Nanopatents and their impact on the medical environment

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SUMMARY

The nano-medical field is seen, by governments as well as the business sector, as a very promising one. The process of converting basic research in nanomedecine into commercially viable products has already begun, even if it might be long and difficult.

Part of the difficulties that could occur comes from regulatory and safety issues. Some of them are also coming from patent uncertainty in the global nanotechnology field. Indeed, the rush towards patents in the nanotechnology arena has already begun. Nanopatents are about to alter the legal landscape of the innovation economy, of research and development, and of industry – no doubt to an unprecedented extent because of the scope covered by these technologies.

From a global point of view, the very delineation of the scope of nanotechnologies confronts patent law with complex problems of definition. The emergence and characteristics of this technology are also giving rise to a reassessment of the criteria for patentability that could be prejudicial to innovation. In the medical environment, this issue is even exacerbated in the real challenges which pharmaceutical companies are running up against.

Key-words: Nanotechnology, Medicine, Science, Technology, Patents, Nanomedicine, Intellectual Property, Discovery, Social control over science, Fundamental research, Industrial research, Conflict of interest, Government financing, Drug industry, Safety, Entrepreneurship.

RÉSUMÉ

LES BREVETS EN NANOTECHNOLOGIE ET LEUR IMPACT SUR L'ENVIRONNEMENT MÉDICAL

Le domaine de la nanomédecine est perçu, par les pouvoirs publics comme par les industriels, comme très prometteur. Même s'il promet d'être long et difficile, le processus consistant à convertir les recherches fondamentales en produits commercialement viables est déjà lancé.

Les risques, toxicologiques comme juridiques, font partie des enjeux de ce développement. Les incertitudes concernant les brevets dans le domaine des nanotechnologies sont également en cause. Malgré ces risques, la course aux brevets est bel est bien lancée. Les nanobrevets sont même sur le point de porter atteinte aux fondements juridiques de l'économie de l'innovation, de la recherche et développement et de l'industrie dans une mesure jusqu'ici ignorée, du fait de l'immense variété des applications entrevues pour ces technologies.

De manière générale, le champ des nanotechnologies suscite des problèmes complexes de définition du champ de la brevetabilité. Le caractère émergent et générique de ces technologies entraîne également une extension de

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l'appréciation portée sur les critères de délivrance des brevets qui pourraient s'avérer préjudiciable, à terme, pour l'innovation dans son ensemble. Dans le domaine médical, ces problématiques sont, en outre, exacerbées par les challenges auxquels les grandes compagnies pharmaceutiques sont confrontées, à l'heure où la plupart de leurs brevets les plus lucratifs tombent dans le domaine public, pour maintenir leur position face à des concurrents nouvellement entrés dans l'arène.

Mots-clés : *Nanotechnologie, Médecine, Science, Technologie, Brevet, Nanomédecine, Droits de propriété intellectuelle, Découverte, Contrôle social de la science, Recherche fondamentale, Recherche industrielle, Conflit d'intérêts, Financement par le gouvernement, Industrie pharmaceutique, Sécurité sanitaire, Stratégie d'entreprise.*

In addition to the electronics area, one of the record impacts of nanotechnology is likely to take place in the interdisciplinary field of biotechnology and, of course, medicine. According to Robert Freitas, "*the early genesis of the concept of nanomedicine sprang from the visionary idea that tiny nanorobots and related machines could be designed, manufactured, and introduced into the human body to perform cellular repairs at the molecular level. Nanomedicine today has branched out in hundreds of different directions, each of them embodying the key insight that the ability to structure materials and devices at the molecular scale can bring enormous immediate benefits in the research and practice of medicine*[1]". The author foresees that although there will be a benefit in nanomedicine applications in the near future, the big step will be taken in the longer term.

The exploitation of improved and often novel physical, chemical and biological properties of materials at the nanometer scale to achieve breakthroughs in healthcare[2] is, however, already happening nowadays.

This field is seen, by governments as well as the business sector, as a very promising one, and the process of converting basic research in nanomedecine into commercially viable products has already begun, even if it might be long and difficult. Part of the difficulties that could occur comes from regulatory and safety issues. Some of them are also coming from patent uncertainty in the global nanotechnology field. Indeed, the rush towards patents in the nanotechnology arena has already begun. Like the gradual extensions of the realm of patentability initiated by the United States in the 1980s[3], nanopatents are about to alter the legal landscape of the innovation economy, of research and development, and of industry – no doubt to an unprecedented extent because of the scope covered by these technologies.

Any such race for patents will inevitably prompt departures from the norm, which will occur both at the core of the system of industrial property law, which has been in place since the French revolutionary times, at the end of the 18th century, and in its philosophy. In addition to the boundaries of matter that are crossed by nanotechnologies on the scientific and technological levels, other lines have surely been crossed as well – lines that are initially less obvious, but whose consequences may prove important over time. At a moment when the marketing of nanotechnology applications is only in its infancy[4], there is perhaps still time to consider the upheavals these technologies could cause in the patent system and, more broadly, the innovation economy.

