

consider particularities and complexities of each field of technology, but when this flexibility is created by the unclear definition of terms like the distinction between *invention* and *discovery*, the interpretation of the patenting rules, in hands of the administrative authorities, may be based on arguments out of policy considerations and in this way, the system may be jeopardized in a way contrary to the objectives that it pursues.

#### *4. Ethical concerns on nanotechnology and the impact on patentability issues*

Discoveries are not the only subject matter excluded from patentability. According to EPC “[...] patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to *ordre public* or morality [...]”.<sup>36</sup>

Some products incorporating nanotechnological inventions have started to raise concerns on risks for the health of the people exposed to those materials. Nanoparticles is an area of main concern, for the reason that they can penetrate into the gas exchange region of the lungs, impeding in some cases the organism to defend against the presence of the strange substance.<sup>37</sup> Self-duplicating nanorobots, are also mentioned as a future concern from an environmental perspective, even when these devices are far from reality today.<sup>38</sup>

Environmental and public health concerns that may appear in connection with nanotechnology resemble the European experience with asbestos.<sup>39</sup> Learning from the experience of this case, some commentators believe that “consumers are involuntarily exposed to unlabeled nanomaterial ingredients in products, without being informed of potential risks [whereas] nanomaterials are disposed of and released into the environment despite unknown impacts and inadequate means to

36 EPC, Article 53(a), Exceptions to patentability. This provision is in line with TRIPS Agreement, Section 5, Article 27, Paragraph 2. TRIPS Agreement allows members to exclude from patentability inventions in order to protect “[...] *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment [...]”.

37 See, Commission de l’Ethique de la Science et de la Technologie, Ethic, Risk and Nanotechnology: Responsible Approaches to Dealing with Risk, 2008.

38 *Id.*

39 Asbestos is the name given to a group of naturally occurring minerals. This product was broadly used during decades as thermal insulator in buildings, to find later the high risk of disease the material causes for people exposed to it, obliging to invest millions in isolating or replacing the textile from all buildings. For example, the EPO headquarters, along the Isar river in Munich, Germany, was partially closed for the period 2008-2010 for asbestos removal.

detect, track or remove the new materials.”<sup>40</sup> While experts consider that there is still much to understand from the toxicity and other risky factors of nanoparticles, questions arise, e.g. how governments may decide to protect the population while a clear risk assessment is developed and to the extent nanotechnology is considered a real risk for public health, may this lead to declaring some nanotechnological inventions excluded from patentability.<sup>42</sup> Investigating how the convention was understood in other relevant cases may help to predict the spirit of this rather general provision.

The concept of *ordre public* and morality, as considered in Article 53 of EPC has been developed in case law by EPO. The TBA established that “Under Article 53(a) EPC, inventions the exploitation of which is likely to seriously prejudice the environment are to be excluded from patentability as being contrary to *ordre public*”.<sup>43</sup> This is a clear indication that inventions capable of producing environmental damage are considered excluded from patentability. However, the exclusion from patentability would need to be justified on factual details at the moment of deciding the exclusion.<sup>44</sup> The EPO, in affirming that “a decision in this respect presupposes that the threat to the environment [needs to] be sufficiently substantiated at the time the decision is taken by the EPO” seems to limit the possibility to exclude from patentability substances which have not yet been proven as harmful for people or environment, but that may in the future be considered as such.<sup>45</sup>

In providing an example of inventions that are considered as contrary to *ordre public*, the EPO presents the case of anti-personnel mines, as an *obvious* example.<sup>46</sup> Apart from discussing the obviousness of the example, we can agree in the danger that these devices may represent for people in general, but it is at least arguable why, based on this same principle, EPO allows patentability of other weapons.

In trying to find a balance, the Boards of Appeal has constructed the meaning of morality and *ordre public* for the field of plant varieties, and clearly established that this concept should be defined narrowly under a case-by-case analysis.<sup>47</sup> While the

40 David M. Berube, *Intuitive Toxicology: The Public Perception of Nanoscience, Nanotechnology and Society: Current and Emerging Ethical Issues*, F. Alloff, P. Lin, 2008.

41 ETC, *Principles for the Oversight of Nanotechnologies and Nanomaterials*, 2008. Available at <http://www.icta.org/pubs/index.cfm> (last visited September, 2009)

42 *Id.*

43 T 0356/93.

44 *Id.*

45 *Id.*

46 See, Guidelines for Examination in the European Patent Office, European Patent Office, December 2007. Available at <http://www.epo.org/patents/law/legal-texts/guidelines.html> (last visited May, 2009).

