

**The installation in the United States of a new Regime of Intellectual
Property Rights
Origins, Content, Problems**

(Notes on some recent changes in the US National System of Innovation)

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June 2001

First Draft :

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Abstract

The purpose of the paper is twofold i) describe the dramatic changes that have occurred in the United States, in the system of IPR's since the 1980's, ii) to question its meaning and its long-term sustainability.

The paper first presents the continued extension of the domain of patentability to living entities, computer programs and business models. He insists on the concomitant changes which affected jurisprudence on the relaxation of the criteria patentability and on the hardening of penalties pronouncements against the imitators.

On this basis the main features of the new regime which settled down in the USA are presented. Finally, in light of recent evolutions, the paper wonders on the long-term sustainability of such a regime.

1. THE SIMPLE ECONOMICS OF PATENTS, IPR'S AND INNOVATION : SOME BASIC PRINCIPLES.

In order to highlight the nature and the meaning of the changes that have dramatically affected the US system of IPR's, we think useful to recall some of the basic principles that have been put forward to justify why institutional devices – like different types of IPR's – were judged necessary to maintain R&D activities at socially sufficient level of dynamism.

Two series of contributions should here be recalled, since they still constitute the « bulk » and the theoretical foundations of any system of IPR's.

1. Information, Knowledge and the “private” vs “social cost” trade off

In its seminal paper Arrow (1962) introduced the idea that since scientific knowledge can be – even if this is not simple - assimilated to information, the good “knowledge” presents some precise characteristics. They are as follows.

If we consider the dimension of « *non rival* » *good* of the knowledge: it costs to produce it, but the cost of its reproduction is very low . Thus arises a *market failure* and a « *free rider* » problem. Let in the “invisible hand” of market mechanisms, there is no “natural” incentives stronger enough to push the firms to invest in the production of knowledge at “socially optimal” levels. Consequently the society envisaged as a whole is in danger to always *under-invest* in the production of knowledge. To overcome this type of « market failures », *non market mechanisms are required to create the right incentives* and have to be designed and implemented. Basically two types of incentives can thus be designed :

(1) *Patents* : i.e. partial and temporary “monopolies” granted to the inventors under a set of conditions (utility, non obviousness, ...) are the first series of non market devices able to overcome the “free rider” problem. To achieve that objective they have to be conceived in such a way that they provide the right incentives to the research activities of the firm, without creating the market inefficiencies that can arise from strategic behavior and anti-competitive practices of the firm enjoying the monopolies granted by the patenting offices.

If the design and enforcement of such non market mechanisms are smartly designed, the consumers pay for the « rent » granted to the innovators whilst the risk of anti-competitive practices from the firms granted with monopolies is lowered.

(2) *Public funds* allocated to research (especially basic research) is the other direction that the non market mechanisms implemented may take.

In that case the information and knowledge produced through public subsidies is made *freely available for all* and it is the tax payer who covers the cost of delivering the “public good” necessary to maintain the flux of knowledge guaranteeing the progress of the society. Firms (and other agents engaged in innovative activities) can thus enjoy the basic “raw material” they need to engage into innovative products, at zero or very low costs. The purpose of achieving the progress of knowledge whilst avoiding the ex-post inefficiencies associated with monopoly conditions generated by IPR's is thus pursued through this original way.

One has to notice here that in both cases (patents and or public subsidies) the problem is to limit the social cost of the innovation : i.e. the rent granted to the patentee by the consumers and tax payers.

2. “Open Science” vs “Private Science”

Later on the analysis of the world of basic and publicly founded research has gain momentum with the seminal paper by David and Dasgupta (1987) that have initiated the series of analysis known under the “Open Science” paradigm.

Basically this analysis of the world of “open science” highlights the specific coordination mechanisms at work in this domain of R&D activities, provide some convincing arguments about the relative efficiency of the set of formal and informal rules governing that world, and contrasts those rules with the ones governing the world of “private” innovation activities, the so-called “kingdom of technology”.

Roughly speaking the two worlds can be contrasted as follows

- *open communication* among scientists is the one of the key rule of the world of Open Science; it has to be opposed to the world of private monopolies, patents and “*right to forbid*” that governs the world of private science;
- “*peer evaluation*” by the community of scientists *vs evaluation (by the specialized Patent Office) of the “utility” of the inventions granted with patents* is a second key feature allowing to contrast the two worlds;
- finally *competition among scientists driven by “rules of priority” and “reputation” vs competition to capture rents from the monopolies granted* is a third key element allowing to contrast the two worlds.

At this point, let’s recall that if this “opposition” is analyzed from the point of view of national systems of innovation it appears, before all, as a series of complementarities between two key sub-domains of an NSI. In fact, it is obvious that this very simple opposition has to be refined : many subtle relations, - formal and informal - tightening together the two “worlds”. But for our purpose here and from a theoretical point of view (how to overcome the very tricky question of insuring a dynamic innovation process in a domain where “free rider” mechanisms are central), one may remind that the distinction between the principle of granting “patents”, and the one of allocating public “subsidies” *has been the key principle underlying the rationale of the different types of non-market mechanisms designed and implemented in different national systems of innovations.*

The main thesis presented in this paper is to argue that, beginning in the United States at the turn of the 1970, the traditional “frontiers” and “boundaries” between the two logics have been smashed, giving rise to a completely knew regime of IPR’s, putting R&D and innovation activities into dramatically new orientations and dynamics. Moreover, our point is to wonder whether these changes are conducive to “better suited” non market mechanisms regarding activities in the concerned fields, as far as innovation and social welfare is concerned.

2. NEW IMPULSE OF PUBLIC POLICIES AND RULINGS DESIGNED TO BOOST INNOVATION : AN IMPRESSIVE SERIES OF « DOMESTIC » DRAMATIC CHANGES

To fully understand the meaning and the deepness of the changes, we think, it is not sufficient to review and list the series of institutional changes affecting the IPR's system (as impressive as this list of changes can be). One has to put them in their context. And the right starting point for that is certainly to come back to the 80's and to the debate, that took place at that time, among industrial strategists and policy makers, with the involvement of many high skilled academic scholars.

1. The context of the 1980's : a short note on the origin and the scope of the changes

Under the title « *What happened in the 1980's ?* » R Hunt (1999b), in a paper to which we shall come back later wrote : « *During the late 1970s and early 1980s, businessmen and policymakers became increasingly concerned about the apparent deterioration of America's comparative advantage in high technology industries, such as the semiconductor industry. In fact, trends within that industry became a catalyst for dramatic changes in the way the U.S. protects intellectual property* ».

Indeed, and as it can be shown from a long list of essays (of which Laura Tyson's book 1996, is doubtless the most typical expression), the idea became dominant that the loss of competitiveness of the American firms could be explained¹, at least partially, by two "features" of the US national system of innovation.

On one hand (1), the system, regarded as too much oriented towards basic research, was judged to be poorly designed to quickly and efficiently deliver its results to the firms, in an age where time to market had become a key competitive argument; on the other hand, the opinion grew that (2) the results of the research were too easily available for the rivals and insufficiently protected by the patent system. In that circumstances, foreign rivals, quite specially Japanese firms could take advantage of American discoveries and inventions, at zero or very low costs, and turn them into a series of competitive products in the US domestic market itself. (See on this point the papers edited by Bransom, Kodama and Florida 1999, as well as Edquist 1997).

This double thesis, which becomes quickly dominant in the circles of the decision-makers is at the origin of a bloom of studies and works often sponsored by authorities, aiming to modify the general framework in which operate the various actors surrounded in innovation². Some of the recommendations formulated in these studies aim at almost marginal adjustments of the legislation or the rules. Others, on the contrary are conceived to introduce real and profound changes. Finally, as we will argue later on, the addition of these changes introduced new institutional complementarities, in such a way that in less two decades, the functioning and the dynamics of the American NSI will be totally upset.

¹ Here again a long list of essays emphasize loss of the US competitiveness. The most prominent being her the famous essay published by the MIT under the title *Made in America* (1989)

² The book edited by Branscomb, Kodama and Florida (1999) proposes a series of well documented papers allowing to recall the very peculiar « climax » prevailing in the 80's in the United States. For a presentation of the American SNI as such, cf. Mowery and Rosenberg in Nelson (ed 1993).

Table 1, below gives a first (not exhaustive) idea of the importance of this legislative activity throughout the 1980's and during first half of the 1990's.

