Developments

The Gordian Knot of European Union Competence: Commercial Aspects of Intellectual Property After the Judgment in Case C-414/11 *Daiichi Sankyo*

By Boryana Gotsova[*]

A. Introduction

The division of external competences between the European Union and the Member States is a long-standing object of contention for constitutional and practical reasons. The competence to negotiate and conclude international agreements in a given area has as many highly political implications as concrete policy-making ones. This tension is well illustrated by the field of the commercial aspects of intellectual property. Community, and later Union, competence over this area was established only gradually. After multiple Treaty revisions and legal disputes over competence, the Treaty of Lisbon now lists the field as one of the main elements of the Union's Common Commercial Policy (CCP).[1] The CCP itself is one of the founding policies, dating back to the European Economic Community.[2] It structures the Union's trade relations with third countries, encompassing bilateral and multilateral trade and tariff agreements, as well as unilateral trade defense measures such as anti-dumping and anti-subsidy instruments.[3] Today, the Treaty of Lisbon expressly provides for exclusive Union competence over the CCP,[4] codifying the case law of the Court of Justice.[5]

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[1] Consolidated version of the Treaty on the Functioning of the European Union art. 207(1), Mar. 30, 2010, 2010 O.J. (C 83) 47 [hereinafter TFEU].

[2] Treaty Establishing the European Economic Community, pt. 3, tit. II, Ch. 3, Mar. 25, 1957, available at http://ec.europa.eu/economy_finance/emu_history/documents/treaties/rometreaty2.pdf.

[3] For an up-to-date overview of the Union's activities under the CCP, see Directorate-General for Trade, http://ec.europa.eu/trade (last visited Feb. 27, 2014).

[4] TFEU art. 3(1)(e).

[5] See Opinion 1/75, *Understanding on a Local Cost Standard*, 1975 E.C.R. 01355.

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Because the commercial aspects of intellectual property fall within the CCP, the Union's exclusive competence spreads over this field. Consequently, legal scholars[6] considered that the Treaty of Lisbon firmly established exclusive competence over the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[7] The Agreement provides for the protection and enforcement of various intellectual property rights, including copyright, trademarks, geographical indications, industrial designs, patents, and trade secrets, for the benefit of nationals of the WTO members. In the 1990s, when TRIPS was created, the European Community did not have sufficient competence to conclude it by itself.[8] Therefore, both the Member States and the Community concluded the Agreement. The Lisbon provisions regarding the CCP, however, seemed to grant the Union exclusive competence over TRIPS.

The exact scope of the change was recently put to the test in Case C-414/11 *Daiichi Sankyo*.[9] The case, brought before the Court of Justice of the European Union under the preliminary reference procedure,[10] concerned the distribution of competence between the Union and the Member States over the TRIPS Agreement. The dispute highlighted the Gordian knot of competence over TRIPS, tied by successive Treaty revisions and the case law of the Court of Justice. The riddle proved so hard that the Advocate-General offered a solution that would further entangle the question of competence.[11] The Court of Justice cut the knot, recognizing the TRIPS Agreement as falling within the CCP and thus giving effect to the new Treaty provisions. The interpretation of "the commercial aspects of intellectual property," given by a Grand Chamber of the Court, however, has a legal significance beyond the development of the CCP. It is a step towards a clearer division between shared competence and exclusivity.

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[6] Angelos Dimopoulos, *The Common Commercial Policy after Lisbon: Establishing Parallelism between Internal and External Economic Relations?*, 4 CROATIAN Y.B. OF EUR. L. & POL'Y 101, 108-09, 119-22 (2008); Marc Bungenberg, *Going Global? The EU Common Commercial Policy after Lisbon*, EURO. Y.B. OF INT'L ECON. L. 123, 132 (2010); Gonzalo Villalta Puig & Bader Al-Haddab, *The Common Commercial Policy after Lisbon: An Analysis of the Reforms*, 36(2) EURO. L. REV. 289, 293 (2011).

[7] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, anx. 1C, [hereinafter TRIPS Agreement], available at: http://www.wto.org/english/docs_e/legal_e/27-trips.pdf. The conclusion of the Agreement on behalf of the European Community was approved by Council Decision 94/800, 1994 O.J. (L 336/1).

[8] Opinion 1/94, *Agreements annexed to the Agreement establishing the World Trade Organization*, 1994 E.C.R. I-05267 [hereinafter Opinion 1/94].

[9] Daiichi Sankyo and Sanofi-Aventis Deutschland v. DEMO, CJEU Case C-414/11 (July 18, 2013), http://curia.europa.eu/juris/liste.jsf?&num=C-414/11 .

[10] TFEU *supra* note 1, at art. 267.

[11] Opinion of Advocate-General Cruz Villalón, *Daiichi Sankyo*, CJEU Case C-414/11.

The nature of Union competence is a key issue in EU law because it delineates the room for maneuver left to the Member States. Under exclusive competence, only the Union is entitled to adopt legally binding acts, such as international agreements.[12] Under shared competence, however, the Member States may act[13] as long as the Union has not exercised its competence.[14] Therefore, the question of competence over a particular international agreement impacts the capacity for Member State involvement in future amendments. Furthermore, EU law uses competence as a critical factor for determining the legal effects of an agreement.[15] The nature of Union competence also differs for the various policy areas. The Treaty of Lisbon offers a very concise competence catalogue.[16] As a result, the Court of Justice of the European Union has to demarcate in its case law the exact substantive scope of the competence categories, as well as draw the line between the different policy areas such as the CCP and the Internal Market. Hence, judgments like *Daiichi Sankyo* flesh out the Lisbon provisions on competence with the resulting effects for the Member States and their nationals.

