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# Patenting in Europe: The Jurisdiction of the CJEU over European Patent Law

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## Abstract

This paper will deal with EU competence over patent law, especially in the context of the TRIPS Agreement with reference to the ruling of CJEU in the Daiichi Sankyo case (CJEU case C-414/11 Daiichi Sankyo v DEMO Anonimos). The first part will explain the process of claiming patents at the national as well as the European level in order to understand the complexity of patent law, the second part will deal with the implications of jurisdiction and developments in EU patent regulations, the third part will deal with the effects of EU competence over the TRIPS patent provisions and the fourth part will deal with the interpretation of substantive patent law in the light of the Daiichi Sankyo case.

## Key-words

Substantive patent law, EU competence, TRIPS Agreement



## 1. Patenting inventions in the EU – national and European approaches

The protection and enforcement of intellectual property rights are crucial for Europe's ability to stimulate innovation and compete in the global economy; intellectual property rights are key means through which companies and inventors generate returns on their investment in knowledge, innovation and creativity. A recent study has estimated that IPR-intensive sectors account for around 39% of the EU's GDP (EPO Industry Level Analysis Report: 2013) while 90% of the EU's trade with the rest of the world is related to European intellectual property intensive industries. Knowledge-based industries play a core role in the 'Global Europe' (COM (2006) 567 final) and 'Europe 2020' (Horizon 2020) strategies.

The European Charter of Fundamental Rights states that intellectual property shall be protected, meaning that the EU therefore recognizes its responsibility for protecting the IP rights of its citizens (Art. 17(2) Charter of Fundamental Rights). The protection of IP rights in the context of the establishment and functioning of the internal market is also envisioned in article 118 of the TFEU. Furthermore, article 207 (1) of the TFEU states that the common commercial policy of the EU is based on uniform principles including, among others, the commercial aspects of intellectual property rights. Common commercial policy is conducted in the context of the principles and objectives of the Union's external actions. According to Article 262 of the TFEU the Council may adopt provisions to confer jurisdiction on the Court of Justice of the European Union in disputes relating to the application of acts on the basis of treaties which create European intellectual property rights.

The EU's competence to create European intellectual property rights thus comes within its shared competence with the Member States for matters relating to the internal market (C- 274/11 Kingdom of Spain v Commission). So far the EU has adopted Union wide legislation on patent law only for Biotechnological inventions (Directive 98/44/EC), and on the enforcement of intellectual property rights. Although the patent law provisions are in most part harmonized within the EU, the CJEU has so far been reluctant in dealing with the interpretation of substantive provisions of patent law in regards of patentable subject matters as quite often the Union hasn't legislated in the area.



Currently, the EU does not provide for a unified EU-wide patent protection, nor does it have at its disposal any legal mechanisms, or the judicial infrastructures, to counteract the fragmentation of the internal market, owing to the diverging interpretation of the scope of protection of European patents in national courts (Straus 1996). At the moment, obtaining patents in all different fields of technology within Europe is governed outside the EU legal framework, by the European Patent Convention (Aerts 2014: 88). Both EU and non-EU Member States are the contracting parties to the convention.

In order to understand the complexity of patent law and how it fits within the competence of the EU, it is useful to explain how patents are obtained inside the Union. Bearing in mind that there is no such thing as a European patent then it means that although the European Patent Office (EPO) is responsible for doing the patent search as well as technical analysis of the patent subject (for European patent applications), the patent granted has, in the later stage, to be validated in selected EU Member States in order to take effect and therefore an European patent eventually becomes just a bundle of national patent rights enforceable according to national legislation of a specific jurisdiction.

Therefore, the fundamentally autonomous procedures for the granting of European patents, is linked to the national patent law of the Member States of the European Patent Organization, and at a number of stages it interfaces with the national legal systems (Herwig et al. 2011: 89). Patent applications can be applied for either nationally, regionally (European patents under European Patent Convention - EPC) or internationally (under Patent Cooperation Treaty - PCT). It means that different rules apply for each case. In most countries in case of national patent applications, the local patent office performs patent searches as well as technical analysis. But since EU Member States operate on different systems of viewing patent applications, respectively either using the system of registration like in Latvia, Lithuania, Macedonia or examination system like Estonia, Norway, Sweden then it means that the criteria for assessing patentability vary quite significantly among the Member States. In consequence, where there is no provision for the requirement to perform examination in countries where the registration system exists, patents are thus granted only if formal requirements are met, while novelty and inventive step is not evaluated at all. Furthermore, legislation for procedures is also different, for example the grace period before filing date (any act that makes an invention available



before the filing date or priority date, has the effect of barring the invention from being patented).

According to the provisions of the EPC, national courts are competent to decide on both the infringement and validity of European patents. In practice, this gives rise to a number of difficulties: high costs, time factor, diverging court decisions and thus an overall lack of legal certainty. Forum shopping is also inevitable. In consequence, despite patent law being in most part harmonized in the Union, differences in interpreting legal norms as well as procedural laws exist( for example the availability of interim injunctions in a specific jurisdiction, presenting evidence and proving its case) and therefore create different outcomes for patentees as well as for third persons.

Traditionally, patent law has always enjoyed national treatment, first established in the Paris Convention, as Member States of the Convention are free to determine the scope of patentability, subject matter and procedures (Art. 2 Paris Convention). Patent law has a national character, and even in case of issuing an European (regional) patent for a subject matter, the European patent (regional) has to, as mentioned already, be validated in selected Member States. As long as formal requirements are fulfilled, the patent eventually ends up being a national patent, its enforceability being governed by the independent laws of the numerous contracting states (Zekos 2006: 426).

