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Patent law and bioprospecting in Antarctica

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ABSTRACT. The number of patents and patent applications related to inventions based on biological material from the Antarctic is increasing. Bioprospecting in the Antarctic is happening with no explicit regulation of property rights or benefit sharing requirements. This leaves patent law as the only legal system to establish exclusive rights to genes, bacteria, and other biological material found in the Antarctic. Patent law is general in form and is applied to all areas of invention with very few adaptations to single fields of innovation. Therefore, it is interesting to identify the issues in patent law in cases in which the biological material from the Antarctic is likely to create challenges or loopholes. The aim of this article is to couple the understanding of this particular legal regime and of biological circumstances in the Antarctic with knowledge of the international patent system for the purpose of contributing to the work of the Antarctic Treaty Consultative Meetings (ATCMs) regarding bioprospecting in the Antarctic.

Contents

Introduction

'Bioprospecting' is generally understood to be the search for new (and valuable) biological material, biochemical or genetic material (see Farrell and Duncan 2005). Advances in biotechnology and gene technology have led to increased interest in the use of biological material and genetic resources. This article analyses patent law relevant to bioprospecting in the Antarctic. The desolate character of the Antarctic has made it primarily a region for exploration and scientific research. Recently, pharmaceutical and biotechnology industries have shown considerable interest in searching for new biological components there (ATCM 2006c, 2007b). The number of patents that include biological material of Antarctic origin is growing rapidly (Rogan-Finnemore 2005: 3–4).

The increased interest of bioprospectors and scientists can be explained from different angles. Cold and remote with no native human population, the Antarctic differs significantly from all other continents (Rogan-Finnemore 2005b). Its low temperatures, high aridity and salinity, and generally extreme and harsh conditions have led organisms to develop special characteristics and traits in order to survive (Nichols and others 2002: 86); only the hardiest of species cling to life in the Antarctic. As yet we know relatively little about life in the region, and it may prove to house new and unknown organisms of great potential. Increased technological possibilities have spurred the search for new biochemical and genetic properties in both science and commercial activities.

Despite the rapid growth of search and sampling of biological material in the Antarctic, the regulatory framework for this activity remains unclear, if it exists at all (Hemmings and Rogan-Finnemore 2005a: 237). A main concern raised by increasing bioprospecting relates to the exploration and exploitation of this biological diversity as a natural resource, with the need for avoiding conflicts among stakeholders that claim rights to the same resources. There are the issues of equity and fairness concerning the distribution of resources extracted.

As recently as in 2003 it was noted that '[b]ioprospecting has not yet touched a serious nerve among the Antarctic custodians' (Jabour-Green and Nicol 2003: 19). And at the same meeting Norway and the UK submitted an information paper on existing regulations (ATCM 2003). In the time after 2003 the focus on bioprospecting has become more intense. Bioprospecting entered the agenda of the Antarctic Treaty Consultative Meeting (ATCM) at the 25th session in September 2002 as agenda item CEP 4d (see ATCM 2002). In 2004 an information paper on industry involvement was submitted (ATCM 2004). At the ATCM in 2005 in Stockholm a working paper and two information papers addressed the issue (ATCM 2005a, 2005b, 2005c). At the ATCM in 2006, bioprospecting was discussed with the point of departure being an academic paper (ATCM 2006a) and in an information paper from Argentina regarding their bioprospecting activities in the Antarctic (ATCM 2006b) and in an academic paper about recent trends (ATCM 2006c). At the 30th ATCM in Delhi 2007 biological prospecting was again at the agenda. Two papers were presented. The Netherlands Belgium and France presented 'WP 036 Biological prospecting in the Antarctic Treaty area – scoping for a regulatory framework'; and the United

Nations Environment Programme (UNEP) introduced 'IP 067 Biological prospecting in Antarctica: review, update and proposed tool to support a way forward' (ATCM 2007a, 2007b). This ATCM agreed to establish an informal open-ended web-based intersessional contact group (ICG) working until the next ATCM to examine the issue of biological prospecting in the Antarctic Treaty area (ATCM 2007c: final report, paragraph 258–263). At the 31st meeting, this topic was on the agenda as item 17, in which the report from the intersessional contact group was discussed (ATCM 2008). At the 32nd ATCM the topic of bioprospecting was again at the agenda in several documents (ATCM 2009a, 2009b, 2009c, 2009d), and there was a call for completing the survey of the bioprospecting activities of each nation (SCAR 2009: section 4.3, also presented to the ATCM as ATCM 2009e).

Bioprospecting encompasses activities with different ends, from strictly academic or taxonomic research to the highly commercial search for economically valuable traits for the biotechnological or pharmaceutical industry (Farrell and Duncan 2005: 11). When bioprospecting first was addressed as an activity in the 1990s, a clear distinction was made between purely academic and purely commercial ends concerning the use of biological diversity.

Bioprospecting occurs at two levels:

1. study of genetic materials and determination of commercially important genetic codes and
2. harvesting of *in situ* organisms for extraction of biochemicals (SCAR 2002).

Since 2002, this distinction has become more and more blurred, as it has become increasingly common for academic and private activities to include commercial aims in collecting and doing research on biodiversity. For example, many academic institutions now use intellectual property rights, as patents, to secure rights to commercial returns on their academic research (ACTM 2007b).

