

# Of TRIPS and traps: the interpretative jurisdiction of the Court of Justice of the EU over patent law

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## **ABSTRACT**

*Using the pending Daiichi Sankyo case as a point of reference, this article examines whether EU exclusive competence under Article 207 TFEU requires the CJEU to interpret the patent provisions of the TRIPS Agreement and, if so, what are the implications for patent protection in the EU. It examines whether the Court's jurisprudence on the direct effect and interpretation of the substantive patent provisions of the TRIPS Agreement is good law in the post-Lisbon era, arguing that the Court has acquired interpretative jurisdiction over the entire TRIPS Agreement. Secondly, it looks into the implications of a CJEU interpretative jurisdiction over TRIPS on the development of uniform EU patent rules in light of the recent developments regarding the establishment of a Unified Patent Court and a EU Patent with Unitary Effect. It concludes that the CJEU can play a key role in safeguarding coherence and consistency in the application of the different regimes of patent protection in the EU.*

## **1. Introduction**

The Court of Justice of the European Union (CJEU) has always played a key role in the development of common rules in the field of intellectual property (IP) law. Since the establishment of the common market, the Court has systematically expanded the reach of EU law in the field of IP, despite the lack of an explicit power-conferring provision in primary EU law. Initially, the Court found that national rules on IP have a great impact on the exercise of the free movement of goods and competition rules.<sup>1</sup> Exercising judicial activism, the Court formulated the theory of core rights. It held that rules concerning the existence of

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<sup>1</sup> Case C-30/90, Commission v. UK [1992] ECR I-892.

IP rights could not infringe EU rules, while the exercise of these rights may in certain circumstances do, so that the exercise of IP rights can be the subject of EU rules.<sup>2</sup> Later on, it was the Court which ruled that EU rules can also interfere with the core substance of IP rights, so that regulation of IP rights concerning not only their exercise but also their existence can be adopted at EU level, especially by means of harmonisation.<sup>3</sup> As a direct consequence of the jurisprudential recognition of EU competence to regulate in the field of IP, whenever it is necessary to attain the objectives of the internal market, the EU adopted significant pieces of legislation harmonising most aspects of IP law, from trademarks and designs to aspects of copyright and enforcement of IP rights.<sup>4</sup>

Of all IP rights the protection of patents is the least harmonised within the EU. Bearing in mind the existence of an extra-EU legal system on patent protection<sup>5</sup> and the political complexities regarding patent protection in Europe,<sup>6</sup> the EU has been very cautious in developing common rules on patents. Rather than following its practice in other areas of IP law, all successful initiatives concerning patent regulation have been rather partial and incomplete.<sup>7</sup> Initiatives for complete harmonisation and the establishment of a common Union patent system have not been fruitful so far, even after the introduction of a specific legal basis on IP harmonisation under the Lisbon Treaty.<sup>8</sup> Following a similar path, the CJEU has been very self-restrained in the field of patent law. Although the Court continues examining whether patent protection is a restriction to free movement and competition law rules, when an issue of substantive protection of patents arose in the past, the Court carefully avoided setting any substantive rules concerning patent protection, paying deference to national law.

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<sup>2</sup> Case 24/67, *Parke Davis v. Probel* [1968] ECR 55; For an analysis of the existence v. exercise doctrine see U. Immenga and J. Mestmäcker, *EG- Wettbewerbsrecht: Kommentar*, Band II (Beck, 2007), at 15-43.

<sup>3</sup> Case C-350/92, *Spain v. Council* [1995] ECR I-1985.

<sup>4</sup> See Directive 89/104/EEC on the approximation of the Laws of the Member States Relating to Trade Marks, [1989] OJ L 40/1; Directive 2004/48/EC on the enforcement of intellectual property rights [2004] OJ L 157/45.

<sup>5</sup> See the Patent Cooperation Treaty (1970) and the European Patent Convention (1973)

<sup>6</sup> National interests with regard to official languages, translations and jurisdictional arrangements stopped the efforts towards a EU patent. For the failed initiatives for the establishment of an EU patent see below section 4.

<sup>7</sup> For example, there are rules in the fields of medicinal products and plant protection products (Regulation 1768/92 concerning the creation of a supplementary protection certificate for medicinal products OJ 1992 L 182/1 and Regulation (EC) 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products OJ 1996 L 198/30), while the Biotechnology Directive regulates the patentability of biotechnological inventions (Directive 98/44/EC on the legal protection of biotechnological inventions OJ L 213/13).

<sup>8</sup> Article 118 TFEU confers powers to the Union to create European intellectual property rights, aiming to provide “uniform protection of intellectual property rights throughout the Union”. See indicatively Council Decision 2011/167/EU authorising enhanced cooperation in the area of the creation of unitary patent protection, OJ L76/53

The limited role of the CJEU in the field of patent protection was confirmed in its jurisprudence regarding the application and implementation of international agreements on patent protection and in particular the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Although the TRIPS Agreement presents an annex to the World Trade Organisation (WTO) agreement, and is as such a matter of particular EU interest, the Court has been hesitant to apply and interpret the TRIPS patent provisions. In a series of cases concerning the TRIPS Agreement, as they were crystallised in *Merck Genericos*,<sup>9</sup> the CJEU clarified that the interpretation of the substantive patent provisions of the TRIPS Agreement lie outside its jurisdiction and Member States can decide according to national law whether to grant direct effect and how to interpret the TRIPS provisions on patents.

However, after the entry into force of the Lisbon Treaty it is questionable whether *Merck Genericos* presents good law. Article 207 TFEU vests the EU with exclusive competence in all fields covered under the EU common commercial policy, including “the commercial aspects of intellectual property rights”. As a result, the question arises whether EU exclusive competence under Article 207 TFEU requires the Court to interpret the patent provisions of the TRIPS Agreement and, if so, what are its implications for substantive patent protection in the EU. The relevance and topical character of these questions is confirmed, as they present the subject matter of a recent reference for a preliminary ruling. In *Daiichi Sankyo*<sup>10</sup> the Athens Court of First Instance asked the CJEU, if in cases where national patent law protected only the process of manufacture of a pharmaceutical product at the time of the filing of a patent application, whether after the entry into force of the TRIPS Agreement, the patent also protects the pharmaceutical product as such.

Within this framework, this article examines whether the CJEU has acquired a legal basis for extending its interpretative jurisdiction in the realm of patent law and the implications for patent protection in the EU. After revisiting the Court’s jurisprudence on the direct effect and the interpretation of the TRIPS Agreement and in particular its patent provisions, the impact of EU exclusive competence on the CJEU’s jurisdiction over TRIPS is explored, reviewing whether the Court can decide on matters of direct effect and interpretation of the patent provisions of the TRIPS Agreement. Finally, this article analyses the implications of a CJEU interpretative jurisdiction over TRIPS on the development of EU patent rules, concluding that the Court’s jurisdiction over TRIPS presents an important step in the process of harmonisation of patent rules in the EU.

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<sup>9</sup> Case C-431/05, *Merck Genéricos Produtos Farmacêuticos* [2007] ECR I-7001.

<sup>10</sup> Case C-414/11, *Daiichi Sankyo and Sanofi-Aventis Deutschland*, OJ C298/17, 08.10.2011.

## 2. The jurisprudence of the Court of Justice over the TRIPS Agreement

The jurisprudence of the Court of Justice over the TRIPS Agreement has been the subject of a long and very controversial debate, which remains topical after almost forty years. Since the judgment in *International Fruit Company*, where the Court discussed for the first time the effects of the GATT agreement in the EU legal order and the extent of the Court's jurisdiction,<sup>11</sup> the determination of the legal effects of the different WTO agreements in the Union legal order remains an open question. An examination of the legal effects of different WTO norms requires first an examination of how WTO law is perceived in the EU legal order; and secondly if the entirety of WTO law has effects in the EU legal order, given that the WTO agreements were concluded jointly by the EU and its Member States. The latter question has been particularly important for the patent provisions of the TRIPS Agreement, which remains a field where few EU rules exist.