The national characteristic of patent law is also evident in different provisions of the EPC, for in each of the contracting states for which the European patent is granted, this has the effect of, and is subject to, the same conditions as a national patent granted by that state, unless otherwise provided in the EPC (Art. 2(2) EPC). Under Article 67(1) EPC, European patent application provisionally confers on the applicant the same rights as would be conferred by a national patent granted in those states. In addition, the European patent can only be revoked under the laws of a contracting state on certain grounds (specified in EPC Articles 138 and 139) with effect only in that State.

The same principle is evident in a CJEU judgment where the court said that a European patent continues to be governed, (as Articles 2(2) and 64(1) of the EPC), by the national law of each of the contracting states for which it has been granted. By the same token, any action for infringement of a European patent must, as is apparent from Article 64(3) of that convention, be examined in the light of the relevant national law in force in each of the states for which it has been granted. European patents, once conferred,



basically become a bundle of national rights, where disputes have to be solved by national courts of the contracting states (COM (2011) 287 final). The patent opposition procedure of the European patent is therefore the only exception to the rule that, after the grant of a patent, the right becomes a bundle of national rights; the opposition procedure (reviewed by the Boards of Appeal of EPO) is a centralized procedure for the evaluation of validity of a European patent directly after grant, thus affecting the patent right in all EU Member States (Aerts 2014: 88-89).

National patents, whether or not granted by EPO, continue to be subject to the Brussels I Regulation regarding rules assigning jurisdiction (Cook: 2012, 569). This means that under the EPC patents, either national or regional (EU), are enforced at national level, on per-country basis. Furthermore, the European Court of Justice held that European patents are national rights that must be enforced nationally, that it was unavoidable that infringements of the same European patent have to be litigated in each relevant national court, even if the lawsuit is against the same group of companies, and that cross-border injunctions are not available (C-4/03 *Antriebstechnik v Lamellen*; C-539/03 *Roche v Primus*).

The national treatment principle is also present in article 3 of the TRIPS Agreement as well as the Paris Convention. The applicability of national law also derives from article 8 of Regulation (EC) 864/2007 regarding the laws applicable to non-contractual obligations in the context of intellectual property rights. When viewed from the practice standpoint, it could be stated that, despite the existence of international agreements, the states still have certain discretion in applying national patent law in local patent offices when going through with actual patent applications in every day practice. Such national competence is especially evident for national patent applications when each country continues to conduct separate patent examinations (Webster et al. 2012: 6).

The whole picture may change when the Unified Patent package enters into force, as alongside the Unified Patent national as well as regional European patents will continue to exist. Therefore, in order to seek for protection in the EU, the applicant will have options to either apply separately for the national patent in every Member State of interest, or as a second option, for the European (regional) patent, and then have it validated as is the currently existing option, or as a third option, have the patent validated as an Unified Patent, or as the last option to apply for the Unified Patent and have it later validated in



EU Member States that are not part of the Unified Patent package. Still, even in case of applying for the European Unified Patent, it will not be granted if the set of patent claims differ between the Member States where they were applied for and the Unified Patent it would create significant risks considering that Unified Patent system works on the all-or-nothing principle.

Also, as the national patent claims and regional European patents will remain to exist alongside the Unified Patent system, there is a concern that it will affect dispute settlement and jurisdiction issues because the Unified Patent Court will not have any jurisdiction over national patent disputes, or over disputes involving non-Members of the Unified Patent package. Therefore, in extreme situations, when the infringement claim for example involves identical patent claims granted on national level, regional level as well as under the Unified system in three different countries, then it could very well mean that the jurisdiction will fall within the competences of the CJEU, the Unified Patent Court as well as the national court.

Enhanced cooperation in the area of unified patent protection is aimed at fostering scientific and technological advance and the functioning of the internal market. In other words, it furthers the objectives of the Union, protects its interests and reinforces its integration process in accordance with article 20(1) of the TEU (C- 274/11 Kingdom of Spain v Commission). In the context of this unified patent scheme, the EPO has been entrusted with the task of granting unified patents, if the system eventually takes effect. It is also foreseen that the EPO will be in charge of centrally administering the unitary patent, levying the annual renewal fees and distributing them to the participating EU Member States. The role of EPO will still remain in question considering that in the current state of affairs it is not linked to the EU.

## **2. The implications of jurisdictions and developments in EU patent regulations**

Substantive patent law relates mainly to acts of direct or indirect infringement. In this regard, simple judicial cooperation and discussions alone cannot avoid contradictory interpretations of European patent law as there is a lack of uniform rules of interpretation throughout Europe (Luginbuehl 2011: 137). As already mentioned, according to the EPC



art 2 (2) and article 64 (1) the grant of European patents falls in the competence of national laws. Following this logic, all cases of patent infringements, should also be dealt by national laws that established the legal basis for granting a patent in a specific territory in the first place. Therefore, substantive patent law should, by deduction from the same logic, also be interpreted according to national laws. Article 16(4) of the Brussels I Regulation provides for exclusive jurisdiction of national courts in proceedings concerned with the registration or validity of patents (van Engelen 2010).

As for European patent claims, according to articles 1 and 2 of the Protocol on Jurisdiction and the Recognition of Decisions in respect of the Right to the Grant of a European Patent, the courts of the Contracting States shall, in accordance with Articles 2 to 6, have jurisdiction to decide claims, against the applicant, to the right to the grant of a European patent in respect of one or more of the Contracting States designated in the European patent application. From the logic of article 16(4) of the Brussels I Convention, one could therefore deduct that the exclusivity of national competence extends not only to infringement cases, but also to the claims regarding challenges to patent registration and validity. Just as a remark, needless to say, the grounds for challenging validity and infringement claims have different grounds.

