

***Daiichi*: the Court of Justice of the EU as the highest European IP court**



Case Note
Court of Justice EU, 18 July 2013, *Daiichi Sankyo and Sanofi Aventis v DEMO*, [IPPT20130718](#)

Dick van Engelen*

CJEU, 18 July 2013, (C-414/11)¹ (*Daiichi Sankyo and Sanofi-Aventis v DEMO*) (Opinion of A-G P. Cruz Villalón), Judges: V. Skouris, K. Lenaerts, A. Tizzano, M. Ilešič (rapporteur), L. Bay Larsen, T. von Danwitz, A. Rosas and E. Jarašiūnas, U. Löhmus, J.-C. Bonichot, A. Arabadžiev, A. Prechal and C. G. Fernlund.

Introduction

The *Daiichi judgment* of the Court of Justice in 2013 has so far had the status of a 'wallflower' in intellectual property circles ('IP'), and did not receive the attention it deserves. This is strange for several reasons, if only because the Japanese word "*daiichi*" stands for "*number one*" and is therefore directly a flag that covers the content of the judgment: the Court of Justice becomes the highest court for almost the entire domain of intellectual property law ("IP") within the European Union.

The judgment shows that with the entry into force on 1 December 2009 of the Treaty of Lisbon, all intellectual property rights contained in the² TRIPs Agreement annexed to the World Trade Treaty³ have become part of EU law. TRIPs is an acronym for "*Trade Related Aspects of Intellectual Property Rights*" and the TRIPs Agreement covers a large part of IP law. Thus, given the almost global coverage of the WTO, important elements of IP law are to a large extent globally harmonised, so that, for example, US, Chinese, Russian and European IP law are to a large extent uniformly regulated.

* Prof. Th.C.J.A. van Engelen is Professor of Intellectual Property, Litigation and Transaction Practice, Maastricht University and a lawyer at Ventoux Advocaten in Utrecht. This Case Note is a translation of a case note originally published in [Dutch in Ars Aequi 2017, p. 132-138](#)

¹ ECLI:EU:C:2013:520; IEPT20130718.

² Annex IC. Agreement on Trade-Related Aspects of Intellectual Property Rights.

³ Agreement establishing the World Trade Organisation, Marrakesh, 15 April 1994, Trb. 1995, 130.

It is difficult to overestimate the impact of the *Daiichi judgment* within the European Union because it means that the Court does not only have jurisdiction when there are European IP directives or regulations, but that it is sufficient if the subject in question is covered by the TRIPs Agreement. This has made the Court, for example, the highest European patent court, while until now it was often assumed that the Court had no jurisdiction with regard to patent law, apart from those subjects that fall within the scope of the European Biotechnology Directive of 1998. All the more reason, therefore, to reflect on this ground-breaking judgment, albeit a little late.

The case

A Greek court – the Polymeles Protodikio Athinon – refers a question to the Court of Justice for a preliminary ruling in proceedings concerning the placing on the market of a generic medicinal product by *DEMO Anonymos Viomichaniki kai Emporiki Etairia Farmakon* ('*DEMO*'). This would be an infringement of the patent rights of Daiichi Sankyo Co. Ltd ('*Daiichi Sankyo*') - in short - an antibiotic containing the active substance *levofloxacin hemihydrate*. The third party to the proceedings, Sanofi-Aventis Deutschland GmbH, is the licensee and distributor of this antibiotic marketed in Greece under the brand name '*Tavanic*'.

Daiichi had a Greek patent on (i) both the active ingredient levofloxacin hemihydrate and (ii) a method of manufacturing it. Daiichi's Greek patent application dates from 20 June 1986, so that this Greek patent expired on 29 June 2006. For pharmaceutical products, it is possible to extend the duration of patent protection on the basis of a European regulation (no. 1768/92), which provides for the possibility of a so-called Supplementary Protection Certificate ("SPC"). This supplementary protection ended in 2011. In 2008 and 2009, medicinal products containing *levofloxacin hemihydrate* as an active substance were authorised for the Greek company DEMO and DEMO was preparing to market such a medicinal product under the name "*Talerin*". On 23 September 2009, Daiichi Sankyo and Sanofi-Aventis brought patent infringement proceedings against DEMO before the Athens Court.