Patent law is general in scope and grants time-limited exclusive rights to inventions that are considered novel, inventive and with potential industrial application. Biological material is widely recognised as patentable even if it previously existed in nature in a slightly different form (naturally occurring rather than in isolated and purified form). This in turn makes patent law highly relevant for bioprospecting anywhere, including in the Antarctic. There is an increasing number of patent applications and patents granted for biological inventions from the region (ACTM 2007b: 5–11). The main intention of this paper is to contribute to the knowledge base on how the key principles of patent law apply to the biological resources from the Antarctic, and to contribute to the debate on regulating property rights to genetic resources and biological resources. In the larger picture, this may, it is hoped, contribute to finding a proper balance between the industrial/commercial potential of Antarctic biological material and maintaining the common use of the Antarctic region. Such balance is a main challenge for law in the future (Jabour-Green and Nicol 2003: 111)

The remainder of this paper discusses core elements of the patent system and identifies crucial questions and problems for patents for Antarctic biological material. The second section gives an overview of the existing relevant laws for bioprospecting in the Antarctic. The third section looks more closely into the eligibility of inventions from the Antarctic. The remainder of the paper considers a number of particular challenges for biological inventions from the Antarctic regarding patent criteria, the disclosure requirement and the scope of protection granted by a patent respectively.

Bioprospecting in the Antarctic: outlining existing regulations

The Convention on Biological Diversity (CBD) is the main international legal instrument for regulating biological diversity and genetic resources. The CBD regulates various aspects regarding genetic resources and biological diversity, with the latter defined as: 'the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems' (CBD 1992: article 2). It establishes sovereign rights for states over genetic resources, including the right to regulate access to genetic resources and to sharing the benefits accruing from their use (CBD 1992: article 15 (1), (2), (7)).

A main objective of the CBD is to capture part of the value drawn from the use of genetic material, to be allocated from those utilising the genetic material to others, for example, the custodians who have worked to preserve such biological diversity, or the countries that have conserved biodiversity without extracting the bulk value of the biological resources. (For ananalysis of the rationale behind benefit sharing and further suggestions, see Tvedt and Young 2007). The CBD applies to 'components of biological diversity, in areas within the limits of its national jurisdiction' (CBD 1992: article 4). The delimiting criterion for the area in which states, according to the CBD, have the sovereign right to exploit their own natural resources is 'within their jurisdiction'. As the issue of sovereignty in the Antarctic remains open under the Antarctic Treaty, there is, no clear answer concerning who would exercise such a right to exploit biological resources.

The United Nations Convention on the Law of the Sea (UNCLOS) is the main international treaty regulating the use of the oceans and their resources. UNCLOS also regulates the rights and duties of states in areas outside the limits of national jurisdiction, although property rights to living marine resources such as biological material and genetic resources in that part of the seabed are not dealt with specifically. On the high seas, the principle of the freedom of the seas applies. Living marine resources in the high seas are open to access and use by all, subject to conservation regulations. Work is being undertaken

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both under the UNCLOS and the UN General Assembly regarding bioprospecting on the oceans (see ACTM 2007: 15–16).

The scope of discussions concerning the Antarctic is broader than the scope of the benefit sharing obligations stipulated in the CBD. 'Bioprospecting' also targets regular biological and biochemical use of biological material: it is not confined solely to the inherent genetic material only. Furthermore, bioprospecting is geared more towards activities than resources. Jabour-Green and Nicol (2003: 85–87) propose discussing bioprospecting in terms of four phases:

sample collection;
isolation, characterisation and culture;
screening for pharmaceutical activity;
development of product, patenting, trials, sales and marketing.

Dividing bioprospecting into these phases might promote insight into the process, but from a legal viewpoint it is not particularly useful. Property rights issues arise mainly in connection with the first and the fourth phases of this structure. The property rights situation for genetic resources and biological resources in the Antarctic and in the high seas and sea bed beyond national jurisdiction is not regulated in detail and remains unclear. This leaves patent law as the most relevant legal tool to create exclusive rights to biological material and genetic resources taken from these areas.

Antarctic Treaty system

The Antarctic Treaty system (ATS) is the mechanism for regional cooperation in respect of the Antarctic. The main normative component of this system is the Antarctic Treaty, which has been in effect since 1961 and applies to the area south of 60°S, including all ice shelves. Although this wording seems to include the sea areas, the exercise of the rights of states under international law with regard to the high seas within that area are not in any way affected by the treaty. (For an extensive analysis on the relationship between the Antarctic Treaty system and the law of the sea, see Vidas 1996).

The Antarctic Treaty is of unlimited duration and is based upon three principles: the continuance of freedom of scientific investigation and cooperation (Antarctic Treaty 1959: article 2), the dedication of Antarctica for peaceful purposes (Antarctic Treaty 1959: article 1) and the preservation of the Antarctic environment (Antarctic Treaty 1959: article 9 (1)(f)).

The treaty has no permanent organs, but the regular practice of consultative meetings has produced a considerable body of rules and provided a limited co-administration of the Antarctica within the scope of the treaty's objectives. Growing environmental focus has also led to the adoption of the 1991 Protocol on Environment Protection to the Antarctic Treaty, which has introduced new dimensions with respect to the Antarctic Treaty area. Also, the Convention for the Conservation of Antarctic Seals, the Convention on the Conservation of Antarctic Marine Living Resources (CCAMLR) and the Convention on the Regulation of Antarctic Mineral Resource Activities (CRAMRA) fall within the scope of the ATS and reflect special features more distinctively than does the Antarctic Treaty itself.

Patentability and bioprospecting in the Antarctic

Several patents have been taken out on substances from the Antarctic (ATCM 2007b). This indicates that the patent system is being used for establishing exclusive rights for biochemical and genetic resources from the region. The general justification for granting time limited patent rights is to encourage research and development and to create an incentive for private companies to make new products and bring them onto the market.

Often the term 'the patent system' is used, with the definite article, and in the singular, erroneously implying that there exists one coherent and universal patent system in the world. Today, there exists no one single coherent world patent system, but a number of nation and region specific systems tied together by global harmonisation and regional cooperation. However, there are several indicators that a system for the grant of worldwide universal patents may be on its way (see Tvedt 2007a).

