitors. Macro and middle levels.	Predominance of activities aimed at knowledge and utilization of internal organizational potential, of sectors, of the nation and/or economic blocs. Strategies focused on core competencies, for development and/or maintenance. Middle and micro levels.	Predominance of activities aimed at constructing a vision of the future in a collaborative fashion, with the aim of strengthening systems of innovation (local, regional, national and sectoral). Interpreting, identifying and prioritizing themes/emerging and/or cutting-edge technologies based on internal and external movement in innovation systems. Macro, meso and middle levels.
8)Principal sources of information	Scientific and business articles, patents, specialized Internet sites, events and trade fairs.	Scientific articles, reference data from directories, specialized internet sites, panels and/or interviews with specialists.	Patents, panels and/or interviews with specialists, Delphi, sectoral technology reports.

Source: adapted from Canongia, (2004).

which biotechnology presents itself as a key technology of the future (Ernst and Yong, 2001; OECD, 2004 apud Salicrup and Fedorkova, 2006), in the hope of contributing to the areas of innovation management and decision-making, especially for Brazil, given its place in the global market. According to the World Economic Forum, Brazil was in 66th place in the ranking for competitiveness in 2006, worst than the following emerging countries: India (43rd), South Africa (45th), China (54th) and Russia (62nd), called BRICS. Such a ranking reinforces the need for the priority of new management models oriented towards local development and based on global movements.

4. The model of a prospecting strategy for R&D-intensive sectors

The challenge for the future is the development of models capable of: a) increasing capacity for analysis of R&D-intensive sectors; b) having a greater focus on simulation and modeling; c) forming collaborative networks; d) datamining with increasing application to R&D, with generation of knowledge maps. For this, the concepts of IC, GC and TF, seen in a synergistic fashion are extremely important as support for the strategy of prospecting.

In proposing a strategy model for prospecting R&D-intensive sectors, an important element is an understanding of the existing synergies between IC, GC and TF in regard, for example, to vision, objectives, principal methods, points of departure and goals and techniques. These are presented in Table 1, with emphasis on the synergies.

The model proposed aims to explore such synergies and to integrate two previous phases: the first (previous phase A), in which are presented data on the topic and/or problem to be studied; and the second (previous phase B), in which the factors critical to the R&D-intensive sector of interest are identified, given that sector's function as a barometer of change. Among the effective stages, five moments of analysis are proposed, which take into account the synergies between IC, GC and TF: 1) identification of trends in R&D and technologies and the competencies of the country or countries; 2) content analysis: trends in R&D and technologies and the competencies of the country or countries); formation of specialized opinion; 3) general evaluations of the trends identified

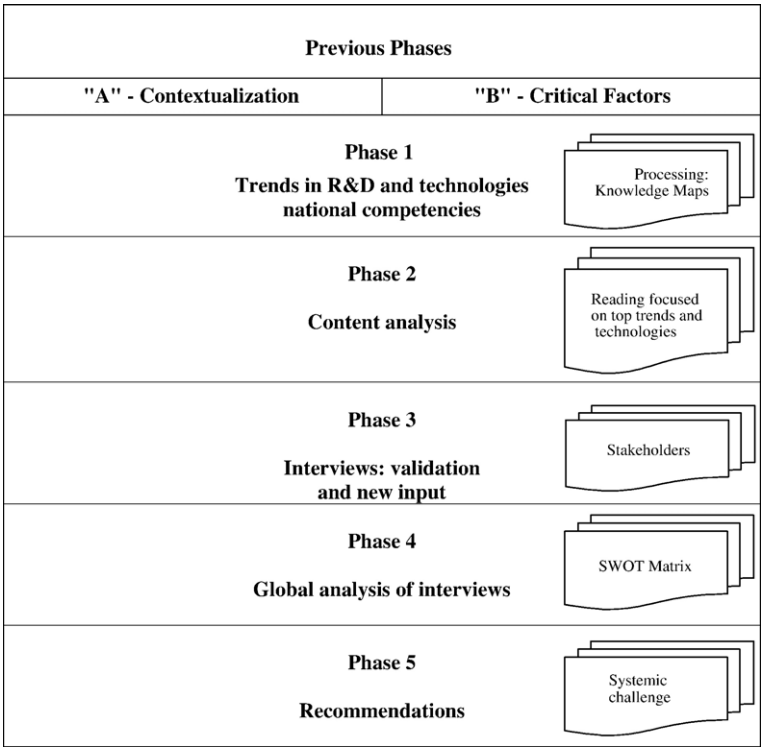

Fig. 2. Outline of the Prospecting Strategy for R&D-intensive sectors. Source: Canongia (2004).

by means of interviews with stakeholders, seeking validation and new input; 4) global analysis of the content obtained in the previous stages, in order to indicate opportunities and forces, threat and weaknesses; 5) recommendations aimed at defining actions related to the economic, social and technological aspects, and prioritizing these in the short, medium and long terms, in order to support the decision-making process. Fig. 2, represents an outline of the proposed model with a focus based on R&D-intensive sectors which are active in a hybrid manner.[1]

5. Application of the strategic model of trends and prospecting: the use of biotechnology in the development of drugs against breast cancer — a vision of the potentialities and opportunities for Brazil

The relevant arguments for a focus on breast cancer and biotechnology were presented in detail in the paper "Technological Foresight — the use of biotechnology in the development of new drugs against breast cancer",[2] when the doctoral thesis studies have been developed. One of the important things to emphasize is that among women worldwide, breast cancer appears as the second most common malignant neoplasm, as well as being a significant cause of death from cancer. Technological advances have been aimed at early diagnosis and treatment, intended to increase survival rates (Parkin et al., 2002).

5.1. Model: previous phase A

This phase is that of contextualization of breast cancer. Aspects such as statistics, characteristics, treatment and market considerations are presented below, with the goal of supporting the prospecting strategy.

With regard to chemotherapy drugs, the most-used protocols consist of more than one drug used at the same time, with the intention of minimizing damage to the blood and maximizing damage to the cancerous cells. Cells within a single tumor accumulate enormous differences among themselves. They are genetically unstable, and for this reason, the task of discovering the "magic bullet" is complex. The so-called "intelligent drugs", created by biotechnology, have come along to prolong and improve the quality of life of cancer patients. The choice of the best drug, in the near future, will be based on the genetic characteristics of each patient and his or her capacity to tolerate side effects, that is, personalized treatment. (Segatto, 2004).

Globally, around 6.2 million people are dying of cancer, of which 2.6 million are in developed, and 3.6 million in developing, countries, according to Ullrich (2003). The global market for cancer drugs is worth around US$ 18 billion. A report produced by World Pharmaceutical Market Summary, 2000 mentions that 1000 cancer drugs are being developed, with 89% of these being biotechnological.

5.2. Model: previous phase B

In regard to the critical factors which have an effect on the hybrid sector which is the focus of this article (pharmaceutical/biotechnological), as a guide for the prospecting strategy, there are those factors which contribute content relevant to the construction of a holistic view. As an example, factors based on an analysis of the Brazilian situation will be identified: A) in the area of drug supply, more than 30 countries are represented in the ranks of the producers of anticancer *active ingredients*. The leading countries which supply anticancer agents for ongoing use by the Brazilian Ministry of Health[3] are: China (18), followed by India (11), the USA (10) and Italy (9). (Antunes et al., 2004); B) In *drugs*, the leadership of the USA is marked. In Brazil, 181 pharmaceutical specialties are marketed by 35 companies. In addition, amongst the 35 companies which are active in this area, 9 produce generic drugs (25.7%): Abbott, Asta Medica, Biosintética, Bristol, Cristália, Eurofarma, Hexal, LAFEPE and Novartis; C) In regard to the *critical factor of medical and hospital services* for breast cancer, there are two reference centers active in Brazil, the Cancer Hospital III (public sector), which is a unit of the National Cancer Institute (INCA) exclusively dedicated to the treatment of breast cancer, and the A C. Camargo Cancer Hospital of São Paulo (private sector); D) In the *critical factor area of distribution, sales and marketing*, there are a number of actors: drug companies, doctors, drugstores, health clinics,

[1] This has been a tendency in the Knowledge Age, which favors multidisciplinarity and interdisciplinarity. Sectors which exemplify these are mechatronics, bio-computer, pharmaceutics/biotechnology and pharmaceutics/nanotechnology, amongst others.