From a global point of view, the very delineation of the scope of nanotechnologies confronts patent law with complex problems of definition. The emergence and characteristics of this technology are also giving rise to a reassessment of the criteria for patentability that could be prejudicial to innovation (This topic will

1. Robert A. Freitas Jr., What is nanomedicine?, *Nanomedicine: Nanotech. Biol. Med.* 1 (1): 2–9, 2005.
2. See Strategic Research Agenda Nanomedicine, November 2006. ftp://ftp.cordis.europa.eu/pub/ nanotechnology/docs/nanomedicine_bat_en.pdf
3. For an economic analysis of this trend and its consequences, see B. Coriat, "Le nouveau régime américain de la propriété intellectuelle. Contours et caractéristiques clés", *Revue d'économie Industrielle*, No. 99, 2nd quarter 2002, pp. 17ff.
4. For a catalogue of products already on the market, see the Internet site of the Woodrow Wilson International Center for Scholars (http://www.wilsoncenter.org/).

be explored in Section I). In the medical environment, this issue is even exacerbated in the real challenges which pharmaceutical companies are running up against (to be explored in Section II).

I. THE COMPLEX REALITY OF PATENTS IN THE NANOTECHNOLOGIES REALM

A. Nanotechnologies: from apparent unity to complex reality

The complex boundaries of nanotechnologies: Nanotechnologies are generally portrayed in mainstream articles and the most common definitions as having a number of characteristic traits. The first of these special features – their size – seems self-evident[5]. The second follows logically from the first, insofar as it would appear that, at the nanometric level, matter exhibits unique properties which constitute the appeal of this field of research[6]. But these technological elements carry a substantial cost. Material access to such scales entails massive investment in precision instrumentation[7]. The requirement for such a high level of basic capital outlay was not present in the earliest stages of biotechnologies, even if, there too, new tools had to be developed[8].

Government funding in this field rose to such record heights as soon as the technology emerged that the concept of return on investment became vital for the Member States of the European Union. Following the model of US science and technology policies from the Reagan era, the European Commission, beginning with the Lisbon summit, formulated a theory of competitive valuation of research which in nanotechnologies found an extensive arena for *in vivo* experimentation[9]. Such developments could not take place without consequences for the law governing patents of invention.

The thwarted boundaries of patent law: Patent applications for inventions in the realm of nanotechnologies are generally being filed at a very early stage[10], and across a very broad range of subject matter, and it would seem that in many instances their characterisation as inventions should be questioned. Logically, nanopatents feature the same characteristics as the subject matter they are meant to protect: blending fundamental and applied science, they upset the distinction that had been laid down between discoveries and inventions.

Despite the vigour with which it is being called into question[11], the subject matter of patent law continues, in many legal systems, to be inventions[12]. Because of this restriction on subject matter, standard-setting

5. Some authors, however, are openly critical of the omnipresent references to the scale of nanotechnologies in the usual definitions, which they consider far too rigid. See R. Bawa, "Patents and Nanomedicine", Future Medicine, *Nanomedicine* (2007), Vol. 2, No. 3, pp. 351-374.
6. The appearance, at this size, of quantal effects which were long only theorised and which are now becoming observable is but one of these edifying properties.
7. Including scanning tunnelling microscopes, but also atomic force microscopes.
8. See the contribution by V. Mangematin.
9. In this regard, the communication from the European Commission [COM(2004) 338] entitled "Towards a European Strategy for Nanotechnology" is unambiguous. See p. 16: *How can European industry capitalise upon our strength in nanoscience to realise wealth generating products and services? The ability to unlock the potential of this knowledge via nanotechnologies is crucial for giving new impetus to industries that are no longer competitive due to strong international competition, as well as cultivating new European knowledge-based industries*.
10. Mark Lemley even claims that patenting, in the United States in particular, has taken place at a far earlier stage than was the case for biotechnologies or information technologies. See M. A. Lemley, "Patenting Nanotechnology", *Stanford Law Review*, Vol. 58, January 2005, pp. 601ff. See, ETC Group, *"Second Nature" Patents: Implications for the Global South*, June 2005, *op. cit*.
11. On the notion of invention, departures therefrom, and an attempt at re-definition, see M. Vivant (dir.), *Protéger les inventions de demain*, INPI, "Propriété intellectuelle" collection, La documentation française, 2003.
12. This is, of course, the case in French law, where Article L. 611-10, par. 1 of the Intellectual Property Code (CPI) stipulates that "Patents may be granted to inventions ..." See also the European Patent Convention, Article 52 of which states that "European patents shall be granted for any inventions …", or the TRIPS Agreement, Article 27 of which applies to "any inventions, whether products or processes, in all fields of technology …" For its part, American law does not accord the same value to this notion. There, patents are categorised as utility patents, and, according to Title 35 U.S.C. 100, "the term 'invention' means invention or discovery". However, regarding the basis for the utility requirement and the distinction between products of nature and products of man, the United States Supreme Court until excluded scientific discoveries from the scope of patenting (see Brenner v. Manson, 383 U.S. 519, 1966). But this precedent has been mitigated in recent years due to the effects of biotechnology patents. See F. Orsi, "La constitution d'un nouveau droit de propriété intellectuelle sur le vivant aux États-Unis: Origine et signification économique d'un dépassement de frontière", *Revue d'économie industrielle*, No. 99, 2nd quarter 2002, pp. 65ff.

