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Editorial

The current issue of elni Review (2/2011) covers a variety of topics on international environmental law, including standardisation of environmental NGOs, conservation law and two country specific contributions from Brazil regarding access to environmental information and biotechnological inventions.

Special focus in this issue is placed on two different topics: Firstly on intellectual property rights on genetic resources. The second subject is devoted to access to environmental information and access to justice within the framework of the Aarhus Convention.

First of all, *Christoph Then and Ruth Tippe* examine the impact of biopatents on animal and plant breeding in their article "Patents on melon, broccoli and ham?". After shedding light on current German and European patent legislation they discuss the consequences of patents on conventional breeding regarding genetic resources and food production.

The second article "Biopatents in Brazil" by *Edson Paula de Souza* provides insights into current legislation on biotechnological inventions in Brazil. He explores the impact of limitation on patent protection for R&D.

Susette Biber-Klemm and *Michelangelo Temmerman* then provide us with an overview of Rights to Animal Genetic Resources by comparing the different legal frameworks for plant and animal breeding/genetic resources on national and international levels.

The two subsequent articles address different aspects of the Aarhus Convention:

Sandra Aline Nascimento da Nóbrega gives an overview of access to environmental information in Brazil (access to environmental information is one of the three pillars of the Aarhus Convention). She compares the Aarhus Convention with Brazilian legislation and discusses which regulations have been implemented in Brazilian law.

In her contribution *Eva Julia Lohse* asks whether there is unrestricted access to justice for environmental NGOs. She examines the judgement of the European Court of Justice (Case C-115/09) on the non-conformity of the German Environment Appeals Act with Directive 2003/35 and the Aarhus Convention.

Ralf Lottes's article analyses what civic society can expect from the Commission's proposal for a legislative review of the European standardisation policy. He concentrates on the standardisation of NGOs through the review of the EU framework for standardisation regarding environmental NGO participation on a national level.

Hendrik Schoukens' contribution on temporary na-ture and conservation law examines the adaptability of European nature conservation law for temporary nature, focusing on the situation in Belgium.

Finally, we cover recent developments in environmental law with three different contributions concentrating on intellectual property rights in terms of genetic resources.

The article by *Lisa Minkmar* provides insights from a biopatent case: the "Teff-Patent" (EP 1646287).

Subsequently; *Claudia Fricke* reviews the current debate on the revision of Directive 98/44/EC on the legal protection of biotechnological inventions.

Lastly, *Graham Dutfield* comments on the United Nations Special Rapporteur on the Right to Food and the interplay between traditional knowledge, intellectual property rights and the right to food.

Contributions for the next issue of the elni Review are very welcome. Please send contributions to the editors by mid-February 2012.

Claudia Fricke/Martin Führ
November 2011

Rule of Law for Nature

9-11th May 2012
in Oslo, Norway

The year 2012 marks a number of watershed points in international environmental affairs: The 40th anniversary of the adoption of the Stockholm Declaration, the 30th anniversary of the UN World Charter for Nature and the UN Convention on the Law of the Sea, the 25th anniversary of the Brundtland Report, and the 20th anniversary of both the Rio Declaration, Agenda 21, and the UNCED Conventions: the Framework Convention on Climate Change and the Convention on Biological Diversity.

This is an appropriate point in time for reflection on the legal status of nature, how environmental goods and services are valued and taken into account in decision-making, and the implications of the rule of law in this respect.

While the rule of law generally is used with regard to citizens' rights, this conference aims to explore the application of the rule of law to environmental protection, and its implications. How can the legal protection of the natural environment be strengthened? This also opens for reflections on the temporal and geographical extension of the rule of law.

The conference aims at analysing these basic issues of international and national environmental law and looking at new trends in this area of law.

For more information about participation, including registration forms, please visit:

http://www.jus.uio.no/forskning/omrader/naturressurs/arrangementer/2012/05-09-rule-of-law

Biopatents in Brazil

Edson Paula de Souza

1 Introduction

Biotechnology is at the core of bioeconomy and plays a key role in modern societies. Currently, Brazil is engaged in many cutting-edge projects in the biotech sector, from energy production to promotion of health and provision of foodstuffs. Also, Brazil's rich and complex biodiversity, which accounts for 15-20% of the entire world's biological diversity[1], may provide a great source of new molecules to the industry. Moreover, awareness and use of the intellectual property system have expanded in the country and the number of patent applications filed by residents has substantially increased over the years. In fact, statistics show that filings with the Brazilian Patent Office rose from 5,666 applications in 1997 to a peak of 7,502 applications in 2004, decreasing a little in 2007 to 6,975 applications.[2] However, due to a very particular regulatory framework, researchers and companies still find some difficulties to do research and protect their inventions in the country.

Biotechnological inventions rely upon high investments, specialised infrastructure and detailed regulatory approval. Therefore, in order to foster such inventions, there must be an adequate protection system that compensates the time and money spent on research and development (R&D).

Hence, intellectual property rights are critical to the flourishing and maintenance of the biotech sector. This article will focus on patent protection for biotechnological inventions in Brazil and will discuss the main issues arising from the existing legislation and practice.

2 The evolution of the Brazilian patent system

In Brazil, patent protection was first provided by law on 28 April 1809.[3] That was the first law among many others that were subsequently passed by the Brazilian Congress. However, at the end of the last century, the Brazilian legislation was lagging behind, especially because no protection was afforded to pharmaceuticals, chemicals and foodstuffs. This was due to a flexibility set forth in the Paris Convention[4]. Decree No. 1,263, dated 10 October 1994, transposed the revised text of the Convention into the Brazilian legislation[5]. In view of that, the Brazilian Government decided to update the national legislation for industrial property. Law No. 9,279[6] was finally passed by the Congress on 10 April 1996 and approved by former President Fernando Henrique Cardoso on 14 May 1996.