Tableau 1
Selected Legislation Enabling a Competitiveness Research and Development Policy

Year	Legislation
1980	Public Law 96-480, Stevenson-Wydler Technology Innovation Act, as amended in 1986 and 1990
1980	Public Law 96-517, Patent and Trademark Amendments Act Patent and Trademark Amendments Act, and 1983 Reagan's memo on government patent policy
1981	Public Law 97-34 Economic Recovery Act
1982	Public Law 97-219, Small Business Innovation Development Act
1983	Public Law 97-414, Orphan Drug Act, as amended in 1984, 1985, 1990
1984	Public Law 98-462, National Cooperative Research Act
1986	Public Law 99-502 Federal Technology Transfer Act
1986	Public Law 99-660, Drug Export Amendments Act de 1986
1987	Presidential Executive Order 12591
1988	Public Law 100-418, Omnibus Trade and Competitiveness Act
1993	National Cooperative Research and Production Act.
1993	Public Law 103-182, North American Free Trade Agreement
1993	Public Law 230-234, Defense Appropriations Act, Technology Reinvestment Program
1994	Public Law 103-465, General Agreement on Tariffs and Trade

Source : Slaughter & Roades (1996, p. 317).

Remark: Besides the *Patent and Trademark Amendments Act* voted in 1980 (more known under the name of Bayh-Dole Act) and on which we are going to return, it is necessary to note in this new arsenal set up by the Congress, quite specially : i) the *National Cooperative Research Act* of 1984 which authorizes the relaxation of laws antitrust for the activities of R&D As well as ii) the *Trade and Omnibus Act* of 1988, including notably a section " 301 special " dedicated to the defense and the international promotion of the system of American IPR's. For lack of place these two laws (and their effects) will not be here examined in details³.

In the following, we shall concentrate on two of the changes that have contributed drastically to modify the frame in which operate the agents. It is from this change of the general set up of IPR's that more particular alterations concerning the IPR' system on semi conductors, software programs and biotech (analyzed sections 2 and 3 of this article) can be understood and their meaning more completely evaluated.

- i) The first among the major modifications to consider, is the introduction in 1980 by the vote of the *Patent and Trademark Amendments Act*, more known under the name of, Bayh-Dole Act. This Amendment Act opens to a strategic bend of the American public policies of R&D, by creating a series of incentives and legal tools allowing the public institutions of research (especially Universities) to patent the results of their works and to exploit the fruits of it (even though these research were financed by

³ An analysis of the conditions in which was promoted the " Omnibus and Trade Act " of 1988, including the section of " 301 special " dedicated to IPR's is proposed in Coriat 2000.

- public funds), either directly by the launching of new business start-up (issued from university teams) or under the form of joint ventures with firms of the private sector.
- ii) During the same period, another major change is introduced. It concerns the institution of a new Circuit for Courts of Appeal, specialized in IPR's cases, which dramatically modified the jurisprudence on patents.

2. The Bayh-Dole Act, and its meaning⁴

One of the very first measures by which the United States engage the radical revision of their public policies, with the aim of promoting and boosting academic research, is established by the set of new legal devices introduced with Bayh-Dole Act of 1980. As we have suggested it, the idea then dominating is resumed by the formula : “while Americans perform breakthrough research, it is the Japanese who turn the new knowledge into products and profits Bendavid, 1988).

In that context the explicit objective of legislative measures incorporated into Baye-Dole Act is to allow universities, governmental research laboratories and small firms which arise from it, to apply for patents on inventions financed with federal funds. Aiming to simplify and to standardize existing procedures, the Bayh-Dole Act translates the will of the American Congress to direct more tightly the academic research to the business world. According to the terms of the Congress : “*it is the policy and objective of the Congress to promote collaboration between commercial concerns nonprofit organisations, including universities*” (quoted in, Slaughter and Rhoades, on 1996).

Based on the idea that granting with patents the results of the public research, the Bayh-Dole Act indicates the rise of new public policies aiming to favor the transfer of the results of the academic search towards the industry. Summarizing the spirit of the new provisions Nelson could write that « *The Act' provisions represented a strong expression of support for negotiation of exclusive licenses between universities and industrial firms for the results of federally funded research. Finally, it constituted a Congressional endorsement of argument that failure to establish patent protection over the results of federally funded university research would limit the commercial exploitation of these results.*» (Mowery et al, 1999, p.274).

The institution of a system of rents through licenses, is from then on, presented by the defenders of Bayh-Dole Act as a means to increase the return of investment of the public research, while insuring its exclusive valuation by American firms. Key piece of a much more complex arrangement the system of licenses within the public search, Bayh-Dole Act fits into a series of vaster legal measures pursuing the same objective : to organize transfers of the results of the public research towards the industry. As shown by Slaughter and Roades, this series of legislative measures began with the vote of the law Stevenson-Wydler which, opened the way to the developments of mechanisms of legal and administrative transfers between public and private entities (Slaughter and Roades, 1996). It is in fact, the Federal Technology Transfer Act voted in 1986 which operates really as legal frame for the agreements on R&D between public laboratories and industry. These agreements of Research and Development, allow any entity to enter in association with Federal Laboratories to participate in the launch on the market of new products⁵.

⁴ This section lies heavily on Orsi (2001a)

⁵ Three major conditions must be respected, i) the financial investment of the contracting party (the Federal laboratory not contributing directly to the financing of the search under contract), ii) the

At the same time as increased the number of patents granted to universities and other publicly founded institutions, the number of licenses considerably grew, generating a strong growth of royalties perceived by universities

It is important to notice that the enforcement of these new provisions coincides with the technological breakthroughs made in the academic research, mainly in the field of information technologies and of biomedical research, as regards IT and computer software, or techniques of genetic engineering. Concerning these last techniques, most of them were focusing in American university research laboratories. The technique recombinant DNA which opened the way to the study and to the manipulation of the genetic patrimony of the human being was finalized by two university researchers of Stanford's university. American academic research is also at the origin of the automation of the techniques of sequencing : it is within the University of California that ADN's first automatic sequencer is born. So, at the same time as these technological breakthroughs were giving a new breath to the biomedical research, the activity of patenting and licensing assumed a large development in universities at the origin of these inventions. This point is emphasized by a recent empirical study by Mowery and al, who compare the evolution of the activity of patents and license in the universities of Stanford, California and Columbia, these three institutions being the ones occupying for several years a dominant place in the field of biomedical research and being today the most active of the American Universities engaged in the patenting movement (Mowery, et al, 1999).

Our point is not to discuss the detailed impacts of The Bayh Dole on university licensing. An already large literature is directed to this evaluation⁶. For our purpose, it is sufficient to highlight her the nature of the qualitative changes introduced by the Bayh-Dole Act and to put them in the context of the other changes that have affected the US IPR's regime.

3. The “Court of Appeals for the Federal Circuit (CAFC)”, and the relaxation of the conditions of patentability

The vote in 1982 by the Congress of *Federal Courts Improvement Act (FCIA)* creating an unified authority of judicial appeal for all the cases concerning "*patent, trademarks, government contracts, tax, and international trade*" represents another major institutional innovation introduced by the Congress, within the framework of its new policy aiming to strengthen the competitiveness of the national firms through the valuation of R&D.

At first, the creation of these Courts of Appeal, heard satisfying a demand of the firms which considered the judgments Courses too rigorous (and besides, not homogeneous from a State to another). In reality, however the installation of these new Courts was accompanied by an essential change in the conditions of the patentability then prevailed in United States. In practice, the new Courts of Appeal showed more open to patenting than the ones existing before. Quite specially it is the criterion of "*no - obviousness*" which was the most completely loosened. The Courts of Appeal going as far even as considering that the criterion

negotiation of the rights of intellectual property among the partners (the laboratory receiving a part of profits by means of license or of royalties), iii) the not disclosure of certain results during a duration of five years. In fact, this legal frame insists especially on the problem of transfers of the rights of intellectual property towards commercial firms.

