McDermott Will & Emery

# The European IP Bulletin

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## Hot Topics

### 1. ANNUAL REPORT BY THE US TRADE REPRESENTATIVE ON FOREIGN IP PROTECTION

The US Trade Representative (USTR) "Special 301" report is issued annually and is based on section 301 as amended of the US Trade Act of 1974. Section 301 empowers the USTR to identify countries where trade barriers exist on the following priority basis: 1) Priority Foreign Country (worst); 2) Priority Watch List; 3) Watch List. Countries in the Priority Foreign Country list may face investigation and sanctions. On 29 April, the 2005 Special 301 report was issued.

Ukraine remains a Priority Foreign Country and faces a $75M sanction because of inadequate Intellectual Property Rights (IPR) protection combined with failure to enter "good faith negotiations".

Fourteen countries have been placed in the second, Priority Watch List category. These countries are Russia, Argentina, Brazil, Egypt, India, Indonesia, Israel, Kuwait, Lebanon, Pakistan, the Philippines, Turkey Venezuela and China. China was elevated to this group after a special 'out of cycle' review (OCR) reported on the implementation of the bilateral agreements of 1992 and 1995 with the US. The USTR found levels of piracy and counterfeiting remained high, the result of an inadequate deterrence regime. The USTR has committed itself to tough action against China both in the WTO and in bilateral forums.

The aggressive stance of the USTR, whilst apparently to the benefit of IPR owners, is targeted even at TRIPS territories that are compliant with the World Trade Organisations Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) such as the EU. Russia remained on the list due to insufficient IPR enforcement and lack of data protection. The USTR identified primary concerns with its 'bilateral commitments' rather than TRIPS compliance. Russia will be subject to an OCR.

Thirty-six countries are on the Watch List including the European Union and Canada along with Azerbaijan, Belarus, Bulgaria, Kazakhstan, Mexico, Vietnam and others. The EU and Canada will also face OCRs.

The USTR said, "Strong intellectual property rights, protections and enforcement at home and abroad are critical for the success of America's innovative economy and are top priorities for this Administration...We are committed to vigilantly enforcing US intellectual property laws and procedures and to working with our trading partners around the world to effectively protect the ideas, brands and inventions of our businesses and entrepreneurs".

### 2. UK LABOUR PARTY'S INTELLECTUAL PROPERTY MANIFESTO FOR THE DIGITAL AGE

"We will modernise copyright and other forms of protection of intellectual property rights so that they are appropriate for the digital age. We will use our presidency of the EU to look at how to ensure content creators can protect their innovations in a digital age. Piracy is a growing threat and we will work with industry to protect against it."

So states the UK Labour Party's election manifesto published in advance of their victory in the general election on 5 May 2005. The UK will hold the EU presidency from July to December 2005.

This reflects the recent direction taken by the UK government to promote awareness of intellectual property rights, which include the announcement of a pan-European "Creative Economy" to take place in London in October 2005 and which will be endorsed by the Department for Culture Media and Sport as well as the Department of Trade and Industry.

It is not yet clear what steps are proposed, although it appears likely that the UK's presidency of the European Union will promote debate in relation to copyright reform in Europe over the next few months.

### 3. SPANISH AUTHORITIES TO FIGHT PIRACY: CRIMINAL CODE REFORM AND SUCCESSES OF POLICE ACTIONS

The avowed commitment by Spanish authorities to combat counterfeiting is finally beginning to show its first results, after complaints from the music industry about the serious challenge of piracy.

According to the International Federation of the Phonographic Industry (IFPI), Spain has traditionally been a country with high levels of piracy via several large-scale organisations illegally reproducing and distributing CDs and DVDs.

Recently, the Spanish authorities proclaimed a number of initiatives in order to provide the Spanish police with effective means to counter the problem.