The most comprehensive global harmonisation of international patent law to date is the trade related aspects of intellectual property rights (TRIPS) agreement of the World Trade Organisation (WTO 1994), which requires all member countries to provide patent protection for 'any inventions, whether products or processes, in all fields of technology' (WTO 1994: article 27, paragraph 1). From this comprehensive main rule, discretion is left to individual countries to exempt from patentability 'animals and plants other than micro-organisms'; and to exempt 'essential biological processes'. The TRIPS agreement thus requires that countries grant patents on micro-organisms and on non-biological processes, which narrows down the scope for exemptions. The literature contains frequent references to the discretion for exemptions in eligibility for patent protection, without discussing how these relate to the scope of patent protection, thereby leaving much of the picture hidden. Westerlund (2001) discusses the scope of patent protection in relation to the exemptions and provides a thorough analysis of the issue.)

Partly due to the TRIPS agreement, the comprehensive scope of patent eligibility has been expanded to be global in scope, but its detailed implementation in the various national patent systems results in some country specific differences regarding the scope of patentability. There is no general exemption from eligibility for patent protection for resources found in the Antarctic. In the major patent offices of the USA, Europe (the European Patent Organisation) and Japan, exemptions from patent eligibility are interpreted and implemented in a narrow manner, most probably leaving the exemptions without any effect for biological material from the Antarctic

(Jabour-Green and Nicol 2003: 90). Patent law is not concerned about the provenance of the biological material (such as genes or biochemicals) used to develop the invention. This means that biochemicals, genes, proteins and micro-organisms found in the Antarctic will be patentable, provided that the invention in question meets the general patent criteria of novelty, inventiveness and industrial application.

The core term of patent law is 'invention.' Inventions are patentable, but 'discoveries' are not. As bioprospecting involves the search for new biochemical or genetic material, the essential question is whether these findings can be characterised as inventions or as mere discoveries. This dicotonomy has been subject to debate (see for example Jabour-Green and Nicol 2003: 89, referring to one major protest based on ethical and religious grounds) but current patent laws and practice in developed countries are fairly clear on this point: naturally occurring biological materials, including living organisms as micro-organisms, are generally considered as inventions and are thus patentable (Jabour-Green and Nicol 2003: 90–93). For example, according to the European Union (EU) directive on biotechnological patents (EU 1998):

> [I]nventions [. . .] shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.
>
> 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. (EU 1998: article 3, paragraphs 1, 2)

Thus, if substances, genes or micro-organisms from the Antarctic are isolated from their natural environment, they are eligible for patent protection if they otherwise meet the general patent criteria. The scope of patentability and the interpretation of what is an invention vary to some extent among countries, but the TRIPS agreement does not allow countries discretion to implement a general exemption for applying patents to all biological material inventions or a general exemption for Antarctic biological resources.

Patent criteria and the Antarctic

For a patent application to be granted, the invention must meet the general patent criteria: it must be 'new, involve an inventive step and [. . .] capable of industrial application' or be 'new', 'non-obvious' and 'useful' (WTO 1994: article 27, paragraph 1, with footnote). The practice and more detailed interpretation of these criteria are left to the patent law and patent office of each country.

These criteria are among the outstanding major topics in patent law that will have to be harmonised before patents can be granted globally in a worldwide patent system (Tvedt 2007a). Therefore, the harmonisation of these pre-grant issues has been identified as of central importance by the group of developed countries in the World Intellectual Property Rights Organisation (WIPO), and was suggested should be negotiated first detached from other remaining issues. All attempts to get developing countries to agree to fragmentise the agenda failed. The diverging opinion expressed by the developing countries regarding whether these topics should be negotiated separately was one important reason why work in the standing committee on the law of patents finally broke down in April 2006, after years of deadlock and lack of progress in negotiations. Developed countries are currently negotiating these topics without the developing countries in an informal forum. As regards the Antarctic, such negotiations cannot be expected to include any specific references to the considerations of patent criteria for biological material from the area. The general scope of patent law implies that it will apply also to inventions based on biological material of Antarctic origin, so they will have effect for patenting of Antarctic based biological inventions.

Prior art and the Antarctic

Despite the absence of complete international harmonisation it is possible to identify some critical patent issues for Antarctic based inventions. According to patent law an invention is 'new' if it has not already been made available to the public in an item of prior art. The most relevant 'item of prior art' is what has already been patented by others or described in a written publication. For biological material from the Antarctic published scientific papers constitutes the most important single body of prior art. 'Novelty' in patent law does not mean that it must be absolutely new. Already existing biological material meets this criterion if it has been isolated from its natural form and has not been described or presented in writing previously. With regard to the Antarctic, this point is highly pertinent, as the act of isolation and acquiring knowledge about the function of the biological material can, in the major patent systems, suffice to fulfil this criterion. Whether it is easy to obtain a patent on biological material from the Antarctic will depend upon the body of items of prior art that are searched. The existence of only a minimal body of literature makes obtaining a patent easier: when there are only few publications, the patent application is more likely not to be identical with what is described in existing publications. An additional practical matter is whether the patent offices have sufficient access to this material to prevent already published insights from being patented. The relatively limited knowledge about the living organisms in the Antarctic opens the field for patents to be granted.

Novelty and Antarctic based inventions

Just how similar to what has been described in existing published academic papers can the new invention described in the patent application be, and still be considered 'novel'? This is a highly relevant question, since the answer will indicate whether the commercial application of existing and published knowledge might come to be patented by another commercial actor than the original

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researcher. The more specific practice regarding the novelty consideration rests with national legislation. The WIPO standing committee on the law of patents had drafted a substantive patent law treaty (draft SPLT) (WIPO 2003), which can give an indication of how the global standard for the patent criteria might be in the future. After all, the B-Group countries, which are the industrialised countries with an interest of stronger patent law world wide, are already using parts of this draft SPLT as the basis for their harmonisation negotiations outside the WIPO (Tvedt 2005). This draft treaty proposes an international standard for novelty:

> [Novelty] A claimed invention shall be novel. It shall be considered novel if it does not form part of the prior art [as prescribed in the regulations] (WIPO 2003: article 12 (2), regulation: SCP/10/4 22).