legislation generally excludes discoveries from the realm of patentability[13], although in most cases neither of these concepts is defined. The diacritical function of the notion of invention is justified, essentially, by other distinctions which make a patent a very particular tool. By setting invention, which is patentable, apart from discovery, which is not, patent law involves the difference between what exists and creation[14], between science and technology, or more precisely between fundamental science and the applications thereof. Pouillet put it eloquently: "patent law is written in the interest of industry and not in the interest of science"[15]. Consequently, even if the contours of the notions of invention and discovery can at times seem quite blurred, it is to this dichotomy that we believe one should refer to when seeking to reach the basics of the purpose of patent law.

It so happens that this is precisely one of the points that seem most difficult to put into practice with regard to nanopatents. As stated earlier, innovations in the realm of nanotechnologies exhibit quite distinctive characteristics, one of which is that they emanate fairly frequently from public research institutions[16], and, more generally, that they represent very fertile ground for collaboration not limited to scientific disciplines among themselves, but involving ever-closer association with competencies of a more technological nature[17].

Moreover, "bottom-up" nanotechnologies, which are considered the most promising, involve the manipulation of atomic-level building blocks of elements that in some cases exist in their natural state, but which nonetheless give rise to massive patenting as soon as the basic principles of the technology have been laid. This in itself is not a problem if the patents in fact cover only one or more specific technical applications of the elements in question. It would seem, however, that even under these circumstances the fuzzy boundary between the products discovered and their applications has at times been crossed. Examples of this, as cited by numerous authors[18] and reports[19], include patents already issued for carbon nanotubes, which are interesting also from a medical point of view, as we will see later.

B. Nanopatents: from the complexity of the subject matter to confusion over conditions

Other characteristics of nanotechnologies, including the fact that they are profoundly interdisciplinary and empowering, raise a number of problems with regard to conditions for patentability.

Nanometric-scale convergences: By their very essence, nanotechnologies would seem to be interdisciplinary. In addition, they are not merely an extension of miniaturisation and a top-down approach, but they are also building matter, atom by atom[20], in a bottom-up approach that is portrayed as revolutionary. This last characteristic stems from earlier development of new instruments whereby matter can be seen and

13. This exclusion is justified, as Professor Schmidt-Szalewski states so eloquently, by the fact that "while it would seem desirable to foster the development of fundamental research, the incentives should not take the form of monopolisation of the results. Such a solution would in fact lead to the issuance of 'patents of principle', covering all material achievements harnessing the scientific discovery; industrial development would be paralysed, thus thwarting the very technical progress that one seeks to promote." See J. Schmidt-Szalewski and J.-L. Pierre, *Droit de la propriété industrielle*, 4th edition, Litec, 2007, p. 38.
14. Above all, an invention is in fact a creation, *i.e.* something that before appearing did not exist. Along these lines, see P. Gaudrat, "Les démêlés intemporels d'un couple à succès, le créateur et l'investisseur", *RIDA*, October 2001, No. 190, p. 71; S. Lacour, "Le temps dans les propriétés intellectuelles", Litec, *Bibliothèque de droit de l'entreprise*, No. 65, 2004, pp. 27ff.
15. Pouillet, *Traité théorique et pratique des brevets d'invention*, Paris 1909, p. 13.
16. The proportion of patent applications to the EPO by public research institutions is very much higher in the field of nanotechnologies than in other areas. This holds true for the USPTO as well. Along these lines, see Masatura Igami and Teruo Okasaki, *Capturing Nanotechnology's Current State of Development via Analysis of Patents*, OECD, *op.cit*.
17. This finding has been asserted very often. See J.-L. Robert, "Les nanosciences, à l'intersection des sciences fondamentales et des technologies", *Annales des Mines, Réalités industrielles*, February 2004, pp. 16-21.
18. See V. K. A. Singh, *Intellectual Property in the Nanotechnology Economy*, article downloadable from http://www.nanoforum.org/; and G. I. Zekos, "Nanotechnology and Biotechnology Patents", *International Journal of Law and Information Technology*, 1 September 2006, p. 310, or M. A. Lemley, *Patenting Nanotechnology, op. cit*.
19. The report entitled rapport *Nanotech's "Second Nature" Patents: Implications for the Global South* by the ETC Group in 2005, is an especially abundant source of examples. (http://www.etcgroup.org)
20. A property that lent its name to the title of one of the brochures of the National Science and Technology Council of the United States, "Nanotechnology, Shaping the World Atom by Atom", in 1999.

manipulated on a nanometric scale. It is in fact central to the very concept of nanotechnologies[21].