⁶ For a recent assesment of the effects of the Bayh Dole Act of university patenting cf. Mazzoleni et al (2001).

of " commercial success " could compensate for the criterion of obviousness and replace it. On this point Hunt 1999a writes : « *Prior to passage of the FCIA, patents were regularly invalidated at trial, even though they had passed an investigation by the U.S. Patent and Trademarks Office. CAFC decisions raised the presumption of patent validity and altered the test of nonobviousness. Before the FCIA, the prevailing test of non obviousness considered three factors: (1) the scope and content of the prior art; (2) the differences between the prior art and the patent claims; and (3) the level of ordinary skill in the relevant art.*²⁰ *Secondary factors, such as commercial success, failure of others, and long felt need, might also be relevant, but they could not override the three factors. CAFC decisions elevated the secondary factors -- in particular, commercial success -- to a fourth and sometimes overriding factor ».*

So, an observer was able to declare « *Many patent attorney believe that the obviousness defense is dead and that the cause of the death lies in the decision of the Court of Appeals for the Federal Circuit »* (L. Krastiner 1991). In an article strikingly informed on this point, Quillen in 1993 indicates in a precise way, from a study of the jurisprudence, the way the decisions of the CAFC modified gradually , by weakening them, all the essential criteria of patentability. As a consequence, the USPTO which at first continued to rule according to more rigorous traditional criteria, modified its doctrine and let it know in a series of formal statements intended for the pretenders in the patent registration. This appears very clearly in the new "Guidelines" on Utility published by the USPTO (01/05/2001)

A direct consequence of those changes, is huge surge of the number of patents patents, a surge which translates a change of regime. While traditionally the American system was presented as very rigorous for what regards the criteria of allocation of patents - rigor compensated with a wide and strong protection granted to the holders - (Ordovery on 1991), *new criteria applied from the decade 1980, stretch out the system towards a much weaker protection* and with an increase of the cases contesting the rights awarded to the holders of patents. (R. Hunt 1999a)

Many other institutional changes, always aiming at favoring the competitiveness of the firms through R&D activities can be mentioned. For our object however, the two series of changes which we have just presented will be enough, since we think, they indicate enough clearly the direction and dimension of the changes introduced.

In the following sections the more precise analyses of the changes that took place into the two key domains of information technologies and bio-technologies, will allow to go deeper into the analysis and make some step further.

3. BETWEEN COPYRIGHT AND PATENT : THE CONSTRUCTION OF A SPECIFIC AMERICAN RIGHT FOR SEMICONDUCTORS AND "COMPUTER PROGRAMS "

Even though essential developments will occur only from 1980's, it is in 1970's, that it is necessary to go back, to find the origin of the discussions which are going to end in the implementation of legislation's specific for Semiconductors (1984) and computer programs (1980-1986).

1. The Asian challenge on IT : The case of the Semi-Conductor Protection Act

According to Hunt who concentrated himself on the recent history of the semi-conductor industry (1999a and 1999b) : « *In fact, trends within that industry became a catalyst for dramatic changes in the way the U.S. protects intellectual property* ».

After decades of complete domination, the United States discovered with some surprise this loss of competitiveness in a domain which they had created and at which, until the entry of 1980's, they excelled⁷. In front of the impressive ascent in power of the Japanese firms, (even already Korean ones), in the field of semiconductors, the American business community, called upon the practices of "reverse engineering " of which they claimed to be victims on behalf of their Asiatic rivals. This practice of *reverse engineering* was at that time, common between American firms and allowed of fast and continuous progress in the technology. R Hunt (1999b), in his paper presents the situation then prevailing, as follows : “ *Within the U.S. semiconductor industry, re-verse engineering was a well-established practice. But by the late 1970s, American firms objected to similar behavior by Japanese firms when they began to increase their market share in the more standardized products, such as computer memory chips. The level of competition eventually became so intense that, by the mid 1980s, most American companies abandoned these segments entirely... When it became clear they could no longer dominate Japanese firms on the basis of production technology alone, American firms attempted to consolidate their comparative advantage in research and development. To do this, they would have to find ways of reducing their competitors’ ability to reverse-engineer their products... “To that end, American companies began to lobby Congress to increase intellectual property protection for their semiconductor designs”.*

A Commission in charge to investigate into this domain and to make of propositions for the Congress was organized : the famous CONTU. Its recommendations, as the numerous and intense debates to which this recommendations are going to give place, were finally translated into a series of major modifications among which the *Semiconductor and Chip Protection Act* (*SCPA*) voted in 1984, is one of the major outcome. Finally, the SCPA created a new type of intellectual right of property entitled « *mask works* ». To the beneficiaries were thus « ... *granted exclusive rights to reproduce, distribute, and import products embodying the mask work for a period of 10 years* » (Hunt 1999b).

Box 1

Mask Rights and « reverse engineering »

The primary limitation to the mask owner’s exclusive rights is the defense of *reverse engineering*. The SCPA specifies a two-pronged test for the determination of infringement. The original and the allegedly infringing chip are compared. If they are "substantially identical," the court will find infringement. However, if the designs are only "substantially similar," the defendant is immune from liability if the following conditions are satisfied: (1) the defendant must demonstrate substantial toil and investment in the development of its chip; (2) the resulting design must satisfy the standard of originality specified by the SCPA.¹²

A successful defense of reverse engineering appears to require that the defendant’s design be better than the plaintiff’s. One author argues, "More likely, than not, for a defendant to prevail ... its resultant ‘original mask work’ must be one that is functionally superior to the protected work, as measured by the relevant technological criteria." He continues, "The proof of

⁷ On this point Hunt writes : « *Between 1972 and 1982, the dollar value of semiconductor shipments increased more than 450 percent. If the decline in prices of computer chips during this period is taken into account, shipments in 1982 were 17 times higher than in 1972. Also, employment in the industry increased 71 percent.* »

improvement, therefore, becomes the ultimate issue in establishing the defense of reverse engineering."

Source : R. Hunt (1999b)

Note that under certain conditions, the SCPA authorizes firms to appropriate one another some of the novelties contained in the new designs of microprocessors. These mutual exchanges, were indeed considered as required by the development of the innovation. The counterpart of the protections guaranteed to the innovative firms becomes then, to shorten the delay during which a firm granted with a protection could enjoy its benefits. As noted by Hunt (1999b) the new ruling has to find its own way between contradictory objectives : « *SCPA strikes a bargain between protecting the economic rents of existing inventions and encouraging firms to build on those discoveries as freely as possible* ».

It remains that a key result of these changes was that « *Congress specified a non obviousness requirement considerably weaker than the one for patents* » (idem), contributing "to weaken" the classical conditions of patentability in this particular domain.

2. The case of software packages and of computer programs

A) The progressive walking towards the patentability of mathematical algorithms

This same tendency to the extension to new domains of patentability spread into the crucial domain of software packages and computer programs, including the patentability patentability algorithms and systems of equations, incorporated into the computer programs

Here again, one should start from the 1970's. In the course of the that decade, the software industry in United States develops quickly, notably because "autonomous" endowed software packages being able to be moved from a machine to the other one ("inter-operability") were conceived and grew at fast speed. This property of inter-operability with which is endowed an increasing number of software packages makes it possible that they are incorporated such into trade objects and of business. From then on, two connected but different questions are going quickly to arise : i) *that of the fight against the piracy* (illicit copies prepared for commercial purposes) and ii) *that " of the "imitation" by rival firms of existing solutions*; this problem is especially puzzling, because, in a world which chooses " the opening " through the extension of the compatibility, margin is narrow between pure and simple "imitation" (case of imitation of existing software packages to be sold on the market under different brand names, without substantial improvement) and necessary *adaptation on existing products to propose improved software solutions*, compatible with the practices of the users and the dominant standards

It is in this context, let us remind, that is organized the CONTU Commission, which recommendations will make date. After intense consultations, the CONTU will pronounce for an extension and a deepening of copyrights principle to cover products software packages. These recommendations will be translated by the *Computer Software Act* of 1980. In practice however this legal frame, which suggests treating software packages within the framework of laws on the Copyright, (without excluding, in exceptional cases the granting of patents), proved to be not sufficiently smartly designed to bring a definitive solution to the problems posed. The Courts of Appeal settled in 1982, will soon consider the *Computer Software Act* as a too narrow and binding frame. Often relieved (or preceded) by some Supreme Court

important rulings, the Courts of Appeal will introduce by their jurisprudence, the common practice of granting with patents software programs. Thus, a gliding is made : from "copyrights" to "patents".

Other glidings are going to result from the jurisprudence which, from rulings to rulings, is going to spread the principle of patentability of software packages to always more novel dimensions, sometimes in very unexpected ones....

It is necessary here to remind that at first, the USPTO had took a clear hostile position to the granting of patents on computer programs, this, because of their very nature : they were analyzed by USPTO as made of chains of abstract stages and/or mathematical algorithms, characteristic which is explicitly excluded from patenting by the US code on Patents. And so Besen and Raskind (1991) in the important survey which they dedicated to the evolution of the IPR's system, could write: « *When Visicalc was developed in 1979, The Patent Office, relying on Supreme Court case law, took the positions that the mathematical algorithms in computer programs were not protectible subject matter* ».

In the same way, throughout the 1970's, by a series of repeated decisions, as the USPTO as the Supreme Court, opposed to the granting of patents, in processes including the use of software packages, in the motive that algorithms used by processes subjected to the patent constituted an essential part of the process. According to this vision, a computer software program being assimilated to « *a procedure for solving a given type of mathematical problem* »⁸ could not, on any account, be covered with patents rights.

