Designing Substantive Patent Law: from Life Sciences to Climate Change?

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The purpose of this article is to emphasise that we have to learn from previous experience when addressing the issues of patent law and climate change in order to suggest appropriate solutions. If we address the problem while turning a blind eye to former failures we will never succeed. Especially in this area, where traditional environmental law and traditional patent law have had their glory days, there are lessons to be learnt by future lawmakers and policymakers working in the field of climate change.

1. Human health, climate change and patent law

A World Health Organization poster states that climate change hurts, not only in terms of environmental and economic damage, but also in terms of human lives.[1] The poster pictures a black foot on a cracked soil background, symbolising that drought hits harder in the undeveloped world where people are most likely to suffer from climate change.

Human lives are often at stake. That is why we have a huge pharmaceutical and biotech industry serving human needs as well as economic purposes. The history of safeguarding human lives worldwide is nothing to be proud of. In this regard, the patent law system has been identified as a major contributor to continuing health problems in the least developed countries. Our efforts to transfer patent laws to less and least developed countries have diminished the legitimacy of exclusive rights. What will happen when we add food and energy scarcity as well as climate change issues to our present experience of safeguarding humans? To be more specific, will issues such as climate change demand special IPR treatment?

The lifecycle of patents can broadly be divided into two phases. Phase one, the *pre-grant* phase, covers the period from the filing of the patent application to the grant of the patent. Phase two, the *post-grant* phase, covers the period from the grant until the patent term expires (or lapses due to non-payment of fees). This article mainly addresses the *pre-grant* phase, the requirements for patentability and the balancing of public and private interests. However, *post-grant* measures are also important and will be briefly discussed.

2. Waves of law

As people get older, most discover that in some ways life repeats itself. Simple things, like the clothes they wore decades ago, come back into fashion and are reused by the new generation. Perhaps as lawyers get older, they too may wonder if law and policymaking repeat themselves and follow such *waves of life*, or '*waves of law*'. Some things never or seldom change, and one may ask if that is a sign of quality. Design classics, such as the Arne Jacobsen Egg Chair, seldom go out of date. Is patent law comparable to designer furniture? If that were the case, patent law would still be useful in a changed context, surviving the challenges of changing society without being swept away.

Although, the patent regime has expanded rapidly into parts of the world that do not have the infrastructure, capacity, or inventors to

benefit from the regime, its design has been absorbed in its traditional form, without fundamental changes. Furthermore, it has expanded to include new subject matter and embrace some of the emerging technologies. This expansion has triggered some changes in the wording of the European patent laws, but not a rethinking of the system. Business has continued as usual.

To elaborate on the *waves of law* metaphor which is the theme of this article, in the following there will be a focus on five developments in the law: the first wave is traditional international and EU environmental law; the second wave is traditional patent law and environmental law; the third wave is patent law and life sciences; the fourth wave is patent law and the biotech experience; and the fifth and final wave is patent law and climate change.

2.1. Traditional international and EU environmental law

By the early 1970s environmental law and policy had become a major issue. The UN Conference on the Human Environment, held in Stockholm in 1972, encouraged national and international societies to protect and improve the human environment.[2] The Stockholm Declaration (1972), and later the Brundtland Commission report (1987) on Environment and Development, *Our Common Future*, directed the world's attention to environmental law in its more modern form.[3] By emphasising that pollution is not absorbed by air and water (and is not solved, for example, by building high chimneys or piping waste water into the ocean), and that it is likely to have cross-border effects, the focus on shared responsibility became a priority on the international agenda.[4] In its different forms shared responsibility became an important issue in international environmental policy in the following years. Thus, the 2002 Johannesburg Declaration on Sustainable Development assumed the existence of collective responsibility[5] and most recently point 1 of the Copenhagen Accord 2009 emphasised the 'strong political will to urgently combat climate change in accordance with the principle of common but differentiated responsibilities and respective capabilities'.[6]

At the regional level, awareness of transboundary pollution and of the interplay between environmental policies and a competitive European industry was developed in the first place by the European Court of Justice and then by the adoption of the Single European Act in 1987. As a dynamic lawmaker, the European Court of Justice has contributed to the change of priority of environmental interests which was enshrined by the inclusion of Treaty provisions designed to protect the Environment, see the former EC Treaty, Articles 130r, 130s, 130t and Articles 100a(3) and (4).

This development continued. The Maastricht Treaty (1992) was also an important phase, with the Treaty *expressly* incorporating powers aimed at safeguarding the environment as part of its general principles in Articles 2 and 3 (referring to sustainable growth, for example). Furthermore, the Amsterdam Treaty (1997) contributed *by* changing the wording of the sustainability principle (Article 2: promoting a harmonious, balanced and sustainable development of economic activities), and *especially by* the promotion of the integration principle in Article 6.[7] The latest stage in this agenda is the Treaty of Lisbon (2009) where not only has the Charter of Fundamental Rights of the European Union (2000)[8] been replaced from the date of entry into force of the Treaty of Lisbon, but new provisions relating to climate change and energy have been adopted. See Article 191 in the consolidated version of the Treaty on the functioning of the European Union where Union policy on the

environment shall contribute to promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change. In the context of Union energy policy Article 194, there is a reference to the need to preserve and improve the environment in a spirit of solidarity between Member States.