The relevant test is to measure the similarity between the claimed invention and the previously published item of prior art:

> (1) [Item of prior art] (a) An item shall qualify as an item of prior art only if it enables a person skilled in the art to make and use the claimed invention. (WIPO 2003: rule 14 (1), regulation: SCP/10/5 26.)
>
> Thus, the draft regulation under the SPLT sets a qualitative requirement as to items of prior art.

This requirement must be read in conjunction with the next paragraph of the draft:

> (b) Any item of prior art relevant to the determination of lack of novelty may only be taken into account individually and may not be combined with other items of prior art. (WIPO 2003: rule 14 (1) (b), regulation: SCP/10/5 26.)

The definition limits the novelty assessment to single items of information that enable other persons to redo the invention. In terms of assessing novelty, a person skilled in the art must be enabled to make and use the invention on the basis of each of the items of prior art, judged individually. On the other hand, under certain conditions, items of prior art can be assessed together, when one of the items of prior art is 'incorporated by explicit reference in another item' (WIPO 2003: rule 14 (1) (c), regulation: SCP/10/5 26).

The existing body of literature about the Antarctic flora and fauna will determine how easily a patent will be regarded as novel and inventive. A scarce literature describing the functions of the genes or the biochemical traits or properties from the Antarctic will permit an easier satisfaction of the patent criteria. Already published academic papers and insights about biological resources from the Antarctic risk being deemed insufficient to be considered 'items of prior art', if they are not regarded as sufficient to teach a person skilled in the art about another invention; and it opens the scientific body of literature to indicate the useful biological material for bioprospectors. If the novelty requirement is practiced strictly, as referring to near identity between the invention and each item of prior art, it will be fairly easy to meet this requirement for biological inventions based on Antarctic material.

Inventiveness and Antarctic based inventions

When assessing novelty, the main aim is to prevent identical inventions from being patented. For the inventiveness or non-obviousness criterion, the aim is to grant patent protection only for inventions involving a sufficient level of development of the state of the art. Once again, it is useful to inquire into the possible future legal situation:

> [Inventive step/non obviousness] A claimed invention shall involve an inventive step. It shall be considered to involve an inventive step (be non obvious) if, having regard to the differences and similarities between the claimed invention and the prior art as defined in Article 8(1), the claimed invention as a whole would not have been obvious to a person skilled in the art at the priority date of the claimed invention [as prescribed in the regulations]. (WIPO 2003: article 12 (3), regulation: SCP/10/4 23).

To assess inventiveness or non obviousness, the claimed invention shall be compared with the prior art. The wording starts out by referring to 'inventive step', but then the wording shifts to 'not being obvious', which is a much more lax consideration from the point of view of the patent applicant and which opens the way for more patents to be granted. The assessment of differences and similarities concerns whether 'the claimed invention as a whole would not have been obvious to a person skilled in the art' based on the information explicitly or inherently disclosed as parts of the prior art for a person skilled in the art. There is no necessity that academic reports provide the information in a manner that will make a subsequent commercial invention, based on already published knowledge, to be regarded as 'obvious' for a person skilled in the art. *Not* to be obvious would require a high degree of similarity between the existing items of prior art and the invention as a whole. This will probably enable biological material from the Antarctic to be protected under patent protection, even if it has already been scientifically described.

The third patent criterion, industrial applicability, is even easier to meet. Current practice in the most important patent systems operates with a very low threshold for demonstrating industrial application. A group of patent law specialists, appointed as the Nuffield Council, has recommended that the practice of granting product patents to genes (and biological material) should be revised, and that patent offices should require a more specific and detailed description of the industrial application or use of the gene (Nuffield Council on Bioethics 2001). This would probably have the effect of limiting the breadth of product patent protection for naturally occurring genes. A low requirement as to the industrial applicability of the patent makes it relatively easy to patent biological material from the Antarctic, even in cases when the patentee does not foresee a specific and concrete utilisation or use of the gene or biological component. In the longer run, this would exclude others from using the same biological material in research and development, due to the scope of the exclusive right conferred by the patent.

Disclosure of the invention: deposit of the biological material

Patent law uses the term 'disclosure' with two different meanings: the regular disclosure requirement as a basic principle in patent law; and the highly disputed requirement for disclosure of origin (source and legal provenance) for the biological material used in the invention. Both these discussions are of relevance for bioprospecting in the Antarctic.

Disclosure of the invention as a basis for the patent

The main principle in patent law is that the patent applicant must describe his invention by the use of written language. This is often referred to as the *quid pro quo* in patent law: the patentee gets an exclusive right, but must make the invention available to the public in a written description (Bostyn 2002). When the patenting of living organisms, in particular micro-organisms, started in the 1970s, the countries involved decided to accept the deposit of biological material as a supplement to, and replacement for, the written description requirement. Such deposit then makes it easier to be granted a patent to inventions covering biological material even if the patent applicant is not able to describe the invention by the use of language only. This is regulated by the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (BT) (BT 1977) and the supplementing Budapest Treaty regulations (BT regulations 1977, and amendments).