This situation, however, will change quickly with the ruling of the Supreme Court known as " *Diamond vs Diehr* ". This ruling introduces a radical change of doctrine, thus because, according to Besen and Raskind (1991) the Supreme Court negating its previous decisions. ... « *did find patentable subject matter in a process utilizing a computer algorithm. Since that case the Patent Office has begun to grant patents to computer programs* ». Always according to Besen and Raskind (id, 1991) the Supreme Court supports then notably « *Excluded from ... patent protection are law of nature, natural phenomena, and abstract ideas... An algorithm... is like a law of nature, which cannot be subject of a patent....* » seeming so to confirm its previous position. In practice it was not the case, because the same ruling continues by supporting that « *[Here] ... patent protection [is sought] for a process curing synthetic rubber. Their process admittedly employ a well known mathematical equation, but they do not seek to preempt the use of that equation . Rather they seek only to foreclose from others the use of equation in conjunction with all the other steps in their claimed process* » (id).

Finally, in this famous ruling, the Supreme Court considers as patentable a process of drying of the rubber using a computer program. According to the statements accompanying the ruling, it is enough that *algorithm is highlighted in a specific way to define structural relations between the physical elements of the device (in an application for a patent aiming at an equipment) or to optimize processes (in an application aiming at a process)* so that the process to which a law of nature or algorithm was applied can be protected by a patent. To say

⁸ Cf. the famous case (Benson S . Ct 175 USPQ 673) by which after a long judicial procedure the Supreme Court eventually rejected the application for a patent. This decision is essential and will make for a long time Jurisprudence because the Supreme Court justified its refusal by a principal argument : the refusal of the patenting of the computer programs being justified by the fact that the later implied usage of algorithms, that could not be patented. For a detailed presentation the various cases of jurisprudence on software packages before as after their patentability cf. R. Sigonre (1988).

it in other words, at this stage of the jurisprudence, a computer program alone will not be able to be patented as such, but this same program introduced in a process will be able to be patentable, under reserve that it satisfies the other conditions required by the Law, namely the "utility" requirements.

In fact, the jurisprudence will pass gradually of a situation where the existence of an algorithm in a program of computer can not constitute a motive to refuse the granting of a patent, to a situation in which :

- i) The patent is granted to programs (including algorithms) if they present some *industrial utility*; at this stage, however the precise and careful technical description of the invention justifying the allocation of the patent is required to be patented;
- ii) The patent is granted to pure " business models " or " intellectual methods " without at all being necessary demonstrating its "utility " dimension by long technical descriptions : it is the "method" as such which is now protected .

The case of the patent " One Click "(Amazon.com) (cf. « US 5960411 Method and system for purchase order via a communication network ») gives on this point a perfect illustration of the current trends. So, because, the application does not concern a particular technical process conceived by Amazon.com, but the *method* as such, allowing to order of an object without having to specify again the address of delivery if the customer has previously made some order. Through the method, it is indeed the algorithm in the base of the data processing which is patented.

In practice, this application (today very controversial) joins in a tradition of jurisprudence which began to form in the middle of the 1980's. Case *Whelan vs Jaslow* (1986) is here a key reference. As far as this ruling introduced the principle " *of an extension of the protection of the copyright to the literal code (expressing a program) to its structure, sequence and organization* " (*Zimmerman 1996*), this ruling of the Supreme Court opened the way to a series of decisions of the USPTO, and of the Courts of Justice, confirming this gliding of the American doctrine (cf. Box 2 below)

Box 2

Whelan vs Jaslow :

The patenting of the "SSO" of the computer programs

Whelan Associates v. Jaslow Dental Labs., Inc. was the first American appellate decision to consider whether the "structure, sequence, and organization" ("SSO") of computer programs could be protected by copyright law.

The Third Circuit Court of Appeals in *Whelan* decided that "SSO" was protectable under U.S. copyright law on both doctrinal and economic grounds. The doctrinal analysis relied on this syllogism: computer programs are literary works under U.S. copyright law, and since the structure, sequence, and organization of literary works are generally protectable by copyright law, the structure, sequence, and organization of programs should be protected by copyright law as well.[36] This aspect of the *Whelan* analysis would likely resonate with European intellectual property specialists.[37]

Complementing this doctrinal analysis, however, was an economic argument that focused on the need for

software developers to have sufficient protection to recoup development costs. A second economic concern was the locus of value in computer programs. Consider, for example, this excerpt from the Whelan decision:

“By far the larger portion of the expense and difficulty in creating computer programs is attributable to the development of the structure and logic of the program, and to debugging, documentation and maintenance, rather than to the coding. See Frank, *Critical Issues in Software* 22 (1983) (only 20% of the cost of program development goes into coding); Zelkowitz, *Perspective on Software Engineering, 10 Computing Surveys* 197-216 (June, 1978). See also *InfoWorld*, Nov. 11, 1985 at 13 (“the ‘look and feel’ of a computer software product often involves much more creativity and often is of greater commercial value than the program code which implements the product . . .”). The evidence in this case is that Ms. Whelan spent a tremendous amount of time studying Jaslow Labs, organizing the modules and subroutines for the Dentalab program, and working out the data arrangements, and a comparatively small amount of time actually coding the Dentalab program.[38]

The Third Circuit seems to have been persuaded to this position by a friend-of-the-court brief submitted by a software industry organization which argued that if copyright protection did not extend to the structure, sequence, and organization of a program, the software industry would be jeopardized because the law would provide too little protection to induce an optimal level of investment in development of computer programs.[39] The Third Circuit directly responded to this plea: “The rule proposed here, which allows copyright protection beyond the literal computer code, would provide the proper incentive for programmers by protecting their most valuable efforts, while not giving them a stranglehold over the development of new computer devices that accomplish the same end.”]

Source Samuelson P. (1998)

The case *Refac vs Lotus* (1989) that became to a classic, confirms this very particular element of the new emerging American doctrine. In this case *Refac* attacked *Lotus* for usage of a technique called " *natural order Recalc* " consisting in working out again the effects on a Table, after a change of contents of one of the cells of the sheet of calculation, a technic on which *Refac* claimed to have a patent while this principle of calculation rests on algorithms used by almost all the editors of software packages. The Court gave earning of cause to *Refac*, provoking a deep emotion among the software editors.

A supplementary step has even been crossed with the granting of patents in programs which consist finally of the application of pure mathematical formulae in computerized processes of calculation. (For a recent case see : «US 6081597 Public Key cryptosystem method and apparatus (2000)). According to J. P. Smets-Solanes (2000): " *The formulation of this patent is interesting because it is almost only mathematical (mathematical theorem of proof of existence), while traditionally, patents on the techniques of encoding are 'coated' with different technical devices allowing to hide their intrinsically mathematical nature. This patent illustrates the fact that, in practice, the question of the patentability of software computer programs is intrinsically linked with the one of the patentability of systems of mathematical equations* " (p. 64). It is necessary to note that however surprising it can appear, this patent is in fact in the exact lineage of that granted as soon as 1993⁹.

⁹ One can refer here to US 193056 Data processing system for hub and spoke financial services configuration which consisted in patenting the usage of mathematical formulae in a program of computer (the protection covering these formulae as such) aiming to facilitate the execution of different financial operations.

Finally, and to conclude on this point, one can present the evolution, by saying that we passed *from a situation where the presence of an algorithm is not considered as a motive to refuse an application if the technical novelty which is associated to the algorithm and its " utility" are established, to a situation in which " novelty " (and/or " utility ") consists of the use of the algorithm itself, the algorithm as such being a candidate for patent protection.*

This evolution has not yet reached its end. In many " *business models* " today covered by patents, the algorithm is not described : the written description concerns only the " *intellectual method* " allowing to reach the goal pursued by the method, in such a way that the *claims* "could cover the protection of the method as such. (On this point see notably *Merges 2000*).

