Feedback on the Intellectual Property Action. Plan Roadmap of the European Commission

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Joint response from the **Association Henri Capitant des amis de la culture juridique française** and the **Institut Stanislas de Boufflers**

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Association Henri Capitant des amis de la Culture juridique française

Founded in Paris in 1935, the **Association Henri Capitant des amis de la culture juridique française** (*Henri Capitant Association of Friends of French Legal Culture*) has been working for more than 80 years to promote, disseminate and modernise civil law legal systems. It organises periodic national and international congresses devoted to the study of legal issues that highlight values of civil law tradition.

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Opening Remarks

This feedback is a joint response from the ASSOCIATION HENRI CAPITANT DES AMIS DE LA CULTURE JURIDIQUE FRANÇAISE and the INSTITUT STANISLAS DE BOUFFLERS to the European Commission's roadmap of the 2020 intellectual property action plan [1]. The structure of the document is in line with the main objectives of the Commission's roadmap:

- **Chapter 1**: Further harmonisation of intellectual property legislations;
- **Chapter 2**: Better uptake and deployment of intellectual property;
- **Chapter 3**: Protection of better licensing and sharing of IP-assets;
- **Chapter 4**: Reinforcement of the fight against counterfeiting and IP theft.

The ASSOCIATION HENRI CAPITANT DES AMIS DE LA CULTURE JURIDIQUE FRANÇAISE and the INSTITUT STANISLAS DE BOUFFLERS remain at the European Commission's disposal to answer any request on the legal issues addressed in this feedback.

1. European Commission, *Roadmap of the Intellectual Property Action Plan*, 10 July 2020, Ref. Ares(2020)3662148.

Contents

Executive Summary

General Remarks

§A. — Creative human effort, understood as a unique, autonomous and identical intellectual phenomenon for all creators, is a means of acquiring property [2]. Creative acts are thereby the very subject of intellectual property law [3]. Appropriation makes it possible to create value insofar as "creator and investors reserve for themselves the potential market for the creation at issue" [4]. The intellectual property legal system thus structures the knowledge-based economy while intellectual property rights (IPRs) have emerged as key elements on the value chain and revenue sharing.

§B. — The Lisbon Treaty explicitly gave the European Union the competence to create unitary IPRs in order to establish a uniform system of protection in the context of the establishment and functioning of the internal market [5]. However, the EU internal competence in the field of intellectual property [6] remains a shared one, allowing Member State action to the extent that the Union has not exercises its competence [7]. In this respect, the persistence of national legislations, in particular on copyrights and patent laws, prevents the full potential of the Single Market from being unleashed acting as investment restrictions. If the territorial scope of intellectual property rights were unavoidably that of the territory of the Union, then the prospects for exploiting creations and inventions ought to be conceived, as a matter of principle, at EU level. Such a wider basin to exploit would be of much greater interest to investors.

§C. — In particular, the legal framework of the Benelux Economic Union could serve as a model for the further integration of the internal market. In order establish a common market, Uniform Laws on Trade Marks (1971) and Designs (1975) repealed national laws then in force in the Kingdom of Belgium, the Grand Duchy of Luxembourg and the Kingdom of the Netherlands. The intellectual property titles issued are therefore necessarily in force throughout the Benelux territory.

§D. — Although the EU legislature is multiplying sectorial reforms, it still lacks a unifying impetus to enable intellectual property to be a strong and integrated support for a growing and innovative European Single Market. More generally, the Commission should promote an even more unitary approach for property rights and contractual principles to provide a simple and coherent legal background for the 4th Industrial Revolution regulations to come (big data, internet of things, artificial intelligence, etc.).

2. Jean CARBONNIER, *Flexible droit*, 10th ed., LGDJ, 2001, p. 355.
3. Nicolas BINCTIN, *Droit de la propriété intellectuelle* [Intellectual Property Law], 5th ed., Manuel, LGDJ, 2018, pp. 28-29, §2.
4. Michel VIVANT and Jean-Michel BRUGUIÈRE, *Droit d'auteur et droits voisins* [Copyright and related rights], 4th ed., Précis, Dalloz, 2019, pp. 13-16, §6: "[*Le mécanisme*] qui s'exprime dans la catégorie juridique de la propriété intellectuelle consiste à réserver au créateur le marché potentiel de sa création."
5. Article 118(1) Treaty on the Functioning of the European Union (hereinafter reffered to as "TFEU").
6. Yole TANGHE, "The Borders of EU Competences with Regard to the International Regulation of Intellectual Property Rights: Constructing a Dam to Resist a River Bursting Its Banks", *Utrecht Journal of International and European Law* 2016, 27, pp. 27-43.
7. Article 2(2) TFEU.

§E. — This feedback, led by the INSTITUT STANISLAS DE BOUFFLERS, is part of ongoing discussions and work of the ASSOCIATION HENRI CAPITANT DES AMIS DE LA CULTURE JURIDIQUE FRANÇAISE about the possible revitalisation of moves to integrate business law across the European Union. Specialists of business law, including intellectual property, aim to identify common roots and identical tensions driven by business laws throughout the Union territory, in order to create a European business code. There is no insurmountable incompatibility between property regimes and contractual principles of Member States. There is, undoubtedly, some dogmatic reluctance to overcome and, naturally, each State would have to accept some changes in domestic law. However, this approach would ensure a better understanding of judicial practices and the Union law would become a reference system, able to impose its values and techniques in international negotiations.

Chapter 1: Further harmonisation of intellectual property legislations

§F. Search for an EU copyright and EU related rights. — Harmonisation of national copyright legislations have been achieved through several directives on a step-by-step basis: software integration, term of protection of property rights, limitations and exceptions, orphan works, resale rights, collective management and multi-territorial licenses. As a result, national copyright laws are very close, with main elements of property law being very similar in all the different EU Member States: property right acquired on creation, no need to file, appropriation of the form, concept of originality, 70-year term, etc. Nevertheless, approximating national legislations has also shown its limits, which has increased the incentive to create a unitary copyright at EU level. Because of the *à la carte* nature of these transpositions, Member States have been able to retain their own customs, creating difficulties when adapting to local differences. An EU unitary copyright would be different from the existing situation because difficulties of enforcing copyright in the different Member States would be eliminated largely. The holder of an EU copyright would hold that copyright for one, sole territory, *i.e*. that of the EU, and there would be only one set of rules to apply. There must be a European ambition for copyright and related rights. Legal certainty would be increased, as the economic confidence required by the knowledge-based economy would be given a real boost.

§G. Failure of the EU patent. — Even if the European Patent Convention (EPC) is a regional collaboration success, it cannot compensate for the failure to introduce a unitary right in Union law. The European patent with unitary effect (EPUE), established within the framework of an enhanced cooperation (Art. 329 TFEU; Reg. 1257/2012, Reg. 1260/2012 and the Agreement on a Unified Patent Court [AUPC]), is not attached to a unitary legal regime. It is a national property right enforceable in the territories of the other Member States, which distinguishes it clearly from EU unitary IP rights. In order to provide uniform protection throughout the territory of the countries in which it has unitary effect, the scope of the property rights conferred by the EPUE and its applicable limitations have been harmonised. However, the creation of an EU patent would have ensured consistency between the property right and the innovation market in which patent rights are exploited. Fragmented property rights does not allow for the emergence of strong companies integrated in the knowledge economy. The European Union needs a patent property right that is parallel to the market, in the absence of which, investors do not follow innovative projects.

The European Union could have taken advantage of the achievements of the EPC implementation to fully harmonise substantive patent law through a directive or a regulation. Instead, the scope of the EPUE rights and applicable limitations have been reduced to a set of minimum specific prerogatives (Art. 25 to 27 APUC). While these provisions will apply to EPUEs and European patents, the corresponding, non-harmonised domestic provisions will continue to apply to national patents. Such legislative disparities could have been avoided by EU normative action.

The withdrawal, with immediate effect, of the ratification of the Agreement on a Unified Patent Court by the United Kingdom on 20 July 2020 should make it possible to improve the "Unitary Patent Package". It would be a pity if the Preparatory Committee merely amended the APUC to change only the seat of the central division that was originally intended to be located in London. The European Commission should seize this opportunity to move the provisions related to the scope and limitations of the EPUE rights to Reg. 1257/2012 and, more broadly, propose a complete harmonisation of national and European patent legislations. This EU Regulation on substantive patent law would thus imposed on the Unified Patent Court to ask the CJEU to give preliminary rulings on questions of interpretation raised by provisions dealing with the scope and limitations of EPUE rights. More generally, the European Union should legislate in subjects closely or remotely related to patent law, as this would help to place the CJEU at the pinnacle of an international construction built on the fringes of Union law.

§H. Expected EU actions on software patents. — Patentability of computer-implemented inventions is a crucial topic for modern patent law. In this respect, the European Patent Office (EPO) has developed a large boy of decisions relating to computer-implemented inventions in which assessing the patentability of computer programs often boils down to assessing their technical character. However, this case law has several drawbacks. First, even if the EPO Technical Boards of Appeal have developed a uniform approach to assess on a case-by-case basis the technical character of computer-implemented inventions, national courts are not bound by EPO decisions. Discrepancies of interpretation of EPC provisions between the EPO and European national courts are regrettable as they allow for forum shopping. Then, the EPO Boards of Appeal voluntarily leaves the technicality undefined, relying on "individual decisions to provide clues as to what is considered patentable" (Stefan V. STEINBRENER, *JIPLP*, 2018, Vol. 13, No. 1, pp. 13-35), which is source of significant legal uncertainty. Finally, this case law has an esoteric nature as it is understandable only to initiates and obscure to others. Given the rise of artificial intelligence, an EU legislative action to establish a clear regulatory framework would accelerate investments and foster integration in the Digital Single Market.

The European Commission could introduce specific provisions for the software patentability as part of a comprehensive reform of patent law (*see above*, **§G**) or, at the very least, bring back onto the agenda a Proposal for a Directive on the patentability of computer-implemented inventions, but drawing lessons from the 2005 fiasco, which was largely attributable to the mobilisation of public opinion by the Open Source community. Consequently, such a long-term legislative project that would recognise the patentability of computer programs, and which could benefit from current and future debates on the patentability of artificial intelligence applications, should be accompanied by a very slick communication strategy.

§I. Supplementary protection certificates with unitary effect. — The creation of a SPC with unitary effect would be the final element of the European patent reform. In its Study on the Legal Aspects of Supplementary Protection Certificates in the EU, under the direction of Reto HILTY and Roberto ROMANDINI, the Max Planck Institute (MPI) gives a detailed overview of the institutional issues and substantive requirements for SCPs granted on the basis of a European patent with unitary effect.

Among other things, the MPI Study focuses on the articulation between the territorial scope of the basic patent and that of the marketing authorisation when granting a SPC with unitary effect. The territorial scope of a future unitary SPC will necessarily results from the superimposing of those of the basic patent and marketing authorisation, what the above-mentioned study refers to as "the mandatory consonance of territories". When a SPC with unitary effect is granted on the basis of a European patent with unitary effect and a European MA, the territories involved are "consonant" as the territory covered by the MA include the territory covered by the EPUE. The same applies when the scope of a bundle of national MAs issued under mutual recognition or decentralised procedures covers at least all the EU Member States where the EPUE has unitary effect. However, when the applicant for a SPC with unitary effect relies on a bundle of national MAs covering a territory narrower than that of the basic EPUE, the

MPI suggests that the EU legislature could experiment with an advanced system: the unitary SCP would be granted only for the territory in which at the critical date the unitary patent is in force and an MA exists. As attractive as this system may be, it has one major drawback: the creation of an *à la carte* territorial protection for pharmaceutical companies is necessarily to the detriment of the EU single market integration. The unitary SPC would then be an IP title with variable territorial protection, depending on the strategic choices of the holders who will inevitably target the most profitable national markets. On second thought, such a system would create a SPC with "limited unitary" effect. The expression is an oxymoron however. How can the unit be limited? How to share what makes one? To limit unity is to recognise an underlying plurality, and thus to deny unity. The unitary effect ensures uniform protection throughout the territory of the UPCA Member States. Attempting to safeguard the unitary effect by considering that the SPC is valid throughout the Union's territory, but that it is enforceable only on a part of it, is a sleight of hand.

As a result, the application for a unitary SPC should rely on a European MA or a bundle of national MAs only a national MA has been granted in all countries in which the European patent has unitary effect.

§J. EU GI system for non-agricultural products. — The lack of unitary protection for handicraft goods is an obvious shortcoming of Union law. The needed extension of EU quality schemes to the protection of non-agricultural products is an opportunity to question the overall coherence of the EU GI system. Implementing such a system can follow two paths: extend EU quality schemes (PDOs and PGIs) or create a unitary protection based on the sole PGI quality scheme. The current EU GI dual system is characterised by two different links, one stronger than the other. It is however hard to explain that two distinct legal instruments provide for identical protection, *i.e.* that the intensity of the link does not affect the scope of the protection conferred. Since it seems difficult (if not impossible) to harmonise the GI system merging PDOs and PGIs, the legislature should create an independent single legal framework for non-agricultural GIs, based on the PGI quality scheme.

§K. Advocacy for a fully integrated EU design law. — Design law has greatly benefited from the approximation of national laws and from the creation of unitary titles. The EU legal framework thus currently consists in a two-tiered system of design protection at both national and Union level. Design Directive (Dir. 98/71/CE) has harmonised central provisions of substantive design law, which at the time of adoption were considered as most directly affecting the functioning of the internal market by impeding the free movement of goods embodying designs in the Union. For this reason, there remain residual but substantive divergences as well as procedural disparities within the European design law. Their removal would make the two-tiered system more comprehensible to European businesses in particular small and medium-sized enterprises. The design system reform with the drafting of a European "Design Package" must aim at full harmonisation of national legislations along the lines of new EU Design Regulation. Nevertheless, generalisation of the "repair clause" might remain a disputed issue, as evidenced by the recent French failure to liberalise the automotive aftermarket in spare parts. Political dissents between Member States should not delay or jeopardise further harmonisation in European design law. Moreover, it must be borne in mind, that the lack of European ambition for harmonised copyrights weakens the unitary character of the protection conferred by Community designs.

Once national design laws have been harmonised along the lines of EU design law, the question will arise as to whether a dual European system of national and unitary rights should be maintained. Unlike the European trade mark system, the coexistence and balance of design systems at national and EU level should not constitutes a "cornerstone" of the Union's approach. The rationale for the coexistence and complementarity principles, which govern the European trade mark system, has no equivalent in the design system. Maintaining national channels for design applications is then justified by the following grounds: lower fees, faster issuance of titles and national language as language of proceedings.

Further harmonisation of the two-tiered system should only be a step in the full integration process of Union law in Member States legislations. To meet the expectations of system users attached to the proximity of national channels, national and regional IP offices could become local relays for the EUIPO, which would keep centralising the EU design system. European registration fees, which today serve as a balancing variable in the distribution of national and Community design applications, should be lowered without undermining the economic balance of the design system. Finally, improve the reliability of computer translations through machine learning should, in the coming years, help to overcome the national language barrier within the Union.

§L. Further harmonisation of the status of employed creators. — Free movement of workers is one of the pillars of the European Union. However, the heterogeneity of the status of creators, in national law and also between each of the EU countries for each of the intellectual property regimes, hinders the movement of employee authors and the setup of creative businesses in the Union. It also hampers the development of collaborative, creative and transnational working. Union law should provide a unified approach to this issue in order to improve the situation of creators, facilitate exchanges and the use of new methods of creation, which would increase creativity and competitiveness of the European Union.

Chapter 2: Better uptake and deployment of intellectual property

§M. Set up of platforms to speed up the circulation of IP-assets. — Implementation of licenses of right would offers new economic and legal models for operating patents. However, the application procedure laid down in Article 8 EPUE Regulation remains to be clarified. Its generalisation to national patents could be considered, after consultation with stakeholders and domestic IP offices.

§N. Securitisation of IP-assets as a lever to get access to finance. — Securitisation of IP-assets is still an epiphenomenon. However, this financial engineering technique could be of particular interest to innovative companies facing heavy R&D expenses. By mobilising IP-assets, these enterprises could obtain immediate financing, without having to resort to borrowing or wait to receive future revenues from the operation of the underlying assets. However, there are still significant differences between national laws as to the nature of the assets that can be securitised, which limits the structure of possible arrangements. Securitisation is a financial engineering technique structured by an arranger, whereby an originator assigns assets to a special purpose vehicle (SPV), which finances acquisition by issuing securities in financial markets. Operating revenues deriving from the securitised assets pays investors. Securitisation arrangements can be classified according to the way in which IP-assets related risks are transferred. In indirect securitisations, royalties are assigned to the SPV whereas in direct securitisations, the originator directly assigns IP-assets to the SPV, which grants it a (exclusive) license in return for royalties (*sale-and-license-back*). The choice between direct and indirect securitisation arrangements depends upon the law applicable to the SPV, as it determines the nature of the assets that can be securitised, and the fiscal viability of the envisioned transaction. Under French law, no SPV was previously allowed to acquire intangible assets and domestic financing vehicles could thereby only be used in the context of royalty-backed securitisations, *i.e.* direct securitisations. However, under the impetus of the European Union, French law has provided for a new investment vehicle in 2018, the so-called "specialised financing vehicle" ("*organisme de financement spécialisé*"), which can be used as a SPV in a direct securitisation.

The European Commission should promote prospective securitisations of IP-assets through non-legal actions, *e.g.* commissioning a report from independent national experts assessing the legal and fiscal obstacles to such arrangements in each of the Member States. Significant legislative disparities exist between Member States. Some have regulated securitisation through specific laws (Belgium, France, Italy, Luxembourg and Spain) while others have not adopted any particular regulation (Germany). As

a result, legal and fiscal frameworks in place are more or less restrictive. Such a report would help raise awareness of IP-asset securitisation among stakeholders, *i.e.* knowledge-based companies and financial players within the European Single Market, and might instil confidence among potential investors.

§O. Development and standardisation of valuation methods for IP-assets. — Valuation methods for intellectual property assets are tools to assist in negotiations. Some simple valuation methods are commonly used (industry standards, relief from royalty or multi-period excess earnings methods), whereas more advanced ones are scarcely implemented (Monte-Carlo or real option pricing methods). In partnership with national, regional or international IP offices, the European Commission could fund programmes dedicated to developing and standardising valuation methods for IP-assets. Reliable and commonly accepted metrics used to valuing IP-assets would greatly contribute to strengthening the infrastructure of the European knowledge-based economy, in particular by promoting the circulation of intellectual goods.

Chapter 3: Protection of better licensing and sharing of IP-assets

§P. Improve transparency and predictability on licensing of SEPs. — Technology standardisation is a driving force for the knowledge-based economy, maximising the growth potential of the digital economy by creating a level playing field incentivising innovation, and enabling better access to digital goods and services for consumers and businesses. However, without regulation, standards can give rise to anti-competitive behaviours. Improving essentiality checks and clarifying FRAND licensing rules could help to avoid unreasonable or abusive exercise of IPRs embedded in technical standards.

There is no commonly accepted unambiguous definition of what an essential patent is. Each standards developing organisation (SDO) has therefore adopted its own definition of essentiality in its patent policy. However, discrepancies between definitions are delaying the emergence of an established case law that would contribute to a uniform interpretation of essentiality, regardless to SDOs' patent policies, facilitate essentiality checks and thereby streamline SEP negotiations over FRAND terms. Under a preliminary ruling, the European Commission should encourage the CJEU to define essentiality and make it an autonomous concept of Union law. Besides, in accordance with current contractual practices, declarations made by IPR holders only confer a simple presumption of essentiality, which can be rebutted by any means, to the patent recorded by the SDO. Except in the case where an independent expert assess essentiality, this qualification is not subject to any *a priori* control. As a result, institutionalising the standardisation process could improve essentiality checks. SDOs could voluntarily/compulsorily register standard-related patent pools with the European Patent Office. Introduction of additional fees for confirming declarations after standard release and patent grants would encourage a thorough assessment of essentiality by SEP right holders themselves. Profits made could finance a system of invalidation of recorded declarations along the lines of the patent opposition procedure. After the standard release, any person should be able to challenge SEP recorded declarations before the European Patent Office but only for a limited period. After that, disputes as to whether a patent claim is essential to a standard would be within the jurisdiction of UPC or national courts. This system would make it possible to focus essentiality checks on disputed patents. Moreover, no legal interest in bringing proceedings would allow straw men to use it. The resulting anonymity could be useful to avoid undue tensions between the right holders engaged in the implementation of the standard.

Even if both the CJEU in the *Huawei Technologies* case and the European Commission in its decisions *Rambus*, *Motorola* and *Samsung* have clarified the conditions under which SEP holders can seek injunctions parallel to FRAND licensing negotiations, the legal framework established by the Court and the Commission is still too vague to be used in practice. The European Commission could order a collection of commented case law on FRAND contractual practices among EU jurisdictions, updated annually

(as for the EUIPO *IPR Enforcement Case Law Collection*). This would help specify the FRAND licensing framework, drawing inspiration from the many decisions handed down by European courts. Such a digest would facilitate the resolution of these disputes by increasing legal certainty.

§Q. Set up of an EU-wide compulsory licensing system. — The COVID-19 pandemic has highlighted the importance of patents and SPCs in access to health care. Current research for treatments is mainly based on known active pharmaceutical ingredients (API) or new vaccines, which are or will be covered by patents or SPCs. However, whilst EU pharmaceutical laboratories continue drug formulation activities, the API production has been massively offshored under patent licenses to manufacturers located mainly in India and China (more generally referred to as "API exporting countries"). At stake is therefore the supply of anti COVID-19 medicines or vaccines to the EU internal market, which will depend heavily on Chinese and Indian API production capacities.

