

Community law, patent law and TRIPs: a complicated cocktail to mix

Otto P Swens and Titus AF Engels take a closer look at the ECJ decision of 11 September 2007 in the case of *Merck/Merck Genericos*

For quite some time now, the European Court of Justice (ECJ) has adhered to the view that patent law has not been harmonised in Europe, but is a purely national matter. After crushing European cross-border injunctions in *GAT vs LuK*¹ and *Roche vs Primus*², the ECJ, in its judgment in *Merck/Merck Genericos*,³ drills another nail in the coffin of any legal practitioner who likes to think in terms of European patent law.

The decision confirms it again: patent law is and remains a weak changeling in EU Community law. In summary, the ECJ takes the view that patent law is not (or in any case, hardly) provided for in Community law and that, consequently, it has no business instructing the Member States how to deal with provisions of international agreements to which the European Community is a party, and which relate to patent law. The most important of these agreements is, of course, the TRIPs Agreement. This view of the ECJ means that the courts of the Member States can each decide on their own how to interpret TRIPs provisions that relate to patent law, and whether granting these provisions has a direct effect in their national laws.

In *Merck/Merck Genericos*, the provision at issue was art 33 of TRIPs, which stipulates that the minimum term of protection of a patent is 20 years. The result is that all Member States can now decide for themselves whether to give this provision direct effect, which means that there is no certainty that a patent in each country of the European Union will have the same period of protection. Although most western European Union Member States have by now stipulated in their national laws a patent protection period of 20 years after application, this cannot be said for the 'newer' Member States in the east of Europe. Moreover, as in the case of

Portugal, 'old' laws can still be of influence in the new millenium. All in all, the decision is another blow to the concept of a single European technology market and a more than annoying situation for technology-based companies with market presence across Europe.

The question is, of course: can the ECJ be blamed? In other words: could the ECJ legally have come to a different decision? As we will make clear in this article, we certainly believe that a decision ventilating a more harmonised approach was possible. Another aspect of the decision we look at is the ECJ's decision to accept jurisdiction to hear this matter, even though – at the same time – it takes the view that patent law is not 'Community law'. We believe that this approach opens the door to the undesirable situation that the ECJ will deem itself competent to answer prejudicial questions in fields of law where there is Community law.

The facts in *Merck/Merck Genericos*

On 8 April 1981 Merck was granted a Portuguese patent on the basis of the Portuguese Code of Intellectual Property relating to an industrial process for the preparation of derivatives of amino acids as a medicinal product for high blood pressure. The process in this patent was used by Merck in the manufacture of Renitec (enalapril). Fifteen years later, in 1996, a Portuguese generic manufacturer, Merck Genericos (what's in a name?), launched a generic version of Renitec onto the Portuguese market. In response, Merck initiated a patent infringement action against Merck Genericos in Portugal. The Portuguese Court of First Instance concluded that Merck Genericos did not infringe Merck's process patent, as this patent had expired on 8 April 1996.

The Court of First Instance considered that despite the fact that a new Portuguese

Code for Intellectual Property had come into force, the 'old' act still applied to the matter at hand, which provides a patent protection of 15 years after grant. Merck appealed the judgment and prevailed. The Portuguese Court of Appeal argued that indeed the first instance court was correct in applying the 'old' act, but it considered that this 'old' national law is set aside by art 33 of TRIPs that has direct effect in Portuguese law. As this provision stipulates a minimum period of protection of 20 years, the Court of Appeal concluded that the period of protection extends at least until 1999 (20 years after the application), and may even extend until 8 April 2001, 20 years after the grant of the patent.

The Portuguese Court of Cassation confirms the analysis by the Appeal Court, but it has doubts as to whether the question relating to the direct effect of art 33 TRIPs is a purely national (Portuguese) matter or a Community law matter. Therefore, the Court of Cassation asks the ECJ two prejudicial questions. First, does the ECJ have jurisdiction to interpret art 33 TRIPs? If the Court answers this question in the affirmative, must the national Member States apply art 33 of TRIPs in proceedings instituted in their country, either of their own motion or if a party invokes this article in proceedings?