From the perspective of the Antarctic Treaty this raises the question of the public availability of research results for other researchers. The BT itself does not regulate the availability of research results for others than the patentee, but the regulation under its rule 9.2 specifies a principle of secrecy:

> No international depositary authority shall give information to anyone whether a microorganism has been deposited with it under the Treaty. Furthermore, it shall not give any information to anyone concerning any microorganism deposited with it under the Treaty except to an authority, natural person or legal entity which is entitled to obtain a sample of the said microorganism under Rule 11 and subject to the same conditions as provided in that Rule (BT regulations 1977: rule 9.2 secrecy)

The regulations according to rule 11 imply restricted access to the biological material in deposit. It is not open for everyone to secure access to the deposited material for experimental use of the invention. This is narrower than the normal situation in patent law, in which the disclosure of the invention makes the insight open to the public. The open publication of the invention is regarded as an important balancing principle of the patent system, enabling others to know about the invention and understand it by experimental use. Under the BT system, private parties cannot access the samples in deposit.

The lack of availability of the biological material in deposit needs to be seen in the light of the Antarctic Treaty system. The Antarctic Treaty states that: '[s]cientific observations and results from Antarctica shall be exchanged and made freely available' (Antarctic Treaty 1959: article III (1) (c)). When the Budapest system restricts the availability of the biological samples deposited, it restricts to some extent the availability of results from research, and does not encourage the exchange of such. At this point the general rules of the patent system run counter to the Antarctic Treaty.

Disclosure of the origin of the biological material

One of the politically contentious issues in the crossfire between the CBD and the TRIPS agreement is whether to require the patent applicant to disclose the source/origin/legal provenance of the biological material used as a basis for the invention. There is a comprehensive body of literature on this issue (see for example Biswajit and Anuradha 2004; Dross and Wolff 2005; Dutfield 2002; Girsberger 2004; Tvedt 2007b; Tvedt 2006; WIPO 2004: study 3). The matter is being discussed in the TRIPS, in the inter governmental committee of WIPO and in the groups dealing with the Patent Cooperation Treaty (PCT) and in the CBD.

The demand from the developing countries requiring openness from patent applicants regarding the origin/source/legal provenance of biological material is equally strongly opposed by the industry and developed countries (Finston 2005; Wolfe and Zycher 2005). The main reason why developing countries want such a requirement in patent law is the hope that this can lead to benefit sharing as required in the CBD (CBD 1992: article 15, (7)) and the maintenance of the public domain and respect for the sovereign rights of countries to genetic resources and biological material. Industry argues that it would be too burdensome to have to provide such information in the patent application. This sounds however, rather odd, as it would be surprising if commercial companies did not keep records of the origin or provider of the biological material in which they invest considerable sums as a basis for innovation and development of a new product. The obvious fact that they might want to go back and acquire more of the same biological material if needed is a strong indication that companies would keep such records for internal purposes. Thus far, very few countries have implemented an obligation to provide such information in the patent application. Lack of compliance with these requirements has no bearing on the validity of the patent in these countries. For example, in Norway it has been made a public criminal offence (Norwegian Patent Act 1967: 8; Norwegian Penal Code 1902: 166). There is, however, a discrepancy between requiring information to be given, and the benefits actually to be shared from a beneficiary from utilisation of genetic resources to the provider of the resources. This might prove to be an obstacle, preventing the disclosure requirement from ensuring effective sharing of benefits as prescribed in the CBD (Tvedt 2007b).

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In the Antarctic context, the best a disclosure requirement could bring would be that the patentee discloses that the biological material used to make the invention is to be found in the Antarctic. If at some point the countries should decide to regulate the legal status of biological and genetic resources from the Antarctic, information about where these are found could prove to be useful. This would especially be so if there are established rules stipulating some type of benefit sharing from the utilisation of the Antarctic biological material.

The scope of patent protection and the Antarctic

Patent protection to biological inventions

The basic principle of the patent system is that the patent claims describe the invention to which the patentee has exclusive rights. The TRIPS agreement sets an internationally harmonised standard for what is to be conferred by patent protection:

> A patent shall confer on its owner the following exclusive rights:
>
> (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product (WTO 1994: article 28)

This wording sets a comprehensive rule conferring on the patentee the right to make, use, offer for sale, sell or import what is described in the patent claims as the invention. This alternative in the TRIPS agreement refers to product patents. The other main alternative is process patents; however, the latter targets processes and not Antarctic biological resources as such, and will therefore not be further examined here.

These generally formulated actions included under the exclusive right raise several specific questions for biological material, such as the following. What is meant by 'making' a gene or micro-organism? Does the reproduction of the biological material described in the patent claim constitute the 'making' of an invention? When is a patented gene or other part of biological material 'used'? According to a linguistic interpretation, 'using' a gene would include cases in which an organism renews itself by drawing upon the patented gene. If a researcher reproduces an organism from the Antarctic with the effect that the patented gene or cell is transferred to the next generation of organisms, does that mean that the gene is 'used' in the sense covered by the scope of protection according to the TRIPS agreement? If researchers other than the patentee do research on the patented gene or micro-organisms, are they then 'using' the invention if it covers the isolated gene? None of these questions are specifically solved either in global treaties or by national case law (there are, however, regional attempts to make these rules more concrete, for example Directive on Biotechnological Patents 98/44/EC of the European Union (EU 1998: articles 8 and 9)).

The point of departure for determining any patent right involves an interpretation of what is covered by that product as described in the patent claim. Since the patent claim describes the individual invention it is difficult to discuss this at a general level. One interesting case is if the patent claim targets a biological resource with Antarctic origin in a patentable manner. The wording of the patent claim describes the invention and is legally binding. A fundamental difference between regular inventions and patents on naturally occurring biological material is that the vast majority of other inventions do not pre-exist in nature but are totally man made; by contrast, a gene or other biological material is already there in nature, only in a slightly different form. The fact that the gene or other biological material already occurs in other individuals that exist independently of the specimen held by the patentee gives rise to several difficulties. To determine this, patent law requires the patented invention to be compared with the acts of the other user. It is, however, difficult to say something general about this since the case of an infringement must be determined concretely. The more specific rules about the scope of the patent protection are subject to national legislation and case law in each jurisdiction. Therefore, these questions will probably not be solved identically in all countries.