Along the five years of discussion at the Congress and the Senate, some key aspects were taken into consideration, particularly the creation of a favourable environment for foreign direct investment and incentives for innovation. Also, it was necessary to have provisions that were not at odds with the newly drafted regulations arising from the TRIPS Agreement. In Brazil, Decree No. 1,355, of 30 December 1994, transposed the contents of the Agreement into the national legislation[7].

This law has led to other initiatives to foster the landscape of innovation in Brazil, such as the enactment of the Innovation Law (Law No. 10,973)[8] in 2004, which provides incentive measures for innovation and scientific and technological research in the production environment, facilitating private/public research partnerships and the transfer of innovations from public research institutions and universities to the private sector.

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1 Convention on Biological Diversity (CBD). 2011. [online]. Available from: http://www.cbd.int/countries/profile.shtml?country=br#status [Accessed 29 July 2011].

2 World Intellectual Property Organisation (WIPO). 2011. [online]. Available from: http://www.wipo.int/wipo_magazine/en/2010/05/article_0005.html [Accessed 4 August 2011].

3 Alvará de 28 de abril de 1809, que isenta de direitos as matérias primas do uso das fábricas e concede outros favores aos fabricantes e da navegação nacional. [1809]. [online]. Available from: http://www.inpi.gov.br/menu-superior/legislacao/pasta_legislacao/alvara_28_04_1809_html/?searchterm= alvará%201809 [Accessed 4 August 2011].

4 Paris Convention for the Protection of Industrial Property of March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and as amended on September 28, 1979.

5 Decreto No. 1.263, de 10 de outubro de 1994, que ratifica a declaração de adesão aos arts. 1º a 12 e ao art. 28, alínea l, do texto da revisão de Estocolmo da Convenção de Paris para Proteção da Propriedade Industrial. [1994]. [online]. Available from: http://www.planalto.gov.br/ccivil_03/decreto/1990-1994/D1263.htm [Accessed 4 August 2011].

6 Lei No. 9.279, de 14 de maio de 1996, que regula direitos e obrigações relativos à propriedade industrial. [1996]. [online]. Available from: http://www.planalto.gov.br/ccivil_03/Leis/L9279.htm [Accessed 4 August 2011].

7 Decreto No. 1.355, de 30 de dezembro de 1994, que promulga a Ata Final que Incorpora os Resultados da Rodada Uruguai de Negociações Comerciais Multilaterais do GATT. Acordo sobre Aspectos dos Direitos da Propriedade Intelectual/TRIPS. [1994]. [online]. Available from: http://www.planalto.gov.br/ccivil_03/decreto/Antigos/D1355.htm [Accessed 4 August 2011].

8 Lei No. 10.973, de 2 de dezembro de 2004, que dispõe sobre incentivos à inovação e à pesquisa científica e tecnológica no ambiente produtivo e dá outras providências. [2004]. [online]. Available from: http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2004/Lei/L10.973.htm [Accessed 4 August 2011].

3 The protection of biotechnological inventions

The granting of a patent is not automatic and depends on a lengthy process involving the filing and examination of an application before the Patent Office. According to Law No. 9,279, the term of protection of patent for invention can either be of 20 years counting as from the date of the filing of the application or 10 years counting as from the date of the issuance of the patent, whichever lasts longer.[9] Once granted, a patent shall confer on its owner the right to prevent third parties from using and exploiting the object of the patent.[10]

In order to qualify as a patentable invention, the subject matter must meet the patentability requirements and cannot be included in the statutory bars provided in the law.

3.1 Patentability requirements

The patentability requirements are novelty, inventive activity and industrial applicability. Two other important requirements that are also carefully analysed, especially in inventions in the field of biotechnology, are sufficiency of disclosure and clarity.

The first patentability requirement is novelty. According to Art. 11 of Law No. 9,279, an invention is new when it is not comprised by the state of the art.

Pursuant to Art. 11 (1), the state of the art comprises everything made accessible to the public before the filing or priority date of a patent application.

However, in some exceptional situations, the Brazilian legislation provides a grace period, within which the object of the invention can be divulged without being considered novelty-defeating.

According to Art. 12 of Law No. 9,279, the disclosure of an invention which occurs within the twelve months preceding the filing date or priority date of the patent application will not be considered as part of the state of the art, provided that the disclosure is made by i) the inventor; ii) the Brazilian Patent Office by means of the official publication of a patent application filed without the consent of the inventor; or iii) by third parties, on the basis of information received directly or indirectly from the inventors or as the result of their acts.

This provision has proven to be important in trying to remedy the gap between the number of scientific articles published by Brazilian researchers and the number of corresponding patent applications filed, as awareness of the patent system has expanded.

The second patentability requirement is inventive activity. Article 13 of Law No. 9,279 establishes that the invention will be considered to involve inventive activity if it is not derived in an obvious or evident manner from the state of the art.

In assessing inventive activity in Brazil, it is necessary to consider whether the skilled person would have been led to realise the combination or modifications required to achieve the invention. The use of hindsight is not allowed in this analysis.

Although the Brazilian Patent Office is yet to issue guidelines for the assessment of the inventive activity requirement in the field of biotechnology, there are some understandings that have been repeatedly followed by examiners. For example, in general terms, the analysis of whether a given sequence is inventive is performed in a similar way to that carried out to chemical compounds. Accordingly, the similarity of structure will not be enough to prove lack of inventive activity unless the activity is identical in at least qualitative terms.

In Brazil, a certain idea can be considered obvious if the materials used were available and ready for a researcher to use, even if the skilled man faced a number of obstacles in proceeding to his goal. On this basis, in the Patent Office's view, a non-naturally occurring polynucleotide or polypeptide[11] might be deemed obvious if all techniques needed to produce the sequence were well known by the skilled person.