[2] Technovation Journal. Vol. 24(4), April, 2004c. p. 279–370.

[3] Ministry of Health/Secretary of Health Policy, 2002.

NGOs and the media/Internet; in Brazil the state also plays a significant role in distribution. Drugs are controlled and are generally high-priced; E) As an example of the action of the state in regard to the *critical factor of consumption*, it is worth mentioning that the annual expenditure of the public Unified Health System is US$ 50 million, a significant portion of total public health spending; F) Consideration of the *critical factor related to input into innovation* reveals the existence of hospitals, companies, research centers and universities, amongst which, once again, are INCA and the A. C. Camargo Cancer Hospital of São Paulo, because of their clinical research structures. There are the university research groups active in research fields which support the process of innovation in this therapeutic class in partnership with companies (UFRJ[4], UFRGS[5], USP/Ribeirão, UNICAMP[6] and others), as well as those researchers situated in well-known research institutions (FIOCRUZ[7] and the Ludwig Cancer Institute); G) Considering the *factor of quality*, the global adoption of international standards for drug production and manufacture is an essential action. In Brazil, the two reference sectors for cancer, INCA and the A. C. Camargo Cancer Hospital, currently require that their drug-buying procedures include proof of good manufacturing and laboratory practices (GMP and GLP), as factors when evaluating tenders, as well as presentation of bioequivalence and biodisposability certification in the case of generics; H) For the *systemic environment factor*, it is fundamental to take into account that each country must create its strategic plan for cancer control, tightly linked to a R, D and I[8] program and harmonized with international forces moving in the same direction (Ullrich, 2003), placing cancer control on the agenda of priorities for the health sector of each nation. In 2004, the Brazilian Ministry of Health released "Breast Cancer Control: a Consensus Document", which is a sign of the importance of this factor. Additionally, the questions of regulation and monitoring, under the control of the Agência Nacional De Vigilância Sanitária[9] agency, are strongly present in the field, given the effect which this organ has within the scope of its activity. Another essential aspect related to this factor are patent-related issues, which in Brazil are the concern of the Instituto Nacional De Propriedade Industrial-INPI[10], principally in the area of biotechnology, in which many ethical values have been objects of debate between society and the scientific community; I) The *promotion/financing* factor refers to sources of support which can be sought. Examples of these in Brazil are the Sectoral Funds for Health, Pharmaceuticals and Biotechnology (Ministry of Science and Technology), which issue public tenders, as well as PROFARMA of the development bank, BNDES[11], and other sources of funding, such as the Foundations for Research Support (FAPs). Example of these is FAPERJ (FAP — State of Rio de Janeiro, with its Edital Rio Inovação, and investment funds (CRP — the Rio Grande Investment Company); J) *The non-profit sector/associations* in Brazil, with representation from companies and universities, as well as patients. Amongst the latter are found the Brazilian Association for Assistance to Families and Children Suffering from Cancer (ABRACE), the Avon Institute, the Brazilian Institute for Cancer Control (IBCC), the Cancer Patient Support Group (NAPACAN), amongst others, which mount information campaigns and support patients and their families; K) Finally, in regard to the critical factor which permeates the whole sector, *strategic management and innovation*, there is growing trend of joint ventures and strategic alliances as a regular policy of companies. An example of this is the effort of three Brazilian companies: Cristália, Biosintética and Eurofarma.

5.3. Phase 1 model: R&D and technology trends; Brazilian competencies in biotechnology and breast cancer

Results obtained from both databases were processed automatically, generating frequency lists, maps and reference tables, using, for example, Vantage Point software as an information and data and text mining tool.[12] The correlations of different variables are presented, allowing a decision-maker to globally visualize the movements and behaviors of the variables which are

[4] Federal University of Rio de Janeiro.
[5] Federal University of Rio Grande do Sul.
[6] State University of Campinas.
[7] The Oswaldo Cruz Foundation.
[8] Research, development and innovation.
[9] National Health Vigilance Agency.
[10] National Industrial Property Institute.
[11] National Bank for Economic and Social Development.
[12] In the methodology used in this study, various approaches and software programs were used, amongst these Vantage Point, developed by the Georgia Technology Institute-USA, which makes possible the creation of maps in which it is possible to show the most frequently cited substances, combinations of drugs, countries and institutions; as indicated in the article of Porter and Detampel (1995).

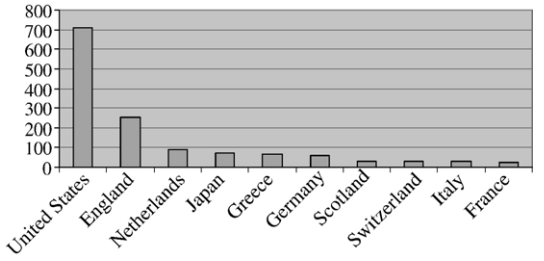

Fig. 3. Graphic Top Ranked countries in terms of publication of articles on breast cancer and biotechnology— 2001 and 2002. Source: Canogia et al. (2004b).

of interest. It should be noted that these tools are based on bibliometric algorithms, cluster analysis and fuzzy logic.

5.3.1. R&D trends

Technical–scientific production, that is, articles, reveal the extent of the explosion in biotechnology in healthcare. Research undertaken in the last two years (2001–2002) in the medical and related bibliographic reference database MEDLINE, reveals more than 30,000 articles on cancer (the diversity of the types of cancer is high) and biotechnology, related to therapy, diagnosis or prevention. This shows the extent to which health research based on biotechnology has grown rapidly and fertilized discoveries fundamental to the improvement of the quality of life. Leadership in cancer research is held by the USA, followed by the UK. Brazil, on the other hand, appears minimally in this area of activity. (Fig. 3).

Analyzing the substances cited in the articles, it is possible to identify more than a thousand distinct substances, with the highest frequency (342) belonging to Paclitaxel. This demonstrates the high degree of diversity of substances referred to in the articles; more than eight hundred substances show a frequency of 1.

Keeping in mind the complexity of the network of correlations between the drugs, it is possible, using automatic procession software resources, to restrict the results to those drugs presenting a frequency of 80 or higher citations in the sample articles, producing a drop in the number cited to 25 drugs, as shown in Knowledge Map (Fig. 4), which reveals four groups with a much higher degree of correlation.

In the *first group* there is a high degree of correlation between the articles which deal with monoclonal antibodies and this which mention the drug Trastuzumab, which is specific to breast cancer therapy. With a slightly lower degree of correlation, the *second group* contains drugs based on Paclitaxel and Docetaxel, which are correlated with chemotherapy protocols, since new anticancer drugs are always adopted in the form of combinations with already tested drugs. The *third group*, seen on the lower part of Map 1, represents the drug Tamoxifen, a hormonal anticancer agent, situated close to the estrogen receptor region, that is to say, its location is evidence of the way in which this drug acts. The *fourth group* gives emphasis to the correlation between Cyclophosphamide and Fluorouracil, pointing out the protocols for this chemotherapy combination.