This article discusses the case in six substantive sections. Section B lays down the facts of the main dispute and the questions of the Greek referring court. Section C proceeds with a summary of the judgment, according to which the TRIPS Agreement now falls within the scope of the Union's exclusive competence over the CCP. To put the judgment in perspective, section D analyzes the pre-Lisbon organization of shared competence over the Agreement. Section E offers a comparative review of the changes in the CCP provisions over the course of European integration. Hence, the article demonstrates that, by recognizing the exclusive EU competence over the TRIPS Agreement, the Court gave effect to the latest Treaty revision of the Common Commercial Policy. Section F examines the condition, under which acts such as the TRIPS Agreement are deemed to fall within the *commercial aspects* of intellectual property. Finally, section G evaluates the consequences of the *Daiichi Sankyo* judgment for the effects of the TRIPS Agreement within the national legal orders of the Member States.

[12] TFEU *supra* note 1, at art. 2(1). The Member States may act only if the Union has authorized them or when they seek to ensure implementation.

[13] Subject to compliance with EU law.

[14] TFEU *supra* note 1, at art. 2(2).

[15] *See* Section D.

[16] TFEU *supra* note 1, at art. 3-6.

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B. Facts of the Case

The dispute, originating in a Greek court, concerned the scope of patent protection that should be given to a chemical compound, levofloxacin hemihydrate, used in antibiotic treatment. The company Daiichi Sankyo, which had applied for protection for both the pharmaceutical product and the production process, was given a patent in Greece in 1986 over the production process only. In 1995, the TRIPS Agreement entered into force for Greece. Daiichi Sankyo's patent, upon extension under EEC Regulation 1768/92, ultimately expired in 2011. In the meantime, however, the defendant in the main proceedings—the company DEMO—received authorization by the Greek authorities to market generic pharmaceutical products with the same active ingredient. As a result, Daiichi Sankyo, as patent holder, and Sanofi-Aventis, the company licensed by Daiichi Sankyo to market products with that ingredient in Greece, brought an action against DEMO. Their claim included seizure and destruction of DEMO's products with that ingredient, termination of marketing, penalty payment per package, and access to DEMO's information on the manufacturing process.[17]

For the referring court, the solution to the case depended on the interpretation of the TRIPS Agreement—namely, whether the entry into force of the Agreement conferred protection, upon which Daiichi Sankyo and Sanofi-Aventis could rely, over the chemical compound itself. To ascertain the existence, and possible scope, of that patent protection, the Greek court asked what the distribution of competence was between the Member States and the Union in that particular field. The TRIPS Agreement had been concluded as a mixed agreement, with the Member States and the Community sharing competence. Union rules, however, can progressively be adopted in a specific field. In that case, EU law requires that the relevant national rules are applied as far as possible in conformity with the TRIPS Agreement, considering the interpretation of TRIPS by the Court of Justice. Nevertheless, TRIPS cannot have direct effect. Alternatively, if the Member States retain competence over the particular field due to the lack of Union rules, the national courts may decide whether to recognize the direct effect of a TRIPS provision.[18] With this background in mind, the referring court posed three questions to the Court of Justice, seeking answers about: (1) Member State competence over Article 27 of the TRIPS Agreement[19] on patentable subject-matter; (2) the patentability of chemical and pharmaceutical products; and (3) the effect of the entry into force of the TRIPS Agreement

[17] *Daiichi Sankyo*, CJEU Case C-414/11 at paras. 16, 23-38.

[18] Merck Genéricos v. Merck & Co. & Merck Sharp & Dohme, CJEU Case C-431/05, 2007 E.C.R. I-07001, paras. 34-35.

[19] TRIPs Agreement *supra* note 7, at art. 27.

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on chemical compounds, which had until then been protected only in terms of the manufacturing process.[20]

C. The Judgment

The Court of Justice tackled the issue of competence from the perspective of the novelty introduced by the Treaty of Lisbon: The rewording of the main provision of the Common Commercial Policy. Noting the express inclusion of "the commercial aspects of intellectual property" in Article 207(1) of the TFEU,[21] as well as the stark difference between Article 207 of the TFEU and the previous Treaty provisions in that field, the Court found that its earlier case law was no longer relevant to distribution of competence.[22]

However, the Court was not willing to automatically label any intellectual property agreement as an agreement concerned with the *trade aspects* of intellectual property and hence falling within exclusive Union competence.[23] The Court insisted that "of the rules adopted by the European Union in the field of intellectual property, only those with a specific link to international trade are capable of falling within the concept of 'commercial aspects of intellectual property.'"[24] Applying this criterion to the TRIPS Agreement, the Court of Justice found a sufficiently strong link to international trade in the central place of the Agreement within the WTO system, the proximity between the wording of Article 207(1) TFEU and the title of the Agreement, and the objective of TRIPS and its provisions.[25] Nevertheless, the Court emphasized the distinction between the CCP and the Internal Market with respect to intellectual property rules. While international agreements on the trade aspects of intellectual property come within the scope of the CCP and hence exclusive competence, internal EU rules on intellectual property fall within the Internal Market, an area of shared competence.[26] In keeping with this distinction, the Court declared that the TRIPS Agreement, and thus Article 27 of the Agreement, belongs to a field of exclusive Union competence since the entry into force of the Lisbon Treaty. This conclusion of the Court and its significance within the competence case law are the focus of the present article.