How does this apply to the Antarctic situation?

The lack of identical principles among countries for the interpretation of the scope of patent protection exposes the legal situation as different in different countries even if the patent targets an identical biological invention. Regardless of these potential differences, the most relevant rule under the Antarctic Treaty system is the article III (1) (c): 'Scientific observations and results from Antarctica shall be exchanged and made freely available' (Antarctic Treaty 1959: article III (1) (c)). It is a difficult question to determine the scope of this obligation as 'scientific observations and results' is not a precisely defined term.

The paper presented by the Netherlands, Belgium and France to the 30th ATCM deals with patenting as follows.

> Commercialization. Pursuant to Article III.1 of the Antarctic Treaty, scientific observations and results from Antarctica shall be exchanged and made freely available to the greatest extent feasible and practicable. The patenting of substances and/or technology derived from genetic resources, resulting from biological prospecting in Antarctica, would therefore not seem to be inconsistent with Article III.1. It merits consideration whether commercialization should be subject to further regulation. (ATCM 2007a)

This is the expressed view by three countries and is not agreed text, and it seems that these three countries express a view that article III is not in conflict with patenting Antarctic biological inventions for commercial purposes. This is, however, a question which is open for further discussion and clarification.

The underlying difficult question is whether there is conflict between establishing an exclusive right covering,

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for example, using and making the Antarctic based invention and the accessibility of scientific observations and results. This is a question concerning the availability of research results and use by others of the modified/isolated/found biological material and derived products. A similar question was due for discussion regarding the relationship between scientific research and property at the time when minerals were an active topic for the ATCM (see for example Tessensohn 1987).

The underlying difficult question is whether the patent on the isolated naturally occurring gene or other biological expression will be available for other researchers. Under the current patent law situation this will depend on the interpretation of the scope of patent protection.

The scope of patent protection raises also the question of to what extent a granted patent will hinder other researchers who are doing research on the same or similar naturally occurring biological material found in the Antarctic. This is also a matter for the interpretation of the scope of the conferred patent protection under patent law. Research on patented biological material, even when other specimens are taken from the wilderness, might in some situations be interpreted as being covered by the scope of the patent. Again this will depend on the patent legislation and court cases in the countries in which the patent is granted.

Both these major legal challenges stem from the fact that patent law is general in scope and not particularly developed for the sampling and use of biological material from the Antarctic. To bring products based on Antarctic biological material to the market is a complicated and often expensive process. Thus, there is a clear need to recapture such investment. The availability of research results stands against the need for exclusive rights to products developed from bioprospecting in the Antarctic. The interesting legal and political question which needs to be solved is how a balance could be achieved.

Possibilities for a research exemption for the Antarctic

Perhaps one approach to resolving these challenges can be sought in using the flexibility of TRIPS article 30, specifying the conditions under which others may use research results from the Antarctic. One interesting question is whether the rule under the Antarctic Treaty could be implemented as an exemption under TRIPS article 30, which reads as follows.

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties (WTO 1994: article 30).

This sets two criteria that must be met: 'do not unreasonably conflict with a normal exploitation' and '(do not) prejudice the legitimate interests'. The problematic criterion is that such exemption should not be in unreasonable conflict with normal exploitation. Normal exploitation is far from a situation in which everyone has the right to use the patented subject matter: Instead, the general rule is that the patentee enjoys exclusive rights. Reference here is made to normal exploitation of a patent, not normal use of the resource that served as the basis for the invention. This indicates that article 30 of the TRIPS agreement does not provide sufficient discretion for countries to implement a broad exemption for the use of biological material from the Antarctic. The second criterion is that the exemption to the patent right should not prejudice legitimate interests. This is less difficult, as the patentee of inventions based on biological material from the Antarctic should be (and would normally be) aware of this general condition for using such biological material. The word 'and' indicates that these criteria are cumulative: failure to meet the criterion of 'normal exploitation of patent protection' would mean general failure to meet the criteria of article 30. One way of lessening the problem of fulfilling the first criterion might be to link the exemption to research rather than to commercial interests.

Thus, the interpretation of TRIPS agreement article 30 is not evident in leaving the parties to the WTO discretion to implement a general exemption regarding the scope of patent protection for Antarctic biological material. The need for maintaining the accessibility of 'scientific observations and results' under the Antarctic Treaty is an argument in favour for harmonising these treaty obligations in a manner which takes the both of them into account. Perhaps one fruitful manner to address this issue is to deal with it as a research exemption from the patent protection. The scope of research exemption is also not conclusively determined in a general treaty under patent law. Thus more work is needed to explore further this link between the TRIPS agreement and patent system and the Antarctic Treaty.

Conclusions: patent law applied to Antarctic bioprospecting

In the case of conflict between patent law and current Antarctic regulation relevant to bioprospecting, patent law seems most likely to prevail. This will leave the biological resources in the Antarctic open and available for appropriation by those who find them and include them in a patentable invention (subject to the patent criteria). What is left to be used by others will be the biological material that falls outside the scope of exclusive patent rights, after the interpretation of patent law. The way in which patent law is currently applied to Antarctic biological resources leaves them open for inclusion under time limited exclusive rights.

By leaving the Antarctic biological resources subject to be included under patent protection, the rules for appropriation of resources are left to patent law. The ATCM leaves another legal arena in charge of the property rights situation for bioprospecting (in the case

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where the bioprospecting does not raise issues under the environment protocol). *De facto*, this will also link exclusive rights to Antarctic biological resources to changes of patent law. If, for example, it becomes easier to obtain a patent on a discovery of biological material, then more Antarctic organisms will probably become subject to private exclusive patent rights, leaving the ATCM without much to say. This indicates that, for resources like genetic resources or biological resources in the Antarctic where no particular system of property rights is in place, the patent system and the patent practice will automatically set the limits for what is openly available and what is not.

