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Patent Cultures
Diversity and Harmonization in Historical Perspective

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9 Mediation and Harmonization

Construction of the Spanish Patent System in the Twentieth Century

Ana Romero de Pablos

9.1 Introduction

Mediation and harmonization are two key words that aptly summarize the Spanish patent system of the twentieth century. Patents have served as intermediaries, and the manner of their regulation has generated complaints from both within and beyond Spain. To analyze this reality, I will compare two case studies that illustrate different patent cultures, subject to specific times and places: the introduction between 1948 and 1950 of the main patents to protect penicillin production processes in Spain under the law of 1929, and the 1988 market launch of the Spanish patent “An improved method for determining the nucleotide base sequence of a DNA molecule,” under the 1986 law. Both cases highlight a significant issue within the processes of harmonization and mediation: the language in which a patent is written does not necessarily need to coincide with the language required by the legitimizing formalities. Patents are therefore subject to different mediations, and have been, and still are, points of conflict at attempts at international harmonization.

The first case study, the arrival in Spain of the first North American patents to protect penicillin production, illustrates this mediating role. The second, the market launch of a Spanish patent for a DNA polymerase, the product of research carried out in a Spanish laboratory and patented in the United States in 1988, demonstrates the effect of local regulations and the limitations of international harmonization.

Patents connected practices, languages, and interests from different Spanish and North American professional communities – clinical, industrial, and political – at the end of the 1940s, the beginning of the 1950s, and through the 1980s. While penicillin patents attracted US industry to the Spanish market – which was, as we will see, not highly competitive but fully able to incorporate new technologies – the polymerase patent had the opposite effect: a group of Spanish researchers, at the suggestion of an American university professor with links to the industry, protected their invention in the United States before doing so in Spain.

These two case studies demonstrate the multiplicity of actors who participate in the construction of inventions and patents1 and bring to mind the concept that Carolyn C. Cooper has termed “patent management.”2 Patents are more than legal documents with technical descriptions; they are also interesting political instruments.3 These cases present different patent cultures, each subject to a specific time and place;4 they allow an analysis that goes beyond the local and national space, suggesting a redistribution of the places where knowledge is produced and challenge the use of terms such as transference and appropriation. A more suitable term, I would suggest, is circulation: a circulation always mediated by homogenizing logic and local cultures. The importance of local history lies in the local actors who incorporate and shape knowledge and practices. The cases studied here take on a greater significance in the framework of common networks of interaction woven by people, laboratories, tools, technologies, practices, and politics.5

The years 1929 and 1986 were crucial for patent legislation in contemporary Spain.6 From the Estatuto de la Propiedad Industrial (Industrial Property Statute, EPI in its Spanish acronym) of 1929 until 1986, the year in which the Spanish Law on Patents (LP) was approved, important political, economic, and technical changes took place that had severe repercussions for social development.

The law of 1929 was created at a time of intense tension between the process of modernization, begun at the outset of the twentieth century, and the authoritarian political control of Primo de Rivera’s dictatorship (1923–9). Antiquated authoritarian attempts to reduce social and political problems did not limit public works programs and the introduction of new technologies. These technologies – including electricity, the telephone, and an increased use of automobiles and other means of

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1 C. Bauer, _The Language of Edison’s Light_ (Cambridge, MA: MIT Press, 1999).
transport—had developed rapidly since the beginning of the twentieth century, making a reconsideration of patent policies imperative. In this context, a new type of patent was introduced: the Patent of Exploitation. This was added to the already existing Patent of Invention (twenty years) and Patent of Introduction (ten years), and was designed to cover objects already invented but not put into practice in Spain, to protect any kind of industrial development that had not previously existed, or that incorporated novel refinements of those already existing, over ten years, as long as they were in the interests of national industry.