The Greek court ruled that it was relevant to the procedure whether Daiichi Sankyo's SPC (i) only concerned the method of manufacture - the 'production method' - of the active substance, or (ii) also protected that active substance as such - the 'product'. In the latter case, Daiichi Sankyo would only have to prove that DEMO's Talerin product contains that active substance. However, if the SPC only protected the production method, the presence of the active substance only creates a suspicion that Talerin has been produced using the production method protected by the SPC, and DEMO will release itself if it rebuts this suspicion by demonstrating that the said medicinal product has been produced in a different way.

A complicating factor is that, under Greek law, it was not possible to obtain a patent on a

pharmaceutical substance before 7 October 1992. Therefore, the active ingredient levofloxacin hemihydrate - the product - was not protected by the Greek patent granted to Daiichi Sankyo in 1986. However, Article 27 of the TRIPS Agreement, which deals with patentable subject matter, provides that patents may be granted "for any inventions, whether products or processes, in all fields of technology", so that the Greek exclusion of pharmaceutical product patents may be in breach of this TRIPS obligation.

That raises the question of which court has jurisdiction to interpret Article 27 TRIPS. Is it the Greek national court or the European Court of Justice? In addition to the individual Member States, the European Union itself is also a party to the Agreement establishing the World Trade Organization. The jurisdictional issue results in preliminary questions to the Court of Justice, the first of which is whether Article 27 TRIPS is still a matter to be decided by national courts of the Member States or whether this is a matter of EU law with the European Court of Justice as the highest authority.

Opinion of the Advocate General P. Cruz Villalón

In his Opinion, the Advocate General indicates that the question is essentially whether, with the entry into force of the Treaty of Lisbon, the old case-law of the Court of Justice still applies unchanged. The Treaty of Lisbon introduced the Treaty on the Functioning of the European Union ('TFEU') as an amended version of the EC Treaty with effect from 1 December 2009. Article 3(1)(e) TFEU gives - as before - an exclusive competence to the Union in the field of the "common commercial policy". What is new, however, is that Article 207(1) TFEU has since then included "the commercial aspects of intellectual property". Since TRIPS, according to its title, also deals with "the commercial aspects of intellectual property", it justifies the question whether this has changed the substance of European law and brought the TRIPS Agreement within the exclusive jurisdiction of the European Union.

Under the EC Treaty, the Court of Justice ruled in its *Merck Genéricos judgment* of 11 September 2007⁴ that if the European Union has not yet legislated with regard to a particular topic of IP law covered by the TRIPS Agreement, that topic still fell within the competence of the Member States and was not covered by EU law. It was therefore also a question of national law to what extent a TRIPS provision has direct or indirect effect under the laws of the Member State concerned.

The Advocate General considered that Article 27 of the TRIPS Agreement was not, as Union law presently stands, covered by the 'commercial aspects of intellectual property' referred to in Article 207(1) TFEU and that the old case-law therefore remained in force.

In the alternative, the Advocate General suggested that the Court should declare, on the basis of its settled case-law, that this provision does not have direct effect, since Article 27 of the TRIPS Agreement does not lend itself for direct effect. In a further alternative, he advised the Court to rule that "*The mere entry into force of the TRIPS Agreement does not have the effect that persons acquire a patent on the product itself where they held patents on the production of a pharmaceutical product under a law which did not allow patents on pharmaceutical products, even in cases where at the time of applying for the patent on the process those persons applied for a patent on the pharmaceutical product.*"

Finally, he identified a transitional problem and indicated that whatever interpretation the Court would give, it was important to provide that this interpretation "in view of the particular features of the case, should have no effect in situations which are the outcome of a final court judgment."