The Single European Act introduced Treaty-based environmental principles, such as the principle of a high level of protection, the principle of sustainable development, the integration principle, the precautionary principle, the prevention principle, the source principle, and the polluter pays principle. Since its introduction, scholars of European environmental law have debated the legal quality of the environmental principles of the Single European Act. The Act has not been followed by an immense body of case-law, but the European Court of Justice (ECJ) accepts that some of the principles are legally binding.[9] In particular, Case C-284/95 *Safety Hi-Tech* has been highlighted as interpreting the former Article 130r. In paragraph 37 of its judgment, the ECJ stated that:

'in view of the need to strike a balance between certain of the objectives and principles mentioned in Article 130r and of the complexity of the implementation of those criteria, review by the Court must necessarily be limited to the question whether the Council, by adopting the Regulation, committed a manifest error of appraisal regarding the conditions for the application of Article 130r of the Treaty'.

The discussion of environmental principles as legally binding is still ongoing, and it is important to remember this when considering the transfer of environmental principles to patent law.[10] As Treaty-based principles they guide lawmakers, courts and, one can argue, authorities granting authorisations and exclusive rights.[11] In her legal writing *Astrid Epiney* has argued that all scholars, whether or not they support the binding effect of principles, tend to focus on the legal significance of the principles. The purpose of an open-ended principle can require only the balancing of different interests.[12] On the basis of the environmental principles we may consider whether the requirement to integrate environmental protection as a general principle of EU law or the precautionary principle can be enforced at the level of the European Patent Organisation. This issue will be dealt with below.

The protection of the environment became subject to multi-level regulation already in 1972, and one can find interplay on environmental protection between lawmakers at the global, regional and national levels. However, in general terms the environmental focus peaked after *the Amsterdam wave*, emphasising the importance of environmental protection by promoting the integration principle as a general Community principle. Since then environmental protection has lived a more retired life, where compliance with and enforcement of European environmental law are issues that remain to be solved.[13] However, climate change has brought the environment more into focus.

2.2. Traditional patent law and environmental law

Patent laws are not a new invention. National laws for reward schemes have been an integral part of industrial development since at least 1500.[14] The overall idea of patents has been to balance society's interests in new developments on the one hand and reward for inventors on the other hand. This is known as the reward doctrine.[15] Thus the disclosure of how an invention works is an essential requirement for granting a patent for an invention. Substantive patent law has long been harmonised at the regional and international levels. Since 1972, the European Patent Convention (EPC) has provided a common system of law for the grant of patents,

and since 1994 the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has provided detailed rules on substantive patent law and the enforcement of IPRs. Thus, as with environmental law, patent law is subject to multi-level regulation. Furthermore, the elements of balancing the interests in patent law and the interests of less and least developed countries can be recognised as issues in environmental law which can be classified as issues of social responsibility.

Turning to what may be termed 'traditional' patent law, one will find an attempt to reflect an express environmental focus. In this regard TRIPS contain more modern wording of patent law's traditional clause on exclusions from patentability on ethical grounds. The '*ordre public* and morality' clause, expressing environmental concern, is found as a minimum standard in TRIPS Article 27(2), which refers to the avoidance of 'serious prejudice to the environment'. As such, patent law supports an ethic norm that a law that rewards a polluting inventor is not good law.

The wording of TRIPS Article 27(2) suggests broader protection than Article 53(a) EPC. The wording is as follows:

TRIPS Art. 27(2): 'Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal and plant life or health or to avoid serious prejudice to the environment…'

EPC Art. 53(a): European patents shall not be granted in respect of 'inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.'

Despite the differences in wording, it must be pointed out that EPO case law, through the interpretation of the *ordre public* standard, does make references to the environment.[16] Thus, the *ordre public* standard of Article 53(a) EPC does constitute a bar to patentability for the exploitation of inventions that are *likely to seriously prejudice the environment*.