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[20] *Daiichi Sankyo*, CJEU Case C-414/11 at para. 32.

[21] TFEU *supra* note 1, at art. 207(1).

[22] *Daiichi Sankyo*, CJEU Case C-414/11 at paras. 45-48.

[23] *Id.* at paras. 50-51.

[24] *Id.* at para. 52.

[25] *Id.* at paras. 53-58.

[26] *Id.* at paras. 59-60.

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On the second question, the Court stated that a chemical product was in principle patentable under the TRIPS Agreement, unless a WTO member had applied one of the derogations provided in the Agreement.[27] The Court then turned to the last question, considering the relevant Greek law, the European Patent Convention, Regulation 1768/92, and the obligations imposed by the TRIPS Agreement. As a result, the Grand Chamber held that the entry into force of the TRIPS Agreement did not extend patent protection to the chemical compound, when the original patent had covered only the production process.[28] The national court was to settle the dispute, respecting this interpretation of the TRIPS Agreement.

D. TRIPS: Shared Competence Until the Lisbon Treaty

The recognition that the TRIPS Agreement now falls within exclusive Union competence is a momentous shift. This novelty can be fully appreciated only if it is viewed against the background of previous case law classifying the Agreement under shared competence. In fact, the referring court, the parties to the main dispute, and the nine governments that submitted observations, all based their written arguments on the presumption that the Agreement belongs to an area of shared competence, within which the Member States retain "primary competence."[29] This position is not surprising, considering the Court's earlier rulings on the TRIPS Agreement. Back in Opinion 1/94, the Court held that the Community and the Member States shared competence to conclude the Agreement.[30] Although intellectual property rights have the capacity and even the purpose of affecting trade, the Court rejected the claim that the CCP covered the TRIPS Agreement.[31] The relevant Treaty provision, then-Article 113 of the EC,[32] did not refer to intellectual property at all. The Court then examined other avenues for recognizing the exclusive competence of the Community: The *AETR* doctrine[33] on affecting the existing rules; the Opinion 1/76 doctrine[34] on requiring external competence in order to exercise the internal powers of the Community; and the internal harmonization powers, combined with the residual

[27] *Id.* at para. 68.

[28] *Id.* at para. 83.

[29] *Id.* at paras. 30 and 41; see also, the referring court's first preliminary reference question in para. 32.

[30] Opinion 1/94.

[31] *Id.* at para. 57.

[32] Treaty Establishing the European Community art. 113, Aug. 31, 1992, 1992 O.J. (C 224) [hereinafter Maastricht TEC].

[33] See Commission v. Council, CJEU Case 22/70, 1971 E.C.R. 00263.

[34] See Opinion 1/76, *Draft Agreement Establishing a European Laying-up Fund for Inland Waterway Vessels*, 1977 E.C.R. 00741.

competence given by then-Article 235 of the EC[35] (now Article 352 of the TFEU[36]).[37] However, the Court denied exclusive Community competence over the TRIPS Agreement.

The Court's reasoning on shared competence over TRIPS has been elaborated over the years. When called upon to interpret a TRIPS provision, the Court underlined the fact that "the WTO Agreement was concluded by the Community and ratified by its Member States without any allocation between them of their respective obligations towards the other contracting parties."[38] Without specifying the Community obligations, the Court asserted its jurisdiction to interpret those provisions of the TRIPS Agreement that could affect cases under Community law, as well as cases under national law.[39] Drawing a line between these two types of circumstances would later prove to be crucial for determining the effect of the TRIPS Agreement.

In *Dior*, the Court of Justice rejected the direct effect of the TRIPS provisions under Community law.[40] Still, national courts were bound to "apply national rules . . . as far as possible in the light of the wording and purpose" of a specific TRIPS provision, if the Community had already exercised its powers in that area.[41] National courts, however, were under no obligation or ban to recognize the direct effect of a provision "in a field in respect of which the Community has not yet legislated and which consequently falls within the competence of the Member States."[42] Consequently, the obligations—or freedom—of the national courts would depend on the expansion of Community legislation in a particular field. Under the hat of shared competence over the TRIPS Agreement, the separate relevant fields would progressively fall within EC law as the Community exercised its powers. This distribution of competence, based on the creation of Community acts, was confirmed in the *Merck Genéricos*[43] judgment of 2007.

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[35] Maastricht TEC *supra* note 32, at art. 235.

[36] TFEU *supra* note 1, at art. 352.

[37] Opinion 1/94, paras. 99-105.

[38] Hermès International v. FHT Marketing Choice, CJEU Case C-53/96, 1998 E.C.R. I-03603, para. 24.

[39] *Id.* at paras. 25, 32.

[40] Parfums Christian Dior v. TUK Consultancy, Joined Cases C-300/98 and C-392/98, 2000 E.C.R. I-11307, para. 44. For a brief critique of the case, see Juliane Kokott and Kai-Guido Schick, Parfums Christian Dior SA v. Tuk Consultancy BV*, and* Assco Gerüste GmbH v. WilhelmLayher GmbH &Co. KG. *Joined Cases C-300/98 and C-392/98*, 95(3) AM. J. INT'L L. 661 (2001).

[41] *Dior*, Joined Cases C-300/98 and C-392/98 at para. 47; see also Anheuser-Busch v. Budějovický Budvar, CJEU Case C-245/02, 2004 E.C.R. I-10989, para. 55.