It should be mentioned at this point that the graphic representation on the map, created by means of data processing and map-generating software, is quite flexible, allowing for zooming in order to more closely examine details of the correlations. The potential of this representation, however, is compromised by the limitations of the printed format, but this does not prejudice the analysis or the importance of the use of this type of tool for the analysis of large volumes of data or indicators.

5.3.2. Technological trends

Patents, as indicators of innovation (Leydesdorff, 2001; Wilson, 1987) also demonstrate the potential of bioindustry in healthcare. At the beginning of this century (the period 2001–2002), for example, chronic cancer was responsible for the issue of 4282 patents based on biotechnology. The leadership is held by the USA, followed by the UK.

Following automatic processing, the 330 patents strongly related to the prospecting focus of this article[13] were indexed by the top factors: priority countries and companies or entities which have registered patents, and the content of article titles and abstracts were analyzed, checking trends. There is little concentration of patent registrants: amongst 330

[13] This is the result of several factors, amongst which are: a) there are general patents which do not identify the type of cancer to which the drug will be applied; b) there is a diversity in the typology of cancer, with more than 100 listed by the FDA; c) there are other synonyms related to breast cancer in addition to those used in the data and text mining mentioned in the title and abstract; d) there are patents in which certain are present only in the claims fields. In this article, given the main objective of proposing a model for a prospecting strategy and its application as a test of its viability, the analysis was not deepened to include the content of the 4300 patents in the wider context of cancer and biotechnology in an attempt to exhaustively identify the patents referring to breast cancer.

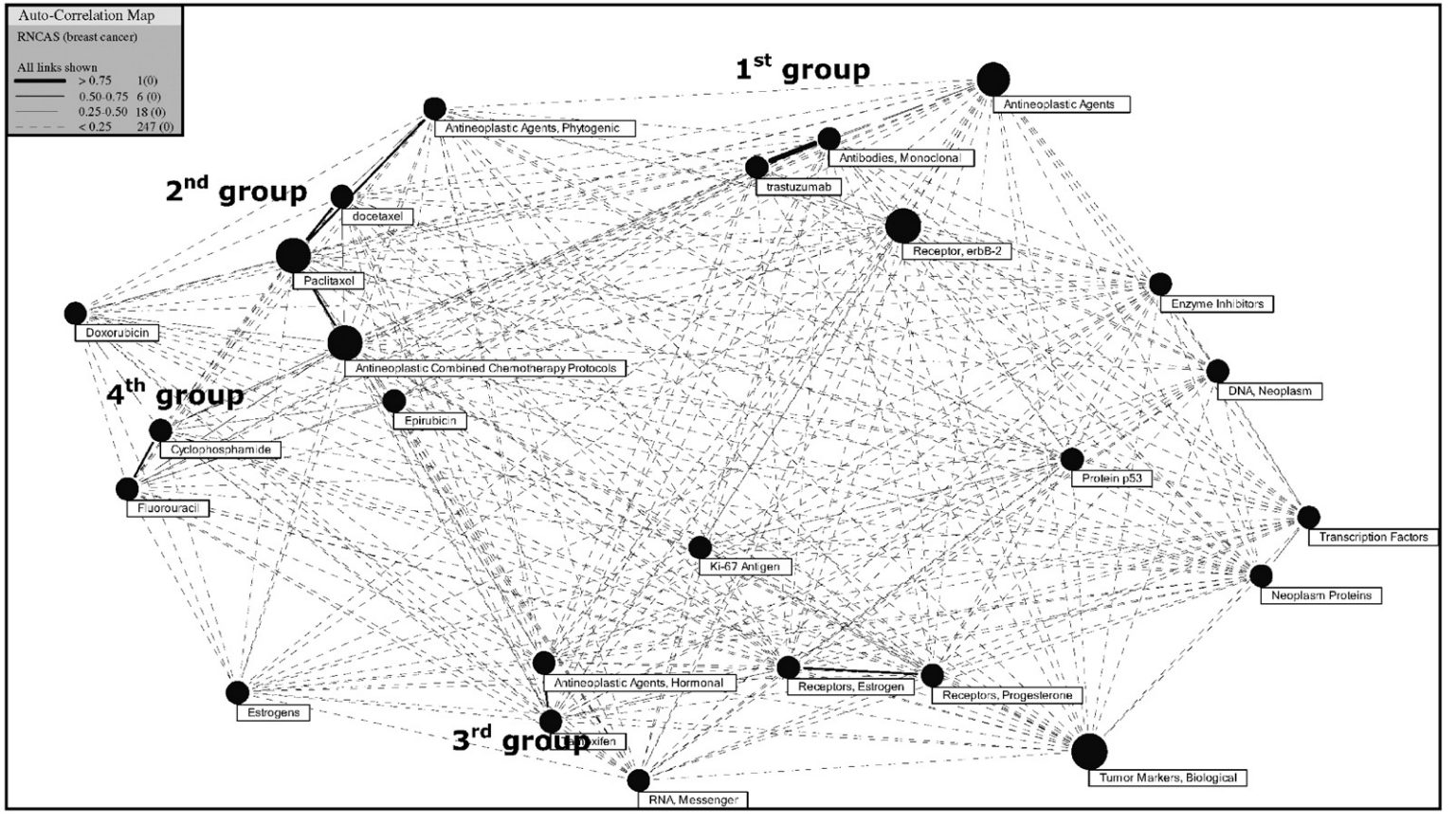

Fig. 4. Map Autocorrelation of 25 Drugs with citations equal to or greater than 80 in articles on Breast Cancer and Biotechnology in the Medline database — 2001/2002. Note: this visual distribution map contains 25 drugs with a frequency higher than, or equal to, 80 articles, from a total of 1888 drugs. Source: Canongia (2004).

patents, only 44 registrants are responsible for two or more patents.

Of the ten top registrants in the sample analyzed, from a total of 330 patents, nine are companies and one is a university, shown in Table 2. Additionally, investigating initiatives in breast cancer drugs, it is possible to identify which among the top ten registrants are active in this area and in which directions they are focused: therapy (T), prevention and therapy (P,T), therapy and diagnostics (T,D), and therapy, diagnostics and prevention (T,D,P). From this angle, it can be seen that the Corixa company is a leader, both globally and in terms of the therapy focus, while the Incyte company, second in global ranking, drops to fourth place in terms of the therapy focus, along with the University of California and the Millenium company. Two companies occupy second place in the ranking for the therapy focus: Oxford and Takeda. (Table 2).

The companies in Table 2 are distributed geographically as follows: 7 in the USA, 2 in Japan, 2 in the UK (the Millenium company has a subsidiary in the UK). The US companies show a slight concentration in California.

Another possible avenue of analysis involves the use of the Patent Classification. Looking at the Derwent database, 231 patents present only three classes as focus of patenting: B04 (natural products and polymers), D16 (industrial fermentation) and S03 (scientific instrumentation), indicating the technological trend in relation to these topics.

The correlation between the 44 registrants indicates that the USA is the most active country, as the location of the highest concentration of advances in biotechnology applied to breast cancer drugs.