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9 Art. 40 of Law No. 9,279. The possibility of granting a patent for 10 years counting as from the date of the issuance thereof was adopted in order to compensate applicants for any delays in the granting process of a patent in Brazil. In the pharma and biotech fields, examination only starts after roughly seven years from the filing date.

10 Art. 43 of Law No. 9,279 provides a list of exceptions to this right, as follows:

"I - to acts practiced by unauthorised third parties privately and without commercial ends, provided they do not result in prejudice to the economic interests of the patentee;

II - to acts practiced by unauthorised third parties for experimental purposes, related to studies or to scientific or technological research [The so-called research exemption is a limitation of the patentee's rights that allows one to pursue acts with the purpose of advancing the state of the art. This provision may apply to protect experimental acts performed by researchers in order to produce scientific knowledge or other sources of developments, as long as they relate "to studies or to scientific or technological research"];

III - to the preparation of a medicine according to a medical prescription for individual cases, executed by a qualified professional, as well as to a medicine thus prepared;

IV - to a product manufactured in accordance with a process or product patent that has been placed on the internal market directly by the patentee or with his consent;

V - to third parties who, in the case of patents related to living matter, use, without economic ends, the patented product as the initial source of variation or propagation for obtaining other products; and

VII – to acts performed by unauthorised third parties relating to the patented invention carried out exclusively to produce information, data and test results seeking market approval in Brazil or abroad, in order to exploit or commercialise the patented product after the term set by article 40 has expired." [It is known as "bolar exemption", called after the judgement of Roche v. Bolar in the USA. It allows unauthorised parties to use the patented invention with the purpose of producing "information, data and test results" in order to apply for marketing approval of the product covered by the patent after the expiration of the patent].

11 A naturally occurring polynucleotide or polypeptide is not patentable, even if artificially made or isolated/purified from nature, in view of the statutory prohibition of Art. 10, IX, of Law No. 9,279. More details on this issue will be discussed in section 3.2.

It should be noted, however, that if overcoming the obstacles required some imagination beyond that attributable to the skilled man, then there may be elements of inventive activity. Not to mention that if the manufactured molecule shows an unexpected and new technical effect, there is a great likelihood it will be considered inventive.

Moreover, claims directed to cDNA molecules obtained from naturally occurring sequences have been rejected with basis on the lack of inventive activity as well. According to the examiners, the techniques available at the time of the invention for the production of cDNA were well known to the skilled person and the pertinent information conveyed by that molecule is said to be that of the naturally occurring sequence, without any substantial differences.

When it comes to selection patents, they may in principle be granted provided that the selection is not specifically disclosed in the prior art document, and there is support for an unexpected and distinguishing feature of the selection over the disclosed group.

With regard to the industrial applicability requirement, Art. 15 of Law No. 9,279 establishes that an invention is industrially applicable whenever its object can be manufactured or applied in any industry. The Brazilian Patent Office's interpretation of industry is quite broad, encompassing any technical activity that is useful and practical, and distinct from the artistic field. With this broad interpretation, inventions relating to agriculture are also susceptible of industrial application.

Another important requirement assessed by the Brazilian PTO is the sufficiency of disclosure requirement. This is an internal requirement for patentability. According to Art. 24 of Law No. 9,279, the specification shall describe clearly and sufficiently the object of the invention in order to enable a person skilled in the art to work the invention. An analysis of whether a specification provides an adequate written description of a claimed invention requires one to read the complete specification to determine whether the text as a whole conveys the invention.

The Brazilian PTO has taken a very restrictive view of this requirement.The rationale behind that position is that patent protection should be granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Although there is no requirement that the claims should be limited to the features of the examples, Art. 24 of Law 9,279 requires that the specification should be commensurately enabling relative to the invention claimed. Accordingly, a general example and test for each class of compound claimed must be included. Extrapolation to all compounds falling within that class should be immediate, that is, it must not take undue experimentation for one skilled in the art to produce embodiments falling within the scope of the claims. Hence, to be sufficient, the specification must identify the characteristics of each class claimed and the respective method of manufacture. Further, all the claimed compounds must in substance have the characteristics of the classes characterised and tested.

Article 24, sole paragraph, of Law No. 9,279 also sets out that the deposit of biological material must be made if (1) it is essential for the skilled person to work/reproduce the invention, (2) it cannot be described in writing, and (3) it is not available to the public. In addition to the requirement for a deposit, in order to meet the sufficiency of disclosure requirement, it is expected that the specification of the patent application as filed should contain as much relevant information on the characteristics of the biological material as is available to the applicant.

Further, the deposit may be made in either an institution authorised by the Patent Office or indicated in an international treaty in force in the country. However, there is neither a national institution authorised by the Patent Office to function as a depositary entity nor an international treaty concerning this subject matter in force in Brazil.[12]

For this reason, item 16.1.1.2., of Normative Act 127/97, issued by the Patent Office[13], establishes that in the absence of a national institution authorised by the Patent Office or indicated in an international agreement in force in Brazil, the applicant is allowed to make the deposit in any one of the international deposit authorities recognised in the Budapest Treaty.

Another requirement that has been used to ground objections to supposedly broad claims is the clarity requirement. Article 25 of Law No. 9,279 sets out that the claims must define clearly and precisely the subject matter to be protected. On this basis, definitions of nucleotide/polynucleotide sequences by % of homol-ogy or identity have been rejected. Apparently, ac-cording to item 2.3 of the existing guidelines for the examination of patent applications in the fields of biotechnology and pharmacy filed after 31 December 2004[14], issued by the Patent Office, the only possible way to clearly define a sequence is by its respective

12 Brazil is not a member of the Budapest Treaty on the international recognition of the deposit of microorganisms for the purposes of patent procedure. Nonetheless, some efforts have been made to create a national depositary centre for biological materials and, given the importance of biotechnology in Brazil's industrial policy, the Government is currently considering signing the Budapest Treaty.