It is perhaps these last two specifics of nanotechnologies that best characterise the radical change which they represent, and that cause previous trends to crystallise in an entirely new context. Here, the traditional borderlines between scientific disciplines are swept away in point of fact[22]. Biologists, chemists, electronics specialists, matter physicists, etc. all contribute in their own ways to discovery and innovation, and all seem isolated and less effective without input from other disciplines. This interdisciplinarity, linked *inter alia* to the fact that the elements manipulated, and the tools used to do it, are common to all because of the scales in question, can be found, like an echo, in the outcomes of research and in the resultant applications. The nanoworld is in fact a land of immense complexity which is to be found at the heart of one of the notions most frequently juxtaposed with nanotechnologies: technological convergence.

Moreover, nano-objects, emanating from an entirely new field, pose recurring problems involving the standardisation of technical vocabulary and determination of the state of the art into which applicants have leapt hastily, hoping to obtain very broad patents much more easily. Because of these characteristics, both the conditions of patentability and the subject of the law have given rise in the realm of nanotechnologies to a number of departures from standard procedure which I find unfortunate. Indeed, while satisfying the invention requirement can be problematic in the field of nanotechnologies, the least that could be said is that subject matter that clears this hurdle is still not exempt from the conditions of patentability as they emerge from most of the relevant standards. Thus, to be patented, an invention must be new, it must have involved an inventive step and it must be suitable for some industrial application[23].

Strains on the conditions for patentability: The first of these difficulties, which results from the industrial-application criterion, the slight separation of science and its applications within nanotechnology[24]. Caught by the speed at which this area of science and technology is developing, and under pressure from government agencies impatient for results on the international economic scene to protect the fruits of their efforts, people applying for patents of invention are in many cases still at a stage in the development of the subject of their application at which it is extremely difficult to project any actual technical applications or to get past the stage of what some authors do not hesitate to categorise as abstract ideas[25].

The two other conditions for patentability – novelty and an inventive step – entail a comparison of the invention with what is known as the state of the art. This state of the art may be defined, broadly[26], as the sum total of knowledge in the public domain before the patent application was filed, *i.e.* the invention's prior art. But such a comparison obviously entails knowing the state of the art, which can prove difficult in fields in which the technology in question is recent and complex. Such is the case for nanotechnologies.

Moreover, the difficulty in ascertaining the relevant state of the art is compounded by another complexity. Many of the inventions emerging from

21. See National Consultative Ethics Committee for Health and Life Sciences, Opinion No. 96, *Ethical Issues Raised by Nanosciences, Nanotechnologies and Health*, available on the CCNE website (http://www.ccne-ethique.fr/docs/en/avis096.pdf). See also, highlighting the fundamental nature of instrumentation in the development and characterisation of nanotechnologies, J.-P. Dupuy and F. Roure, *Les nanotechnologies, éthique et prospective industrielle*, published by Conseil Général des Mines and Conseil Général des Technologies de l'Information, 15 November 2004, available in French only at:
http://www.cgm.org/themes/deveco/develop/nanofinal.pdf
22. The elements demonstrating this interdisciplinary nature are complex. They involve both a necessity, in some realms, and a development programme that comes closer to the notion of technological convergence. However, an additional item of proof is suggested by A. Hullmann, who analyses the periodicals in which articles on nanotechnologies are most frequently cited. The result of this analysis is that the most general-purpose, the most multi-disciplinary publications, *Nature* and *Science*, lead the pack in this area. See A. Hullmann, *The economic development of nanotechnology - An indicators-based analysis*, Commission staff working paper, 28 November 2006, especially page 34. May be downloaded from http://cordis.europa.eu/.
23. Article L. 611-10 CPI, but these conditions also apply at the European level (Article 52 of the Munich Convention of 5 October 1973) and, more broadly, they also appear in Article 27 of the so-called TRIPS agreement (Marrakesh Agreement of 15 April 1994) whereby the World Trade Organization governs intellectual property rights.
24. Meaning slight time lag. See Masatura Igami and Teruo Okasaki, *Capturing Nanotechnology's Current State of Development via Analysis of Patents, op. cit.*
25. G. I. Zekos, "Patenting Abstract Ideas in Nanotechnology", *The Journal of World Intellectual Property* (2006), Vol. 9, No. 1, pp. 113-136.
26. In French law, the definition is laid down in Article L. 611-11 CPI and is somewhat different, depending on whether the focus is on novelty or inventive step.