A relevant question in this regard is the extent of environmental protection taken into account by patent authorities. Do they consider sustainability and the precautionary principle and even make a risk assessment before granting a patent? An answer from the EPO Boards of Appeal in T 356/93, paragraph 18.5 hints at future decisions. The Board held that the *ordre public* standard presupposes that the threat to the environment is sufficiently substantiated at the time when the decision to revoke is taken by the EPO. The Board further emphasised that most of the applicant's arguments were based on the *possible* occurrence of harmful events (e.g. the transformation of crops into weeds, the spread of herbicide-resistant genes to other plants, damage to the ecosystem etc.). However, the documentary evidence must sufficiently substantiate the existence of a threat to the environment such as to represent a bar to patentability under Article 53(a).[17]

Thus it seems that the *precautionary principle* is far from being recognised by the EPO Boards of Appeal. The attitude is as follows:

'patent offices are placed at the crossroads between science and public policy. However, at this crossroads patent offices are not alone, but find themselves side-by-side with increasing number of other authorities and bodies, in particular regulatory authorities and bodies, whose function is inter alia to ensure that the exploitation of a given technology, *regardless of whether it is protected by a patent or not*, takes place within the regulatory framework provided by laws, international treaties, administrative provisions'.[18]

The exploitation of a patent has to be assessed within the framework of national laws and regulations on the use of an invention. The Board pointed out that potential risks cannot be anticipated merely on the basis of the disclosure of the invention in the patent specification. The balancing test elaborated in the *Harvard Onco Mouse* case[19] is only applicable when there is an actual risk of harm in the form of 'conclusively documented hazards'.[20]

Is has been suggested that a patent examiner should require an environmental impact assessment from specialised authorities before granting a patent.[21] As the results of such tests are usually not available to patent offices during the processing of a patent application, this would doubtless extend the period of patent application proceedings. Today, the actual approval by the authorities is often obtained *after* the grant of the patent. If we start requiring environmental impact assessments prior to the granting of a patent, we start mixing the exploitation of a patent with the grant, and too many grey areas will distort the objective of the patent system, subjecting it to even further problems of loss of legitimacy. Article 53(a) does not provide a legal basis for controlling and preventing technological hazards.[22]

Following the discussion of environmental principles, one can hardly blame patent examiners or the Boards of Appeal if they do not rely on EU environmental principles which still are associated with legal uncertainty in their own legal system. As to the EPO, the EU has no legal power or authority over it.[23] Yet, the principle of sustainability in particular is not only a general principle of the EU, it is recognised in international conventions. This principle has the global aim ensuring that technological development does not bring about the end of the world and/or that the legal protection of developments takes social responsibility into account. The author's opinion is that these principles are very useful in the post-grant phase, whereas the pre-grant phase must keep patent law to the straight and narrow, separating grant from exploitation.

2.3. Patent law and life sciences

The TRIPS Agreement's explicit reference to serious prejudice to the environment has been less controversial than its relation *to life saving medicine*.[24] We all know by now that the patent system *as such* is not transferable to less and least developed countries. The obvious question that scholars ask in this regard is whether the Doha process on pharmaceuticals has lessons for climate change. The focus is now on *post-grant measures* and there is an issue of accessibility, ensuring that IPRs do not unjustly prevent access to technologies.[25] One could say that post-grant measures are all about to rebalancing the system and achieving global social goals.[26]

Facilitating access to essential medicines in developing countries is an obvious starting point for assessing access by developing countries to environmentally sound technologies (ESTs). The Doha waiver enables a pharmaceutical product produced or imported under a compulsory licence in a member country to be exported to the markets of those other less or least developed countries that share the same health problem.[27] Thus, finding solutions to the barrier of *insufficient capacity* for developing countries to make effective use of compulsory licences, as in the case of HIV and malaria, can now be considered for environmentally sound technologies.[28]

Comparing the UN Framework Convention on Climate Change (UNFCCC, 1992) to the Doha agenda appears to be straightforward. The distinction of less and least developed countries in Doha terms and UN Annex II Parties and non-

Annex I Parties guides us in the same direction, whether we talk about pharmaceuticals or combating climate change. The principle of common but differentiated responsibility is behind both systems in terms of technology transfer and financial resources. However, as emphasised by several scholars, it is questionable whether the feasibility of a waiver for the transfer of environmentally sound technologies is similar to that for public health. And unfortunately, the Doha process has only influenced the global pharmaceutical industry at the margin, so its structure and behaviour has been largely unaffected.[29] According to *Frederick Abbott*, at its best the Doha Declaration on the TRIPS Agreement and public health process has positively influenced governments and multilateral organisations towards taking greater responsibility for ensuring that populations and developing countries have adequate access to medicines.[30]

Frederick M. Abbott points to one positive outcome of the WTO public health negotiations, which is that a number of Public Private Partnerships (PPPs) have been formed on drugs for neglected diseases, e.g. the Drug for Neglected Diseases initiative (DNDi), the US President's Emergency Program for African Relief (PEPFAR), and the WHO UNITAID scaling up access to treatment for HIV/AIDS, malaria and tuberculosis.[31] There are now also orphan drugs arrangements in the EU for rarer diseases, such as Gaucher's disease, Fabry's disease.[32]

Perhaps one of the lessons we can learn from the experience with *life saving medicines* for neglected diseases is to use Public Private Partnerships for *adaptation technologies* directed to the least developed countries.