47 *Id. supra* note 43.

mentioned Board affirmed that an invention cannot be considered patentable or non patentable merely because the product is subject to an authorization or a bar to be commercialized in the market of some member countries, it established that the risk of hazard to the environment may constitute an impediment for patentability.<sup>48</sup>

The patentability exclusions based on morality and *ordre public* have been criticized in the past under the argument that rights granted by patents are defined as negative rights, transferring to the patent owner the right to exclude others in using, manufacturing, etc. the invention, but not the right of exploiting the invention. This negative right can be understood also in terms of authorizations needed by the patent owner to manufacture and commercialize the technology, authorization that doesn't come from the grant of the patent but usually from other governmental procedures.<sup>49</sup> The most visible examples come from the pharmaceutical industry, where even after obtaining a patent for a new medicine the patent owner must receive authorization to put the pharmaceutical product into the market. Such further authorization is based partially on the requirement that the product does not pose a danger to public health.<sup>50</sup> In this way, the inventors are not excluded from the possibility of obtaining protection for valuable technology and at the same time public health is protected by controls and other mechanisms developed by governments. Other examples can be found in the chemical, automotive or electronic industry.

A further critique levelled against *ordre public* and morality criteria on patentability requirements refers to the fact that these concepts are evolutionary and change throughout the years. Something that is against morality today may be accepted by society in the future and *vice versa*. Nanotechnological inventions which may not be allowed to be patented today may be accepted in the future, after technology evolves in a way that potential harm is controlled by technical measures. This would lead to an unfair situation in which a previous inventor, who could not receive patent rights based on this "out of date" moral criteria, is left out in the cold.

While there is contradiction in a patent system that functions to encourage the creation and disclosure of inventions that may be problematic for public health, the exclusion from patentability of nanotechnological products that are not yet proved to be dangerous may delay the development of technology that is later proved to be safe. At the same time, exclusion from patentability of nanomaterials that are considered risky may increase the investment and encourage parties to develop "risk-free" technologies.

48 *Id.*

49 Peter Drahos, *Biotechnology patents, markets and morality*, E.I.P.R. 21(9), 441-449, 1999.

50 See, for example, Regulation (EC) No 726/2004, for the authorization and supervision of medicinal products for human and veterinary use.

## 5. Concerns on the patent thicket

Other policy issues apart from *ordre public* and public health in connection with nanotechnological inventions are raising concerns. The early stage of development of nanotechnology and the rush of developers to file patent applications, a situation where the building blocks of nanotechnological inventions in areas such as biology or materials science may be patented, has been mentioned as an issue to consider. It has been remarked that these applicants following aggressive patenting strategies may take control over a wide range of basic inventions able to be applied in a broad spectrum of fields, with the ability to define whom, how, when and where the technology is going to be used.<sup>51</sup> The issue may have a big impact on nanotechnology related businesses if the same patent owners, following a commercial strategy, decide to restrict access and not to allow potential users or improvers to have access to the technology. This may represent an issue for countries without research exceptions or with a narrow understanding of them.<sup>52</sup> The relevance of the subject is based on the perception that nanotechnology will generate such an immense impact on the future life of people, from a radical increase in the productivity of food generation techniques to the development of revolutionary methods to treat diseases, that governments should assure that private ownership will not generate an unbalanced situation concerning access to the advance and benefit of technology for the majority of the population.<sup>53</sup>

From a policy perspective, patent law is accepted to be a tool by which some economic objectives are met. Accordingly, a substantial part of patent law was developed as an instrument to encourage generation and commercialization of technology, which produces economic development for the country.<sup>54</sup> By encouraging people to invent, to negotiate access to technology and to put in the market their inventions, the welfare of society is increased, among other reasons, by the improvement of life quality of people. Nevertheless, increasing welfare of society appears only as a secondary result of patent law, as there is no requirement in the statutes that an invention to be patentable needs to be beneficial for the society. In the same way, no distinction is made among patent rights granted to

51 Mark Lemley, *Patenting Nanotechnology*, Stanford Law School, John M. Olin Program in Law and Economics Working Paper No. 304, June 2005.

52 For a list with countries without research exception provisions see Carlos M. Correa, *The International Dimension of the Research Exception*, AAAS, 2005.

53 *Id. supra* note 51.

54 For a discussion on how patents can put inventions into use, see Kieff, F. Scott, *IP Transactions: On the Theory & Practice of Commercializing Innovation*, Stanford Law and Economics Olin Working Paper No. 311, October 2005 and Kieff, F. Scott and Troy, A. Paredes, *Engineering a Deal: Toward a Private Ordering Solution to the Anticommons Problem*, Stanford Law and Economics Olin Working Paper No. 330, November 2006.