nanotechnologies are interdisciplinary, but to determine whether the inventive-step and non-obvious conditions are met entails assessing the presumed knowledge of the person skilled in the art[27]. But which person, skilled in which art? Obviously, the issue of determining the qualifications expected of this person is not unknown to specialists in patent law. Case law even offers multiple examples on the subject. The EPO, for instance, has agreed that the person skilled in the art may, so to speak, be plural, consisting of a team rather than a single individual[28], but this approach would seem to be challenged by the Cour de Cassation, which has ruled that "the person skilled in the art is the one who possesses the usual knowledge of the art in question and is capable, drawing on his expert knowledge alone, to devise the solution to the problem that the invention proposes to solve"[29]. Here, we must confess that in the realm of nanotechnologies, such a person is likely to be a rare find indeed! How could any single individual possess the basic knowledge needed to create interdisciplinary teams as extensive as those that were necessary, for example, to develop a DNA biochip: biologists, medical doctors, physicists, electronics engineers – none of whom is superfluous and each of whom is fully part of the necessary synergy of talent?

Apart from this quite "singular" skilled person, there are other factors that may raise problems when any given definition is held up against the reality of nanotechnologies. One of them is the fact that this skilled person is reputed to be merely an average technician in the field, whose knowledge, according to a 1994 ruling by the district court of Paris, could be categorised as "acquired and unchallengeable facts of knowledge"[30], which is problematic in an emerging field in which university textbooks are far from constituting the majority of available sources. Likewise, it may be difficult, in judging inventions in the field in question, to ascertain the skill of the skilled person. As enabling technologies, nanotechnologies can cause upheavals in the boundaries of a large number of fields at the same time. A single invention can then solve technical problems in a multiplicity of industrial disciplines. If one tries to hold that reality up against the definition of the skilled person as a member of the industrial discipline in which the technical problem that the invention seeks to solve arises, it can be readily seen that this reality may be a source of intense dispute[31].

Lastly, these findings are heightened by two practical considerations, the importance of which is undeniable. The first is the time allotted for examining patent applications by the examiner(s) of the office in question. Here, the EPO can be cited as a model, and the quality of its examination process is frequently praised. Some other offices, however – and by no means the least amongst such offices, since they include the USPTO – exhibit greater difficulties. At the USPTO, during the two, if not two and a half, years that it takes for the average application to be examined, examiners will in fact actually work on it for about 18 hours[32]. If one factors in the increasingly condemned flight of patent examiners to more highly-paying businesses once they are properly trained in the examination of applications as complex as those involving nanotechnologies, the first practical barrier turns out to be a substantial one.

The second practical consideration is even more sensitive, and more specific to the field of nanotechnologies. Comparing an invention to the state of the art requires that the description of that state in the patent application and supporting arguments meet certain criteria. The first of these involves the vocabulary that is used. Examiners are not equally familiar with all languages. This is undoubtedly even more the case if a field of knowledge is very recent, and if its own vocabulary has not yet taken shape[33]. These semantic variations have repercussions in patent law, one of the major strengths of which they paralyse by mitigating the effects of the review of past art. There can be no doubt that they also result in partial blockage of the patent's unveiling effect. What will be the

27. Article L. 611-14 CPI.
28. See also EPO Directives, Part C, Chapter IV, 11.3, "There may be instances where it is more appropriate to think in terms of a group of persons, *e.g.* a research or production team, than a single person." The Office has repeatedly confirmed this interpretation in its decisions. See, *inter alia*, EPO, Technical Board of Appeal, 31 August 1990, No. T 60/89: *OJ EPO*, p. 268. For further discussion of EPO case law see *Case Law of the Boards of Appeal of the EPO*, 5th edition, December 2006, Legal Research Service of the Boards of Appeal, esp. p. 136.
29. Cass. com., 7 October 1995, Ann. Propr. Ind. 1996. 5.
30. TGI Paris, 16 November 1994: PIBD 1995, III, p. 115.
31. As noted by the authors of notes to the Intellectual Property Code published by Dalloz, the inventive step criterion, because of the subtlety and complexity of the analyses it prompts, is a prime source of legal disputes. It can safely be wagered that nanopatents, when they start to be the subject of lawsuits, will be no exception.
32. See M. A. Lemley and C. Shapiro, "Probabilistic Patents", *Journal of Economic Perspectives*, Vol. 19, No. 2, Spring 2005, p. 75698.
33. See M. Berger, *Growing Nanotechnology Problems: Navigating the Patent Labyrinth*, on www.nanowerk.com

informational value of the contents of a patent that cannot be found because it is classified incorrectly due to dubious vocabulary?