In API exporting countries, compulsory licensing will help increase production by allowing new companies to join the active ingredient supply chain. However, Article 31(f) TRIPS Agreement limits exports under compulsory licenses since production must be predominantly for the supply of the domestic market. Under international law, only eligible importing countries, *i.e*. least-developed countries or WTO Member States that has made a notification to the Council for TRIPS, can benefit from the export waiver under Article 31bis thereof. As the European Union deliberately opted out from this system, the granting of compulsory licenses to supply their population with anti COVID-19 generics of patented medicines may be ineffective due to insufficient supplies of APIs. As a result, without a political will for coordination at Union level, each of the Member States will manage locally the supply of its domestic market with APIs or finished medicine product, thus reinforcing protectionist resurgences and nationalist retreats within the EU. More than ever, all Member States shall coordinate their actions in a spirit of European solidarity to be ready to supply rapidly the whole Single Market with anti COVID-19 medicines or vaccines. In the short term, the European Union should undertake political and multilateral cooperation actions to ensure that proprietors of patents and SCPs covering promising drugs will voluntarily grant non-exclusive licenses to APIs manufacturers and pharmaceutical laboratories under FRAND conditions.

In addition, the European Union must ensure better availability of critical IP in times of crises. In the absence of government-coordinated compulsory licensing, rights holders can decide where to manufacture within the Union, which Member States they should supply first, and even set prices (in countries where administrative authorities largely abstain from pricing decisions). This can lead to the segmentation of the EU Single Market against the backdrop of health emergency. To avoid distortion of competition in such times of crises, an EU-wide compulsory licensing mechanism should be set up. To facilitate access to cross-border supplies of patented pharmaceuticals, an EU mandatory patent pool could be created. It would consist of a bundle of import and export compulsory licenses granted by Member States' governments. As the re-export of pharmaceutical products imported under compulsory license is prohibited by international law, the European Commission, assisted by the European Medicines Agency (EMA), would have to centralise and coordinate national procurement and shipments. Both the IP territoriality principle and the prohibition of re-exportation redraw national borders within the Single Market by thwarting the free movement of goods. Managing this EU mandatory patent pool would thus mainly consist of supervising the supply of 27 national markets by avoiding domestic import surpluses since they cannot circulate freely between Member States. However, the implementation of this EU-wide compulsory licensing system requires the European Union to opt back in the Article 31*bis* TRIPS Agreement system, harmonise the grounds for granting compulsory licenses for public health and amend legislation on marketing authorisations.

Chapter 4: Reinforcement of the fight against counterfeiting and IP theft

§R. IP-related customs activity. — Regulations 608/2013 and 1352/2013 are powerful legal instruments in the fight against counterfeiting. However, the effectiveness of the law depends on the means allocated to those responsible for enforcing it. Given that counterfeiting of intellectual property rights is estimated to account for 5-10 % of world trade, the fight against counterfeiting must become one of the European Commission's priorities. Consequently, customs authorities must be provided with adequate human resources to combat effectively the introduction, export, re-export or exit of counterfeit goods into or from the Union customs territory.

§S. Civil IP law. — IPR Enforcement Directive (IPRED) has provided all litigants within the Union with similar means to defend intellectual property rights. As regards the computation of the amount of financial remedies, IPRED is only intended to compensate prejudice in full. Setting up a mechanism to impose punitive damages, provided that the intention to infringe is demonstrated, would be a major step forward in strengthening the fight against counterfeiting.

Besides, despite the harmonisation of means of enforcing IPRs, the multiplicity of fora, in particular for European patent rights, lead to the fragmentation of EU cross-border litigation into a set of national trials, to the detrimental to the fight against cross-border infringements. The 2006 *Roche Nederland* judgement has ruined cross-border jurisdiction in European Patent infringement proceedings. In this case, the CJEU adopted a strict assessment of the requirement of connectedness laid down in Article 6(1) Brussels Conv. (Art. 6(1) Brussels I Reg.; Art. 8(1) Brussels I*bis* Reg.), by considering that infringement actions separately brought against defendants in different Member States would not raise necessarily mutually irreconcilable judgements, due to the IPR territoriality principle. The rationale is to be found in the general rule of exclusive jurisdiction of the courts of the state of patent registration regarding its validity, irrespective of whether the issue is raised by way of an action or as a defence (Art. 16(4) Brussels Conv. as interpreted by the 2006 *GAT* decision; Art. 22(4) Brussels I Reg.; Art. 24(4) Brussels Ibis Reg.). Since challenging the validity of a patent is a common defence, centralising infringement actions will not prevent the fragmentation of litigation in a bundle of national validity actions. However, one could have imagined that the single court seized pursuant to Article 8(1) Brussels I*bis* Regulation would rule on a plea of nullity without staying the proceedings. Counterclaims for invalidity would then have been brought in parallel before the courts of the States for which the European patent is registered. On the one side, if the plea of nullity is accepted, it would nevertheless only have an *inter partes* effect. On the other side, if the national part of a European patent is revoked by a court in the State where it is registered, the invalidation would have an *erga omnes* effect. Conflicting decisions that could arise between these different procedures conducted in parallel would be settled according to the following principle of priority: retroactive and absolute invalidation of the national part of a European patent shall not allow the revision of an earlier irrevocable and unappealable judgement of conviction for infringement. Therefore, pending the entry into force of the unitary patent system, in which the Unified Patent Court will have exclusive jurisdiction over European patents and EUPEs, the European Commission should advocate the preservation of unity in cross-border lawsuits, when submitting observations to the CJEU for preliminary rulings.

§T. Criminal IP law. — The reluctance to rely upon criminal law to deal with counterfeiting of intellectual property rights is regrettable. While criminal prosecution is certainly not suitable for all infringements, it is appropriate for IPR offences committed with criminal mind (*mens rea*), regardless to market forces or competitive spirit. The European Commission decision to withdraw its Proposal for a criminal IPR Enforcement Directive was partly due to the foot-dragging strategy of the United Kingdom, which was particularly resistant to its adoption. Therefore, since the latter has left the EU, the Commission could again draw up a Proposal for a directive so that repressive mechanisms ensuring IPR enforcement are finally harmonised within the Union.

Chapter 1

Further harmonisation of intellectual property legislations

§1. — Intellectual property is identified with the construction of EU intellectual property law, within the framework of both cross-border proceedings and property rights. European intellectual property law still leaves a lot of room for national approaches in this field. However, this space is constantly shrinking and should eventually disappear. Trade mark law now only makes sense in a European context, along with the design law and the plant varieties law. Even so, the substantive law of the European Union is still fragmentary in the field of intellectual property, although there is a movement towards total harmonisation [8] (**1.1**). In parallel, the principle of procedural autonomy of the Member States leads to a still too marginal harmonisation of procedural rules (**1.2**). Despite all this, it is nevertheless possible to sketch the outlines of what could or should be a European intellectual property code [9].

1.1 Substantive laws

§2. — Intellectual property rights of the European Union, *i.e*. European Union trade marks, Community plant variety rights and Community designs, are a pleasing reality. Agricultural geographical indications could also be added to this list [10]. However, the construction of a harmonised substantive EU IP law is still not complete. The two key intellectual property rights, namely copyrights/related rights (**1.1.1**) and patents (**1.1.2** and **1.1.3**), are still not governed by EU-wide rules. In addition, the creation of a European patent with unitary effect calls for the recast of SPC Regulations (**1.1.4**). An EU system for non-agricultural geographical indications is also missing, resulting in a patchwork of national regulations with variable levels of protection within the Single Market to the detriment of producers (**1.1.5**). On another note, the design system reform with the drafting of a "Design Package" is an opportunity to achieve full harmonisation of European design law (**1.1.6**). Finally, the status of salaried creators needs to be further harmonised in order to make the EU IP system more coherent (**1.1.7**).

8. See Jean SCHAPIRA, Georges LE TALLEC, Jean-Bernard BLAISE and Laurence IDOT, *Tome 1 — Droit européen des affaires* [European Business Law], 5th ed., Puf, 1999, p. 456 *et seq.*, "Vers un droit communautaire de la propriété industrielle" [Towards a Community Industrial Property Law].

9. Nicolas BINCTIN, "Pour un code communautaire de la propriété intellectuelle" [For a Community Intellectual Property Code], *Mélanges Georges Bonet*, LexisNexis 2010, coll. IRPI, t. 36, p. 51.

10. Georges BONET, notes ECHR, 11 October 2005, *Anheuser-Busch Inc.*: *Propr. intell.* 2007, No. 22, p. 103; CJEC, 16 November 2004, case C-245/02: *Propr. intell.* 2002, No. 15, p. 189; Cass. com., 18 February 2004: *Propr. intell.* 2004, No. 13, p. 853.

1.1.1 Search for an EU copyright and EU related rights

§3. International IP law. — The schedule for the communitisation of copyright and related rights is timid and could be more ambitious. It is noteworthy that the possibility of an EU unitary copyright has not even been mentioned. The current system, which favours national rights, on the one hand, and international law, on the other, is the preferred model. The Berne [11] and Rome [12] Conventions deal mainly with the concerns of copyright holders, at the price of limited integration. All the more so as these international treaties must be applied in the light of the constraints of EU law, specifically in accordance with the principle of non-discrimination between nationals of the Union [13]. Thus, restrictions on trade within the EU produced by the disparity of national copyright laws are justified as long as they result from the difference in regimes and that this difference is inextricably linked to the very existence of copyrights [14]. The French Court of Cassation follows this trend in its new interpretation of Article 5(2) of the Berne Convention [15]. In order to avoid any discrimination between EU nationals and in the absence of a unitary copyright, the Court discarded traditional solutions of the Berne Convention in favour of a harmonised EU solution. More specifically, the reference to the *lex loci originis* for the determination of the first copyright owner is dropped in favour of the *lex loci protectionis*. It leads to the exclusion of all conflict rules favourable to the original law that derive from a national source. To be clear, the law of the country for which protection is claimed governs the existence, enjoyment and exercise of copyright. Although this interpretation of the Berne Convention allows for an easier application of European solutions, it carries with it a regrettable "retreat into home territory" [16] which is at the opposite of current global dynamics [17]. This hegemonic solution brings serious legal uncertainty for foreign operators: a contract in compliance with a foreign local law could thus be challenged on the basis of the *lex loci protectionis* principle [18]. As a result, contractual certainty and predictability of law are diminished. The use of the principle of non-discrimination to circumvent the disparities between the different copyright legislations within the European Union is more than questionable.

The right of creation and exchange, which is influenced by authors of the Enlightenment, operates within a system that is unlikely to produce a creative future. There must be a European ambition for copyright and related rights, which are at the heart of the knowledge economy. By retaining a fragmented approach, we refuse to contribute to the emergence of an integrated and standardised European market for the new economy, which is vital if we are to respond to new global economic challenges.

§4. EU copyright. — At the present time, the lack of a fully integrated market is one of the EU's greatest weakness. To complete the Single Market, Union law needs to touch upon specific domestic regulations. In addition to harmonising competition law, property rights and probably contractual principles need to be harmonised as well.

National copyright legislations in the EU are very close, with main elements of property law being very similar in all the different Member States: property right acquired on creation, no need to file, appropriation of the form, concept of originality, 70-year term, limitations and exceptions to the property

11. Berne Convention for the Protection of Literary and Artistic Works of 9 September 1886, lastly amended on 28 September 1979.

12. International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations done at Rome on 26 October 1961.

13. See CJEC, 30 June 2005, case C-28/04, *Tod's*; and CJEU, 27 January 2011, case C-168/09, *Flos*.

14. Articles 34 and 36 TFEU.

15. Cass. com., 7 October 2014, No. 12-16.844, *La Redoute v Tod's*.

16. Édouard TREPPOZ, "Le repli territorialiste de la Cour de cassation en droit d'auteur" [The Court of Cassation's retreat into home territory in the field of copyright law], *JCP E* 2013, 701.

17. Nicolas BINCTIN, "Droit international privé et propriété littéraire et artistique: le repli français" [Private International Law and Literary and Artistic Property: the French Retreat], *Les Cahiers de propriété intellectuelle*, Vol. 28, No. 2, pp. 325-354.

18. *E.g.* in the event of a non-European conflict: Cass. 1st civ., 10 April 2013, No. 11-12.508, No. 12-12.886 and No. 12-14.525, *ABC News*, *Bull. civ.* I, No 72; Cass. 1st civ., 19 June 2013, No. 12-18.032, *Culture Press*, *Bull. civ.* I, No. 128.

right, etc. An EU copyright would be different from the existing situation because interested parties would have more confidence in the property right. The difficulties of enforcing copyright in the different Member States would be eliminated to a great extent. Under the Berne Convention, a copyright comes into existence in the State of creation, and then the work is received in the Member States as a national work, without national differences fading away. Above all, this assimilation may be a source of weakness when the right does not have exactly the same scope in different Member States, as can be seen with the overlapping of copyright and design rights in Italy or Germany [19]. The holder of an EU copyright would hold that copyright for one, sole territory, that of the EU: there would be only one set of rules to apply, without any difficulties due to adaptation to local differences. Legal certainty would be increased as would the credibility of the field. The Internal Market would be more coherent and the economic confidence required by the knowledge economy would be given a real boost.

§5. Harmonisation of national copyright laws. — Approximating national copyright laws has also shown its limits, which has increased the incentive to create a unitary copyright at EU level.

On the one hand, instead of a single directive proposing full harmonisation, approximation of national copyright laws is achieved through several directives on a step by step basis: software integration [20], term of protection of property rights [21], limitation and exceptions [22], orphan works [23], resale rights [24], collective management and multi-territorial licences [25]. The legal treatment of each of these issues is harmonised at EU level, but copyright unfortunately is unwilling to be part of a fully harmonised scheme. Therefore, the European Court of Justice is harmonising copyright law by stealth, for its own purposes [26]. Naturally, this approach generates an imbalance in national intellectual property regimes.

On the other hand, choosing to act by means of directives may leave a certain margin of discretion to Member States. The Information Society Directive (2001) and the Directive on Copyright in the Digital Single Market (2019) both show the weaknesses of this approach. Thanks to the many exceptions to copyright law as well as the *à la carte* nature of these transpositions, Member States are able to retain their local customs [27]. In this respect, the movement of works is now only slightly easier [28]. Considering harmonisation difficulties, copyrights and related rights could have been introduced by means of a regulation, which would have allowed for the emergence of EU-wide property rights. Unfortunately,

19. CJEU, 21 June 2012, case C-5/11, *Titus Alexander Jochen Donner*.

20. Council Directive 91/250/EEC of 14 May 1991 on the legal protection of computer programs, amended and subsequently codified in Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009.

21. Council Directive 93/98/EEC of 29 October 1993 harmonising the term of protection of copyright and certain related rights, substantially amended and subsequently codified in Directive 2006/116/EC of the European Parliament and of the Council of 12 December 2006.

22. Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society; and most recently Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC.

23. Directive 2012/28/EU of the European Parliament and of the Council of 25 October 2012 on certain permitted uses of orphan works.

24. Directive 2001/84/EC of the European Parliament and of the Council of 27 September 2001 on the resale right for the benefit of the author of an original work of art.

25. Directive 2014/26/EU of the European Parliament and of the Council of 26 February 2014 on collective management of copyright and related rights and multi-territorial licensing of rights in musical works for online use in the internal market.

26. CJEU, 1st December 2011, case C-145/10, Eva Maria Painer; CJEC, 16 July 2009, case C-5/08, Infopaq; see also Cass. com., 15 June 2010; CCE 2010, comm. 120, obs. Christophe CARON; Prop. Intell., January 2011. 83, obs. Jean-Michel BRUGUIÈRE; CJEU, 1st March 2012, case C-604/10, Football Dataco.

27. *E.g.*, see Art. 25 of the Directive on Copyright in the Digital Single Market (2019) : "Member States may adopt or maintain in force broader provisions, compatible with the exceptions and limitations provided for in Directives 96/9/EC and 2001/29/EC, for uses or fields covered by the exceptions or limitations provided for in this Directive".

28. See Célia ZOLINSKI, *Méthode de transposition des directives communautaires* [Method of transposing Community directives], Dalloz, 2007, No. 305 *et seq*.

literary and artistic property law has not yet benefited from such a movement. As a consequence, harmonisation, which was the objective, has only been partially achieved.

The European Court of Justice has embarked upon a dangerous undertaking, namely the single-handed construction of a copyright. The French approach to the concept of originality must give way to the copyright harmonisation movement set in motion by the Court. According to the directive on computer programs, originality exists when the software is "the author's own intellectual creation" [29]. This wording is repeated in successive directives which deal with copyright, although none of them aims to harmonise the concept. For example, a photograph of a portrait may be covered by copyright, if it is the author's intellectual creation and if it reflects the author's personality, which can be manifest in the free and creative choices made by the author when the photograph was taken [30]. The originality resides in the arbitrary choices of the author in the creation of the form for which he claims copyright [31]. With respect to the application of copyright to a database, the Court held that a database is protected by copyright if the selection or arrangement of the data that it contains constitutes an original expression of the author's creative freedom [32].

§6. — With respect to related rights, the general observations on copyright may be transposed *mutatis mutandis*. There must be a strong, not merely a political, ambition in order to fully harmonise related rights within the Union's territory.

§7. — Thanks to the work of those who specialise in the law of literary and artistic property, primarily academics, it should be possible to identify a consensus on an EU law of literary and artistic property which may then be presented to the political authorities [33] by all those concerned. Beyond the question of the exceptions, this work should be able to identify common roots and identical tensions that drive this subject throughout EU territory. There is no insurmountable incompatibility between the literary and artistic property regimes of Member States. At worst, there is some dogmatic reluctance to overcome and, naturally, each State will have to accept some changes. This approach would ensure a better understanding of judicial practices in other countries, and the EU law of literary and artistic property would become a reference system, able to impose its values and techniques in international negotiations.

1.1.2 Failure of the EU patent

§8. Community patent. — Unlike copyright, the ambition to have an EU patent law was first envisaged in the Luxembourg Community Patent Convention of 1975 [34], then updated in the Luxembourg Agreement related to Community patents of 1989 [35]. The failure of the ambition, which is now certain, is explained by the omnipotence of the European Patent Office and the inability of the EU Member States to understand the strategic challenges of this property right. Small administrative quarrels and conflicts of interest between the national industrial property offices representing Member States in the negotiations got the better of the EU patent.

29. Art. 1(3) Directive 2009/24/EC.
30. CJEU, 1st December 2011, case C-145/10, *Eva Maria Painer*, para. 87-89.
31. CJEC, 16 July 2009, case C-5/08, *Infopaq*, para. 37, 44 and 45.
32. CJEU, 1st March 2012, case C-604/10, *Football Dataco Ltd*, para. 38; Cass. 1st civ., 13 May 2014, No. 12-27.691 and No. 13-14.834.
33. See Jean LAPOUSTERLE, *L'influence des groupes de pression sur l'élaboration des normes* [The influence of pressure groups on the preparation of standards], Dalloz, 2009, p. 355 *et seq*.
34. The Luxembourg Convention is even mentioned in the French Intellectual Property Code, in Articles L. 614-25 *et seq*.
35. The Convention for the European Patent for the common market, 15 December 1975: *OJEC* 26 January 1976, ratified by Law No. 77-681 of 30 June 1977: OJ 1st July 1977; Agreement relating to Community Patents of 15 December 1989 amending the Convention of 1975: *OJEC* 30 December 1989, L. 401.

§9. European patent. — The European Patent Convention (EPC), also known as the Munich Convention, is based on regional collaboration. It is a success: a model agreement probably even beyond the field of intellectual property, and proof that mechanisms of international law allow for coordinated action by several States. However, the success of one tool of international law cannot compensate for the failure to introduce an EU unitary property right.

§10. Advantages to introduce an EU unitary patent. — The creation of an EU patent would have ensured consistency between the property right and the market of innovation in which rights are exploited. Fragmented property rights does not allow for the emergence of strong companies integrated in the knowledge economy. The EU needs a property right that is parallel to the market, in the absence of which, investors do not follow the project.

Unfortunately, innovation in the EU is still thought of in national terms. If the company is French, it will first seek a French patent and will look for a French investor. This base is too weak to carry the natural risk involved in innovation. The approach is the same in all European countries. Over the same period, the same innovation in Japan would, with a single property right, have a much wider basin to exploit and therefore much greater interest for investors. The same applies to India, Brazil, China and obviously the United States. The fact that the domestic market in which the innovation is launched lacks critical size seriously penalises the EU economy. Patent law should have been a tool with which to forge a unified domestic market, helping to grow the financial resources of companies, and strengthen the EU's place in the knowledge economy. The Commission has therefore actively supported the construction of an EU patent and has repeatedly stressed the need for such a property right. European credibility will come with the adoption of an EU patent, a unitary property right that may be challenged before an EU court.

§11. European patent with unitary effect. — The EU's delegation of patent law to international bodies, namely the European Patent Organization and the Unified Patent Court, is a serious setback in the construction of an EU patent and marks the abandonment of an essential element of the knowledge economy, which has underpinned the fundamental development of the EU since the Lisbon summit on March 2000.

Within a framework of enhanced cooperation based on Article 329 TFEU, all the EU Member States with two exceptions — Spain and Italy, but the latter eventually joined the enhanced cooperation — used an option from Part IX of the Munich Convention relating to special agreements, in particular Article 142, which allows the creation of a European patent with unitary effect (EPUE). Two regulations (Reg. 1257/2012 and Reg. 1260/2012) were adopted in December 2012 [36] in order to establish rules for a EPUE and also for the language regime of this property right [37]. In addition, an international Agreement on a Unified Patent Court (AUPC), which was signed by 25 of the 28 States of the Union (United Kingdom was still an EU Member State), establishes an *ad hoc* Court which, in particular, has exclusive jurisdiction for disputes involving invalidation or infringement of European patents and EPUE. This agreement lays down a framework for litigation and elements of substantive law [38]. It will be necessary to connect these elements with the rules for referrals of EPUEs and international private

36. Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (hereinafter referred to as "EPUE Regulation"); and Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, *OJEU* 31st December 2012, L. 361, p. 1.