The judgment

In response to the first question - whether the Member States have jurisdiction over Article 27 TRIPS - the Court first considered that the addition of "commercial aspects of intellectual property" to the scope of the concept of "common commercial policy" in Article 207(1) TFEU, which entered into force on 1 December 2009, differs "significantly" from the former Article 133 of the EC Treaty and "even more" from "the provision that was in force when the TRIPS Agreement was concluded" (then Article 113 of the EC Treaty). In paragraph 48, the Court classified this as a "significant development of primary law", which implied that the question of competence under this new provision had to be re-examined and that previous opinions and judgments of the Court were "no longer "material for determining to what extent the TRIPS Agreement, as from the entry into force of the TFEU Treaty, falls within the exclusive competence of the Union in matters of the common commercial policy". Thus starting from scratch, the Court ruled (under 50) that the "common commercial policy" of Article 207 TFEU, which falls within the exclusive competence of the Union on the basis of Article 3 TFEU, "is within the context of 'the Union's external action'" and that this policy "relates to trade with non-member countries, not to trade in the internal market." The "common commercial policy" of Article 207 TFEU therefore relates to external relations from the Union's perspective and not to the internal market. In paragraph 51, the Court then referred to its previous case-law, according to which it followed that any act of the Union "falls within the common commercial policy if it relates specifically to international trade in that it is essentially intended to promote, facilitate or govern trade and has direct and immediate effects on trade." The Court of Appeal then considered measuring this standard:

"52 It follows that, of the rules adopted by the European Union in the field of intellectual property, only those with a specific link to

⁴ ECLI:EU:C:2007:496; IEPT20070911.

international trade are capable of falling within the concept of 'commercial aspects of intellectual property' in Article 207(1) TFEU and hence the field of the common commercial policy.

53 That is the case of the rules in the TRIPs Agreement. Although those rules do not relate to the details, as regards customs or otherwise, of operations of international trade as such, they have a specific link with international trade. The TRIPs Agreement is an integral part of the WTO system and is one of the principal multilateral agreements on which that system is based.

54 The specific character of the link with international trade is illustrated in particular by the fact that the Understanding on Rules and Procedures governing the settlement of disputes, which forms Annex 2 to the WTO Agreement and applies to the TRIPs Agreement, authorises under Article 22(3) the cross-suspension of concessions between that agreement and the other principal multilateral agreements of which the WTO Agreement consists.

55 Moreover, when providing in Article 207(1) TFEU that the 'commercial aspects of intellectual property' are now fully part of the common commercial policy, the authors of the FEU Treaty could not have been unaware that the terms thus used in that provision correspond almost literally to the very title of the TRIPs Agreement.

56 The existence of a specific link between the TRIPs Agreement and international trade justifying the conclusion that the agreement falls within the field of the common commercial policy is not rebutted by the argument of the governments which took part in the oral proceedings that at least the provisions of Part II of the TRIPs Agreement, concerning the availability, scope and use of intellectual property rights, which include Article 27 of the agreement, fall within the field of the internal market, by virtue in particular of Articles 114 TFEU and 118 TFEU.

57 That argument does not take sufficient account of the objective of the TRIPs Agreement in general and Part II of the agreement in particular.

58 The primary objective of the TRIPs Agreement is to strengthen and harmonise the protection of intellectual property on a

worldwide scale (Case C-89/99 *Schieving-Nijstad and Others* [2001] ECR I-5851, paragraph 36). As follows from its preamble, the TRIPs Agreement has the objective of reducing distortions of international trade by ensuring, in the territory of each member of the WTO, the effective and adequate protection of intellectual property rights. Part II of the agreement contributes to attaining that objective by setting out, for each of the principal categories of intellectual property rights, rules which must be applied by every member of the WTO.

59 Admittedly, it remains altogether open to the European Union, after the entry into force of the FEU Treaty, to legislate on the subject of intellectual property rights by virtue of competence relating to the field of the internal market. However, acts adopted on that basis and intended to have validity specifically for the European Union will have to comply with the rules concerning the availability, scope and use of intellectual property rights in the TRIPs Agreement, as those rules are still, as previously, intended to standardise certain rules on the subject at world level and thereby to facilitate international trade.