Such effects are unfortunate, especially for stakeholders in the system themselves, be they in science or industry. A patent issued wrongly, or too broadly, offers none of the promised advantages to the community in terms of increasing scientific knowledge, and it may also, for others, block the marketing of certain products or promising research[34].

II. THE NANOPATENTS IMPACTS ON MEDICAL ENVIRONMENT

Nanotechnology promises to have a profound impact on health care and medicine. The application of nanoscale technologies to the practice of medicine (diagnosis, prevention, and treatment of disease) is expected to move forward through advances in delivering nanotherapies, miniaturization of analytic tools and improved computational and memory capabilities. According to Raj Bawa, a very well known expert in the field, "*nanomedicine has many applications in drug delivery, diagnosis, detection, discovery, sensing, imaging, devices, etc. […] Pharmaceuticals, biotech and life science operations will continue to benefit from the ongoing research in nanopharmacy because it has the ability to enhance the delivery and effectiveness of traditional drugs*[35]." Patent uncertainty (A) and contradictory business strategies (B) will certainly have a significant impact in this field.

A. The impact of patent uncertainty on medical environment

Although nanotechnology enabled pharmaceuticals will eventually be an integral part of modern medicine, their path is paved with patent uncertainty, according to some experts[36]. This uncertainty in the field of medicine and pharmaceuticals mainly comes from some of the issues we have already examined in the previous description of the nanopatents landscape. Nanopharmaceutical and nanomedicine R&D is mainly coming out the public sector and the pressure on researchers to patent as soon and broadly as possible seems very high.

A public funded and fully patented research: Reaching front and centre on the scientific, technical and media stage after information technologies and biotechnologies, the rise of nanotechnologies illustrates trends that these other forms of technology had already triggered. A number of major trends in science and technology policies that could be considered specific to nanotechnologies, such as massive investment by government and public institutions or strong incentives to steer research towards concrete applications and industrial partnerships, also stem from earlier trends, even if here they are reaching pinnacles.

Back in the 1980s, the United States paved the way for a new form of funding for public-sector research by promoting the use of patents of invention by public research bodies, and thus a more applications-oriented slant to their research[37]. A similar drive was underway in Europe, in particular through Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions. The change spurred by this directive in the relationships between fundamental and applied science had already been flagged by the doctrine even before its transposition into French law. From that point onward, the boundaries were more blurred between public and private research, and between fundamental and applied research[38]. Nanotechnologies are not set apart from these trends – quite the opposite, since their special features help accentuate the trends. In 2005, some experts predicted that "*the Bayh-Dole Act [would] assist nanomedicine related companies in the way it helped biotechnology startups: by liberalizing the transfer of university-owned patents funded by government grants*.[39]"

34. See Zaki Laïdi, "La propriété intellectuelle à l'âge de l'économie du savoir", *Esprit*, 11 November 2003.
35. R. Bawa, S. R. Bawa, S. B. Maebius, T. Flynn, C. Wei, "Protecting new ideas and inventions in nanomedecine with patents", Nanomedecine: nanotechnology, Biology, and Medecine 1 (2005), p. 150-158.
36. See "Nanopharmaceuticals, Patenting Issues and FDA Regulatory Challenges", by R. Bawa, S. Malethil, W. J. Simmons and D. Harris, Published in the SciTech Lawyer, Volume 5, Number 2, Fall 2008.
37. For more information on this trend, initiated by the Bayh Dole Act of 1980 in the United States, see the OECD report "Patents and Innovation: Trends and Policy Challenges", 2004, available at http://www.oecd.org/dataoecd/48/12/24508541.pdf, and especially pp. 19ff.
38. See J.-C. Galloux, *La transposition en droit français de la directive 98/44 du 6 juillet 1998 relative à la protection juridique des inventions biotechnologiques*, AFRI 2003, Vol. IV, pp. 893ff.
39. R. Bawa, S. R. Bawa, S. B. Maebius, T. Flynn, C. Wei, "Protecting new ideas and inventions in nanomedecine with patents", prec.

The nanotechnology related pharmaceutical and medical landscape in particular strongly illustrates this. According to the ETC Group report on nanomedicine[40], "*governments, not corporations, are so far taking the lead in nanomedicine R&D. Of the estimated $1.6 billion devoted to nanotech R&D related to life sciences in 2005, a paltry 8% came from industry*[41]." Those trends have certainly fostered biotech expansion since the end of the 20th century. It also had a very high impact on the field of patentability, opening the patent system to a very large range of objects, which were previously excluded. The risk of unwarranted patenting is accentuated by the prevalence in this areas of interdisciplinary research, while patent examiners in the field of pharmaceuticals are often more specialized and therefore limited in the number of disciplines (scientific and technological) with which they are familiar. Thus, novelty and inventive step can be more difficult to assess in this particular field, as some examples can already show.