The core project has been a reform of the criminal code. The current resulting legal amendment removes the obstacle of the previous Article 287 of the criminal code, which restricted the permitted locus standi required to start a legal action. The new law also increases the sanctions for pirates belonging to organisations established with the aim of infringing IP rights, and it imposes severe sanctions in cases where minors are used to commit such criminal offences.

Like other Member States, such as Italy, Spain has widened the definition of "distribution for profit". Jurisprudence now interprets the "for profit" provision (Article 270(1) of the Spanish criminal code) to extend to all economic benefits apart from the personal benefit of the holder of a legal copy. This could lead to the imposition of criminal sanctions to users of peer-to-peer networks.

In terms of digital rights management, Article 270(3) was amended to include, in the category of criminal offences, the production, distribution and possession of any instruments specifically designed to eliminate or deactivate technical means for the protection of IP digital contents.

Finally, the new Article 270(2) establishes that the importation of material protected by intellectual property rights without prior authorisation from the rightholders also constitutes a criminal offence.

It is clear that a legal reform alone is not sufficient to reduce the level of piracy. The Spanish government is currently acting in cooperation with the Guardia Civil and other institutions for the protection of intellectual property, especially in the entertainment markets such as the SGAE (the collecting society representing authors and publishers of musical and audiovisual works). This body has invested in activities to improve public awareness on the broad range of criminal activities sanctioned under the new rules. SGAE commends the numerous initiatives by the police and, in February 2005, issued a press release underlining the importance of large-scale police operations, which recently seized €909.550 worth of illegal copies of CDs and DVDs, colour photocopiers and blank digital devices. SGAE has reiterated that criminal organisations are damaging the industry and the labour market.

**Copyright**

### 4. FRANCE: A STEP BACKWARDS FOR DIGITAL RIGHTS MANAGEMENT IMPLEMENTATION

In Stéphane P and Association UFC v Universal Pictures Video France (22 April 2005), the French Court of Appeal confirmed the validity of the private copy exception, whereby consumers may make a private copy of a work strictly for their personal use. In doing so, it reversed the judgment at first instance but, more importantly, it restricted the use of Digital Right Management systems (DRM) which do not allow the user to make copies intended for private use.

The appellant bought a DVD of the movie “Mulholland Drive”. He wanted to watch it at his mother’s house but she only owned a video recorder. He decided to copy the DVD onto a VHS cassette but was prevented from doing so by DRM protection. He made a complaint to UFC, the consumers’ body, and they decided to act jointly against Universal Pictures Video France. After the first decision went against them, both decided to appeal.

The French Court of Appeal noted that the circumstances had to be considered under the framework laid down by Article 9(2) of the Berne Convention and Article 5(5) of the Infosoc Directive (2001/29/EC)(“the Directive”), as they define the necessary requisites to grant exceptions to copyright infringement. The “three-step-test” establishes that an exception can be granted only in special cases, when it does not represent an obstacle to the normal exploitation of the work, and when it does not prejudice the legitimate interest of the right holder. The Court of Appeal found that those conditions were fulfilled.

Moreover, the Court of Appeal referred to the alleged violation of Article L111-1 of the French Consumers Code. The Court stated that while the packaging of the DVD did contain the copy prohibited label, the characters were far too small and essentially insufficient to fulfil the obligation to inform consumers of the obligations not to copy.

In ruling in favour of the Appellants, the Court of Appeal warned against the use of such technological measures preventing such private use copying.

Interestingly, as well as providing judgment in the case at hand, the Court also offered a clarification of the French legal framework in respect of copyright. It pointed out that the Directive delegates to the Member States the establishment of national exceptions under the condition that “the right holders receive fair compensation” (Article 5(b)). The French Intellectual Property Code was found to comply with the European provisions, including the levies imposed on blank digital (CD and DVD) and recording equipment. Levies are designed to redistribute income to authors who cannot obtain returns for unauthorised copies. Levies have so far not been adopted in the UK, where they have encountered severe opposition.