[42] *Dior*, Joined Cases C-300/98 and C-392/98 at para. 48.

[43] *Merck Genéricos*, CJEU Case C-431/05.

In this context, the referring jurisdiction in *Daiichi Sankyo* posed the question whether a specific TRIPS provision comes "within a field for which the Member States continue to have primary competence and, if so, can the Member States themselves accord direct effect to that provision."[44] The wording of this question reveals the conviction of the Greek court that the rule on shared competence, drawn in *Dior*, still stands. The referring court had doubts only as to the extent to which EU legislation had grown in the area of patent protection and thus taken away Member States' competence. Of all participants in the case, the European Commission was the only one to argue that the above case law on competence distribution within an area of shared competence had become obsolete after the Lisbon Treaty.[45] Discussing this minority viewpoint proved to be essential for the oral stage,[46] the Advocate-General's Opinion,[47] and the Court's judgment. As the Advocate-General argued, if a shift towards EU competence were to occur, it would not be because "European Union law on intellectual property has, through harmonization, changed significantly."[48] Under the *Dior*/*Merck Genéricos* case law, and considering the limited extent to which the Union had exercised its powers, the Member States would still hold competence over TRIPS. The path to exclusive EU competence could only lie in Article 207 of the TFEU. Therefore, the conscious decision of the Court to diverge from its established case law warrants careful consideration.

E. The Evolution of the Treaty Provisions on the CCP

The recognition of the TRIPS Agreement as now falling within the CCP turns the Lisbon Treaty into a watershed for Union competence. This change, however, should not come as a great surprise. When looking at the gradual Treaty revisions of the CCP, the judgment of the Grand Chamber does little more than give effect to the new competence provisions signed in Lisbon.

As the Court of Justice said, the ruling was largely based on the "significant development of primary law" over the years of European integration.[49] Indeed, the original phrasing of Article 113 of the EEC Treaty, in addition to providing a transition period for the CCP, referred only to "uniform principles, particularly in regard to changes in tariff rates, the conclusion of tariff and trade agreements, the achievement of uniformity in measures of

[44] *Daiichi Sankyo*, CJEU Case C-414/11 at para. 32.

[45] *Id.* at para. 43.

[46] *Id.* at para. 44.

[47] Advocate-General's Opinion, *Daiichi Sankyo*, CJEU Case C-414/11 at paras. 2-4.

[48] *Id.* at para. 42.

[49] *Daiichi Sankyo*, CJEU Case C-414/11 at para. 48.

liberalization, export policy and measures to protect trade such as those to be taken in case of dumping or subsidies."[50] The provision remained essentially unchanged in the Maastricht version of the EC Treaty. Therefore, when examining it in Opinion 1/94, the Court refused to read intellectual property into Article 113 of the EC Treaty.[51] Although one part of the TRIPS Agreement—the ban on the release in free circulation of counterfeit goods—fell within the scope of Article 113 of the EC Treaty, the same was not true for intellectual property.[52] Assessing the connection between the TRIPS provisions and the Common Commercial Policy, the Court stated: "Intellectual property rights do not relate specifically to international trade; they affect internal trade just as much as, if not more than, international trade."[53] Despite the trade context of the WTO Agreement and its annex, the TRIPS Agreement, the Court of Justice gave a strict interpretation of the CCP provisions.[54] Hence, the decision on intellectual property was left up to the Member States in a possible future Treaty amendment.

The masters of the Treaties took up the cue as early as the Amsterdam Treaty. Article 133(5) of the EC Treaty[55] (previously Article 113 of the EC Treaty) provided that the Council could unanimously, following a consultation with the European Parliament, apply the CCP provisions "to international negotiations and agreements on . . . intellectual property insofar as they are not covered" by the Treaty. Then, the Commission would have the power to submit proposals to the Council and conduct negotiations on behalf of the Community, while the Council would be competent to conclude the agreements. The Amsterdam revision was a direct response to Opinion 1/94, confirming the Court's judgment that the CCP did not encompass intellectual property rights, while affording an opportunity to bring the field within the Community framework. The competence knot was tied yet again in the Nice Treaty.[56] The revised provision created a distinction between intellectual property and "the commercial aspects of intellectual property." For the former, Article 133(7) of the EC Treaty[57] preserved the option to be governed by the CCP

[50] Treaty Establishing the European Economic Community *supra* note 2, at art.113.

[51] Opinion 1/94.

[52] *Id.* at para. 55.

[53] *Id.* at para. 57.

[54] For a discussion of Opinion 1/94, see Meinhard Hilf, *The ECJ's Opinion 1/94 on the WTO – No Surprise, but Wise?–*, 6 EURO. J. OF INT'L L. 245 (1995).

[55] Consolidated version of the Treaty Establishing the European Community (Amsterdam version) art. 133, Oct. 2, 1997, 1997 O.J. (C 340).

[56] See the critique of Bungenberg *supra* note 6 at 130-132; Dimopoulos *supra* note 6; Opinion of Advocate-General Kokott, *Commission v. Council*, CJEU Case C-13/07 (Mar. 26, 2009).