Delineating the scope of protection can be problematic in the field of nanotechnology. As many authors point out, the terminology in this emerging field is in fact very much in a state of flux, and patent examiners are in many cases still hesitant because of the technology's extremely wide range. As Raj Bawa[42] points out, in the applications filed to protect multi-walled carbon nanotubes, the subject matter has been referred to as "nanofibres" and "nanotubes", as well as "fibrils". Likewise, the expressions "single-shelled nanocylinders", "buckytubes" and "nanowires" have been used to describe single-walled carbon nanotubes. One can very readily imagine that such variations in vocabulary cause prohibitive problems for the examiners of the patents in question.

Indeed, it is not just a single patent that has been issued on the building blocks of this technology, but a very large number of patents, which very surely overlap and may give rise to major disputes. Such a risk is already known to economists and has been modelled under the name of "the tragedy of the anticommons", which has been shown repeatedly to be detrimental to the paramount goal of patents, by causing a paralysis of innovation[43]. One can thus only regret the absence of serious consideration, earlier in the process, in the specification of what a patent can and should cover[44], as an instrument of social well-being[45], if one believes that patents should continue to play their proper role in the innovation economy.

A very competitive field: With the current patent expiries on numerous "blockbuster" drugs and the development of generics industries, large pharmaceutical companies are searching for new competitive business strategies.

Some solutions have already been tested in the nanopharmaceutical field, with a view to changing this situation. Indeed, "*Analysts note that nanotechnology enabled drugs will play a role in securing and extending exclusive monopoly patents on existing drug compounds".*[46] This solution could be adopted by Big Pharma if novel reformulations at the nano-scale could allow an existing compound to qualify as a New Chemical Entity. "*This may increase profitability, expand a firm's intellectual property estate, and discourage competition during a drug's most valuable years*".

Developing countries do also have a role to play in the field. Some first examples of such strategies are already happening in China, were, according to the ETC Group report on nanopatents[47], lives the largest single holder of nanotechnology patents in the world. "*He is a Chinese researcher, Yang Mengjun, who is taking ancient Chinese medicinal herbs, reducing them to nano-scale formulations, and claiming exclusive*

40. *Nanotech Rx, Medical applications of Nano-scale technologies: What Impact on Marginalized communities?*, ETC Group, September 12, 2006, p. 6.
41. Lux Research Inc., 2006 reference study, *The Nanotech Report*, 4th Edition. The figures attributed to Lux, cited in the following paragraphs, are from this study, www. luxresearchinc.com.
42. Raj Bawa, "Patents and Nanomedicine", Future Medicine, *Nanomedicine* (2007), No. 2, Vol. 3, pp. 351- 374.
43. See C. Shapiro, "Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard-setting", Conference on Innovation Policy and the Economy, p.1, March 2001. The tragedy of the anticommons was modelled in respect of patents on biomedical research in 1998 by M. A. Heller and R. S. Eisenberg, ("Can Patents Deter Innovation? The Anticommons in Biomedical Research", *Science*, Vol. 280, No. 5364, 1 May 1998).
44. On this question, and on the need to raise it whenever a new, still largely unknown, technology enters into the scope of patenting, see R. Eisenberg, "Analyse This: A Law and Economics Agenda for the Patent System", *Vanderbilt Law Review*, Vol.53, No. 6, 2000.
45. V. Benjamin Coriat, "Le nouveau régime américain de la propriété intellectuelle. Contours et caractéristiques clés", *Revue d'économie industrielle*, No. 99, 2nd quarter 2002, pp. 17ff.
46. *Nanotech Rx, Medical applications of Nano-scale technologies: What Impact on Marginalized communities?*, ETC Group, September 12, 2006, p. 27.
47. *Nanotech's "Second Nature" Patents: Implications for the Global South*, prec.

monopoly over the herbs or the process used to nano-size them. He holds over 900 patents on nanoscale versions of traditional Chinese medicinal plants[48]."

These example are amplifying the trend of poor and broad patents, and the creation of a chaotic patent landscape, were competing players are unsure as to the validity and enforceability of numerous issued patents.