To complete this analysis of the specificity of the new American regime on software packages, other precisions are necessary. Without aspiring at all to the exhaustiveness in this domain highly complex and unstable, at least two dimensions of the new right must be clarified. They concern the responsibility of the editor on one hand, and the right to recompile on the other hand

B) Responsibility of the editor and " recompilation "

Recompilation

By *recompilation* is meant the right (recognized or refused) to an individual to freely have access to the "source code" of a given program, to modify and improve the program This possibility is essential, because by allowing newcomers to have access to source codes *creates conditions for the inter-operability of the considered products and allows so to improve them.* One here have to remind that the software packages sold in the market contain defects, " bugs ", and series of limitations of use, some of them being deliberately introduced in the programs by the editors. In the case of the European Union, the directive of May 14, 1994, authorizes the correction of errors within the framework of the foreseen use, as well as the recompilation in a perspective of interoperability programs, so as to insure to the users a certain degree of adaptability and to avoid confinement in the program sold by the editor. This right favors so the development of *open solutions* " Smets-Solanes (2000) for software packages. As it was noted this right for recompilation is in fact " *... an instigation for developers to publish the information relative to interfaces, to push towards inter-operable standards and to give positive and appropriate answers to the demands of individual the users*" (id). Thus, the right to recompile, coupled with a set of copyrights protecting the pioneer, aims to encourage companies to enter into processes of incremental innovations allowing to improve software packages in a continuous way. Those provisions aim to avoid that the pioneer firm - often a large firm, leader in its field - can shielded from legal barriers protecting its software, to lock the consumer into a "closed" technology. The right aims so, to limit the risks of catching the users in lock ins.

In the case of United States, after a period of hesitance, the question of the recompilation was clear-cut, one again by the jurisprudence, with a ruling of the Supreme Court (*Sega vs Accolade*), that became since then the key reference on this point. This ruling is essential because it signs the victory of the big editors on the small ones and on the pretenders to enter on the market. From then on, if recompilation is not allowed, it is going to work as an important barrier to entry, guaranteeing to the large companies the mastery of their standards, as well as the rhythm in which they decide to develop it. Certain companies which were able so to impose some of their product as de-facto standards are able, by this means, to establish

practically impregnable positions of monopoly. Recent Anti-Trust actions against Microsoft put in evidence the way Bill Gate's company was able (using strategically some of the provisions guaranteed by the Law) to prevent the rise of any real competitor. At the same time as, according to numerous authors, the technical quality of many of the software packages sold by Microsoft, stay at a level considered generally weak or very weak. (Di Cosmi and Nora 1998)

Responsibility of the editor and obligation of result

The question addressed here, is the one of the nature of the obligations of the software editors with regard to the performances of their products

In Europe every editor of software is - in limits clearly established - subjected to such types of firm commitment undertaking. It is necessary to note that the principle of these obligations is coherent with the license to recompile. It is only by access given to source codes, to introduce the modifications which are necessary in case of "bugs" or to introduce lines of supplementary programs allowing to transform software to overcome certain rigidity or limitations it may contain, that the constraints put on the editors can be respected by them.

In United States, and however surprising it can be, the editors are not subjected to an obligation of result. Thus, because jurisprudence is leaned on the fact that - handled within the framework of the *copyright law* - one assimilates the status of the software to that of "objects of art", and by extension the conceivers of software enjoy the same immunity than the one covering an "object of art". *There is so no legal provisions allowing to guarantee that software sold on the market will not contain errors and will perform the functions for which it was foreseen.* The protection of the consumers is not so as effective as in Europe, because an user noticing the defect of a software will not be able (in most cases) to prosecute the editor and obtain damages¹⁰.

This absence of clause of obligation of result is translated by the fact that *the editor of software does not have to correct errors and actual defects in his product, even though these are voluntary.* The point here is that it is today established that number of editors deliberately chose to introduce into software packages commercialized some "errors" or "bugs". And in two explicit purposes: i) *to limit compatibility with the rival products*, so as to capture the users in its technology ii) *to impose on the clients the purchase of versions of update for a price sometimes as high as the one at which they acquired their initial products.* Here again the material gathered by the Anti-trust authorities on the Microsoft case illustrates clearly those types of practices.

To sum up, the cumulative effects of the two rights (recompilation and firm commitment) allow the large editors of software packages *to enjoy immediate rents, while creating conditions to insure their positions in the long run by coupling the benefits of monopolies with the ones of network externalities* (cf. Arthur 1989).

¹⁰ It is so, for example in the contract for "Office" of Microsoft. The user has to undertake to respect before using any the software's included in the package, a series of provisions. Among others, one these provisions states that (§6 of the contract) " *Either Corporation Microsoft, or its subsidiaries do not supply an assistance for the software product. For the assistance, please contact the number of assistance of the manufacturer of computers supplied in the documentation of the computer* "

The Table below summarizes the state of the right on this point (to introduce supplementary comparative elements, the position of Japan - which occupies an intermediate position between United States and Europe - was added)

Table 4
European, American and Japanese Regulations on Computer Programs and Software Packages

	USA	EU	Japan
Copyright on the user interface	Unclear interpretation	Unclear interpretation	Unclear interpretation
Patent on an algorithm, a standard or software	Authorized	Forbidden by the European directive on software	Authorized
Recompilation of a software	Forbidden	Authorized in purposes of interoperability	Authorized, except on American software packages (*)
Responsibility of the editor	No	Yes	Yes

Source: Smets-Solanes (1999)

(*) The suspension of the right to recompilation for American software packages, results from a strong action of the American authorities with Japanese authorities, to force them to introduce into the Japanese national system, this clause coming directly from the American regulations

This Table, shows clearly the very strong peculiarities of the American provisions.

III. FROM THE " CHAKRABARTY " RULING TO THE PATENTING OF HUMAN GENES : THE ESTABLISHMENT OF A NEW REGIME ON IPR'S ON LIVING MATERIALS¹¹

1. On some conditions of the change of regime

If, as regards semiconductors and software packages, the change of the regime was achieved through legislative changes (SCPA and Copyright Amendment Act), the case of biotechnologies, and more particularly genomics on which we concentrate here, distinguishes itself by the fact that the evolution has been achieved from case law decisions. Everything here leaves on certain specificities of the American legal tradition. As it is well known the dominant regime in United States is that of " Common Law ", which singularity is, compared to the Romano-Germanic tradition prevailing in Europe, to leave a major space to the jurisprudence and the rulings of the judicial Courts. This type of legal regime gives so a possibility of fast and marked evolution, without being necessary to resort to the legislator. Applied to the right of patents, and more particularly to the field of the alive which we examine here, the practice of Common Law, presents two distinguishing features.

¹¹ This section is based on Orsi (2001)

1. For lack of text including explicit reference to the limits of patentability on living entities, American jurisprudence operated from a tacit distinction between "product of the nature" and "product of the man" (a distinction which is absent in the Roman right of patents). And so, the Congress of United States was able to declare that could be granted with a patent: "*anything under the sun that is made by man*" (Cong. 2d Sess, 5 (1952)).

2. Besides, hold a key role in all the American doctrine, the notion "of utility" applied to any type of "inventions" or "discoveries". So, patents are declared such in the name of the Utility ("Utility Patent") which they can present for the progress of the society. In practice is so privileged "*the utility*" of the objects proposed for application rather than their "novel" or "creative" character. It is so, because the US Law stipulates: "*the term 'invention' means invention or discovery*" (art 100a), a type of equivalence totally impossible in the European tradition, where the distinction between "*discovery*" (applying to the case of scientific discoveries i.e. in the production of knowledge) and "*inventions*" (technical artifacts allowing the exploitation of knowledge) is the *basic principle underlying the whole patent doctrine*.

The peculiarities of the doctrinal bases from which jurisprudence is going to operate being so clarified, the history of the change of regime, driving to the patentability of living organisms and finally to human genes can be reconstituted. It took place through the three stages described below.

2. 1971-1980 : The Chakrabarty ruling of the Supreme Court of United States : the entry of unicellular alive organisms to the field of patents

At the conclusion of a long judicial procedure : an application for a patent in 1971 having been at first refused with the USPTO, by a ruling of the Supreme Court, is granted to General Electric a patent concerning *a genetically modified micro-organism capable of intervening in the absorption of certain navy pollutions*.

The meaning of this ruling is of considerable reach. In this occasion, the Supreme Court establishes indeed a new distinction between "products of the nature" and "products of the man". Distinction which will make jurisprudence and which will lead, the USPTO which had at first opposed to the granting of a patent at the request of General Electric, modified substantially its doctrine. Jurisprudence established by the Supreme Court, and endorsed by the USPTO puts that *henceforth the alive is not considered any more as "product of the nature" since it requires the intervention of the man*.

In the stride of this ruling, another major moment is the granting, to request of Stanford's University in 1980, of a patent concerning a technique of recombinant ADN. It is about a technique of genetic engineering allowing to transplant a gene stemming from a living entity into another one.

Enter so the field of patentability (according to terms of the "claims" of Stanford's University in its application for a patent) "*a process of production of molecular fancies based on biologic functioning*". Such a process, which, par excellence, is a means of production of scientific knowledge based itself on new knowledge in genetic engineering, was *not patentable before the Chakrabarty ruling*.

The field of patents opens so to new biotechnological processes, allowing to produce transgenic animals (or plants) defined as pure "research tools" and which use is for scientific experiments. This supplementary step will be, effectively crossed on 1987.

