Chapter 14
Emerging Questions for Emerging Technologies: Is There a Law for the Nano?

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Nanotechnologies are a rapidly growing field of researches and applications. Their interdisciplinary scope, as well as the wide range of products they permit, qualified them, early, as enabling or general purpose technologies [1]. Almost all the fields of social life, from research, innovation, work safety, health, consumption, etc., to waste treatment, are, thus, affected by their development. These fields are already framed by legal norms. Thus, a rapid answer to the question we have raised might be, yes, there is plenty of law for the Nano [2].

However, as everyone can observe, this answer needs to be tempered. Indeed, if scientific and technological activities and attainments must logically be integrated into the existing legal and, broadly, normalized frameworks, it must also be raised that these should also be re-evaluated in view of the specificities that the emerging technologies are bringing about. This is not too easy, because of the intrinsic complexity of nanotechnologies as well as of the normative framework.

On the one hand, grouping activities and objects arbitrarily merely, according to physical dimension in the order of nanometers, nanotechnologies are still emerging in many ways, whereas some of their concrete application are already flooding the market and are having a concrete impact on health and environment as well as also on worker's and consumer's life.

In order to consider the social impacts of this complex reality, looking at laws is not sufficient. Confronted with a very broad and heterogeneous emerging field on the other hand, the normative landscape appears to be destabilized and fragmented and numerous other norms are challenging the legal system so as to give an appropriate framework to the "nanoworld".

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In the nano-arena, knowledge is still under construction and the uncertainties that society has to deal with are outstripping health and environmental issues to reach the social behavior of various scientific and technological stakeholders. Working on the existing normative frameworks and looking at those which are especially built in order to foster the responsible development of nanotechnologies can help the development of knowledge on uncertainty and of complexity framing, both applied to the nano-arena and extended to future emerging technologies issues.

Indeed, nanotechnology is unique and complex enough to challenge the usual normative frameworks for emerging technologies (I); their study could make sense in future scientific and technological contexts (II).

14.1 The Complexity of Nanotechnology as a Normative Challenge

Nanotechnology is obviously a complex field of study, assuming that complexity is a "web of heterogeneous components inseparably associated" [3]. Spearhead of European scientific and technological policies, the research it generates is multifaceted. Often described as inherently interdisciplinary and highly applied, definitions similar to those given to technosciences [4], the areas of investigation it includes are, in fact, far more diverse, ranging from the most basic research in small disciplinary fields to large interdisciplinary cooperation and applications. Applications, existing or planned, are also extremely varied.

Faced with such profusion, one of the first issues the regulation has to deal with is, of course, that of the concepts, which should allow the development of a relevant normative framework for each stage of the life cycle of nanotechnology (Sect. 14.1.1). In addition, the whish not to make in nanotechnology the same mistakes as those that have delayed the development of biotechnology, is pushing public authorities to promote a responsible development of nanotechnologies (Sect. 14.1.2).

14.1.1 The Central Challenge of Concepts

What is nanotechnology? Is this world designed well enough to understand and forge a critical view of the present regulating trends or is it just a portmanteau word [5], fashioned in the 1990s in order to foster broadly the development of researches and which should now be replaced by more accurate and defined concepts? A careful examination of scientific and technological policies on nanotechnology that have been published, worldwide, can help to measure the evolution undergone by the concepts used, despite their relative youth (Sect. 14.1.1.1). The continued use, by all stakeholders, of a common lexical field, built

on the prefix "*nano*", does not mean that the significance of these concepts is now stabilized. Furthermore, it raises questions about the ability of the public authorities to impose more stringent standards for the management of these technologies (Sect. 14.1.1.2).

14.1.1.1 The evolution of Concepts: From Nanotechnology to the French "Substances in a Nanoparticulate State"

The same trend can be noted in the various documents which have been published by public authorities, both French and European. According to a meta-analysis type of approach, nanotechnologies have gradually come to encompass problems involving health and the environment (nanoparticles and nanomaterials), problems inherent to funding research (nanosciences, nanotechnologies, nanosystems), and sometimes more specific queries about the industrial strategies to be adopted (nanoproducts). It is therefore noteworthy that, starting with a very wide-reaching definition "nanosciences and nanotechnologies" in 2004, the European Commission progressively reduced its field of intervention to nanoparticles and nanomaterials in the years following the enactment of its plan of action.