On the other hand, Big Pharma is also tempted by the *status quo*. Innovative therapies are, apparently, half as important in their budgets as promotion[49] and they fear that health and drugs agencies, like AFSSAPS[50] in France or the FDA in USA, might change their regulatory and safety guidelines for therapeutic nanoparticles, according to their environmental, health and societal implications. "*While the majority of Fortune 500 companies are investing in nanotech R&D, in the life sciences sector, the major pharmaceutical companies have taken a wait-and-see attitude – an approach reminiscent of the early days of biotech. Big pharma is collaborating with nanobio startups, but since nanotech is still an unproven technology […], the major drug companies haven't made big investments yet.*[51]"

This strategy is highly constructed. Indeed, when an invention is patented regardless of its scope or quality, , the recipient is conferred the temporary right to exclude others from making, using , selling, offering for sale or importing the invention into the country he claimed for, for up to 20 years from the filing date. At the same time, however, it is solely up to him to protect or enforce the patent, at his own cost. Thus, regarding the particular situation of nanomedicine, several scenarios are conceivable:

– National agencies for health and drugs could put a very restrictive safety regulation in place, which could keep those inventions out of the competition, thereof Big Pharmas would prefer to be safe;

– If regulatory and safety issues stayed like they are today, patents will be another issue, a lot of patents have been filled in the area by start-ups and the public sector, but Big Pharma will still get a chance to exploit those inventions, through an aggressive licensing strategy, grounded on the uncertainty of their scopes and objects, their probable overlapping and on the deterrent judicial strength they represent.

In both cases, thus, the wait-and-see attitude Big Pharma companies are adopting for the moment can be a winning one in the traditional pharmaceuticals arena. But another gap is more specific to nanopharmacy. Such companies are used to relying on some very specific business strategies, which could be greatly improved through the arrival of other actors in the field.

B. The hazardous exploitation of patents in the medical environment

Nanotechnology's specific nature could have another effect on the medical, and mostly the pharmaceutical, environment. This technological field, indeed, is very distinct from the one companies are used to operating. Nanomedical inventions are arising from the application of technologies that have already been in use in physics or materials science. According to Miss van Velzen, who is working as an IP counsel at Philips Intellectual Property and Standards, "*this convergence of fields can be seen from the names of the patent applicants. Applicants come from a first category including pharma, medical diagnosis companies and biotech companies […]. A second category contains companies that have experience in the electronics industry*[52]*",* like Samsung, Siemens, Motorola or Philips.

Yet, with these two categories of companies, two ways of doing business will have to find a new strategy. The "wait-and-see" Big Pharma strategy is very well adapted in a field where patents are relatively few. These patents are actually used to create a certain term of exclusivity for the owner, during which timehe can set a high price for the protected product, with the aim of regaining the money invested in the development of the product. The time required and

48. To view a sample of the patents, go to: http://v3.espacenet.com/results?sf=a&CY=ep&LG=en&DB=EPODOC&TI=&AB=nano&PN=&AP=&PR=&PD=&PA=&IN=Yang+Mengjun&EC=&IC=&PGS=10&FIRST=31
49. See M.-A. Gagnon & J. Lexchin, The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States, 5 PLOS MED. 29 (2008).
50. Namely « *Agence Française de Sécurité Sanitaire des Produits de Santé* », french agency for health and drugs.
51. 2006 Nanomedicine, Device and Diagnostic Report, from the publisher of NanoBiotech News, 2006, p. 4.
52. M. M. van Velzen, *IP in nanomedicine – Perspective from an IP professional in industry*, World Patent Information 30 (2008) 294-299, p. 295.

the high risks linked with the development of a single molecule which can be exploited are the main explanations for this culture currently. Companies, like those in Big Pharma, which have shoulders wide enough to use infringement procedures to put the pressure on their competitors (usually start-ups), can base their strategy on waiting until this risky time is over and, thereafter try to obtain a quite cheap license of the final endproduct.

The electronics business landscape is very different. Here there are usually a lot of patents, covering the different features of such products. Competitors often exchange their patents, thereby facilitating access to the markets, which are mainly driven by standardization. Patents pools and cross licensing phenomena are usual, which can offer some good solutions to overlapping situations.

How will those two cultures create a new market field? Miss van Velzen seems positive, regarding to this issue, even if she notes that no one knows, yet, which types of cooperation and dealings with patent licensing will occur in the new market field of nanomedicine. Will Big Pharma's strategy be effective? This second question is even more complicated to answer. They seem to gamble on an imbalanced market field, where they would, once again, win the challenge. But the other players won't give in without a fight.

One can, at least, regret the absence of serious consideration, earlier in the process, to specify what a patent can and should cover[53], as an instrument of social well-being[54], if one believes that patents should continue to play their proper role in the innovation economy and, maybe, play a better role in the future humanity's health. ■

53. On this question, and on the need to raise it whenever a new, still largely unknown, technology enters into the scope of patenting, see R. Eisenberg, "Analyse This: A Law and Economics Agenda for the Patent System", *Vanderbilt Law Review*, Vol.53, No. 6, 2000.

54. V. Benjamin Coriat, "Le nouveau régime américain de la propriété intellectuelle. Contours et caractéristiques clés", *Revue d'économie industrielle*, No. 99, 2nd quarter 2002, pp. 17ff.