[57] Consolidated version of the Treaty Establishing the European Community (Nice version) art 133, Feb 26, 2001, 2002 O.J. (C 325).

provisions, if the Council decided so. For the latter, however, the CCP provisions would immediately govern the negotiation and conclusion of agreements. Nevertheless, the Nice Treaty included an important reservation, which negated the idea of exclusive Community competence. According to Article 133(5) of the EC Treaty,[58] the new rule could not "affect the right of the Member States to maintain and conclude agreements with third countries or international organizations in so far as such agreements comply with Community law and other relevant international agreements." Shared competence over the commercial aspects of intellectual property was thus entrenched. Nevertheless, Community competence became effective at once, rather than pending a future Council decision as under the Amsterdam regime. Little by little, the pre-Lisbon Treaties established Community competence over the commercial aspects of intellectual property, while protecting the shared nature of that competence.

The new wording of the provision in the Treaty of Lisbon, on the other hand, represents a turning point in favor of exclusive competence. Article 3(1)(e) of the TFEU,[59] conferring explicit exclusive Union competence over the Common Commercial Policy, should be read in conjunction with Article 207(1) of the TFEU, stating that "[t]he common commercial policy shall be based on uniform principles, particularly with regard to changes in tariff rates, the conclusion of tariff and trade agreements relating to trade in goods and services, and the commercial aspects of intellectual property."[60] The commercial aspects of intellectual property are moved from the lower paragraphs to the main provision, defining the scope of the CCP. Hence, the Treaty turns the field into one of the central components of the policy. Furthermore, the Member States no longer retain the ability to negotiate and conclude agreements independently. In the Nice Treaty, Community competence over the commercial aspects of intellectual property was an exception, an appendage to the CCP provisions that was governed by its own rules on shared competence. Today, this field is an integral part of the CCP, not an afterthought tucked among the other provisions. Although the Council may need to decide on the negotiation and conclusion of agreements with unanimity rather than a qualified majority[61], the field now firmly falls within exclusive Union competence. This new CCP provision, however, no longer refers to intellectual property beyond its commercial aspects. As a result, the Treaty of Lisbon makes the transition from shared to exclusive competence, while focusing only on the *commercial aspects* of intellectual property.

This evolution of the Treaty provisions over time led to the change in the Court's case law. After pointing out that Article 207 of the TFEU "differs noticeably from the provisions it

[58] *Id.*

[59] TFEU *supra* note 1, at art.3.

[60] TFEU *supra* note 1, at art. 207(1).

[61] TFEU *supra* note 1, at art. 207(4).

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essentially replaced," as well as from the earlier wording of the CCP, the Court set aside the string of rulings between Opinion 1/94 and *Merck Genéricos*.[62] With the new Treaty in force, it was time to adjust the case law accordingly. At the core of this change would be the meaning of the phrase "commercial aspects of intellectual property."

F. Interpreting the "Commercial Aspects" of Intellectual Property

The conclusion that the Lisbon Treaty marks a new stage for Union competence does not by itself mean that the TRIPS Agreement falls within exclusive competence. As the Advocate-General emphasized in his Opinion, intellectual property law consists primarily of the substantive rules on protection and a legal order ensuring this protection, the commercial aspects being only an element of the framework.[63] Hence, the "commercial aspects of intellectual property" must be given a specific interpretation, which acknowledges the confined field envisioned by Article 207 of the TFEU. Furthermore, intellectual property rights in the Union fall within an area of shared competence, the Internal Market, as the Court confirmed.[64] In particular, Article 118 of the TFEU[65] provides for the establishment of European intellectual property rights. Therefore, an excessively broad interpretation of the new CCP provision could encroach upon the competence, which the Member States retain within the Internal Market.

This distribution of competence between the Internal Market and the CCP is itself a Gordian knot, considering the Advocate-General's Opinion. When discussing Article 207(1) of the TFEU, Advocate-General Cruz Villalón insisted that "understanding the provision as an exclusive 'external' competence, capable of existing alongside a shared 'internal' competence, leads only to a dead end."[66] This conclusion, however, does not take account of Article 3(2) of the TFEU, which confers exclusive Union competence "for the conclusion of an international agreement when its conclusion is provided for in a legislative act of the Union or is necessary to enable the Union to exercise its internal competence, or in so far as its conclusion may affect common rules or alter their scope."[67] Article 3(2) of the TFEU does not refer to the areas in which the Union already has express exclusive competence. On the contrary, it envisions exceptional situations, in which the Union acquires external exclusivity to conclude international agreements. As a result, the Union may suddenly have

[62] *Daiichi Sankyo*, CJEU Case C-414/11 at paras. 46-48.

[63] Advocate-General's Opinion, *Daiichi Sankyo*, CJEU Case C-414/11 at paras. 49-50.

[64] *Daiichi Sankyo*, CJEU Case C-414/11 at para. 59.

[65] TFEU *supra* note 1, at art.118.

[66] Advocate-General's Opinion, *Daiichi Sankyo*, CJEU Case C-414/11 at para. 60.

[67] TFEU *supra* note 1, at art. 3(2).

exclusive external competence over an agreement in an area, for which it only has shared internal competence.