The prospecting of patents oriented to products (specific oncological drugs) was undertaken for two periods. The period 1984 to 1985 was examined in order to determine which patents are close to expiry (future generics offering the possibility of innovation), and the period 2002 to 2003 as a way of outlining the most recent potential for innovation of each of the antineoplastic drugs on the National Essential Medicines List of

Table 2
10 leading registrants of breast cancer and biotechnology patents — 2001 and 2002

Patent registrant	Total no. of patents	No. of patents in therapy overall	No. of patents by categorization in therapy			
			T	P,T	T,D	T,D,P
Corixa Corp [a]	12	8	1	–	1	6
Incyte Genomics Inc. [b]	11	4	–	–	–	4
Diadexus Inc. [c]	9	6	5	–	–	1
Oxford Glycosciences UK Ltd [d]	8	7	–	–	2	5
University of California [e]	7	4	1	1	2	–
Isis Inc. [f]	7	2	–	–	–	2
Millenium Pharm Inc. [g]	7	4	–	1	1	2
Takeda Chem Ind Ltd [h]	7	7	3	–	–	4
Bode Gene Dev Co Ltd Shanghai [i]	6	6	2	–	4	–
Human Genome Inc. [j]	5	2	–	1	1	–

Notes to Table 2:
Source: Canongia, (2004).

[a] Seattle-USA-www.corixa.com-"Corixa is a developer of immunotherapeutics with a commitment to treating and preventing autoimmune diseases, cancer and infectious diseases by understanding and directing the immune system".

[b] California-USA-www.incyte.com-"Incyte is a drug discovery company applying its expertise in genomics, medicinal chemistry and molecular, cellular and in vivo biology to the discovery and development of novel small molecule and protein therapeutics".

[c] California-USA-www.diadexus.com-DiaDexus, Inc., is "a privately held biotechnology company, is focused on the discovery, development, and commercialization of novel, patent protected diagnostic and therapeutic products with high clinical value".

[d] Oxon-UK-www.ogs.com-Oxford Glycosciences UK Ltd, "is a biopharmaceutical company where the first Proteomics Lab in the world was created. At this lab, many kinds of proteins – amino acids – have been discovered through image analysis and sequence databases".

[e] California-USA-www.berkeley.edu-"Graduate program in computational and genomic biology".

[f] Alpharma Inc-USA-"Is a growing specialty pharmaceutical company which bought Schwarz Pharma (German company), including Isis Pharma"-www.isispharma.de.

[g] USA e UK-Millenium Pharm-www.mlnm.com-"Applies genomics in the development of life-science-based products and services. The goal is to use his deep understanding of mechanisms and pathways of disease together with the unique characteristics of the individual to accelerate the prevention, detection and cure of disease. This is an approach called Personalized Medicine".

[h] Tokyo-Japan-www.takeda.co.jp-"Takeda is a research-based global company with its main focus on pharmaceuticals. It is the largest pharmaceutical company in Japan and among the leaders in the world. Takeda discovers, develops, manufactures and markets a broad range of superior pharmaceutical products to improve the health and quality of life of people around the world".

[i] Shanghai-Japan-Shanghai Bode Gene Development Co. Ltd. "merged with Guangdong Zhaoqing Star Lake Biological Science and Technology Co. Ltd. at end of August, 2000, to form the large biochip company in China. Shanghai Bode Gene Co. use their biochip technology to evaluate their shares. It is reported that Shanghai Bode Gene Co. has applied for over 2000 patents for gene pharmaceuticals".

[j] Maryland-USA-www.hgsi.com-Human Genome Sciences, Inc., "is a pioneer in genomics for the discovery and development of new pharmaceutical products. Its goal is to become a global biopharmaceutical company that discovers, develops, manufactures and sells its own gene-based drugs".

the Brazilian Ministry of Health (RENAME[14]/MS). (Antunes et al., 2004). The technology prospecting was complemented by means of searching for and processing of information and automatic treatment of a further 640 patents. In terms of the most-patented drugs for the 84–85 period, that is, those set to expire in 2004–05, three were identified as having patenting focused on therapy for various types of cancer, including breast cancer: Fluorouracil (32), Methotrexate (24) and Bleomicine (21). It merits observing that these patents are not biotechnology focused. For the period 2002–03, the three drugs with focused patenting of twenty or more patents, demonstrating innovation potential, are Fluorouracil (25), Methotrexate (25) and Tamoxifen (20). Looking at the patents related to these three drugs, biotechnology appears as a supporting element, with the Ribozyme Pharm company being one of the most active in terms of patenting, evidence of the recent tendency towards biotechnology applications observed in the prospecting focused on recently patented developments.

5.3.3. Identification of Brazilian competencies — the local view

The prospecting strategy aims to undertake analysis on two levels: one general and one more specific.

5.3.3.1. First level: Brazilian competencies in the use of biotechnology for cancer treatment. In the direction of developing the identification of competencies, focusing on the central subjects of this article, research was initially undertaken in the Research Group Directory of the Lattes/CNPq[15] (National Council for Scientific and Technological Development), searching for synonyms for both cancer and biotechnology. 78 leading research groups in the use of biotechnology in cancer treatment were found, in which medicine and genetics were found to have strong participation, with these two areas accounting for around 70% of the sample analyzed.

Analysis of the institutional aspect of this sample reveals that, in Brazil, the state of São Paulo is home to 23 leaders, concentrated in the University of São Paulo (USP-10), followed by the State University of Campinas (UNICAMP-3). In the state of Rio de Janeiro, with 14 leading research organizations, equal distribution was found between the Oswaldo Cruz Foundation (FIOCRUZ), the National Cancer Institute (INCA) and the State University of Rio de Janeiro (UERJ).

5.3.3.2. Second level: Brazilian competencies in the use of biotechnology for breast cancer treatment. In regard to Brazilian competencies specific to breast cancer, the search methodology used examined the location of the leading research groups specializing in breast cancer in the database of the Research Group Directory of the Lattes/CNPq, in which were found 136 leaders with 70 lines of research. Cross-referencing the leaders of the resulting group related to breast cancer (136) with the leaders resulting from the search for leaders in the use of biotechnology in cancer (78), it was possible to identify twelve superpositions, arriving at a total of 202 leaders active within the focus area of this study. It is worth noting that, behind each leader there exists a network of researchers, which serves to amplify the competencies in the areas which are the subject of the present study.

5.4. Phase 2 model: content analysis

Given the necessity of undertaking content analyses which complement automatic analyses and taking into account the importance of systematic monitoring in specialized media, below are presented the methodological steps applied and the results of the content analyses referent to R&D and technological trends, Brazilian competencies and the formation of specialized opinion.

5.4.1. Analysis of R&D trends (articles)

The main article titles and abstracts were examined, identifying 23 drugs and/or combinations for breast cancer treatment. Content analysis is of high usefulness, as it allows for observation of the most applied research trends in the articles, checking studies on prognostic factors, such as the expression of oncogene c-erB-2, which increases metastatic activity and offers greater resistance to chemotherapy drugs (Table 3 shows 12 examples of this drugs).

5.4.2. Analysis of R&D trends (patents)

Based on an analysis of the content of 330 patent titles and abstracts, there is a clear demonstration of a wide-ranging patenting trend (therapy and/or diagnostics and/or prevention), a typical value-added mark of the Knowledge Society. Of note also is the trend for patents to be directed at more than one disease, which increases market niche and competitiveness. Besides cancer, citations are found for diseases such as diabetes, Alzheimer's Disease, Parkinson's Disease, osteoporosis and glaucoma, amongst others.

[14] National Essential Medicines List of the Brazilian Ministry of Health.
[15] Details at http://www.cnpq.br.