60 Consequently, as the Commission observes, to regard the rules on patentable subject-matter in Article 27 of the TRIPs Agreement as falling within the field of the common commercial policy rather than the field of the internal market correctly reflects the fact that the context of those rules is the liberalisation of international trade, not the harmonisation of the laws of the Member States of the European Union.

61 In the light of the above considerations, the answer to the first part of Question 1 is that Article 27 of the TRIPs Agreement falls within the field of the common commercial policy."

After thus excluding national law of the Member States from TRIPs matters, the Court had to answer the second question. This question concerned two issues of substantive patent law, namely (i) patentable subject-matter and (ii) scope of protection:

"63 By its second question, the referring court asks essentially whether the invention of a pharmaceutical product such as the active chemical compound of a medicinal product is patentable subject-matter within the meaning of

Article 27 of the TRIPs Agreement and, if so, what is the scope of the protection conferred by a patent for such a product.

64 DEMO did not specifically adopt a position on this issue. Daiichi Sankyo, the governments which submitted written observations, and the Commission all consider that it follows from the actual wording of the TRIPs Agreement that inventions of pharmaceutical products are patentable.

65 This argument must be accepted. Article 27(1) of the TRIPs Agreement provides that any invention, whether a product or a process, which is new, involves an inventive step and is capable of industrial application is patentable, provided only that it belongs to a field of technology.

66 As regards that condition, it is clear that pharmacology is regarded by the contracting parties to the TRIPs Agreement as a field of technology within the meaning of Article 27. That follows in particular, as the Italian Government and the Commission have observed, from Article 70(8) of the TRIPs Agreement, a transitional provision dealing with the situation in which ‘a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical ... products commensurate with its obligations under Article 27’ which provides that, in that situation, the WTO member in question must at least provide, as from that date, ‘a means by which applications for patents for such inventions can be filed’. As follows from the wording of that provision, Article 27 of the TRIPs Agreement includes the obligation to make inventions of pharmaceutical products patentable.

67 Nor, moreover, is that conclusion called into question in any way by paragraphs 2 and 3 of Article 27. Article 27(2) allows members of the WTO to exclude from patentability inventions the prevention of whose commercial exploitation is necessary for overriding reasons of the public interest, while Article 27(3) allows them to exclude from patentability certain products and processes, among which are ‘diagnostic, therapeutic and surgical methods for the treatment of humans or animals’. Those derogations provided for by Article 27(2) and (3) cannot, without depriving Articles 27(1) and

70(8) of the TRIPs Agreement of effectiveness, be interpreted as laying down a general exclusion for inventions of pharmaceutical products.

68 In the light of the foregoing, the answer to the first part of Question 2 is that Article 27 of the TRIPs Agreement must be interpreted as meaning that the invention of a pharmaceutical product such as the active chemical compound of a medicinal product is, in the absence of a derogation in accordance with Article 27(2) or (3), capable of being the subject-matter of a patent, under the conditions set out in Article 27(1).

69 In so far as Question 2 relates also to the scope of the protection conferred by a patent for a pharmaceutical product, it suffices to observe, in the context of the present request for a preliminary ruling, that Article 27 of the TRIPs Agreement concerns patentability, not the protection conferred by a patent. The question of the protection conferred by a patent is governed in particular by Article 28 of the agreement, ‘Rights Conferred’, Article 30, ‘Exceptions to Rights Conferred’, and Article 33, ‘Term of Protection’. As it does not appear from the order for reference that an interpretation of those other provisions would be of use for resolving the dispute in the main proceedings, there is no need to answer the second part of Question 2.”

The third question which then came up was the transitional question, on which the Court held (paragraph 83) that “that a patent obtained following an application claiming the invention both of the process of manufacture of a pharmaceutical product and of the pharmaceutical product as such, but granted solely in relation to the process of manufacture, does not, by reason of the rules set out in Articles 27 and 70 of the TRIPs Agreement, have to be regarded from the entry into force of that agreement as covering the invention of that pharmaceutical product.”