37. Jean-Christophe GALLOUX, *RTD com.* 2013. 243; "Le brevet européen à effet unitaire : un volapük juridique intégré ?" [The European patent with unitary effect: an integrated legal volapük?], *D.* 2013. 520.

38. Nicolas BINCTIN, *Droit de la propriété intellectuelle* [Intellectual Property Law], *op. cit.*, §577 et seq, p. 365 *et seq*.

law, particularly the provisions of "Brussels I*bis*" [39], "Rome I" [40] and "Rome II" [41] Regulations [42]. It is not clear that this solution will make the patent proprietors' life easier. It risks eliminating at the litigation stage the gains made in terms of proceedings, translations and royalties promised by the EPUE delivery procedure [43].

§12. Assessment of the unitary effect. — The European patent with unitary effect is not attached to a unitary legal regime. It is a national property right enforceable in the territories of the other States, which distinguishes it clearly from the EU unitary IP rights [44]. In order "to provide uniform protection" throughout the territory of the Member States in which it has unitary effect, the scope of the property right conferred by the EPUE and its applicable limitations have been harmonised. However, the EPUE unitary nature remains partial as it does not apply to the whole IP regime. As an object of property, the EPUE is treated in its entirety and in all the participating Member States as a national patent of the State with which it has links [45]. There are therefore as many possible property regimes as there are possible States with which it has links [46].

§13. Grasp Brexit opportunities. — The European Union could have taken advantage of the achievements of the EPC implementation to fully harmonise substantive patent law through a directive or a regulation [47]. Instead, the scope of the EPUE rights and applicable limitations have been reduced to a set of minimum specific prerogatives [48]. While these provisions will apply to EPUEs and European patents [49], the corresponding, non-harmonised domestic provisions will continue to apply to national patents [50]. Such legislative disparities could have been avoided by EU normative action.

The withdrawal, with immediate effect, of the ratification of the Agreement on a Unified Patent Court by the United Kingdom on 20 July 2020 should make it possible to improve the "Unitary Patent Package". It would be a pity if the Preparatory Committee merely amended Article 7(2) AUPC to change the seat of the central division that was originally intended to be located in London. The European Commission should seize this opportunity to move the provisions related to the scope and limitations of the EPUE rights to Reg. 1257/2012 and, more broadly, propose a complete harmonisation of national and European patent legislations.

The EU's regulation of substantive patent law would thus impose on the Unified Patent Court to ask the CJEU to give preliminary rulings on questions of interpretation raised by provisions dealing with the scope and limitations of EPUE rights [51]. Such interference by Union law in international patent

39. Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Bruxelles I*bis*).

40. Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I).

41. Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II).

42. Bernard AUDIT and Louis D'AVOUT, *Droit international privé* [International Private Law], 7th ed., Economica, 2013, No. 852 *et seq.*; Louis D'AVOUT, "Droit du commerce international" [The Law of International Trade], *D.* 2011, Panorama 2434.

43. For an overview of the EPUE and of the UPC, see Nicolas BINCTIN, *Droit de la propriété intellectuelle* [Intellectual Property Law], *op. cit.*, No. 577 *et seq*. and No. 1492 *et seq*.

44. Nicolas BINCTIN, "Le projet de brevet européen à effet unitaire : en attendant un brevet de l'Union ?" [The European patent with unitary effect project: waiting for an EU patent?], *Prop. Intell.*, No. 40, July 2011, p. 270; Édouard TREPPOZ, "Le brevet unitaire est-il enfin pour demain ?" [Is the unitary patent finally about to happen?], *RTD eur.* 2011. 864.

45. Article 7 EPUE Regulation.

46. Nicolas BINCTIN, *Droit de la propriété intellectuelle* [Intellectual Property Law], *op. cit.*, §580, p. 368.

47. The European Commission had initially proposed that the scope of the rights conferred by EPUE and its limitations be defined in Regulation (EU) No 1257/2012 (COM(2011) 215final).

48. Articles 25 to 27 AUPC.

49. Articles 2(g), 3(a) and (c) AUPC.

50. Eskil WAAGE, Protection unitaire par brevet. — Brevet européen à effet unitaire [Unitary patent protection. — European patent with unitary effect] (Fasc. 4440), *JurisClasseur Brevets*.

51. Combining Article 21 AUPC and Article 267 TFEU.

law happened before, when 1998 Biotech Directive has regulated the patentability of living organisms and the patentability of biotechnological inventions [52]. In this particularly sensitive field, ECJ's interpretations have had major repercussions [53]. As harmonisation has been piecemeal, the Court has had to answer numerous questions in applying the law. The interpretation of Biotech Directive when preliminary questions were put called for a definition of the concept of a patentable invention, and of the conditions of patentability. It opened a door and the Court has occupied the space that was created, going beyond the text simply in order to have the means to interpret it.

To sum up, the European Union must seize every opportunity to legislate in subjects closely or remotely related to patent law. This would help to place the ECJ at the pinnacle of an international legal construction built on the fringes of Union law.

1.1.3 Expected EU actions on software patents

§14. Computer-implemented inventions. — Patentability of computer-implemented inventions is a crucial topic for modern patent law [54]. However, on 6 July 2005, the European Parliament's rejection of the Proposal for a Directive on the patentability of computer-implemented inventions [55] led to the status quo. The rise of artificial intelligence (AI), which is essentially an invention in the field of information technology, needs an EU legislative action to establish a clear regulatory framework that would accelerate investments and foster integration in the Digital Single Market.

§15. Patentability requirements. — The European Patent Convention (EPC) establishes under Article 52 a non-exhaustive list of items that are not patent-eligible "as such" (so called "non-inventions"). It includes, in particular, computer programs. From an *a contrario* reading of these provisions, the invention requirement has been inferred. Invention being defined as a technical solution to a technical problem, the condition reduces to a requirement of technicality. Assessing the patentability of computer programs often boils down to assessing their technical character.

> **Article 52 EPC.** — "(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.
>
> (2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
>
> (a) discoveries, scientific theories and mathematical methods;
>
> (b) aesthetic creations;
>
> (c) schemes, rules and methods for performing mental acts, playing games or doing business, and ***programs for computers***;
>
> (d) presentations of information.
>
> (3) Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such." [56]

§16. Software protection. — Historically, this exclusion was born in the 1960s in the United States. The Copyright Office admitted copyright protection for computer programs as early as 1964, while a

52. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (hereinafter referred to as "Biotech Directive").

53. See *e.g.* CJEU, 6 July 2010, case C-428/08, *Monsanto Technology*.

54. Christophe GEIGER, "Les inventions mises en œuvre par ordinateur : actualité et enjeux de l'extension contemporaine de brevetabilité" [Computer-implemented inventions: topicality and stakes of the contemporary extension of patentability], in *Les inventions mises en œuvre par ordinateur : enjeux, pratiques et perspectives* [Computer-implemented inventions: challenges, current practices and perspectives], Matthieu DHENNE and Christophe GEIGER (eds.), Collection du CEIPI, LexisNexis, July 2019.

55. Proposal for a Directive of the European Parliament and of the Council on the patentability of computer-implemented inventions, COM(2002)0092 final, *OJEC* 151E , 25 June 2002, pp. 129-131.

56. Emphasis added.

Presidential Commission devoted to the protection of new technologies through patent law issued an unfavorable opinion on computer programs patentability in 1966[57]. Following the US Government's antitrust action, the 1969 IBM's decision to sell hardware and software separately tilted the balance in favour of copyright protection[58]. Thus, in France, in 1968[59] and in Europe in 1977[60], legislators adopted an identical position, in order to prevent US companies from having more rights in Europe than Europeans in the United States. A reverse position would have represented a departure from the principle of reciprocity and would undoubtedly have hampered the development of the software industry in Europe.

However, the scope of copyright protection is very limited, as it relates only to source code. The value of software does not lie in the form of the code, but in the functions it performs. Moreover, proof of code infringement is particularly difficult to provide. These reasons explain, among other things, why software copyright has been seldom used and hardly ever is. In parallel, since the early 1980s, patent offices and courts in the United States and Europe have already developed case law favourable to the protection of software[61]. For its part, the European Patent Office (EPO) has developed a large body of decisions relating to computer-implemented inventions[62].

§17. EPO case law. — There is now no doubt that on both sides of the Atlantic computer programs are patentable according to Patent offices. Nevertheless, the exclusion of computer programs as such has required the development of particularly complex case law before the EPO.

The EPO Technical Boards of Appeal (TBA) have developed a two-step approach to assessing the patentability of computer-implemented inventions. The patent applicant must successively overcome two hurdles[63-64]. First, the requirement of invention, within the meaning of Article 52(1), must be met. The EPO Boards of Appeal adopt a broad interpretation of the concept of invention, taking into account all the technical and non-technical characteristics of the claimed invention. A non-technical element integrated into a technical assembly ensure that a technical character is conferred to the whole. Thereby, an excluded element under Article 52(2) is no longer an element "as such" within the meaning of Article 52(3) as soon as it is linked to known technical means. Second, only an inventive step of a technical nature can satisfy the inventive step requirement (Art. 56 EPC), *i.e.* inventiveness must be assessed on the sole basis of the set of claimed features that contribute to the technical character of the invention. In a nutshell, the assessment of technicality is moved to the inventive step examination

57. The [US] President's Commission on the Patent System, Report to Promote the Progress of Useful Arts, 1966.

58. Martin CAMPBELL-KELLY, *From Airline Reservations to Sonic the Hedgehog: A History of the Software Industry*, MIT Press, January 2003.

59. Article 7(2)(3°) of Loi n° 68-1 du 2 janvier 1968 tendant à valoriser l'activité inventive et à modifier le régime des brevets d'invention [Law No 68-1 of 2 January 1968 to enhance the value of inventive activity and to modify the patent regime]: "Do not constitute, in particular, industrial inventions: [...] 3° Financial or accounting methods, game rules and any other systems of an abstract nature, including programs or series of instructions for the operation of a calculating machine".

60. The Munich Convention, signed on 5 October 1973, entered into force on 7 October 1977.

61. In the US, see CCPA, 30 March 1978, *In re Freeman*, 573 F.2d 1237; and USSC, 3 March 1981, *Diamond v Diehr*, 450 U.S. 175 (1981). In Europe, see, EPO, TBA, 15 July 1986, *Vicom*, case T208/84: *OJ EPO* 1987, p. 14.

62. EPO, TBA, 1st July 1999, *Computer program product/IBM*, case T1173/97: *OJ EPO*, p. 609; EPO, TBA, 8 September 2000, *Controlling pension benefits system/PBS PARTNERSHIP*, case T931/95: *OJ EPO* 2001, p. 441; EPO, TBA, 26 September 2002, *Two identities/COMVIK*, case T641/00: *OJ EPO* 2003, p. 352; EPO, TBA, 21 April 2004, *Auction method/HITACHI*, case T258/03: *OJ EPO* 2004, p. 575; EPO, TBA, 15 November 2006, *Estimating sales activity/DUNS LICENSING ASSOCIATES*, case T154/04: *OJ EPO* 2008, p. 46.

63. Stefan V. STEINBRENER, "L'appréciation de la brevetabilité des inventions mises en œuvre par ordinateur par l'OEB" [Assessment of the patentability of computer-implemented inventions by the EPO], in *Les inventions mises en œuvre par ordinateur : enjeux, pratiques et perspectives* [Computer-implemented inventions: challenges, current practices and perspectives], Matthieu DHENNE and Christophe GEIGER (eds.), *op. cit.*, pp. 89-97.

64. For a "whitelist" of positive cases focusing on patent-eligible inventions, see Stefan V. STEINBRENER, "Patentable subject matter under Article 52(2) and (3) EPC: a whitelist of positive cases from the EPO Boards of Appeal", *Journal of Intellectual Property Law* & *Practice*, Part 1: Vol. 13, Issue 1, January 2018, pp. 13-35; Part 2: Vol. 13, Issue 2, February 2018, pp. 103-119.

stage after circumventing Article 52 EPC [65].

Moreover, case law is different from one European jurisdiction to another. Some are close to EPO jurisprudence and some are not [66]. Indeed, even if EPO Technical Boards of Appeal have developed a uniform approach to assess on a case-by-case basis the technical character of computer-implemented inventions [67], national courts are not bound by EPO decisions. Discrepancies of interpretation of EPC provisions between the EPO and European national courts are regrettable. While EPO relies on an interpretation of EPC provisions to grant a patent, a divergent interpretation by a national court may paradoxically lead to the invalidation of the national part of the European patent.

§18. Drawbacks. — The case law derived from the EPO has 3 drawbacks:

(i) lack of harmonisation between European jurisdictions, which allows forum shopping;

(ii) source of significant legal uncertainty; and

(iii) esoteric nature as it is understandable only to initiates and obscure to others.

The principle of legal certainty make it necessary to clarify the current EU legal framework. This reform appears all the more necessary as the vast majority of innovations are now located in the information technology sector.

§19. Recommendations. — These observations lead us to suggest two recommendations. First, the European Commission could introduce specific provisions for the software patentability as part of a comprehensive reform of patent law (*see above*, **§13**) or, at the very least, bring back onto the agenda a Proposal for a Directive on the patentability of computer-implemented inventions, but drawing lessons from the 2005 fiasco, which was largely attributable to the mobilisation of public opinion by the Open Source community [68]. Consequently, such a long-term legislative project that would recognise the patentability of computer programs, and which could benefit from current and future debates on the patentability of AI applications, should be accompanied by a very slick communication strategy. Second, the United Kingdom's exit from the European Union may be the opportunity for an ambitious reform of European and national substantive patent laws. In accordance with Article 27(1) TRIPS Agreement, which states that "patents shall be available for any inventions, whether products or processes, *in all fields of technology*" [69], lists of non-inventions should be deleted from both the EPC and national laws in favour of the introduction of an autonomous condition of a technical nature.

The technical character should be the sole criterion for patent-eligibility, regardless to inventive step and reference to prior art. Then, patentability would remain classically assessed according to the conditions of novelty, inventive step and susceptibility to industrial application. Such a technicality requirement would imply that the invention is *operational*, *i.e.* it must be capable of performing the function described in the patent application or in the patent, and that the invention has a *direct* and

65. Matthieu DHENNE, "L'appréciation de la brevetabilité des inventions mises en œuvre par ordinateur par les juridictions françaises" [Assessment of the patentability of computer-implemented inventions by the French courts], in *Les inventions mises en œuvre par ordinateur : enjeux, pratiques et perspectives* [Computer-implemented inventions: challenges, current practices and perspectives], Matthieu DHENNE and Christophe GEIGER (eds.), *op. cit.*, pp. 149-156.

66. For a comparative case law study, see Matthieu DHENNE, "Caractère Technique" [Technical character], *JurisClasseur Brevets*, Fasc. 4720, §62 *et seq*.

67. EPO, EBA, 12 May 2010, *Programs for computers*, G3/08: *OJ EPO* 2011, p. 10.

68. For a study on the coexistence/compatibility between Open Source and the patentability of computer-implemented inventions, see Benjamin JEAN, "Open Source et brevetabilité des inventions mises en œuvre par ordinateur: quelle coexistence ? quelle compatibilité ?" [Open Source and patentability of computer-implemented inventions: which coexistence? which compatibility?], in *Les inventions mises en œuvre par ordinateur : enjeux, pratiques et perspectives* [Computer-implemented inventions: challenges, current practices and perspectives], Matthieu DHENNE and Christophe GEIGER (eds.), *op. cit.*, pp. 243-276.

69. Emphasis added.

concrete application [70]. Technicality would thus remain a flexible requirement while assuming the role of "guardian of the borders" of patent-eligibility, which is its due.

More specifically, when applied to computer-implemented inventions, the technicality condition requires that the program be described in its structure, *i.e*. by a functional algorithm, and its application. On the one hand, if the structure of the program is not described and the program is an essential element of the invention, the patent application must be rejected. On the other hand, if the program has no concrete application, the patent application must be rejected because it then consists of an abstract item that is not patent-eligible) [71].

1.1.4 Recast of Regulations on supplementary protection certificates

§20. Rationale of SPC Regulations. — The purpose of EU Regulations on supplementary protection certificates (SPCs) for medicinal products (Reg. 469/2009) [72] and plant protection products (Reg. 1610/96) [73] is to establish a simple and balanced system providing for sufficient protection to encourage pharmaceutical research. Actually, the period that elapses between the filing of a patent application for a new medicinal or plant protection product and the grant of the marketing authorisation makes the period of effective protection under the patent insufficient to cover the investment put into research [74].

§21. — Given the considerable financial stakes involved, some provisions of theses EU Regulations gave rise to numerous disputes, and CJEU's interpretations on preliminary rulings have sometimes destabilised the main principles governing SPCs to the detriment of legal certainty [75]. More specifically, difficulties encountered regarding the interpretation of Article 3 Reg. 469/2009 have led to divergent practices between national IP offices with regard to the granting of SPCs. For example, the recent 2020 *Santen* judgement has finally clarified some of the uncertainties raised by the *Neurim* case (**1.1.4.1**). That being said, SPCs Regulations still leave room for diverging interpretations. As the UPCA Agreement is hardly articulated with SPC legislation, the entry into force of the "Unitary Patent Package" will necessary need the recast of Reg. 469/2009 and Reg. 1610/96. New regulations will have to incorporate the CJEU case law and prevent, as far as possible, interpretational disputes over the new provisions. Besides, the EU legislature should complete the system of European patents with unitary effect with the creation of supplementary protection certificates with unitary effect (**1.1.4.2**).

1.1.4.1 Protection of the new therapeutic application of a known drug

§22. *Santen* case. — The central question raised in the 2020 *Santen* case [76] was whether a supplementary protection certificate only rewards the development of *new* active substances for medicinal use or any research for new treatments for known substances.

> Santen owns European patent (EP 057959306) for an ophthalmological emulsion in which cyclosporin is an active ingredient, plus a marketing authorisation for the drug IKERVIS®, an eye drops emulsion containing said cyclosporin, which is intended for the treatment of severe keratitis in adult patients.

70. Matthieu DHENNE, *Technique et droit des brevets : l'invention en droit des brevets* [Technique and patent law: invention in patent law], Bibliothèque de droit de l'entreprise, LexisNexis, August 2016.
71. See the report of the French AIPPI Group at the 2017 Sydney Congress.
72. Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, *OJEU* L 152, 16 June 2006, pp. 1-10.
73. Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products, *OJEC* L 198, 8 August 1996, pp. 30-35.
74. Recital (4) Reg. 469/2009 and recital (5) Reg. 1610/96.
75. Jean-Christophe GALLOUX and Jacques AZÉMA, *Droit de la propriété industrielle* [Industriel Property Law], Précis Dalloz, 8th ed., 2017, p. *340 et seq*, §486 *et seq.*
76. CJEU, 9 July 2020, case C-673/18, *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*.

> On the basis of these patent and MA, Santen filed an application with the French IP office, the "Institut national de la propriété industrielle" (INPI), for a supplementary protection certificate covering a product entitled "cyclosporin for the treatment of keratitis". The Director General of the INPI rejected this application, considering that the marketing authorisation on which it was based was not the first for cyclosporin, since another authorisation had already been issued for a SANDIMMUN® drug, which included this same active ingredient, in the context of post-graft medication. Faced with the applicant's appeal against this rejection, the Paris Court of Appeal referred two questions for a preliminary ruling to the CJEU, with a view to determining, in substance, whether an SPC could be granted for a new therapeutic application of a known drug or not.
>
> The ECJ firstly considered that the definition of the notion of "product" in Article 1(b) Reg. 469/2009 is independent of the approved therapeutic application of said product, which therefore implies that it has a therapeutic effect of its own. The Court concluded, secondly, that this strict interpretation of the concept of product implies that Article 3(d) thereof must be understood as relating to the first marketing authorisation of any medicinal product incorporating the active ingredient.

§23. — Initially, the European Court of Justice had consistently adopted a literal interpretation of provisions laid down in SPC Regulations by excluding the grant of SPCs for new therapeutic applications [77]. However, the 2012 *Neurim* judgment [78] departs from the wording of Article 3(d) Reg. 469/2009, holding that a SPC could be granted despite an earlier marketing authorisation for the same active ingredient, so that:

> "[...] the mere existence of a marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product [...], provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate."

However, the CJEU later restricted the scope of this reversal in the *Abraxis* case [79], by rejecting the protection of new formulations of a known product. Nevertheless, the interpretation of the *Neurim* case law has given rise to considerable debate as to whether its application was limited to the case at hand, *i.e.* from veterinary use to human use or *vice versa*, or meant that any new therapeutic application was protectable by a SPC. National patent offices took different positions on this question.

§24. Reasons for the *Santen* decision. — In *Santen*, the European Court of Justice unambiguously put an end to SPCs for second therapeutic applications and thus to the legal uncertainty surrounding them. It is thus an important turnaround. The judgment is part of a trend towards a literal reading of Reg. 469/2009, in particular after the *Abraxis* case above-mentioned. It should be reaffirmed in the pending Novartis case [80], which relates to the question whether a new SPC can be granted to the holder of a first SPC concerning the same active ingredient.

This ultimately brings us back to the idea, once developed by Michel DE HAAS in connection with patents, that a new treatment is not protectable because it was already inherent in the first product [81]. The rationale of Reg. 469/2009 is to foster research for new active ingredients. A SPC aims to compensate for the period that elapses between the filing of a patent application for a new drug and the grant of the MA *due to the performance of pharmaceutical tests and clinical trials*. Consequently, this Regulation is not intended to reward any further research that would result in a patentable invention between the

77. CJEC, 19 October 2004, case C-31/03, *Pharmacia Italia SpA*; CJEC, 4 May 2006, case C-431/04, *Massachusetts Institute of Technology* (MIT); and CJEC, 17 April 2007, case C-202/05, *Yissum Research and Development Company of the Hebrew University of Jerusalem v Comptroller-General of Patents*.