Table 3
Drug and/or drug combinations for breast cancer therapy — 2001 and 2002

Drug combinations	
1. Trastuzumab + chemotherapy	13. Cyclophosphamide + thiotepa + carboplatin-CTC
2. Doxorubicin + taxanes (docetaxel or paclitaxel)	14. Docetaxel + epirubicin
3. Cationic liposome (E 1A gene + DC-CHOL cationic liposome-DCC/E1A)	15. Letrozole ("nonsteroidal aromatase inhibitor")
4.Vinorelbine + paclitaxel + G-CSF (granulocyte colony stimulation factor)	16. Paclitaxel + capecitabine
5. Vinorelbine + docetaxel + G-CSF)	17. Cyclophosphamide + epirubicin + 5-fluorouracil-CEF + G-CSF
6. Eniluracil + 5-flourouracil + docetaxel	18. Gemcitabine + cyclophosphamide + 5-fluorouracil + folic acid + G-CSF
7. Paclitaxel + 5-florouracil + adriamycin + cyclophosphamide-Pac/FAC	19. Mitoxantrone + cyclophosphamide with G-CSF + citroploxacin for hematological recovery
8. Paclitaxel + 5-florouracil + epirubicin + cyclophosphamide-Pac/FEC	20. Mitoxantrone + paclitaxel
9. ABI-007 (protein-stabilized-monoparticulate of paclitaxel)	21. Protaxel
10. Docetaxel + trastuzumab	22. Angiogenis
11. Gemcitabine + doxorubicin + paclitaxel	23. Raloxifene
12. Hemocyanin vaccine	–

Source: Canogia et al. (2004b).

Analysis of the patents of the leading companies allows for identification of patenting trends, presented here: A) *Corixa Corp.* — proteins – breast tumors – prevention, diagnostics and prevention; B) *Incyte Genomics Inc.* — enzymes and recombinant DNA – breast cancer, Alzheimer's Disease, leukemia, AIDS, cardiovascular diseases – prevention, diagnostics and therapy; C) *Diadexus Inc.* — genes and proteins – breast cancer – detection, monitoring and treatment (gene therapy applications); D) *Oxford Glycosciences* UK Ltd — protein detection (BCMP 7, BCMP 11 and BCMP 84) – breast cancer – screening, diagnostics, prevention and treatment; E) *University of California* — diversified – antibodies and genes – breast and ovarian cancer – diagnosis, prognostics and treatment; F) *Isis Pharma Inc.* — oligonucleotide encoding casein kinase 2 (alpha or beta) – breast and prostate cancer – diagnostics and treatment; G) *Millenium Pharm Inc.* — polypeptides – cancer (breast, lung, ovarian), Alzheimer's and Parkinson's Disease, AIDS – diagnostics and treatment; H) *Bode Gene Dev. Co. Ltd.* Shanghai — hormones and polypeptides – breast cancer, AIDS, hypertension, arteriosclerosis – diagnostics and treatment; I) *Takeda Chem Ind. Ltd.* — G-protein – breast cancer, diabetes, respiratory diseases – treatment and diagnostics; J) *Human Genome Sci. Inc.* — nucleic acids – breast cancer, cardiovascular, neurological disorders – prevention, diagnostics and treatment.

Turning to the research undertaken on the patents of the essential anticancer drugs employed by the Brazilian Ministry of Health (RENAME) registered in the period 2002 to 2003, analysis of the content reveals that: A) In regard to *Fluorouracil*, patenting trend in the most recent period shows that, of the 34 patents analyzed, 22 are related to the drug Fluorouracil and/or derivatives, 8 are treatment auxiliaries, 3 are for appliances and 1 for a substitute product. Of the 22 patents focused on the drug, 19 are for the treatment of cancer and other diseases, that is, they are of wide-ranging use, and only three are concerned with the drug production process. Of the total of the patents analyzed, it is noted that, for the companies involved, there is a trend in patenting of this drug towards new formulas. There are 32 distinct actors, demonstrating a low level of concentration amongst the patent registrants, with only the Ribozyme Pharm and Bristol-Myers Squibb companies possessing two patents each, with biotechnology as a supporting element; B) In the case of *Methotrexate*, the patenting trend in the period 2002 to 2003 shows that, of the 32 patents, 25 are focused on the drug and 7 are correlated (of these, three are for substitute drugs and four are for treatment auxiliaries). As well as this, 20 patents are directed to therapy. It is notable that only three companies are responsible for more than one patent: Bristol-Myers Squibb (3), Aventis Pharma (2) and Ribozyme Pharm (2), which is evidence of a certain diversity of actors in relation to this drug. There is an occurrence of patents with a biotechnological focus, particularly those featuring combinations with monoclonal antibodies. C) As for the most recent trend in patenting related to *Tamoxifen*, an analysis of 28 patents shows that 14 are for treatment focused on the drug. There is also an evident trend towards patenting formulas (16), that is, more than 50% of the total. In terms of

actors, the leading patenter is AstraZeneca (7), followed by Schering (3), while 18 patents (64.2%) were registered by distinct registrants.

5.4.3. Analysis of Brazilian competencies (Lattes CVs and directories)

5.4.3.1. First level: analysis of Brazilian competencies in the use of biotechnology in cancer research (Lattes CVs). Amongst the researcher CVs registered in the Lattes/CNPq database, the 78 leaders identified as being active in cancer-related biotechnology research are found in the following areas: 1. "*Medicine*" — among 19 distinct institutions, those with two leaders each are UNICAMP,[16] UFRGS,[17] PUCRS[18] and UFC,[19] whose lines of research are more oriented to gene mutations, pharmacogenetics, gene expression and genotyping, respectively. Four institutions show breast cancer-related research: HNSC,[20] UFG,[21] UFRJ and UFMA;[22] 2."*Genetics*" — amongst the 18 distinct institutions are the USP and the UFPA,[23] with three leaders each, whose lines of research are respectively directed towards cancer biomarkers and the genetics of cancer, amongst others. The institutions with two leaders are the INCA, the UFRGS and the UnB,[24] and the lines of research are oriented, respectively, towards genome analysis, gene therapies, and the production of biopharmaceuticals. In this category, the institutions whose lines are clearly oriented to research in breast cancer are the UFMG[25] and the INCA; 3."*Biochemistry*" — six distinct institutions, with the UERJ having two leaders whose lines of research are oriented explicitly towards gene expression and sequencing. There is no explicit evidence of breast cancer research, but the UERJ stands out, with research on the gene p53, a new gene identified as having a possible correlation with breast cancer; 4. "*Immunology*" — the leaders are found in the institutions INCA, PUCRS, UFRGS and UnB, with lines of research strongly directed at monoclonal and polyclonal antibodies, as well as gene expression and gene therapy. There is no clear evidence of breast cancer research, but competencies in the mentioned technologies is fundamental to the development of biodrugs for the treatment of the illness under study; 5. "*Pharmaceutics*" — three institutions were identified: UNESP,[26] UFMG and UNICRUZ, with dispersed lines of research in medulla transplant and cervical cancer, amongst others; 6."*Community Health*" — the FIOCRUZ, UERJ, UFSC[27] and UnB institutions are present, with lines of research aimed at epidemiological studies and the illness–health relationship; and, 7. "*Microbiology*" — the UFRN[28] and UFF[29] present lines of research in the area of cervical cancer.