In all types of innovative activity, intellectual freedom is necessary to allow experimentation and the search for applicable solutions. For genetic resources and biological material, the need for flexibility in science is evident and exists on several levels. The question is how this open space of genetic resources and biological material can be safeguarded; at the same time that rights to products developed from the region are safeguarded. For the parties to the Antarctic Treaty this points up the need to examine whether and, if so, how to regulate property rights concerning the genetic resources and biological material of the Antarctic in a more specific manner.

References

Antarctic Treaty. 1959. Adopted 1 December 1959. 401 UNTS; entered into force 23 June 1961.

ATCM (Antarctic Treaty Consultative Meeting). 2002. Biological prospecting in Antarctica – working paper by the United Kingdom, 25th ATCM. Warsaw (WP-043).

ATCM (Antarctic Treaty Consultative Meeting). 2003. Bioprospecting: the intenational regime for bioprospecting existing policies and emerging issues for Antarctica. Information paper by Norway and the UK. 26th ATCM. Madrid (IP-075-UK, NO Agenda Item: VI CEP 7).

ATCM (Antarctic Treaty Consultative Meeting). 2004. Industry involvement in Antarctic bioprospecting. Information paper IP 106. 27th ATCM. Cape Town (agenda Item CEP 7 and ATCM 17).

ATCM (Antarctic Treaty Consultative Meeting). 2005a. Biological prospecting in Antarctica. Working paper WP 13 submitted by New Zealand and Sweden. 28th ATCM. Stockholm (agenda item 18).

ATCM (Antarctic Treaty Consultative Meeting). 2005b. Biological prospecting in Antarctica. Information paper IP 008 submitted by Spain. 28th ATCM. Stockholm (agenda item 18).

ATCM (Antarctic Treaty Consultative Meeting). 2005c. Recent developments in biological prospecting relevant to Antarctica. Information paper IP 93 presented by UNEP. 28th ATCM. Stockholm (agenda item 18).

ATCM (Antarctic Treaty Consultative Meeting). 2006a. A la recherche d'un régime juridique pour la bioprospection en Antarctique. Information paper IP 13 submitted by France. 29th ATCM. Edinburgh (agenda item 18).

ATCM (Antarctic Treaty Consultative Meeting). 2006b. Argentine activities of bioprospecting and bioremediation in Antarctica. Information paper IP 112 presented by Argentina. 29th ATCM. Edinburgh (agenda item 18).

ATCM (Antarctic Treaty Consultative Meeting). 2006c. Recent trends in the biological prospecting. Information paper IP 116 presented by UNEP. 29th ATCM. Edinburgh (agenda item 18).

ATCM (Antarctic Treaty Consultative Meeting). 2007a. Biological prospecting in the Antarctic Treaty area – scoping for a regulatory framework.. Working paper WP 036, submitted by the Netherlands, Belgium and France. 30th ATCM. New Delhi.

ATCM (Antarctic Treaty Consultative Meeting). 2007b. Biological prospecting in Antarctica: review, update and proposed tool to support a way forward. Information paper IP 067, submitted by UNEP. 30th ATCM. New Delhi.

ATCM (Antarctic Treaty Consultative Meeting). 2007c. Final report. 30th ATCM. New Delhi.

ATCM (Antarctic Treaty Consultative Meeting). 2008. Report of the ATCM intersessional contact group to examine the issue of biological prospecting in the Antarctic Treaty area. WP 4, presented by the Netherlands. 31th ATCM. Kyiv.

ATCM (Antarctic Treaty Consulative Meeting). 2009a. The Antarctic biological prospecting database. Document WP 1 submitted by a group of countries.. 32nd ATCM. Baltimore (agenda item ATCM 17).

ATCM (Antarctic Treaty Consulative Meeting). 2009b. Regulation of biological prospecting under the Antarctic Treaty system. Document WP 18 submitted by Australia and New Zeland. 32nd ATCM. Baltimore (agenda item 17).

ATCM (Antarctic Treaty Consulative Meeting). 2009c. A gap analysis of the Antarctic Treaty system regarding the management of biological prospecting. Document WP 26, submitted by a group of countries. 32nd ATCM. Baltimore (agenda item 17).

ATCM (Antarctic Treaty Consulative Meeting). 2009d. Bioprospecting: baselines and parameters. Document WP 49 rev. 2, submitted by Chile. 32nd ATCM (Baltimore (agenda item 17).

ATCM (Antarctic Treaty Consulative Meeting). 2009e. Biological prospecting in the Antarctic: an update on the review by SCAR. Document IP 65 presented by SCAR. 32nd ATCM. Baltimore (agenda item 17).

Biswajit, D., and R.V. Anuradha. 2004. Access benefits-sharing and intellectual property rights. *Journal of World Intellectual Property* 7(5): 597–640.

Bostyn, S.J.R. 2002. A European perspective on the ideal scope of protection and the disclosure requirement for biotechnological inventions in a harmonised patent system – the quest for the Holy Grail? *Journal of World Intellectual Property* 5 (6): 1013–1046.

BT (Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure). 1977. Adopted 28 April 1977, entered into force August 19, 1980, amended 26 September 1980, 20 January 1981, 1 October 2002 (WIPO (World Intellectual Property Rights Organisation) publication 277).