In *GAT v LuK*, the CJEU held that Article 16(4) of the Brussels Convention is to be interpreted as providing exclusive jurisdiction to the courts of the territory of registration in all matters concerning the validity of a patent, irrespective of how such issue is raised. Any proceedings which relate to the validity of the patent may only be heard by the courts in the territory in which the patent is granted (*C-4/03 Antriebstechnik v Lamellen*). In addition the exclusive national jurisdiction provided for by that provision should apply whatever the form of proceedings in which the issue of a patent's validity is raised. Considering that for challenging the validity of European patents in pre-and post-grant proceedings under the provisions of EPC, there is no principle of binding case law (*EPO T- 1099/06, Max-Planck-Gesellschaft v BASF*) then it means that the binding effect of the EPO's Boards of Appeal decisions is extremely limited.

A patent held to be valid by the EPO in respect of some or all of the claimed subject matter can still be attacked at the national level. Furthermore, the national challenges of patent validity can be brought before the national court despite the limitation of the 9 month time period foreseen for challenging validity claims for European patents granted



by EPO, meaning that the national litigation on validity can, in principle, take place in parallel to the EPO claims. It is important to point out though that as a general principle, the EPO's decisions should enjoy primacy before national patent decisions while national decisions regarding patentability should have no effect on future application procedures at EPO. Both applications either under PCT or EPC can be made directly without applying for a national patent first, and in regards of a European patent then in the case of invalidation in one of the Member States, it still remains valid in others.

The validity claim of a patented subject matter made in national jurisdictions should be contested in the place of patent registration. While the EPO centralized procedure is without any doubt the cheapest and fastest way to challenge patent grant (around half the price compared to litigation in each EPC contracting state separately), as opposed to challenging the validity at the national level, it has a time limit (Thomas et al. 2014). At the same time, both the litigation and the EPO procedures for challenging the validity are time consuming, usually taking around 5 years before the final decision is reached. In the context of patent rights, it certainly has a crucial significance as the economic situation is in constant flux.

In this context, it is interesting to point out the characteristic of European patent law meaning that national patents may actually co-exist alongside European patents, thereby simultaneously falling under the same jurisdiction. For example it may occur in a situation mentioned in article 139(3) of the EPC: Any Contracting State may prescribe whether and on what terms an invention disclosed in both a European patent application or patent and a national application or patent having the same date of filing or, where priority is claimed, the same date of priority, may be protected simultaneously by both applications or patents.

In an era in which intellectual property rights are still for the most part national rights – and a proprietor mostly owns a bundle of national intellectual property rights instead of one supranational IP rights– having to deal with an infringement in multiple jurisdictions still means litigation might be needed in a great number of countries to enforce intellectual property rights within the European Union (Cook 2012: 596). The comprehensive and exclusively applicable set of rules of the Brussels Convention should be applied by the national courts in an uniform way and, in order to ensure uniformity of the judgments, the Contracting States to the Brussels Convention agreed in the Luxembourg Protocol of June 3, 1971, that the supreme courts of the Contracting States can submit questions of



interpretation to the European Court of Justice for preliminary rulings (Mayss 1998: 230-237).

As already mentioned, cases related to infringements of patent rights also fall in the competence of national courts. Under Article 64(3) of EPC, any infringement of a European patent shall be dealt with by national law, with the EPO having no legal competence to deal with, and to decide on patent infringements, in the Contracting States to the EPC. It means that patent infringement of both national and European Patents are dealt with by national courts. There is currently no avenue of appeal from the EPO to the CJEU directly.

In the same way as for the cases dealing with patent infringement in the context of multiple locations, the EU patent cannot be disputed in a centralized manner but every infringement case (although potentially being identical) has to be sued in every single territory separately and therefore is dealt with national jurisdiction. For example, The CJEU ruled in *Roche v Primus* that a patentee cannot rely upon Article 6(1) of the Brussels Convention to bring proceedings for infringement of a European patent against defendants incorporated in other Contracting States, even where such defendants are connected by being part of the same group, and have acted in an identical or similar manner in accordance with a common policy conceived by one of them (C-539/03 *Roche v Primus*).

From the patent owner's perspective, such multiple claims are not only costly but also time consuming, and also different procedural rules are applied meaning that the same case might end up with contradictory judgments in every national jurisdiction. The Court has held that for Article 6(1) of the Brussels Convention to apply there must exist, between the various actions brought by the same plaintiff against different defendants, a connection of such a kind that it is expedient to determine the actions together in order to avoid the risk of irreconcilable judgments resulting from separate proceedings (C-616/10 *Solvay v Honeywell*).

However, in order to determine whether there is a likelihood of contradiction, it is not sufficient that there might be a divergence in the outcome of the dispute, because the divergence must also arise in the context of the same situation of law and fact. Therefore, there must be a close connection between the claims, and even if it is targeted against the same defendants in all states or in case of different defendants, still dealing with the same type of infringement, it is not enough to tie the cases together.



As a general rule applicable to patent infringement claims, according to the Brussels Convention article 2, the case should fall in the competence of the court where the defendant is domiciled. As patent litigation is usually linked to legal entities then it may create not only confusion but also a chance for forum-shopping, as for legal entities the place of domicile can be defined very differently among Member States. The whole picture becomes foggier when dealing with a litigation involving a branch of the main business or in case of multiple co-defendants. For example, under current circumstances it could very well happen that an American company holding a European patent that is validated in Germany, England and the Netherlands may sue the infringer domiciled in France, for a patent infringement occurred in Germany, in the Netherlands national court. It gets even more confusing in cases related to tort or delict as according to article 5 of the Brussels Convention the case should be reviewed in the jurisdiction where the harmful event occurred. The problem is that this concept can be interpreted in either being a place where the harmful event actually occurred or the place that gave rise to the harmful event.