5.4.3.2. Second level: analysis of Brazilian competencies in breast cancer (Lattes CVs). For the 136 leaders, an analysis was undertaken of the CVs registered in the Lattes/CNPq database, and the foci of activity were distributed according to the following categorization: 1. "*Diagnostics and/or prognostics*" — within this category there is prominence of advances in less invasive digital techniques for breast cancer detection. Ten institutions possessing this type of competency were identified, mostly concentrated in São Paulo, where the PUC/SP,[30] UNICAMP and USP jointly present seven lines of research; 2. "*Women's Health*" — this is fundamental to any breast cancer diagnosis process. In general, the most satisfactory results are obtained when the patient has access to adequate care, both in terms of control of the illness (drugs) and in psychological support and rehabilitation. There are 14 lines of research distributed in 13 institutions, evidence of concentration in the competencies. Examining geographic locations of the research, the Southeast and South of Brazil are more prominent, with eight and three institutions respectively, and a focus on psychosomatic support and rehabilitation. 3."*Biotechnology*" — of the 13 lines of research with this focus, eight are concentrated in the Southeast region institutions: UNICAMP; USP; PUC/SP; FIOCRUZ; and UFMG, with emphasis on oncogenetic studies, DNA expression and biological markers, amongst other important areas of knowledge in the development of biopharmaceuticals and/or biomedications; 4. "*Treatment and prevention*" — in nine institutions are found 13 lines of research in this type of competency, with the PUC/SP and the UFSM evidencing three each, with little concentration. Research in these institutions is focused on chemotherapy and

[16] State University of Campinas;
[17] Federal University of Rio Grande do Sul;
[18] Pontifical Catholic University of Rio Grande do Sul;
[19] Federal University of Ceará;
[20] Nossa Senhora da Conceição Hospital;
[21] Federal University of Goias;
[22] Federal University of Maranhão;
[23] Federal University of Pará;
[24] University of Brasília;
[25] Federal University of Minas Gerais;
[26] State University of São Paulo;
[27] Federal University of Santa Catarina;
[28] Federal University of Rio Grande do Norte;
[29] Federal University Fluminense;
[30] Pontifical Catholic University of the State of São Paulo;

hormone therapy, as well as surgical interventions aimed at saving the breast. This focus includes attention to drug mechanisms and effects. Only one institution presents an ongoing line of research on new drugs, the Nossa Senhora da Conceição Hospital (HNSC), in the state of Rio Grande do Sul; 5.“*Patient profile and epidemiological research*” — among the 6 institutions active in this category, five are located in the Southeast region. This focus is important in the identification of the way in which breast cancer occurs in the Brazilian context and in how patients respond to chemotherapy and hormone therapy; 6.“ *Clinical Studies*” — this is an important stage in research on new drugs. The sample analyzed shows that, of the 70 lines of research, only three refer to this type of competency; these are located in only two institutions: the Cancer Institute of Ceará (ICC) and the National Cancer Institute (INCA). The low level of occurrence in this category confirms the lack of Brazilian activity in this area, as well as systemic impediments to its development.

5.4.3.3. Specialized opinion-makers. The specialized media[31] play a surprisingly strong role in disseminating data and information about the topic of this study. Published materials on breast cancer and the hybrid sector in question for the period 2002 to 2004 were examined, and those considered relevant were used in formulating this stage of the model. Several analytical taxonomies were created: under “*Medications*, *prognostics and therapies*”, it is observable that activity related to gene therapy and/or pharmacogenetics is increasing, with substantial investments by companies in the hybrid pharmaceutical/biotechnological sector, and development of new drugs. Examples of the latter are: AstraZeneca’s Arimidex (aromatase inhibitor — anastrozole); Novartis’s Femara (aromatase inhibitor — letrozole); Genentech’s Herceptin (monoclonal antibody — trastuzumab); Introgen Therapeutics’ Advexin (gene p53); Novartis’s Glivec (monoclonal antibody — imatinib); Roche’s Avastin (monoclonal antibody — bevacizumab) and Pharmacia’s Aromasin (aromatase inhibitor — exemestane), amongst others. Amongst the international bioindustrial leaders, Genentech and Amgen are both active in the area of cancer treatment, including breast cancer.

Looking at the category “*Health sector*”, a preoccupation is observable, at both the international level and in Brazil, with the costs of new breast cancer therapy, which, employing cutting-edge technologies, are very expensive and have even provoked crises in private medical services. At the same time, therapies which use antibodies have produced promising results, generating a strong trend. Within Brazil, there is an evident need to increase the number of centers on the CACON (High Complexity Oncological Centers) model, based on the necessity for more specialized centers for the treatment of cancer sufferers, as presented above in relation to the critical factor of medical-hospital services.

The content analysis of the category “*Pharmaceutical/Biotechnological hybrid sector*” shows a growing vision of personalized medicine and indicates the importance of the participation of Brazilian business in international trade fairs in order to expand the market, find new partners and stimulate economic, social and technological development. There was identified a preoccupation at the international level in relation to the dissemination of information on the clinical tests undertaken by companies on new drugs, pointing to a new trend.

5.5. Phase model 3: interviews: validation and new input from stakeholders

Of the various existing techniques used to gather opinions and to interact with the multiple actors in the field under examination, the choice was made in this case of that of semi-structured interviews with stakeholders. This type of approach has come to be seen as a new management tool, Stakeholder Dialogue or Stakeholder Engagement, whose role is to gather, by means of interviews, the perceptions and expectations of those involved in decision-making processes. (Vinha, 2002).

Two basic questions were posed as a way of gathering points of view and gaining new knowledge: A) the first asked about the results of data prospecting in the area of breast cancer and biotechnology *vis a vis* the experience of each stakeholder; B) the second was framed in regard to the importance of prospecting and

[31] Examples: ABIFINA — Brazilian Fine Chemistry, Biotechnology and Specialties Association (http://www.abifina.org.br); ABIQUIF — Brazilian Pharmachemical Industry Association (http://www.abiquif.org.br); ABIQUIM — Brazilian Chemical Industry Association (http://www.abiquim.org.br); ABRABI — Brazilian Association of Biotechnology Companies (http://www.abrabi.org.br) Annual Meeting of the American Association for Cancer Research (AACR) (http://www.aacr.org); ANVISA — Health Vigilance Agency (http://www.anvisa.gov.br); Biotechnology Industry Organization (http://www.bio.org); Breast International Group (BIG) (http://www.breastinternationalgroup.org); Cancer Information Service (http://cis.nci.nith.gov); FDA — US Food and Drug Administration (http://www.fda.gov); Global Forum for Health Research (http://www.globalforumhealth.org); IMS HEALTH — Intercontinental Marketing Services-HEALTH (http://www.imshealth.com); National Cancer Institute/US National Institutes of Health (http://www.nci.nih.gov); Gynecology Portal (http://www.portaldeginecologia.com.br); SBOC — Brazilian Clinical Oncology Society (http://www.sboc.org.br).

feedback from the interviewees on the proposed model of a prospecting strategy. Thirty stakeholders from twenty-four Brazilian institutions representing the critical factors of the hybrid pharmaceutical/biotechnology sector were interviewed.

The results of the interviews are treated in frameworks, offering a view of each critical factor analyzed. The frameworks present the strengths and opportunities, as well as the threats and weaknesses, identified in the interviews, and serve as markers for a better arrangement of the critical factors for global analysis and for the final phase of the prospecting strategy.

5.6. Phase model 4: global analysis: applying the SWOT[32] matrix

It is of note that the stakeholders in general tended to focus their opinions in the interviews more on economic and technological aspects rather than on the social. (Canongia et al., 2006).