13 Ato Normativo No. 127, de 5 de março de 1997, que dispõe sobre a aplicação da Lei de Propriedade Industrial em relação às patentes e certificados de adição de invenção. [1997]. [online]. Available from: http://www.inpi.gov.br/menusuperior/legislacao/pasta_legislacao/ato_127_97_html/?searchterm=ato%20normativo%20127 [Accessed 4 August 2011].

14 Instituto Nacional da Propriedade Industrial. 2002. Diretrizes para o Exame de Pedidos de Patente nas Áreas de Biotecnologia e Farmacêutica Depositados Após 31/12/94. [online]. Available from: http://www.inpi.gov.br/menu-esquerdo/patente/pasta_download/oculto/DiretrizesQuimica.pdf/download [Accessed 4 August 2011].

SEQ ID number or the precise nucleotide/amino acid sequence.

Although it is apparently not possible to claim a sequence otherwise, it is important to point out that other equivalent sequences (in terms of homology or identity, if bearing the same function) may be said to be within the scope of the claim by the doctrine of equivalents[15].

According to Art. 186 of Law No. 9,279, used to support the doctrine of equivalents in the country, patent infringement may occur *"even if the violation does not affect all the claims of the patent or if it is restricted to the use of means equivalent to the subject-matter of the patent."* [emphasis added]

The correct construction of this legal provision is that there will be patent infringement even if not all the claims are being reproduced in the accused product or process. It suffices that only one claim has all its elements reproduced (literally or by equivalency).

In addition to the requirements above, if the invention encompasses a pharmaceutical product or process, the National Sanitary Surveillance Agency (ANVISA) has to grant prior consent thereto, in accordance with Art. 229-C, introduced by Law No. 10,196[16]. ANVISA has been quite strict and a lot of controversy has arisen particularly over claims drafted in the Swiss-type format[17] which, mainly for policy views adopted by that Agency, should not be patentable[18]. In addition, it was always questioned whether Art. 229-C had em-powered ANVISA to re-examine the patentability requirements or whether a different attribution had been envisaged to that Agency.[19]

Some recent court decisions rendered by the federal courts of Brasília and a legal opinion issued by the General-Attorney's Office[20] have shown that Article 229-C should not be read to allow ANVISA to assess the patentability requirements. Rather, ANVISA is only supposed to assist the Patent Office with the evaluation of whether the claimed invention is contrary to the public health, pursuant to Art. 18, I, of Law No. 9,279.[21]

Finally, a decision issued by the Patent Office or ANVISA may always be brought to a Court of Law's review. In this connection, as per Section 109, Subsection I, of the Brazilian Constitution[22], any lawsuit challenging an act performed by the Federal Public Administration must be filed with a Federal Court. Infringement lawsuits, on the other hand, should be filed with a State Court. Yet, parties should bear in mind that case law is still under construction in Brazil and every case is a leading case.

3.2 Statutory bars

As mentioned above, the Brazilian legislation adopted a negative definition of invention, excluding what should not be regarded as such. As far as biotechnological subject matter is concerned, the following shall not be considered to be inventions, for lacking at least one of the patentability requirements:

a) Discoveries (Art. 10, I, of Law No. 9,279): A discovery is the result of the perception of a pre-existing natural phenomenon. A natural fact is simply observed and there is no inventive step. Discoveries, in general, do not aim to solve any problems, that is, they do not have any practical purposes. In principle, they only enlarge the human knowledge on a certain natural phenomenon, law of nature, etc.

b) Surgical, therapeutic and diagnostic methods and techniques practiced on the human or animal body (Art. 10, VIII, of Law No. 9,279): This prohibition only concerns the methods and not the substances, products and active compounds used in surgery, diagnosis or treatments.

Any method requiring a surgical step, such as implanting artificially fertilized embryos, therapeutic surgery, etc., is not considered an invention according to this prohibition.

As for diagnostic methods, they are likely to be considered non-statutory subject matter if they are performed on the human or animal body, and enable the practitioner to identify a disease. By requiring that the method be *"practiced on the body"*, *in vitro* diagnostic tests, performed on blood or other samples

15 The doctrine of equivalents is a set of rules that help the person assessing infringement to build up a criterion based on moderation and equality, even if that opposes to the literality of the claim.

16 Lei No. 10.196, de 14 de fevereiro de 2001, que altera e acresce dispositivos à Lei 9.279, de 14 de maio de 1996, que regula direitos e obrigações relativos à propriedade industrial, e dá outras providências. [2001]. [online] Available from: http://www.planalto.gov.br/ccivil_03/Leis/LEIS_2001/L10196.htm [Accessed 4 August 2011].

17 Second or subsequent medical uses of a known compound or composition may in principle be protected by a claim in a patent application. These claims are known as Swiss-type claims, since the Swiss Patent Office was the first to allow them. In this regard, see Bentley, L. and Sherman, B. 2004. Intellectual Property Law. 2nd edition. Oxford: Oxford University Press. 458-463.

18 Assunção, S. W. de and Rosman E. C. 2005. "'Segundo Uso' – Remédios Jurídicos contra a ANVISA". Revista da ABPI (74):62-70 and Souza, M. T. de. 2008. "Should Brazil Allow Patents on Second Medical Uses?" Revista da ABPI (93):53-67.

19 Leonardos, L. and Licks, O. B. 2002. "A Exegese do Artigo 229-C da Lei da Propriedade Industrial após a Edição das Medidas Provisórias 2.006, de 15/12/99, e 2.014, de 21/12/2000, e a Promulgação da Lei No. 10.196, de 14/2/2001". Revista da ABPI (61):57-68 (2002), and Rosman, E. C. 2004. "O Limite Normativo da Agência Nacional de Vigilância Sanitária - ANVISA". Revista da ABPI (71):32-36 (2004).