BT Regulations 1977. Regulations under the Budapest Treaty on the international recognition of the deposit of microorganisms for the purposes of patent procedure, adopted on 28 April 1977 and amended on 20 January 1981 and 1 October 2002, in force with its latest amendments 2 October 2002. URL: http://www.wipo.int/treaties/en/registration/budapest/trtdocs_wo048.html.

https://doi.org/10.1017/S0032247410000045 Published online by Cambridge University Press

CBD (Convention on Biological Diversity). 1992. Adopted 5 June 1992, entered into force 29 December 1993. 31 *International Legal Materials* 818.

Dross, M., and F. Wolff. 2005. *New elements of the international regime on access and benefit-sharing of genetic resources – the role of certificates of origin*. Germany: Federal Agency for Nature Conservation.

Dutfield, G. 2002. Sharing the benefits of biodiversity: is there a role for the patent system? *Journal of World Intellectual Property* 5(6): 899–932.

EU (European Union). 1998. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. Brussels: EU (Official Journal L 213, 30/07/1998 P. 0013 – 0021).

Farrell, R., and S. Duncan. 2005. Uniqueness of Antarctica and potential for commercial success. In: Hemmings A.D., and M. Rogan-Finnemore (editors). *Antarctic bioprospecting*. Christchurch: University of Canterbury: 10–40.

Finston, S.K. 2005. The relevance of genetic resources to the pharmaceutical industry: the industry perspective. *Journal of World Intellectual Property* 8(2): 141–156.

Girsberger, M.A. 2004. Transparency measures under patent law regarding genetic resources and traditional knowledge: disclosure of source and evidence of prior informed consent and benefit-sharing. *Journal of World Intellectual Property* 7(4): 451–490.

Graham, A. 2005. Environmental, ethical and equity issues. In: Hemmings A.D., and M. Rogan-Finnemore (editors). *Antarctic bioprospecting*. Christchurch: University of Canterbury: 41–68.

Hemmings, A.D., and M. Rogan-Finnemore. 2005a. The issues posed by bioprospecting in Antarctic. In: Hemmings A.D., and M. Rogan-Finnemore (editors). *Antarctic bioprospecting*. Christchurch: University of Canterbury: 234–244.

Hemmings, A.D., and M. Rogan-Finnemore. 2005b. Science and commercial issues. Environment, ethics and equity issues. In: Hemmings A.D., and M. Rogan-Finnemore (editors). *Antarctic bioprospecting*. Christchurch: University of Canterbury: 248–268.

Jabour-Green, J., and D. Nicol. 2003. Bioprospecting in areas outside national jurisdiction: Antarctica and the southern ocean. *Melbourne Journal of International Law* 4 (1): 76–111.

Nuffield Council on Bioethics. 2001. *The ethics of patenting DNA*. London: Nuffield Foundation of Bioethics.

Rogan-Finnemore, M. 2005. Setting the scene. In: Hemmings A.D., and M. Rogan-Finnemore (editors). *Antarctic bioprospecting*. Christchurch: University of Canterbury: 1–9.

SCAR (Scientific Committee on Antarctic Research). 2002. SCAR group of specialists on environmental affairs and conservation (GOSEAC). Report No 22/2002. URL: www.scar.org/publications/reports/22/ (Report of GOSEAC 12 meeting, College Station, Texas, United States, 24–27 April 2002).

SCAR (Scientific Committee on Antarctic Research). 2009. The International Council for Science. Cambridge: Scott Polar Research Institute (SCAR bulletin 172. Report from the SCAR delegation to 32nd ATCM, Baltimore, USA, 6–17 April 2009).

Tessensohn, F. 1987. Geophysical and geological data in Antarctica – the overlap between science and prospection. In: Wolfrum, R. (editor). *Antarctic challenges*. Berlin: Duncker and Humboldt (Proceedings of an Interdisciplinary Symposium 7 –12 July 1987. Berlin).

Tvedt, M.W. 2005. How will a substantive patent law treaty affect the public domain for genetic resources and biological material? *Journal of World Intellectual Property* 8(3): 311–344.

Tvedt, M.W. 2006. Elements for user country legislation to meet the fair and equitable commitment. *Journal of World Intellectual Property* 9(2): 189–212.

Tvedt, M.W. 2007a. The path to one universal patent. *Journal of Environmental Policy and Law*, 37(4): 297–305.

Tvedt, M.W. 2007b. The disclosure obligation in Norwegian legislation: is it likely to lead to fair and equitable benefit sharing? *Environmental Policy and Law* 38 (1/2): 100–107.

Tvedt, M.W., and T.R. Young. 2007. *Beyond access – exploring implementation of the fair and equitable sharing commitment in the CBD*. Gland, Switzerland: IUCN.

Vidas, D. 1996. The Antarctic Treaty system and the law of the sea: a new dimension introduced by the protocol. In: Stokke, O.S., and D Vidas (editors). *Governing the Antarctic, the effectiveness and legimacy of the Antarctic Treaty system*. Cambridge, New York: Cambridge University Press. 61–90.

Westerlund, L. 2001. *Biotech patents – equivalency and exclusions under European and U.S. patent law*. Stockholm: Stockholm University, Faculty of Law.

WIPO (World Intellectual Property Rights Organisation). 2004. WIPO technical study on patent disclosure requirements related to genetic resources and traditional knowledge. Geneva: WIPO (WIPO publication no. 786(E). Study no. 3).

WIPO (World Intellectual Property Rights Organisation). 2003. Draft Substantive Patent Law Treaty. URL: http://www.wipo.int/edocs/mdocs/scp/en/scp_10/scp_10_4.pdf.

Wolfe, T.A., and B. Zycher. 2005. *Biotechnological and pharmaceutical research and development investment under a patent-based sccess and benefit-sharing regime*, California: Pacific Research Institute.

WTO (World Trade Organisation). 1994: Agreement establishing the World Trade Organization of 15. April 1994 ANNEX 1C: Agreement on trade-related aspects of intellectual property rights (TRIPS).