The approach by the ECJ

The ECJ does not answer these two questions separately, but rephrases the questions and declares that what the Portuguese court in fact wants to be advised on is whether Community law opposes the direct application of art 33 TRIPs in its national laws. By combining the two questions and treating the matter as one issue, the ECJ appears to want to take a practical approach, but the effect is that the question by the Portuguese Court of Cassation regarding the jurisdiction of

the ECJ is in fact not properly dealt with. This is remarkable, since the question of jurisdiction is of particular relevance when judging in situations such as these, where international agreements and treaties are (partly) interwoven, and their relation is a complicated one.

The ECJ does not really deal with the jurisdiction question but instead immediately focuses on the substantive question on the direct effect of TRIPs provisions under Community law. In this respect, the ECJ refers to the decision in *Dior vs Tuk – Assco vs Layher* where it was decided that if a TRIPs provision regards a field where there is Community law, the national Member States must apply their national rules as much as possible in the light of the wording and purpose of said TRIPs provision. If the TRIPs provision does not regard such a field, then the field belongs to the jurisdiction of the individual national Member States and the ECJ does not require, nor does it rule out, that these national Member States assign direct effect to the TRIPs provision.

The ECJ subsequently considers that it is important for the Portuguese Court of Cassation to learn from the ECJ what the situation is in this respect for art 33 of TRIPs. The ECJ decided that it should entertain the question and answer it, and thus accepts jurisdiction.

The ECJ then deals with the question of whether art 33 TRIPs fall within Community law. The ECJ clearly thinks that it does not. It states that there is very little Community legislation in the field concerned by art 33, ie patent law. In essence, there is only the Biotechnology Directive, the Regulation on Supplementary Protection Certificates and some patent-related Community legislation within the field of plant breeders' rights. The ECJ believes that this is too limited for accepting Community legislation in that field. Therefore, the ECJ rules that it does not require, nor rule out, that the Portuguese law assigns direct effect to art 33 TRIPs.

Jurisdiction

In our view, both practically and legally, the approach that the ECJ takes on the issue of jurisdiction is questionable. According to

the standing ECJ case-law (the decisions in *Hermès* and *Dior/Tuk*) the jurisdiction of the ECJ, to answer prejudicial questions on the interpretation of TRIPs provision, is limited to questions that relate to TRIPs provisions which have a Community law nature or which have both a Community law and national nature.

In the *Hermès* decision, the ECJ decided that trademarks are dealt with in Community law, which means that TRIPs provision relating to trademarks have a Community law nature and, thus, the ECJ has jurisdiction to answer questions by the Member States how to interpret such provisions.⁵

In its decision in *Dior/Tuk*, the ECJ decided that even though copyrights are not yet dealt with in Community law, the TRIPs provision that it was requested to interpret (art 50 sub-section 6), contains procedural rules that also relate to trademark rights. Due to the imperative necessity of the same application of procedural rules governing proceedings within the Community, the ECJ therefore accepted jurisdiction to also interpret art 50 subsection 6 of TRIPs in a situation where it was applied in national copyright proceedings.⁵

In this matter, which deals with the application of a patent law TRIPs provision, the ECJ concludes that patent law, and in any case the period of protection of patents, cannot be considered a matter of Community law. The ECJ reviews Community law and considers that the Community has not yet exercised 'its powers' in the field of patent law in a sufficient extensive manner to conclude that patent law is Community law. In our view, the ECJ should then have decided to deny jurisdiction to answer the (second and most important) prejudicial question by the Portuguese Court of Cassation. Although the ECJ would then have left the main question unanswered this would have been no problem. After all, the basis for the decision to deny jurisdiction would have given the Portuguese Court of Cassation more than sufficient guidance. Clearly, the conclusion could then have been that art 33 TRIPs is not covered by Community law and, thus, concerns a provision that the Portuguese

Court of Cassation can decide itself, according to national Portuguese law, whether to give direct effect.

More importantly, if the ECJ had denied jurisdiction on this basis, it would have prevented uncertainty that has risen. After all, in its current assessment of jurisdiction, the ECJ has not – as it should have – examined whether art 33 of TRIPs concerns a field of law for which there is Community law. Instead, it has examined whether the interpretation of art 33 TRIPs requires an examination into the division of jurisdiction between the Community and the individual Member States.