Unlike Patents of Introduction, a Patent of Exploitation could continue beyond ten years, provided no new innovation had been added. Although this patent was in force for barely two months—it was repealed under the Royal Decree-Law of March 15, 1930—it illustrates the attitude of the Spanish authorities: their willingness to encourage and support the introduction of new technologies, and recognition of the responsibility to fulfill international agreements. The speed with which the Patent of Exploitation was eliminated highlights two interesting issues I will address in this chapter: the conflict between local and transnational legislation, and the harmonization of patents required within a common regulatory space.7

The law of 1986 was enacted under very different circumstances. Since the law of 1929 the country had undergone a civil war (1936-9), the Franco dictatorship (1939-75), and on January 1, 1986, as a democratic country, Spain had joined the European Economic Community. Between 1939 and 1955—the year in which Spain was accepted into the United Nations—the country had remained politically, economically, and socially isolated, and Francoist autarkic policies were designed to favor native industrial development by imposing restrictions on foreign imports.8 Despite having a negligible effect on industrial development for many years,9 this protectionism did create the basis for the effective development of imports from the end of the autarkic period onwards.10 Patents were the legal space where technologies could enter an economy like Spain’s, which was centered on sectors such as agriculture, construction, and services.11 There was even a proposal to modify the EPI, the most notable attempt being made between 1956 and 1966 by the Justice Section of the Institute for Policy Studies. No modifications were made, however, due to the lack of both political will and practical necessity.12 It was entrance into the European Community that necessitated making Spanish patent legislation—as well as legislation in other areas—compatible with that of other member states. A draft law on patents dating to 1981 had content very similar to that later approved in 1986.13

Following Franco’s death in November 1975, Spain experienced immense political, economic, and social change. For many historians the new Constitution of December 1978 ended the period known as the Transition, which began with the death of the dictator, and in which a series of political events transformed the Francoist regime into a social state with democratic rule of law, under the political form of a parliamentary monarchy.

Between 1929 and 1986, therefore, significant changes—political, social, economic, and industrial—favored the arrival of foreign patents, the creation of new spaces for research, and new opportunities for industry. Although it took time for these changes to be incorporated into Spanish legislation on industrial property, they had a significant effect on scientific, technological, and industrial practice.

The journey from 1929 to the other and the two cases outlined here, contain distinctive elements to reflect on patent culture in Spain. The political, social, and economic changes that protection systems demand differ from one place to another, and do not always coincide with voices calling for harmonization.

9.2 Penicillin Patents in Spain

The first patents granted in Spain to protect penicillin production were the subject and object of mediation: they connected researchers,

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10 S. López, El saber tecnológico en la política industrial del primer franquismo (Madrid: Universidad Complutense, 2002).
12 I. Catalán, La economía española y la segunda guerra mundial (Barcelona: Acad, 1997).
16 A. Becerril, La marca Ley de Patentes. Ideas introductorias y antecedentes (Barcelona: Tecnos, 1986).
17 Ibid., 89-100.
politicians, and healthcare authorities with procedures, instruments, and facilities; they brought politics and policies to industrial and research spaces; and they mediated in processes associated with training and practices. At the same time, the necessary translations, the obligatory changes in the way to state claims and in certification, the putting of these into practice, and the effective use of the content of patents, all turned them into objects of mediation.

In 1948, the Ministry of Industry declared the manufacturing of penicillin to be of “national interest.” The decision to construct two plants to produce these antibiotics, under strict state control, was made public. At this time, Spanish doctors, pharmacists, and the general public were well aware of the therapeutic properties of this drug. The trip that Antonio Gallego took to the Merck plant in Rahway, New Jersey, at the beginning of 1949—at the request of Spain’s only industrial bank, Banco Urquijo—is a good example of the role played by doctors: the agreement signed by Merck and Banco Urquijo in January 1949 marked the initial step in the competition to install these factories or manufactury plants.13

In July of 1949, the first application for a patent to obtain penicillin was made to the Spanish Patents and Trademarks Office (Oficina Española de Patentes y Marcas, OEPM, in its Spanish acronym) by the Danish company, Lovenex Kemische Fabrik. Alexander Fleming, regarded as the discoverer of penicillin, had been given a hero’s welcome by the Spanish authorities when he visited Madrid and Barcelona a month earlier. This trip had been used politically to portray the Francoist regime as being on the side of progress and modernity.15