Also, from the patentee's perspective, other determinants that could affect the final outcome of the case should be taken into account when calculating where to bring the action to court, such as the availability of interim junction measures in the national jurisdiction or even proving one's case and providing evidence that is also practiced differently among Member States. Moreover, there are aspects to take into consideration in respect of the diverging quality of national courts (as there are usually no patent or intellectual property specific courts, then the judge is expected to not only have legal knowledge but also expertise in the area of chemistry, engineering etc. to be able to understand the real substance of the case) and in different practices which could lead to diverging court decisions.

As for the future of litigation procedures, Community competence will probably gradually replace current practices after the ratification of the Community Patent package as patent litigation concerning validity and infringement will be handed to the Unified Patent Court having the competence only over the contracting states (excluding for example Spain). The Unified Patent Court will also have competence over currently existing regional European patents (at least during the transition period of 7 years if the patentee explicitly decides to opt-out for example in a licensing agreement).



However controversy in patent claims may arise where the patent claim is challenged only in one Member State, as in that case both the Unified Patent Court as well as the local one will enjoy jurisdiction and it might lead to forum shopping. The problem of forum shopping currently exists too, as the Brussels Convention allows considerable flexibility for patentees when seeking enforcement of their IP rights. For example, Article 2 (as a general rule) of the Brussels Convention ( Council Regulation EC 44/2001) states that the plaintiff may sue the defendant in the latter's domicile, meaning that in case of patent infringement, there is no need to bring a patent infringement action in a country where the infringement occurred (Bender 2000: 9).

Forum shopping in patent matters is exercised also in national level as the quality and the experience of courts varies greatly (Luginbuehl 2011: 42).

In conclusion, considering that with the unified patent package national as well as regional European patents will still remain in co-existence with the unified patent, further confusion might be created on determining jurisdiction and the place of litigation. This is especially important when considering that the EPO decisions will become appealable to the Unified Patent Court (the first instance of the UPC may and the court of appeal must address the prejudicial questions regarding the applicability of EU law to the European Court of Justice), while the latter will still have no jurisdiction over national patent disputes or disputes involving Member States that are not part of the unified system.

### 3. The effects of EU competence on the TRIPS patent provisions

After the entry into force of the Lisbon Treaty, in terms of the EU's exclusive common commercial policy, competence now covers commercial aspects of intellectual property rights and is likely to be broader than the EU's internal exclusive competence to legislate IP. Although the TRIPS Agreement was signed as a mixed agreement, the rulings of CJEU could *de facto* harmonize the Member States laws even for parts belonging to their sphere of competence (Mylly 2014: 8). Therefore, Member States are in practice subject to a collective management of many mixed agreements whereby the Commission is often in charge of the negotiation of international agreements. On the other hand, taking into account that the EU possesses legal personality doubts might be raised in regards of the extent of its actual competence, bearing in mind that such an entity could be either limited



according to their limitations of competences, or whether it is indeed unlimited and independent of the limited competences of an organization.

If it was limited, it would mean that the EU would only be bound to those parts of the WTO agreement for which it had competence (Steinberger 2006: 841). Considering the breadth of art 216 of the TFEU one could say that the EU has unlimited legal personality and therefore could potentially bind itself to all provisions of the WTO agreement. This would mean that Member States are not only absent for the negotiating aspect, as intellectual property law falls in the sole external competence of the Union, but it also can be said that the final effects of TRIPS are determined by the EU, and through the final interpretation of the CJEU. Although article 3 (1) of the TFEU states that the areas of exclusive competence only refer (among other areas) to aspects of common commercial policy, in the light of art 207 TFEU that declares intellectual property law as belonging to the commercial sphere of the Union, the competence obviously embraces a much wider spectrum than it initially appears.

In one of the first documents dealing with the issue, Opinion 1/94 of the Court of Justice, the Commission recognized that there is a connection between intellectual property law and the trade of goods, as the objective of TRIPS is to harmonize the protection of intellectual property on a worldwide scale. At the same time, the Commission of the day did not recognize the exclusive external competence of the EU as regards TRIPS. The Commission stated that the EU shared joint competence to conclude TRIPS (Opinion 1/94) and that the exclusive competence of the EU was limited to certain areas of intellectual property law and it did not necessarily extend to commercial aspects of the latter. It was stated in the Opinion that intellectual property rights do not relate specifically to international trade; they affect internal trade just as much as, if not more than, international trade. Also, the Commission pointed out the fact that there were many areas of intellectual property law covered by TRIPS that had not been harmonized in the Union level by that time. As for patent law, there are currently two directives legislated on the Union level, namely the Biotech Directive (Directive 98/44/EC) and the Directive on the Enforcement of Intellectual Property Rights (Directive 2004/48/EC).

This scenario has recently changed with the entry into force of the Lisbon Treaty, as intellectual property rights are considered to fall fully within the context of the international commercial policy of the Union.



On the one hand this certainly strengthens the EU's position not only from the legal aspect, but from the political aspect as well considering that in this way the EU could maintain its image as a global market player, while at the same time clearing any uncertainty as regards to defining competence; especially useful when negotiating international agreements as there is no need for defining the line between the competence of the Union and of its Member States. The TRIPS Agreement states that the term intellectual property refers to all categories of intellectual property, therefore it should embrace everything from copyright to undisclosed data and the protection of integrated circuits.

On the other hand the preamble of the TRIPS Agreement clearly states that it is primarily targeted at the liberation of international trade and to strengthen the protection of intellectual property right on a worldwide scale (TRIPS Agreement preamble). Considering that the substantive contents of TRIPS is not particularly trade related, one could say that there is some room for debate as to what might exactly be considered under the notion of the EU's common commercial policy in the context of trade agreements relating to commercial aspects of intellectual property rights. It seems that in the case where an act is targeted to promote, facilitate or govern international trade, it should fall within the notion of common commercial policy, but whether the idea was to create a link of extension between TRIPS and TFEU art 207, meaning that the commercial aspects of intellectual property rights are meant as the ones encompassing in TRIPS, is not certain.