Such a trend can be seen in the first 2007 report on the plan of action because it includes a clause intending to specify the precise scope of the immediate concerns of the Union: "While N&N offer a number of beneficial applications, the potential impact on the environment and human health of certain "nanomaterials" and "nanoproducts" is not yet fully understood" [6].

The terminological turning point was confirmed a year later. Directed to list the regulatory texts applicable to nanotechnological development, the European Commission chose to restrict its inventory to texts that were capable of regulating nanomaterials [7]. In 2009, the distribution of areas of competency was clearly and definitively established on a European level. Indeed, the second report on the implementation of European strategy for nanosciences and nanotechnologies does states that it requires "[…] deepening the research efforts and roadmaps for key nanotechnology sectors, to enhance innovation and competitiveness. This is considered inseparable from advancing fundamental understanding of how nanomaterials throughout their life cycle interact with living organisms, to ensure a high safety level and protection of human health and the environment." [8].

However, the European Parliament, known for its very critical view of the Commission's position on nanotechnology development, did not pick up on this subtle change in the definition of the interventive scope [9]. By recentering the definition efforts, *per se,* on the term nanomaterials, the European Commission seems to be enacting this exclusion or, at the very least, to endorse a new distribution of roles among public authorities—those responsible for protecting health and the environment in terms of nanomaterials—and the scientific authorities—in charge of supervising more freely nanotechnological development. The French position, denoted by the seemingly original word choice of 'substances in a nanoparticulate state', seems to be following the same direction, even if the shift is less marked.

Such a change in vocabulary is nothing new. Similar adjustments in the socially competent arenas of public and scientific powers have already been investigated in the past, through the concepts of "science" and "trans-science", or through "risk assessment" and "risk management", as detailed in Sheila Jasanoff's work [10]. This type of dissociation does not clarify the contents of the various fields targeted, but its immediate effect is to remove certain stakeholders from sectors where specific regulations are being considered.

14.1.1.2 Definitions as an Entire Issue

Although we perhaps tend to perceive them as self-evident, or as having an obvious technological or scientific basis, definitions are truly the products of human activity. They are social constructions, meaning that they arise from concrete actions, from operations on language and from transactions, before possible institutional acceptance. In the nano-arena, as we saw, the activity of giving names to the concepts was crucial, but even when the issue is limited to nanomaterials, it still seems difficult to construct an appropriate regulation, as it is illustrated by the current debates surrounding their definition.

The first and main question to be solved is certainly the need of definition. A positive answer was expectable in the context of the European Union, both because of its regulative traditions—usually based on opening lists of definitions, created to insure a proper interpretation of the main concepts in various existing cultural and legal national frames—and because of the increasing role of this question in the current balance of power between the European Commission and the European Parliament [9]. It also occurred, more surprisingly, in the particular French context, where, the "substances in a nanoparticulate state", being neither a scientific concept nor a legal concept, the Parliament was free to define them as it chose or even to refuse to enter in the vicious circle of their definition.

An international echo of this controversy can be found in the exchanges between Andrew D. Maynard [11] and Hermann Stamm published in "Nature" last summer [12]. Even if the controversy between them can be seen as the expression of their position facing the challenge of choosing a precise type of regulation rather than concerning the need of definition, the manner they are taking issue is indicative of the trouble that it raises.

Several elements contribute to create a particularly difficult and perhaps insoluble problem of definition, whether it applies, as in the European Union, to nanomaterials, or, as in France, to the "substances in a nanoparticulate state".

First, because the policy makers lack a reliable census of nanomaterials, to begin their work, they are forced to make this census. This constraint leads to a vicious circle in which they get lost. Searching for nanomaterials requires distinguishing them from all other types of materials or chemicals, otherwise their proposed legal status and, hence, the rules of law attached to it, would lose their effectiveness. To distinguish them from other types of materials, it seems necessary to determine what makes them unique, while having a relatively accurate idea

of what is research and technical means that could easily circumvent the rules. Furthermore, at the request of public authorities, which are overwhelmed by the highly technical nature of the case in the particular field of nanomaterials [13], scientific considerations are perhaps considered more than elsewhere. Anticipating the fact that regulation is intended to protect health and environment, experts are naturally seeking the limits of the proposed definition, by inference, in the characteristics of nanomaterials which are known as likely to cause health or environmental dangers. But the existing knowledge on the characterization's needs to understand better the nanomaterials and their dangers and, thus, the existing knowledge on the risks associated with nanomaterials are still very fragmentary [14]. The proposed definition, despite its apparent scientific nature, will thus necessarily be arbitrary and will not satisfy all those concerned. The purpose of the regulation is not here, at least initially, to supervise the development of known objects, but at the very least to understand them, it might be prudent to avoid excessive zeal in the definitions.