The overall consensuses revealed are as follows:

5.6.1. Opportunities

There is an agreement that the arrival on the scene of new technologies like biotechnology could mean opportunities for the sector, once the stumbling block of the lack of investment in Brazil is overcome, and if there were an integrated industrial policy for the sector. The issue of the wave of patents which are about to expire, and which are worth around $3 billion on the American market, and the increase in strategic partnerships, mergers and acquisitions with bioindustry are all considered opportunities for increased innovation in the sector, in the line of development of generics and/or "me too" drugs. Other opportunities are also singled out: the general growth of biotechnology in the development of cancer drugs, and the strong trend towards the use of taxanes (paclitaxel and docetaxel) for breast cancer treatment is recognized, as are partnerships with biotechnology as a means of stimulating innovation. That working in networks is a motor of development, especially in relation to clinical studies, is agreed upon. New receptors offer promise in hormonal treatment for breast cancer, which also opens opportunities in innovation-oriented R&D.

5.6.2. Strengths

There is currently in Brazil an increase in integrated planning between the Ministries of Science and Technology (MCT),[33] Development, Industry and Foreign Trade (MDIC)[34] and Health (MS),[35] although this process is still under construction. R&D investments in plant-based medicines are generally lower than is needed for chemical synthesis, but given the potential strength of the country in terms of biodiversity and human resources, this type of production is viewed as a niche which can create new opportunities for competitiveness. Other strengths mentioned are: the two internationally respected reference centers for cancer, the National Cancer Institute in Rio de Janeiro and the Cancer Hospital in São Paulo, the country's competency and capacity for the production of generic and "me too" drugs, and the growth of the understanding among management in the sector that patents are mechanisms for technological development. The country possesses clear competencies in bioprocesses (genes, DNA and plant-based medicines), mainly as a result of the investments in the development of human resources undertaken by the government in the 1980s and early 1990s. In addition, the Ministry of Health is planning to expand and create another 20 High Complexity Oncology Centers (CACON), distributed regionally.

5.6.3. Threats

Threats mentioned for the sector are increased costs, risks in drug development, including biodrugs, along with the fact that the cost of cancer treatment with the new drugs is high and the lack of interest by the multinationals in locating production in Brazil; these factors have contributed to a critical situation, as underlined by the stakeholders. The government is presented with a substantial dilemma and challenge: how to attract foreign capital and stimulate production by multinationals in the country, while simultaneously promoting the domestic industry and guaranteeing universal access to medications, which means low prices. In recent years, countries like China and India have increased their industrial plant for the production of pharmaceuticals by, in some cases, attracting foreign investment.

[32] Allows an analysis of strengths, weaknesses, threats and opportunities. The potential of this approach, according to Kahaner (1996), is in the possibility it offers for examination of relationships and impacts, in the light of such issues as markets, labor force, capital investments (infrastructure), raw materials, technology and processes, finances and time.

[33] Ministry of Science and Technology;
[34] Ministry of Development, Industry and Foreign Trade;
[35] Ministry of Health;

5.6.4. Weaknesses

The almost complete lack of technical barriers to the importation of pharmaceutical products, the bureaucratic sluggishness and multiple bureaucratic requirements of ANVISA, and the absence of effective support for technology-based small businesses are the main weaknesses identified in the Brazilian context. Also emphasized as weaknesses are the costs and risks associated with the process of developing new drugs, which can be as high as 50 to 80 million dollars for the development of new molecules, and from 500 to 800 million for stages of clinical testing, marketing and sales, figures which Brazil has not yet achieved. The issue of domestic production is even more critical when the fact is taken into account that prices for medications produced by India and China will tend to increase. Another important point raised in the interviews is that there is a lack of knowledge outside Brazil about the country's R&D competencies, due to the fact that the country's participation in the world patent system is still in its early stages, and a lack of marketing of the competencies of Brazilian universities, as well as a low level of participation in trade fairs to share results with strong innovation appeal.

5.7. Phase model 5: recommendations

Based on the information gathered, correlations identified and analyses undertaken in the various phases of the model: previous phases A and B and the four phases: 1) R&D and Technology Trends and country competencies, 2) Content Analysis, 3) Interviews: validation and

Table 4
Recommendations for time-based and systemic actions for the pharmaceutical/biotechnological sector active in the breast cancer area: short term

Recommendations		
Actions	A	Timeframe for implementing actions Short term (=<2 years)
Offensive actions	E	Examine investments in R&D and innovation in therapy, diagnostics and breast cancer prevention in the sector analyzed in terms of tax incentives.
	S	Expand and/or create networks for the promotion of systematic dialog on innovation in breast cancer drugs, with inclusion of all the actors representing the critical factors in the pharmaceutical/biotechnology sector (e.g. the SBOC — Brazilian Clinical Oncology Association-network).
	T	Decrease bureaucratic obstacles in the areas of the public sector which most closely participate in the sector under study, especially ANVISA (monitoring and regulation) and INPI (patents). Push the Innovation Act, given that this was approved by the President of Brazil in December, 2004 and regulated in October, 2005. Promote coordinated action in regard to the application of financial resources between the Ministry of Science and Technology/ Sectoral Funds: Pharmaceuticals and Biotechnology; Ministry of Health/Health Innovation Project; BNDES/Profarma (Support Program for the Development of the Pharmaceutical Productive Chain) — resources available from other potential sources of financing, directed to assist biotechnology companies in partnership with universities/R&D centers, and/or in consortia with pharmachemical or pharmaceutical companies, for the development of vaccines, biopharmaceuticals and diagnostic kits for breast cancer. Increase funding for technological training and professional development in the sector, especially with regard to biotechnology.
Defensive actions	E	Support, through joint funding (MCT, MDIC, SEBRAE and FAPs), activities in the area of trend monitoring in Brazil in order to systematically disseminate analyzed information by therapeutic class, and to valorize technological information.
	S	Increase the number of High Complexity Oncology Centers (CACON) by means of public–private partnerships.
	T	Accelerate the process of understanding of the therapeutic impact of any new drug not associated with existing drugs, while respecting ethical implications. Define a strategy for acceptance of the production of new higher added-value molecules in order to stimulate investment.
Combating weaknesses	E	Increase the activity and synergy between the Pharmaceutics and Biotechnology Competitiveness Forums in the coordination of strategies which promote effective development partnerships between universities, R&D centers and companies, with the support of industry/sector associations, with the aim of increasing competitiveness in the cancer treatment sector.
	S	Speed up the incorporation of new technologies into breast cancer therapies, with government subsidies and supranational support.
	T	Create a Breast Cancer Research, Development and Innovation Council, to coordinated by INCA, with substantial participation from the medical research community and breast cancer and biotechnological researchers in general, in order to debate strategic propositions for the development of drugs (both new and "me too") for the treatment, diagnosis and prevention of the disease, with the support of the Pharmaceutics and Biotechnology Competitiveness Forums (coordinated by the MDIC) and other decision-makers.

Source: Canongia (2004).
Legend: A = Aspects; E = Economic; S = Social; T = Technological.

new inputs, and 4) Global analysis, the fifth and final phase, recommendations, is presented below, in which the prospecting strategy allows for the suggestion of actions to support the decision-making process.

In this phase, the recommendations presented are categorized as offensive and defensive actions, as well as actions intended to overcome weaknesses and vulnerabilities, *vis a vis* economic, social and technological aspects, distributed in a projected timeframe for their execution: short (less than 2 years); medium (from 2 to 5 years), and long (more than 5 years) term. This article will present as an example those recommendations oriented to the short term (Table 4), underlining the importance of action frameworks as a solution for the formulation of recommendations for R&D-intensive sectors.

6. Final considerations

This article presents evidence that foresight studies based on the methodology used here are of great value when employed in the development of R&D and innovation in scientific areas with social applications, as in the present case of biotechnology for the development of breast cancer drugs.

It is evident that technological foresight has a common base in the process of gathering and treatment of strategic information, the implementation of analytical and reflexive capacities, and the creation of multiple interpretations.