### 2.1. Direct effect and the WTO agreements

The WTO agreement, like any other international agreement concluded by the EU,<sup>12</sup> presents a benchmark for the assessment of the legality of EU and Member State legislation. Based on Article 216(2) TFEU, which provides that EU international agreements are binding on EU institutions and on Member States, the Court has been very eager to review the legality of EU and Member State acts on the basis of their compatibility with EU international agreements. Recognising international law norms as an important source of EU law,<sup>13</sup> the Court has extensively dealt with the application and interpretation of Union agreements, including the WTO agreement. The basic test for reviewing the legality of EU and Member State measures was formulated by the Court in *International Fruit Company*,<sup>14</sup> subjecting judicial review in light of Union agreements in a two-prong test. The first prong requires that an international agreement is binding on the EU, while the second prong requires that the provision of the international agreement has direct effect.<sup>15</sup>

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<sup>11</sup> Cases 22-24/72, *International Fruit Company* [1972] ECR 1219, paras. 7-8.

<sup>12</sup> The terms EU international agreements and Union agreements will be used interchangeably, including mixed agreements that have the same status as pure Union agreements.

<sup>13</sup> Case 181/73, *Haegeman* [1974] ECR 449.

<sup>14</sup> *International Fruit Company*, above note 11.

<sup>15</sup> The direct effect of an international agreement is not required in cases of enforcement actions brought against Member States according to Article 258 TFEU. The EU has an interest in compliance with a Union agreement

Although both conditions have raised particular concerns as regards the legal effects of the WTO agreement, the lack of direct effect of WTO rules has been the focal point of attention. In a number of cases, the Court has firmly established that none of the WTO agreements or any WTO rule has direct effect, since “having regard to their nature and structure, the WTO agreements are not in principle among the rules in the light of which the Court is to review the legality of [Union or Member State] measures”.<sup>16</sup> The failure of the WTO agreement, due to its nature and structure, to satisfy the conditions for direct effect, deprives, thus, individuals and Member States, of the possibility to rely on WTO norms so as to challenge the legality of national or Union law measures.<sup>17</sup> Given that individuals do not have access to the WTO dispute settlement mechanism, this denial of direct effect of the WTO agreement is particularly important, as it deprives individuals of the opportunity to raise claims based directly on WTO rules.

However, the Court has drawn specific exceptions, where WTO norms can still trigger judicial review of EU and Member States measures. WTO norms can be relied upon in order to review measures that are meant to execute a particular obligation undertaken under the WTO,<sup>18</sup> or if the Union act explicitly refers to specific provisions of the WTO agreements.<sup>19</sup> More importantly, judicial review is possible, as EU and national legislation has to be interpreted in consistency with the provisions of Union agreements. Mitigating the negative impact of the lack of direct effect of Union agreements, the Court has emphasized that the primacy of EU international agreements over provisions of secondary Union law and subsequently national law means that “such provisions must, as far as possible, be interpreted in a manner that is consistent with those agreements”.<sup>20</sup> In that respect, the principle of consistent interpretation has presented an efficient method for reviewing the legality of national and secondary EU law in light of WTO rules, leading in many instances in results that do not differ in substance from those that would have been reached if the agreement had direct effect.<sup>21</sup>

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irrespective of whether it produces direct effect, since non-compliance triggers its international responsibility. Case C-61/94, *Commission v Germany* [1996] ECR I-3989, para. 52; See Eeckhout P., *External relations of the European Union: legal and constitutional foundations* (OUP, 2011), at 300-302.

<sup>16</sup> Case C-149/96, *Portugal v. Council* [1999] ECR I-8385, para. 47.

<sup>17</sup> On the nature and structure of the WTO Agreement and its failure to satisfy the conditions for judicial review see indicatively P. Kuipjer & M. Bronckers, ‘WTO Law in the European Court of Justice’ (2005) 42 *CMLR* 1313; F. Snyder, ‘The Gatekeepers: The European Courts and the WTO’ (2003) 40 *CMLR* 313.

<sup>18</sup> Case 69/89, *Nakajima All v. Council* [1991] ECR I-2069.

<sup>19</sup> Case 70/87, *Fediol III* [1989] ECR 1805.

<sup>20</sup> *Commission v Germany*, above note 15, para. 52; Case C-89/99, *Schieving-Nijstad* [2001] ECR I-5851. On the exceptions to direct effect see Eeckhout, above note 15, at 355-365.

<sup>21</sup> Kuipjer & Bronckers, above note 17, at 1326, 1328-1329.

## 2.2. TRIPS and EU competence before Lisbon

A key prerequisite for denying direct effect of and requiring consistent interpretation with WTO norms is that the latter are binding on the EU. This question has gained particular attention as regards the TRIPS Agreement. Considering that the WTO agreement was concluded jointly by the EU and its Member States as a mixed agreement,<sup>22</sup> the effects of the WTO agreement in the Union legal order depend on whether the EU and its Member States have a Union law obligation to implement and apply the agreement. As the Court has clearly stated, the implementation of a mixed agreement follows the division of powers between the EU and the Member States,<sup>23</sup> so that mixed agreements “have the same legal status in the [Union] legal order as purely [Union] agreements insofar as the provisions fall within the scope of [Union] competence”.<sup>24</sup> Following this logic, the determination of EU competence over the TRIPS patent provisions has been crucial for the determination of their Union law effects.

More specifically, since the creation of the WTO the EU has struggled to determine its competence over the TRIPS Agreement and delimitate it from Member State powers. The existence of Community exclusive competence to conclude the TRIPS Agreement was originally the focus of the benchmark decision of the Court of Justice in *Opinion 1/94*.<sup>25</sup> In this much-discussed case, the Court ruled that the majority of TRIPS provisions were outside the scope of the Common Commercial Policy, and thus EC exclusive competence, as their primary purpose was not the regulation of trade but the harmonisation of IP rights protection.<sup>26</sup> Nevertheless, the Court did not preclude that the Community might have exercised its shared competence with regard to (parts of) the TRIPS Agreement.

Due to the unclear delineation of competence based on *Opinion 1/94*, the Intergovernmental Conference in Nice expanded the scope of the Common Commercial Policy to trade-related aspects of IP, creating, however, a complex system of rules. By adding paragraphs 5-7 to Article 133 EC Treaty, it established Community competence over “commercial aspects of IP protection”, providing however numerous exceptions and complex

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<sup>22</sup> Council Decision 94/800/EC concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994), OJ L 336/1, 22.12.1994.

<sup>23</sup> *Opinion 1/78* [1978] ECR 2151, para. 36.

<sup>24</sup> Case C-239/03, *Commission v. France (Etang de Berre)* [2004] ECR I-9325, para. 25.

<sup>25</sup> *Opinion 1/94 (WTO Agreement)* [1994] ECR I-5267.

<sup>26</sup> For a critical analysis of *Opinion 1/94* see indicatively J Bourgeois, ‘The EC in the WTO and Advisory Opinion 1/94: An Echernach Procession’ (1995) 32 *CMLR* 763; P Koutrakos, *EU International Relations Law* (Hart, 2006), at 46-48.

procedural rules.<sup>27</sup> Despite the establishment of express powers over commercial aspects of IP, Article 133 EC Treaty did not confer exclusive competence to the EU,<sup>28</sup> thus keeping the ruling of Opinion 1/94 valid as regards the question of which parts of the TRIPS Agreement fell under the scope of exclusive EC competence.

### 2.3. TRIPS and the scope of EU law

Bearing in mind the lack of clarity regarding the exercise of Union competence over IP rights protection, the determination of the legal effects of TRIPS provisions has been based on the existence of Union rules in the fields where the TRIPS applies. In its landmark decisions in *Hermes*<sup>29</sup> and *Dior*,<sup>30</sup> the Court held that “where a provision can apply both to situations falling within the scope of national law and to situations falling within the scope of [Union] law, it is clearly in the [Union] interest that, in order to forestall future differences of interpretation, that provision should be interpreted uniformly, whatever the circumstances in which it is to apply.”<sup>31</sup> Avoiding the difficult question of determining the exercise of its competence in the field of IP rights, the provisions of the TRIPS Agreement were considered to create Union law effects, to the extent that they fell within the scope of EU law and there were EU rules that could be affected by their application and interpretation.<sup>32</sup> The EU has a broad interest in the performance of the provisions of TRIPS that fall within the scope of EU law; hence their legal effects are determined by EU law, irrespective of whether their interpretation concerns in a given case the judicial review of EU law or national law provisions.<sup>33</sup>

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<sup>27</sup> For a critical analysis of EU competence in the field of the Common Commercial Policy after the Nice Treaty see C Hermann, ‘Common Commercial Policy after Nice: Sisyphus would have done a better job’ (2002) 39 *CMLR* 26; M. Cremona, ‘Balancing Union and Member State interests: Opinion 1/2008, choice of legal basis and the common commercial policy under the Treaty of Lisbon’ in (2010) 35 *ELRev.* 678.