### 5. BBC CREATIVE LICENCE ON ARCHIVE COPYRIGHT

On 13 April 2005, the BBC along, with other British broadcasters, launched an online initiative, which will allow people to legally download, manipulate and share film. The BBC, Channel 4, the British Film Institute and the Open University have joined to create the Creative Archive Licence.

The Creative Archive Licence will allow people to download and use footage and audio files for non-commercial purposes. Each user will agree to abide by the licence conditions before gaining access to any of the available material. The scheme aims to:

- Pioneer a new, more refined approach to rights in the digital age
- Encourage the establishment of a public domain of audio-visual material
- Help stimulate the growth of the creative economy in the UK
- Establish a model for others in the industry and public sector to follow
- Exemplify a new, open relationship between the four partners in the pilot schemes and other industry players

It is hoped that pilot download schemes will help fuel creative activity across Britain as people utilise the footage in personal projects, classroom presentations and their own artistic creations.

The long-term aim is that some of those creations can be uploaded back on to the website from where the content was obtained, to be shared with others across the internet.

During the pilot, the BBC plans on making footage from natural history and factual programmes available to view, edit and share under the Creative Archive Licence. There is however, a commitment to add extracts from other genres in due course.

The British Film Institute will offer selected footage in a number of categories, including silent comedy, early literary adaptations, newsreel footage and archive footage of British cities in the early 20th century.

The Open University will make available video and audio teaching material from a range of genres including geography, science and history, as well as footage from the popular Open University and BBC series Rough Science during the pilot scheme.

Channel 4's content will include specially commissioned establishing shots and general views (GVs) available via Channel 4's broadband documentary channel, FourDocs, alongside copyright-cleared video clips for Video Jockeys currently available via its IDEASFACTORY creative careers site and other material from Channel 4 Education.

The Creative Archive Licence is inspired by the Creative Commons System, a US system that offers a flexible range of protections and freedom for authors and artists.

Since the BBC is licence fee funded, it is releasing the content only to UK internet users, using a technology called GeoIP filtering which will ensure the content will only be available to UK hosts.

### 6. DUTCH INDUSTRY ANXIOUS OVER PROPOSED MP3 TAX

The Stichting Thuiskopie foundation has proposed a tax on MP3 players that could soon become law unless the European Commission intervenes. The tax, which aims to compensate right holders for lost royalties from private copying of music, images and movies, will be based on the amount of storage at €3.28 per gigabyte. This would increase the price of a 40Gb Apple iPod by more than €130. The levy will be administered by the foundation, which already collects levies on blank recording media such as CDs, and DVDs imposed under the 1912 Copyright Act and the 1933 Neighbouring Rights Act.

The proposed tax could severely affect sales of MP3 players and there are fears that although the current scope of the legislation is limited to hard drive MP3 players, it could be extended to other media storage devices such as PC hard drives. Consumers argue that because most iPods have Digital Rights Management (DRM) protection, meaning that access is limited to authorised users, they will be paying twice for the copyright once the tax is in place. In addition, where MP3 players are not DRM protected, the levy might lead to infringement of copyright by users who may argue that they will have already paid for the copyright through the levy.

Consumer electronics companies such as Apple, Sony and Philips are concerned that the tax could hit sales and also fear that the proposed tax will deter hardware companies from launching new products in Europe.

There are also proposals in Belgium for a similar levy on MP3 players while Germany already imposes a levy on PC hard drives. In Canada, MP3 players are taxed at the rate of CDN $15 for players with 1 to 10 GB and CDN $25 for those over 10GB.

The Information and Communications Technology industry and consumer groups are currently lobbying against the introduction of the tax and as there is no indication of intervention by the European Commission, is it only a matter of time before a decision is made by the Dutch parliament.