Case Note

The importance of the judgment is already apparent from the fact that it is a judgment of a Grand Chamber of the Court, composed of 13 judges. The same is true for the *Merck judgment* of 2007, which *Daiichi* has now replaced. It is noteworthy that the Court of Justice interpreted the distribution of competences between the Union and the Member States adopted in the *Merck judgment* and earlier judgments differently, because in the intervening period European Union law has substantially changed as from 1 December 2009 with the inclusion of the concept of “commercial aspects of

intellectual property” in the definition of the “*common commercial policy*” (Articles 3 and 207 TFEU), which is the exclusive domain of the Union.

The Treaty of Lisbon

The Court attaches great importance (paragraph 55) to the fact that the terminology used corresponds almost literally to the title of the TRIPS Agreement – “*Agreement on Trade-Related Aspects of Intellectual Property Rights*” – and that the authors of the TFEU could not have been unaware of that. This observation is noteworthy when you realise that, in the procedure, the eight Member States that submitted observations to the Court, were all of the opinion that after the Treaty of Lisbon everything was still the same as before. They thus claimed an ignorance which, from the point of view of the Court, did not entirely suit them as parties to the Treaty of Lisbon. It also seems remarkable that at the hearing, the representative of the Portuguese Government did not hesitate to dismiss the European Commission – which was opposed to the position of the Member States and was subsequently adopted by the Court – as the only dissonant vote. It shows that the law-making process requires perseverance. It also shows that Member States must be reminded by and independent court that signing a text that explicitly differs from a previous treaty provision is not without consequences. These Member States are responsible for the new legal landscape created by their own legal acts. However, those same Member States, in their national parliaments and media, often do not shy away from pretending that this growing influence of European law that they themselves have created would be something that only happens to them, without simply acknowledging their responsibility. Justice therefore not only requires perseverance, but also a straight back and no weak knees, but these are features that many governments and politicians lack and which is not necessarily properly diagnosed by the media.

Following this ‘legal health certificate’ regarding the signatory Member States, we will now concentrate on the further legal consequences of this judgment. These consequences have been far-reaching and, moreover, seem to have been underexposed so far.⁵

The Union's external trade policy

It should first be noted that the Court's finding that the TRIPS topics are part of the Union's “*common commercial policy*” is a recognition of the harmonisation of IP law on a worldwide scale as a

result of the TRIPS Agreement as signed in Marrakesh in 1994.

This is evident from what the Court considers under 56-60. In this context, the Court addresses the Member States' argument that “*the availability, scope and use of intellectual property rights [...] fall within the field of the internal market*”. In particular, reference was made to Article 118 TFEU, which states that “*in the context of the establishment and functioning of the internal market, the European Parliament and the Council [...] shall establish measures for the creation of European intellectual property rights to provide uniform protection of intellectual property rights throughout the Union*” That provision is in line with the historical development (i) of the Court's case law on IP rights and (ii) of the Union's legislative activity with directives and regulations for specific IP rights and sub-topics thereof. The interface between IP rights and European law is historically determined by the fact that non-harmonised national IP rights are an obstacle to the realisation of the internal European market. Harmonisation of IP rights has traditionally been relatively high on the European agenda because of the frustrating effect of exclusive national IP rights in creating a *level playing field* on the European internal market. The fact that, with the Treaty of Lisbon, Article 118 TFEU now explicitly provides for the creation of supranational, pan-European IP rights underlines the continuing importance of the ‘usefulness and necessity’ of the unification of IP law within the European Union for internal European reasons.

