

The newsletter of the Life Sciences Group



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Welcome to the Autumn issue of BioBrief. In this edition we discuss recent developments on Animal Testing and on UK Immigration Law and look at the case of Monsanto Technology LLC v Cefetra BV and others on Patent Infringement and the Biotechnology Directive.

ANIMAL TESTING UPDATE

The UK's legislation on Animal testing has been in place for some 24 years, and with the advances that have taken place in science since 1986, the European Commission felt that more EU harmonisation was needed. Protracted debate on this very emotive issue over the last two years has recently culminated in a compromise text of a new Directive being agreed by the EU Parliament to replace the current Directive 86/609.

Directive 8869/10 sets out a harmonised set of minimum requirements for the protection of laboratory animals throughout the EU, balanced against the legal requirements placed on the therapeutic sector to conduct animal testing as part of the regulatory process.

Although the agreed text had not been officially published as at 1 October 2010, it is expected to provide:

- that all animal testing will be subject to ethical review and prior authorisation;
- minimum animal housing requirements;
- that systematic controls and inspections will be needed to aid enforcement regulator;
- that a wider range of animals will be protected, including some invertebrates and foetuses in their last trimester;
- that it will include a general prohibition on the use of great

apes (chimpanzees, gorillas and orangutans amongst the group). Research and testing on some great apes (macaques and ouistitis) is to be permitted where there is scientific evidence that the research cannot be achieved otherwise.

As with most compromise legislation there are differing views on the effectiveness of the proposals, with some lobby groups feeling it does not go far enough, whilst other groups welcome the changes. However, as the 'new' minimum standards are below the current UK requirements laid down in the Animals (Scientific Procedures) Act 1986 and subordinate legislation, there are real concerns that the government might opt to reduce the UK rules as a cost saving measure; it need not do so as higher standards are permitted.

We will need to wait to see the final UK regulations over the next few years. Like all EU Directives, it will enter into force some 20 days after its official publication. Member states will have two years thereafter to transpose the Directive into their national legislation. It will take effect on 1 January 2013.



MAKING A MEAL OF PATENT INFRINGEMENT

The Scope of Protection under the Biotechnology Directive (98/44/EC).

In July 2010 the European Court of Justice (ECJ) ruled on the scope of protection offered under the Biotechnology Directive (98/44/EC) ("the Directive") in the case of Monsanto Technology LLC v Cefetra BV and others (C-428/08, 6 July 2010) ("the Monsanto case").

The Directive governs the legal protection of biotechnology inventions in the EU. The Directive was given a restrictive interpretation by the ECJ as to the protection it offers to product patents containing recombinant DNA claims.

The Case

Monsanto was (and is) the holder of a European patent for a DNA sequence which, when introduced into the DNA of a soya plant, codes for an enzyme which makes the plant resistant to the herbicide 'Round-Up™'. This genetically modified soya is known as 'Round-up Ready™' soya or 'RR soya'.

In 2005 and 2006 the defendants imported into the Netherlands three cargoes of soya meal made from soy beans grown in Argentina. Monsanto used Dutch customs-seizure procedures to obtain samples of the soya meal, which were analysed and found to contain traces of the DNA sequence characteristic of RR soya.

Monsanto brought patent infringement proceedings against the importers for bringing into the EU soya meal which was produced from genetically modified soya, for which Monsanto holds the EU patent. Monsanto alleged that the meal infringed its patent because amongst other things it contained traces of its patented DNA sequence.

The Directive governs this area of law in the EU. The Dutch court held that interpretation of the Directive was required to resolve the dispute. As the Directive is European legislation it needed to be interpreted by the European courts so that such interpretation applied equally to all EU member states. As a result, the Dutch case was stayed and numerous questions were referred to the highest court in the EU, the ECJ.

The most relevant question was regarding the scope of patent protection under Article 9 of the Directive which provides that:

"The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material...in which the product is incorporated and in which the genetic information is contained and performs its function."

In effect the question was whether Article 9 of the Directive was to be interpreted as protecting the DNA that is contained in the meal where it does not perform its function – of protecting the plant from the herbicide – notwithstanding that it has previously performed that protective function and might be able to perform its function again

once extracted and inserted into the cell of a living organism.

The ECJ Decision

The ECJ focused on the present tense used in Article 9, namely the phrase 'material...in which' and stated that this implied that the function should subsist in the material at the time of the alleged infringement. In the current case, the function would be to protect the soya plant from the effect of certain herbicides.

The ECJ stated that the use of an herbicide on soya meal was not foreseeable and even if it was the product (i.e. the DNA sequence coding for herbicide resistance) could not perform its function in the soya meal as it was only found in a residual state (i.e. dead material).

The Court held that the protection provided for in Article 9 of the Directive could not be available to Monsanto, on the grounds:

- i. that the genetic information performed its function previously in the material containing it; or
- ii. that it could possibly perform that function again in another material

and to allow such protection would cause the Directive to lose its effectiveness since either one of these situations could, in principle, always be relied on.