3. The patentability of multicellular organisms and the new doctrine posted of the USPTO.

Registering the changes intervened in 1987: the USPTO in a public proclamation which remained famous ("historic" will say some observers) let know that "*the USPTO now considers nonnaturally non-human multicellular living organisms, including animals, to be patentable*"

The explicit consequence of this statement is immediate : *as soon as 1988 is granted a patent on a genetically modified mammal*: the "Harvard mouse ", a prelude to patents granted since then, to many transgenic animals created by different laboratories.

The meaning of such changes is that the field of patents extends still, to open *in any biologic material having required the intervention of the man*. It is this " intervention of the man " which confers, according to the Supreme Court and the USPTO, their character of " non natural ", even though properties then revealing are those of the nature, as it is case for what regards the sequencing and the identification of the properties of a particular gene.

Implicitly, these decisions mean that the patentability of genes is accepted, under condition " of utility ", confirming so the primacy of the notion of utility. In the same time is confirmed implicitly the equivalence between "discovery" and "invention".

4. 1991: patent registration of the NIH on ADN's partial sequences (EST's), conflict with the PGH and opening of the debate on the patentability of human genes

It is here about the ultimate development which pushes things to their extreme, because involving partial sequences, the " utility " of the sequences, can not be established. Of what, the NIH which was originally on the initiative of a massive demand of patents for partial sequences (EST's), provoking strong oppositions and reactions of the international Scientific Community, could not ignore.

It is the reason why, the NIH in its claims, will try to by-pass difficulty by supporting that there are indeed some "utility" of the sequences proposed to patenting, as far as those sequences, although without clear identified functions, may help "*to develop the knowledge of the genetic foundations of the health, the disease and the biological functions*". In other words, the argument of the NIH, is that these partial sequences have a "utility" dimension since they may contribute to the identification of genes implied in certain diseases and in the search of new therapeutic targets.

It is here interesting to note that the USPTO will pronounce for a refusal of the demands of the NIH, only in view of : "*considering what is revealed in the demand, more ample works are necessary to establish the utility of the claimed object*".

In practice, as we have already mentioned, this application for a patent of the NIH has provoked a real crisis in the international scientific circles of the "open science" community. This episode marks in fact awareness at the international level of the meaning of the

malpractice to which the new regime on IPR's initiated in the beginning of the 80's may lead. Since then, the debate on the patentability of human genes went out of the circle of the specialists to become a highly controversial matter.

It is nevertheless in the scientific circles that controversy is the most lively. The initiative of the NIH is in complete contradiction with the *ethos* (to follow here Merton's statement) of the researchers gathered within the Human Genome Program built on the rules of Open Science, and to the promotion of which the NIH himself had played a major role! ...

The principle of the marchandisation of the knowledge through the granting of patents - the later being able to be analyzed as a series of mini monopolies granted to the patent holders - is in complete opposition with the spirit which presided over the implementation and over the functioning of the HGP. One here has to recall that the HGP is an international academic program built on an open science model. Launched in 1988 to the initiative of the NIH and the DOE with the aim of sequencing the human genes, its basic rule is *the free circulation of knowledge*. Designed to avoid duplications and to promote the collaboration among the community of scientists, its central activity is in fact, the constitution of data banks containing partial sequences of ADN identified by the teams of the HGP, put at free disposal of the researchers. The sensitive point is that it is often the same partial sequences (often produced in the frame of the PGH) which were submitted to the granting of patents by teams of the NIH;

Controversies will be all the more lively as, in 1998 a decision of the USPTO to grant a patent to the firm Incyte Pharmaceuticals concerning partial sequences (to identify and to code some proteins "kinases" expressed in various cells and human tissues), will confirm a new dimension of the extension of the patentability domains (USPTO, 1998). From then on, anymore nothing opposes the patenting of the partial sequences contained in data bases stemming from the academic research on the Human genome, with a risk of eclipse of the principle of free access to the information to very preliminary stages of the basic research. This concern is expressed by an American scientist involved in the HGP who observes that :
" ...A more direct warning posed by private sector is that academic researchers risk losing equal access to critical research tools. These tools, such as advanced instrumentation for DNA analysis, are increasingly seen as a means through which their developers can acquire intellectual property rather than as products in their own right. Perhaps if the microscope were a contemporary invention, we would find optical companies competing to sell images rather than microscopes. Basic scientists need access to state-of-the-art research tools, not just to the output of these tools. However, the tools themselves are now universally refined, manufactured, and marketed by private companies rather than by basic researchers themselves. Hence, tool-making companies are in a powerful position to influence the directions that basic research takes and the distribution of that research between non-profit and for-profit sectors "¹².

5. From IPR's to financial markets : towards "a finance driven" model of production of knowledge.

More clearly than in the case of software packages and computer programs, the case of the opening to patent granting of living entities provides evidences of the deepness of the changes

¹² Cf. Maynard V. Olson, House Committee on Science, Subcommittee on Energy and Environment, June 17, 1998, in [http : // www.house.gov/science/olsen](http://www.house.gov/science/olsen)

introduced in the new IPR regime by the US public authorities, with the aim of turning the academic research system as a means to improve the competitiveness of the firms.

This evolution, initiated with the Chakrabarty ruling, led to a real *privatization (at least partial) of the academic research in molecular biology*. From the first steps (patenting of genetic engineering methods, to the last ones : patenting of EST's) the changes were conducted in a such a way that decisive pieces of the basic research in the field of molecular biology, is now in the hand of private firms, often through joint ventures with academic teams, the results being covered by bi-lateral monopolies, with immediate economic profits for the holders of the new property rights. It is so, for example that the patent granted to Stanford University on the technique of the recombinant ADN, turned out to be *the most profitable patent of the decade 1980-1990*. In the same spirit the famous "Harvard Mouse" which in the principle, is nothing but a research tool for cancer, once covered by a patent was given up under shape of exclusive right of license for the Dupont Corporation firm.

However important they are, the immediate gains obtained by firms and other profitable institutions, enjoying the benefits of the new IPR's, *are only a small dimension of the economic effects produced by the changes on the IPR's system* A more complete evaluation of these effects supposes to consider another field of analysis, namely the changes which intervened in the financial sphere to allow the entrance of financial capital into these new domains, and through it, to insure the promotion of new branches of the industry, often belonging to its most dynamic segments.

It is on this point, that we would now like give some indications. The case of bio-technologies is here privileged because it clearly illustrates the phenomena which we want to put in evidence¹³.

In that case the "venture capital" has been the first source of financing of the new firms launched on the market. From "love money" to "business angels" and finally to venture capital and IPO's launched on formal stock markets, the different stages are now well known and described. Our point here is to emphasize the fact, that during the 1980's, some major changes took place, with huge consequences as regards the mechanisms of the launching of new firms. So, because along with the changes by the Bayh Dole Act's provisions *aiming to link publicly founded research with private business firms*, another set of new regulations were introduced *aiming at promoting on financial markets new high tech firms among which, the central target was the ones engaged in research activities*.

At least two of these changes, implemented in the financial regulations have to be mentioned. Those, on one side, which ended with the transformation of Nasdaq (created in 1971 as a market of secondary titles - the so called "OTC market") in a stock market dedicated to the launching of "innovative" firms, and those of the other side, which allowed the entrance of the pension funds on the "risky" companies launched in the Nasdaq.

On the two points just mentioned, Gompers and Lerner (1998), in a recent article, shows how the making on this particular stock market dedicated to the launching of new innovative (but loosing) firms, could not be achieved without the help of a series of statutory changes.

- On one hand, the new regulations regarding the Nasdaq are characterized by the following two traits: i) unlike the traditional stock exchanges (AMEX and NYSE), the new regulations

¹³ These developments are based on Orsi and Moatti (2001b) and on Orsi, PhD thesis, forthcoming, 2001.

authorize to introduce and to maintain on Nasdaq *companies not realizing any profit* and having registered losses during several successive years and ii) these non profitable firms may include.... a series of intangible assets : a portfolio of patents and other IPR's being the most important ones.

- On the other hand though new regulations concerning the pension funds (ERISA), modified the rule "*prudent man*", *in such a way that* the commitments of pension funds on "risky" investments were redefined, and relaxed. The rule was modified to authorize the pension funds to invest largely in new "innovative" (but "non profitable" companies), a situation which modified the offer of capital and the liquidity of these markets due to the novel and massive entry of the pensions funds.

These changes in the financial regulations are going so to enter in complementarily with those that affected the regime of IPR's. At first (the 1980's) they will favor the launching of IPO's of the new companies often created from discoveries made in research laboratory, and which after a phase of experiment, were promoted through equity-capital before being promoted in the Nasdaq. This "model" often used for electronic firms, will be of use to the promotion, some years after, of the biotech companies.