Whether in Europe, where the question of the definition of nanomaterials has been raised as a preliminary to a major regulatory intervention by the European Commission [15], or in France, which only arrived at a later stage—after "Grenelle's Acts" that laid down the outline of the legal regime that will now apply to substances in the nanoparticle state—the results are disappointing. The failure is clear. Yet, Parliament was free to define them as it pleased, if not to define them at all, leaving to legal scholars and, ultimately, judges, the burden of doing so. Such a practice is, by no means, foreign to our regulatory system, at least in France. The terminological or partially normative definition [16], which are understood as accessory statements, do not meet to the usual frame of French law, which usually conforms to the injunctions of Portalis, that "the office of the law is […] to establish principles […], and not go into detail on issues that may arise on every subject" [17].

The need to define, nevertheless, is exposed to criticism and the result reflects the ambiguity of the interface, between law, science, and technology, which seems to ignore the fact that the rule will be subject to interpretation. The apparent technical nature of the chosen definition does not resolve, far from it, all the questions that may arise in the application of the text.

The very real difficulties encountered in attempts to define the subject of a regulation of nanomaterials testify the difficulties the governments faces in implementing their commitment to the promotion of the responsible development of nanotechnology.

14.1.2 The Responsible Development of Complex Technologies

In the regulation of nanotechnology, the legal fiction of the gradual adaptation of an existing framework is certainly insufficient. The difficulties met in the adoption

of an appropriate definition are an illustration of the gaps still existing in the texts of law. Rapid changes in the technologies surrounding nanoscale undoubtedly calls for the implementation of a framework reflecting them [18], able of rapid adaptation. This framework must also take careful not to undermine the foundations of non-stabilized economic developments, which appear to be promising. The renewed mistrust of our society in front of the scientific and technological progress is, finally, a factor, not to be disregarded.

All these specificities remove the desired framework for the development of nanotechnology from the legal positivist utopia set out by Hans Kelsen. They seem to be more flexible and renewed forms of regulation, than what is sometimes called more modern governance [19]. The same is true of the evolution of scientific research. Its current models are far from the ivory tower of Merton [20]. In the words of Sheila Jasanoff [21], they must avoid the drift toward a form of sequestration of knowledge that would be detrimental to all society. All these complex issues are essential premises for the responsible development of nanotechnology, a goal that is highlighted by public authorities (1). Its implementation, especially through public debate (2) is probably insufficient.

14.1.2.1 Responsible Development as a Leitmotiv

The concept of responsible development is central to the terminology that accompanies the plans and strategies which have been published in the field of nanotechnology. It is true in France, where it can be found in the Committee of precaution and prevention report, in 2006 [22], but also in the opinion of the Economic and Social Council in 2008 [23] and in the report of the National Consumption Council in 2010 [24]. This concept is also applied to the particular case of scientific research, according the opinion that the Ethics Committee of Sciences of the CNRS, published in 2006 [25]. The whish to promote responsible development of nanotechnology is thus emerging as one of the reasons that have led authorities to organize a national public debate on the issue, in France, in 2009 and 2010 [26].

The concept also appears in the literature of other European countries such as United Kingdom, where the Royal Academy of Sciences was the first, in 2004, to publish a lengthy report on the issue of opportunities and uncertainties of nanotechnologies in which several paragraphs are devoted to it [27].

However, the issue of the responsible development is not strictly European. It also appears in Canadian [28] and U.S [29] reports and in the documents accompanying the work of international organizations, such as the OECD [30]. Nevertheless, it is in the texts of the European Commission that this terminology is most considered. The Communication of the European Commission “Towards a European strategy for nanotechnology” [31] mentions it repeatedly. The “safe, integrated and responsible strategy”, advocated in its action plan [32] is a continuation.

Generally advocated in response to concerns about the development of nanotechnologies and, more broadly, technologies in general, the need for responsible development of nanotechnologies is based on findings from the previous experiences of appearance and development of poorly controlled new technologies. Examples of asbestos and biotechnology, particularly GMOs, are often cited as typical of those should be avoided.