Prospecting strategy based on Competitive Intelligence, Knowledge Management and Technological Foresight, supported on the tripod of trends – analysis – stakeholder, offer a range of opportunities which contribute to an examination of the conditions in which the future will unfold, and of the warnings and signs to be overcome in the globalized market.

Biotechnology brings the promise of new scenarios for the 21st century in various economic sectors, especially health, providing new techniques and drugs for the treatment of, amongst other chronic illnesses, cancer, and in particular, the focus of this study, breast cancer. The challenge is to maintain the opportunities for increased biotechnology transfer to developing countries and improving socio-economic development. This article demonstrated that the USA concentrates both the technical–scientific production and patent registry in this area.

International trends observed in relation to the use of biotechnology for breast cancer drugs are in the direction of prevention (vaccines), diagnosis (biological markers) and treatment (23 drugs and drug combinations stand out as the main therapies, with the drug Paclitaxel being the most cited). The importance of clinical research has been underlined as being essential in the process of innovation, based on the goal of increasing survival rates of cancer sufferers and of minimizing side effects.

On the prevention front, thanks to biotechnological advances in vaccines (using genes specific to breast cancer as antigenes), a range of possibilities is opening up, which promises to bring progress in dealing with the currently alarming rates for this illness. On the treatment front, the results of data mining bring to light more efficient possibilities, with fewer toxic effects, depending on the stage of the illness.

Given that there are 202 CVs of research leaders with competency in breast cancer and/or cancer and biotechnology registered in the Lattes/CNPq database, and that there exist 295 post-graduate biotechnology programs in Brazil producing MAs and PhD, it is possible to characterize the situation as a comfortable one for the country in attracting partners and investments to this area.

Finally, the prospecting strategy model for an R&D-intensive sector, its critical factors, actors and the understanding of the functions which impact it, is proposed as a robust methodology to support decision-making.

References

Agência Nacional De Vigilância Sanitária. http://www.anvisa.gov.br.

Antunes A, Canongia C, Alencar S, Martini AM, Mendes C, Mangueira AC, Tibau F, Arnor M. Prospecção Tecnológica da Indústria Farmacêutica Nacional: Prospecção Tecnológica e Mercadológica das drogas por Classes Terapêuticas, dos Medicamentos de Alto Custo e dos Genéricos da RENAME. (Study in 8 volumes undertaken for FIOCRUZ as part of the Innovation in Health Project). Rio de Janeiro: SIQUIM/EQ/UFRJ, vol. II, Issues 1–6; 2004.

Canongia C. Modelo de estratégia de prospecção: sinergias entre inteligência competitiva (IC), gestão do conhecimento (GC) e foresight (F). Estudo-de-caso: Uso da Biotecnologia em Drogas contra o Câncer de Mama. (doctoral thesis). Rio de Janeiro: EQ/UFRJ. December, 2004. 485f. (Vols.l I and II).

Canongia C, Santos DM, Santos M, Zackiewicz M. Foresight, Inteligência Competitiva e Gestão do Conhecimento: instrumentos para a gestão da inovação. Revista Gestão Produção 2004a;11 (2):1–20.

Canongia Claudia, Antunes Adelaide, Pereira Maria de Nazaré Freitas. Technological Foresight: the use of biotechnology in the development of new drugs against breast cancer. Tech J 2004b;24 (4):279–370 April.

Canongia C, Pereira MNF, Antunes Adelaide. Modelo de estratégia de prospecção de setores intensivos em P and D: sinergias entre Inteligência Competitiva (IC), Gestão do Conhecimento (GC), e Foresight (F). DataGramaZero 2006;7 [n. February].

Cimoli Mario, Dosi Giovanni, Nelson Richard R, Stiglitz Joseph. Institutions and policies shaping industrial development: an introductory note. (Working Paper Series — Prepared for the Task Force on "Industrial Policies and Development", within the Initiative of Policy Dialogue (IPD)) Italy: Sant'Anna School of

Advanced Studies/Laboratory of Economics and Management (LEM); 2006. January, 24 pp.

Ernst, Yong. Economics consulting and quantitative analysis. The economics contributions of the biotechnology industry to the US economy. Biotechnology Industry Organization; 2001. 11 pp. [Accessed on September 15, 2002-http://www.bio.org].

FOREN — Foresight for Regional Development Network. A Practical Guide to Regional Foresight. [Report EUR 20128 EN]. "European Commission: Institute for Prospective Technological (ITPS), Policy Research in Engineering, Science and Technology (PREST), CM International e Sviluppo Italia". 2001.120p.

Georghiu L. Third Generation Foresight — integrating the socio-economic dimension. International Conference on Technology Foresight. Japan; 2001. March.

Humbert M. Globalização e glocalização: problemas para países em desenvolvimento e implicações para políticas supranacionais, nacionais e subnacionais. In: Lastres Helena MM, Cassiolato José E, Arroio Ana, editors. Conhecimento, Sistemas de Inovação e Desenvolvimento. Rio de Janeiro: Editora UFRJ; Contraponto; 2005. p. 259–89.

Instituto Nacional Do Câncer Do Brasil-INCA-http://www.inca.gov.br.

Instituto Nacional De Propriedade Industrial-INPI-http://www.inpi.gov.br.

Kahaner L. Competitive intelligence: from black ops to boardrooms — how businesses gather, analyze, and use information to succeed in the global marketplace. New York: Simon and Schuster; 1996.

Leydesdorff Loet. Indicators of innovation in a knowledge-based economy. CyberMetrics — International Journal of Scientometrics, Infometrics and Bibliometrics 2001;5(1) [http://www.cindoc.csic.es/cybermetrics/articles/v5i1p2.html].

Malerba F. Sectoral systems and innovation and technology policy. Rev Bras Inov 2003;2(2):32-375 [July/December].

Ministério Da Saúde/Secretaria De Políticas De Saúde. RENAME 2002: Revisão da Relação de Medicamentos Essenciais. Diário Oficial da União: Portaria n° 1.587; 05/09/2002. [accessed on July 30, 2004-http://www.anvisa.gov.br/legis/portarias/1587_02.htm].

Parkin M, Bray F, Tycynski JE. Breast Cancer in Europe. European network of cancer registries: cancer fact sheets vol. 2; 2002. December 4 pp. [Accessed on May 2, 2003-http://www.encr.com.fr].

Porter Alan L, Detampel Michael J. Technology Opportunities Analysis. Technol Forecast Soc Change. New York 1995;49:237–55.

Salicrup Luis A, Fedorkova Lenka. Challenges and opportunities for enhancing biotechnology and technology transfer in developing countries. Biotechnol Adv 2006;24:69–79.

Segatto CO. câncer sob controle. report on the annual meeting of the American Society of Clinical Oncology, New Orleans/2004, vol. 317. Revista Época; 14/06/2004. p. 68–73.

Ullrich A. Research needs for international cancer control: the Alliance on Global Cancer Control as a momentum for new directions in cancer control research. 7th Global Forum for Health Research. Geneva; 2003. 02–05 December [Accessed on July 20, 2004-http://www.globalforumhealth.org/pages/index.asp].

Vinha VG. Estratégias empresariais e a gestão do social: o diálogo com os grupos de interesse (stakeholder). IX Congresso Brasileiro de Energia. Rio de Janeiro: Hotel Glória; 2002. May 20–22 [Accessed on September 18, 2004.

Wilson RM. Patent analysis using online databases: technological trend analysis. World Pat Inf 1987;9(1):18–26.

World Pharmaceutical Market Summary — Issue 1/2000. [email, IMS Health, service@open.imshealth.com to claudia@ibict.br on January, 2000].