

Patents and biotechnology

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**JORGE NIOSI
PROFESSOR
DEPARTMENT OF MANAGEMENT AND TECHNOLOGY, UQAM
CANADA RESEARCH CHAIR ON THE MANAGEMENT OF
TECHNOLOGY**

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Presentation plan

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- Role of patents in biotechnology
- Company strategies in patenting
- Mercosur patents in the international comparison
- Markets of biotechnology products for Mercosur firms
- Competition for biosimilar products
- The role of the state in biotechnology
- Implications for public policy and company strategies

Role of patents in biotechnology

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- Not all industries and technologies use the same tools to protect intellectual property (IP)
- Copyright is mostly used in software (including bio-informatics), patents are used in information technology, pharmaceuticals and biotechnology, trademarks in several industries (including pharmaceuticals), industrial design in furniture and electrical appliances, industrial secrets are used in every industry
- Chemicals, pharmaceuticals and biotechnology are the strongest users of patents

Role of patents (continued)

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- The main role of patents in biotechnology is to protect IP from counterfeiters and imitators.
- In pharmaceuticals, the chemical or biological composition of a drug must compulsorily be revealed to users, thus the risks of imitation are higher than in other industries.
- Most often, companies use patents in combination of industrial secrecy (i. e. on processes) because these do not need to be revealed to the public and imitation is much harder.

Role of patents (cont.)

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- Patents serve biotechnology companies to show to potential financiers the technical competencies of the patent assignee, and thus attract venture capital firms, large pharmaceutical or chemical companies, or get national or international service contracts.
- Venture capital (VC) firms almost exclusively invest in companies with patents, so that these are used as collateral of investment in case things go bad.
- At the same time, DBFs with good patents show the world that they have exclusive novelty

Role of patents

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- Not all patents are equally valuable in the world market for IP. USPTO patents are the most valuable for several reasons:
 - In the US you need world novelty to get a patent
 - US patents are written in English while European or Japanese patents are not
 - US patents are cheaper than those of the EPO
 - Most VC is located in English speaking countries, but everywhere English is the language of VC
 - American, British and Canadian VC invest overseas on the basis of what they find in the USPTO web site (they search for quality patents)

Role of patents

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- Also, business, university or government laboratory patents in each country take into consideration what is patentable and what is not in each country. (Up to the early 2000s in Argentina, pharmaceutical products were not patentable, for instance; after the signature of TRIPS they became patentable).
- The cost of patents and the returns on investment on patents is also a major consideration to be weighted when looking for patents.

Role of patents (cont.)

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- Besides general legislation of what is patentable, countries differ on the regulations and incentives on patenting in universities and public laboratories
- In the USA, the Bayh-Dole Act (1980), endows universities and public laboratories with all the IP generated by research projects supported by the state
- In Canada, the EU and Japan, there is no such regulation, but over the years, these countries tend to align themselves on this type of legislation

Role of patents

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- In most US and Canadian universities, professors and researchers are obliged to disclose to the university any novelty they consider having commercial value.
- The university has 3 months to decide whether they will patent or not; if the university patents and licenses out the novelty, the royalties generated will be split between the university and the researchers. If not, the university gives back the IP to the researchers and these can either commercialize it by themselves, with or without patenting.
- In Canada, close to 50% of the novelties patented and invented by academics belong to universities, 45% to companies and 5% to the researchers. Similar figures are published for the US and several European countries.

Role of patents (cont.)

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- In all the large OECD countries (mainly the USA, Germany, France, Canada, UK) universities and public laboratories are owners of thousands of biotechnology patents
- Combined with VC pools, such IP has generated thousands of biotechnology firms in the USA, Western Europe, Canada and Japan. China is now joining the more active nations in this field.
- This does not mean that universities manage properly such IP. Several examples will suffice

UBC: a case of an entrepreneurial university

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Indicator	Numbers	Source	Year
Full-time faculty	2213	Research Infosource	2009
2009 Research funds	C\$524 M	Research Infosource	2009
US Patents granted	474	USPTO	Up to 2011
Spin-off companies	140	www.ubc.ca	Up to yesterday
C\$ per full time faculty	C\$351,000	Research Infosource	2009

Role of patents: Stanford and UCSF, the model

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- The Cohen-Boyer patents, granted in 1980, 1984 and 1987, were invented in these two universities and laid the basic tools of genetic engineering
- In its licensing strategy, Stanford made an effort to balance the public role of universities in the dissemination of knowledge, and the interest of Stanford and its professors to get a return on hard work
- Stanford applied a non-exclusive licensing system with a minimal fee of \$10000 per year plus a decreasing percentage of sales (from 6% to 0,5%) for companies whose products were developed using these tools
- These patents were used by 340 firms, paid \$255 million in royalties to the universities and produced over \$35 billion in product sales.

Columbia, Cambridge, UQ: the bad practices

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- In the 1970s, professor Richard Axel invented tools to cut parts of DNA in human cells and create proteins. Columbia University patented the tools, and licensed the technology to several firms for high prices. Those patents expired in 2000 and Columbia was able to renew them for 17 years in 2002. Biogen and Genzyme sued Columbia arguing that they had patented again the same invention; they won. Columbia appeared as a university uninterested in the public good.