<sup>28</sup> Article 133(5)(4) EC Treaty provided that provided an express derogation from the exclusivity rule, and it grandfathered prior Member States agreements and reaffirmed also their right to conclude new agreements on commercial aspects of IP.

<sup>29</sup> Case C-53/96, *Hermes International v. FHT Marketing* [1998] ECR I-3603.

<sup>30</sup> Joined Cases C-300/98 and C-392/98, *Parfums Christian Dior SA v Tuk Consultancy* [2000] ECR I-11307.

<sup>31</sup> *Dior*, para. 32.

<sup>32</sup> C. Hillion, ‘Mixity and Coherence in EU External Relations : The significance of the ‘Duty of Cooperation’’, in Hillion & Koutrakos (eds) *Mixed Agreements Revisited* (Hart, 2010), at 97.

<sup>33</sup> M. Cremona, ‘Defending the Community Interest: the Duties of Cooperation and Compliance’ in M. Cremona and B. deWitte (eds) *EU Foreign Relations Law- Constitutional Fundamentals* (Hart, 2008), at 147-148, 152-153; P. Koutrakos, ‘Interpretation of Mixed Agreements’ in Hillion & Koutrakos (eds) *Mixed Agreements Revisited* (Hart, 2010), at 123-125.

Within this framework, the Court had the opportunity to interpret provisions of the TRIPS Agreements in a number of disputes concerning trademarks.<sup>34</sup> This was also true for procedural provisions, such as Article 50 TRIPS concerning the adoption of provisional measures for the protection of national trademarks, since that provision could affect the interpretation of the corresponding Union rule on Community trademarks.<sup>35</sup>

On the other hand, as the Court declared in *Dior*, in areas under the TRIPS where the EU had not legislated yet, Union law “neither requires nor forbids that the legal order of a Member State should accord to individuals the right to rely directly on the rule laid down by [...] TRIPS or that it should oblige the courts to apply that rule of their own motion”.<sup>36</sup> In that respect, in areas where there are no Union rules (such as industrial designs under *Dior*), a specific TRIPS provisions was deemed to fall outside the scope of EU law, and hence the legal effects of that provision could be determined according to national law. The application of this rule in the field of patent law was confirmed and clarified in *Merck Genericos*, where the Court of Justice dealt with the interpretation of Article 33 TRIPS on the minimum term for patent protection. After considering that the Union had not yet exercised its powers in the sphere of patents and, hence, that sphere did not fall within the scope of EU law, the Court concluded that Member States remain principally competent and can choose whether or not to give direct effect to that provision and how to interpret it.<sup>37</sup>

As a result, the Court left to the discretion of Member States and their courts to decide whether to allow individuals to rely on the patent provisions of the TRIPS Agreement, and if so, how to interpret them. The Court’s jurisprudence sparked a heated debate concerning its ramifications on coherence and unity in EU external relations, as well as on the effective protection of intellectual property rights. By excluding patent provisions from the scope of EU law, the Court deviated from previous jurisprudence where it had held that within the scope of Union law come the provisions of a mixed agreement that cover an area which is covered “in large measure” by EU legislation.<sup>38</sup> Moreover, even if patent provisions do not fall within the scope of Union law, the EU still has an interest in their uniform interpretation

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<sup>34</sup> *Hermes*, above note 29; *Dior*, above note 30; *Schieving-Nijstad*, above note 20; Case C-49/02, *Heidelberger Bauchemie GmbH* [2004] ECR I-6129. For a discussion of these cases see indicatively M. Karayigit, ‘Why and To What Extent a Common Interpretative Position for Mixed Agreements?’, (2006) 11 *EFA Rev.* 445.

<sup>35</sup> *Hermes*, above note 29, paras. 24-33.

<sup>36</sup> *Dior*, above note 30, para 49.

<sup>37</sup> *Merck Genericos*, above note 9, paras. 46-48. For a critical reading of this case see R. Holdgaard, ‘Case C–431/05, *Merck Genéricos — Produtos Farmacêuticos Lda v. Merck & Co. Inc. (M & Co.) and Merck Sharp & Dohme Lda (MSL)*, Judgment of the Court of Justice (Grand Chamber) of 11 September 2007, [2007] ECR I–7001’, (2008) 45 *CMLR* 1233.

<sup>38</sup> *Commission v. France*, above note 24, paras. 29-30; *Koutrakos*, above note 33, at 130-135.

across the EU. Member States and Union institutions alike have an obligation for close cooperation, based on Article 4(3) TEU, in fulfilling the commitments undertaken by them under joint competence when they concluded the WTO Agreement, including TRIPS<sup>39</sup> As AG Colomer suggested in his opinion in the *Merck* case, uniform interpretation is necessary, since it “would be extremely difficult for the national courts to adopt a different solution, even when ruling on provisions relating to areas in which the Member States remain competent [...] without running the risk of infringing their obligation to help ensure unity in the international representation of the [Union]”.<sup>40</sup>

Despite the existence of a convincing argumentation from an EU external relations law perspective, the Court did not grant Union law effects to the patent provisions of the TRIPS Agreement. In order to understand the hesitation of the Court, it is important to highlight that the Court considers that patent protection does not fall within the scope of EU law. As a result, the lack of uniform legal effects and interpretation of the TRIPS patent provisions allow for different positions to be taken by different national courts and offer a different level of protection of patent rights throughout the EU. Although this may lead to distortion of competition in the internal market, the fact that harmonisation in the field of patents remains limited has prompted the Court to avoid imposing common rules and uniform standards on patent protection in the EU.<sup>41</sup>

### **3. The legal effects of the patent provisions of the TRIPS Agreement after Lisbon**

Although the Court has avoided so far applying and interpreting substantive patent provisions, the entry into force of the Lisbon Treaty provides a new impetus for reconsidering the role of the Court of Justice in the field of patent law. The establishment of EU exclusive competence in the field of the Common Commercial Policy has a great impact on the determination of the legal effects of the patent provisions of the TRIPS Agreement, obliging the Court to determine whether, when and how to interpret the TRIPS patent provisions. In that respect,

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<sup>39</sup> See indicatively Hillion, above 32, at 94-97; C. Caddous, ‘Effects of International Agreements in the EU Legal Order’ in M. Cremona and B. deWitte (eds) *EU Foreign Relations Law- Constitutional Fundamentals* (Hart, 2008), at 292-293.

<sup>40</sup> Opinion of AG Colomer, para 82.

<sup>41</sup> O. Swens and T. Engels, ‘Community law, patent law and TRIPS: a complicated cocktail to mix’ in (2008) *Pharmaceutical Law Insight* (March 2008).

the pending case in *Daiichi Sankyo*<sup>42</sup> presents a unique opportunity for the Court to clarify these questions and acquire an active role in the interpretation of patent law in the EU.

### 3.1. EU exclusive competence and the TRIPS Agreement

One of the most significant changes brought about by the Lisbon Treaty is that it introduces clear rules with regard to the scope of Union competence in the area of IP protection. As was discussed above, since the creation of the WTO, the EU has struggled to determine its scope of competence in this area and delimitate it from Member State powers. Notwithstanding the introduction of express competence over commercial aspects of IP with the Treaty of Nice, the exact scope and the nature of Union competence in the fields covered by the Common Commercial Policy was ambiguous. Addressing these criticisms, the Lisbon Treaty introduced new wording with regard to EU competence on IP, enhancing clarity and preciseness. A striking difference from Article 133 EC Treaty is that the Lisbon Treaty ends the distinction between trade in goods and trade in services and commercial aspects of IP. Former Articles 133(1) and 133(5)(1) EC Treaty are “merged”, so that trade in services and commercial aspects of IP are no longer a different category from trade in goods.<sup>43</sup>

More importantly, since *Opinion 1/2008*, it is clearer that the term of commercial aspects of IP is meant to cover all fields to which the TRIPS Agreement applies.<sup>44</sup> Still, Article 207 TFEU, even after the Lisbon Treaty does not offer a definition of the term commercial aspects of IP. Nevertheless, it is widely suggested that the term should be interpreted by reference to the WTO and the TRIPS Agreement.<sup>45</sup> Similar to the term “trade in services”, “commercial aspects of IP” should not be limited to any internal market definitions, but it should reflect the scope of IP protection expressed in the WTO Agreements.<sup>46</sup> Besides, the term “commercial aspects of IP” is dynamic, as it confers competence not only in the areas that were covered by the TRIPS as it stood at the time of its

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<sup>42</sup> Above note 10.