2.4. Patent Law and the Biotech experience

Biotechnology has had an influence on several disciplines of law. As examined by *Han Somsen*, there are lessons to be learnt from environmental law, such as issues of risk regulation, where the precautionary principle has been acknowledged outside EU environmental law, as in the example of food safety regulation.[33] Risk assessment and the precautionary principle are appropriate as bases for voicing opposition on behalf of the environment and future generations when these are at stake.[34] This is also the approach of legitimacy.

Turning to patent law, we may consider Han Somsen's concept of 'genetic governance'.[35] The European Community had severe difficulties with the adoption of Directive 98/44/EC (the Biotech Directive). There was a 10 year struggle before the Directive was finally adopted in 1998. Patenting life forms caused much debate, mainly by establishing a regime without field restrictions. The biotech revolution has left its own footprint on substantive patent law, and this has led to the European Community making changes to the established EPO law. The author's view is that this is where we have learnt our lesson: Patent law flexibility and dynamic is not best safeguarded by detailed rules.

How can we cope with new patentable subject matter with patentability requirements that have been established at a time when the emerging technology (in this case biotech) was immature and when the political environment is reluctant and resistant to change, while the industrial lobby is positive about change? Now, as result of *a political compromise* we are locked into outdated rules. For example, there are rules that have created a phoney doctrine of isolation. Thus, Directive 98/44/EC Article 3(2), states that:

'Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature'.

This doctrine governs biological material in general, as well as human genes; see Article 5(2):

'An element isolated from the human body … may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.'

Comparing the patentability requirements to those of traditional patent law, the requirement for industrial application is the only criterion that has adopted a kind of field restriction, if it is to be interpreted as a strict requirement for industrial application.[36] Directive 98/44/EC, Article 5(3) states:

'The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application'

While the focus of the debate was on human genes, the Directive was adopted without changes to the patentability of plants and animals. Plant and animal varieties are excluded from patentability if the technical feasibility of the invention is confined to a particular plant or animal variety (Directive 98/44/EC, Article 4(2)). Essentially biological processes for the production of plants or animals are excluded. Essentially biological processes are defined in the Directive, which is not the case in traditional patent law. However this definition is more open-ended than precise.[37]

Finally, the *worst outcome of law making* is the EU system creating its own detailed moral standard for Europe. Article 6(1) of the Directive repeats EPC Article 53(a), and Article 6(2) is as follows:

'On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(a) processes for **cloning** human beings;

(b) processes for **modifying** the germ line genetic identity of human beings;

(c) uses of **human embryos** for industrial or commercial purposes;

(d) processes for **modifying the genetic identity of animals** which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes' (emphasis added).

Given the heading of Article 6(2), it is obvious that one or more areas are missing. The non-exhaustive list provides examples concerning humans or animals used for human purposes (mainly) but there is not a word on environmental protection.[38] Maybe the EC legislator found this was already covered by the traditional clause (Article 6(1)) or perhaps the focus was more on human genes – 'genetic governance' in the term of Han Somsen.

2.5. Patent law and climate change

Climate change has been on the EU agenda for more than 20 years, and the EU is a major player on the international scene.[39] However, as pointed out by *Streck and Freestone*, the 'implementation gap', which is always a big problem of European environmental policy, is particularly obvious in the context of climate change.[40]

With this background to patent law, the question is whether a change in the regulatory environment is necessary. Can patent law repair what environmental regulation cannot? Are we explicitly to make our patent law system ensure the reduction of green house gas emissions? Or should we emphasise that patent law favours environmentally sound technologies, or at least add environmental damage to our detailed moral standard? One could ask whether patent law is neglecting its social responsibility if it does not act to deal with climate change.

Patent law must develop in line with developments in society, and the surrounding legal society often collides with patent law, requiring the outdated regime to hang on for dear life. But if *real life* requires the adoption of new rules, the experience from the biotech adventure warns us that EC interference with the current state of patent law is not to be wished for. The provisions on isolated DNA sequences as patentable subject matter have revealed legal uncertainty and the different approaches of the EU Member States.[41] France, Italy and Germany have a strict requirement for industrial application of gene sequences, and France also prohibits patents on sequences themselves. The EU Commission has been very reluctant to adopt a position and as a result it has been left to national courts to interpret. The legal approach to this by the EU has been a failure, and the EPO and the EU are stuck with the outdated and mistaken creation of patent law. The USPTO 2000 Utility Guidelines as a supplement to the US statute, and the case law approach in the USA seems better able to adapt smoothly to shifting directions as to the patentability of gene technology on different grounds (35 US §§ 101, 102 or 103). Lately, in a case before the United States District Court – Southern District of New York[42] in March 2010, the claimed isolated DNA was not markedly different from DNA existing in nature, and was therefore not patentable under 35 U.S.C § 101. Detailed regulation of the patentability of emerging technologies is not an appropriate solution, but the case law approach adapts smoothly to developments. If pre-grant conditions are concise, this may also affect blocking patents as a narrower scope of protection will diminish the blocking effect of a patent.