Later, I will give examples of some concrete applications of this concept in terms of applied norms. In terms of governance, however, a line was crossed in 2008 with the adoption of a Recommendation from the European Commission on a Code of Conduct for responsible nanosciences and nanotechnological research [33]. This was originally intended to be reviewed every 2 years and to promote integrated, safe, and responsible nanosciences and nanotechnologies for the benefit of the whole society in Europe. This code of conduct, for member states of the European Union, as well as more broadly, for those to whom the Commission refers as those concerned, namely "Member States, employers, research funders, researchers and more generally all individuals and civil society organizations engaged, involved or interested in N&N research", states that "research activities in N & N are conducted in accordance with the precautionary principle, anticipating potential impacts their opportunities in the environment, health and safety and taking due precautions, the level of protection, while encouraging progress for the benefit of society and the environment". The concrete measures that it suggests are grouped into sub-themes and aim not only to implement the precautionary principle by a set of rather general incentives, but also to "implement good governance research" and "promote an inclusive approach".

They add few little practical recommendations to those that were issued until 2008 by various French and European scientific and ethics committees, in which the issue of risks associated with the development of nanotechnology was set out. However, this Code has the merit of placing the issue of governance and specifically the discussion of scientific and technological choices at the heart of the debate related to the responsible development of nanotechnology.

It is regrettable that this recommendation has received little support from the member countries of the European Union. If are to believe the intermediate results of opinion polls and surveys of those concerned already carried out under the NanoCode project [34], 80 % of the concerned interviewed expressed support for the Code of EU, but only 20 % of organizations had formally adopted it, and only the Netherlands did so as a member state. Neither did, the European Commission keep its promises [35] regarding the review of that Recommendation as well as of all the policy texts it has published to support responsible development of nanotechnology, such as the Action Plan of 2005. No revised text was published in 2010, any more than in 2009, leaving the issue of responsible development of nanotechnology at present in abeyance in Europe.

Finally, it is regrettable that no major public debate has been organized on the development of nanotechnology at European level, as seemed to be heralded by the plan of action of 2005 [6] and as the second report of implementation of this plan also seemed to encourage the Commission to do so in 2009 [36].

This absence of the organization of direct public debates was partially offset, at least in France, by the organization of a national public debate on policy development for nanotechnology. The means given to this debate, however, were clearly insufficient for a real illumination of the issues that were discussed there.

14.1.2.2 Responsible Development Through Public Debates

A lot of informal public debates have been carried out, in France, since 2006. In 2007, a very large colloquium was even organized, in Paris, to check the issues that had been discussed during a large set of previous initiatives. On this occasion, and despite this wealth of public meetings, the government decided to organize a national debate about nanotechnological development. This engagement lasted until 2009, when the French Environment Round Table, also known as the "Grenelle de l'Environnement" [37] concerning nanotechnologies began to be applied.

The debate was launched on the 15th of October 2009 by the French national committee on public debate (CNDP). A Special Committee, on development and regulation of nanotechnology, is historic, because of its theme and of the procedure that was followed. No less than seven Ministers charged the CNDP with the organization of a national debate on the subject [38]. The theme set by the government and agreed in its decision of the 4th of March 2009, by the CNDP was to debate: "general options for development and regulation of nanotechnology". However, in deciding to charge the CNDP to organize this debate, the Government thereby subjected it to the constraints of the legal framework concerning it [39]. Several elements of the regime of public debate, as it exists in current law, illustrate the difficulty of the latter to meet the criteria of "dialogic democracy" [40] desirable in the field of emerging technologies. This institution is made for debates rooted in the linking of projects and territories. When its fields of competence were further opened, in 2002, to broader topics of discussion, the following processes, delays, especially, were not adapted, and the form of concrete public debates, which is the in-house CNDP expertise field, was not adapted either.

This situation led to a rather disappointing result, for two main reasons. The first of these reasons is that the French authorities did not bother to answer in any manner whatsoever, the report and appraisal published by the CNDP and prepared by the special committee. In spite of the concern of members to hold a timely discussions on time, despite the difficulties to be overcome because of "noise" made by opponents of nanotechnology [41], despite their determination to pursue the debate while extensive publicity was made by the French government concerning the guidelines of its policy on nanotechnology [42], it appears that silence should be understood as a definitive answer. It is obvious that such a response does not satisfy anybody. The other reason, it is that few people who were ultimately willing or able to participate in these discussions. Public debates were largely disregarded, either because of the public themselves or opponents,

this preventing any exchange of opinion to be heard. The online debate has likewise been little pursued.