<sup>43</sup> On the impact of the Lisbon Treaty on the scope of the Commercial Policy see A. Dimopoulos, ‘The Common Commercial Policy after Lisbon: Establishing parallelism between internal and external economic policy’ (2008) 4 *Croatian Yearbook of European Law and Policy* 102; M. Krajewski, ‘The Reform of the Common Commercial Policy’ in A. Biondi, P. Eeckhout & T. Ripley (eds) *European Union Law after the Treaty of Lisbon* (OUP, 2012).

<sup>44</sup> *Opinion 1/2008* [2009] ECR I-11129.

<sup>45</sup> Cremona, above note 27, at 683-684

<sup>46</sup> *Opinion 1/2008*, para. 119.

conclusion, but also to future developments.<sup>47</sup> The Lisbon Treaty did away Article 133(7) TEC, which granted the possibility to the Council to extend the scope of paragraphs 1-4 of Article 133 EC Treaty to the negotiation and conclusion of international agreements on IP in general. Therefore, in order to safeguard that the EU can conclude any future agreement on IP under the WTO or another international framework, a dynamic interpretation of commercial aspects of IP should be adopted.

The extensive scope of EU competence over all aspects of IP, including patent protection, is not affected by the fact that the EU has not legislated yet in that specific field apart from limited sectoral interventions.<sup>48</sup> Article 207(6) TFEU preserves the powers of Member States in fields excluded entirely from Union interference or from harmonisation by means of EU secondary legislation.<sup>49</sup> This provision precludes the Union from taking action in relation to third countries in fields where its competence in the internal market is limited, thus preserving the competences of Member States insofar as they have retained the power to regulate a specific issue in the internal market. However, this does not mean that the lack of exercise of Union internal competences poses a limitation on the existence or the exercise of external competence, even at the procedural level.<sup>50</sup> Considering that harmonisation in the field of patent protection is now explicitly allowed under the Treaty, the lack of common rules on patents does not present an impediment for the determination of EU external competence.

The most important novelty of the Lisbon Treaty with regard to IP is that it provides explicitly for the exclusive character of Union competence in the field. In contrast with the Nice Treaty which distinguished between trade in goods and trade in services and commercial aspects of IP, the Lisbon Treaty assimilates all fields of the Common Commercial Policy, in the sense that they all fall under EU *a priori* exclusive competence. More specifically, Article 3(1)e TFEU clearly stipulates that the CCP falls under the

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<sup>47</sup> On the debate concerning the static or dynamic interpretation of the term in the pre-Lisbon context see indicatively C. Hermann, 'Common Commercial Policy after Nice: Sisyphus would have done a better job', (2002) 39 *CMLR* 7, at 18-19; H.G. Krenzler and C. Pitschas, 'Progress or Stagnation? The Common Commercial Policy After Nice', (2001) 6 *EFA Rev.* 291, at 302.

<sup>48</sup> See above note 7.

<sup>49</sup> Article 207(6) TFEU provides that "the exercise of the competences conferred by this Article in the field of the common commercial policy shall not affect the delimitation of competences between the Union and the Member States, and shall not lead to harmonisation of legislative or regulatory provisions of the Member States insofar as the Treaties exclude such harmonisation".

<sup>50</sup> W. Shan and S. Zhang, 'The Treaty of Lisbon: Half Way toward a Common Investment Policy' (2010) 21 *EJIL* 1049, 1064-1065.

exclusive competence of the Union, while Article 2(1) TFEU integrates the principle that express powers are of *a priori* exclusive nature.<sup>51</sup>

As a result, the simplification and exclusive nature of EU competence over commercial aspects of IP presents a major step towards a uniform external representation in matters of IP law. A basic objective of the reform of the Common Commercial Policy was to grant competence to the Union to participate in the WTO and negotiate future amendments to WTO Agreements. Consequently, there is no doubt that that the entire scope of the TRIPS Agreement, as well as any future agreement on IP protection falls now under EU exclusive competence.

### **3.2. The impact of exclusivity on the legal effects of the TRIPS Agreement**

The establishment of exclusive competence does not automatically mean that the EU can decide on the legal effects of the patent provisions of the TRIPS Agreement. The TRIPS Agreement remains an international agreement that was concluded as a mixed agreement, hence binding both the EU and its Member States internationally. More importantly, the impact of exclusive external competence under the Common Commercial Policy should not be broadly interpreted as affecting the exercise of Member State internal concurrent powers in the field of IP protection.<sup>52</sup> Even though the EU can adopt international agreements on a specific subject matter, this does not signify that the EU obtains exclusive powers to regulate in this field in the internal market, as exclusivity under the Common Commercial Policy is relevant only for relations with third countries.

Nevertheless, the existence of exclusive external competence brings the TRIPS Agreement, including its patent provisions, within the scope of Union law, and requires the EU to determine its legal effects. As was already discussed, the determination of the legal effects of mixed agreement depends on whether their provisions fall within the scope of EU law. Turning now to the determination of the scope of EU law, the Court has repeatedly emphasised that the provisions of a mixed agreement, which cover an area that is covered “in

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<sup>51</sup> Article 207 TFEU does not distinguish between the different fields of the Common Commercial Policy in terms of the nature of competence, nor does Article 3 TFEU limit its scope to trade in goods. Besides, Article 207 TFEU does away with Article 133(5)(4) EC Treaty, which retained the right of the Member States to maintain and conclude agreements with third countries. See also J. Ceyssens, ‘Towards a common foreign investment policy? – Foreign investment in the European constitution’, (2005) 32 *LIEI* 259, at 286-287.

<sup>52</sup> M. Cremona, ‘A constitutional basis for Effective External Action? An assessment of the provisions on EU External Action in the Constitutional Treaty’, EUI Working Paper 2006/30, at 32.

large measure” by EU legislation, fall within the scope of Union law.<sup>53</sup> However, the discussion concerning the level of legislative activity that is of ‘sufficient importance’ to bring a provision of a mixed agreement within the scope of EU law is only important for provisions falling under shared competence.

Areas of EU exclusive competence fall within the scope of Union law, irrespective of whether the Union has legislated in this field.<sup>54</sup> As was already discussed, the determination of the scope of Union law, and subsequently of the legal effects of a provision found in a mixed agreement, arises within the context of the obligation of Member States and Union institutions to perform mixed agreements under Article 216(2) TFEU.<sup>55</sup> Hence, given that the implementation of a mixed agreement follows the division of powers between the EU and the Member States, Member States have an obligation to perform the parts of a mixed agreement falling under EU exclusive competence. Member States shall not jeopardise the fulfilment of EU international obligations, and hence they are pre-empted from taking any action in a field of exclusive competence, irrespective of whether the EU has exercised its competence or whether national legislation actually conflicts with EU rules.<sup>56</sup>

Moreover, the fact that EU competence has become exclusive after the entry into force of the TRIPS Agreement does not negate the impact of exclusive competence on the determination of the legal effects of the TRIPS in the future. The fact that the TRIPS Agreement was concluded as a mixed agreement, binding on both the Member States and the EU is still relevant for determining its international law effects, and more importantly the EU and Member State international responsibility.<sup>57</sup> Without prejudice to the international responsibility of Member States for violations of the TRIPS Agreements under the WTO, Articles 216(2) TFEU and 4(3) TEU create only internal, EU legal effects.<sup>58</sup> Hence, Member States incur Union law obligations as regards the fields of mixed agreements that fall under

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<sup>53</sup> Commission v. France (Etang de Berre), above note 24, paras. 29-30; Merck Genericos, above note 9, para 33; Case C-459/03, Commission v. Ireland (Sellafeld) [2006] ECR I-4635, paras. 99-106.