So far patent law has collided with trade aspects of IPRs, environmental concerns, access to pharmaceuticals for least developed countries, biotech and ethical issues. What has been learnt so far is that when global concerns are at stake patent law often lacks legitimacy. These collisions have had the major impact on the patent regime that it has lost its legitimacy, stuck between efforts to adopt new approaches and failing to do so. The outcome has been devastating to the scope of protection and quality of the patents issued. *This lesson is worrisome* when we now return to climate change. It seems that exactly the same components are present – law and policymaking repeats itself. And one can ask, do we need new rules favouring green inventions and creating uncertainty? The answer depends on which phase we address: the pre-grant phase or the post-grant phase.

To answer the question regarding the *pre-grant phase* it is necessary to focus on the nature of the environmentally sound technologies which ask for legal protection.[43] When referring to environmentally sound technologies, environmenttal lawyers think of adaptation and mitigation technologies. The former includes regional and local climate modelling, early warning, coastal zone management, water resources, agriculture and public health. The latter, mitigation technologies, includes energy supply, carbon dioxide capture and storage, and technologies for the reduction of green house gas emissions.[44] Today *feasible technologies are available*, but not all are commercially competitive without government or other support.[45] We have to identify the key barriers to more rapid development and deployment of *state-of-the-art* technologies and mechanisms that can accelerate these processes.[46]

Patent law today already embraces improvements and new technologies on turbine blades,[47] different sorts of clean technologies,[48] climate-tolerant crops for developing countries such as drought resistant crops, flood resistance, salt

resistance, sea grass and other crops for bio fuels can be protected. Clean farm animals are being developed, such as pigs (not a contradiction but a difference in genetic make-up); enviro-pigs expel up to 60 per cent less phosphorus than their non-transgenic counterparts.[49] A naked or featherless chicken is being genetically engineered, saving poultry farmers large amounts of money on ventilation to prevent their chickens from overheating.[50] Isolated and clean human genes may also be patented if we find solutions for enhancing the human metabolism in order to make humans eat less or perhaps dislike meat.

Against this background is it really necessary to regulate patent law in detail, given that patentable subject matter today generally covers environmentally sound technologies? There are several options for amending patent law, however taking previous experience into account, patent law must be kept to the straight and narrow.

One option is to insert environmental principles and objectives in patent law conventions, either as mission statements or terms in the preamble. The *mission statement option* is a preamble text in European and international patent conventions referring to internationally recognised environmental principles which, as a measure of global legitimacy, patent law has to respect.[51] The preambles are to be respected by signatory states as parties to the conventions. Starting with environmental principles, the most suitable principles are the principle of sustainability and the precautionary principle. The sustainability principle is globally recognised and it seems to be behind almost every piece of environmental legislation or climate change regulation today. As such, the principle is very suitable for being inserted in a preamble giving a political signal that patent law aims to promote technologies that can preserve the world for future generations. The precautionary principle is more connected to risk assessments, and perhaps this is most useful as a guiding principle for granting authorisations. However, one way to use the principle and that is for regulating the scope of protection.[52] If patent examiners are faced with applications on new emerging technologies, it might be appropriate to limit the scope of protection, and not to grant a product patent. Climate change has its own principles. Apart from the principles of sustainability and the precautionary principle, the most commonly referred to principle is that of common but differentiated responsibility. In his opening speech at the conference on 'Regulation Global Concern' in Sandbjerg, May 2010, *Thomas Cottier* addressed climate change as a *common concern of mankind*.[53] He pointed out that the principle is treaty-based and defined. Referring to the concept of a common concern of mankind in patent convention preambles may prompt awareness of the importance of a regulated *post-grant phase* such as a waiver-option for environmentally sound adaptation technologies for least developed countries.

Thomas Cottier has also written about the Doha Waiver and the amendment of TRIPS as introducing 'a new dimension to intellectual property and competition law: they reflect concerns for human rights, in particular the right to health and right to life….The right to health and life entail components of distributional justice which intellectual property and competition laws per se should support and assist in realization'.[54]

The *option of changing the wording* can work in several ways. Patent law provisions on patentability can favour inventions of environmentally sound technologies or can fast-track processing of such patent applications.[55] The fast track option has gained ground since 2009. The United Kingdom and the USA have

introduced a fast track system for green technology. The former has an accelerated procedure called the 'Green Channel' and the latter has a more detailed system.[56] This is a burden on the patent examiner but nothing indicates that a petty patent is the outcome. Some also argue that the term of protection for environmentally sound technologies ought to be extended or the fees reduced.[57]