However, the Court then points out (in paragraph 58) that the primary objective of the TRIPS Agreement is (i) to strengthen and (ii) harmonise (iii) the protection of IP rights (iv) on a worldwide scale. TRIPS thus broadens the traditional - internally oriented - European view on IP rights to a global perspective. Just as the European Union creates a European internal market, the World Trade Organisation (“WTO”) creates a global market. Just as EU law must harmonise IP rights in order for the European internal market to function, TRIPS harmonises those same IP rights worldwide in order to facilitate that global market. This explains why intellectual property (and trade agreements) should no longer be seen as (only) an internal EU matter. That is why, under the Lisbon Treaty, those trade aspects of IP rights have also been incorporated by the EU legislator into the external common commercial policy of the European Union. This is also inevitable if the Union is to be a full player on the world market.

The realisation that IP rights are globally harmonised with the TRIPS Agreement in order to create a level playing field within the WTO world market also leads to the realisation that the harmonisation of IP rights realised with the TRIPS Agreement on the world market outside the EU is not compatible with a different IP law regime for the European internal market. Against this background, it is then only logical that the Court, as a consequence of incorporating the trade aspects of IP rights into the

⁵ About Daiichi: Van Damme, *The impact of the Lisbon Treaty on Union competence with regard to the TRIPS Agreement*, SEW 2014/120, p. 335-343; J. Larik, *No mixed feelings: The post-Lisbon Common Commercial Policy in Daiichi Sankyo and Commission v. Council (Conditional Access Convention)*, *Common Market Law Review* 2015(52), issue. 3, pp. 779-799; M. Minn, *Patenting in Europe: The Jurisdiction of the CJEU on European Patent Law*, *Perspectives on Federalism* 2015(7), issue 2: 1-28; Th.C.J.A. van Engelen, *From Einstein's Relativity to a Unified Patent Law*, *Oratie Maastricht*, Publishing Book 9, Utrecht, 2016.

EU's common foreign trade policy, takes the position that the same standards also have to apply in full and uniformly in the European internal market and that therefore a deviation from TRIPs by (i) national laws of Member States or (ii) EU laws can no longer be accepted for those aspects of IP rights that belong to the TRIPs domain. To the extent that the European Union harmonises IP law with a view to the internal market and thus "intended to have validity specifically for the European Union", the TRIPs standards must be respected, as the Court considers in paragraph 59. In short, there is no longer any room for divergent, restrictive European or national rules on subjects covered by TRIPs. Article 1(1) TRIPs teaches that TRIPs countries have the power to apply in their national legislation protection more extensive than that required by TRIPs "provided that such protection does not conflict with the provisions of this Agreement".

The TRIPs domain: availability, scope and use of IP rights

The Court also makes clear in paragraph 59 what "commercial aspects of intellectual property" are. These are "the rules concerning the availability, scope and use of intellectual property rights in the TRIPS Agreement". This covers the lion's share of the subjects that are of importance in the IP field.

All this is limited to those IP rights that are regulated in TRIPs. Article 1(2) TRIPs provides that for the purposes of the TRIPS Agreement, "intellectual property" shall mean "all categories of intellectual property listed in Part II, Titles 1 to 7". This concerns (1) copyright and related rights, (2) trademarks, (3) geographical indications, (4) design rights, (5) patents, (6) semiconductor topographies and (7) trade secrets. The IP rights that are not covered are plant variety rights, trade name rights and rights of celebrities with regard to their likeness.

The "availability" of IP rights concerns everything that has to do with the type of assets that can or should be protected by IP rights. This concerns for example (a) the concept of a copyrightable "work" of Article 2 of the Berne Convention, to which Article 9 TRIPs refers, or (b) the requirements for a trademark (Article 15 TRIPs) and (c) patentable subject matter (Article 27 TRIPs).

The "scope" of IP rights concerns the scope of protection that copyright protected work, a trademark or a patented product or process is entitled. It concerns where the boundaries between the exclusive rights of the IP rightholder and the public domain for third parties are to be drawn. Where these lines have to be drawn is, for example, provided for in Article 12 of the Berne Convention, concerning "adaptations, arrangements and other alterations" of a work. This provision is incorporated into TRIPs by Article 9 TRIPs. Article 9 TRIPs also states that the protection of copyright extends to "expressions and not to ideas, procedures, methods of operation or mathematical concepts as such." The scope of trade mark protection should, in accordance with Article 16 of the TRIPs,

include, for example, the right to prevent third parties "from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trade mark is registered, where such use would be likely to cause confusion." For patent law, Article 28 TRIPs states that the patent holder has an exclusive right to the patented "product" or "process". The question of the scope of protection to be granted to such patented "product" or "process" – and whether that scope also includes equivalents, for example – is thus a TRIPs question.