We do not intend, here, to give a sociological analysis of this debate, but to try to see how the changes made later in the Code of Environment might help improve the quality of such debates. By its expansion, in Article L 121-10 of the Code, the assumptions of referral to the CNDP, in particular by the incorporation of the issue of general options for sustainable development [43], the "Grenelle n°2 Act" [44] opens the possibility of a profound renewal of the role given to participatory democracy in science and technology policies. In doing so, it is in line with previous reforms that are marked by a steady source of law governing the development of debate in local or national projects since the early 1980s [45]. If passed after the organization of a national public debate on nanotechnology, a law could have taken greater advantage of its teachings [46].

A discussion of options of general national interest in sustainable development obviously implies public information. The time to debate differs from other debates on infrastructure projects or local equipments can be laid. The topics, often technical, as well as the scope of the issues raised, often international, as well as the relevant public…, everything differs between these two types of public debates. It is not surprising that these national debates have been included only in 2002 within the scope of competence of the CNDP. The scope of this extension of the legal framework for public discussion, however, has not really been considered. It is probable that the CNDP, whose competencies are large in terms of practical organization of debates, will eventually develop a doctrine and appropriate methodologies for them, just as it did, in the past, for the territorial debates. It is unfortunate that it remains constrained by a legal framework that seems ossified, in many of its aspects. Therefore, the time limits provided in the article L. 121-11 of the Code of the environment, often insufficient for complex and territorially broken debates, as evidenced by the debate on nanotechnology.

Furthermore, despite the welcome adoption, which is to be welcomed, of the 7th article of the Charter of the environment, which states that "everyone has the right, under the conditions and limits defined by law, to access to information about the environment held by public authorities and participate in the development of public decisions affecting the environment", French law remains behind the building of Europe's right of citizens' information, because it has no general principle of justification for administrative decisions. Thus, rules put in by article L. 121-10 al.3, and explicitly bearing on by the owner of the debate on the disclosure requirements, greatly risk to disappoint the public. This obligation is not subject to any time limit; neither is the form of information specified. Such inaccuracy is regrettable. The doctrine in its overwhelming majority does not argue for a replacement but only a complement of dialogic democracy next to the procedures of representative democracy. Many are concerned about the loss of credit that these devices suffer when, from reading the decisions that followed, the public feels that it is being ignored or, worse, that it has been used to ensure the social legitimacy of actions it disapproves.

Finally, the French Code of the environment is now extending the sphere of the legal concept of public debate to public information and public participation following the debate. This precision is supplemented by a reading of Article L. 121-13-1 of the Code, which sets out the conditions for monitoring the phase which follows the public debate on the assumption that it was intended for a project. However, it exceeds this framework, as is now mentioned in the section related to the missions of the National Committee on Public Debate and to the scope and purpose of public debate. It should, therefore, apply to proceedings provided for broader debates. This is a considerable extension of the powers of the CNDP. This opening of public debate would then imply that the total independence of the CNDP would be followed by a more relative autonomy in the realm of issues for which it would seek to ensure effective monitoring. It also implies that sufficient resources would be allocated for the administrative authority, means that far exceed, the personnel, time, and investment, those that required by the previous definition of public debate. Those, citizens involvement in the debates could be more continuous, and they could participate in the concrete development of policy guidelines. The regulatory part of the Environmental Code has not been amended to reflect these changes, but it's never too late to do.

Nanotechnologies, due to their complexity and generality, posed, in all these respects, problems which are difficult to resolve in the space provided by public debates as built nowadays, they can still serve as an example for the future. In this, as on many other aspects, they are an exemplary field of study for legal scholars.