<sup>54</sup> Eeckhout, above note 15, at 285-286.

<sup>55</sup> Commission v. France (Etang de Berre), above note 24; Commission v. Ireland, above note 53, paras. 16, 18, 19.

<sup>56</sup> R. Schütze, ‘Supremacy Without Pre-Emption? The Very Slowly Emergent Doctrine of Community Pre-Emption’ (2006) 43 *CMLR* 1023, at 1037-1038. Cremona, above note 33, at 129.

<sup>57</sup> On EU and Member State international responsibility for WTO law violations see indicatively P. Eeckhout, ‘The EU and its Member States in the WTO- Issues of Responsibility’ in L. Bartels & F. Ortino (eds), *Regional Trade Agreements and the WTO System* (OUP, 2006); F. Hoffmeister, ‘Litigating against the European Union and Its Member States – Who Responds under the ILC’s Draft Articles on International Responsibility of International Organizations?’ in (2010) 21 *EJIL* 723.

<sup>58</sup> Koutrakos, above note 26, p. 185; P. Kuijper & E. Paasivirta, ‘Further Exploring International Responsibility: The European Community and the ILC’s project on responsibility of international organizations’, (2004) 1 *International Organizations Law Review* 111, at 134.

EU exclusive competence, which are dependent on the time EU competence becomes exclusive, rather than the time when an agreement was concluded.

Consequently, EU exclusive competence over the TRIPS Agreement means that the Court of Justice can no longer offer any discretion to Member States to determine the legal effects of the patent provisions of the TRIPS Agreement. The jurisprudence, which the Court developed in *Dior* and *Merck*, cannot be applied any longer in the field of the TRIPS Agreement, although it remains relevant for determining the legal effects of mixed agreements in other fields of shared competence. Hence, the Court of Justice has to decide whether the patent provisions of the TRIPS Agreement have direct effect, and, more importantly, how national laws have to be interpreted in order to secure their consistent interpretation with the TRIPS Agreement.

### **3.3. Determining the legal effects of the TRIPS patent provisions: The *Daiichi Sankyo* case**

The re-determination of the legal effects of the patent provisions of the TRIPS Agreement does not only have doctrinal significance, but has significant practical implications. It presents a topical and pragmatic question, which can have wide consequences for the resolution of patent disputes in the future. In that respect, the *Daiichi Sankyo* case<sup>59</sup> presents a unique opportunity for the Court to clarify its jurisdiction over the TRIPS patent provisions and determine their specific legal effects.

In this case, the claimant Daiichi Sankyo Company Limited holds since 1986 a Greek national patent for a chemical compound that constitutes a new invention and is protected by a supplementary protection certificate for pharmaceutical patents, issued by the Greek IPO in 2006. However, according to Greek patent law the European patents that protected pharmaceuticals and were issued based on applications filed before 7.10.1992 were considered void in Greece and for the same period patents were granted in Greece only for the method of production of pharmaceuticals and not for pharmaceuticals as such.<sup>60</sup> In particular, when Greece acceded to the EPC, it made the reservation provided for in Article

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<sup>59</sup> Above note 10.

<sup>60</sup> Article 167, para 2(a) (OJ EPO 1986, 200), provides that “European patents, in so far as they confer protection on chemical, pharmaceutical or food products, as such, shall, in accordance with the provisions applicable to national patents, be ineffective or revocable; this reservation shall not affect protection conferred by the patent in so far as it involves a process of manufacture or use of a chemical product or a process of manufacture of a pharmaceutical or food product”. This reservation ceased to have effect after 7 October 1992 (OJ EPO 1992, 301).

167 (2)(a) according to which European patents are granted only for the method of production and not for pharmaceutical products as such.

The defendant, DEMO AVEEF, obtained a marketing authorisation from the Greek National Organisation of Pharmaceuticals to place in the Greek market a medicine that contains quantitatively and qualitatively the same active ingredients as Daiichi's patented chemical compound. DEMO AVEEF argued that placing its medicine in the Greek market does not infringe the claimant's patent and supplementary protection certificate, because their patent was issued in 1986 and, hence, according to Greek patent law at the time, it protects only the method of production of the pharmaceutical and not the product as such. However, the claimant argues that such an interpretation of national patent law would be in breach of the prohibition of discriminatory treatment of patent rights as regards fields of technology of Article 27(1) TRIPS, according to which "patents shall be available for any inventions, whether products or processes, in all fields of technology".

Within this context, the national court had to identify the scope of protection offered to pharmaceutical patents granted in Greece before 7.10.1992, the duration of which is stretching after the expiry of the reservation provided for in Article 167(2)(a) EPC. In other words, in cases where the patent was filed to protect the invention of a pharmaceutical, however because of the time of the filing of the application, it protected only the process of manufacture of the pharmaceutical, the question arises whether after the adoption of TRIPS, the patent also protects the pharmaceutical product as such, or whether it still protects only the process of manufacture of the pharmaceutical.

The national court referred the case to the Court of Justice, asking explicitly from the CJEU to identify the legal effects of the patent provisions of the TRIPS Agreement. In its first question, the national court asks if Member States can *still* decide according to national law whether Article 27 TRIPS has direct effect and how it should be interpreted.<sup>61</sup> Hence, the Court of Justice has the opportunity to declare that *Merck Genericos* is not good law for determining the legal effects of Article 27 TRIPS and, as a matter of fact, any other TRIPS provision as well as of the provisions of the Paris Convention incorporated by reference into TRIPS.<sup>62</sup>

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<sup>61</sup> "Does Article 27 of the TRIPS Agreement setting out the framework for patent protection fall 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, and can the national court apply it directly subject to the requirements laid down by national law?"

<sup>62</sup> Article 2(1) TRIPS incorporates articles 1-12 and 19 of the Paris Convention for the protection of industrial property. However, the Paris Convention did not set a harmonised supranational set of norms and principles. With the exception of compulsory licensing requirements, it was restricted to basic principles for securing

By establishing its jurisdiction to decide upon the legal effects of Article 27 TRIPS, the Court will have to answer firstly whether this provision can have direct effect in the Union legal order. Bearing in mind the long-standing case law of the Court of Justice on the direct effect of WTO norms, including TRIPS provisions,<sup>63</sup> it is highly unlikely that the Court reverses its previous jurisprudence and declares Article 27 TRIPS directly applicable. Nevertheless, similar to *Hermes*, *Dior* and the rest of the trademark cases based on the TRIPS,<sup>64</sup> the Court can decide how national law can be interpreted consistently with the TRIPS Agreement.

The importance of the principle of consistent interpretation and the broad powers it confers to the Court in matters of patent law is clearly illustrated by the second question asked by the national court in *Daiichi Sankyo*. More specifically, the national court asks the CJEU to determine the temporal scope of patent protection under the TRIPS Agreement and to identify what is the extent and content of that protection.<sup>65</sup> Hence, if the Court exercises its jurisdiction, and in particular if it answers the second sub-question, it will interpret one of the core provisions of patent law, concerning patentability and the prohibition of discriminatory treatment of patent rights as regards fields of technology. As a result, by exercising its jurisdiction and offering a uniform interpretation of the patent provisions of the TRIPS Agreement, which it is obliged to do according to the principle of consistent interpretation, the Court of Justice can become a new actor influencing the scope of substantive patent protection in the EU.

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readier access to the patent systems maintained by different contracting parties (principle of national treatment, principle of priority and principle of independence).

<sup>63</sup> Above notes 16 and 17.

<sup>64</sup> Above note 34.

<sup>65</sup> “Under Articles 27 and 70 of the TRIPS Agreement, do patents covered by the reservation in Article 167(2) of the 1973 Munich Convention which were granted before 7 February 1992, that is to say, before the above agreement entered into force, and concerned the invention of pharmaceutical products, but which, because of the aforementioned reservation, were granted solely to protect their production process, fall within the protection for all patents pursuant to the provisions of the TRIPS Agreement and, if so, what is the extent and content of that protection, that is to say, have the pharmaceutical products themselves also been protected since the above agreement entered into force or does protection continue to apply to their production process only or must a distinction be made based on the content of the application for grant of a patent, that is to say, as to whether, by describing the invention and the relevant claims, protection was sought at the outset for the product or the production process or both?”