**Patents**

### 7. REGULATORY DATA PROTECTION FOR MEDICINAL PRODUCTS: R (ON THE APPLICATION OF MERCK SHARP & DOHME LTD) V THE LICENSING AUTHORITY

On 28 April 2004, Moses J. gave his judgement in the case of *R (on the application of Merck Sharp & Dohme Ltd) v The Licensing Authority* [2005] EWHC 710 (Admin)

Merck Sharp and Dohme Ltd (MSD) hold market authorisations for Fosamax 5mg, 10 mg and 70 mg (Fosamax Once weekly), used for treating osteoporosis. These marketing authorisations were granted in July 1993, May 1995 and November 2000 respectively after submission of relevant regulatory data by MSD as required under Article 8 (3) of the Directive 2001/83/EC. The generic companies sought to manufacture and market the generic version of Fosamax Once weekly by relying and cross-referencing to the previous data submitted by MSD for all three versions of Fosamax.

The reliance and cross-reference by an applicant is permitted under Article 10 of the directive for certain situations. One such situation is under Article 10 (1) (iii) of the directive. This stipulates that an applicant need not be required to provide the relevant data where his medicinal product is essentially similar to a medicinal product that has been authorised within the Community for not less than six or ten years (ten years in UK) - a procedure also known as “the abridged procedure”. The proviso to Article 10 further provides that where the two medicinal products are not essentially similar, an applicant can rely on the original data and submit additional “bridging” data to cover the aspects of differences between the two, a procedure called “hybrid abridged procedure”.

The authorisation was accordingly granted in favour of generics by the competent authority in the UK without the need for any additional data. This was notwithstanding the fact that Fosamax 10mg and 70 mg have been authorised for less than ten years. Unhappy with the decision, MSD filed the present appeal contending that such reliance by generic manufacturers and the competent authority on its data is outside the scope of Article 10. It further contended that the present case does not fall within the previous ECJ decisions of *Generics*, *Novartis* and *APS* as these decisions do not cover the following two situations of the present case: first, the dosage and administration of Fosamax 70 mg is different than the other two products; and secondly, there are multiple differences between the three Fosamax products.

The court rejected the submissions of MSD by holding that ECJ decisions given in the cases of *Generics*, *Novartis* and *APS* also apply with full force to the present case. The Could held that:

- The difference in posology, that is dosage and administration, will not prevent the generic company cross-referring to the regulatory data submitted by the original innovator for their original product such as Fosamax 5 mg (authorised for more than six or ten years) and its line extension such as Fosamax 70 mg (authorised for less than six or ten years). Product B is a line extension of product A where the differences between them are either expressly identified in the proviso or generally implied.
- A generic company seeking to market a product C, identical to product B, is not required to produce any fresh data where the product B has been authorised earlier despite having multiple differences with product A. The generic company can make a cross-reference to the data submitted earlier for both the original product and its line extension.

## 8. WHEN IS A NON-EEA MARKETING AUTHORISATION AN EEA MARKETING AUTHORISATION?

The European Court of Justice (ECJ) recently handed down its decision in the joined cases C-207/03 and C-252/03 *Novartis AG, UCL and the Institute of Microbiology and Epidemiology v Comptroller-General of Patents, Designs and Trade Marks for the United Kingdom* and *Ministre de l'Économie v Millennium Pharmaceuticals Inc.,* relating to Supplementary Protection Certificates (SPC) and marketing authorisations.

The first case was referred to the ECJ by the UK High Court. In this case, the parties, Novartis AG, University College London and the Institute of Microbiology and Epidemiology, sought an SPC for Basiliximab, an immunosuppressant and the other for an antimalarial combination of Artemether and Lumefantrin. The second case concerned Millennium Pharmaceuticals Inc's application for an SPC in Luxembourg for Eptifibatide an anti-blood clotting agent.

SPCs are granted pursuant to Regulation No 1768/92 to compensate for the long period that elapses between the filing of a patent application in respect of a medicinal product and the granting of authorisation to place that product on the market. The object of the SPC is to allow an overall maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community. A patent must have been granted for the product and a marketing authorisation in force. The term of the SPC is determined by reference to the date of grant of the patent and the date of the first marketing authorisation in the EEA.