The open question is how to make environmental impact assessments of a technology during the processing of a patent application without leaving patent examiners behind. *Estelle Derclaye* has argued that patentees ought to calculate the carbon footprint of their products.[58] Legislators just have to decide a standard, as in environmental law, and make it applicable to patents. She argues that for products it will be relatively simple, such as a reduction of emissions below a threshold in order to get favoured treatment.[59] One very promising option is to ask the patent applicant to disclose information about the environmental impact voluntarily. The only effect of this requirement would be at the infringement stage or in opposition proceedings.[60] This is a familiar approach, recalling the disclosure of origin of genetic resources.[61]

The *moral standard option* merely requires the addition of a new subparagraph (e) to the list in Directive 98/44/EC, Article 6(2), covering processes that are likely to cause harm to the environment. Adding the likelihood of harm relates to the precautionary principle.

3. Conclusion

As emphasised in the first section of this article, it is necessary to learn the lessons from environmental and biotechnology regulations, as well as from patent law when designing regulations on climate change. It is useless to repeat environmental principles that no one relies on and think that this is how to solve climate change problems. It is also useless simply to amend patent law with highly specific and detailed rules on environmentally sound technologies. As the biotech experience must have taught us, this may only lead to confusion and disharmony. The biotech lesson in particular, with its mix of competences between the EU and the EPO, is not the way forward. Until we adopt an EU patent, with its own patent Court of Justice, this area must be settled at the level of the EPO or the WTO.

To return to the starting point, it can be concluded that the shape of patent law is still good law. We can have a dynamic patent law system by keeping patent law to the straight and narrow. Patent law can adapt to the changing nature and pace of technology if we keep patentability standards straight and thereby restore its global legitimacy. The case law approach can be guided by terms in preambles, but to suggest that patent examiners should ask for technical advice or should address assessments long before the authorisation authorities are capable of doing so, is perhaps not the most appropriate solution. Patent law can consider the *common concern of mankind.* But amending pre-grant patent law cannot solve the emerging problems of lack of capacity and more urgent concerns in the least developed countries. In other words, patent law cannot save us from climate change.

We have to be open to new methods, other market-based instruments and guidance by means of taxation, fines and standards. Environmental rules are in themselves indirect incentives to promote clean technologies, and adding economic incentives may be more effective than amending *pre-grant* patent law. Given market forces, environmental regulation

has an impact on the kinds of inventions seeking protection, thereby reducing the global carbon footprint without changing the wording of patent law.

Why not consider a system awarding firms with prizes for technology transfer arrangements? The emphasis on climate change must put severe pressure on solving emerging problems in the least developed countries. To add common concern principles to patent convention preambles would reflect the social responsibility of patent law. Inventions benefiting a cleaner environment also benefit future generations and must be disseminated throughout the world. Efforts must be made to focus on adaptation technologies for the less developed world where people are most likely to suffer from climate change.

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[1] The WHO poster says: 'Climate change hurts, besides environmental and economic damage, the ultimate impact of climate change represents a toll on our most precious resource – human lives and health', see http://www.who.int/globalchange/multimedia/photos_posters/foot_corr.pdf.

[2] See New Challenge for the United Nations, OPI/433/-02726, February 1971.

[3] The Stockholm Declaration was adopted on 16 June 1972; see Philippe Sand: Principles of international environmental law, p. 40.

[4] See Philippe Sand: Principles of international environmental law, Ed. 2, 2003, p. 3; and Rudolf E. Blum, 'The Treat to our Environment and the Protection of Intellectual Property', in Industrial property and copyright: monthly review of the World Intellectual Property Organization, Geneva 1973, p. 243, for a description of the problems to be faced, p. 244. See Staffan Westerlund, 'Theory for Sustainable Development; Towards or Against?', in Hans Chr. Bugge & Christina Voigt (eds.): Sustainable Development in International and National Law, pp. 54-56.

[5] See The Johannesburg declaration at point 5: 'Accordingly, we assume a collective responsibility to advance and strengthen the interdependent and mutually reinforcing pillars of sustainable development — economic development, social development and environmental protection — at the local, national, regional and global levels', http://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/POI_PD.htm; and Marie-Claire Cordonier Segger, 'Sustainable development in International Law', in Hans Chr. Bugge & Christina Voigt (eds.): Sustainable Development in International and National Law, p. 87.

[6] See Decision -/CP15 at http://www.um.dk/NR/rdonlyres/AA2E8765-4158-4BD1-B29E-1CEDC5BF2CCE/0/COP15CopenhagenAccord.pdf.

[7] In its original version the integration principle was inserted in Article 130r(2). See also Jan H. Jans and Hans H.B. Vedder: European Environmental Law, Ed. 3, Ch. 1, development and principles.

[8] The principles of a high level of environmental protection, integration and sustainability are in Article 37 of the Charter.