The "use" of IP rights mainly seems to concern (i) their enforcement against infringers and (ii) their exploitation through transfer or licensing to third parties.

On balance, this means that, in principle, almost all essential elements of IP law are covered by TRIPs, with the exception of questions of property law, such as ownership, transfer of ownership, the relationship between several joint owners of an IP right and, for instance, the status of a license in the event of a transfer of the licensed IP right or in case of a bankruptcy of the IP rightholder.

European IP law

The consequence of the entry into force of the Lisbon Treaty on 1 December 2009 is therefore that all TRIPs IP standards have become a matter of European Union law. The main practical consequence seems to be that the Court of Justice has thus become the highest IP court within the EU, even when the Union itself has not yet enacted legislation in the form of regulations or directives. This means that national courts will no longer have the competence to interpret TRIPs IP standards, but will have to ask the Court of Justice. This makes the role of national supreme courts as IP courts even more marginal than before, given that the lion's share of the issues in IP cases concern "the availability, scope and use" of these rights.

European patent law

The consequences of the *Daiichi judgment* seem to be particularly far-reaching in the field of patent law and the development of a uniform scope of protection for patented products or processes. This is a TRIPs issue which now falls within the jurisdiction of the Court of Justice of the EU as the Court implies under 69 of the *Daiichi-judgment*: "In so far as Question 2 relates also to the scope of the protection conferred by a patent for a pharmaceutical product, it suffices to observe, in the context of the present request for a preliminary ruling, that Article 27 of the TRIPS Agreement concerns patentability, not the protection conferred by a patent. The question of the protection conferred by a patent is governed in particular by Article 28 of the agreement, 'Rights Conferred', Article 30, 'Exceptions to Rights Conferred', and Article 33, 'Term of Protection'. As it does not appear from the order for reference that an interpretation of those other provisions would be of use for resolving the dispute in the main proceedings, there is no need to answer the second part of Question 2."

Since the 1970s, several attempts have been made to create supranational patent law within Europe, ideally with a central European court for its enforcement. These efforts resulted in the adoption of an EU regulation for a European unitary patent in 2012⁶ and a European Patent Court Agreement in 2013.⁷ Preparations for its effective entry into force were almost complete and only 13 countries, including the three countries with the highest number of registered patents – Germany, France and the United Kingdom – had to be obtained for the required minimum number of ratifications.⁸ With the Brexit outcome of June 2016, the outcome of this project to establish a Unified Patent Court ("UPC") within the European Union has been 'in limbo', also in view of the uncertainties that accompany Brexit. It seems therefore likely that the Unified Patent Court will remain a 'fata morgana' for the time being. The development of a uniform European patent law could thus also remain an illusion in the absence of a supreme European court capable of leading the pack of the various national courts. That seems to have changed with the *Daiichi*-judgment.

In the field of patent law in particular, there was actually no European legislative activity, apart from the Biotech Directive of 1998.⁹ Under the *Merck doctrine*, this meant that the Court of Justice had no jurisdiction, except for biotechnological patents. With the *Daiichi judgment*, the Court of Justice has now established its jurisdiction for patent law issues. The fact that this must be done via the detour of the TRIPS Agreement may be a bit embarrassing, but this detour at least results in a step forward on the way to uniform application of patent law within the European Union.