The ECJ went on to say that a DNA sequence does not enjoy patent protection when the function performed by that DNA sequence is not specified.

The ECJ also held that the Directive is exhaustive in this area and therefore national law cannot provide for a level of patent protection which is wider than that provided under the Directive.

The Court also held that it made no difference if the patent in question was issued prior to the Directive being adopted.

Conclusion

This decision will apply generally to all cases in which a product is derived from the processing of a genetically modified plant, in a non-EU country and then imported into a member state where there exists a valid European patent.

This is a relatively restrictive interpretation of the scope of the Directive. This is bad news for patent holders of biotechnological inventions seeking to prevent the importation of materials containing their patented genetic material into patented territories. However, the impact of this decision will be felt far less for those who can obtain patents in the territories where the crops are produced.

UK IMMIGRATION LAW UPDATE

Since the end of 2008, immigration to the UK for work has been on a 5 tier points-based system in which applicants are awarded points for attributes such as their qualifications, age, previous earnings and UK experience, their ability to maintain themselves and their English language skills. Highly skilled workers may apply under Tier 1, while those who are skilled workers or who do not have sufficient points to apply as highly-skilled workers may apply under Tier 2 and require a certificate of sponsorship from their employer.

Cap on migration

Since 19 July 2010, the government has imposed an interim limit on the number of applications for Tier 1 and Tier 2 (General), but not Tier 2 (Intra company transfers). The cap aims to achieve an overall reduction of 5% in the number of applicants in those categories and will remain in place until 31 March 2011, after which it is proposed that new permanent limits will come into force. Consultation closed on 17 September and the government intends to announce the final figure at the end of the year.

Sponsors who have assigned all their certificates of sponsorship may request additional certificates but requests will only be approved in exceptional circumstances; the sponsor will need to show that it has used all its certificates of sponsorship and has a pressing need to issue further certificates.

Recent changes to Tier 1 immigration

Also since 19 July, the pass mark for an initial Tier 1 (General) application has increased to 100 points from 95 points. Recently, the government has also introduced the following changes to the number of points awarded for certain attributes:



- Applicants are now awarded points for Bachelor's degrees whereas previously points were only awarded for a Master's degree or above.
- The number of points awarded for PhDs has been reduced from 50 to 45.
- Those with earnings over £150,000 or an MBA automatically meet the attributes requirement and will therefore be eligible for entry to the UK providing they meet the English language and maintenance requirements.
- The earnings bracket has been raised for all new applicants (those extending their permission are subject to the points criteria in place at the time of their initial application). Points are no longer awarded for earnings under £25,000, making it more difficult for applicants to meet the requisite number of points.
- The age bracket has been extended with points now awarded to applicants under 39. Previously points were only awarded to applicants under the age of 32.
- Individuals making an initial application will be awarded two years' leave to remain in the country instead of three, though they will then be granted a three year extension if they have been in highly skilled employment.

Recent changes to Tier 2 immigration

Intra company transfers

Since 6 April 2010, there have been three types of intra-company transfer:

- Established Staff;
- Skills Transfer; and
- Graduate Trainee.

The number of points awarded for intra-company transfers has been reduced to 25 and the minimum salary has increased from £17,000 to £20,000, though the number of points awarded for salaries over £32,000 has increased. Applicants are also awarded points for their qualifications, ability to maintain themselves and English language ability or skills.

Established staff now require 12, not 6 months, service to apply for an intra-company transfer to fill a post that can not be filled by a settled employee. Certificates in the new categories, Skills Transfer and Graduate Trainees, will only be available for a limited period and holders will not be permitted to switch immigration categories. Graduate trainees with three months service will be permitted to stay in the UK for up to one year on an accelerated promotion or career development program. The Skills Transfer category allows companies to transfer new hires with graduate level degrees to the UK for up to six months to teach or learn skills relevant to their position.

The changes are supposed to provide greater flexibility for companies to transfer staff to the UK, though such transfers will no longer lead to permanent residence. Tier 2 intra-company transferees who entered the UK before 6 April 2010 will not be affected by these changes and will be able to qualify for indefinite leave to remain.

Impact on employers

Businesses in the life sciences sectors often employ significant numbers of highly skilled workers from overseas. The latest changes to the immigration system could make recruitment of overseas nationals more difficult for employers, so it is now more important than ever that employers in these sectors pay careful attention to the attributes of their potential employees to ensure that they will actually be able to employ the individuals whom they wish to recruit. This has recently been highlighted by Prof Mike Stratton, Director of the Sanger Institute in Cambridge, who fears that the current visa rules could jeopardise its pioneering work on genetic variations, and have a knock-on impact on medical advances in the treatment of diseases such as AIDS, malaria and 'flu.

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