14.2 The Nanotechnology's Normative Challenge as an Example

The general purpose characteristic of nanotechnology is, in addition to its complexity, of particular interest for the exploration the resources offered by various norms in framing emerging technologies. They arouse hopes as much as they inspire fears. As we have seen, they create a breeding ground for the concept of responsible development. Behind this, and beyond the wish of the public to be more involved in the discussion of strategic options for their development, hide strong principles, which find here an opportunity to register their declarations of intent to seek an effective implementation. The precautionary principle is obviously one of these, and its interrelation with other principles in force in specific areas of law sought during the life cycle of nanotechnology raises new problems. Despite the difficulties faced, by public debates on scientific and technological choices, in our legal system, the various discussions held on nanotechnology since 2007 have all focused on the characteristics: complexity, general purpose, public funding, and significant promise for the future together with increasingly unequal distribution of wealth between the North and South that question the evolution of our regulatory system. The uncertainty is part of the latter, as is the issue allowing technical, social, and economical innovations to take place. However, where the

first calls for a reactivation of pre-existing principles and may ultimately allow for a better control of the tools which could be used for a concrete implementation and for the articulation of these principles (Sect. 14.2.1), others are sources for a questioning in depth of the faculty of our legal systems to meet the challenges for which they were built (Sect. 14.2.2).

14.2.1 Reactivating Fundamental Principles to Face Uncertainty

If we take the time to carefully realize the uncertainty associated with nanotechnology, is different from what usually pertains to Law in the field of science and technology. Where our legal system mainly sees uncertainty in terms of uncertain risks, it is striking that this feature likewise pertains to the scientific principles used and studied on this scale, to the benefits expected. The statement could be seen as a truism. It is, also, true not merely in the field of nanotechnology [47], even if the promises of benefits that have been used to promote the latter are, particularly spectacular [48].

To consider the problem of uncertainty in terms of the relationship between uncertain promises of benefits and uncertain risks, however, allows for some of the criticisms that have been made in respect to the instrument that the law favors for the management of uncertainty: the precautionary principle (Sect. 14.2.1.1). The proposal also seems to be a renewed focus on the interactions of this principle with other principles in the various branches of special rights that may be expected to concern the life cycle of nanotechnology (Sect. 14.2.1.2).

14.2.1.1 The Precautionary Precaution at the Heart of Responsible Development

In France, the development of nanotechnology is, marked by the reference to the precautionary principle. The first committee of experts which ruled on the issue was the Committee of prevention and precaution [22], in 2006. Such a referral is not surprising. As they are emerging technologies, nanotechnologies are logically placed in the wake of the development of previous science and technologies, and, have thus, inherited the symbolic weight of a principle which had also just been adopted as a constitutional one [49]. At the European level, the approach was similar even if the reference to this principle has been less formal, at least initially. The European Action Plan for nanosciences and nanotechnologies [6] as well as the communication that preceded it in 2004 [31], placing the consequences of nanotechnology's development at the heart of the approach of the authorities, reminded that "an essential element of this responsible strategy for N & N is the integration of health, safety and environmental issues in the technological

development of N & N, […] to steer developments in a way that preserves the negative societal impact". By 2005, however, the matter of nanoparticles and nanomaterials was submitted to the scientific committee on emerging and newly identified health risks (SCENIHR) [50], and the 2008 Communication on regulatory aspects of nanomaterials [7] completed the merger, by stating that "when the scale of a risk is unknown, but concerns are so strong that management measures are deemed necessary, as is currently the case for nanomaterials, measures must be based on the precautionary principle".

Faced with risks such as those feared in the field of nanotechnology, the precautionary principle as defined in our Charter of the environment and even in previous laws [51], might however seem completely swamped. The criticism of the narrowness of its definition in French law has been mitigated. Yet, because of the scope the European Union Tribunal of First Instance gave to it by interpreting it as a general autonomous principle of Union law and allowing the grasp of the risks potentially caused not only for the environment but also for public health and safety [52]. This interpretation may be reinforced, here, by the complexity of its subject, the environment [53], and the undeniable progress of its logic in the field of risk assessment.

To think that a scientific background, as perfect as it may be, is not enough to understand the world in all its complexity and its richness is not to question the integrity or the scientific expertise usually called by the government to decide on the risks of technology. The segmentation of knowledge has certainly done nothing to improve the situation, but the scientists of the past, steeped in the humanities, never claimed omniscience. It is, in fact, impossible for experts to carry, as part of a scientific approach, all the legitimate conflicting views that the complexity of the debate displays. Modern sociology, analyzing the controversies leading to the decision-making in science does not lead to other conclusions and it also focuses on the scientific divisions themselves, particularly through the quarrels of experts [54]. The violence expressed at present by concerns often referred as societal, in the controversies related to new technologies and their products, is certainly no stranger to this recognition. As demonstrated by recent public debates organized by the CNDP, the risk of nanotechnology is not an area easily contained in a narrow discussion. On the contrary, whatever the subject set for discussion, the social concerns expressed often exceed the expectations and claims for an open framework in which the common future should be discussed. To be sure, these expectations include the implementation of the precautionary principle, but they cannot be reduced to it. Together with the precautionary principle and sometimes faced with its practical implementation, other principles and methods must be sought in the development of nanotechnology.