20 Advocacia-Geral da União. Procuradoria-Geral Federal. 2010. Parecer No. 337/PGF/EA/2010. Available from: http://www.agu.gov.br/sistemas/site/TemplateImagemTextoThumb.aspx?idConteudo= 153676&id_site=3 [Accessed 4 August 2011].

21 See more details in this regard in section 3.2 below.

22 Constituição da República Federativa do Brasil. [1988]. [online]. Available from: http://www.planalto.gov.br/ccivil_03/Constituicao/Constituicao.htm [Accessed 4 August 2011].

removed from the body may be said to fall outside that prohibition.

By turn, according to item 2.36 of the examination guidelines issued by the Patent Office[23], therapeutic methods are those that imply the cure and/or the prevention of a disease or bad functioning of the human or animal body, or the relief of symptoms of pain, suffer-ing and discomfort, for the purpose of re-establishing or maintaining the normal health conditions.

Therapeutic method claims may be converted into Swiss-type use claims, which best preserve the scope of the original method claim. However, these claims must strictly fit the template "*use of the product X characterised by being in the manufacture of a medicament intended for treating the disease Y*". In fact, claims defining the use in terms of the mode of administration, or the quantity, frequency or timing of dosage, are not accepted as they are said to effectively define a new method of treatment.

Notwithstanding that, the patentability of Swiss-type use claims is still a gray area in the country. On the one hand, the Brazilian PTO has long been allow-ing claims in this format. On the other hand, as mentioned above, ANVISA, whose consent is necessary prior to the grant of applications covering pharmaceutical products and processes, refuses to allow applications including Swiss-type use claims, owing to the current health policy adopted by that Agency. In addition, there are two legislative proposals being discussed in the House of Representatives regarding second medical uses. The first one, Bill No. 2,511[24], seeks to exclude therapeutic indications of pharmaceutical products and processes from patentability. Bill No. 3,995[25], by turn, aims at including second medical uses in the prohibitions of Art. 10, thereby not considering them as inventions.

d) Natural living beings, in whole or in part, and biological material, including the genome or germplasm of any natural living being, when found in nature or isolated therefrom, and natural biological processes (Art. 10, IX, of Law No. 9,279): The exclusion of biological material isolated or purified from nature is one of the most controversial and debated provisions of the Brazilian Law No. 9,279. Indeed, Brazil is a country full of natural resources. Much of its flora may contain valuable active compounds for the manufacture of pharmaceuticals. However, the isolation/purification process is allegedly not sufficient for the product to be considered new and different from the one existing in nature.

In addition, biological material produced by means of a technical process is not eligible for patent protection in case it has a natural equivalent and cannot be distinguished therefrom.

As far as claims directed to chemically synthesised sequences are concerned, although the chemical synthesis of these molecules could not mimic exactly the chemical bond properties of the naturally occurring material with other biochemical compounds, the Patent Office has been very strict, determining that if the sequences have a natural equivalent, they cannot be protected.

Also, even in those cases where a particular portion of a larger naturally occurring sequence cannot be found in nature, patent protection for the smaller fragment is not granted. For instance, if the naturally occurring sequence has been truncated at the 5' end, with the deletion of few nucleotides/amino acids, the resulting molecule is not considered an invention in the sense of article 10, IX, of the Law.

In fact, only those sequences that do not exist in nature at all may be patented, provided that they meet the patentability requirements.

The scientific society and the Brazilian Intellectual Property Association (ABPI) have been working in tandem with some congressmen in an attempt to amend Art. 10, IX, of Law No. 9,279. Bill No. 4961/05[26] is one of these initiatives and seeks to in-clude a proviso in the Patent Law, deeming as patentable substances or materials extracted, obtained or isolated from nature which involve the patentability requirements and that do not consist of mere discoveries. At this juncture, however, it is difficult to anticipate how this amendment, if passed[27], will be implemented by patent examiners.

Natural biological processes are not patentable either. According to the definition provided in item 2.28 of the guidelines issued by the Patent Office[28], a natural biological process is either i) any process that does not make use of artificial means to obtain biological prod-

23 Instituto Nacional da Propriedade Industrial, supra note 14.

24 Projeto de Lei No. 2.511, de 29 de novembro de 2007, que altera a Lei 9.279, de 14 de maio de 1996, que "Regula direitos e obrigações relativos à propriedade industrial". [2007]. [online]. Available from: http://www.camara.gov.br/proposicoesWeb/prop_mostrarintegra;jsessionid=0707B9AF685F91ECD284DD6F9FA30E36.node1?codteor=526755&filename=PL+2511/2007proposicoesWeb/prop_mostrarintegra;jsessionid=2C883305CCE710BA380120BE46A308FF.node1?codteor=526755&filename=PL+2511/2007 [Accessed 4 August 2011].

25 Projeto de Lei No. 3.995, de 3 de setembro de 2008, que acrescenta incisos ao art. 10 da Lei 9.279, de 14 de maio de 1996, que regula direitos e obrigações relativos à propriedade industrial. [2008]. [online]. Available from: http://www.camara.gov.br/proposicoesWeb/prop_mostrarintegra?codteor=596154& filename=PL+3995/2008 [Accessed 4 August 2011].

26 Projeto de Lei No. 4.961, de 29 de março de 2005, que altera dispositivos da Lei 9.279, de 14 de maio de 1996. [2005]. [online]. Available from: http://www.camara.gov.br/proposicoesWeb/prop_mostrarintegra;jsessionid=E974C607B910D77BF7D7CECAEAED0556.node1?codteor=289059&filename=PL+4961/2005 [Accessed 4 August 2011].