Compañía Española de Penicilinas y Antibióticos (CEPA) and Antibióticos S.A. were the companies created to compete for penicillin production within Spain. Although the Danish company was the first to apply for the patents, it was Merck and Schenley18 that obtained the contracts. CEPA produced penicillin with patents from Merck; Antibióticos S.A. with those of Schenley. The correspondence at the time—of the granting of the first patents, the notice of competition,

and the allocation of plants—suggests a well-planned and carefully thought-out process.19

As such, a new area for the pharmaceutical industry was opened up under a government that authorized and controlled the construction of a market for licenses.20 Regulations were the connecting point between the scientific and the technological, the political and the institutional, between private initiative and society.21 As we shall see, diverse practices and languages became homogenized due to patent regulations. Penicillin patents were more than just legal documents with technical descriptions: they became useful political tools for the Francoist government.22

The first problem faced by foreign companies was the impossibility of patenting drugs or pharmaceutical products in Spain. Political and economic concerns had led to this prohibition, particularly the beliefs that product patents could facilitate industrial secrecy, diminish incentives for industry to continue carrying out research, and encourage price fixing.23 Therefore, what was patentable were the processes and equipment used to obtain products. For this reason, Merck and Schenley had to modify the wording of their claims, ensuring they referred to the processes not the products. Some claims were redrafted with more general headings, while others were completely removed from the final draft. The initial invention descriptions laid out the terms and limits the inventor wished to establish, and therefore, what he or she wanted to protect. The final text indicates how this knowledge was to be protected from then on. This is a good example of how patent specifications are subject to modification and changes according to place and context.24 Thus, regulations determined how the contents of patents were expressed, making patents both the object and subject of mediation processes.25

The Spanish tendency to import technologies, and the absence of technical examination in the EPI of 1929, have been cited by many as driving the interest of foreign industries in presenting patents for

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13 Decrees published, respectively, in the BOE of October 6, 1948 and in the BOE of August 11, 1949.
16 Participatory, “Patent Is Political.”
17 A. Becerril, La patentabilidad de las invenciones y la industria químico-farmacéutica (Madrid: Monteceorro, 1979); C. Lema Devesa and A. Tato Plaza, Patentes farmacéuticas y medicina (ADPC: Granada: Comares, 2000).
18 Bowler, “What’s in a Patent?”
19 Romero de Pablo, “Regulation.”

penicillin production. But files kept in the OEPM archive show that the strategy used by North American companies in Spain was similar to that used in other countries: the applications made in Spain were made in other European countries at the same time.26 The Spanish geopolitical situation, along with the fact that the pharmaceutical industry was mostly made up of small companies, explains the willingness to patent and produce penicillin in Spain. Nevertheless, the North American pharmaceutical companies’ desire for expansion should not be forgotten.27

The 1929 law favored those Spanish industrial firms capable of taking advantage of imported technical developments. Patents have been considered some of the principal tools for technological appropriation,28 but it is also necessary to state that part of the Spanish pharmaceutical industry was able to benefit from international technical improvements. The screening program for new antibiotics established by CEPA and Merck in Madrid in 1954 is a good example of this. This program – that opened a research laboratory inside a manufacturing space – incorporated techniques and tools, both physical and conceptual, originating from industrial production.29

By the mid-1960s, support for a revision of the ban on patenting pharmaceutical products had grown significantly and in 1986, when Spain joined the European Patent Convention (EPC), the prohibition was officially lifted. Lobbying by the pharmaceutical industry, however, succeeded in delaying implementation until October 7, 1992.30

9.3 The DNA Polymerase Patents

The second case I examine is the 1989 Spanish patent entitled “An improved method for determining the nucleotide base sequence of a DNA molecule.” Research, techniques, and laboratory practices form part of this patent, but it also reflects the changes in Spanish economic, industrial, and scientific policies since the 1960s. These changes were in response to new realities and contributed to the formation of new cultures. The patent resulted from research carried out in the molecular biology laboratory of a public research center in Madrid, the Centro de Biología Molecular (Centre for Molecular Biology) at the Consejo Superior de Investigaciones Científicas (Spanish National Research Council, CSIC in its Spanish acronym). The developments introduced since the end of the 1950s – nuclear energy, biochemistry, and molecular biology are good examples – needed to be harmonized with policies, institutions, management styles, and legislation.31 But this patent also shows how unusual patenting was for research scientists. Neither the work undertaken in the laboratory since the mid-1960s, nor the decisions made, indicates a consideration of possible industrial applications.