In both cases, the Swiss marketing authorisation had been the first relevant authorisation to be considered only because it extended automatically to Liechtenstein. The UK Patent Office and the Luxembourg government said that the

Liechtenstein authorisation was relevant. Grubb (Patents for Chemicals, Oxford, 3rd Edn, p149-150) was also of this opinion. The parties all argued that a relevant marketing authorisation was only one granted within an EEA state. Given that Swiss procedures may be quicker than that of EEA states, this would give the parties a greater SPC period.

The ECJ found that the EEA agreement recognised that two parallel marketing authorisations may exist in Liechtenstein, the Swiss and the EC/EEA compliant. This reciprocal recognition thus characterised the Swiss-Liechtenstein authorisation as a relevant marketing authorisation. Submissions by various governments that a Swiss marketing authorisation was not relevant to circulation of products on the EEA market were dismissed by the ECJ on the basis that authorisations within the EEA were territorially limited in nature as well.

The ECJ said that to not take into account a Swiss marketing authorisation could give greater than 15 years marketing authorisation to a medicinal product. The Court held that although the SPC regime granted additional protection to pharmaceuticals, it was not intended to provide a complete solution to patent holders where there are delays in marketing authorisations which affect their patent rights. The Court considered that the preamble to Regulation 1768/92 recognises that the interests of all parties connected with the health sector, not just the patent holders, must be taken into account.

The lesson patent holders can take from this decision is that patents are not considered to grant a right to market a product, rather there is a right to exercise a veto over others' use of the invention. Therefore, more imaginative ways of exploiting these rights, such as cross-licence trading to enhance collaborative research, should be pursued. It is time the pharmaceutical industry learnt this and opened up to technology collaboration over mere monopoly profits.

## Trade marks

### 9. WIPO MEMBER STATES AGREE BASIC TEXT FOR REVISED TRADE MARK LAW TREATY

On 28 April 2005, the World Intellectual Property Organisation (WIPO) Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications agreed on a text to form the basis of negotiations at a Diplomatic Conference for the Adoption of the Revised Trademark Law Treaty in March 2006. According to WIPO, there seems to be a certain level of consensus among members, as the proposal does not include any alternative texts.

The 1994 Trademark Law Treaty (TLT), which currently has 33 signatories, successfully introduced standard procedures to be followed before national trade mark offices. The aim of the current negotiations is to update the TLT in order to keep pace with developments in telecommunications and to allow for changes to its administration. The main revisions proposed are provisions on electronic filing of trade mark applications and associated communications; the formalities concerning the representation of all types of marks, including visible signs as well as non-visible signs; the recording of trade mark licenses; and relief measures when certain time limits have been missed.

In a preparatory meeting for the March 2006 Conference, it was decided that member states of WIPO and certain inter-governmental organisations (the European Community, the African Intellectual Property Organisation and African Regional Intellectual Property Organisation) should be invited to the Conference as member delegations. Other non-member UN countries and organisations would also be invited as observers. As the list of current signatories remains very short, it seems that WIPO is trying hard to persuade new members to join the TLT or at least to participate in the discussion leading to harmonisation of trade mark laws.

### 10. FINAL RULINGS ADOPTED IN WTO GEOGRAPHICAL INDICATIONS DISPUTE

On 20 April 2005, the Dispute Settlement Body of the WTO adopted the Panel report on the European Communities' protection of trade marks and geographical indications for agricultural products and foodstuffs. The report was made public on 15 March 2005.

The dispute related to claims from Australia and the United States that provisions under the 1992 EC Regulation on the protection of geographical indications violated WTO national treatment rules.