[9] See Astrid Epiney, in Richard Macrory (ed.): Environmental Principles, in Reflections on 30 Years of EU Environmental Law – A High Level of Protection?, pp. 20 and 21.

[10] See Estelle Derclaye, 'Should patent law help cool the planet? An inquiry from the point of view of environmental law: Part 1', in EIPR. 2009, 31(4), pp. 168-184.

[11] Derclaye (n. 10) pp. 227-235; and Derclaye, 'Patent Law's role in the protection of the environment – reassessing patent law and its justifications in the 21st Century', in IIC 2009, 40(3), pp. 249-273.

[12] Epiney (n. 9) p. 21. For a more deterrent binding effect, see Estelle Derclaye, 'Not only Innovation but also Collaboration, Funding, Goodwill and Commitment: Which role for Patent Laws in Post-Copenhagen Climate Change Action', in 9 J. Marshall Rev. Intell. Prop.L 657 (2010), p. 659.

[13] See Peter Pagh, 'The Battle on Environmental Policy Competence', in Richard Macrory (ed.): Reflections on 30 Years of EU Environmental Law. A High Level of Protection?, p. 5.

[14] For justifications for patents, see Lionel Bentley and Brad Sherman, Intellectual Property Law, Ed. 3, p. 339;

and Nuno Pires de Carvalho: The TRIPS Regime of Patent Rights, Ed, 2, p. 9.

[15] Nuno Pires de Carvalho: The TRIPS Regime of Patent Rights, Ed. 3, p. 31.

[16] PGS/'Basta T356/93, February 1995, Official Journal of the European Patent Office, 1995, 545, the concept of *ordre public* also encompasses the protection of the environment; see also Ulrich Schatz, 'Patents and morality', in Sigrid Sterckx (ed): Biotechnology, Patents and Morality, p. 222.

[17] See T356/93 Plant cells/PGS; and Tine Sommer, 'Interpreting ordre public and morality in a patent law context: Which is the correct approach?', in Bio-Science Law Review, 2006/2007, 2 at p. 69.

[18] See T 356/93 at points 18.2 to 18.4 of the decision; and Sommer (n. 17) p. 69.

[19] Harvard/Oncomouse [1990] O.J. EPO 476.

[20] See Ulrich Schatz, 'Patents and morality', in Sigrid Sterckx (ed): Biotechnology, Patents and Morality, p. 222.

[21] See Estelle Derclaye, 'Patent Law's role in the protection of the environment – reassessing patent law and its justifications in the 21st Century', in IIC 2009, 40(3), p. 258.

[22] Schatz (n. 20) p. 222.

[23] See Tine Sommer, 'Interpreting ordre public and morality in a patent law context: Which is the correct approach?', in Bio-Science Law Review, 2006/2007, (2).

[24]See Frederick M. Abbott & Graham Dukes: Global Pharmaceutical Policy, Ensuring Medicines for Tomorrow's World, 2009, EE; Thomas Cottier, 'The Doha Waiver and Its Effects on the Nature of the TRIPS System and on Competition Law, The Impact on Human Rights', in Inge Govaere & Hans Ullrich (eds.): Intellectual Property, Public Policy and International Trade, at p. 175: 'a permanent regime of *lex specialis* on access to essential drugs in the TRIPS system of intellectual property protection'.

[25]See Meir Perez Pugatch, 'The process of intellectual property policy–making in the 21st century – shifting from general welfare models to a multidimensional one', in EIPR 2009 31 (6), p. 311.

[26] See e.g. Brad Sherman, 'Intellectual property and environmental protection', in EIPR 1991, 13(5), pp. 165-170 at p. 172.

[27]See Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of the General Council of 30 August 2003, cf. Article 6 (i). Article 7, first sentence, adds that Members recognise the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration.

[28] See Frederick M. Abbott, 'Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health', ICTSD, Issue paper No 24.

[29] Abbott (n. 28) p. 14.

[30] The waiver is still on the agenda. The TRIPS Council Meeting in June 2010 is set to review the little-used waiver, and boost availability of affordable medicines in developing countries, see http://www.ip-watch.org/weblog/2010/05/31/drug-access-waiver-debate-looms-for-june-trips-council-meeting/.

[31] Abbott (n. 28) p. 13.

[32] Abbott & Dukes (n. 24) p. 133 f.

[33] See Han Somsen, 'Some reflections on EU Biotechnology Regulation', in Richard Macrory (ed.): Reflections on 30 Years of EU Environmental Law. A High Level of Protection?, p. 329.

[34] Somsen (n. 33)p. 333.

[35] Somsen (n. 33) p. 335.

[36] For this discussion see, Tine Sommer, 'Scope of Gene Patent Protection and the TRIPS-Agreement – An Exclusively Nondiscriminatory Approach?', in in 38, IIC 1/2007.

[37] See Tine Sommer, 'Patenting the Animal Kingdom? From Cross-Breeding to Genetic Make-up and Biomedical Research', in 38, IIC 2/2008, p. 149 ff.