14.2.1.2 Around the Precautionary Principle: Other Principles and Methods

Designed as it is to support the uncertain risks of damage, the precautionary principle is often presented, in the area of legal tort, as following, the prevention principle both logically and chronologically. Thus, the logic of repairing damages caused by the technical work would be moved to their prevention, which would then progress to an earlier consideration of still emerging risks, and to the promotion of precautionary positions. Therefore, always in a chronological context, the implementation of this principle would logically be limited on the one hand by the scientific demonstration of uncertain risks, without which nothing would be began, and on the other hand by the ability to measure the probability of these risks, by shifting certainties and implementing the principle of prevention [55].

If such a description of the relationship between these two principles is rightly advocated, however, it is on two conditions. On the one hand, it deals only with the description of the principles of precaution and prevention in the area of the liability of public authorities concerned with technological developments. On the other hand, it is realized only in cases where the interaction between these principles is seen through a simple and well-defined object. These two conditions are not met where we observe the relationship between these two principles in several distinct branches of law (e.g., tort law and employment law) or if the review bears on a complex object (e.g., nanotechnology). And yet this issue has found echoes in both these registers.

First, because through their employers, workers are now in contact with nanomaterials, it is necessary to think of protective measures to be adopted toward them. The question deserves to be raised all the more that the risks associated with these nanomaterials are currently still very uncertain, even though if the available knowledge on the subject is increasing [50]. The implementation of the precautionary principle might be considered as following general risks prevention principles to workers, as part of employment law. In the workplace as in the field of public health or the environment, two hypotheses should therefore be distinguished in terms of nanomaterials. In one case, the risks associated with these products are known or at least probable and preventive measures would have to apply. In the second case, these risks remain uncertain according to present scientific knowledge, and it is appropriate to refer to the precautionary principle in this case. This interpretation should however be compared to the way in which our current labor law has interpreted the general risks prevention principles to workers.

Under French law, the Labor Code provides that “the employer shall take the necessary measures to ensure safety and protect the physical and mental health workers. These include: (1) Actions of prevention of occupational hazards; (2) to information and training; (3) The establishment of an organization and appropriate resources. The employer shall ensure the adaptation of these measures to take account of changing circumstances and aim to improve existing situations”. Since 2002 and the litigation relating to asbestos, this obligation of the employer has been interpreted as an obligation of result [56]. No mention is made here of the

precautionary principle, and protection is exclusively considered, at work, through the risks prevention principles. What, then is to be done in the presence of a risk which still remains uncertain, in the present state scientific knowledge? The existence of such a risk is well known in the field of nanomaterials. Would it be sufficient to engage the employer's liability? A negative answer to this question emerges in the field of civil or administrative liability (depending on the status of the employer). Should it have any effect on the extent of the preventive measures he is required to implement in the organization of work?

The interpretation given to the precautionary principle in its field of election might indeed result, in this case, in a decline of measures intended to protect the health and safety of workers or, alternately, in such a strengthening that any commercialization of N & N would become illusory.

Second, in a certain number of fields including for example the regulation concerning chemical products, the legal standard may be evaluated both from the point of view of the expressed and embodied principles, and of the standards and technical documents necessary for putting them into practice. Such standards and technical documents are expressly included in a "new" approach put forth since the mid 1980s by the European Commission for the construction of the European Common Market [57]. In the matter of nanoparticles and nanomaterials, "the public authorities prefer to make use of a more instrumental approach which is both integrated and open to evolution, conjugating the use of voluntary approaches, adoption of recommendations, and guides of best practices and adaptation" [58] rather than the elaboration of a specific legislation. This approach has manifested itself especially since 2008 [7]. Thus, in the light of the efforts of the European Commission, it seems possible to assert that the accurate texts for risk management of nanomaterials, to be adapted from a legal point of view, are simply the technical documents which offer an explanation of the application of existing legislation, apparently without any need to further investigate the content of the existing legislation. This interpretation of the texts of European Union has met with a strong opposition of the part of the European Parliament [9]. The explanation of this contradiction in the interpretation of the text can be found in the very heart of the pertinent regulatory disposition.