27 Bill No. 2,695, of 9 December 2003, a previous proposal that sought to amend Art. 10, IX, of Law No. 9,279 in a similar fashion, was rejected by the House of Representatives in 2007.

28 Instituto Nacional da Propriedade Industrial, supra note 14.

ucts, or ii) any process that makes use of an artificial means but occurs naturally without human intervention (natural phenomenon).

Besides the prohibitions cited above, according to which some subject matter will not be patentable for lacking at least one of the patentability requirements, Art. 27 of the TRIPS provides that national laws can exclude from patentability some biotechnological inventions grounded on criteria other than the patentability requirements.[29]

The first prohibition of this nature is found in Art. 18, I, of Law No. 9,279, and it excludes from patentability *"whatever is contrary to morals, good customs and public security, order and health"*.

It is easy to establish a direct connection between patents and economics, but not between patents and morality and ordre public. In fact, patent laws do not have any vocation for ethical reflection and the Patent Office does not seem to be the most adequate forum to address these concerns. In any event, the Brazilian legislation incorporated that prohibition grounded on Article 27.2 of the TRIPS Agreement.[30]

As mentioned above, the analysis of whether an invention is contrary to public health, in particular, will also be performed by ANVISA, when granting or denying prior consent to applications claiming pharmaceutical products or processes.

In addition, the Biosafety Law No. 11,105[31], enacted on 24 March 2005, and regulated by Decree No. 5,591[32], of 22 November 2005, introduced a further prohibition, excluding from patentability genetic use restriction technologies (GURTs). According to Art. 6, sole paragraph, of the Biosafety Law, these technologies may be defined as any process by which human intervention generates or multiplies genetically-modified plants to produce sterile reproductive structures, as well as any manner of genetic manipulation that aims at activating or deactivating fertility-related plant genes by using external chemical inducers.

The prohibition introduced by the Biosafety Law can only be said to be in agreement with the TRIPS Agreement if it is understood as being within the flexibility provided in Art. 27.2. In fact, the protection of the environment and public health seems to underpin the moratorium on GURTs created through Decision V/5, III, 23, adopted in the Fifth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, in Nairobi in 2000.[33]

Notwithstanding that, a legislative proposal to lift the bar on GURTs was proposed in 2009. Bill No. 5,575[34] is still being discussed in the House of Representatives, but it has already received positive feedback from some commissions of that House.

The second prohibition based on Art. 27 of the TRIPS is found in Article 18, III, of Law No. 9,279, which sets out that living beings, in whole or in part, except transgenic microorganisms meeting the patentability requirements, and which are not mere discoveries.

According to that legal provision, transgenic animals, plants or parts thereof are not patentable. Patent protection, as far as transgenics are concerned, may only be afforded to microorganisms. Art. 18, sole paragraph, sets out that transgenic microorganisms are those organisms, except the whole or part of plants or animals, which exhibit, by means of direct human intervention in the genetic composition thereof, a characteristic normally not achievable by the species under natural conditions.

The Patent Office has adopted a very restrictive interpretation of the term *"microorganism"*. At the international level, the term "microorganism" includes both animal and plant cells, whereas in Brazil, these cells are excluded from patentability, even if they are

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29 Article 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 or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."
Article 27.3: "Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.".

30 See supra note 29.

31 Lei No. 11.105, de 24 de março de 2005, que regulamenta os incisos II, IV e V do § 1o do art. 225 da Constituição Federal, estabelece normas de segurança e mecanismos de fiscalização de atividades que envolvam organismos geneticamente modificados – OGM e seus derivados, cria o Conselho Nacional de Biossegurança – CNBS, reestrutura a Comissão Técnica Nacional de Biossegurança – CTNBio, dispõe sobre a Política Nacional de Biossegurança – PNB, revoga a Lei no 8.974, de 5 de janeiro de 1995, e a Medida Provisória no 2.191-9, de 23 de agosto de 2001, e os arts. 5o, 6o, 7o, 8o, 9o, 10 e 16 da Lei no 10.814, de 15 de dezembro de 2003, e dá outras providências. [2005]. [online]. Available from: http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2005/Lei/L11105.htm [Accessed 4 August 2011].

32 Decreto No. 5.591, de 22 de novembro de 2005, que Regulamenta dispositivos da Lei no 11.105, de 24 de março de 2005, que regulamenta os incisos II, IV e V do § 1o do art. 225 da Constituição, e dá outras providências. [2005]. [online]. Available from: http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2005/Decreto/D5591.htm [Accessed 4 August 2011].

33 Convention on Biological Diversity (CBD). 2011. [online]. Available from: http://www.cbd.int/decision/cop/?id=7147 [Accessed 4 August 2011].

34 Projeto de Lei No. 5.575, de 7 de julho de 2009, que altera a Lei nº 11.105, de 24 de março de 2005, que regulamenta os incisos II, IV e V do § 1º do art. 225 da Constituição Federal, estabelece normas de segurança e mecanismos de fiscalização de atividades que envolvam organismos geneticamente modificados - OGM e seus derivados, cria o Conselho Nacional de Biossegurança - CNBS, reestrutura a Comissão Técnica Nacional de Biossegurança - CTNBio, dispõe sobre a Política Nacional de Biossegurança - PNB. [2009]. [online]. Available from: http://www.camara.gov.br/proposicoesWeb/prop_mostrarintegra?codteor=670277&filename=PL+5575/2009 [Accessed 4 August 2011].

used as host cells, with a genetic composition different from that originally found in nature.

As far as the protection of plant varieties is concerned, the Brazilian Government enacted Law No. 9,456[35], on 25 April 1997, in order to comply with the obligations under Article 27.3 (b) of the TRIPS Agreement[36]. This national law was based on the 1978 UPOV Act[37], but it also encompasses provisions of the 1991 UPOV Act. It provides a sui generis system of protection for any new plant variety which is distinguishable from others by a set of minimum genetically-inherited morphological, physiological, biochemical or molecular features. These characteristics, known as descriptors, must be homogeneous and stable after repeated propagation. Implementation regulations of Law No. 9,456 were enacted through Decree No. 2,366[38].