Columbia, Cambridge, UQ (cont)

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- In Cambridge University, the discovery of the principles for the production of monoclonal antibodies by Milstein and Köhler was considered not commercially valuable by the UK National R&D Corporation and was not patented. Cambridge and the researchers lost hundreds of millions dollars, as their techniques were widely used later on to produce new drugs
- In Montreal, three researchers of the UQ and McGill developed the first compound against AIDS. The universities decided that it was not interesting from a commercial point of view. They founded a company (Biochem Pharma) that they sold to a British firm (Shire Pharmaceuticals) for \$6 billion in 2000. The product was put in the market by Glaxo. The two universities lost a fortune.

To summarize the role of patents

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- Patents are very important in biotechnology for many reasons: to protect IP, to announce technical capability, to market research results and reward researchers
- They are valuable assets that attract capital to the company and to the country that own patents
- It is important for developing countries and growing companies to produce these assets and learn how to manage them.

2. Patents and medicines in Mercosur

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- In Mercosur there are no country patenting strategies in biotechnology, and no clear company strategies.
- These countries have invented few novelties and are marginalised from the North America/Western Europe/South East Asia in the area of biotechnology
- The following table gives an idea on the issue of biotechnology patents

USPTO patents in biotechnology

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Inventor country	Before 2003	2004-9	Total	Patents per million population
Argentina	21	12	33	0,8
Brazil	47	31	78	0,4
Chile	1	9	10	0,6
Mexico	53	6	59	0,5
China	104	125	229	0,2
Korea	387	380	767	16
India	279	186	465	0,4
Singapore	39	77	116	26
Canada	2638	1749	4387	133

Slow progress in Latin America

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- Note that Argentina and Brazil started to patent before Korea or Singapore. These Asian countries caught up and moved ahead of any LA country and now have a large reservoir of patents that attracts foreign investment and venture capital
- Korea is developing a pharmaceutical strategy tending to develop a biosimilar industry for export, and at the same time develop their own proprietary products
- Brazil has seen part of its pharmaceutical industry fall under foreign control and is developing a new one fairly fast
- Argentina has national bio-pharmaceutical industry producing biosimilar drugs and exporting them in competition with ten other countries (at least) but few patents

Biosimilar medicines

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- Since the beginnings of the application of biotechnology to medicine, some 125 drugs were developed, for human health (I am not counting medical devices such as diagnostic tests, or human health products such as artificial blood or tissues)
- Almost 80% of these drugs were invented in the United States and the other in Western Europe (Britain, Denmark, France, Germany and above all Switzerland)
- First generation products (insulin, interferon, EPO, and others) have lost patent protection and their generic versions are called “biosimilar drugs”.

Biosimilar products

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- Argentina got a quick start in these products, and now has a dozen companies producing them
- But now such countries as Brazil, Canada, China, Germany, India, Israel, and Korea, to name a few, also want a piece of the action, and they have strong government support.
- The USA, EU and Japan are fairly closed to biosimilar drugs not produced within their borders. Thus developing countries sell biosimilar drugs to each other
- Argentina will have to move forward and try to develop its own patented products and/or develop a national biosimilar strategy such as Korea has one.

Biosimilar products

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- The analysis of patents in the new fields show that LA is doing almost nothing in the new and rapidly growing fields of MABs, stem cell medicines or gene therapy
- The following table shows that the US still leads the field in these new areas.

US MAB and stem cell patents

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Country	US patents in stem cells	US patents in MABs
USA	293	2220
Japan	42	455
Canada	17	122
UK	16	132
Germany	12	208
Sweden	12	48
Italy	9	36
Brazil	0	3
Argentina	0	1
Spain	0	0
Total	470	3712

3. The role of the state in biotechnology

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- The US are the leading country in biotechnology for many reasons
 - The federal and local states invest every year several tens of billions of dollars in biotechnology through the NH, SBIR, STTR, tax credits for R&D and other schemes. Such support is permanent.
 - Universities hire internationally on the basis of merit (not political affiliation or place of birth) and pay high salaries
 - Governments protect biotechnology by many different means, starting with patent regulations
 - The public accepts biotechnology in all its applications
 - Similar policies are applied in leading European and Asian countries. (Yet in Europe the patent system has problems and the hiring system is basically endogamous)

The role of the state

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- In Mercosur the state does not invest much in science and technology, and particularly it gives little support to private sector R&D compared to the US or Canada, Germany or the UK, China or Korea.
- Granting agencies are relatively poor, state support is not steady and recruitment is national or local as in Continental Europe.
- (I always say that Latin universities, both in Europe and LA, the secret of the success of the Barça is not understood: hire the best, wherever they are from)

Conclusion

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- The development of biotechnology is a long process of accumulation of human capital and knowledge in universities, public laboratories and private firms, and requires a generous and permanent public support of public and private R&D, as well as an understanding of basic IP, R&D and human capital management
- Only under these conditions can Mercosur countries accelerate the adoption and development of biotechnologies, nurture the development of a competitive pharmaceutical industry and avoid relying on one or two seeds for export
- Patents – both public and private – will be the result of those efforts