[38] The recital 10 in the preamble to the Directive states that regard should be had to the potential of the development of biotechnology for the environment and in particular the utility of this technology for the development of methods of cultivation which are less polluting and more economical in their use of ground; whereas the patent system should be used to encourage research into, and the application of, such processes. Furthermore recital 11 addresses developing country issues, and recital 36 refers to TRIPS Article 27(2).

[39] See Charlotte Streck & David Freestone, 'The EU and Climate Change', in Richard Macrory (ed.): Reflections on 30 Years of EU Environmental Law. A High Level of Protection?, p. 87.

[40] Streck & Freestone (n. 39) p. 88.

[41] For this discussion see, Tine Sommer, 'Scope of Gene Patent Protection and the TRIPS-Agreement – An Exclusively Nondiscriminatory Approach?', in 38, IIC 1/2007.

[42] See Case 1:09-cv-04515-RWS, document 255, filed 3/29/2010: American Civil Liberties Union Foundation and Public Patent Foundation.

[43] See The new 'tagging clean energy' database created as part of a joint study on IP and climate change mitigation technologies carried out by the United Nations Environment Programme (UNEP), the EPO and the International Centre for Trade and Sustainable Development (ICTSD): http://www.epo.org/topics/news/2010/20100611.html.

[44] See Background paper: Climate Change: Technology Development and Technology Transfer, Beijing High-level Conference on Climate Change: Technology Development and Technology Transfer, Beijing, China, 7-8 November 2008, UN Department of Economic and Social Affairs, pp. vii, viii, and 2.

[45] Background paper (n. 44) p. 2 f.

[46] Background paper (n. 44)

[47] See for example US 2010/0135806 A1: a wind turbine blade includes a plurality fins, each fin rotatably-joined to a tip of the blade.

[48] Cf. http://greenenergyreporter.com/2010/06/8696/.

[49] Sommer (n. 37).

[50] http://www.nytimes.com/2002/05/24/world/rehovot-journal-cluck-cluck-chickens-in-their-birthday-suits.html. Although due to prior art it is not patentable.

[51] See in general a proposal for a mission statement as a clear statement of the purpose of the patent system that might facilitate decisions on whether to include new subject matter under the patent system, and might be a valuable source of reference in court cases on patent related matters, STOA, Policy Options for the Improvement of the European Patent System (IP/A/STOA/FWC/2005-28/SC16 at page 33.

[52] See also 'The future of the patent system', The Danish Board of Technology, page 22 http://www.tekno.dk/subpage.php3?article=1132&toppic=kategori11&language=uk.

[53] UN GA Resolution 43/53, 1988: The UN Framework Convention on Climate Change, UNFCCC, in its preamble stated that changes in the Earth's Climate are a common concern of humankind, and the Convention on Biological Diversity, CBD, stated that the conservation of biological diversity is a common concern of humankind. See Thomas Cottier and Sofya Matteotti-Berkutova, International environmental law and the evolving concept of 'common concern of mankind' in Thomas Cottier, Olga Nartova & Sadeq Z. Bigdeli (eds.): International Trade Regulation and the Mitigation of Climate Change, p. 38.

[54] Thomas Cottier, 'The Doha Waiver and Its Effects on the Nature of the TRIPS System and on Competition Law, The Impact on Human Rights', in Inge Govaere & Hans Ullrich (eds.): Intellectual Property, Public Policy and International Trade, p. 198

[55] See the USPTO pilot project, http://www.uspto.gov/patents/init_events/green_tech.jsp. For the UK, see http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-green.htm.

[56] See Estelle Derclaye, 'Not only Innovation but also Collaboration, Funding, Goodwill and Commitment: Which role for Patent Laws in Post-Copenhagen Climate Change Action', in 9 J. Marshall Rev. Intell. Prop.L 657 (2010), pp. 662-661.

[57] Derclaye (n. 10) pp. 227-235; and Derclaye, 'Patent Law's role in the protection of the environment – reassessing patent law and its justifications in the 21st Century', in IIC 2009, 40(3), pp. 249-273.

[58] EIPR/IIC. See also Derclaye (n. 56) p. 660.

[59] Derclaye (n. 56) p. 660.

[60] See Carolyn Abbott & David Booton, 'Using Patent Law's teaching Function to introduce an Environmental Ethic into the Process of Technological Innovation', in 21 Geo. Int'l Envtl. L. Rev. 219 (2009), pp. 248-249, cited in Estelle Derclaye, 'Not only Innovation but also Collaboration, Funding, Goodwill and Commitment: Which role for Patent Laws in Post-Copenhagen Climate Change Action', in 9 J. Marshall Rev. Intell. Prop.L 657 (2010), p. 660.

[61] See e.g. the preamble to Directive 98/44/EC, recital 27.