It has been argued that the notion of commercial aspects of intellectual property rights envisioned in art 207 TFEU can be viewed either *via* applying dynamic, or static interpretation (Dashwood et al. 2001: 72). Therefore it is not certain whether art 207 TFEU has a narrower meaning of intellectual property rights compared to what is envisioned in TRIPS, as it does not contain an exposition of such rights. Whatever the notion may be, TFEU art 207 (6) states that exercise of the competences conferred by Article 207(6) 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 harmonization of legislative or regulatory provisions of the Member States in so far as the Treaties exclude such harmonization. Taking into account current practices, for example in the light of CJEU decision on Daiichi Sankyo case (C-414/11), there is obviously a gap between a written text and the reality.

While trade and intellectual property rights have not always gone hand in hand, the



approach, as already mentioned, has changed. Intellectual property law has now become a part of the trade agenda. Although the TRIPS Agreement was signed as a mixed agreement, the uncertainty regarding competence already arose during the negotiations of the Uruguay Round. Despite having agreed upon who should be conducting the negotiations, there was certainly doubt as to who should eventually sign the agreement; Member States viewed TRIPS as a mixed agreement but the Union itself saw the WTO agreement as something falling within its sole competence as the latter had the competence to conclude international agreements in the area of commercial policy. Considering that the European Community can be considered as possessing legal personality at that time, it is therefore bound by the treaty provisions; hence the European Community as well as its Member States became party to the agreement because otherwise neither would have been competent to sign the treaty alone (Steinberger 2006: 839).

It is interesting to observe that at the time (from 1986 until the entry into force of TRIPS in 1994) intellectual property law was not considered as a part of common commercial policy, but such an interpretation was slowly starting to change. If the Community had managed to maintain its position, it would have meant that it could have had the right to harmonize the Union's intellectual property protection while at the same time escaping from constraints otherwise applicable (voting for example). Considering that the Agreement was signed by both the Union as well as its Member States, it created uncertainty to third countries as there would always be a need to draw a line between competences. This issue however, was resolved by the entry into force of the Lisbon Treaty as already discussed above.

Post Opinion 1/94, one could deduce that, as for substantive patent provisions, the Member States could still have had the competence to rely on national law when interpreting its provisions where: 1\ there is no Union wide legislation put down that does not recognize the Union's exclusive competence as regards to TRIPS, 2\ there was minimal harmonized legislation on the Union's level, and 3\ the fact that the TRIPS Agreement was initially signed as a mixed agreement setting only general standards. Such a viewpoint can be backed up by CJEU's decision for Merck Generics (before the Lisbon Treaty) (C-431/05 Merck Genericos v Dohme ) where the court ruled that the Member States would remain principally competent in the areas where the Union itself had not yet legislated, as in that case the Union lacked the competence to interpret the TRIPS



provisions (C-431/05 Merck Genericos v Dohme).

Therefore one could say that, at the time, patent law for example could not fall in the sole competence of the Union due to the lack of harmonized legislation. However, with the entry into force of the Lisbon Treaty, and especially in the light of the Daiichi Sankyo case, substantive patent law, irrespective of whether legislated or not, would now fall within the sole competence of the Union as falling in the category of foreign trade, or more precisely, using the broader notion of the TFEU, to the commercial sphere of the latter. Therefore, what may be deduced is that the Union's competence is in fact broader than that simply envisioned in the TRIPS, which only deals with the trade related aspects of intellectual property rights, which are obviously a narrower notion compared to the one in the TFEU (commercial aspects). Of course, it raises another concern as to whether any possible future agreements containing intellectual property provisions would also fall within the competence of the Union, as while the competence over the TRIPS can be justified by its trade related nature, it is questionable whether the Union will have sole competence for any other type of intellectual property related agreement even after the Daiichi Sankyo case, as the notion of commercial aspects of intellectual property rights are not so far clearly defined.

It is still a matter for debate as to whether after the Daiichi Sankyo case there is a need to further worry about drawing a distinguishing line between on the one hand the commercial aspects of intellectual property law, and on the other non-commerce related intellectual property law, when simply interpreting substantive patent law for example. However it certainly makes a difference when negotiating Free Trade Agreements with third countries which obviously would still be covered by the exclusive competence, although in the context of TRIPS, it would not extend to 'TRIPS plus provisions'<sup>1</sup> that fall outside the TRIPS Agreement but at the same time are widely enforced during negotiations for Free Trade Agreements. The other side of the coin is the fact that while acknowledging its wide competence in the area of intellectual property law, the Union also takes on responsibility for its role as an international body.



#### 4. Interpretation of substantive patent law in the light of the *Daiichi Sankyo* case

The entry into force of the Lisbon Treaty provided a new impetus for reconsidering the role of the Court of Justice in the field of substantive patent law. The establishment of the EU's exclusive competence in the field of common commercial policy has an impact on the determination of legal effects of the patent provisions of the TRIPS Agreement (Dimopoulos and Vantsiouri 2012: 10). At the time of the entry into force of the Lisbon Treaty, jurisdiction to interpret the TRIPS Agreement, whether that of the Court of Justice or that of the national courts, was determined on the basis of whether the specific subject-matter at issue fell within the European Union's or the Member States' area of competence.

The EU is a signatory to the TRIPS Agreement, as opposed to the EPC or Paris Convention. The WTO Agreement, of which the TRIPS Agreement forms part, was signed by the Community and subsequently approved by the Council (Council Decision 94/800/EC). As for the EPO and its relation to TRIPS, the Enlarged Board of Appeal observed in G 2/02 and G 3/02 that although the EPO is not a party to TRIPS, and not bound by it, the national legal systems of the EPC Contracting States might be affected by TRIPS and they may be under an obligation to see to it that the EPC is in conformity with TRIPS (EPO case-law of the Boards of Appeal).