78. CJEU, 19 July 2012, case C-130-11, *Neurim Pharmaceuticals Ltd v Comptroller-General of Patents*.

79. CJEU, 21 March 2019, case C-443-17, *Abraxis Bioscience LLC v Comptroller General of Patents*.

80. Case C-354/19.

81. Michel DE HAAS, *Brevet et médicament en droit français et en droit européen* [Patents and medicines in French and European law], Litec, CEIPI, 1981, No. 493.

filing of the application and the grant of the MA. The reason for this is that, when applying for the authorisation to market a medicinal product that incorporates a new active ingredient not previously authorised, the applicant must submit a large amount of clinical, non-clinical and pharmaceutical data. The conduct of the necessary trials and tests requires to invest time and resources, which lead to a significant reduction of the patent term, more so than the length of the granting procedure itself[82]. However, when applying for a MA covering the new indication of a previously authorised active ingredient, *i.e.* a hybrid application[83], the applicant may rely on the clinical tests included in the previously granted MA, provided that the data exclusivity period has ended (*see below*, **§108**).

§25. — While legal certainty is undoubtedly the first social value to be attained, it should not be overlooked that it is achieved here at the price of a significant reduction in the incentive for research in the pharmaceutical sector. However, despite the insecurity, many SPCs have been granted and exploited in accordance with previous case law. Some companies have even been built based on the economic model of reusing known drugs (for example, developers of personalised drugs or orphan drugs, or companies using data and artificial intelligence to identify new therapeutic uses). Therefore, although it increases legal certainty, this judgment is nonetheless a loss for many players in the sector, who will ultimately no longer have the incentive to invest in the development of new applications for known medicines.

Perhaps this restrictive approach of the CJEU should be seen as an appeal to the European Commission since. As the Advocate General pointed out in *Santen*, it is for the European Union legislator alone, and not the Court, to decide to extend the scope of protection of SPCs.

1.1.4.2 Supplementary protection certificates with unitary effect

§26. MPI Study on SPCs. — The creation of a SPC with unitary effect would be the final element of the European patent reform. In its *Study on the Legal Aspects of Supplementary Protection Certificates in the EU*[84], under the direction of Reto HILTY and Roberto ROMANDINI, the Max Planck Institute (MPI) gives a detailed overview of the institutional issues and substantive requirements for SPCs granted on the basis of a European patent with unitary effect (EPUE).

§27. *De lege lata*. — The MPI Study points out that, with minor modifications to current SPC Regulations, national IP offices could grant a national SPC on the basis of an EPUE albeit within the exclusive jurisdiction of the Unified Patent Court. The main difficulty lies in Article 30 UPCA, which states that:

> "A supplementary protection certificate shall confer the same rights as conferred by the patent and shall be subject to the same limitations and the same obligations."

SPC applications filed with national offices are subject to the law of the place of filing. It can be inferred from the very spirit of the provisions of Reg. 469/2009 and Reg. 1610/96 that only national IP title may be issued by national IP offices. If the latter were allowed to grant unitary SPCs, *i.e.* IPRs with extra-national scope, Article 30 would have to be interpreted as a tacit surrender of sovereignty. Such reasoning is hardly admissible because sovereignty concerns of EU Member States must be given precedence. As a result, national IP offices should be able to grant SPCs with national scope on the basis of European patents with unitary effect[85].

82. Max Planck Institute for Innovation and Competition (MPI), *Study on the Legal Aspects of Supplementary Protection Certificates in the EU*, published on 31 May 2018 and commissioned by the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs of the European Commission, p. 53.

83. Article 10(3) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, *OJEC* L 311, 28 November 2001, pp. 67-128.

84. Max Planck Institute for Innovation and Competition (MPI), *Study on the Legal Aspects of Supplementary Protection Certificates in the EU*, *op. cit.*

85. *Ibid.*, pp. 540-543.

§28. ***De lege feranda.*** — The MPI Study focuses, among other things, on the articulation between the territorial scope of the basic patent and that of the MA when granting a SPC with unitary effect. The territorial scope of a future unitary SPC will necessarily results from the superimposing of those of the basic patent and marketing authorisation, what the above-mentioned study refers to as "the mandatory *consonance* of territories" [86].

When a SPC with unitary effect is granted on the basis of a European patent with unitary effect and a European MA [87], the territories involved are "consonant" as the territory covered by the MA include the territory covered by the EPUE. The same applies when the scope of a bundle of national MAs issued under mutual recognition or decentralised procedures [88] covers at least all the EU Member States where the EPUE has unitary effect.

However, when the applicant for a SPC with unitary effect relies on a bundle of national MAs covering a territory narrower than that of the basic EPUE, the MPI suggests that the EU legislature could experiment with an advanced system: the unitary SCP would be granted only for the territory in which at the critical date the unitary patent is in force and an MA exists.

> "On the one hand, the lawmakers can decide that in the countries where no MAs have been granted at the date an application for a unitary SPC is filed, the unitary patent can still be designated as basic patent once the MA is awarded in those countries, provided that the deadline of Art. 7 Reg. 469/2009 is respected and that the patent is still in force at the time the application for a certificate with effect in that country is filed. This solution combines **a unitary SPC with a static territorial scope** with national SPCs granted on the same unitary patent [...]."
>
> "On the other hand, the lawmaker could even experiment with a more sophisticated option, providing for **a unitary SPC with dynamic territorial scope**. In this approach, the owner of a unitary SPC may apply for territorial extension of the granted right once national MAs have been granted for EU States that are covered by the basic unitary patent and in which at the critical date a valid MA has yet to be granted. This solution does not seem to challenge fundamental principles of Union law such as the protection of legitimate expectations and legal certainty for third parties, nor does it create protection in situations where it would no longer be possible to obtain an SPC under the current legislation."

§29. Criticisms. — As attractive as this system may be, it has one major drawback: the creation of an *à la carte* territorial protection for pharmaceutical companies is necessarily to the detriment of the EU single market integration. The unitary SPC would then be an IP title with variable territorial protection, depending on the strategic choices of the holders who will inevitably target the most profitable national markets.

On second thought, such a system would create a SPC with "limited unitary" effect. The expression is an oxymoron however [89]. How can the unit be limited? How to share what makes one? The unitary effect ensures uniform protection throughout the territory of the UPCA Member States. Attempting to safeguard the unitary effect by considering that the SPC is valid throughout the Union's territory, but that it is enforceable only on a part of it, is a sleight of hand.

§30. Conclusion. — As a result, the application for a unitary SPC should rely on (i) a European MA or (ii) a bundle of national MAs only a national MA has been granted in all countries in which the European

86. *Ibid., p. 577. Emphasis added.*

87. Issued under Article 13(1) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

88. Articles 28 to 34 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, *OJEC* L 311, 28 November 2001, pp. 67-128; and Articles 31 to 43 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, *OJEC* L 311, 28 November 2001, pp. 1-66.

89. To limit a unitary IPR is to recognise its underlying plurality, and thus to deny its unitary nature.

patent has unitary effect. It is worth noting that a unitary SPC granted on the sole basis of a European MA would be discriminatory as some medicinal products are excluded from the centralise procedure [90] and that there is no such EU-wide marketing authorisation for plant protection and veterinary products.

1.1.5 Need for an EU GI system for non-agricultural products

§31. — EU geographical indications (GIs) — including protected designations of origin (PDOs), protected geographical indications (PGIs) and geographical indications of spirit drinks and aromatised wines — identify agricultural products having specific characteristics embedded into their place of origin. These geographical names, which are part of the EU system of intellectual property rights [91], are governed by EU Regulation on quality schemes for agricultural products and foodstuffs [92].

§32. Protecting geographical names of non-agricultural products. — However, only GIs for agricultural products and foodstuffs can benefit from unitary protection granted exclusively at EU level. Specific national legislations or other EU intellectual property right (IPR) instruments thus protect geographical names identifying non-agricultural products [93].

It is worth noticing that the European Union Trade Mark (EUTM) system allows the appropriation of names designating the geographical origin of goods only through the registration of collective marks, excluding individual marks [94] and certification marks [95]. However, the EU legislator has conceived collective mark as an IPR instrument protecting geographical names in the territory of the Union complementarily to EU GI system [96]. This is because collective EUTMs and GIs are governed by distinct legal regimes and pursue different aims [97] (*see below*). Accordingly, craftsmen and local manufacturers cannot use it to make up for the absence of EU quality schemes for non-agricultural products.

§33. Articulation between the EUTM and French GI systems. — Furthermore, because of the precedence principle which guarantees the superiority of Union law over national law [98], it can be difficult to coordinate the European trade mark system with national GI systems for non-agricultural products. French experience deserves attention.

On March 2014, French Law on consumption [99] (also known as "Loi Hamon") introduced legal framework to protect geographical names for non-agricultural products. The French GI system already had the "*Appellations d'origine contrôlée*" (AOCs), which entitle protection regardless to classes of products. However, AOCs require a strong link between products and their place of origin (*terroir* link; *see below*). This has led to the registration of a vast majority of AOC agricultural products while very few non-agricultural products seemed likely to meet protection requirements [100]. As a result, the French legislator has intervened by creating a national protection for industrial and handcrafted products.

90. If the preconditions set out in Article 3(1) and (2) of Reg. 726/2004 are not met.
91. CJEC, 10 November 1992, case C-3/91, *Turrón de Jijona*, para. 37; CJEC, 20 May 2003, case C-108/01, *Prosciutto di Parma*, para. 64.
92. Regulation (EU) 1151/2012 of the European Parliament and of the Council of 21st November 2012 on quality schemes for agricultural products and foodstuffs (hereinafter referred to as "GI Regulation").
93. EU Green Paper: Making the most out of Europe's traditional know-how: a possible extension of geographical indication protection of the European Union to non-agricultural products (COM/2014/0469 final).
94. Article 7(1)(c) EUTM Regulation; see also CJEC, 4 May 1999, cases C-108/97 and C-109/97, *Windsurfing Chiemsee*.
95. Article 83(1) EUTM Regulation.
96. Article 74(2) EUTM Regulation.
97. CJEU, 20 September 2017, Cases C-673/15 P, C-674/15 P and C-675/15 P, *The Tea Board v EUIPO (Darjeeling)*, para. 62.
98. CJEC, 15 July 1964, case C-6/64, *Costa v Enel.*
99. Law No 2014-344 of 7 March 2014 on consumption.
100. National Assembly, M. Razzy HAMMADI and Mme Annick LE LOCH (Representatives), Rapport fait au nom de la Commission des affaires économiques sur le projet de loi relative à la consummation, p. 239: there are some AOC registered for non-agricultural products "such as lace from LE PUY, handkerchiefs and canvases from CHOLET, pottery from VALLAURIS, enamels from LIMOGES and monoï from TAHITI, but (with the exception of the latter) very old".

In order for this *sui generis* regime to be compatible with the French trade mark system, a coexistence solution had been implemented [101]. Article L. 713-6(c) IPC used to read as follows:

> "The registration of a trade mark shall not preclude the use of an identical or similar sign such as a geographical indication [*designating non-agricultural products*], unless the trade mark, having regard to its reputation and renown and duration of use, is exclusively responsible for the consumer's reputation or knowledge of the product for which a geographical indication is applied for."

Nevertheless, this provision has proved to be contrary to European trademark law. Since Trade Mark Directive left no room for discretion as to the transposition of trade mark right limitations [102], the French legislator abolished this coexistence provision, what unbalances the articulation between national trade marks and GIs for industrial and handcrafted products. In the present case, the total harmonisation of trade mark laws has been to the detriment of an *avant-garde* national IP right. However, on the basis of Article 114(4) TFEU, the French legislator could have initiated a derogation procedure in relation to Union law in order to be authorised to maintain this provision. It would have ensured the consistency of a national system for "the protection of industrial and commercial property" (as referred to in Article 36 TFEU). It is regrettable that it did not do so.

§34. Rationale of the EU GI system. — The lack of unitary protection for handicraft goods is an obvious shortcoming of Union law. The needed extension of EU quality schemes to the protection of non-agricultural products is an opportunity to question the overall coherence of the EU GI system.

Above all, the economic rationale of GIs should be fervently reasserted to deal with critics of a strong EU GI system, who denounce a manoeuvre "to use monopoly rents from GIs to subsidize European agricultural production" [103]. The EU GI system is not only one of the various aspects of the Common Agricultural Policy. Like trademarks, GIs are also legal regulatory tools for undistorted competition in the common market, as required by European primary law [104] (**§36**). This can be stressed comparing the objectives pursued by the GI regulation with those of trade mark law (**§35**).

§35. Trade marks. — A trade mark distinguishes the goods or services of one undertaking from those of other undertakings [105]. It thus correlates the goods or services covered by its registration with a single commercial origin [106]. Thus, by applying for a trade mark registration, an undertaking reserves a sign identifying goods or services in order to acquire and retain customers without any risk of confusion with competing goods or services. Rights conferred by a trade mark provide its proprietor with a presquare, an "exclusion zone" [107], in its speciality and near thereof. The economic rationale is that, in order to develop his business in an undistorted competitive market, the trade mark proprietor must

101. Jean-Christophe GALLOUX, "Les lois n° 2014-315 du 11 mars 2014 renforçant la lutte contre la contrefaçon et n° 2014-344 du 17 mars 2014 relative à la consommation" [Laws No 2014-315 of 11 March 2014 strengthening the fight against counterfeiting and No 2014-344 of 17 March 2014 on consomption], *RTD Com.* 2014 p. 579.

102. Article 14 Trade Mark Directive.

103. Justin HUGHES, "Champagne, Feta, and Bourbon: The Spirited Debate About Geographical Indications", *Hastings Law Journal* 2006, Vol. 58:299.

104. This is why the European legislature has introduced unitary protection for GIs through Regulation (EU) 1151/2012 having regard to Article 43(2) TFEU (dealing with the establishment of the common organisation of agricultural markets and the pursuit of the objectives of the common agricultural and fisheries policies) and Article 118(1) thereof (dealing with the creation of EU unitary intellectual property rights in the context of the establishment and functioning of the internal market).

105. Article 4(a) Regulation (EU) 2017/1001.

106. CJEC, 22 June 1976, case C-119/75, *Terrapin v Terranova*, para. 6.

107. Opinion of the Advocate-General, Eleanor SHARPSTON, in *Intel Corporation v CPM United Kingdom Ltd.*, case C-252/07, para. 5 and 6: "A significant function of a trade mark is to link goods or services to a source of supply, whether the original producer or a commercial intermediary. [...] The supplier can establish a reputation, which is protected from usurpation by competitors, for products bearing the mark, and can thus promote trade in those products. [...] Trade marks are therefore protected by a basic rule which prevents the registration or use of a sign identical or similar to a registered trade mark, for goods or services identical or similar to those for which the mark is registered. To put it more graphically, around each trade mark there is an 'exclusion zone' which other marks may not enter".

be assured that the efforts and investments he would make will only benefit to the goods or services actually marketed under his brand.

Furthermore, as reputation is a fair competitive advantage, European trade mark law protects trade marks with a reputation against detrimental infringements [108]. A free rider, which takes undue advantage of the reputation of a trade mark, or an infringer, which tarnishes the brand image, breaks the competing equality between undertakings. By assimilating the competitive advantage of others, it distorts free competition. Condemning free-riding and tarnishing is, here again, a manifestation of market regulation [109].

§36. Geographical indications. — Geographical indications and trade marks are distinctive signs, but the former differ from the latter in that they distinguish goods as originating in a territory from those originating in others territories. For a good to be considered "as originating" in a territory, its quality, reputation or other characteristics have to be essentially attributable to its geographical origin [110]. The natural or cultural link between a product and its place of origin can be intense, involving the interwoven of natural and human factors (terroir link for PDOs) [111], or a looser link involving natural or human factors (for PGIs). It results from the activity of a local producers' community, which "generated and accumulated across its history a collectively developed knowledge of production" rooted in a given geographical area [112]. This traditional and local knowledge has stirred up a legitimate expectation of quality among consumers regarding goods originating in the territory at issue [113]. Thus, by applying for a geographical indication registration, a private collective body of local producers reserves a geographic name identifying goods whose quality is guaranteed because they were produced in accordance with specifications [114]. Consequently, as for trade marks, GIs aims to acquire and retain customers but without confusion about the geographical origin of marketed goods as unauthorised uses might degrade expected quality.

Where reputation anchors products in a geographical area, due to the history of the products or their manufacturing process, geographical names entitle protection because they raise specific expectations in consumers' minds regarding as to the quality of the product [115]. The ECJ endorsed this approach in the *Exportur* [116] case holding that:

> "such [*geographical*] names may nevertheless enjoy a high reputation amongst consumers and constitute for producers established in the places to which they refer an essential means of attracting custom" (para. 28).

As with trade marks — and even more so because it can be a GI protection requirement — reputation is a competitive advantage that is fairly earned. Free riders thereupon distort free competition because they cheaply and effortlessly make the most of others' reputation. GIs are thus regulation tools ensuing a fair equality between competitors.

§37. Protecting geographical indications. — As shown above, valuing traditional and local knowledge can give producers a fair competitive advantage in a free trade market. Within the Single Market,

108. Article 10(2)(c) Trade Mark Directive and Article 9(2)(c) EUTM Regulation.
109. Romain David BOURDON, "Prouver l'atteinte à une marque renommée" [How to Prove the Infringement of a Trade Mark with a Reputation], *Les Cahiers de propriété intellectuelle*, Vol. 31, No 3, p. 417.
110. Article 22(3) TRIPS Agreement.
111. Article 5(1) Regulation (EU) 1151/2012.
112. Andrea ZAPPALAGLIO, "The Debate Between the European Parliament and the Commission on the Definition of Protected Designation of Origin: Why the Parliament is Right", *IIC* 2019, 50:595-610, quoting from the INAO Applicant's Guide (November 2017), 26.
113. Jérôme PASSA, *Traité de droit de la propriété industrielle* [Industrial Property Law Treaty], Vol. 1, 2nd ed., LGDJ, §533 *et seq.*, p. 759 *et seq*.
114. Article 7 GI Regulation.
115. Andrea ZAPPALAGLIO, *The why of geographical indications: The transformation of the link between the product and its place of origin in Europe*, Thesis, 2018, University of Oxford.
116. CJEC, 10 November 1992, case C-3/91, *Exportur v LOR and Confiserie du Tech*.

an EU GI system for non-agricultural products could benefit both producers (raising visibility of goods and willingness to pay for the product) and consumers (increasing the level of information about products) [117]. It would provide for better enforceability of rights on geographical names and might decrease of losses stemming from infringement. Besides, EU regions concerned could indirectly gain visibility and generate tourism through cultural activities.

§38. Possible paths. — Implementing an EU GI system for the protection of non-agricultural products can follow two paths:

(i) extending the two EU quality schemes (PDOs and PGIs); or

(ii) creating a unitary protection based on the PGI quality scheme.

In most cases, handicraft products are embedded in a geographical area due to the traditional know-how of local producers, that is excluding a natural link with the soil (*terroir* link). However, in a study dealing with the suitability of the EU GI quality scheme to be extended to non-agricultural products [118], Andrea ZAPPALAGLIO *et al.* have shown that, where the products are made from locally sourced raw materials, PDO model could be applicable; and EU quality schemes (PDOs and PGIs) could then suitably be extended to handicraft products. However, the need of a duel system have to be questioned.

§39. Recommendations. — The current EU GI dual system (characterised by two different links, one stronger than the other) is a legacy of historical divergent approaches to the protection of geographical names among Member States [119]. It is however hard to explain that two distinct legal instruments provide for identical protection, *i.e.* the intensity of the link does not affect the scope of the protection conferred [120].

The EU Commission calls for "a simpler GI system, faster registration of geographical indications and more efficient approval of amendments to product specifications [*that*] would reduce administrative costs of managing the system" [121]. However, since it seems difficult, if not impossible, to harmonise the GI system merging PDOs and PGIs, the EU legislature should create an independent single legal framework for non-agricultural GIs, based on the PGI quality scheme.

1.1.6 Advocacy for a fully integrated EU design law

§40. Legal framework. — Design law, like trade mark law, has greatly benefited from the approximation of national laws and from the creation of EU unitary titles, both needed for the establishment and functioning of the internal market. Design Directive [122] was adopted in 1998, at a time when the EU

117. As it has convincingly been shown in *Economic aspects of geographical indication protection at EU level for non-agricultural products in the EU*, published on 20 February 2020 and commissioned by the European Commission.

118. Andrea ZAPPALAGLIO, Flavia GUERRIERI and Suelen CARLS, "*Sui Generis* Geographical Indications for the Protection of Non-Agricultural Products in the EU: Can the Quality Schemes Fulfil the Task?", IIC 2020, 51:31-69.

119. As Andrea ZAPPALAGLIO explains in *The why of geographical indications: The transformation of the link between the product and its place of origin in Europe* (*op. cit.*), the EU GI system dual approach descends from the historical origins of the two quality schemes. On the one hand, PDO descends from national and international systems based on the concept of terroir. On the other hand, PGI descends from non *sui generis* GI system in which geographical names were protected through unfair competition, passing off or false advertising laws.

120. Delphine MARIE-VIVIEN, "The Protection of Geographical Indications for Handicrafts: How to Apply the Concepts of Natural and Human Factors to All Products", *WIPO Journal* 2013, 4:191-205.

121. European Commission Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products, (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs, (EU) No 251/2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products, (EU) No 228/2013 laying down specific measures for agriculture in the outermost regions of the Union and (EU) No 229/2013 laying down specific measures for agriculture in favour of the smaller Aegean islands, 1st June 2018, COM(2018) 394 final/2, see p. 14.

122. Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs (hereinafter referred to as "Design Directive").

had a dynamic and determined influence on the intellectual property regime of Member States. It covers most of the property regime (substantive requirements, term of protection, scope of protection and validity of the design right) but excludes litigation (sanctions, remedies and enforcement) and ownership. As there were marked legislative divergences between Member States, national laws have had to undergo profound change in order to come into line with EU provisions.

Despite the approximation of national legislations, a design protection system adapted to the needs of the internal market was still needed. Community Design Regulation [123], adopted in 2001, very appropriately introduced two unitary IP rights: the (registered) Community design and the unregistered Community design [124].

§41. — The EU legal framework thus currently consists in a two-tiered system of design protection at both national and Union level. The design system reform with the drafting of a European "Design Package" must aim at full harmonisation of national legislations along the lines of new EU Design Regulation (**1.1.6.1**). Integral alignment of national design laws with each other and with EU design law could eventually lead to the demise of national titles in favour of a single European unitary title (**1.1.6.2**).

1.1.6.1 Full harmonisation of European design systems

§42. — As far as possible, maximum harmonisation should be achieved between Member States' legislations (*see below*). Design Directive has harmonised central provisions of substantive design law, which at the time of adoption were considered as most directly affecting the functioning of the internal market by impeding the free movement of goods embodying designs in the Union [125]. For this reason, there remain residual but substantive divergences as well as procedural disparities within the European design law. Their removal would make the two-tiered design system more comprehensible to European businesses, in particular small and medium-sized enterprises.

Nevertheless, generalisation of the "repair clause" through the recasting of Design Directive might remain a disputed issue, as evidenced by the recent French failure to liberalise the automotive aftermarket in spare parts (**a**). Political dissents between Member States should not delay or jeopardise further harmonisation in European design law.

Anyway, it must be borne in mind that the lack of European ambition for harmonised copyrights weakens the unitary character of the protection conferred by Community designs (**b**).

(a) Aborted implementation of a "repair clause" in French design law

§43. Historical legal background. — Member States have been at loggerheads over whether design protection should be excluded for visible spare parts in the aftermarket for some considerable time [126]. Some of them, including France, has long been opposed to the adoption of a compulsory "repair clause" into Design Directive. Such a clause would limit the scope of protection conferred by design rights for the purpose of repairing a complex product so as to restore its original appearance [127].

In the 1990s, as the full-scale approximation of Member States' laws could not be achieved on this issue, a transitional provision — the so-called "freeze plus rule" — merely operated to maintain the *status quo*. By a kind of legislative "ratchet effect", EU Member States can only amend their national

123. Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs (hereinafter referred to as "Community Design Regulation").
124. Article 1(2) Community Design Regulation.
125. Recital 5 Design Directive.
126. Annette KUR, "Freeze Plus Melts the Ice — Observations on the European Design Directive", *IIC* 1999, 30:620.
127. Where the design is applied to or incorporated in a product which constitutes a component part of a complex product upon whose appearance the protected design is dependent.

design law for the purpose of liberalising the aftermarket in spare parts [128]. In addition, the European Commission was required to propose changes to 1998 Design Directive needed to complete the internal market [129], which it did in 2004 [130]. But ten years later, in 2014, the European Commission withdrew its proposal [131], following the veto of a blocking minority in the European Council in 2008. By contrast, a "repair clause" was originally included in Community Design Regulation [132].

France indicated its position in 2014, by voting down the repair clause in its national legislation, whereas adoption of the clause had been recommended by the French Competition Authority 2 years ago [133]. Political will was lacking. However, in 2019, rising fuel prices triggered a social movement — the "yellow vests movement" — that denounced the importance of car-related spending. As a result, the French Government expressed its intention to take measures to reduce car repair costs by liberalising the automotive aftermarket in visible spare parts, within the framework of the Orientation Law on Mobility ("*Loi d'orientation sur les mobilités*", hereinafter referred to as "LOM"). But before stating the French "repair clause" as set out in Article 110 LOM, it is helpful to give brief overview of the aftermarket structure.

§44. Structure of the automotive aftermarket in spare parts. — Diagrammatically, the automotive aftermarket in spare parts can be divided into two vertical channels (original manufacturer and independent channels) and four horizontal levels (manufacturers, distributors, repair services and consumers). As an authoritative academic study explains [134]: "at the manufacturing level, in order to achieve cost savings, timeliness of supply and ultimately, economies of scale, original equipment manufacturers (OEMs), *i.e.* the ones who developed and assembled the original vehicle, can outsource production to spare part contract manufacturers, the so-called original equipment suppliers (OES). This has led to a division of the market of authorised spare parts into those which derive directly from the producer of the original vehicle and those manufactured under contract by the so-called original equipment suppliers (OES). Spare parts made by OES are, while not manufactured by OEMS, authorised by them and presumptively subject to their quality control. [...] Spare parts which do not derive from OEM/OES sources are manufactured and distributed through networks of independent distributors and repair shops, also referred to as Independent Aftermarket" (*see* Figure 1.1).

128. Article 14 Design Directive.
129. Article 18 Design Directive.
130. European Commission Proposal for a Directive of the European Parliament and of the Council amending Directive 98/71/EC on the legal protection of designs, 14 September 2004, COM(2004) 582 final.
131. Dana BELDIMAN and Constantin BLANKE-ROESER, "European Design Law: Considerations Relating to Protection of Spare Parts for Restoring a Complex Product's Original Appearance", *IIC* 2015, 46:915-919.
132. Article 110(1) Community Design Regulation.
133. Autorité de la concurrence [French Competition Authority], avis n° 12-A-21 du 8 octobre 2012 relatif au fonctionnement concurrentiel des secteurs de la réparation et de l'entretien de véhicules et de la fabrication et de la distribution de pièces de rechange [Opinion No. 12-A-21 of 8 October 2012 on competition in the vehicle repair and maintenance sector and the spare parts manufacturing and distribution sector].
134. Dana BELDIMAN and Constantin BLANKE-ROESER in *An International Perspective on Design Protection of Visible Spare Parts*, Chapter 2, pp. 9-10.

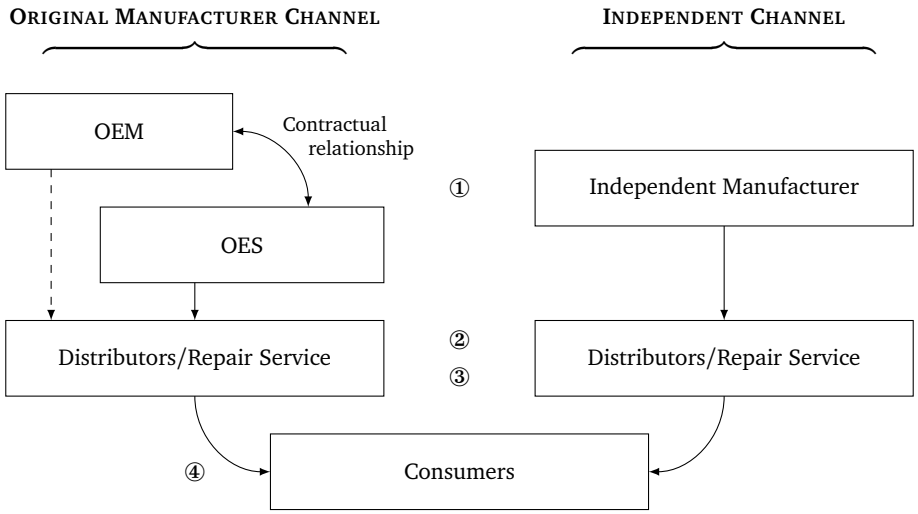

Figure 1.1: Schematic representation of the structure of the automotive aftermarket in spare parts.

§45. French "repair clause". — Seeking a balanced adjustment between stakeholders' divergent interests (OEMs, OES, independent manufacturers and consumers), the French legislature introduced in LOM an excessively complex "repair clause". However, the Constitutional Council has put an end to the French Government's attempt at liberalisation in December 2019. The Court censured the "repair clause" as having the character of a "legislative rider", *i.e.* having no place in the law in question because it was not linked to the initial provisions of the bill [135]. Article 110 LOM would have amended Articles L. 513-1 and L. 513-6 of the French Intellectual Property Code (IPC) [*changes emphasized*]:

> **Article L. 513-6 of the French IPC.** — The rights conferred by the registration of a design shall not be exercised in respect of:
>
> ~~(a)~~ 1° acts done privately and for non-commercial purposes;
>
> ~~(b)~~ 2° acts done for experimental purposes;
>
> ~~(c)~~ 3° acts of reproduction for the purposes of making citations or of teaching, provided that such acts are compatible with fair trade practice and do not unduly prejudice the normal exploitation of the design, and that mention is made of the source;
>
> 4° acts which aim to restore the original appearance of a motor vehicle or a trailer within the meaning of Article L. 110-1 of the Highway Code and which:
>
> (a) Concerns spare parts relating to glazing, optics and mirrors; or
>
> (b) Are made by the original equipment manufacturer.
>
> **Article L. 513-1 of the French IPC.** — Registration shall have effect from the filing date of the application for a 5-year term, which may be extended by periods of five years up to a maximum of 25 years.
>
> [...]
>
> The maximum 25 year-term provided for in the first paragraph shall be reduced to a 10-year term for spare parts design rights referred to in 4° of Article L. 513-6 for which that provision does not provide for any exception to the exercise of the rights conferred by the registration of a design or model.

135. Constitutional Council, Decision No. 2019-794 DC of 20 December 2019, *Loi d'orientation des mobilités* [Orientation Law on Mobility], para. 62: "Article 110 amends the Intellectual Property Law applicable to visible automotive spare parts. Introduced on first reading, these provisions have no link, even indirect, with those of Article 29, which empowered the Government to legislate by ordinance to improve control of the market for vehicles and non-road motorized mobile machinery, nor with those of Article 31, which empowered it to amend by ordinance the provisions of the Highway Code relating to the procedures applicable to impounded vehicles and to the management of such vehicles". Following the decision of the Constitutional Council, the referred law was promulgated and then published: Law No. 2019-1428 of 24 December 2019, *JORF* No. 0299 of 26 December 2019.

§46. Progressive "repair clause". — The entry into force of the "repair clause" would have been progressive. Article 110(III) and (IV) LOM provided for a transitional period in the form of a simple delay in the enforcement of the law. This period would have given domestic suppliers time to adapt. The envisaged liberalisation of the automotive aftermarket was based on types of visible spare parts. The aftermarket in spare parts for glasses (windscreen, rear windscreen, side windows), optical equipment (headlamps, front and rear lights, indicators) and rear-view mirrors would have been the first to be liberalised from 1st January 2020. Then, the aftermarket in all the other visible spare parts, mainly body parts as bodywork and plastic bumpers, would have been liberalised from 1st January 2021 (*see* Figure 1.2).

§47. Partial "repair clause". — Liberalisation was intended to be progressive, but also partial. Whereas the aftermarket in glasses, optical equipment and rear-view mirrors would have been fully liberalised, which means that competition would have take place between all manufacturers (OEMs, OES and independent manufacturers), the opening of the aftermarket in other visible spare parts would only have been partial. In this case, competition would only have occurred between OEMs and OES for 10 years, temporarily excluding independent manufacturers. To this end, French provisions provided that design protection for the repair of these spare parts was to take effect from the filing date of the application for a maximum of 10 years (instead of 25 years). As a result, competition in the bodywork and plastic bumpers aftermarket could not have run in full swing until the end of this shortened period of design protection (*see* Figure 1.2).

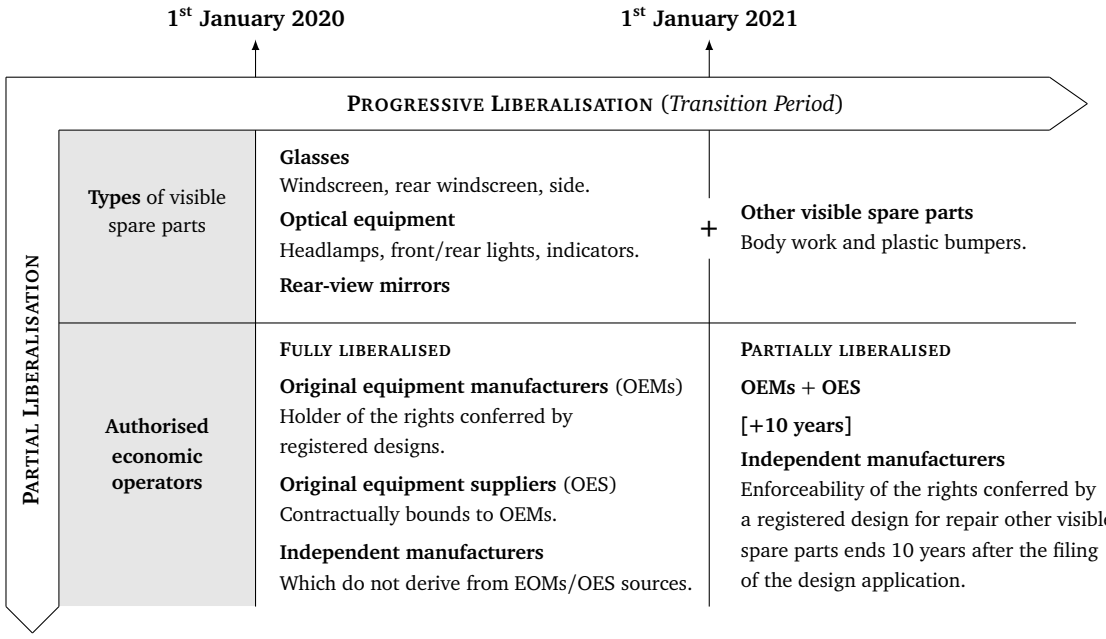

Figure 1.2: **Progressive** and **partial** liberalisation of the automotive aftermarket in visible spare parts.

§48. Cumulative protection. — As French copyright does not discriminate between works on the basis of merit, destination or genre [136] as long as the work is original, visible automotive spare parts can ben-

136. Article L. 112-1, French Intellectual Property Code.

efit from copyright and industrial design protection at the same time [137- 138]. Liberalisation of design law related to spare parts might be found undercut by the cumulation effect with copyright [139]. For liberalisation to be truly effective, Article 110(I) LOM prevented cumulation of protection excluding copyright for the reproduction and distribution of visible spare parts for the purpose the repair of a car so as to restore its original appearance. However, this copyright exception is based on an overplayed interpretation of Article 5(3)(l) and (4) of 2001 Copyright Directive, which expressly states that "Member States may provide for *exceptions or limitation to the reproduction and distribution rights for* use in connection with demonstration or *repair of equipment*" [140].

Article 17 of Design Directive allows protection under copyright law of a Member State as long as a design protected by a design right is registered in a that State, regardless to the subject matter of protection. So that Member States are not blamed for over-transposing Design Directive (or Copyright Directive), the EU legislature should take advantage of the European design law recast to add an exception to design law and to include the same exception in copyright law accordingly. At the EU level, Article 96(2) of Community Design Regulation (equivalent to Article 17 of Design Directive) gives rise to the same observations.

(b) Coexistence between non-harmonised national copyrights and Community Designs

§49. — The *à la carte* harmonisation of national copyright laws allows for local specificities embedded in domestic markets. Insofar as an industrial or handicraft item can benefit from a cumulative protection, discrepancies between national copyrights weakens the unitary character of the protection conferred by a Community design. In the absence of a well-thought-out articulation between these two bodies of rules, cumulative protection raises difficulties, in particular on issues of ownership of the design and copyright (*see below*, **§55** to **§57**), or on the limits and exceptions of thereof [141].

1.1.6.2 Towards the demise of national designs in favour of EU designs?

§50. Issue. — Once national design laws have been harmonised along the lines of EU design law, the question will arise as to whether a dual European system of national and unitary EU titles should be maintained. Unlike the European trade mark system [142], the coexistence and balance of design systems at national and EU level should not constitutes a "cornerstone" of the Union's approach.

§51. Compare of reasons for the duality of the trade mark and design systems. — Comparison between the European design and trade mark systems has to be put into perspective. On the one hand, design protection requirements are absolute, whereas in trade mark law the availability criterion is relative. The point needs to be qualified because the design novelty requirement is assessed taking into account a limited state of the art. Indeed, a design is deemed to have been disclosed if it "has become known in the normal course of business to the circles specialised in the sector concerned, operating within the Community, before the date of filing of the application for registration or, if priority is claimed, the date of priority" [143]. Thus, the universal novelty requirement is tinged with a relative

137. CJEU, 27 January 2011, case C-168/09, *Flos*; CJEU, 6 October 2015, case C-500/14, *Ford Motor v Wheeltrims*.
138. Pascal KAMINA, "Sur le cumul de protection : nature et portée" [On the cumulation of protection: nature and scope], in *Les grands arrêts de la propriété intellectuelle*, Michel VIVANT (ed.), Dalloz, 3rd ed., Dalloz, 2020, pp. 463-474, Cases 79-81.
139. Jos DUMORTIER and Clemens APPL (eds.), *Legal review on industrial design protection in Europe*, 15 April 2016, (MARKT2014/083/D), see in particular Section 6.2.
140. Emphasis added.
141. See Jérôme PASSA, *Traité de droit de la propriété industrielle* [Industrial Property Law Treaty], Vol. 1, *op. cit.*, §837 and §838, pp. 1118-1119.
142. Recital 3 Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks (Trade Mark Directive).
143. Article 6(1) Design Directive and Article 7(1) Community Design Regulation (identically worded).

character because disclosure is defined by mentioning a reference milieu ("specialised circles") limited to a geographical extent ("the territory of the Community") [144]. However, as this protection requirement is common to both national and EU design laws, it results that a design, which is eligible for protection in a Member State, should also be eligible for protection at EU level. Quite the contrary, a trademark available at national level may not be available at EU level. A sign may therefore be registered as a national trade mark in a Member State, but the EUIPO may refuse its registration as a European Union trade mark. These differences in the relative/absolute nature of protection requirements justify that the coexistence and complementarity principles are specific only to the European trade mark system.

On the other hand, the EU legislature intended to make the preservation of the rights connected to the trade mark conditional upon it actually being used, unlike there are no such grounds for revocation under design law. The coexistence of several trade mark systems is thus needed because genuine use of a trade mark is assessed differently at national and EU levels in the course of revocation actions based on non-use [145]. Indeed, genuine use must take place within the geographical extent of the property right [146]. In the case of a registered national trade mark, genuine use has to take place in a substantial part a Member State's territory whereas in the case of an EUTM, genuine use has to occur in a substantial part of the Union territory. Furthermore, the CJEU held in the *Leon Merken v Hagelkruis Beheer* case [147] that:

> "[...] the territorial borders of the Member States should be disregarded in the assessment of genuine use in the Community." (para. 44)

and states that:

> "[...] whilst there is admittedly some justification for thinking that a Community trade mark should – because it enjoys more extensive territorial protection than a national trade mark – be used in a larger area than the territory of a single Member State in order for the use to be regarded as 'genuine use', it cannot be ruled out that, in certain circumstances, the market for the goods or services for which a Community trade mark has been registered is in fact restricted to the territory of a single Member State. In such a case, use of the Community trade mark on that territory might satisfy the conditions both for genuine use of a Community trade mark and for genuine use of a national trade mark." (para. 50)

§52. — From **§51**, it appears that national trade marks continue to be necessary for undertakings which are unable to obtain Union-wide protection while national protection does not face any obstacles [148]. They are also required for those, mainly SMEs, which do not need protection at Union level because of a purely national outlet for marketed goods or services.

There is nothing similar for designs. The rationale for the coexistence and complementarity principles, which govern the European trade mark system, has no equivalent in the design system. Maintaining national channels for design applications is then justified by the following grounds: lower fees, faster issuance of titles and national language as language of proceedings.

§53. Redundant cumulative protection. — Once national and European design rights are fully harmonised, the dual European design system will allow for redundant cumulative protection. Undertak-

144. Nicolas BINCTIN, *Droit de la propriété intellectuelle* [Intellectual Property Law], *op. cit.*, §310, p. 228.
145. However, the concept of "genuine use" is an autonomous concept of European Union law which must be given a uniform interpretation.
146. Nicolas BINCTIN, *Droit de la propriété intellectuelle* [Intellectual Property Law], *op. cit.*, §944, pp. 603-604.
147. CJEU, 19 December 2012, case C-149/11, *Leon Merken v Hagelkruis Beheer*.
148. For a critical approach to the institutionalisation of the coexistence of national and European Union trade mark rights, see Trevor COOK, "New European Union Trade Mark Regime and the Institutionalisation Within it of the Co-existence of National and European Union Trade Mark Rights", *Journal of Intellectual Property Rights*, January 2016, Vol. 21, pp. 57-61: "It would also have been possible to reduce even further the fees associated with use of the EU trade mark, so as to make it even more competitive with national systems. Over time this might well have resulted in reduced use of the national systems, so that in the fullness of time they would wither away and their ultimate abolition [...] could be envisaged".

ings pursuing a maximum protection strategy will cumulate IP rights [149], which will to lead to higher costs to challenge national and EU designs due to the duplication of invalidity proceedings.

Besides, a parallel design protection system does not necessarily benefit right holders, who can suffer from having only filed a national design application. Indeed, publication of a national application for registration discloses the design which prevent a subsequent filing from continuing to be considered new, unless it is made within 6 months prior to the filing date [150]. By contrast, the filing of a Community design confers unitary protection makes it possible to accompany right holders' business development within the territory of the Union.

§54. Conclusion. — To conclude, the European legislature should not introduce in the Design Package preamble a recital making the coexistence of the national and European systems at the level of a "cornerstone" of the European design system as a whole. Unlike European trade mark system, further harmonisation of the two-tiered design system should only be a step in the full integration process of Union law in Member States' legislations.