## 4. The implications of a CJEU interpretative jurisdiction over TRIPS on the development of EU patent rules

### 4.1. The lack of harmonisation of EU patent law

Considering the existence of EU patent law, the CJEU observed in *Merck Genericos* that ‘as [Union] law now stands, there is none’.<sup>66</sup> Nevertheless, this does not signify that there are no uniform rules on patents in the EU. All 27 Member States have acceded to the EPC, which established the European Patent Organisation (EPO) and a system of law for granting patents for inventions.<sup>67</sup> Thus, national laws of EU Member States are *de facto* harmonised in the field of patentability and validity but only as regards the grant of patents.<sup>68</sup> Issues of validity and infringement<sup>69</sup> after the patent grant are matters for national law and national courts. So, any national court can declare European patents invalid or having been infringed, but national judgements are valid only in the territory of the country where the court sits.

But even in the fields covered by the EPC, uniformity is not always present. In many instances the EPO, its Board of Appeal and national authorities interpret the EPC and their implementing national patent law in diverging ways.<sup>70</sup> Although national courts are forced into a legal comparative interpretation by taking each other’s case law into practical consideration,<sup>71</sup> many national authorities remain hesitant to analyse each other’s decisions

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<sup>66</sup> *Merck Genericos*, above note 9, para 40.

<sup>67</sup> According to article 1 EPC “The EPO grants patents by a centralised procedure with uniform conditions, but once granted the patents become national and subject to the divergent national laws of EPO-Member States”.

<sup>68</sup> Articles 52-57 EPC.

<sup>69</sup> Such issues are the determination of acts which constitute infringement, the effect of prosecution history on interpretation of the claims, remedies and infringement or bad faith enforcement, equitable defences, the coexistence of a European patent and a national patent for identical subject-matter, ownership and assignment, extension to patent term for regulatory approval. See V. Rodriguez, ‘From National to Supranational Enforcement in the European Patent System’ (2012) 34 *E.I.P.R.* 402.

<sup>70</sup> The implications of such inconsistent interpretation have been apparent for more than two decades, when in the *Epilady* cases courts of five member states found that the patent was infringed and courts in four other Member States ruled otherwise. *Improver Copr. et al. v Raymond Industries Ltd, et. Al.*, (1990). IIC, 21, 561-571, 572-580; 582-585; 586-589; 589-591; 857-859; 860-868 (1992) IIC 23 391-394; 394-397; (1993) IIC, 24, 388-390; 803-804; 832-838; 838-845. For a discussion of these cases see H. Marshall, ‘The Epilady Case and Issues at Stake’, *Enforcement of Intellectual Property Rights and Patent Litigation*, EPO, script vol. 6, Munich, 2002, at 368-428. For a review of the different approaches between the EPO and national authorities see A. Howes, ‘Disaster Pending? EPO v English Court of Appeal on Excluded Subject Matter’, (2008) 08/07 WIPR, at 25-26.

<sup>71</sup> For example, in the UK section 130(7) 1977 UK Patent Act (as amended) instructs judges in the UK to construe certain provisions “as nearly as practicable [to have] the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention, the Community Patent Convention and the Patent Co-operation Treaty have in the territories to which those Conventions apply”. In Germany, the German Federal Supreme Court held in *Walzenformgebungsmaschine* (BGH, Xa ZB 10/09, 15/04/2010), that German courts are

and pursue a uniform interpretation, thus leading to contradictory outcomes and fragmentation.<sup>72</sup> In other cases, it is the differences in legal traditions and policy choices that lead to different results, despite acknowledgement of foreign contradicting decisions.<sup>73</sup> Finally, practicalities such as different evidence, experts or legal argumentation used in different jurisdictions may lead to contradictory decisions.<sup>74</sup>

The lack of uniform interpretation of patent law and the absence of a common European litigation scheme to deal with infringement and validity of patents has significant undesirable implications. Patentees and their competitors end up litigating the same case in several jurisdictions, under different procedural and evidentiary rules with uncertain timing of outcomes. This is not only costly for rightholders, even to a prohibitive extent for medium sized enterprises, but also for Member States, as multiple proceedings and conflicting decisions can arise. The inconsistencies regarding the interpretation of harmonised patent law and the differences among the national patent litigation systems lead to forum shopping, with the injustices that this may bring, and, more importantly, create legal uncertainty within the internal market, thus influencing business decisions relating to licensing, investments, production and marketing of patented products.

#### **4.2. The prospects for a EU Patent with Unitary Effect and a Unified Patent Court**

Given the economic significance of patents and the problems that arise from the current regime, it is not surprising that an EU patent system has been debated since the 1960s.<sup>75</sup> What

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required to consider decisions of the EPO and other national courts and where appropriate address the reasons leading to a diverging result in the earlier decisions.

<sup>72</sup> Indicatively see *Novartis AG and Cibavision AG v Johnson & Johnson Medical Ltd and other* (2009/2010) (courts in France and the Netherlands found the patent valid, whereas courts in the UK and Germany found otherwise). In *Document Security System v European Central Bank*, the patent was upheld in Germany, the Netherlands and Spain, while was invalidated in the United Kingdom ([2008] EWCA Civ 192 (19 March 2008)), Austria, Belgium and France (Court of Appeal, Paris, France, 17 March 2010, Case No. 08/09140). In *Angiotech Pharmaceuticals v Conor Medisystems, Inc.* the Dutch court invalidated the patent, (2007/101 BIE), whereas the UK House of Lords found otherwise ([2008] UKHL 49). In *Muller v Hilti* the German courts decided that the European patent was not infringed, whereas the Swiss and French courts decided otherwise. See also Rodriguez, above note 69, at 403-404; S. Luginbuehl, *European Patent Law; Towards A Uniform Interpretation*, (Edward Elgar, 2011) at 3-6.

<sup>73</sup> Indicatively see the debate concerning the exclusion from patentability of computer programs ‘as such’ *Aerotel Ltd v Telco Holdings Ltd and Macrossan’s Application* [2006] EWCA Civ 1371; T0154/04 Duns Licensing Associates/Method of estimating product distribution (15 November 2006).

<sup>74</sup> For example Lord Justice Jacob stated that “Coherence of the EPS requires that as far as possible different courts should try to follow each other [...] Of course, this is not so if the cases turn on different points (e.g. different prior art) or different evidence” *Unlin Beheer BV b Berry Floor NV*, [2007] EWCA Civ 364; [2007] Bus. L. R. 1140 at 36.

<sup>75</sup> In 1959 Hans von der Groeben proposed to create a common system of patent law of the European Economic Community. Since then, many legislative initiatives have taken place: 1975 Convention for the European Patent

is surprising is that all the proposed plans have foundered due to disagreements over translations and jurisdictional arrangements.<sup>76</sup> Of course, the lack of success in patent harmonisation may also be attributed to the success of the EPO in terms of sheer numbers of patent applications filed.<sup>77</sup> Nonetheless, as indicated above, a Union patent system which could deliver lower costs, legal uniformity, certainty, efficiency and elimination of forum-shopping is needed.

Currently renewed efforts have been made to establish a European Patent with Unitary Effect (EPUE)<sup>78</sup> and a single system for patent litigation as well as a Unified Patent Court.<sup>79</sup> Without engaging into a detailed analysis of the proposed system, which takes the form of enhanced cooperation in 25 out of 27 Member States, it is worth pointing out that in its current form the proposal does not guarantee the establishment of truly uniform rules.<sup>80</sup>

Firstly, important substantive issues are left outside of the scope of the proposed Unified Patent Protection.<sup>81</sup> The proposed Uniform Patent Protection Regulation (proposed

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for the Common Market (i.e. Community Patent Convention); Protocol on the Settlement of Litigation Concerning the Infringement and Validity of Community Patent, OJ 1989, L 401/34; Green Paper of 24 June 1997, “Promoting Innovation Through Patents – Green Paper on the Community Patent and the Patent System in Europe”, COM(1997) 314 final; Communication from the Commission of 5 February 1999, “Promoting Innovation Through Patents – Follow-up to Green Paper on the Community Patent and the Patent System in Europe”, COM(1999) 42 final; Proposal of 1 August 2000 for a Council Regulation on the Community Patent, COM(2000) 412 final, OJ 2000, C 337/278; Council doc. No.16133/09 Add. 1 of 27 November 2009, Proposal for a Council Regulation on the Community Patent – General Approach.