According to article 216(2) of the TFEU, TRIPS, as a WTO agreement, is binding on EU institutions as well as its Member States. The TRIPS Agreement forms an integral part of the WTO, in accordance with the article 2 of the WTO Agreement, and cannot be dealt with in isolation (Appleton et. al: 2005, 115). However, WTO norms can be relied upon in order to review measures that are designed to execute a particular obligation undertaken by the WTO, or if the Union act explicitly refers to specific provisions of the WTO agreements, as the two cases below illustrate (C- 69/89 *Nakajima v Council* and C- 70/87 *Fediol v Commission of the European Communities*).

In the *Nakajima* case, a litigant argued that the European Council's anti-dumping regulation did not comply with the anti-dumping measures of the GATT; in its decision, the CJEU found that this regulation was adopted to comply with the EU's WTO obligations, and as a result, the regulation could be examined for legality with regard to



WTO obligations. The Fediol case dealt with the existence of a regulation that permitted producers to complain to the Commission about illicit commercial practices of third-party countries (C-70/87 Fediol v Commission of the European Communities). The Court found that, although the GATT had no direct effect, the flexibility that characterizes the provisions of GATT in several areas did not prevent the Court from interpreting and applying the rules of GATT regarding a given case, in order to establish whether certain specific commercial practices should be considered incompatible with those rules. Also, since the economic agents concerned are entitled to rely on the GATT provisions as a basis for their complaint, they had the right to request that the Court review the legality of the Commission's decision in applying those provisions.

Conversely, in the FIAMM case (C-120/06 and C-121/06 FIAMM and Fedon v Council), that dealt with non-contractual liability of EU institutions in the event of breach of WTO obligations, the CJEU found that plaintiffs could not rely on WTO law when arguing for invalidity or for damages; WTO agreements are not in principle among the rules in the light of which the Community courts review the legality of action by the Community institutions. Consequently, the court affirmed that there is no possible way, absent Nakajima and Fediol, for private litigants to invoke WTO law before a court to obtain damages or invalidate EU law.

Therefore, the Nakajima and Fediol cases are the two exceptional scenarios that would create the possibility to rely on WTO/GATT law in order to review the lawfulness of EU acts.

The issue regarding the interpretation of the TRIPS provisions has gained particular attention considering that the agreement was concluded by the EU as well as its Member States as a mixed agreement that has the same legal status in the Union legal order as purely Union agreements, insofar as the provisions fall within the scope of Union's competence (Aerts 2014: 88-89). In this context, before answering the question regarding direct effect, the court should presumably first of all solve the dilemma regarding competence. The latter position has attracted opposing views starting from the 1980s until the Daiichi case decided a few years ago.

As for mixed agreements, Member States must exercise their external competence in consistency with the EU law. They must therefore secure the primacy of mixed agreements over national law, as Member States are accountable under EU law for mixed agreements



in their entirety due to the obligation of loyalty codified in articles 216 (2) TFEU and 4(3) of TEU (Mylly 2014: 9). The CJEU has so far been quite modest in interpreting the TRIPS provisions concerning substantive provisions of patentable subject matters, although TRIPS is by its nature of being an WTO Agreement, an area of interest to the EU in general. The CJEU has in its earlier proceedings stated that the substantive interpretation of patent law lies outside its jurisdiction and therefore Member States can decide whether, according to national law, they apply the Agreement directly and how they interpret the provisions of TRIPS in patent related matters (C- 431/05 Merck Genericos v Dohme).

The lack of uniform interpretation of the TRIPS provisions regarding patentable subject matter has led to different levels of protection of patent rights being offered. At the same time it is vital to point out that the TRIPS Agreement only establishes minimum standards for patent protection, and even if its provisions were not to fall within the competence of the EU, it is questionable whether it has any drastic effects to national patent legislation or implementation of TRIPS norms in general.

According to the Article 27 (1) of the TRIPS Agreement, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. WTO Members have to provide patent protection for any invention, whether a product (such as a medicine) or a process (such as a method of producing the chemical ingredients for a medicine) with some reservations (WTO factsheet: 2006, 5). For example, Members may exclude from patentability inventions where the prevention of the commercial exploitation within their territory is necessary to protect public order or morality, including the protection of human, animal or plant life or health, or to avoid serious prejudice to the environment.

The CJEU has previously held that where a provision can apply both to situations falling within the scope of both national law and Union law then that provision should be interpreted uniformly. In the benchmark case Dior (C-300/98 Dior SA v Tuk Consultancy) the CJEU held that in areas under the TRIPS Agreement where the EU has not yet legislated, Union law is deemed to fall outside the competence of the Union as there are no rules laid down in the EU level. This case, however concerned the interpretation of a specific provision in the TRIPS Agreement that was not yet legislated on the Union level.



Similar interpretation of the TRIPS was confirmed by the CJEU in the Merck Genericos decision (C- 431/05 Merck Genericos v Dohme).

In Merck case the Court stated that it was not contrary to community law that a specific article of the TRIPS Agreement was directly applicable, and Member States remain principally competent to decide whether they implement those norms directly, or not, according to their national laws. A similar viewpoint was confirmed in Hermes case where the Court concluded that jurisdiction to interpret the TRIPS Agreement, whether that of the Court of Justice or that of the national courts, was determined on the basis of whether the specific subject-matter at issue fell within the European Union's sphere of competence, or the Member States' area of competence (C-53/96, Hermes v FHT Marketing).