Furthermore, to meet the expectations of system users attached to the proximity of national channels, national and regional IP offices could become local relays for the EUIPO, which would keep centralising the EU design system. European registration fees, which today serve as a balancing variable in the distribution of national and Community design applications [151], should be lowered without undermining the economic balance of the design system. Finally, improving the reliability of computer translations through machine learning should, in the coming years, help to overcome the national language barrier within the Union.

1.1.7 Further harmonisation of the status of employed creators

§55. Free movement of workers. — One of the pillars of the EU is the free movement of workers in its territory, but this approach is not complete with respect to the knowledge economy. While there is no doubt that workers are able to move, at the present time, the day-to-day working relationship is transnational.

While each person is free to create in the EU country that he wishes, the employee's status has a significant influence on the relationship between the author and the intellectual property. The term "author" should be understood to mean any person who creates an IP intangible asset [152]. The creative act is the bond, the element that unifies intellectual property rights. The heterogeneity of the status of creators, in national law and also between each of the European Union countries for each of the intellectual property regimes [153], hinders the movement of employee authors, and the setting up of creative businesses in the EU. It also hinders the development of collaborative, creative, transnational working within the EU.

§56. Issues. — EU law should provide a unified approach to this issue in order to improve the situation of creators, facilitate exchanges and the use of new methods of creation. For example, a French company

149. Clara GRUDLER, *Entre cumul des droits de propriété intellectuelle et objet spécifique du droit d'auteur : l'enjeu des créations esthétiques* [Between the accumulation of intellectual property rights and the specific object of copyright: the challenge of aesthetic creations], Master's thesis, Panthéon-Sorbonne University, 2020.

150. Article 4 Paris Convention for the Protection of Industrial Property.

151. Jos DUMORTIER and Clemens APPL (eds.), *Legal review on industrial design protection in Europe*, *op. cit.*, p. 48: "A major reduction in RCD fees is capable of significantly affecting national filings, which would inevitably adversely affect the functions performed by national offices in supporting their local designers. The level at which this would occur would depend also on any fee reductions undertaken by national Offices".

152. It is the meaning adopted in Patent French law, which refers to the "author of the invention" in Article L. 611-7 IPC.

153. See *La rémunération des inventeurs salariés : Les documents de travail du Sénat — Série Législation comparée* [The remuneration of employee inventors: The working documents of the Senate — Comparative legislation series], July 2009, No. LC 199.

has R&D teams in three EU countries. The teams work together every day under employment contracts governed by local law, mixing technical and artistic competencies in order to develop new products, the creations being made on a virtual platform. With this kind of arrangement, it is possible to develop software, video games, advertisements, technical parts for planes or cars, websites, collections of clothing, etc. Where is the creation made? Who is the owner of the intellectual property developed by the employees? Which legal regime should apply to each employee? Is it acceptable that EU employees, working in the EU, for a company located in the EU, are treated differently, when they have contributed to one and the same creation? All ambitious projects now form part of a European plan. The active policy of supporting creativity in the EU, particularly through European R&D programmes, is moving in this direction. This issue is of relevance to both employee creators in the private sector and their counterparts in the public sector. Private international law provides solutions for a case-by-case approach: Rome I gives competence to the law of the employment contract; Brussels I*bis* provides clarification about both the regime of the employment contract and the applicable IP regime. However, these two legal frameworks do not deal directly with the question, nor do they offer a harmonised solution when used to approach it indirectly.

§57. Recommendations. — There needs to be a real European ambition to go beyond current differences, and the progress that would result would be undeniable. Such an approach would probably have to be done in two stages.

At the first stage, there would be EU-wide harmonisation for each IP regime. This was initiated within the framework of international patent law. Article 60(1) EPC reads as follows:

> "[...] If the inventor is an employee the right to the European patent shall be determined in accordance with the law of the State in which the employee is mainly employed; if the State in which the employee is mainly employed cannot be determined, the law to be applied shall be that of the State in which the employer has his place of business to which the employee is attached."

It is noteworthy that this connecting factor rule differs from that laid down in Article 7 EPUE Regulation. The latter provides that if the inventor is an employee, the right to a EPUE shall be determined in accordance with the law of the participating Member State, *i.e.* in which that patent has unitary, where the applicant had his residence or principal place of business on the date of filing of the application; if not, where the applicant had a place of business on the date of filing of the application for the European patent [154]. Finally, where no applicant had his residence, principal place of business or place of business in a participating Member State, the right to a EPUE shall be determined in accordance with German law [155]. This divergence will necessarily be a source of conflict. For example, an employee based in France who works for the French subsidiary of a German company will, under EPUE Regulation, to German law, whereas he should be subject to French law under EPC provisions [156]. Consequently, EPUE Regulation should be amended It would be appropriate to harmonise these contradictory connecting factor rules.

At the second stage, the regime of the employee creator would be harmonised regardless of IP regime or regimes that applied to the intellectual property in question. An attempt was made with Article 14 of European Design Regulation. This article puts in place an *ad hoc* solution moderated by the contractual freedom of the parties but includes the possibility of referral to the national solution. This last condition destroys the essential part of the initiative.

Harmonisation of the employee creator's status would help to enhance exchanges between countries, to Europeanise creative teams and, finally, to increase the creativity and competitiveness of the European Union.

154. Article 7(1) EPUE Regulation.
155. Article 7(3) EPUE Regulation.
156. Nicolas BINCTIN, *Droit de la propriété intellectuelle* [Intellectual Property Law], *op. cit.*, §581, pp. 368-369.

1.2 Procedural rights

§58. EU court organisation. — The development of intellectual property law in the EU should provide an opportunity to go beyond the current organisation and allow for the emergence of a European network of intellectual property courts, which would be competent to hear all IP disputes, regardless of the rights in question. This European circuit could be based partly on national courts, which would rule as European courts, as is already the case for designs or trade marks. There would be the possibility of appeal at regional level and unified final appeal proceedings under the aegis of the European Court of Justice. This would mean a reduction in "forum shopping", the end of uncertain solutions from one State to another such as those in the *Babyliss* or *Actavis* cases [157], and greater consistency in this area, across EU territory, would result from this arrangement. It is certain that the introduction of a federal circuit of courts for intellectual property disputes in the United States has made a significant contribution to the strengthening of this field in that country.

157. In these cases, on the basis of the same patent issued by the EPO, different decisions were rendered by national courts within the EU. Some of them cancelled the patent, others confirmed it but did not accept the infringement and finally, a third category confirmed the property right and the infringement.

Chapter 2

Better uptake and deployment of intellectual property

§59. — In the knowledge-based economy, intellectual property rights generally are ones of the most important valuable assets of companies. Paradoxically, if there is no or little tangible assets, companies find it difficult to raise sufficient funds to ensure their development. IP-assets, traded on over-the-counter through private transactions, remain very illiquid and difficult to mobilise.

The setting up of platforms for bringing together licensors and licensees would speed up the circulation of IP-assets within the Union (**2.1**). Moreover, where companies based competitive advantage mainly on IPRs, securitisation appears to be a promising financing instrument to leverage most valuable assets (**2.2**). In any case, valorisation of IP-assets would not be possible without the use of reliable and commonly accepted metrics to value them (**2.3**).

2.1 Setting up of platforms to speed up the circulation of IP-assets

§60. License of right. — Interestingly, Article 8 EPUE Regulation introduces a hybrid license based on a contractual mechanism, the so-called "license of right". The proprietor of an EPUE may file a statement with the EPO to the effect that the proprietor is prepared to allow any person to use the invention as a licensee in return for appropriate consideration. Such a mechanism is not new. Licenses of right exist in English [158] and German [159] patent laws and were envisaged in the 1975 Community Patent Convention (Art. 43) and the 1989 Community Patent Agreement (Art. 43) [160].

In a way, the idea is to transform property into a kind of paying public domain, at the initiative of the patentee. The only condition for becoming a licensee is to pay a royalty. Thus, instead of negotiating a licence agreement on a case-by-case basis, the proprietor might be encouraged by a reduction in fees payable to the EPO to declare that he generally authorises anyone to operate its patent, as a licensee, in return for an appropriate royalty. It is to be expected that the proprietor of an EPUE wishing to use such a procedure will communicate to the office the contractual terms of the licence so that they are public and accessible through the EPO. This general and unconditional offer to contract reinforces the collectivisation of the operation of IP-assets. The owner will be able to appoint a third party manager

158. Section 46 United Kingdom Patents Act.
159. Section 23 German Patent Act (Patentgesetz).
160. Esther VAN ZIMMEREN and Geertrui VAN OWERWALLE, "A Paper Tiger? Compulsory License Regimes for Public Health in Europe", *IIC 2011*, Vol. 42, Iss. 1, pp. 4-40.

to collect the royalties, similar to copyright collecting societies. The appropriate consideration is not clearly a FRAND royalty but it is likely to be subject to control by the EPO [161].

§61. — Implementation of licenses of right offers new economic and legal models for operating patents. However, the application procedure remains to be clarified. Its generalisation to national patents could be considered, after consultation with stakeholders and domestic IP offices.

2.2 Securitisation of IP-assets as a lever to get access to finance

§62. Financing businesses. — Compared to mortgage-backed securities (MBS) or asset-backed securities (ABS), securitisation of IP-assets is still an epiphenomenon. However, this financial engineering technique could be of particular interest to innovative companies facing heavy R&D expenses. By mobilising IP-assets, these enterprises could obtain immediate financing, without having to resort to borrowing or wait to receive future revenues from the operation of the underlying assets.

§63. EU twin-track approach. — Since the subprime financial ended, more than a decade years ago, the European Union has put in place a prudential supervision system of banking and financial activities. Within this regulated and more risk-sensitive prudential framework, the Union has opted for a twin-track approach:

(i) Regulating bank securitisations, mainly refinancing operations that allow the freeing up of banks' balance sheets to grant new loans [162] (prudential approach);

(ii) Encouraging long-term investments in the real economy through securitisation [163] (real economy approach).

In line with this second approach, securitisation operations backed by IP-assets meets the European Commission's objective of enabling intellectual property to be used as lever to get access to finance. However, there are still significant differences between national laws as to the nature of the assets that can be securitised, which limits the structure of possible arrangements (**2.2.1**). Non-legal actions from the European Commission could help to democratise this financing technique to back the booming of the knowledge-based economy (**2.2.2**).

2.2.1 Securitisation arrangements for IP-assets

§64. — Despite a common securitisation pattern (**2.2.1.1**), various modalities for securitisations backed by IP-assets are possible (**2.2.1.2**). However, the choice of the arrangement depends upon the law applicable to the SPV as it determines the nature of the assets that can be securitised. Under the impetus

161. Nicolas BINCTIN, *Droit de la propriété intellectuelle* [Intellectual Property Law], *op. cit.*, §586, pp. 372-373.

162. The prudential regulation of securitisation is mainly based on two EU Regulations:
    1. Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012.
    2. Regulation (EU) 2017/2402 of the European Parliament and of the Council of 12 December 2017 laying down a general framework for securitisation and creating a specific framework for simple, transparent and standardised securitisation, and amending Directives 2009/65/EC, 2009/138/EC and 2011/61/EU and Regulations (EC) No 1060/2009 and (EU) No 648/2012.

163. Regulation (EU) 2015/760 of the European Parliament and of the Council of 29 April 2015 on European long-term investment funds (hereinafter referred to as "ELTIF Regulation"), recital 1: "Long-term finance is a crucial enabling tool for putting the European economy on a path of smart, sustainable and inclusive growth [...]. European long-term investment funds (ELTIFs) provide finance of lasting duration to various infrastructure projects, unlisted companies, or listed small and medium-sized enterprises (SMEs) that issue equity or debt instruments for which there is no readily identifiable buyer. By providing finance to such projects, ELTIFs contribute to *the financing of the Union's real economy* and the implementation of its policies" (*emphasis added*).

of the European Union, French law has recently been modified to make it more conducive to securitisations of IP-assets (**2.2.1.3**).

2.2.1.1 General principles

§65. Securitisation. General approach. — Securitisation is a financial engineering technique structured by an arranger, whereby an *originator* assigns assets to a *special purpose vehicle* (SPV), which finances this acquisition by issuing securities in financial markets. Operating revenues deriving from the securitised assets (also known as the "underlying assets") pays investors (*see* Figure 2.1).

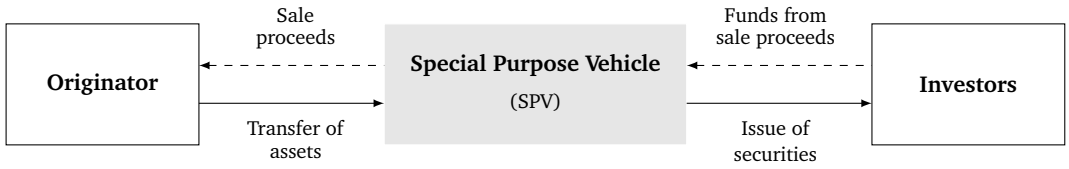

Figure 2.1: Schematic representation of the mechanism structuring a securitisation arrangement.

§66. Securitisation. Specific approach. — From a financial perspective, securitisation allows the transformation of an illiquid portfolio or even illiquid assets into liquid market securities [164- 165]. Illiquid assets are transferred to the SPV, which issues liquid securities to financial investors.

This approach applies to IP-assets. In the absence of organised financial markets where IP rights would be traded [166], or direct quotation exchanges that would fix prices [167], these assets traded over-the-counter trough private and singular transactions remain highly illiquid. On the flip side, when backed by marketable securities issued by the SPV, IP-assets "liquefied" and are thus easier to sell.

However, the marketability of financial securities does not guarantee their liquidity. Investors' interest in securities issued by the SPV depends on their risk of default, *i.e.* their profitability. For example, while risk averse investors (insurers, reinsurers, mutual insurers, pension funds, etc.) are interested in low-risk but low-profit securities, some investment funds prefer to under-write riskier securities because they are more profitable.

§67. Tranching. — To ensure that SPV issued securities are liquid enough, arrangers generally use "tranching". This financial law technique, which relies on debt subordination, changes the priority of payments between investors. Securities issued are split into separate risk and return tranches, which in practice are referred to as *equity*, *junior*, *mezzanine* and *senior* tranches. Cash flows from securitised assets sequentially pay tranches in descending order of their seniority level, *i.e.* monies flow down from the most senior to subordinate tranches (waterfall effect) [168]. The senior tranche is first entitled to cash

164. Financial liquidity refers to how easily and quickly an asset can be sold in a market.

165. Comp. with the definition given by Ambroise FAYOLLE (Vice-President of the European Investment Bank) who prefaced Alexandre QUIQUEREZ in *Droit et techniques internationales de la titrisation* [International securitisation law and techniques], Larcier, 2018, pp. 13-15; see also Yves SIMON, "Titrisation : analyse économique et financière" [Securitisation: economic and financial analysis], in Martine BOIZARD and Philippe RAIMBOURG (eds.), *Ingénierie financière, fiscale et juridique* [Financial, tax and legal engineering], 3rd ed., Dalloz Action, 2015-2016, 973 p.

166. The Intellectual Property Exchange International (IPXI), which was intended to be the world's leading financial market for patent licenses, has miserably failed. For a detailed analysis: see Merritt L. STEELE, "The great failure of the IPXI experiment: why commoditization of intellectual property failed", *Cornell Law Review*, 102, pp. 1115-1142.

167. With the exception of the Ocean Tomo 300 R Patent index (OT300), which is based on the value of the industrial property securities of the 300 companies holding the most liquid portfolios of IP-assets; see Alan SIPRESS, "Ocean Tomo catches the wave in valuing intellectual property", *Washington Post*, 6 May 2007, F03.

168. In fact, this cash flow waterfall is twofold: on the one hand, it concerns interests paid to investors; and on the other hand, it concerns the amortisation of tranches. See Alexandre QUIQUEREZ, *Droit et techniques internationales de la titrisation* [International securitisation law and techniques], *op. cit.*, pp. 233-236, §311 to §316.

flows received by the SPV, followed by the mezzanine tranche and then the junior tranche. Finally, the equity tranche receives the residual cash flow after other tranches have been paid [169]. The senior tranche has low risk of default, while the equity tranche is the riskiest, since it absorbs the first losses (*see* Figure 2.2). After an in-depth analysis of the securitisation transaction, financial rating agencies assess the risks incurred by investors according to the tranche to which securities belong [170].

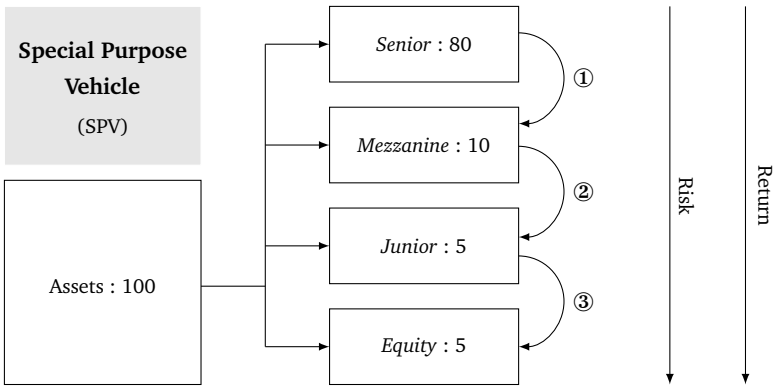

Figure 2.2: Example of tranching of SPV issued securities.

Tranching thus allows the risk profiles of the underlying assets to be redefined. Categorised as subordinated tranches, securities issued by the SPV appeal to a broader range of investors with different requirements in terms of risks incurred and expected returns.

2.2.1.2 Appropriate arrangements for the securitisation of IP-assets [171]

§68. — Securitisation arrangements can be classified according to the way in which IP-assets related risks are transferred. In "traditional" securitisations, either royalties (**a**) or IP-assets (**b**) are assigned to the SPV, implying the transfer of their related risks. In synthetic securitisations, the originator retains the underlying assets, with only their risks being transferred contractually to the SPV. In practice, as synthetic securitisations backed by IP-assets are fringes arrangements, they will not be discussed below [172].

(a) Indirect securitisation: assignment of royalties

§69. Indirect securitisation arrangement. — The originator assigns royalties from the IP-assets operation to the SPV. To secure the payment of royalties owed by licensees, the originator typically pledges the underlying IP-assets to the SPV [173]. In this arrangement, the originator thus transfers the risks of non-payment by licensees and, more generally, the operating risks as future revenues from the underlying

169. Yves SIMON, *Titrisation : analyse économique et financière* [Securitisation: economic and financial analysis], *op. cit.*, pp. 976-979, §311.31 to §311.39.
170. On rating mechanisms for securitisation transactions: see Thierry GRANIER, *Titrisation et organismes de financement. Approche juridique* [Securitisation and financing institutions. Legal approach], RB Edition, 2018, pp. 188-192, §271 to §276.
171. Alexandre QUIQUEREZ, *La titrisation des actifs intellectuels* [Securitisation of intellectual assets], Larcier, 2013, see especially, p. 347 *et seq.*, §262 *et seq.*
172. *Ibid.*, p. 373 *et seq.*, §284 *et seq.*
173. It should be noted, however, that non-payment by a licensee may be the result of mismanagement in the licensed asset operation, but it may also be cyclical. For example, a patent covering an obsolete technology will not generate the expected revenues. Therefore, pledging the underlying IP-assets does not seem to offer full coverage of the risks involved.

IP-assets may be lower than expected [174] (*see* Figure 2.3).

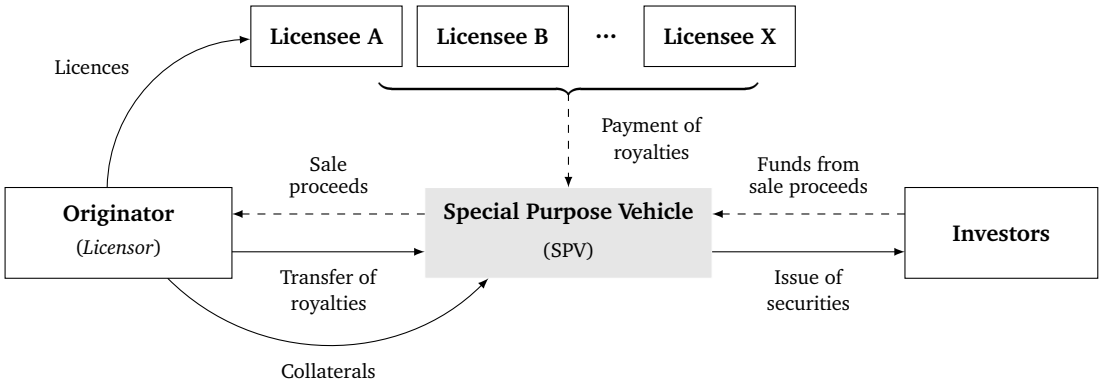

Figure 2.3: Royalties securitisation arrangement.

(b) Direct securitisation: assignment of IP-assets

§70. Direct securitisation arrangement. — The originator directly assigns IP-assets to the SPV, which grants it a (exclusive) license in return for royalties (*sale-and-license-back*). The originator, to whom the IPRs have been retroceded, exploits the IP-assets and may enter into sub-licenses with third party operators (*see* Figure 2.4).

Direct securitisation isolates the IP-assets from the originator's assets. Investors are thus better protected against the bankruptcy of the originator. Typically, a "back-up servicer" is initially designated to ensure continuity of operations in the event of the originator's failure or bankruptcy. In addition, granting back a license by the SPV makes it possible to securitise the originator's business and not only that of its licensees.