<sup>76</sup> Indicatively see the comments of the Max Planck Institute for Intellectual Property, Competition and Tax Law on the 2009 Commission Proposal for the Establishment of a Unified Patent Judiciary, 40 *IIC* 81 (2009). O. Bossung, ‘Rückführung des europäischen Patentrechts in die Europäische Union’ (1995) *GRUR Int.* 923; O. Bossung, ‘Unionspatent statt Gemeinschaftspatent – Entwicklung des europäischen Patents zu einem Patent der Europäischen Union’, (2002) *GRUR Int.* 463; T. Jaeger, ‘The EU Patent: Cui Bono et Quo Vadit?’, (2010) 47 *CMLR* 63; H. Ullrich, ‘National European and Community Patent Protection: Time for Reconsideration’ in A. Ohly & D. Klippel (eds.) *Geistiges Eigentum und Gemeinfreiheit* (Mohr Siebeck, 2007), at 61; H. Ullrich, ‘Patent Protection in Europe: Integrating Europe into the Community or the Community into Europe’, (2002) 8 *Eur. L. J.* 433.

<sup>77</sup> Only in 2011 there were 244,447 applications and 62,112 patents granted. EPO Annual Report 2011, available at <http://www.epo.org/about-us/office/annual-report/2011/statistics-trends.html>.

<sup>78</sup> Proposal for a Regulation of the European Parliament and the Council implementing enhanced cooperation in the area of the creation of unitary patent protection of 13 April 2011, COM (2011) 215 final, as revised by “Presidency compromise text”, Council, Doc. 11831/11 (Presse 184, PR CO 45).

<sup>79</sup> Draft agreement on a Unified Patent Court and draft Statute - Revised Presidency text, Document no 16741/11, Council of the European Union, Brussels, 11 November 2011, available at: <http://register.consilium.europa.eu/pdf/en/11/st16/st16741.en11.pdf>. Draft Agreement on the Creation of a Unified Patent Court – Guidance for future work, Doc. 17539/11 of 24 November 2011 (Henceforth Draft UPC Agreement).

<sup>80</sup> For a description and critic of the processes that led to this initiative see T. Jaeger, ‘All back to square one? An Assessment of the latest proposals for a patent and court for the internal market and possible alternatives’, (2012) 43 *IIC* (forthcoming); M. Lamping, ‘Enhanced Cooperation – a proper approach to market integration in the field of unitary patent protection?’ (2011) 42 *IIC* 879, Luginbuehl, above note 72, at 185-192.

<sup>81</sup> For an elaborate analysis see H. Ullrich, ‘Harmonizing Patent Law: The Untamable Union Patent’, in M. Chr. Janssens & G. Van Overwalle (eds.), *Harmonization of European IP Law. From European Rules to Belgian Law and Practice*, (Bruylant, 2012) (forthcoming).

UPP Regulation)<sup>82</sup> contains substantive rules on the unitary effect of the patent,<sup>83</sup> the definition of infringing acts,<sup>84</sup> the limitation to protection<sup>85</sup> and the principle of exhaustion.<sup>86</sup> However, it does not address the issues of prior user rights, or the unitary patent as an object of property (assignments, voluntary licenses)<sup>87</sup> as well as compulsory licenses and government use.<sup>88</sup> Different prior user rights under national law are important for process inventions and for balancing the patent system,<sup>89</sup> whereas 25 national laws determining the requirements for assignments and licenses, the effects on existing licenses, the admissibility of restricted licenses and the legal quality of such restrictions could impose a substantive burden on trade and competition.<sup>90</sup> Moreover, it would be practically impossible to obtain compulsory licenses covering the territory of enhanced cooperation, given that interested market actors would have to go through different national systems. Besides, any compulsory license granted under national law could be at odds with the proposed UPP regulation, since compulsory licenses affect the very essence of IP rights.

Secondly, in parallel to the EPUE, for which infringement, limitations and its exhaustion will be harmonised under the current scheme, there will be three other types of patents within the Union. These are the national patents, the “old” European patents granted by the EPO, for which the parties wish to keep a bundle of national patents,<sup>91</sup> and the European patents granted by the EPO, which do not have a unitary effect. The latter patents will consist of territorially fragmented national rights, which are harmonised as to the conditions of their grant, the substance and the scope of exclusivity they confer upon their owner.<sup>92</sup>

Thirdly, with Spain and Italy not participating in the enforced co-operation, the European Union is partitioned in three territories. Two Member States are excluded from the

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<sup>82</sup> Proposal for a Regulation implementing enhanced co-operation in the area of the creation of unitary patent protection of 13 April 2011, COM(2011) 215 final, as revised by a “Presidency compromise text” of 23 June 2011, see Council Doc. 11328/11 as agreed upon on 27 June 2011, see Council, Doc. 11831/11 (Presse 184, PR CO 45) (henceforth Proposed UPP Regulation).

<sup>83</sup> Article 3 Proposed UPP Regulation.

<sup>84</sup> Articles 6 and 7 Proposed UPP Regulation.

<sup>85</sup> Article 8 Proposed UPP Regulation.

<sup>86</sup> Article 9 Proposed UPP Regulation.

<sup>87</sup> Article 10 Proposed UPP Regulation.

<sup>88</sup> Recital 9a Proposed UPP Regulation.

<sup>89</sup> Different prior user rights contribute to lowering the social costs of the grant of an absolute exclusivity, whose purpose (i.e. the stimulation of innovation) has already been accomplished by the prior user. See Ullrich, above note 81, fn. 111.

<sup>90</sup> Ullrich, above note 81, at 36-37.

<sup>91</sup> See Article 58 (3) Draft UPC Agreement, which establishes an opt out route for European patents existing at the time of the entry into force of the Agreement.

<sup>92</sup> Article 14f-14i Draft UPC Agreement subjects patents granted by the EPO to a uniform law of patent infringement.

development of patent policy, thus not comprising the internal market as such. It only shifts the national borders and thus the effects of territorial segmentation remain. Although enhanced cooperation has been achieved in the past in other fields of EU law, the internal market has always been a field where legislative initiatives applied to the entire territory of the EU. Next to the issues of legality concerning the procedure of enhanced cooperation,<sup>93</sup> the lack of enhanced cooperation in the internal market can be explained by the fact that it creates an additional threat for economic, social and territorial cohesion in the internal market, it constitutes a barrier to or amount to discrimination in trade between Member States and may distort competition.

As a result, the proposals regarding the EPUE and the UPP are not able to achieve complete harmonisation in the field of patent law, at least in their current form. Besides, given the technical and political complexities surrounding this field, it is still unclear if and when legislation will actually be approved.<sup>94</sup>

#### **4.3. The role of the CJEU in the harmonisation of patent law in the EU**

The interpretative jurisdiction of the CJEU over the TRIPS agreement plays a crucial role for filling in the gaps that the creation of the EPUE introduces and ensuring common standards for different types of patent rights in the EU. While the political issues surrounding the establishment of a unified patent court are being debated, the TRIPS agreement and Article 207 TFEU provide the CJEU with the opportunity to establish uniform rules on patent protection in the EU. Although it cannot contribute to the reduction of litigation costs, at least initially, the CJEU's jurisdiction over TRIPS provisions can promote legal certainty, and the establishment of uniform and comprehensive patent protection in the EU that would be attractive to the industry and conducive to technological progress.

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<sup>93</sup> Lamping, above note 80, at 884; Jaeger, above note 80, at 4-6.

<sup>94</sup> Supposedly, the only remaining obstacle is the decision on the seat of the Unified Patent Court ([http://www.europarl.europa.eu/pdfs/news/expert/infopress/20111219IPR34540/20111219IPR34540\\_en.pdf](http://www.europarl.europa.eu/pdfs/news/expert/infopress/20111219IPR34540/20111219IPR34540_en.pdf)) However, it appears that there are further open political matters (See indicatively the discussions at the UK House of Commons European Scrutiny Committee, available at <http://www.publications.parliament.uk/pa/cm201012/cmselect/cmeuleg/uc1799i/uc1799ii.htm>, Confederation of Swedish Enterprise Letter to Sweden's Prime Minister, 11 June 2012, available at: [https://docs.google.com/file/d/0B\\_U9nV8-MjxrSFBiemZmdEp1MkE/edit?pli=1](https://docs.google.com/file/d/0B_U9nV8-MjxrSFBiemZmdEp1MkE/edit?pli=1).) The 3169th meeting of the Council of the EU in Competitiveness configuration (Internal Market, Industry, Research and Space) held in Brussels on 31 May/1 June 2012 failed to end the process of drafting and implementing a unified European patent infrastructure. The final result was that the decision on the seat of the central division of the EU Unified Patent Court is said to be taken by the European Council at its meeting on June 28 and 29, 2012.

