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LIFE SCIENCES



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RECENT DEVELOPMENTS IN LIFE SCIENCES LAW

Human Gene Patents

The New York Federal Court's decision of 30 March of this year invalidates seven of the twenty three patents granted by the USPTO to Myriad Genetics and the University of Utah. The proceedings brought by the Association for Molecular Pathology and others against the United States Patent and Trademark Office seeks to overturn the patents granted to the Myriad Genetics biotechnology laboratory and the University of Utah Research Foundation in respect of two genes linked to breast cancer and ovarian cancer. The cases against the granting of patents relates to isolated DNA containing all or parts of the BRCA1 and BRCA2 gene sequences and the methods used to "compare" or "analyse" the sequences of those genes to identify the presence of mutations related to the predisposition to breast and ovarian cancer. The arguments presented by the plaintiffs in the case were based around a single and challenging question "Are isolated human genes and the comparison of their sequences patentable?" The plaintiffs based their argument around the claim that genes are products of nature and, as such, cannot be patented. They also claim that these

patents "limit the options for testing and prevent further research and innovation". In turn, the holders of the patent argue that the savoir faire and the human and financial efforts made to isolate the DNA in the organism justify it being patentable.

The truth is that patents over living organisms have been granted over at least the last thirty years and the same arguments have been raised (see the well-known case of *Diamond v. Chakrabarty*, 1980, on the patent of genetically modified bacteria capable of breaking down crude oil). However, in this case, the judge Robert W. Sweet found the patents had been "improperly granted" because they involved "laws of nature" and that the idea of isolating a gene to make it "patentable" was a "lawyer's trick" to get round the legal ban on patenting DNA from our bodies. This decision has called into question the patents for the 20% of human genes already patented and the intellectual property rights those patents confer.

Myriad Genetics has announced that it will appeal the court's decision.



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New Rules on Prescription Payment Framework

Decree Law no. 48-A/2010 of 13 May came into force on 1 June 2010. This law approves the general framework for state contributions to the cost of prescription medicines.

This framework seeks to achieve three principal objectives: (i) better access to medicines for the whole of the population, especially those with the greatest need; (ii) rationalisation of public spending on medicines so as to guarantee the sustainability of the system of state contributions; and (iii) promotion of a more generalised use of generic medicines.

The progressive increase in average life expectancy and the resulting increase in the quantity of medicines dispensed throughout a person's lifetime have caused public spending on those medicines to go up. In the medium term, this fact could call into question

Another relevant change consists of requiring that, for new generic medicines to benefit from state contributions, the price must be at least 5% lower than the retail price for of the cheapest generic medicine that is already on the market with a market share of at least a 5% of the generic medicines in the homogenous group.

the sustainability of healthcare systems that are generally free of charge as is the case in the Portuguese national health system.

To avoid this happening (or – as the more sceptical would say in relation to welfare states – to delay the inevitable), measures are progressively being taken to reduce public spending on medicines and to do so in a true balancing act without compromising the access of citizens to generally free quality medicines.

Thus, it is in this context that the system of state contributions has been revised.

From among the numerous changes introduced by Decree Law no. 48-A/2010 of 13 May we would highlight the following:

The first change worthy of mention is aimed at pensioners in the special regime whose income does not exceed 14 times the Social Benefits Index (that is €5 869.08). In this case, the state will pay 100% of the cost of medicines the retail price of which are amongst the five lowest for the homogenous group they come from, as long as it is the same as or lower than the reference price for this group. This change seeks to provide an incentive for the prescription of cheaper but good quality medicines by guaranteeing that the state will pay for them in full.

Another relevant change consists of requiring that, for new generic medicines to benefit from state contributions, the price must be at least 5% lower than the retail price for of the cheapest generic medicine that is already on the market with a market share of at least a 5% of the generic medicines in the homogenous group. Accordingly, as the “contribution” factor is decisive for the commercial survival of medicines, in practical terms the 5% condition will lead to a generalised reduction in the price of

generic medicines as new medicines come onto the market.

The concept of “reference contribution” is also introduced. This means that the contribution becomes a fixed amount that is applied to the reference price for the respective homogenous group. As a consequence of this measure, all medicines from the homogenous group that are priced within the “reference contribution” will be free, without there being an exponential increase in the relative cost for the state and, as can be seen, there will be a greater incentive to bring prices down.

Lastly, the reduction in reference prices as a result of the reduction by 30% of the retail price of generic medicines approved by Ministerial Order no. 1016-A/2008 of 8 September will finally take effect.

Even without major impact studies is clearly to be expected that these changes will lead to a reduction in the prices of medicines, especially generic ones. It remains to be seen whether this reduction will be enough to increase their rate of prescription (which, as we know, depends to a great extent on doctors). Moreover, it also remains to be seen whether it contributes in any meaningful way to halting the growth of public spending on medicines and to allaying fears of a collapse of the free healthcare model.

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Assisted Reproduction(ART) – Publication of Regulatory Decree no. 1/2010 of 26 April

This decree brings the first alteration to Regulatory Decree no. 5/2008, of 11 February which regulates Law no. 32/2006, of 26 July. This Law approved the application of medically assisted reproductive techniques in Portugal. The legislation alters and amends some of the rules contained in Regulatory Decree no. 5/2008 of 11 February relating to the requirements for technical qualifications of the professionals who

work in the centres for medically assisted reproduction in accordance with the work they do. The specialisation of doctors is extended to at least two specialists in gynaecology and obstetrics, except for centres dedicated exclusively to artificial insemination or the selection of donors and preservation of the samples. In these cases, the staff requirements are set out in the legislation.