As far as we can see, this is a new approach. After all, an examination of the division of jurisdiction between the Community and the individual Member State will be necessary for every TRIPs provision that the ECJ will be asked to interpret. Taking this approach means that the ECJ will have to accept jurisdiction to hear all prejudicial questions relating to the interpretation of TRIPs provisions, regardless the field of law the TRIPs provision concerns. This does not appear to be in line with the earlier decisions in *Hermès* and *Dior/Tuk*. If the TRIPs provision concerns a field of law that falls outside the Community legislation, the ECJ should deny jurisdiction. It should not accept jurisdiction simply because the prejudicial question requires an examination into the division of national laws and Community laws.

Interestingly, although the ECJ here seems to follow the Advocate General, Ruiz Jalabo Colomer, it takes a completely different approach to that proposed in this instance. In his written opinion, the Advocate General gives a number of reasons for an unrestricted jurisdiction for the ECJ to interpret the TRIPs provisions. He believes that the pursued, common goal of an agreement signed by the European Community and the national Member States, in combination with the principle of loyal corporation as laid down in art 10 of the EC Treaty can be better served if it is not only enforced on a legislative level, but also on an executive and a judging level. An unlimited jurisdiction of the ECJ on interpreting the TRIPs provisions is the best way to

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come to a coherent interpretation of international agreements. Besides, this will bring to an end the current unpleasant situation where the ECJ does not have jurisdiction on certain subjects without legislation, while there is ratification on a European level.

Article 33 TRIPs: is patent law Community law?

Substantively, as mentioned, the ECJ considers that the Community legislation which presently exists in the field of patent law is too limited to accept that there is Community legislation in that field. We think that little can be said against this view.

The Biotechnology Directive and the Supplementary Protection Certificate Regulation indeed seem insufficient to that end.¹ And yet, had the ECJ wished, it could have decided differently. In fact the ECJ states that as to the question of whether art 33 TRIPs falls within Community law, or not, it must be examined whether in the specific field of art 33 ie the field of patents, there is Community legislation. It remains to be seen whether it is necessary to interpret 'field' in such a limited sense.

In our view, the ECJ decision of 2004 in *Étang de Berre* gives sufficient support for a strong argument that a broader interpretation to this term may be given.

The *Étang de Berre* case was brought by the European Commission against the French Republic, and concerned a number of agreements between the

European Community and the national Member States pursuant to shared competence concerning the protection of the environment, and more specifically the protection of water against pollution. The European Commission was of the opinion that the French Republic, by failing to comply with the obligations arising from the agreements, did not fulfil its obligations to the Community. The French Republic stated that there was no Community legislation regarding the specific pollution that it was accused of. The ECJ dismissed this argument and considered that the fact that there is not yet any Community legislation relating to a specific matter within a field in which there is already extensive Community law, cannot prevent that specific matter from falling under the jurisdiction of the Community.

Taking this decision, we believe the ECJ could have decided in the *Merck/Merck Genericos* case that even though there is still fairly little Community law in the specific field of patents, there is already extensive Community legislation in the field of intellectual property. Then the ECJ could have concluded that this issue indeed forms a part of wider intellectual property. The fact that Community legislation is still very limited in respect of the specific matter of patent law, does not alter this, because the 'European legislator' has already regulated other subjects within this legal area.

Trademark rights, design rights and copyrights have clearly already been a part

of Community legislation for quite some time. This was also the position that the European Commission took in this case.² The ECJ could then have come to the same decision as in *Dior/Tik*. The ECJ could have answered the Portuguese Court of Cassation and said that it should give an interpretation to art 33 of TRIPs, which is as much as possible in line with the TRIPs agreement, without assigning direct effect to the provision in question. In that case it would have been clear to the Portuguese Court of Cassation – and the courts of all the other national Member States – that a patent has in any case a minimum period of protection of 20 years following the date of filing. This would have created certainty for the industries active in Europe. ■

1 ECJ 13 July 2006, Case C-4/03.

2 ECJ 13 July 2006, Case C-593/03

3 ECJ 11 September 2007, Case C-431/05.

4 ECJ, 16 June 1998, Case C-53/96.

5 ECJ, 14 December 2000, Case C-300/198.

6 The existence of the European Patent Convention is not relevant here, by the way. This Convention may be relevant to the question of whether patent law in Europe has been harmonised, or not, it is not Community law.

7 Although the Commission brought this argumentation in respect of the jurisdiction matter, the examination thereof requires the same approach. See footnote 1.

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