Indeed, the TRIPS Agreement standardises substantive patent law and procedures for its enforcement. It has been argued that “the result [for the patents provisions of the TRIPS Agreement] is impressive, in that the scope and coverage of the section are comprehensive, and makes TRIPS the most important multilateral statement in this field”.<sup>95</sup> The TRIPS Agreement defines patents, albeit indirectly, it introduces a non-discrimination principle and sets a general restriction to the general principle of eligibility to be patented, as well as more “focused” exceptions.<sup>96</sup> Article 29 introduces the “person skilled in the art” test for the satisfaction of the disclosure requirement. More importantly, the agreement also delineates the rights conferred to product patents and process patents<sup>97</sup> and introduces a general exception<sup>98</sup> and a list of specific exceptions (compulsory licences)<sup>99</sup> to the exclusive rights of patent owners. It also provides a relative freedom to transfer or assign patent rights,<sup>100</sup> it requires that any decision to revoke or forfeit a patent must be subject to judicial review<sup>101</sup> and sets the minimum term of protection.<sup>102</sup>

Of course, the TRIPS Agreement is a minimum standards agreement that aims at harmonising the national laws of the WTO Members, yet without establishing uniform rules.<sup>103</sup> It has left many legal concepts undefined, which naturally leaves gaps to be filled by national legislation. Article 27(1), for example, states that “[p]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application”, without defining “novelty”, or what constitutes an “invention”. In that respect, WTO Members have latitude in determining the appropriate method of implementation, within TRIPS parameters.

Despite the broad flexibilities and minimum standards approach taken in the TRIPS agreement, it can contribute significantly to patent harmonization in the EU. First, although the TRIPS agreement is very broad as regards the subject matter of patent protection, it contains specific rules on prior users’ rights and exceptions, including in particular compulsory licenses, which are subject matters left outside the scope of the UPP Regulation. As Article 1 TRIPS requires that WTO members “give effect” to its provisions, which

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<sup>95</sup> D. Gervais, *The TRIPS Agreement, Drafting History and Analysis*, (Sweet& Maxwell, 2010), at 336-337.

<sup>96</sup> Article 29 TRIPS.

<sup>97</sup> Article 28 TRIPS. Article 38 TRIPS is also designed to allow the enforcement of process patents, or a process claim in a patent covering both a product and a process, in cases where direct evidence of the use of the patented process is not available.

<sup>98</sup> Article 30 TRIPS.

<sup>99</sup> Article 31 TRIPS.

<sup>100</sup> Article 28 TRIPS.

<sup>101</sup> Article 32 TRIPS.

<sup>102</sup> Article 33 TRIPS.

<sup>103</sup> Article 1(1) TRIPS.

signifies that a WTO member should take all reasonable measures to ensure consistency between domestic law and the agreement,<sup>104</sup> the CJEU can use its interpretative jurisdiction to establish common minimum rules with regard to the subject matters that were left outside the scope of harmonization in the context of the EPUE.

Secondly and more importantly, the jurisdiction of the CJEU to interpret TRIPS provisions uniformly across the EU can contribute to minimum harmonisation of different types of patent rights. More specifically, the Court's interpretative jurisdiction can result in the establishment of minimum, uniform standards of protection for EPUEs, national patents, as well as European patents granted by the EPO without unitary effects. As the Court held in *Hermes* and *Dior*, "where a provision can apply both to situations falling within the scope of national law and to situations falling within the scope of [Union] law, it is clearly in the [Union] interest that, in order to forestall future differences of interpretation, that provision should be interpreted uniformly, whatever the circumstances in which it is to apply."<sup>105</sup> Considering that the UPP Regulation will be part of Union law, the Court of Justice can employ the TRIPS agreement in order to determine the standards of protection under national and EPO-granted patents by reference to the standards of protection of EPUEs, so as to ensure uniform implementation of the TRIPS agreement in the EU.

In addition, the CJEU can mitigate the danger that arises from the existence of parallel adjudication regimes for patent protection. The establishment of the Unified Patent Court with jurisdiction over EPUEs, but not over the infringement of national or EPO-granted patents without unitary effect<sup>106</sup> may actually result in competition among jurisdictions. The Unified Patent Court and national courts will be aware that in reaction to their rulings, parties may switch to the patent system "run" by the court giving the more "desirable" rulings.<sup>107</sup> At a first glance such judicial competition cannot be remedied by the CJEU, as it will hold competence over matters related to the EPUEs,<sup>108</sup> but cannot review national laws on patent infringement given the lack of harmonising secondary legislation. Nevertheless, by allowing the CJEU to determine whether national courts abide by the TRIPS when they adjudicate patent infringement cases, the CJEU can act as the single, ultimate judicial authority in the EU, ensuring coherence and consistency in the interpretation of the different regimes of patent infringement rules.

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<sup>104</sup> Gervais, above note 95, at 163.

<sup>105</sup> Above note 31.

<sup>106</sup> Articles 3 and 15 Draft UPC Agreement.

<sup>107</sup> Ullrich, above note 81.

<sup>108</sup> Article 14b Draft UPC Agreement.

Consequently, the CJEU's interpretative jurisdiction over the TRIPS can constitute a significant tool in the process of establishing a complete and uniform framework for patent protection in the EU. Despite the minimum standards approach of the TRIPS agreement, the CJEU can use its interpretative jurisdiction in order to fill in the gaps that the recent initiatives left open and ensure coherence and consistency in the application of the different regimes of patent protection in the EU.

## 5. Conclusions

The road towards uniform patent protection in the EU is filled with traps. In the past two decades EU institutions and Member States have been unable to present a simple, efficient and appropriate legal framework providing sufficient and effective patent protection in the EU. The recent initiatives for the establishment of EPUEs and a Unified Patent Court merely reflect and multiply the legal complexities concerning patent protection in the EU.

In that respect, the first trap lies in the determination of the actors and sources of law relevant for patent protection in the EU. In addition to the existing (and proposed) layers of patent protection, it is necessary to consider the CJEU's interpretative jurisdiction over the patent provisions of the TRIPS agreement. The establishment of EU exclusive competence over commercial aspects of IP under Article 207 TFEU brings the TRIPS agreement within the scope of Union law, irrespective of the existence of secondary Union rules on patent protection. As a result, the Court of Justice can no longer offer any discretion to Member States to determine the legal effects of the patent provisions of the TRIPS Agreement, and its jurisprudence under *Dior* and *Merck* cannot be applied any longer in the field of the TRIPS Agreement. In that respect, the CJEU acquires significant powers to determine whether national (and in the future Union) patent rules are to be interpreted consistently with the TRIPS.

The second trap lies in the proper identification of the impact of the CJEU's interpretative jurisdiction over TRIPS on patent law harmonisation. On the one hand, it would be at least naïve to consider that the creation of the EPUE and the Unified Patent Court result in uniform patent protection in the EU, thus rendering the CJEU's interpretative jurisdiction over TRIPS obsolete. Even if the new patent protection and litigation system is successful, the existence of multi-layered and multi-jurisdictional patent protection can result in inconsistencies and fragmentation, which the CJEU can remedy via the use of its

interpretative jurisdiction over the TRIPS. On the other hand, the power to interpret the TRIPS is not a panacea. It does not result in the establishment of uniform substantive rules, as the TRIPS is a minimum standards agreement, while its success depends on the number and subject matter of the actual cases that will reach its jurisdiction under the preliminary reference procedure.

Recognising the constitutional function of the CJEU within the EU legal order, the CJEU's interpretative jurisdiction over the TRIPS rather presents a valuable tool in ensuring coherence and consistency in the application of the different regimes of patent protection in the EU.