This approach has recently received an opposing view from the Commission, as it has stated that the principle established in the context of Merck Genericos and Dior is no longer valid as the TFEU that entered in force in 2012 makes a clear reference to commercial aspects of intellectual property rights. It means that according to the recent interpretations of the CJEU, rules of patentability (covered by TRIPS article 27) that by general principle should be subject to national law, are from now on considered as falling in the competence of the EU. The CJEU concluded that the TRIPS Agreement as a whole is related to the commercial aspects of intellectual property and, as such, falls within the field of common commercial policy.

The TRIPS Agreement states that, for the purposes of the Agreement, the term intellectual property refers to all categories of intellectual property that are the subject of Sections 1 to 7 of Part II of the TRIPS Agreement, namely copyright and neighboring rights, trademarks, geographical indications, industrial designs, patents, layout-designs (topographies) of integrated circuits, and undisclosed information. In this context, TRIPS is viewed as an international treaty promoting and governing international trade; therefore IP law, as a branch of commercial policy, falls in the context what was envisioned in Lisbon Treaty (TFEU article 207(1)) as regards to common external action for trade. It can thus be deduced that for the interpretation of intellectual property law in general, the commercial aspect makes no difference as even in the context of the TRIPS Agreement, intellectual property law is defined in a broader sense and therefore embraces the whole category of the latter.



The concepts held valid so far were turned upside down with the ruling on the Daiichi Sankyo case (C- 414/11 Daiichi Sankyo v DEMO Anonimos) regarding not only substantive patent law, but more broadly intellectual property law in general. Contrary to the Advocate General's observations, the CJEU held that article 27 falls within the exclusive competence of the EU, including the common commercial policy and particularly commercial aspects of intellectual property. The Court also noted that its opinions prior to treaty modifications were no longer applicable. The CJEU further stated that, based on those conclusions, there was no further need to consider whether national courts may accord direct effect to Article 27, as the first question regarding competence was determined, in that competence belonged to the EU. This is a major decision in respect of international intellectual property law within the EU because all the TRIPS provisions may fall within the exclusive competence of the EU.

Firstly, a few words about the Daiichi Sankyo case, which evolved around two aspects. The first was the question of whether the substantive provisions regarding art. 27, (patentable subject matter), of the TRIPS Agreement, falls within the competence of the EU or whether the Member States continue to have a primary competence, and if so then can Member States accord direct effect to that provision. The second question was more specific to intellectual property law, as there was a doubt whether in the case the additional certificate of protection, or even the ground patent, applied solely to the manufacturing process of an active ingredient or would also embrace the active ingredient itself. As for the latter question the court said that the process patent does not extend to the active ingredient but solely to the process.

In seeking to determine the scope of competence of the EU the defendants of the litigation in the Daiichi case pointed out that the TRIPS Agreement was concluded by the Community and its Member States by virtue of shared competence. As the TRIPS Agreement was concluded as a mixed agreement, then in interpreting its provisions it is important to establish the dividing line between the obligations which the European Union assumes and those which remain the responsibility of the Member States (C- 414/11 Daiichi Sankyo v DEMO Anonimos). Therefore, it must be determined whether the European Union has exercised its powers and adopted provisions to implement the obligations which derive from it. The European Commission on the other hand argued that the case-law that was valid for Dior and Merck Genericos, was no longer relevant for



the TRIPS Agreement, since it applied only to agreements which fall within the shared competence of the European Union and the Member States, not to those for which the European Union has sole competence.

The European Commission also added that the TRIPS Agreement as a whole relates to ‘commercial aspects of intellectual property’ within the meaning of Article 207(1) TFEU. Consequently, that agreement in its entirety falls within the field of the common commercial policy (C-414/11 *Daiichi Sankyo v DEMO Anonimos*). The CJEU supported the view of the Commission and concluded in its decision that article 27 of the TRIPS Agreement indeed falls within the competence of the EU, as it is first of all targeted to external actions of the Union; and although those rules (TRIPS) do not relate to the details, as regards customs or otherwise, of operations of international trade as such, they have a specific link with international trade. To regard the rules on patentable subject-matter in Article 27 of the TRIPS Agreement as falling within the field of the common commercial policy, rather than the field of the internal market, reflects the fact that the context of those rules is the liberalization of international trade, not the harmonization of the laws of the Member States of the European Union (C- 414/11 *Daiichi Sankyo v DEMO Anonimos*).

Taking these aspects into account, it is interesting to note that this exclusive competence over substantive patent law is not affected by the fact that the EU has not yet legislated in the specific field, apart from limited sectorial interventions (Directive 98/44/EC). As discussed in respect of the *Dior* or *Merck* cases, the key factor in determining EU competence at the time was whether the Union had exercised EU wide legislation in the field or not. Apparently, this aspect is no longer relevant. Therefore, the lack of common rules on substantive patent law no longer seems to be an impediment for the determination of EU competence.

With regard to the eventual direct effect of TRIPS (in the meaning of the possibility of directly relying on international agreements), it is no longer a question of national laws of Member States (as previously held in *Dior* case C-300/98). Presumably, Member States can interpret Community law as far as may be possible in the light of the wording and purpose of TRIPS (Dimopoulos and Vantsiouri 2012: 12). As the Advocate General wrote in his opinion in *Daiichi* case, TRIPS article 27 does not have direct effect, in that it is not a provision that can be relied on directly by individuals either against the public authorities or, as in this case, against other individuals. Therefore the question of direct effect should



first of all start with the question regarding competence that determines whether there is even a need to deal with the matter of direct effect after resolving the first question at issue.