Thus, the genomic firms most often based on research teams extracted from the public laboratories (Universities, NIH ...), came later on (end of 1980's, beginning of 1990's), go to their tour to benefit, from the existence of the financial markets specialized in the promotion of companies without current profitability but considered of "high potential". *The remarkable point is that in most cases these firms have not a single product to sell.* The only commodity they can market is their research results , to which, since Chakrabarty ruling, patents were granted by the USPTO!....

So, the move in favor of the patentability of genes worked as a point of crystallization which allowed the institutional and financial evolutions already evoked to converge in favor of the development of a sub-segment of an industry. Specialized firms are going to be able to come to existence, whose "capital" is made of patents. If it is the case it is because some of these patents, were letting hope (even in not predictable terms) for new therapies for certain common diseases, often regarded as incurable (cancers,). Thus what is at stake is a series of mass markets estimated at dozens of billion dollars... One understands, that under such conditions, these firms were able to attract very large amounts of financial investments by way of the specific markets which were installed just before the launching of these new firms. *So, the new alliance between intellectual property rights (as source of future rents) and financial markets appears to be the key articulation explaining the rise of new biotech firms as separate industrial actors.*

In practice, just after the Chakrabarty ruling of the Supreme Court of United States, which opened the way to this marchandisation of knowledge, the first firms of biotechnology where launched, though the means of IPO's in the Nasdaq, with the enthusiasm of the financial investors. As an illustration, we can set the example of the first firm of biotechnology created in the United States - Genentech. Whilst the IPO proposed 1 million actions at 35 \$ the one, the titles reached at the end of the quotation the value of 89 \$. The company had finally gathered 36 million dollars and was evaluated at 532 millions, even it had not yet commercialized the least product. In the opinion of a financial analyst, this phenomenon was without antecedence : "*Here are twenty two years which I work at Merrill Lynch and I have never seen that*". (quoted in Sharon McAuliffe & Kathleen McAuffice, 1981. According to the managers of Genentech the cause of this success was evident : referring to the

Chakrabarty ruling they declared " *The Supreme Court has guaranteed the technological future of our country*" (id). From there on, every announcement of a new discovery - susceptible of being patented - is at the origin of a sudden increase of the value of the shares of the firm at the origin of the discovery. Finally patents being the key commercial assets of these firms, *the market share of these companies is the estimated by the relative number of identified and patented genes they control.*

From then on, takes place a highly strategic game aiming at insuring the commercial promotion of patents, and by this way to guarantee and to develop the value of stock-exchange securities. This evolution of the value of titles holds a place all the more crucial, that these companies, do not return any dividends, the shareholders being paid only by the increase of the share-value on the market. The firms are going so to attempt not only to protect their discoveries but go to pursue objectives aiming notably : i) to dissuade the arrival of firms potentially rival by the announcement of patent registrations which play in fact the role of bait in their fields of privileged competence (strategy said with the "minefield" or with the "porcupine") or ii) to try to obtain the widest protection possible on their discovery, with the aim of dissuading competitors' possible arrival. The firms can adopt all the more easily such strategic behavior as the novelty of the right of patents for living entities leaves an important margin of interpretation which they can try manage in their advantage.

V. TO CONCLUDE : A FIRST ASSESSEMENT OF THE NEW IPR's REGIME

The changes which we have just presented are today - in first place in United States themselves- object of analyses and questioning. An important literature wonders about the meaning of the " bend of 1980's ". For our part, in order to contribute to the evaluation of the current and future effects of the dramatic changes which we analyzed, we propose the following propositions.

1. Some highly visible successes ...

At first look, the new policies deployed by the American public authorities, appear as crowned with success.

In the domains which we examined (more particularly in semi-conductor and software), the American firms which in the decade 1980 seemed often supplanted by their Asian rivals *reoccupy leading positions.*

More significant still, *a lot of new firms entered on the market.* The domains which we examined (biotech, genomics, semiconducors, computer software ...), are characterized by a bloom of companies of any sizes, a big part of which consisting of firms which have often less than a decade of age, and of which some are considered already nevertheless as of real stars and new "global leaders".

Furthermore, the modifications of the financial regulations installed during the last years, seem as well designed to insure the promotion of the new innovative firms. On one hand the American financial market, (and notably the Nasdaq) was able to attract a considerable mass of financial capital, coming not only from American investors, but also from European and Japanese ones. This led to a tremendous increase of the market capitalization of number of these new firms. From there, due to the @-money so established, these firms were able to proceed to purchases or alliances which often strengthened and hardened them. On the other

hand, this situation drove to some crossed fertilization between complementary activities and domains, what allowed the American firms to enjoy the benefits of "first movers "; capitalizing their initial advantage. Many of them are now the reference, at the world level for these activities.

These visible successes of the new " American model " came along also of big successes in the field of international relations, as far as *the new American IRR's regime is in the course of extension and enforcement at the world level*. On one hand, in Europe and in Japan, powerful relays of the new American doctrine, were found, (notably within Patent Offices, being European or Japanese ones...), which finally were able to introduce decisive changes in the local doctrine to converge with the new American. On the other hand and especially, within WTO, in 1994 , the United States with the active support of the other developed countries were able to introduce in Trade Agreements new statements regarding the protection at global levels of the new IPR's designed in the last two decades in the USA. The so called TRIPS agreements mark a decisive change in that field. (Reichman 2000)

If however, one questions more profoundly about the foundations and the long-term sustainability of this new regime, a series a question arise. Let's mention some of them.

2. ... Under the threat of heavy uncertainties and contradictions

In spite of the successes mentioned, if we come back to the principles on which the design of an IPR's system should be grounded to promote innovation and the progress of science, one perceives that the future of the new regime is highly uncertain, the new system does not appearing to have been able to realize within it, the difficult balance between two poles and dimensions of any IPR's system.

Let us remind here that any IPR's system has to satisfy two opposite requirements:

-On one side and to incite to the innovation; the basic proposition is here that the pioneer must be rewarded and must enjoy, during a given period, the benefits of his efforts. This is why a "rent" is granted to him by the transfer of a monopoly for the exploitation of his(her) discoveries. This concerns the individual incentive to innovate, by rewarding the effort of the creator. But this type of provision has also a social cost, and has to be evaluated at the society considered as a whole. In the first section of this paper, we have recalled, how, since at least Arrow (1982)¹⁴, economic theory has established that the research activities if they are left to pure market mechanisms, end in sub-optimum investments. Thus, the point is perfectly clear: the innovator must be incited to enter into risky activities, and the pioneer must be protected.

- On the other side however, protection does not have to be excessive. If such is the case, the first mover, would be put in a position of blocking (more or less effectively and durably), the future progress of knowledge. Even worse, the progress of knowledge could rely only in his own discretion, depending on the pursuing of his strategic and commercial objectives. In case the progress of the knowledge can be made only by complex iterative processes, implying several actors who have alternately to lean on the "discoveries" of the previous creators (for example considering the fragmentation of division of labor and its high specialization in certain domains) *an excessive protection can nurture a strong slowing down or even even some stop of the progress of knowledge* In that case, the monopoly granted to the patent

¹⁴ On this issue see also among the most important contributions : Nelson 1959, Cohen et Levinthal 1989, Rosenberg 1990

holder, whilst rewarding the first mover, may play a negative role in the long run, by impeding instead of favoring the commitment of multiple actors in the production of knowledge and discoveries.

Between these two poles - often schematized, by saying that the one has to favor the prediction of knowledge, while the other one has to favor its diffusion, limit is narrow and the risk is high to fall over into dramatic imbalances. *Here the detail of the design of the provisions, as regards the nature and the extension of granted rights matters.* A system of provisions poorly balanced can lead to sub-optimal innovation trajectories and to situations of lock in of innovations processes opposed to those wished and aimed. More than ever in this domain "institutions matter".

Our feeling is that, to observe recent tendencies it seems that the impulses given to the American system were designed in a such a way that they have introduced some heavy uncertainties as regards the future of the system and its efficiency.

More precisely, one may analyze the contradictions at the heart of the new dynamics of the system by focusing on the three following points, which to our view, synthesize the key features on the changes introduced in the last two decades.

A) The extension of the patent eligibility to domains which were previously explicitly excluded from it

As we showed it, this extension was particularly clear in domains of the biotech and the software packages.