4 Inventions derived from the Brazilian genetic heritage

The Convention on Biological Diversity (CBD), signed in Rio de Janeiro on 5 June 1992, introduced important concepts on the protection of biodiversity and genetic resources. Decree No. 2,519, of 16 March 1998[39], transposed the provisions of the Convention into the Brazilian legislation.

Brazil, being one of the richest countries in terms of biodiversity, has used intellectual property rights as one the mechanisms to protect genetic resources and associated traditional knowledge and assure that the benefits from their use are shared with indigenous communities.

With basis on the CBD, Provisional Ruling No. 2,186-16[40] was enacted hurriedly to regulate the access to and use of the genetic heritage and associated traditional knowledge[41] in the Brazilian territory. According to Art. 16 of that Provisional Ruling, individuals and companies must be authorised by the Genetic Heritage Management Council (CGEN)[42] to have access to or use genetic material. It should be noted that only nationals (either public or private parties) can obtain authorisation to access a component of the Brazilian genetic heritage. A special authorisation must be given to foreigners who want to participate in expeditions (which must necessarily be coordinated and joined by a Brazilian institution) to obtain genetic material in Brazil.

Article 18 requires that shipment of samples of Brazilian genetic material to overseas should also depend on prior authorisation and on the execution of a transfer of material instrument.

In addition, pursuant to both Art. 16 and Art. 18 of the Provisional Ruling, if there is expectation of commercial use of the product/process resulting from the use of the collected material, it will be necessary to sign a "contract for use of genetic heritage and benefit sharing".

Further, Art. 31 of Provisional Ruling No. 2,186-16 sets out that the granting of patents shall depend on the disclosure of the origin of the genetic material or the associated traditional knowledge (if any). Following this provision, both CGEN[43] and the Patent Office[44] issued regulations according to which Applicants must inform whether their claimed inventions derive from a component of the Brazilian genetic

35 Lei No. 9.456, de 25 de abril de 1997, que institui a Lei de Proteção de Cultivares e dá outras providências. [1997]. [online]. Available from: http://www.planalto.gov.br/ccivil_03/Leis/L9456.htm [Accessed 4 August 2011].

36 For a comprehensive analysis of the TRIPS Agreement and the protection of plant varieties in developing countries, see Verma, S.K. 1995. "TRIPS and Plant Variety Protection in Developing Countries." European Intellectual Property Review 17(6):281-289.

37 The UPOV Convention was signed in Paris in 1961, principally by developed countries seeking to provide protection for plant breeders in their own and overseas markets. The UPOV Convention was subsequently revised in Acts adopted in 1972 (1972 Act), 1978 (1978 Act), and 1991 (1991 Act).

38 Decreto No. 2.366, de 5 de novembro de 1997, que Regulamenta a Lei No. 9.456, de 25 de abril de 1997, que institui a Proteção de Cultivares, dispõe sobre o Serviço Nacional de Proteção de Cultivares - SNPC, e dá outras providências. [1997]. [online]. Available from: http://www.planalto.gov.br/ccivil_03/ decreto/1997/ D2366.htm [Accessed 4 August 2011].

39 Decreto No. 2.519, de 16 de março de 1998, que promulga a Convenção sobre Diversidade Biológica, assinada no Rio de Janeiro, em 05 de junho de 1992. [1998]. [online]. Available from: http://www.planalto.gov.br/ccivil_03/decreto/D2519.htm [Accessed 8 August 2011].

40 Medida Provisória no. 2.186-16, de 23 de agosto de 2001, que regulamenta o inciso II do § 1o e o § 4o do art. 225 da Constituição, os arts. 1o, 8o, alínea "j", 10, alínea "c", 15 e 16, alíneas 3 e 4 da Convenção sobre Diversidade Biológica, dispõe sobre o acesso ao patrimônio genético, a proteção e o acesso ao conhecimento tradicional associado, a repartição de benefícios e o acesso à tecnologia e transferência de tecnologia para sua conservação e utilização, e dá outras providências. [2001]. [online]. Available from: https://www.planalto.gov.br/ccivil_03/MPV/2186-16.htm [Accessed 8 August 2011].

41 Article 7 of Provisional Ruling 2,186-16 defines the genetic heritage as "information of genetic origin, contained in samples of all or part of a plant, fungal, microbial or animal species, in the form of molecules and substances originating in the metabolism of these living beings, and in extracts obtained from in situ conditions, including domesticated, or kept in ex situ collections, if collected from in situ conditions, within the Brazilian territory, on the continental shelf or in the exclusive economic zone." Associated traditional knowledge, by turn, is defined as "individual or collective information or practice of the indigenous community or local community, with real or potential value, associated to genetic heritage."

42 CGEN is a special administrative council, created by Art. 10 of Provisional Ruling 2,186-16, within the Ministry of the Environment.

43 Resolução No. 34, de 12 de fevereiro de 2009, que estabelece a forma de comprovação da observância da Medida Provisória nº 2.186-16, de 23 de agosto de 2001, para fins de concessão de patente de invenção pelo Instituto Nacional da Propriedade Industrial, e revoga a Resolução nº 23, de 10 de novembro de 2006. [2009]. [online]. Available from: http://www.mma.gov.br/estruturas/sbf_dpg/_ arquivos/res34_cons.pdf [Accessed 9 August 2011].