While dismissing the idea of competence cohabitation, the Advocate-General admitted that giving priority to one area over the other would practically invalidate one part of the Treaty.[68] In fact, the tension between the Internal Market and the CCP provisions could not be better illustrated than by the Advocate-General's Opinion. In the face of this "irreconcilable contradiction,"[69] Advocate-General Cruz Villalón was so divided that he found "that the Member States and the Commission are both correct" in their opposite arguments on competence.[70] Therefore, he put forward an approach of appeasement, cushioning the full effects of Article 207 of the TFEU on the competence of Member States to avoid "immediate 'expulsion' of the Member State from the negotiations for such agreements."[71] His solution lies in a double test: (1) Does the specific TRIPS provision relevant to the case, not the entire agreement, fall within the *commercial aspects* of intellectual property and (2) has EU harmonization in the field of intellectual property developed sufficiently to justify exclusive Union competence over international agreements like TRIPS?[72] The Advocate-General concluded that, currently, Article 27 of TRIPS[73] remains outside the scope of Article 207 of the TFEU, thus making the previous case law on shared competence still relevant.[74]

The proposed approach examines the scope of Article 207(1) of the TFEU based on the possible outcomes for Member State competence. The Advocate-General attempted to make the shift to exclusive competence more palatable to the Member States, envisioning a gradual transition. This result-oriented interpretation, however, detracts from the full effect of the CCP provision and further complicates the situation. The new exclusive competence over the commercial aspects of intellectual property is unconditional. Making it dependent on the development of EU legislation on substantive intellectual property law is unwarranted by the Treaty wording. Furthermore, adding this new test to the already existing *Dior*/*Merck Genéricos* test on shared competence entangles the competence knot even more. This outcome contradicts the simplification and streamlining of competences that the Treaty of Lisbon was supposed to achieve.

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[68] Advocate-General's Opinion, *Daiichi Sankyo*, CJEU Case C-414/11 at paras. 68-69.

[69] *Id.* at para. 70.

[70] *Id.* at para. 55.

[71] *Id.* at para. 76.

[72] *Id.* at paras. 72-80.

[73] See, TRIPs Agreement *supra* note 7, at art. 27.

[74] Advocate-General's Opinion, *Daiichi Sankyo*, CJEU Case C-414/11 at para. 81.

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The Court's judgment, however, did not endorse this proposal. Instead, the Grand Chamber focused on interpreting "the commercial aspects of intellectual property" under the umbrella of the Common Commercial Policy. According to the Court, "of the rules adopted by the European Union in the field of intellectual property, only those with a specific link to international trade are capable of falling within the concept of 'commercial aspects of intellectual property' . . . and hence the field of the common commercial policy."[75] To identify this specific link, the Court went back to earlier case law, stating that an act within the CCP is "essentially intended to promote, facilitate or govern trade and has direct and immediate effects on trade."[76] In practice, the combination of these two definitions calls for a teleological approach. To decide whether a rule has the purpose of advancing international trade and, hence, such an effect, it is necessary to look at the overall picture. Therefore, the Court analyzed the TRIPS Agreement in its entirety, as a set of rules,[77] rather than a series of stand-alone provisions. Indeed, the provisions are interrelated, with some providing the exceptions to others or interacting with them to create a complete system. Dissecting the individual TRIPS articles cannot give a meaningful, comprehensive idea of the purpose and possible effects of the Agreement. The method of scrutinizing separate TRIPS articles was suitable for determining the latest distribution of competences under the old Treaty order of shared competence. The goal-oriented definition of CCP acts, however, requires a new, more inclusive method that takes into account the whole set of rules comprising an agreement. This is what the Court offered when it decided to check whether the TRIPS Agreement, not an individual provision, falls within the concept of commercial aspects of intellectual property.

The Court's conclusion that the TRIPS Agreement comes within the scope of this term and, thus within the CCP, is based on three arguments. First, the Court held that the Agreement is "an integral part of the WTO system and is one of the principal multilateral agreements on which that system is based."[78] As evidence, the Court pointed out the cross-retaliation measures connecting the constituent agreements of the system.[79] This interaction was noted as early as Opinion 1/94, but at the time it only served to highlight the duty of cooperation between the Community and the Member States.[80] Second, the Court referred to the similarity between the phrases "commercial aspects of intellectual

[75] *Daiichi Sankyo*, CJEU Case C-414/11 at para. 52.

[76] *Id.* at para. 51.

[77] *Id.* at para. 53.

[78] *Id.*

[79] *Id.* at para. 54.

[80] Opinion 1/94 (note 8), para. 109.

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property" and "trade-related aspects of intellectual property rights."[81] The Advocate-General, however, opposed an interpretation of EU competence, based on a textual comparison.[82] In fact, the Court did not use the similarity as conclusive evidence, but mentioned it rather in passing as a detail that could not have escaped the Member States' attention in the drafting of the Lisbon Treaty. The Court used this remark and the previous one as supporting arguments demonstrating the place of TRIPS within the CCP. The third and main argument of the Court stemmed from the very purpose of the TRIPS Agreement.

To distinguish the commercial aspects of intellectual property from intellectual property, the Court of Justice addressed the objective of TRIPS. This distinction is crucial for delineating the boundary between exclusive CCP competence and shared Internal Market competence. Returning to the original position in Opinion 1/94, the Court stated: "The primary objective of the TRIP[s] Agreement is to strengthen and harmonise the protection of intellectual property on a worldwide scale."[83] The Grand Chamber, however, offered a new perspective, adding that the purpose of TRIPS is "reducing distortions of international trade by ensuring . . . the effective and adequate protection of intellectual property rights."[84] Within this context, TRIPS provisions like Article 27 were designed as instruments for this protection.[85] Hence, the Court emphasized the external, international orientation of TRIPS. In so far as the Agreement includes substantive rules, they are the means for achieving the goal of better intellectual protection globally. This, in turn, forms a vital aspect of the overall WTO system. The Court thus reached for arguments in its previous case law, giving them a new interpretation to reflect the change in the CCP provision.