The directive on the enforcement of intellectual property rights clearly states that it does not apply to Member States' international obligations, especially to TRIPS. It also adds that at the international level, all Member States, as well as the Community itself as regards matters within its competence, are bound by the TRIPS Agreement and further, all TRIPS provisions may fall within the exclusive competence of the EU. (Directive 2004/48/EC). Furthermore, as the CJEU not only found that the EU has external competence as regards of the TRIPS Agreement, it also said that article 27 of the Agreement determining the patentable subject

It could be argued that this creates confusion in regard of the EU's competence to decide on national laws regarding patentable subject matters, (considering that there are differences in national laws for software patents and also regarding the procedures for granting patents as some Member States apply registration method while others apply examination method). Moreover, in the context of European patents, which basically become national patents after validation procedures, and considering that at this point the EPO is not related to the Union, the former's decisions as regards to granting of patents should not form a part of the competence.

Also, this raises questions in cases of validity claims as patents may be challenged at EPO during the period of nine months after the conferral of a patent, but in cases where this period is missed by a third party interested in challenging the patent, then it is up to the national court to deal with such issues. The situation becomes even more complicated in cases where there is a concurrent validity claim being contested at a national court while the EPO's decision on European patent is still pending. It means that once again, on the one hand the EU has no competence to interfere in decisions regarding the EU patent validity provided by EPO but on the other, once the patents are validated nationally, their validity suddenly does become a concern of the Union. With the decision on the *Daichi* case the CJEU ruled that the EU has exclusive competence on how EU Member States apply the patentability provisions of the Agreement on TRIPS. In effect, the EU Member States are not permitted to make their own law on the subject of the TRIPS provisions.



The CJEU may currently give opinions only in limited areas such as the biotech patenting, as this is governed by specific EU legislation, but the *Daiichi* ruling could potentially be used as legal basis for appeals from national courts to the CJEU on patent matters more generally. It may have a particular significance in areas such as software patenting where there are differences between national laws and the EPC (which both have exclusions from patenting computer programs as such) and the provisions of TRIPS, which contain no such exclusion (Swann 2013). As can be deduced from the *Daiichi* case the EU has a broad competence; the EU's external competence now codified in article 216 TFEU is formulated as broadly as the EU's internal competence based on article 351 (1) TFEU. The EU has thus competence, among other situations, when it is necessary to conclude an agreement or take internal action in order to achieve, within the framework of its policies, one of the objectives referred in the treaties (Mylly 2014: 7).

At the same time TRIPS continues to an extent in having a direct effect in the Union. According to the *Daiichi* case, all TRIPS provisions may fall within the exclusive competence of the EU. Certainly, many provisions of intellectual property law have been harmonized, restricting the competence of Member States to a very narrow field. However, this finding may lead, as the Advocate General wrote, to the general and immediate 'expulsion' of the Member State from the negotiations of such agreements, and to affect indirect harmonization. As a result, as mentioned above, almost no intellectual property law provisions are left to EU Member States (Mateu 2014). It means that for substantive patent law then even in the case where the EU has not legislated in the field, it still has the competence over the interpretation of patent norms on the national level, and actually also for European patents as they also become national patents after the validation procedure.

Therefore, even if the EU has no competence to interfere with the decisions of EPO in the framework of EPC, it can interfere in a later stage when European patents become national patents after the validation at local patent offices; and this competence does not only affect patent infringement cases but also patent validation claims. At the same time, considering that the TRIPS Agreement only establishes minimum standards for setting patentability criteria, then from the substantive patent law perspective, it should not create any significant change (it will most probably affect the issues related to patentability of computer programs that have, despite the *Daiichi* case, been an issue of debate for a while now anyway).



## 5. Conclusion

In conclusion, it can be said that there is some change ahead for European patent law not only in the light of the *Daiichi Sankyo* case that has changed the interpretation of substantive patent law deriving from the TRIPS Agreement, but also in the light of the new unified patent package that may soon take effect. It is difficult to predict the final outcome, but what is certain so far is that with the unified patent package national, as well as current regional European patents, will continue to co-exist. And, with the addition of international applications, as well as the possibility of filing unified applications, confusion might be created. Also, the Unified Patent Court will have no jurisdiction over national patent disputes or disputes involving Member states that are not part of the unified patent package (Spain for example). At the same time it will have jurisdiction over not only the unified patents but also the currently existing regional European patents, at least during the transition period of seven years. In contrast to the current state of affairs, the EPO's decisions will become appealable to the Unified Patent Court, and there will be the possibility to make references to CJEU for preliminary ruling. Considering that the unified patent package does not cover all EU member states (for example Italy only takes part of the unified patent court but not the unified patent package itself), it could lead to further confusion. Also, the role of EPO will need to be clarified as currently it is in no way connected to any EU institutions, but it seems that in the future it is expected to move closer to the latter considering that EPO will be in charge of administering unified patents.

As for the substantive patent provisions of TRIPS, and the possibility for applying direct effect, it seems that it still continues to be exempt as substantive patent provisions fall in the competence of the EU and form an integral part of its commercial policy. Therefore, the question regarding applying direct effect is in fact no longer valid. Previous interpretations regarding competence, as set out in the *Dior* and *Merck* cases that exempted the EU competence as long as there had not yet been legislation at the EU level, seem to be no longer relevant in the light of the *Daiichi Sankyo* case. Considering that currently the CJEU can give limited opinions on substantive patent provisions (on the *Biotech Directive* for example), after the *Daiichi Sankyo* case, its competence on patent matters may become wider in the future. At the same time, almost no intellectual property



provisions are still left to the Member states, but in the context of TRIPS Agreement, it is also useful to keep in mind that as far as interpreting its substantive provisions, it only creates general standards.

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<sup>1</sup> Limitations on the use of compulsory licensing, extending patent protection term beyond the original provisions of TRIPS, forcing data exclusivity provisions for developing countries to avoid generic competition in pharmaceutical industry for example etc.

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