44 Resolução No. 207, de 24 de abril de 2009, que normaliza os procedimentos relativos ao requerimento de pedidos de patentes de invenção cujo objeto tenha sido obtido em decorrência de um acesso a amostra de componente do patrimônio genético nacional revoga a Resolução 134, de 13 de dezembro de 2006. [2009]. [online]. Available from: http://www.inpi.gov.br/menu-esquerdo/instituto/legislacao-1/resolucoes/2009/Res%20207%20e%20 anrxo %20I%20-%20II.pdf [Accessed 9 August 2011].

heritage obtained as from 30 June 2000[45]. In the affirmative, the Applicant must provide to the Patent Office details on the contract allowing such kind of access, in particular the authorisation number granted by CGEN, and information on the origin of the genetic material or associated traditional knowledge, as appropriate.

If on the one hand, the Provisional Ruling seeks to avoid biopiracy and to promote the equitable sharing of benefits from the collection of genetic material in the territory, on the other, it has created a strict regime and much bureaucracy, posing some obstacles to biodiversity prospecting in the country, and yet, some provisions left much unsaid. Not to mention that the disclosure of the origin of the genetic material used (if any) required by the Provisional Ruling in force may be interpreted as another patentability requirement, which would therefore be at odds with the TRIPS.

Finally, there are some legislature proposals seeking to replace Provisional Ruling No. 2,186-16. It is hoped that the law to come will ease research and prospection, and shed some light on issues not fully addressed in the current Provisional Ruling.

5 Conclusion

Biotechnology holds centre stage among all other sciences in this century. The speed of discoveries is truly phenomenal and the commercial possibilities appear to be limited only by the span of the human imagination.

In view of the massive investments in R&D, the growth of the biotech industry relies upon the protection by intellectual property rights. Indeed, without a solid patent system, scientific progress in this field could be stifled. With this in mind, the Brazilian Government enacted Industrial Property Law 9,279/96, extending patent protection to most forms of biotechnological subject matter.

Nonetheless, in accordance with the TRIPS, which permits the exclusion of certain categories of material, limitations to patent protection were inserted in the Brazilian legislation. In fact, concerns have been raised that patents could be granted over inappropriate material, which should not be protected notwithstanding the economic value of the *'invention'*.

The prohibition to the patenting of any naturally occurring product, regardless of isolation, purification or other chemical modification involved during the synthesis of an analogous substance in the laboratory, is one of the major impediments that make Brazil continue to lag behind some other countries. In addition, some criteria that patent examiners use in the assessment of the patentability requirements, especially inventive activity, should be reviewed. The European or American paradigm could shed some light on this task.

Concerns have also arisen over the access to genetic material from which some products are developed, as well as the distribution of benefits to traditional communities.

In accordance with the 1992 Convention on Biological Diversity, the Brazilian Government attempted to address these concerns in Provisional Ruling 2,186-16. Unfortunately, that piece of legislation was enacted in a hurried pace, leaving insufficient time for clear and coherent provisions to be established, especially on intellectual property and benefit-sharing issues.

With a view to streamlining current regulations that slow scientific research and exclude valuable subject matter from patent protection, a series of bills have been proposed and are currently under discussion at the Brazilian Congress. At the heart of some of these proposals is the perceived need to set an adequate level of protection which will encourage more investments in R&D and ensure proper dissemination of the ensuing advances.

It is then hoped that these initiatives will provide those missing features for the country to consolidate its position as a global player in the biotech sector, and to have its stake in the progress of science over this century.

[45] Date at which the first version of the Provisional Ruling No. 2,186-16 was published.

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sofia

The Society for Institutional Analysis was established in 1998. It is located at the University of Applied Sciences in Darmstadt and the University of Göttingen, both Germany.
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elni

In many countries lawyers are working on aspects of environmental law, often as part of environmental initiatives and organisations or as legislators. However, they generally have limited contact with other lawyers abroad, in spite of the fact that such contact and communication is vital for the successful and effective implementation of environmental law.

Therefore, a group of lawyers from various countries decided to initiate the Environmental Law Network International (elni) in 1990 to promote international communication and cooperation worldwide. elni is a registered non-profit association under German Law.

elni coordinates a number of different activities in order to facilitate the communication and connections of those interested in environmental law around the world.

Coordinating Bureau

Three organisations currently share the organisational work of the network: Öko-Institut, IESAR at the University of Applied Sciences in Bingen and sofia, the Society for Institutional Analysis, located at the University of Darmstadt. The person of contact is Prof. Dr. Roller at IESAR, Bingen.

elni Review

The elni Review is a bi-annual, English language law review. It publishes articles on environmental law, focussing on European and international environmental law as well as recent developments in the EU Member States. elni encourages its members to submit articles to the elni Review in order to support and further the exchange and sharing of experiences with other members.

The first issue of the elni Review was published in 2001. It replaced the elni Newsletter, which was released in 1995 for the first time.

The elni Review is published by Öko-Institut (the Institute for Applied Ecology), IESAR (the Institute for Environmental Studies and Applied Research, hosted by the University of Applied Sciences in Bingen) and sofia (the Society for Institutional Analysis, located at the University of Darmstadt).

elni Conferences and Fora

elni conferences and fora are a core element of the network. They provide scientific input and the possibility for discussion on a relevant subject of environmental law and policy for international experts. The aim is to gather together scientists, policy makers and young researches, providing them with the opportunity to exchange views and information as well as to develop new perspectives.

The aim of the elni fora initiative is to bring together, on a convivial basis and in a seminar-sized group, environmental lawyers living or working in the Brussels area, who are interested in sharing and discussing views on specific topics related to environmental law and policies.

Publications series

elni publishes a series of books entitled "Publications of the Environmental Law Network International". Each volume contains papers by various authors on a particular theme in environmental law and in some cases is based on the proceedings of the annual conference.

elni Website: elni.org

The elni website www.elni.org contains news about the network. The members have the opportunity to submit information on interesting events and recent studies on environmental law issues. An index of articles provides an overview of the elni Review publications. Past issues are downloadable online free of charge.

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