Still, the Court had to make room for shared competence over intellectual property within the Internal Market. Referring to this legislative competence, the Court stated that it relates to acts "intended to have validity specifically for the European Union."[86] Furthermore, internal EU acts would need to conform to the external rules set down by the TRIPS Agreement.[87] The Court set the Internal Market apart from the Common Commercial Policy based on an internal-external divide: "[H]armonisation of the laws of the Member States" versus "liberalisation of international trade."[88] Interestingly, the Court discussed

[81] *Daiichi Sankyo*, CJEU Case C-414/11 at para. 55.

[82] Advocate-General's Opinion, *Daiichi Sankyo*, CJEU Case C-414/11 at paras. 56-58.

[83] *Daiichi Sankyo*, CJEU Case C-414/11 at para. 58; see Opinion 1/94, para. 58.

[84] *Daiichi Sankyo*, CJEU Case C-414/11 at para. 58.

[85] *Id.*

[86] *Id.* at para. 59.

[87] *Id*.

[88] *Id.* at para. 60.

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this distinction from the perspective of Union competence only: Whether the Agreement falls within an area of shared EU competence or of exclusive EU competence.[89] Although the judgment would have significant implications for Member State competence, the Court examined the issue in general terms, drawing the line between the two EU policy areas. The distribution of competence between the Union and the Member States would be a by-product—a relevant question only if the Agreement would belong to the Internal Market. Ultimately, the Court performed a difficult balancing act. The judgment preserved shared competence over intellectual property, respecting the Internal Market provisions while recognizing the new exclusive competence of the Union and thus giving effect to Article 207(1) of the TFEU.

G. The Effect of the TRIPS Agreement

A final point worth noting is the effect, which a TRIPS provision could produce in the national legal order. Under the earlier case law on shared competence, "the provisions of TRIP[s], an annex to the WTO Agreement, are not such as to create rights upon which individuals may rely directly before the courts by virtue of Community law."[90] Nevertheless, as mentioned above, national jurisdictions had to interpret national law as far as possible in the light of TRIPS[91] if the Community had exercised its powers; there was no obligation for national courts, but also no ban on recognizing the direct effect of a TRIPS provision if the Member States were still primarily competent.[92] Supposing that this line of case law was still relevant, the referring Greek court in *Daiichi Sankyo* asked whether it could recognize the direct effect of Article 27 of TRIPS. Because the Court of Justice held that the Agreement no longer falls within shared competence, but instead comes under the new exclusive CCP competence, the Grand Chamber did not discuss the issue of direct effect at all.[93]

This silence confirms the Court's earlier conclusion that the TRIPS Agreement does not have direct effect. Unlike the issue of competence distribution, on which the Court expressly diverged from previous case law to accommodate the Treaty revision, the subject

[89] See *Daiichi Sankyo*, CJEU Case C-414/11 at para. 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."

[90] *Dior*, Joined Cases C-300/98 and C-392/98 at para. 44.

[91] For a discussion of the principle of consistent interpretation, see Angelos Dimopoulos & Petroula Vantsiouri, *Of TRIPS and Traps: The Interpretative Jurisdiction of the Court of Justice of the EU over Patent Law*, *in* TILBURG LAW AND ECONOMICS CENTER DISCUSSION PAPER 25 (2012).

[92] *Dior*, Joined Cases C-300/98 and C-392/98 at paras. 47-48; *Merck Genéricos*, CJEU Case C-431/05 at paras. 34-35.

[93] See *Daiichi Sankyo*, CJEU Case C-414/11 at para. 62.

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of direct effect was left untouched. Instead, the Court directly gave an interpretation of the TRIPS provisions, relevant to the *Daiichi Sankyo* case.[94] The referring court could thus settle the dispute before it in line with the TRIPS rules. This approach is similar to earlier cases, when the TRIPS Agreement still fell under shared competence, but the Community had exercised its powers. Then, even though a national court could not recognize the direct effect of a TRIPS provision, the Court of Justice interpreted the Agreement, so that the referring jurisdiction could interpret national law in consistency with TRIPS.[95] The Court acted likewise in *Daiichi Sankyo*. Once the question of competence was settled, the Court proceeded with the second and third preliminary questions, so that the Greek jurisdiction could resolve the case.

Hence, the judgment does not affect the established position that the TRIPS Agreement does not have direct effect under EU law. The observations on the WTO system, based on which the Court has repeatedly refused to recognize the direct effect of TRIPS,[96] remain valid. The only substantial difference is that the TRIPS Agreement is now entirely within exclusive Union competence. This finding means that Member States can no longer retain primary competence over a field within the scope of TRIPS, even if the Union has not exercised its powers. Therefore, national courts lose the right to accord direct effect to a TRIPS provision when settling a dispute. From the perspective of individual rights, by bringing the TRIPS Agreement within exclusive Union competence, the Treaty of Lisbon has removed the possibility of direct effect for the entire Agreement.

H. Conclusion

The judgment in *Daiichi Sankyo* gives a new direction to the case law of the Court of Justice regarding the commercial aspects of intellectual property. It provides greater clarity on the TRIPS Agreement. The Court decided to treat the Agreement as a single unit within the new exclusive Union competence, instead of examining the individual provisions vis-à-vis the existing EU legislation in a specific field. Hence, the Court's approach offers legal certainty.

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[94] *Id.* at paras. 63-83.