Here, the installation of the new regime was able to occur, only thanks to provisions specific to the American tradition (the "Common Law"), which allowed to erase the borders - fundamental in the other rights, (and notably in the European tradition) between "inventions" on one side, and "discovery" of the other (Orsi 2001). If such crossing of the border line, allowed to endow many American firms with particular specific assets, what made possible their spectacular entry in the stock market and related commercial activities, many problems still remain.

For what regards life sciences, the patenting of human genes raises serious ethical problems (cf. for instance the debate inside most of the European Academy of Sciences 1996) and the International Community remains on this point strongly divided. The USPTO - after a long battle - seems on the point to have converted to its sights his European partners: primarily the EPO (European Patent Office of Patents), and it seems today the European Commission itself. But in many countries (including naturally, in United States and in Europe) the point is still very controversial and disputed.

The opponents to the new doctrine are all the more active, as this new doctrine does not seem to offer the necessary guarantees if the process of innovation is considered in the long run, from the point of view of the social costs. So, even without taking into account any ethical consideration, the pharmaceutical firms themselves, while participating actively in the movement for the patentability of EST's and genes (by contributing to the financing of many companies involved in that field) have expressed often openly their doubts as regards the long term sustainability of the process. Considering the delays and risks of research activity in this domain (15 to 20 years are needed to conceive and introduce in the market a new medicine), the pharmaceutical firms are afraid of not being able to any more undertake in these long and

risky processes, if they have to pay royalties "upstream" : to acquire the right to use the relevant scientific information, risking to be blocked in the development of the settling of new therapies, if in the course of execution of their programs of research, they see each other forced to resort to the supplementary scientific knowledge covered by patents even though the access to this information (possessed by private firms) will be effective through the agreements of license, by the means of market mechanisms.

Aware of these problems, in a joint statement intended for the general public, Mrs Clinton and Blair believed to owe, to reassure the community of the researchers, to insure that the knowledge on genes would continue to be distributed freely. Let us just remind on this point that this statement having provoked a rough fall of the stock-exchange value of the genomic firms, it was at once followed by an announcement e of the USPTO, clarifying that the US doctrine US - based on the decisions of the Supreme Court - had been not at all modified, confirming, that in spite of Clinton's and Blair's statements, genes as in the past would continue to be covered by patents ! ... (Orsi 2001). Point, on which the US PTO cannot be contradicted. The Clinton-Blair declaration does not change anything to the state of the current right. For the moment, prevails and will continue to prevail, if it is not modified, the right to patent the human genes.

In the case of software packages and computer programs, if the ethical dimension is absent (or less visible), some of the economic problems related to the patentability of algorithms (and even, of systems of mathematical equations) are similar to those posed by the patentability of genes. One here has to remind that even a very simple computer program uses dozens of algorithms. From then on, if conflicts of properties had to appear between firms using these algorithms, firms and entire segments of the industry - beginning with the one installed around Internet - would be so threatened. Let us remind, for example that British Telecom filed an application for a patent regarding the uses of hypertext links!.

Thus, the way the extension of patents to new fields poses a number of threats and uncertainties for the future

B) Relaxation of the patentability conditions: can a patent be used as " hunting license "?

Another point which stands out the recent evolution of the American IPR's system is the relaxation of the criteria of patentability.

Quillen (1993) reminds us that this relaxation of criterion was made from three complementary axes. Under the title « *Diminished standards for patentability* » he writes « *virtually all commentators have agreed that the standard patentability in the US have been lowered in the past decade* ». He then observes that « *this have been brought by three concurrent changes in the US system (1) the relevance of non statutory factors for the determination of the non obviousness under 35 USC sec 103 (2) the scope of prior art regarded as relevant to the obvious /non obviousness issue ...(3) the presumption of validity* ».

In practice, these changes were largely influenced by the CAFC (cf. above section 1 of this paper). By providing their own interpretation of the body of texts governing intellectual property (even in some cases by interpreting in a very special ways some rulings of the

Supreme Court), they considerably loosened the traditional criteria of *obviousness* and reversed many decisions, even when the " *men of the art* ", experts of the USPTO had refused to grant licenses. The Courts of Appeal went as far as ruling in one of their decisions - which makes henceforth jurisprudence for them- that : « *man of ordinary skill in the art does not keep himself informed of developments in the arts pertinent to this work and that he is a literalist, devoid even the tiniest amount of imagination and creativity, and is totally unskilled at problem solving* » (quoted par Quillen 1993). Such a load against " the men of the art " can be explained by the fact that the CAFC often turned the criteria of "non obviousness" (considered by the law as " statutory ") to promote new principle of eligibility such as " the commercial success " of a product, considered *in posteriori as sufficient proof of novelty*.

The effects of this new doctrine are potentially devastating, and this could be shown at two levels:

i) Since patents are granted under very lax criteria they may produce an effect against that waited. The protection given becomes uncertain. Quillen (1993) summarizes sharply things when he notes that « *at the end of the day every one has more patents, and no one gains an advantage. All have found it necessary to incur higher costs* » (*idem*).

ii) Another effect of this relaxation of criteria, connected to the previous one, lies in the fact the granted protection being able to be disputed at any time by another holder of patents, there is an increase of conflicts between patents holders in domains close one from another.

Finally the effects of the new *situation is to higher the transaction costs and the risks associated to patent registrations*. This is the reason why, some theoretical models were able to establish that in case of sequential innovation, patents granted in a too lax way can strongly hinder the process of innovation (cf Bessen and Makin on 2000)

C) The question of the "penalties" on the imitators

The last change concerns the regime of financial repairs imposed on the imitators who put, illegally in circulation products protected by patents without paying the required royalties.

Until the 1980's, the prevailing doctrine was that of the "compensation" for losses undergone by the holders of patents. But here again the CAFC (leaning on certain rulings of the Supreme Court) modified the current doctrine. More than of a "*compensation*" it is a question henceforth of imposing a "*penalty*" on the imitators. What, in practice means that infringements imposed to the imitators does not aim any more only to return to them repairs of twist financiers undergone by the holder of patents, but to sanction and punish them heavily by very high amounts. The classic doctrine rested on two alternative options. The imitator had either *to compensate* « *the pecuniary loss of the patentee* » either pay « *a reasonable royalty* » . The CAFC is going to merge the two notions. The idea put foreword is « *to give the patentee more than he would have earned in the absence of the infringement and to treat the patent damages statute as punitive, not compensatory!* »... (Quillen 1993). An illustration of the new doctrine is presented by Quillen in his detailed presentation of the *Kodak vs Polaroid* case(cf. Quillen 1992)

As a consequence, this situation generates heavy risks for the firms which wish to operate as " *followers* " by proceeding to incremental innovations. The risk to be caught up and to be punished as abusive imitators (or even as pirates) became so strong that they can be dissuaded to enter into the innovation process.

3 ... Is a “finance driven” model of innovation sustainable ? the recent implosion of the speculative bubble on Nasdaq and its meaning

We had indicated that one of the key changes which occurred in the 1980's, is the very particular articulation (a real "alliance") that took place between financial markets and new innovative firms engaged on basic research. The erection of discoveries as specific intangible (though the IPR's granted to new firms), playing here a driving and often decisive role

If we considers things with some distances, we may notice that this alliance was at first very beneficial for these firms, as for the sectors where they operate (biotech, software ..). A large part of the so called " new economy " is grounded and rooted on this alliance. *Nasdaq so played a powerful accelerating role, amplifying the changes introduced during the 1980's, within the American NSI .*

Force nevertheless is to notice that the year 2000 marks a bend. If that year enjoyed an exceptionally strong increase of stock-exchange values, which saw the Nasdaq composite index, to cross the bar of 5000 points (after an increase of 70 % in 1999), 2000 is also going to stay as the year of the collapse of these same values : fallen again unless 2000 points. To say it in other words the financial Bubble formed on the stock market imploded, bringing a procession of locks, dismissals and drastic adjustments. *Thus the first impressive results of the finance driven model of innovation have to be re-evaluated.* It is now very unclear if such a model will prove itself to be capable of assuming the role of driving efficiently the research activities.

It is still too soon to envisage all the consequences of the new situation created by the implosion of the financial bubble on Nasdaq. But at least, these events provide some lessons concerning the artificial and fragile character of the type of growth which one attended during the last twenty years in some of the of high-tech domains analyzed in this paper.

Of course we don't know where the current period of financial instability, especially on the Nasdaq, is going to find its end. And the size of the slowing down - or of the recession - waited in United States, is not still predictable. But, and we wanted to indicate this point in conclusion, *this recent episode shows well that the future of the American NSI is by no means stabilized.*

Clearly the future still reserves some surprises. But this article will have filled its purpose, if it allows to throw some lights on phenomena highly complex and contradictory concerning the recent evolution of the American NSI.

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