The fact that TRIPS does not always regulate in detail all subjects covered by it, does not affect the importance of these TRIPS standards. For example, Article 28 TRIPS on the scope of protection of a patented "*product*" or a patented "*process*" is rather brief. However, Article 69 of the European Patent Convention ("EPC") goes further by providing that the scope of protection of a European patent is determined by the claims, and that the description and drawings, which are also included in the patent, serve only "*to interpret the claims*". The article then has a further Protocol on its interpretation. These European standards did not fall within the jurisdiction of the Court of Justice and were not formally subject to European Union law, because the European Patent Convention is stand separate from the European Union. Although all 28 EU Member States are party to the European Patent Convention, that Convention has a

total of 38 member countries, including non-EU countries such as Turkey, Switzerland and Norway. The consequence of *Daiichi* seems to be that the Court, via the route of Article 28 TRIPS, is also the competent court to determine the actual meaning of Article 69 EPC and its Interpretation Protocol for all EU Member States.

Worldwide IP law

The primacy of TRIPS IP standards and the jurisdiction of the Court of Justice in TRIPS-matters is based on the objective of removing international trade barriers through uniform IPR standards. The aim is to ensure that, in principle, judicial decisions in international infringement cases will lead to the same results both within the EU and outside of it. The aim is to ensure that, in practice, a product is either infringing or not in all TRIPS countries and thus to create a level playing field, rather than a patchwork of different rulings by national courts. However, in the absence of an international IP court, it will still not be possible to achieve this goal, although TRIPS requires that these national courts will have to take account of each other's decisions. The jurisdiction of the Court of Justice may mean that the until now familiar patchwork of divergent judgments in the European internal market will increasingly become a thing of the past.

At an international level, it will also mean an increase in the weight of, for example, rulings by US court rulings on the application of the same TRIPS standards in European IP cases. This makes comparative law studies more relevant. For the actual standardisation of IP law, as advocated by TRIPS, it is therefore also important that – more than before – the European Court of Justice and the US Supreme Court, in particular, take to heart each other's interpretations of standards codified in TRIPS. Intellectual property thus remains an area of the law that is truly international in its development and application.

Legal development

Until the Brexit issues are resolved, the EU legislator seems to be in a position to be inactive, because many initiatives will be mainly a plaything of negotiating tactics.

With the *Daiichi judgment*, European IP law will be less dependent on the European legislator and the European court will be able to ensure that IP law can continue to develop and thus to some extent keep pace with the ever-changing – and increasingly international – demands that technological and economic developments place on the law. By their very nature, these technological and economic developments are international, so it is clear that IP law can only function effectively at an international level. Since the Industrial Revolution, it was already an illusion to think that IP rights could still be effective at the provincial or regional level instead of the national level. The fact that shortly after the Industrial Revolution the first international regulations for intellectual property rights were in 1883 and 1886 provided for in, respectively,

⁶ Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ EU 31 December 2012, L 361/1).

⁷ Agreement on a Unified Patent Court, 19 February 2013, Trb. 2013, 92.

⁸ See about that: Van Engelen, *The European Unity Patent and the Unity Patent Court - a step forward?* Ars Aequi 2016 (p. 100-103).

⁹ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

the Paris Convention and the Berne Convention speaks volumes here too.

It is a dangerous illusion to think that the problems and concerns that have accompanied economic and technological progress since the Enlightenment in the 18th century can still be effectively solved by national law and with nationally limited jurisdictions. Whether one likes it or not, the market for many products and services has become an international and global market and therefore it is up to the law to facilitate that global market. This is necessary, in particular, to prevent that only established and wealthy companies can effectively operate on that global market. If the laws that apply to a market are not uniform, doing business on that market becomes, *inter alia*, expensive in terms of legal advice and legal proceedings. The victims thereof will be in particular the less well-off market players and the consumer will consequently pay prices for products and services that are unnecessarily high. In short, it is in the general interest that IP rights develop as uniformly as possible on both the European internal market and the world market and can be applied and enforced in the same manner at that level. For this much-needed development of IP law, the European Union, with the *Daiichi judgment*, is for the time being no longer dependent on the EU legislator and the judiciary can move forward. As far as I am concerned, this is a ray of hope in a period in which xenophobic nationalism threatens, among other things, to block the necessary development of (IP) law.

December 2016