[95] See *Dior*, Joined Cases C-300/98 and C-392/98; *Anheuser-Busch*, CJEU Case C-245/02

[96] *Dior*, Joined Cases C-300/98 and C-392/98 at para. 44, read in conjunction with Portugal v. Council, CJEU Case C-149/96, 1999 E.C.R. I-08395, paras. 34-46. For a discussion of the Court's position on the WTO system, see Marco Bronckers, *The Effect of the WTO in European Court Litigation*, 40 TEX. INT'L L.J. 443 (2005); Miguel Ángel Cepillo Galvín, *The Case-law of the Court of Justice of the European Communities Concerning the Law of the World Trade Organization and the Autonomy of the European Community in the Implementation of its Common Commercial Policy*, 2(51) BULL. OF THE TRANSILVANIA U. OF BRAŞOV 173 (2009); Alessandra Arcuri and Sara Poli, *What Price for the Community Enforcement of WTO Law?*, 1 EURO. U. INST. WORKING PAPERS L. (2010).

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When discussing the concept "commercial aspects of intellectual property," the Court adopted a broad perspective, taking into account the objective and effects of an international agreement. TRIPS, being an annex to the WTO Agreement, easily fit the concept, as could be expected. It will be interesting to see how the Court might perceive future international agreements on intellectual property. After all, the Court used the substantive rules on intellectual property protection in TRIPS to reject exclusive competence in Opinion 1/94, while downplaying such rules and emphasizing the overall trade purpose of the Agreement to recognize exclusive competence in *Daiichi Sankyo*. The Court reviewed its case law for a reason: To reflect the development of the CCP provisions over time. Nevertheless, the contrast between these two judgments shows that it is not unimaginable to interpret an agreement in opposite ways, especially if it is a compromise of complex multilateral negotiations. Time will tell how the Court of Justice will perceive other agreements in the field, given the Lisbon provisions on competence. With respect to TRIPS, however, the judgment establishes exclusive Union competence over the Agreement in its current form and over possible future amendments.

Hence, the judgment clarifies competence over TRIPS in a decisive manner. The Court of Justice, however, was careful to ensure that the "commercial aspects of intellectual property" do not cover the entire field of intellectual property, thereby leaving room for shared competence under the Internal Market provisions. When discussing the boundary between shared and exclusive Union competence, the Court contrasted the inward focus of the Internal Market with the external orientation of the CCP. This reasoning emphasizes the objectives and subject-matter of the different EU policies, while also taking account of the precise Treaty (re)wording.

The wording of the Treaty provisions, in turn, raises the larger question of competence conferral. In *Daiichi Sankyo*, the European Commission argued that Article 207 of the TFEU "obviously" referred to the TRIPS Agreement because of the semantic correspondence between the "trade-related aspects of intellectual property rights" and "the commercial aspects of intellectual property."[97] In contrast, all governments submitting observations, including four of the founding Member States, argued that the previous case law on shared competence over TRIPS was still valid. The disagreement reveals that the tensions around the conferral of competence from the Member States to the European Union remain in the post-Lisbon era. Although the latest Treaty revision set out to simplify and specify the division of competences, the Commission and the Member States do not have a common understanding of the Lisbon provisions. This is undesirable, yet expected. The Treaties result from complex, political-level negotiations over vast and sometimes highly technical subject-matters. Furthermore, the final texts must be acceptable to an ever-growing number of Member States in order to be ratified. Consequently, the Member States may not appreciate the scope of the competence, which they have conferred to the Union by revising a Treaty article.

[97] Advocate-General's Opinion, *Daiichi Sankyo*, CJEU Case C-414/11 at paras. 46-47.

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As a result, the Court of Justice finds itself in a difficult situation. On the one hand, the Court proclaimed long ago that the Treaty provisions constitute a "constitutional charter," against which Community and Member State measures are reviewed.[98] Therefore, the Court insisted in *Daiichi Sankyo* on giving effect to the significant recasting of Article 207 of the TFEU. On the other hand, the Court is open to criticism of judicial activism whenever its judgment goes against the legal interpretation supported by the Member States. Hence, *Daiichi Sankyo* underlines the importance of Treaty wording and the need for serious consideration of any future amendments, so that the masters of the Treaties are fully aware of the legal consequences of Treaty revisions.

A final point worth addressing is the lack of direct effect of the TRIPS Agreement. The judgment does not change the long-standing practice of the Court to deny the TRIPS Agreement direct effect under Community law, considering the specific nature and organization of the WTO.[99] Therefore, the Court's acknowledgement that the TRIPS Agreement now falls within exclusive Union competence deprives individuals of the opportunity to rely directly on TRIPS provisions before national jurisdictions.[100] Under the earlier case law, national courts could recognize this right if the Community had not yet exercised its competence over a particular field. Today protection of individuals' rights is limited to the requirement to interpret national legislation in consistency with the TRIPS Agreement. Hence, the recognition of exclusive Union competence comes at the expense of distancing individuals from the Agreement, which was meant to ensure intellectual property rights globally.

[98] Les Verts v. European Parliament, CJEU Case C-294/83, 1986 E.C.R. 01339, para. 23.

[99] For a comparison of the Court's stance on the WTO and on regional trade agreements, see Thomas Cottier, *International Trade Law: The Impact of Justiciability and Separations of Powers in EC Law*, 5 EURO. CONST. L. REV. 307, 307-21 (2009).

[100] See the discussion of individual rights *vis-à-vis* the WTO Agreements in Marise Cremona, *External Relations of the EU and the Member States: Competence, Mixed Agreements, International Responsibility, and Effects of International Law*, 22 EURO. U. INST. WORKING PAPERS L., 30-33 (2006).