The interaction between the various entities involved in auditing, inspections and supervision for public and private centres that uses assisted reproduction techniques (the National Council for Medically Assisted Reproduction, the Inspectorate-General of Healthcare Activities and the Directorate-General of Health) is also defined.



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Portugal Leads the Way in Organ Harvesting and Transplants

According to the statistical data presented last March by the Blood and Transplantation Services Authority, in 2009 Portugal and Spain became world leaders in the harvesting and transplantation of organs and have already passes the milestone of 30 donors per million inhabitants.

It should be noted that in 2006 the number of donors in Portugal was fewer than 19 per million inhabitants so there has been a 64% increase. There was a 25% increase in harvesting from living donors alone. This increase has been mainly made up of kidney and liver transplants and has resulted in a significant reduction in waiting lists in Portugal.

Over the last few years the area of transplants has seen intensive legislative activity to deal with the growing needs that are being felt and also as a result of orientation coming from international sources, namely the European Parliament and Council. These two institutions have issued relevant Directives, for example Directive 2004/23/CE of 31 May and 31 March of 2004 relating to the establishment of quality and safety

standards in relation to the donation, harvesting, analysis, processing, preservation, storage and distribution of human tissues and cells, partially transposed into Portuguese law by Law no.22/2007 of 29 June. Another example is the new Directive on the donation of organs and transplants approved by an overwhelming majority of the European Parliament with 643 votes in favour and 16 against with 8 abstentions, which establishes common rules for quality and safety for the harvesting, transport and use of organs). Orientation has also come from the Council of Europe and its resolutions.

The recently enacted Decree Law no. 38/2010 of 20 April 2010 is an example of the high level of legislative activity in this area in Portugal. This law provides an exemption from payment of medical fees for patients receiving transplanted organs, living donors of organs and cells and bone marrow transplants, potential donors of the said organs and cells and serving and former members of the armed services who are permanently disabled as a result of their military service.

Additionally, Ministerial Order no. 220/2010 – which approved the rates for requests for authorisation referred to in article 32 (1) of Law no. 12/2009 of 26 March which established the legal framework for quality and safety for the donation, harvesting, analysis, processing, preservation, storage and distribution and application of human tissues and cells – published four days before the Decree Law referred to above, is a clear illustration of the Portuguese legislator's growing concern with this issue, especially with the rules for safety and for providing an incentive to living donors.

The targets for 2010 are a continuing increase in harvesting from deceased and living donors so as to bring greater success in the transplant "business".

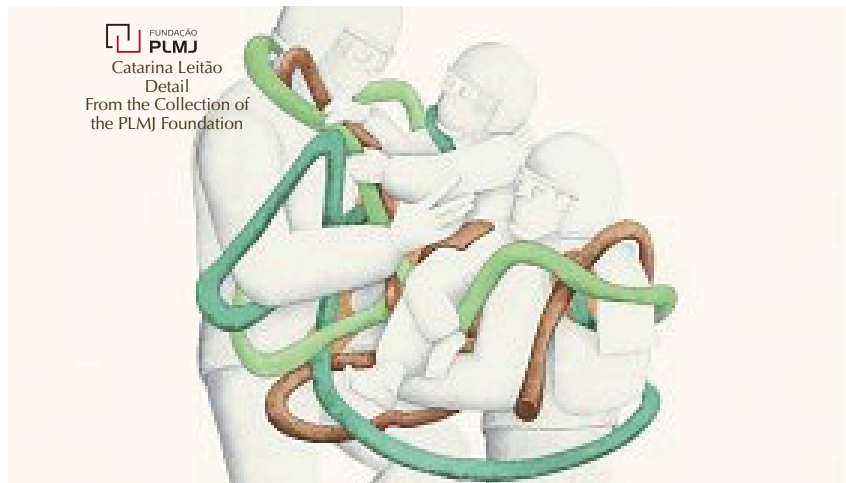
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Nanotechnologies: Publication in France of the Report of the National Commission for Public Debate (CNDP)



“Portuguese Law Firm of the Year”
Chambers Europe Excellence 2009, IFLR Awards 2006, Who’s Who legal Awards 2006, 2008, 2009

“Corporate Law Firm of the Year - Southern Europe”
ACQ Finance Magazine, 2009

“Best Portuguese Law Firm for Client Service”
Clients Choice Award - International Law Office, 2008, 2010

“Best Portuguese Tax Firm of the Year”
International Tax Review - Tax Awards 2006, 2008

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The CNDP delivered a report to the French government that the government had requested on the “public debate on the development and regulation of nanotechnologies”. The report was concluded in April of this year and the main addressees were seven ministries: Ecology, Agriculture, Economy, Employment, Research, Defence and Health. The report reiterated the need for an open and transparent debate in society “which should be associated with the decisions” so as to create a true partnership between science, research and society (including representatives from industry, trade unions, patients associations and environmental

organisations) This report is particularly significant because it recognises the importance nanotechnologies have today (it should be remembered that many objects in our day to day lives contain nanoparticles of distinct materials – electrical devices, cosmetics, clothing) and as an investment for the future. The report dealt with the fundamental issues in this area such as research, health and environmental risks, toxicology, current and potential applications for nanotechnology, medical applications, competitiveness and economic development, national defence, ethics and government.