Following the Napoleonic invasion as it did, the law of 1929 had been strongly influenced by the French: the 1986 Law meant that, once again, Spanish legislation would be subject to Europeanization. It incorporated, almost literally, the decisions made at the Munich Convention on European patents in 1973 and the Luxembourg Convention of 1975 in relation to European community patents. The Treaty of Accession of Spain to the European Communities on June 12, 1985 (that came into force January 1, 1986) included Protocol No. 8 relating to Spanish patents. This established “the obligation of Spain to modify its patent legislation to be compatible with the free circulation of merchandise and with the level of protection of Industrial Property attained within the Community.”32 It was necessary to harmonize the Spanish system with that of the European Community.

One of the main consequences of harmonization with European regulations was elimination of the Patent of Introduction, considered incompatible with the level of protection for inventions within the European Community. This type of patent, present in Spanish legislation since 1811, was designed to encourage the introduction and exploitation of technologies proven abroad, although it had never been put to significant use.33

Modifications made to the admission process in 1986 were also in response to the need for harmonization with Europe. A technical examination and innovation registration were introduced as preliminary requirements.34 Expectations for the patented innovation were then

26 Ibid., 377-9.
30 Lema Devesa and Tato Plaza, Patentes.
32 Bercovitz, Patentes, 22.
33 Ortiz Villalobos, “International Patenting,” 144-5.
34 Chapter II, Articles 31-35.
made public, along with an invitation to anyone wishing to challenge certification. A report on the state of the technology was a necessary intermediate step toward a "strong" patent examination system, and an important condition for patents granted in Spain to have the same value as those legitimized by European processes. This strengthened the system, but took time to be incorporated: the system of granting patents subject to a technical examination was introduced only gradually, beginning in September 2001.25

In 1988, at a workshop of the European Molecular Biology Organization (EMBO) held in the Spanish city of Salamanca, Charles C. Richardson proposed possible industrial applications of the structure of the DNA polymerase of virus α29. He was a researcher in the Department of Biological Chemistry and Molecular Pharmacology at Harvard Medical School and scientific advisor for the US start-up United States Biochemical Corporation (USB). Richardson, who at the time was working with another DNA polymerase virus, had been in contact with the Spanish laboratory and was aware of the work being carried out there.

The research being developed in this Spanish laboratory, and the similarities with work being carried out in the United States had attracted Richardson's attention. The first article referred to in the Spanish patent, in which a group of scientists led by Kary Mullis describe the PCR (Polymerase Chain Reaction) technique, dates to 1985. The PCR technique allows the action of a polymerase to be initiated and stopped at specific points on a DNA chain, and for a fragment of DNA to be amplified exponentially for identification and analysis. Improvement in this technique between 1985 and 1989 made it an extremely useful tool for biologists, and, in 1993, Kary Mullis was awarded the Nobel Prize in Chemistry.

The scientific and industrial potential that interested Richardson and USB must also be understood in relation to the space opened up by the Bayh–Dole Act of 1980. Conceived in order for private companies to patent and license research carried out at universities,27 this act had two  


clear consequences: it increased private research funding and resulted in a qualitative decline in academic patent applications.28

At this time, the Spanish R&D system did not take financial potential into account: research at universities and Spanish public research centers had been financed with public money since the 1986 Science Law. Additionally, the tendency in Spain has been to publish before patenting. For these reasons, the possibility of patenting played no part in the daily practices of Spanish researchers. USB's managers and researchers played a significant role in preparing the PCR technique patent application. In exchange, they were promised the license for commercial exploitation if the application was accepted. In this case, the mediating role of the patent limited the circulation of knowledge.