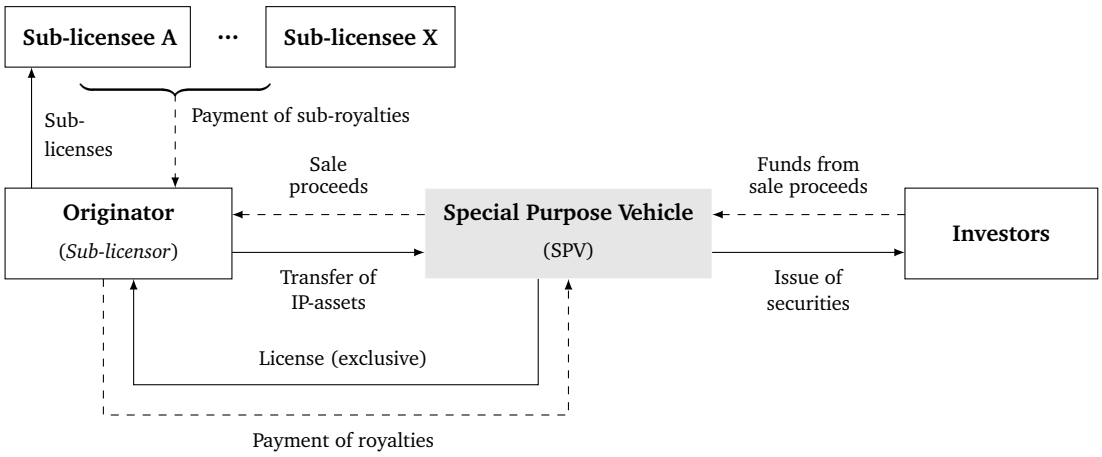

Figure 2.4: Securitisation arrangement through direct assignment of the underlying IP-assets.

174. Except in the case of flat fees, royalties are indexed to the performance of the IP-asset operation. It may be based on the licensee's turnover, the amounts collected, the amounts invoiced, the volume produced, the volume delivered, etc.; see Nicolas BINCTIN, *Droit de la propriété intellectuelle* [Intellectual Property Law], 5th ed., Manuel, LGDJ, 2018, pp. 714-718, §1111 to §1113.

2.2.1.3 Incentives for IP-asset securitisations: French latest developments

§71. Applicable law. — The choice between direct and indirect securitisation arrangements depends upon the law applicable to the SPV as it determines the nature of the assets that can be securitised. Under French law, no SPV was previously allowed to acquire intangible assets. Domestic financing vehicles could only be used in the context of royalty-backed securitisations (*i.e.* direct securitisations).

§72. Legal framework. — However, further to transposition of 2011 AIFM Directive [175] and implementation of 2015 ELTIF Regulation, the EU twin-track approach (*see above*, **§63**) swayed the French financial legislature, which decided that securitisations should not only provide debt financial management but also participate in the direct financing of infrastructures and companies [176]. Consequently, in addition to existing securitisation bodies, a new financing vehicle was created in 2018 [177]: the "Specialised Financing Vehicle" ("*Organisme de financement spécialisé*"; hereinafter referred to as "OFS") [178– 179].

§73. Specialised Financing Vehicles. — OFSs aim to invest directly or indirectly in assets, financing them by the issuance of securities [180]. Their purpose is thus broader that the mere execution of securitisation transactions. However, OFSs may constitute SPVs provided that securities issued fully finance the hedging of their exposure risks. They may invest in debt claims, including royalties due or payable, but also assets, including IP-assets, provided that [181]:

(i) ownership of the asset is based either on a registration, an authenticated deed, or a private deed whose probative value is recognised by French law;

(ii) the asset is not subject to any security interests other than those that may be created for the fulfilment of the fund's management purpose;

(iii) the asset is reliably valued in the form of a price calculated precisely and established regularly, which is either a market price, or a price provided by a valuation system that makes it possible to determine the value at which the asset could be exchanged between informed and contracting parties in an arm's length transaction; and

(iv) the liquidity of the asset enables the fund to meet its redemption obligations to its holders and shareholders as defined in its articles of incorporation or fund rules.

175. Directive 2011/61/EU of the European Parliament and of the Council of 8 June 2011 on Alternative Investment Fund Managers and amending Directives 2003/41/EC and 2009/65/EC and Regulations (EC) No 1060/2009 and (EU) No 1095/2010 (hereinafter referred to as "AIFM Directive").

176. See the Rapport au Président de la République [Report to the President of the Republic] of Ordonnance n° 2017-1432 du 4 octobre 2017 portant modernisation du cadre juridique de la gestion d'actifs et du financement par la dette prise en application de l'article 117 de la loi n° 2016-1691 du 9 décembre 2016 relative à la transparence, à la lutte contre la corruption et à la modernisation de la vie économie (loi « Sapin 2 ») [Ordinance No 2017-1432 of 4 October 2017 on the modernisation of the legal framework for asset management and debt financing pursuant to Article 117 of Law No 2016-1691 of 9 December 2016 relating to transparency, the fight against corruption and the modernisation of economic life ("Sapin 2" Law)].

177. Ordinance No. 2017-1432 was adopted on 4 October 2017 (*op. cit.*) but its provisions entered into force on 3rd January 2018.

178. Article L. 214-166-1 French Monetary and Financial Code.

179. For a complete study of the OFS legal framework: see Michel STORCK, "La régulation de l'activité bancaire des FIA : la finance de marché sort de l'ombre" [Regulation of FIA's banking activity: market finance comes out of the shadows], *RTD com.*, 2017, p. 939; "Création d'une nouvelle catégorie de FIA ayant vocation à financer l'économie : les organismes de financement spécialisé (OFS)" [Creation of a new category of FIAs dedicated to financing the economy: Specialised Financing Organisations (OFS)], *Revue de droit bancaire et financier*, No. 6, November-December 2017; "Les organismes de financement spécialisé enfin opérationnels" [Specialised financing organisations finally operational], *RTD com.* 2018, p. 989; "Décrets d'application portant modernisation du cadre juridique de la gestion d'actifs et du financement par la dette" [Implementing decrees modernising the legal framework for asset management and debt financing], *Revue de droit bancaire et financier*, No. 1, January-February 2019.

180. Article L. 214-168(II) French Monetary and Financial Code.

181. Articles L. 214-154, L. 214-190-1 and L. 214-168(II) French Monetary and Financial Code.

Valuation of IP-assets, *i.e.* condition (iii), is the essential prerequisite for securitisation of intellectual property [182]. Under these strict conditions, OFSs can be used as SPVs in direct securitisations.

§74. Prohibition of tranching. — It is worth noting that Law prohibits OFSs from issuing tranches of subordinated securities [183], thus exempting them from EU prudential regulations on securitisation. OFSs may nevertheless issue securities giving rise to different rights to capital and interest if losses are allocated *pari passu* among the different classes of securities [184].

What is the rationale of this limitation? Why could a SPV not invest in intangible assets and carry out direct securitisation transactions (*sale-and-license-back*) while issuing tranches of subordinated securities? Intellectual property assets are generally riskier than the tangible ones, due to legal risks of invalidation or revocation, related technological risks, etc. It is currently difficult to find a reliable metric to assess these risks (*see below* **Section 2.3** on the valuation of IP-assets). Since tranching involves redefining risk profiles of the underlying assets by issuing tranches of variable yield securities, errors in risk measurements are increased and, ultimately, borne by investors in the financial markets. In short, tranching is about spreading risks. By contrast, in single-tranche securitisations, IP-asset related-risks are spread proportionally over securities issued, thus limiting speculative transactions.

§75. — Summing up, under the impetus of the European Union, current French law provides for investment vehicles that can be used as SPVs in direct and indirect securitisations of IP-assets. More specifically, on the one hand, existing securitisation bodies allow for royalty-backed securitisation arrangements and can engage tranching of securities issued. On the other hand, OFSs can be used in both direct and indirect securitisation arrangements but cannot issue subordinated classes of securities.

2.2.2 Securitisation of IP-assets to finance the knowledge-based economy

§76. — In the immediate future, the European Commission should promote prospective securitisations of IP-assets through non-legal actions, *e.g.* commissioning a report from independent national experts assessing the legal and fiscal obstacles to such arrangements in each of the Member States. Significant legislative disparities exist between Member States [185]. Some have regulated securitisation through specific laws (Belgium, France, Italy, Luxembourg and Spain) while others have not adopted any particular regulation (Germany) [186]. As a result, legal and fiscal frameworks in place are more or less restrictive (*e.g.*, compare France and Luxembourg [187]). Such a report would help raise awareness of this practice among stakeholders, *i.e.* knowledge-based companies and financial players within the European single market, and might instil confidence among potential investors.

Following the United Kingdom's departure from the EU, major European financial centres should act as focal points of expertise bringing together bankers and lawyers specialising in IP-backed structured finance.

182. John M. GABALA Jr, "Intellectual Alchemy: Securitization of Intellectual Property As an Innovative Form of Alternative Financing", *J. Marshall Rev. Intell. Prop. L.* 2004, 3:307-330: "sound calculation of the intellectual property asset value is the paramount prerequisite for intellectual property securitization".

183. Article L. 214-169(V)(1°) French Monetary and Financial Code.

184. Organisme de financement spécialisé (OFS) [Specialised Financing Vehicle], Practical Guide, June 2020, Association Française de la Gestion Financière (AFG) [French Asset Management Association].

185. Alexandre QUIQUEREZ, *Droit et techniques internationales de la titrisation* [International Securitisation Law and Techniques], *op. cit.*, pp. 105-107, §87 to §94.

186. Thierry GRANIER, "La technique de titrisation hors du cadre legal" [The Securitisation Technique Outside The Legal Framework], *Droit et patrimoine*, November 1996, p. 31.

187. Alexandre QUIQUEREZ, *La titrisation des actifs intellectuels* [Securitisation of intellectual assets], *op. cit.*, p. 49 *et seq.*, §16 *et seq*.

2.3 Support for development and standardisation of valuation methods for IP-assets

§77. Variety of valuation methods. — Valuation means assigning a value that can be accounting, fiscal, market, financial, customary, acquisition, investment, etc. In fact, "the notion of value is plural because it only makes sense from the perspective of valuation, *for whom* and *for what* the valuation is made" [188].

Valuation methods for intellectual property assets are tools to assist in negotiations. Some simple valuation methods are commonly used (industry standards, relief from royalty and multi-period excess earnings method), while more advanced ones are scarcely implemented (Monte-Carlo, real option pricing) [189].

§78. Standardisation of advanced valuation methods. — In partnership with national, regional or international intellectual property offices, the European Union could fund programmes dedicated to developing and promoting valuation methods for IP-assets. Reliable and commonly accepted metrics used to valuing IP-assets would greatly contribute to strengthening the infrastructure of the European knowledge-based economy, in particular by promoting the circulation of intellectual goods.

188. Pierre BREESÉ and Alain KAISER, *L'évaluation financière des droits de propriété intellectuelle. Brevets et actifs technologiques: évaluation financière des inventions et des innovations* [Financial Valuation of Intellectual Property Rights. Patents and Technological Assets: Financial Valuation of Inventions and Innovations], Gualino, 2019, pp. 203-206.

189. For an overview, see Richard RAZGAITIS, *Valuation and Dealmaking of Technology-Based Intellectual Property: Principles, Methods and Tools*, Wiley, 2009.

Chapter 3

Promotion of better licensing and sharing of IP assets

§79. — Intellectual property is fertile ground for contract law. Contractual practices are generally limited by access to material goods. As intellectual property is independent of any tangible medium, it do not know this physical limit, which have given rise to specific operating models, like FRAND licensing (**3.1**).

The COVID-19 pandemic stresses out the need for restrictions on contractual practices in order to balance property regimes with the economic and social environment in which they are embedded. In particular, an EU-wide compulsory licensing strategy should be put in place in order to avoid distortion of competition in such times of crisis (**3.2**).

3.1 Improving transparency and predictability on licensing of SEPs

§80. Standards. — Technology standardisation is a driving force for the knowledge-based economy. Interoperability through standardisation is thus a key component of the EU Digital Single Market (DSM). It maximises the growth potential of the digital economy by creating a level playing field incentivising innovation, and by enabling better access to digital goods and services for consumers and businesses. In a nutshell, standards can strengthen dynamic competition and further market integration. This is why standardisation agreements are in principle not prohibited under EU competition law (Article 101 TFEU) [190].

§81. Standard essential patents. — However, without regulation, standards can give rise to anti-competitive behaviours. When companies own patented technologies that are essential to the operation of a standard, they can acquire control over the use of that standard. This could allow standard essential patent (SEP) holders to "hold up" users, once the standard implemented, "by refusing to license the necessary IPRs or by extracting excess rents by way of excessive royalty fees thereby preventing effective access to the standard" [191]. SEP holders could thus control the product market to which the standard relates and "lock-in" consumers into products incorporating patented standard technologies.

190. Roberto GRASSO, "Selected Issues in SEP Licensing in Europe: The Antitrust Perspective", in *Complications and Quandaries in the ICT Sector. Standard Essential Patents and Competition Issues*, Ashish BHARADWAJ, Vishwas H. DEVAIAH, Indranath GRUPTA (eds.), Springer, 2018.

191. Communication from the Commission, "Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal cooperation agreements", *CJEU* C11, 14 January 2011, §269.

§82. — To avoid such unreasonable or abusive exercise of IPRs embedded in technical standards, most standards developing organisations (SDOs) have adopted policies requiring their members to disclose essential IPRs and commit to license on fair, reasonable and non-discriminatory (FRAND) terms. Nevertheless, the assessment of both the essential character of a patent (**3.1.1**) and the FRAND requirements (**3.1.2**) are far from straightforward and triggered significant litigation.

3.1.1 Improvement of essentiality checks

§83. Rationale of the essentiality requirement. — Aggregation of patents in pool reduces transaction costs and royalty stacking by multiple independent licensors [192]. However, the pro-competitive effects of a technical standard require that the associated patent pool be limited to complementary patents that are essential to the standard. Jorge L. CONTRERAS, in the *Cambridge Handbook of Technical Standardisation Law*, exemplifies very clearly the importance of the essentiality requirement to foster innovation in a competitive market [193]:

> "[...] when a pool aggregates patents covering technologies that may be substituted for one another, such as patents covering different standards, innovation may be stifled. For example, if patents covering standards A and B are licensed separately, then the backers of standard B will be motivated to improve standard B to compete for users with standard A. If standard A achieves broad market acceptance in a typical 'standards war', then there will be little or no market for patents covering standard B. As a result, the developers of both standards A and B will strive to outperform the other in healthy market competition. If, on the other hand, the patents covering standards A and B are included in a pool, the developers of standard B will have little incentive to improve B in relation to A, as there is not a competitive market for licensing B independently from A. So long as users license the pooled patents, the backers of both standards will earn revenue, and competition and innovation will suffer."

§84. Definition(s) of essentiality. — There is no commonly accepted unambiguous definition of what an essential claim/patent is. Essentiality is thus defined in each SDO patent policy, leading to definitional differences. For example, the 2020 IPR Policy of the European Telecommunications Standards Institute (ETSI) states that [194]:

> "ESSENTIAL as applied to IPR means that it is not possible on technical (**but not commercial**) grounds, taking into account normal technical practice and the state of the art generally available at the time of standardization, to make, sell, lease, otherwise dispose of, repair, use or operate EQUIPMENT or METHODS which comply with a STANDARD without infringing that IPR. For the avoidance of doubt in exceptional cases where a STANDARD can only be implemented by technical solutions, all of which are infringements of IPRs, all such IPRs shall be considered ESSENTIAL." [195]

Whereas the Standards Board Bylaws of the Institute of Electrical and Electronics Engineers Standards Association (IEEE-SA) provides that [196]:

> "Essential Patent Claim shall mean any Patent Claim the practice of which was necessary to implement either a mandatory or optional portion of a normative clause of the IEEE Standard when, at the time of the IEEE Standard's approval, there was **no commercially and technically feasible non-infringing alternative implementation method** for such mandatory or optional portion of the normative clause. An Essential Patent Claim does not include any Patent Claim that was essential only for Enabling Technology

192. Royalty stacking refers to the situation where a licensee pays royalties to multiple licensors in order to market a patented product.
193. Jorge L. CONTRERAS, "Essentiality and Standards-Essential Patents", in *Cambridge Handbook of Technical Standardisation Law: Competition, Antitrust, and Patents*, Cambridge University Press, 2017, Chap. 13, pp. 209-230.
194. Annex 6, §15(6) of the 2020 ETSI IPR Policy (v41).
195. Capitalisation preserved; emphasis added.
196. Article 6(1) of the 2020 IEEE-SA Standards Board Bylaws.

or any claim other than that set forth above even if contained in the same patent as the Essential Patent Claim." [197]

The two above-mentioned definitions of essentiality differ in that substitutability is purely technical (ETSI definition) or mixed with commerciality (IEEE-SA definition). Indeed, the availability of a technical alternative does not necessarily imply the commercial feasibility of this alternative, the implementation cost of which could prove unreasonable [198]. A purely technical essentiality assessment, however, takes the standard away from the reality of the market into which it is supposed to fit. Moreover, discrepancies between definitions delay the emergence of an established case law that would contribute to a uniform interpretation of essentiality, regardless to SDO patent policies, facilitate essentiality checks and thereby streamline SEP negotiations over FRAND terms.

§85. Institutionalising the standardisation process. — In accordance with current contractual practices, declarations only confer a simple presumption of essentiality, which can be rebutted by any means, to the patent recorded by the SDO. Except in the case where an independent expert assess essentiality, this qualification is not subject to any *a priori* control [199].

Institutionalisation of the standardisation process could improve essentiality checks. SDOs could voluntarily/compulsorily register standard-related patent pools with the European Patent Office. The introduction of additional fees for confirming declarations after standard release and patent grants would encourage a thorough assessment of essentiality by SEP right holders themselves [200]. Profits made could finance a system of invalidation of recorded declarations along the lines of the patent opposition procedure. After the standard release, any person should be able to challenge SEP recorded declarations before the EPO, but only for a limited period. After that, disputes as to whether a patent claim is essential to a standard would be within the jurisdiction of UPC or national courts. This system would make it possible to focus essentiality checks on disputed patents. Moreover, no legal interest in bringing proceedings would allow straw men to use it [201]. The resulting anonymity could be useful to avoid undue tensions between the right holders engaged in the implementation of the standard.

3.1.2 Clarification of FRAND licensing rules

§86. FRAND case law. — The FRAND license is one of the most striking features of the contemporary IP contractual practices [202]. Such contracts are characterised by two key elements: the non-discrimination between contractors and a fair and reasonable royalty.

197. Emphasis added.
198. Jorge L. CONTRERAS, "Essentiality and Standards-Essential Patents", *op. cit.*, Part. B(2), pp. 217-219.
199. Jean-Christophe GALLOUX and Jacques AZÉMA, *Droit de la propriété industrielle* [Industrial Property Law], *op. cit.*, §741, pp. 507-508.
200. European Commission, Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 29 November 2017, COM(2017)712 final.
201. Enlarged Board of Appeal (EBA), 21 January 1999, *Genentech*, G4/97.
202. Nicolas BINCTIN, *Droit de la propriété intellectuelle* [Intellectual Property Law], *op. cit.*, pp. 715-718, §1113; see also, Christophe CARON, "L'efficacité des licences dites FRAND (ou l'indispensable conciliation entre la normalisation et le droit des brevets d'invention grâce à la stipulation pour autrui)", *CCE 2013*, Studies No. 12; Jorge L. CONTRERAS, "A market reliance theory for FRAND commitments and other patent pledges", *Utah Law Review* 2015, p. 479; Jorge L. CONTRERAS, "A brief history for FRAND: analysing current debates in standard setting and antitrust through a historical lens", *Antitrust Law Journal* 2015, p. 39; Tanguy DE HAAN, "Un an de jurisprudence en propriété industrielle au Benelux", *Prop. Indust.* 2012, Chron. No. 1, especially §11; Lauren LEBLOND, *Pratiques anticoncurrentielles et brevets*, Bruylant, 2014; Alison JONES, "Standard-essential Patents: Frand Commitments, Injunctions and the Smarthphone Wars", *European Competition Journal* 2014, p. 1; Cyrille AMAR, "Pratiques contractuelles, Licences Frand", *CCE 2017*, Factsheets No. 15; Pauline DEBRÉ and Simon CORBINEAU-PICCI, "Brevets essentiels: Frandez-vous en terre inconnue", *Prop. Indust.* 2018, Study No. 18.

Both the Court of Justice of the European Union in the *Huawei Technologies* case [203] and the European Commission in its decisions *Rambus* [204], *Motorola* [205] and *Samsung* [206] have clarified the conditions under which SEP holders can seek injunctions parallel to FRAND licensing negotiations. However, the legal framework established by the Court and the Commission is still too vague to be used in practice.

§87. Soft law. — The European Commission could order a collection of commented case law on FRAND contractual practices among European jurisdictions, updated annually [207]. This would help specify the FRAND licensing framework, drawing inspiration from the many decisions handed down by European courts. Such a digest would undoubtedly facilitate the resolution of these disputes by increasing legal certainty.

3.2 Need for an EU-wide compulsory licensing strategy

§88. Compulsory licensing. — The COVID-19 pandemic has highlighted the importance of patents (and SPCs) in access to health care. Current research for treatments is mainly based on known pharmaceutical active ingredients or new vaccines, which are or will be covered by patents or supplementary protection certificates. These IP titles give their proprietors exclusive rights to use the claimed substances. Consequently, third parties will require authorisations of exploitation, in principle granted at the discretion of the rights holders, to manufacture anti COVID-19 drugs or vaccines. The mechanism of compulsory licensing for public health enables third parties to dispense with the granting of such authorisations by compelling the proprietors to grant rights to use the protected inventions.