This in particular is the case for the REACH regulation [59], which seeks to establish a high level of protection for human health and environment while ensuring the free circulation of chemical substances within the Common Market, by regulating their manufacture, distribution, and marketing, and their use. It is fair to point out that this regulation innovates through abolishing the long-established distinction between existing substances and new ones, so that all chemical substances are treated equally. Another innovation is "the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment." (Article 1 § 3). The limits of the regulation concerning nanomaterials have been widely commented upon. The most obvious of them is that, in the text, registry is mandatory only for chemicals which are manufactured or imported in quantities greater than one ton per year and by manufacturer or

importer. It is easy to take this first argument to illustrate the difficulties which the legal system must confront in its understanding of the nano-specificities [60]. It is sufficient to realize that the reglementary threshold of one ton per year and per operator could be difficult to reach on the European market for nanomaterials, with maybe rare exceptions, and may be easily circumvented by accounting tactics between actors in the sector. In theory, greater risk in quantity requires better knowledge of those risks. The Commission states that below the obligation of registry a certain threshold would render the system impractical.

Such a statement, from our point of view, only hides the magnitude of the modifications which are necessary in the heart of REACH's legislation itself, at least if one wishes to take correct account of the availability of nanomaterials in the marketplace. In this case, it is not because of the small quantities of manufacture or importation that the law has a problem, it is because the units of measure used to determine the threshold of applicability are inappropriate. The effects of such products are related to the distribution of particle size rather than to their total mass, as pointed out by the experts of SCENIHR [14]. Simply lowering the threshold is not enough. A complete review of the legislation is clearly necessary to take account of relevant characteristics, so that REACH has some meaning with respect to nanomaterials. Its various requirements seem irrelevant in relation to nanomaterials in view of the lack of standardization of technical means adapted to a risk evaluation for these products.

This situation requires a profound and fundamental questioning of the established legal system, which has been built on categories adapted to large scale chemicals, but have been brought into play in the new fields of nanomaterials. Behind the scenes, there are major interests among the concerned parties on the method employed to accompany the evolution of the standards framework, as well as on the room allowed for the expression of diverging opinions. In this case, not only a concept imported from a different legislative branch is in question, but the way in which the legal principles have been thought out within a coherent legal framework.

14.2.2 Renewing Some Questions About our Legal Systems Ability to Keep Their Goals

Nanosciences and nanotechnologies are both really interdisciplinary and innovative, complex and enabling researches and technologies. In terms of research, an isolated scientist can be baffled by the extraordinary variety of effects that has on the scale of a billionth of a meter. The use of complex instrumentation, which has, since 1980, been necessary to the field to expand, further accentuates the need for complementary skills. Teams exploring this area are therefore frequently made up of scientists and engineers coming from many different disciplines, such as chemistry, physics, biology. In addition, the same nanotechnology innovation, coming from a research laboratory or from the center of research and development of a company's chemical

sector, may receive applications in a variety of products, from cements to electronics, pharmacy or even sports items, after a phase of research and development which tends to accelerate. Such features raise obvious curiosity at first, hence the success, perhaps, of the research in the scientific world. They also stir up lust, as innovation is seen as the guarantee of bundle of power on very large markets and a breeding ground for revenue. Optimization of the results of nanotechnology research is, therefore, one of the major issues to which their development is exposed, and the legal tools of that valuation, patents at first, are logically sought.

Indeed, the rush toward 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, 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 [61, 62]. 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, 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.

Patent applications for inventions in the realm of nanotechnologies are generally being filed at a very early stage [62], and across a very broad range of subject matter, and it would seem that in many instances their characterization 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 vigor with which it is being called into question, the subject matter of patent law continues, in many legal systems, to be inventions [63]. Because of this restriction on subject matter, standard-setting legislation generally excludes discoveries from the realm of patentability, 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, 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" [64]. 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 [65], 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.

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.

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. The first of these difficulties, which results from the industrial application criterion, is the slight separation of science and its applications within nanotechnology [65]. 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 categorize as abstract ideas [66].

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, 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 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. But which person, skilled in which art? [67] 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?

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 among 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 h [67]. 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 [68]. These semantic variations have repercussions in patent law, one of the major strengths of which they paralyze 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 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. One can, at least, regret the absence of serious consideration to specify what a patent can and should cover [69], as an instrument of social well-being, 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.

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