The assistance required by the technique's inventors, Luis Blanco, Antonio Bernard, and Marguarita Salas, demonstrates how distant the culture of patents was from research laboratories, where priority was given to the presenting and publishing of results. The origin of these attitudes could be the weakness of protection provided by the law of 1929, although there was no custom of patenting in either biological research or biomedicine. Only industrial laboratories pursued patents. Another reason can be found in the organization of the Spanish R&D system: the first offices to transfer technology from universities and public research organizations were only established at the beginning of the 1990s.29

The first patent written, "Reactions of the synthesis of DNA (in vitro) that use modified ph29 DNA polymerase and a fragment of DNA that code for said polymerase," was based on two achievements: the lengthening of a DNA fragment and the production of DNA molecules. Both procedures used the action of the ph29 DNA polymerase.

The patent was applied for at the United States Patent Office in 1988 and granted in March 1989. Blanco, Bernard, and Salas were listed as inventors, and CSIC as proprietor, reflecting the changes made to Spanish legislation since 1986 for job-related patents. The category of "job-related inventions" was designed to promote industrial research. Since the beginning of the twentieth century, various scientific policies

had been initiated to change the way research in Spain was carried out and managed. The inclusion of job-related inventions reflected a willingness to recognize research being carried out by Spanish firms (namely electrical and nuclear companies, and sugar confectioners), and the need to reconcile the interests of business owners with those of salaried inventors. However, this was not usual practice in state-controlled research centers.

Following approval of the Spanish group’s patent, a request was made in March 1990 for it to be included in the worldwide PCT (Patent Corporation Treaty) system, the request being made public in October 1991. The PCT system was a North American initiative designed to quickly and cheaply protect the country’s patents throughout the world. Signed in Washington in 1970 and managed by the World Intellectual Property Organization (WIPO), it is currently endorsed by more than 140 countries. Spain’s entry into the PCT system came into force in November 1989. This system, which enables applications for “international” protection of inventions to be made without the need to present different national patent applications, has been widely used by public research centers and universities in Spain since the mid-1990s. It facilitates formalities and allows industry to view applications, enabling applicants to be aware of development and licensing possibilities. The actual granting of patents continues to be the responsibility of national offices. This agreement demonstrates, rather than resolves problems, resulting from the lack of harmonization and international uniformity.

The European patent, however, a project launched by the German patent office, simplifies formalities and lowers costs by having a single processing and licensing procedure, while at the same time strengthening European markets against those of North America.

The patent “An improved method for determining the nucleotide base sequence of a DNA molecule” was applied for at the European Patent Office in 1993 and granted in 1997. This is how it returned to Europe, the patent coming into force in Spain in August that year. Following a long journey, the outcome of research carried out in a Spanish laboratory returned to Spain, protected, normalized, and legitimized. The narrative of this patent is an interesting illustration of the dynamics of circulation.

9.4 Mediation of Language: A Problem for Harmonization

To be valid in Spain, the patent had to be translated into the Spanish language. The same was true for applications to protect penicillin production. In both cases, the original language had been English and in both cases, at one moment or another, in one language or another, the mediation of translation was required for entry to the Spanish market. Both the EPI of 1929 and the LP of 1986 deemed that the originality and innovative advancement of the invention and claims had to be expressed in Castilian Spanish. The EPI of 1929 expressly states that: “The innovative advancement will be written in Castilian Spanish, without abbreviations, amendments or erasures, and without restrictive conditions or legal reserves of any type.” Clear and precise wording was also used in the claims section to avoid any potential confusion. In the LP of 1986 it is expressed in the same terms: “The application as well as the remaining documents that must be presented to the Industrial Property Registry [as of 1992 the Spanish Patents and Trademarks Office (OEPMA) must be written in Castilian Spanish.” Again, we have the patent as a limiting mediator, but for different reasons than in the case of penicillin.

Any patent application presented in Spain that did not meet this requirement had to be translated. For this, and the other formalities required for the presentation of an application, there existed industrial property agents and officially certified translators. The North American pharmaceutical companies, Merck and Schenley, and CSIC for the polymerase patent, used mediators and representatives from the office of Alberto de Elizbure, founded in 1865 and renowned agents for industrial and intellectual property within Spain. The fact that the principal public organization for Spanish research operated in a manner similar to a foreign company, suggests not only that the patent came from abroad but also, as I have already mentioned, how distant the research laboratories were from the practices and mechanisms for protecting innovation.