The following submissions were made by Australia and the United States:

- While the Regulation allows EC rightholders to apply directly to register and protect their geographical indications for EC products, non-EC nationals must rely on their governments to apply for protection in the EC on their behalf, as well as to object to geographical indications applications in the EC;
- Under the Regulation, foreign governments must adopt a system of geographical indications protection that mirrors that of the EC and that provides reciprocal protection to EC products in order that foreign rightholders be able to benefit from the protection of the EC Regulation;
- The Regulation is inconsistent with Article 16.1 of the TRIPS Agreement because it does not ensure that a trade mark owner may prevent the use of geographical indications which would result in a likelihood of confusion with a prior trade mark.

The WTO Panel found that the requirement for government level intervention and the requirement of reciprocal protection for EC products discriminates in favour of EC products and EC geographical indications of rightholders and against the rightholders of and products subject to geographical indications of other WTO Members. In particular, it found that these requirements violated Article III:4 of the WTO General Agreement on Tariffs and Trade (GATT 1994) and Article 3.1 of the TRIPS Agreement.

The Panel rejected the claim that the Regulation violated Article 16.1 of the TRIPS Agreement in allowing for the co-existence of a geographical indication with a similar and pre-existing product trade mark. It found that in this case co-existence was justified by Article 17 of the TRIPS Agreement, which allows fair use exceptions to the protection of trade marks. However, the Panel stated that the co-existence exception applied for geographical indications only as they appeared in the EU register and not to translations, signs, or other forms of indication, unless they are specifically entered into the register. The Panel have therefore recommended that the EC bring its Regulations into conformity with TRIPs and GATT 1994. not time frame has yet been set for this however, and the parties have the option to appeal.

In statements issued after the ruling, all three parties claimed at least partial victory. While Australia and the United States were satisfied that the Panel recognised the discriminatory nature of the Regulation, the EC was pleased that the Panel found the key aspects of the EC regime on geographical indications to be compatible with WTO rules.

## 11. ADIDAS V MARCA AT THE COURT OF APPEAL IN THE NETHERLANDS

On 29 March 2005, the Dutch Court of Appeal in 's-Hertogenbosch delivered its judgment in Adidas v Marca. The case was between Adidas AG and Adidas Benelux BV ("Adidas") on the one side and various other parties on the other, including Marca Mode, C&A Netherland, H&M Hennes & Maurits Netherlands BV and Vendex KBB Nederland BV ("Marca").

The case involves the use of a two-stripe design on clothing by Marca. In 1996, Adidas, owner of the well-known three-stripe emblem, claimed that based on the Benelux Trademarks Act, Marca should stop using signs similar to their three-stripe design, including Marca's use of a two-stripe design on clothing.

Marca sought a declaration of non-infringement arguing that the two-stripe design should merely be viewed as clothing decoration, and further, that it was highly unlikely that the relevant public would confuse the signs (within the context of the Benelux Trademarks Act) as the public is aware of the fact that the Adidas emblem consists of three stripes.

The Court of Appeal ruled that despite the fact that the Adidas sign had acquired a high degree of distinctiveness and thus a broad scope of protection, this did not necessarily forbid other parties from using stripes designs. The Court said that the fact that Marca used a two-stripe as opposed to a three-stripe design greatly reduced any likelihood of confusion between Adidas and Marca's signs.

The Court made specific reference to the protection given to trade marks with a reputation, as provided in Article 13A(1)(c) of the Benelux Trademarks Act. In this respect, the Court stated that there could be infringement of such a mark where the relevant public could establish a link between the sign and the mark. The Court ruled that in the present case, Adidas had not sufficiently demonstrated the presence of such a link.

However, the Court ruled that it was unable to provide Marca with a declaration of non-infringement for the future. In reaching its conclusion, the Court noted that trade mark law cases have to be judged on an individual basis.

The case supports the proposition that in the future use of a two-stripe design on clothing will not necessarily infringe the Adidas trade mark. However, the Court limited the scope of the decision by clearly stating that any future claims will be assessed on a case-by-case basis.

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