The linguistic issue is an important part of the process, from the writing of the patent to possible litigation and other legal proceedings. Although the language problem has been present in diverse legislation matters and in practice (the different ways of carrying out translations and the variety of pricing schemes are just two examples), the search for consensus around a common language has been an important element in the international harmonization of procedures, above all in the desire to

40 M. J. Santamases and A. Romero de Pablo, Radioactividad y biologia: la física y las ciencias de la vida en el siglo XX (Madrid: Universidad Autónoma de Madrid Consejo de Seguridad Nuclear, 2003).

41 Chapter IV, Article 112, 3. 42 Chapter I, Article 21, 9.
establish a European patent system. At an intergovernmental conference held in May 1969 in Brussels, one of the most controversial issues was deciding which languages to use in patent procedures. At this meeting they agreed on English, French, and German, a decision later ratified by the Munich Diplomatic Conference in October 1973. To alleviate the mistrust this choice aroused, the Munich agreement added the possibility of requesting the patent holder provide a translation into any official language of the state in which it sought to extend the application (Articles 65 and 57).

But the significance of language goes beyond formalities and procedures. There are cultural, technological, and political issues that should also be taken into account. For example, returning to the case of penicillin, the translation of patents enabled access to various technologies (the manufacturing procedures) that would have been difficult to understand or reproduce had the patents remained in their original language. Mediation by the translation and the agents who took responsibility for it was culturally and politically important: the translation equalized two technologically and culturally different worlds, both interested in producing and commercializing penicillin. Had the translation not mediated, the consequences for the industry in both North America and Spain would have been very different.

9.5 Conclusions

Legislation is an indication of realities, forming part of political, economic, and cultural interests. Spanish legislation dealing with industrial property has reacted, on one hand, to a reality marked by political-economic objectives, by opting to engage with countries that were technologically stronger in order to protect industrial production. On the other hand, it has responded to political, social, and economic changes that require the adaptation and development of specific protective systems.

Although industrial property rights have been considered fundamental for the promotion of innovation, in the cases shown here the status of the patent as an essential requirement for encouraging “progress” in Spain is ambiguous. For penicillin patents it is more relevant to speak about political and business strategies – on the part of US industries as well as the Spanish state – than about the protection of property rights on inventions and technological advances: the duopoly that CEPA and

Antibioticos S.A. enjoyed eliminated all competition. And in the case of the DNA polymerase patent, a patent was never the researchers’ objective. Parts of the results were patented, but this was based on interests and strategies designed and originating from a space and culture of patents: from US research emerging from private companies and from a pursuit of financing quite different from that which existed in Spain.

The histories evoked by these patents increase their usefulness within the humanities, and challenge the perspective of considering patents as only developers and promoters of new knowledge.

The cases dealt with here forcefully demonstrate the important role played by patents in structuring the production and dissemination of knowledge, in the international transfer of technology, and in the formation of politics. Patent application became attractive not only to scientists and industrialists, but also to politicians.

Both Bentley and Sherman, in their book on the origins of *Intellectual Property Law* in England, have discussed the artifice involved in the construction of “normality.” This is clear in the case studies outlined here. In the construction of the Spanish patent system, legal aspects and the demand for their harmonization have been as important as negotiation processes – mediation – between different actors such as politicians, lawyers, industrial property agents, scientists, clinicians, and the pharmaceutical and biotechnological industries. The penicillin and polymerase patents demonstrate the influence of patents on – and the entanglement between – legal, economic, and scientific aspects within the research process. The combination of business and laboratory practices, of politics and policies linked to specific times and spaces, provides a culture of normalization and control of knowledge that reconfigures, at least in the case of Spain, the narrations and discourses on the circulation of knowledge. The histories of these patents suggest a redistribution of the places of knowledge production and challenge the use of terms such as transference and appropriation. As I have suggested, circulation is a more appropriate term: a circulation always mediated by homogenizing logic and local cultures.