§89. — The current EU compulsory licensing system is based on an international framework, which leaves Member States a certain degree of discretion in the way they implemented it in national laws (**3.2.1**). Any coordinated action at EU level has thus to be grounded in twenty-seven pieces of legislation. However, at a time when vast majority of active ingredient are manufactured outside of the Union, only further cooperation, rather than nationalist and protectionist resurgences, will be the key to ensuring an efficient and fair supply of anti COVID-19 medicines, vaccines, diagnostics or medical devices to the EU single market (**3.2.2**). Finally, lessons from the current pandemic will have to be learnt, in particular by the yardstick of both the creation of a European patent with unitary effect and the Unified Patent Court (**3.2.3**).

203. CJEU, 16 July 2015, case C-170/13, *Huawei Technologies*. For comments, see Laure MARINO, "Brevets high-tech à la CJUE: BEN, licence FRAND et action en contrefaçon", *Gaz. Pal.* 2015, No. 308, p. 17; Andreas HEINEMANN, "Standard-essential patents in standard setting organizations: competition law and the realization of licensing commitments", *Journal of Intellectual Property Law and Practice* 2015, p. 947; Christophe CARON, *CCE* 2015, Comm. No. 65; David BOSCO, Jurisprudence de la CJUE 2015, Bruylant, Bruxelles, 2015, p. 494 ; Miguel RATO and Mark ENGLISH, "An Assessment of Injunctions, Patents, and Standards Following the Court of Justice's Huawei/ZTE Ruling", *Journal of European Competition Law & Practice* 2016, Vol. 7, No. 2, p. 103; Emmanuel PY, Jacques RAYNARD et Gérard WEISS, "Un an de droit des brevets", *Prop. Indust.* 2015, Chron. No. 11, §21; Jérôme PASSA, "Action en contrefaçon concomitante à la négociation d'une licence FRAND sur un brevet essentiel à une norme: conditions de l'abus de position dominante", *Prop. Indust.* 2015, Study No. 20.

204. European Commission decision, 9 December 2009, COMP/C-3/38636, *Rambus*; Franck VIOLET, "Retour sur les embuscades tendues par les patent trolls (Commentaire de la decision *Rambus* de la Commission européenne du 9 décembre 2009)", *Prop. Indust.* 2010, Study No. 11.

205. European Commission decision, 29 April 2014, COMP/AT.39958, *Motorola*.

206. European Commission decision, 29 April 2014, COMP/AT.39939, *Samsung*.

207. As for the EUIPO *IPR Enforcement Case Law Collection*.

3.2.1 Legal framework

3.2.1.1 Article 5 Paris Convention and Article 31 TRIPS Agreement

§90. International law. — In international law, both the Paris Convention for the protection Industrial Property (PC) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) deal with compulsory licenses. On the one hand, Article 5(A)(2) PC states that contracting countries could take legislative measures, but only to prevent abuses resulting from the exercise of the exclusive rights conferred by the patent. On the other hand, Article 31 TRIPS Agreement provides, independently of any abuse, conditions under which Member States may allow the private or government "use of the subject matter of a patent without the authorisation of the right holder" [208] — [209].

Nevertheless, these two international treaties do not exhaustively enumerate the grounds on which Member States may grant compulsory licenses. In particular, the wording of Article 31 TRIPS Agreement has been drafted in such a way as to leave flexibility to Member States to legislate on compulsory licenses in cases of national emergency and other circumstances of extreme urgency, or when the subject matter of the patent is required for public non-commercial use [210]. Rationale of national implementation of a compulsory license for public health is therefore based on the broad scope of Article 31 TRIPS Agreement read in conjunction with Article 8(1), which provides that Member States "may, in formulating or amending their laws and regulations, adopt *measures necessary to protect public health* [...]" [211], and Article 30 thereof [212], which leaves WTO Members States with considerable freedom to define the nature and extent of exceptions to the exclusive rights of patent owners.

§91. National laws. — The national implementation of these flexible international provisions leads to legislative disparities between EU Member States. For example, France [213] and Belgium [214] have introduced specific provisions on compulsory licensing for public health in their patent legislation. By contrast, German patent law, like international law, does not specify the grounds on which a compulsory licence may be granted. It rather relies on a protean "public interest" ground [215].

> Section 24(1) *Patentgesetz* (German Patent Law) thus provides that compulsory licenses may be granted if: (i) an applicant for a license has, within a reasonable period of time, unsuccessfully attempted to obtain the permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions; and (ii) the public interest calls for the grant of a compulsory license.
>
> German case law deserves special attention [216]. Indeed, several compulsory licenses for public health have been issued under German law. The public interest requirement, when it matches public health, has led to several important decisions. In the *Polyferon* judgment [217] of 5 December 1995, the granting of such a license was rejected by the *Bundesgerichtshof* (German Federal Supreme Court), which held that the supply of important drugs to the public could be in the public interest, but that in this case it had not been proven that Polyferon was an essential medicine. This was a strict understanding of the public interest, difficult

208. Matthieu DHENNE, "Covid-19, patents and access to healthcare: a French perspective", 1st May 2020, §4 and §5. http://dx.doi.org/10.2139/ssrn.3614409
209. Elisabeth BERTHET, Matthieu DHENNE, Lionel VIAL, COVID-19: *How to Implement the* Ex Officio *License* [Translation of the French Version], De Boufflers' Editions, 2020.
210. See the EU's paper submitted to the TRIPS Council, for the special discussion on intellectual property and access to medicines, 20 June 2001.
211. Emphasis added.
212. Esther VAN ZIMMEREN and Geertrui VAN OVERWALLE, "A Paper Tiger? Compulsory License Regimes for Public Health in Europe", *op. cit*, pp. 14-16.
213. Article L. 613-16 French Intellectual Property Code.
214. Article XI.38 Economic Law Code.
215. Compare with paragraph 5(b) of the 2001 Doha Declaration on the TRIPS Agreement and Public Health (*see below*).
216. Matthieu DHENNE, "Covid-19, patents and access to healthcare: a French perspective", *op. cit.*, §5.
217. BGH, 5 December 1995, ref: X ZR 26/92, *GRUR* 1996, 190, *Polyferon*.

to satisfy in practice [218]. In the *Raltegravir* decision of 11 July 2017, the same Supreme Court granted a compulsory license holding that there is a "public interest" if it is proven that the active compound at issue had certain therapeutic effects that other commercially available active compounds did not provide, or that by using this active compound, the negative side effects (that other active compounds may induce) can be avoided [219]. In this regard, it is irrelevant whether the user group to which these considerations apply is small as long as the difficulties of this small group are significant.

3.2.1.2 Article 31*bis* TRIPS Agreement

§92. From the Doha Declaration to Article 31*bis*. — The 2001 Doha Declaration on the TRIPS Agreement and Public Health has affirmed the willingness of WTO Members to achieve greater flexibility in the implementation of such a mechanism [220]. Its sixth paragraph states:

> "We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

In the decision of the General Council of 30 August 2003 on the implementation of this paragraph, WTO Members removed a significant barrier to imports of affordable medicines by departing from the limitation in Article 31(f) TRIPS Agreement that compulsory licenses must be granted predominantly for the supply of the domestic market of the authorising Member State [221]. The purpose of this decision is to allow manufacturers in third countries to produce under compulsory license generics of necessary medicines for export to countries that are not enable to ensure access to these medicines at affordable prices and that lack manufacturing capability.

Two years later, on 6 December 2005, WTO Members agreed to incorporate permanently, through the conclusion of a protocol, the 2003 Waiver Decision into the TRIPS Agreement [222]. This amendment entered into force on 23 January 2017, after finally being ratified by two-thirds of WTO Members. It is now an integral part of the TRIPS Agreement by being included in Article 31*bis* added to its Annex.

The system introduced essentially consists of a double compulsory licensing scheme. On one side, an eligible importing country has granted or intends to grant a compulsory license to import, market or distribute the patented pharmaceutical products in question, provided that it has insufficient or no manufacturing capacities. On the other side, a laboratory applies for and obtains a compulsory license issued by an exporting country for the manufacture and export of these medicines. This new system has hardly been used so far [223], certainly because of its complexity [224]. To date, India [225], Brazil [226] and

218. Philipp MAUME, "*Ex officio* Licensing in Germany", in Ex officio *Licensing: Practical Experiences and Ways Forward*, MPI Studies on Intellectual Property and Competition Law, Vol. 22, Reto HILTY and Kung-Chu LIU (eds.), Springer, 2015, p. 95.
219. BGH 11 July 2017, X ZB 2/17: *GRUR* 2017, 1017, *Raltegravir*.
220. WTO, Declaration on the TRIPS Agreement and Public Health, 14 November 2001, WT/MIN(01)/DEC/2.
221. WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, 30 August 2003, WT/GC/M/82.
222. WTO, Amendment of the TRIPS Agreement, 6 December 2005, W/L/641.
223. To the best of our knowledge, only for exports of the HIV antiretroviral combination Apo-TriAvir, manufactured by the Canadian company Apotex, to Rwanda. See Padmanabha RAMANUJAM and Yugank GOYAL, "One view of compulsory licensing: comparative perspectives from India and Canada", *Marquette Intellectual Property Law Review*, 2014, p. 394; see also George TSAI, "Canada's access to medicines regime: lessons for compulsory licensing schemes under the WTO Doha Declaration", *Virginia Journal of International Law*, 2009, p. 1076.
224. See Brin ANDERSON, "Better access to medicines: why countries are getting tripped up and not ratifying article 31*bis*", *Case Western Reserve Journal of Law, Technology & the Internet*, 2010, p. 173; Carlos M. CORREA, "Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?", *South Centre*, Policy Brief No. 57, January 2019.
225. Sandeep K. RATHOD, "Compulsory licenses on pharmaceutical patents in India: A short article", *Journal of Generics Medicines*, 2017, Vol. 13, p. 108.
226. Paul CHAMP and Amir ATTARAN, "Patent Rights and Local Working under the WTO Trips Agreement: An Analysis of the U.S.-Brazil Patent Dispute", *Yale Journal of International Law*, 2002, Vol. 27, p. 365.

South Africa [227] have led the most significant campaigns for the simplification of the mechanism.

§93. Opt-out. — Compulsory licensing for public health is in fact seen as a tool for countries with the most fragile health systems. The system laid down in Article 31*bis* TRIPS Agreement presupposes that least-developed countries with insufficient or no manufacturing capacity in the pharmaceutical sector will seek assistance from developed countries to import generics produced under compulsory licenses [228]. Proof of this is the commitment of some (wrong-headed [229]) WTO Members in the 2003 General Council Decision that they will not use this compulsory licensing system as importing Members, even in situations of national emergency or other circumstances of extreme urgency [230].

§94. Reg. 816/2006. — In 2006, the European Union adopted a regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems in order to implement the above-mentioned WTO General Council Decision following the Doha Declaration [231]. This text aims to establish uniform rules on compulsory licensing for the manufacture and sale of pharmaceutical products, when these medicines are intended for export.

3.2.2 Imperative cooperation of EU's Member States to face the COVID-19 pandemic

§95. Issue. — What is at stake is the supply of anti COVID-19 medicines or vaccines to the European market. However, since opting out from Article 31*bis* TRIPS Agreement as importing countries, EU Member States have gone without a major tool derived from international IP law, in particular when facing the current pandemic [232].

§96. Outsourcing of the API supply chain. — Finished medicine products are made up of two elements: the active pharmaceutical ingredient (API), which is the chemical substance with a therapeutic or preventive effect, and the excipients, which are substances other than the API but formulated alongside with it. The manufacture of a marketable drug can approximately be summed up in two main stages. The API is first synthesised from raw and starting materials. Secondly, the drug is formulated into a finished dosage form by incorporating the active ingredient into the excipients.

Nowadays, whilst EU pharmaceutical laboratories continue drug formulation activities, the API production has been massively offshored under patent licenses to manufacturers located mainly in India and China [233] (or other API exporting countries). On September 2019, a briefing paper from the European Fine Chemicals Group (EFCG), the lobby group of European APIs manufacturers in Brussels, suggested that 80 % of that production would be outsourced abroad [234]. As a result, the supply of a

227. Duane NASH, "South Africa's Medicines and Related Substances Control Act of 1997", *Berkeley Technology Law Journal*, 2000, Vol. 15, p. 485.
228. Frederick M. ABBOTT and Jerome H. REICHMAN, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions, *Journal of International Economic Law*, 2007, 10(4), pp. 921-987.
229. *See below*, §95 *et seq*.
230. Article 1(b), footnote 3, General Council Decision of 30 August 2003; Article 31*bis*, Annex of the TRIPS Agreement, Article 1(b), footnote 3.
231. Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, *OJEU* L 157 of 9 June 2006, p. 1. For comments, see Jean-Christophe *Galloux, RTD com.* 2007, p. 52 or Joanna SCHMIDT-SZALEWSKI, *RTD eur.* 2007, p. 347.
232. Christopher GARRISON, "Never say never – Why the High Income Countries that opted-out from the Art. 31*bis* WTO TRIPS system must urgently reconsider their decision in the face of the Covid-19 pandemic", *Medicines Law & Policy*, 8 April 2020.
233. Vincent LORRAIN, "Europe's suicidal reliance on drugs made in China", *Voxeurop*, 11 March 2020.
234. European Fine Chemicals Group (EFCG) Briefing Paper addressing the acute and complex issue of medicines shortages, September 2020.

future anti COVID-19 medicines or vaccines from the EU's single market could dependent heavily on Chinese and Indian API production capacities.

§97. — In API exporting countries, compulsory licensing will help increase production by allowing new companies to join the active ingredient supply chain. However, Article 31(f) TRIPS Agreement limits exports under compulsory licenses since production must be predominantly for the supply of the domestic market. Under international law, only eligible importing countries, *i.e.* least-developed countries or WTO Member States that has made a notification [235] to the Council for TRIPS, can benefit from the export waiver under Article 31*bis* thereof. As EU Member States deliberately opted out from this system, the granting of compulsory licenses to supply their population with anti COVID-19 generics of patented medicines may be ineffective due to insufficient supplies of APIs [236].

Consequently, in the absence of a political will for coordination at Union level, each of the Member States will manage locally the supply of its domestic market with APIs or finished medicine products, thus reinforcing protectionist resurgences and nationalist retreats within the EU.

> The German special law amending the *Infektionsschutzgesetz* (Infection Protection Law), which was adopted on 27 March 2020, underlies a nationalist attitude, the conformity of which with international law is questionable. It provides that, in order to deal with the COVID-19 epidemic, the Federal Minister of Health will be able to rely on Section 13 of the *Patentgesetz*, which has never been invoked in the past, according to which patents will have no effect if the Federal Government orders that the invention be used in the public interest [237].

§98. Intra-European cooperation. — More than ever, all Member States shall coordinate their actions in a spirit of European solidarity to be ready to rapidly supply the entire EU single market with anti COVID-19 medicines or vaccines. In the short term, the European Union should undertake political and multilateral cooperation actions to ensure that proprietors of patents and SCPs covering promising drugs will voluntarily grant non-exclusive licenses to APIs manufacturers and pharmaceutical laboratories (under FRAND conditions). Furthermore, it is essential to restore and secure the production of the critical pharmaceutical components in Europe. To be effective, the return of pharmaceutical supply chains needs to be planned carefully and strategically at EU level.

§99. — Where a Government decides to grant a compulsory license, it comes under the heading of the exercise of public-authority powers. It thus remains a political tool for exerting pressure in negotiations between States and IP right holders.

> **AbbVie and Kaletra.** — AbbVie's waiver decision, announced on 20 March 2020, strikingly illustrates this point. AbbVie holds the patents on the lopinavir/ritonavir (LPV/r) combination, sold under the brand name Kaletra, which was considered a potential treatment for COVID-19. However, following Israel's grant of a compulsory license for the LPV/r combination, the pharmaceutical company decided not to exercise its patent rights, presumably to avoid being faced with further compulsory licenses [238].

> **Gilead and Remdesivir.** — The controversy over Remdesivir [239] — an antiviral that appears to be effective at least in the early stages of infection — is another good example of the issues at stake. Gilead Sciences (hereafter referred to as "Gilead") has initially developed the Remdesivir molecule to fight Ebola virus

235. Article 1(b), footnote 2, Annex, TRIPS Agreement: "It is understood that this notification does not need to be approved by a WTO body in order to use the system".
236. Christopher GARRISON, *op. cit.*, para. 6.
237. *Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen — Infektionsschutzgesetz* (IfSG), 17 March 2020: *BGBl. I S.* 587, 589.
238. Ellen 'T HOEN, "Covid-19 and the comeback of compulsory licensing", *Medicines Law & Policy*, 23 March 2020.
239. Elisabeth BERTHET, Matthieu DHENNE, Lionel VIAL, *COVID-19: How to Implement the* Ex Officio *License* [Translation of the French Version], *op. cit.*, pp. 6-7, §2.

infections. In September 2016, Gilead filed a PCT application covering the use of Remdesivir for treating MERS-CoV infections in more than 100 countries [240]. National phases of this application were filed in China and Hong Kong. On 9 April 2019, the USPTO granted Gilead a US Patent for "Methods for the Treatment of Arenaviridae and Coronaviridae Virus Infections". Remdesivir, however, remained at an experimental stage: it was in clinical trials for various treatments and had not received regulatory approval as a drug for the treatment of a disease by a health product regulatory authority in any country.

As the COVID-19 pandemic spread to almost every country in the world, Gilead announced on 25 March that it had withdrawn the orphan designation it had received two days ago from the Food and Drug Administration (FDA) for the treatment of COVID-19 [241- 242]. On 29 April 2020 of encouraging, but not spectacular, preliminary results of a clinical trial were published [243] but they were contradicted by the results of another clinical trial published two days later [244]. Nevertheless, Gilead obtained on 1st May 2020 an Emergency Use Authorisation (EUA) from the FDA, allowing it to market Remdesivir for the treatment of severe COVID-19 forms before obtaining a marketing authorisation (MA). Anticipating similar success in the rest of the world for its molecule, Gilead then announced that it had signed voluntary, non-exclusive licensing agreements with five generic manufacturers based in India and Pakistan to in-crease production capacity for Remdesivir. The EU granted Remdesivir a conditional MA on 3 July, with an indication for the treatment of COVID-19 in adults and adolescents with pneumonia requiring supplemental oxygen [245]. Most recently, on 28 July 2020, the European Commission signed a contract with Gilead and financed COVID-19 treatment for 30,000 European patients with severe symptoms.

3.2.3 Set up of an EU-wide compulsory licensing system

§100. — In the absence of government-coordinated compulsory licensing, rights holders can decide where to manufacture within the Union, which Member States they should supply first, and even set prices (in countries where administrative authorities largely abstain from pricing decisions). This can lead to the segmentation of the European Single Market against the backdrop of health emergency. To avoid distortion of competition in such times of crisis, an EU-wide compulsory licensing mechanism, articulated with legislation on marketing authorisations, should be set up.

§101. Mandatory patent pools. — To facilitate access to cross-border supplies of patented pharmaceuticals, Frederick M. ABBOTT and Jerome H. REICHMAN suggested the creation of mandatory patent pools on global or regional basis [246]. Such an idea could be judiciously applied at the European level, building on the existing legal framework of the Union. The EU mandatory patent pool would consist of a bundle of import and export compulsory licenses granted by Member States' governments. As the re-export of pharmaceutical products imported under compulsory license is prohibited by international law [247], the European Commission, assisted by the European Medicines Agency (EMA), would have to centralise and coordinate national procurement and shipments. Both the IP territoriality principle and the prohibition of re-exportations redraw national borders within the Single Market by thwarting

240. International Application WO 2017/049060.
241. Gilead Sciences Statement on Request to Rescind Remdesivir Orphan Drug Designation.
https://www.gilead.com/news-and-press/company-statements/gilead-sciences-statement-on-request-torescind-remdesivir-orphan-drug-designation
242. Elisabeth MAHASE, "Covid-19: Gilead withdraws orphan drug designation from potential treatment after criticism", *BMJ* 2020; 368:m1259.
243. https://www.niaid.nih.gov/news-events/nih-clinical-trial-shows-remdesivir-accelerates-recovery/ -advanced-covid-19
244. Yeming WANG *et al.*, "Remdesivir in adults with severe COVID-19: a randomised, double-blind, placebo-controlled, multicentre trial", *The Lancet*, Vol. 395, Iss. 10236, 16-22 May 2020, pp. 1569-1578.
245. European Medicines Agency (EMA), First COVID-19 treatment recommended for EU authorisation (Press Release).
246. Frederick M. ABBOTT and Jerome H. REICHMAN, "Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic", *Journal of International Economic Law* (Oxford), Vol. 3, Iss. 3, September 2020 (Forthcoming).
247. Annex(3) about Article 31bis (Practice) TRIPS Agreement.

the free movement of goods. Managing the EU mandatory patent pool would thus mainly consist of supervising the supply of 27 national markets by avoiding domestic import surpluses since they cannot circulate freely between EU Member States.

§102. — The implementation of this EU-wide compulsory licensing system requires Member States to opt back in the Article 31*bis* TRIPS Agreement system (**3.2.3.1**); harmonise the grounds for granting compulsory licenses for public health (**3.2.3.2**); and amend legislation on marketing authorisations (**3.2.3.3**).

3.2.3.1 Opting back in

§103. — Frederick M. ABBOTT and Jerome H. REICHMAN advocate various five "legal approaches under which formerly opted-out countries may consider opting back in or otherwise making use of the Article 31*bis* system to import needed pharmaceutical products" under compulsory licenses [248]:

(i) Relying on an interpretation of paragraph 1(b) of the Annex.

> **Annex(1)(b)**: "eligible importing Member means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ('system') as an importer, it being understood that *a Member may notify **at any time** that it will use the system in whole or in a limited way*, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency."

However, it can hardly be argued that the initial unilateral decision to opt out from the Article 31*bis* system was not a final commitment. What would be the point of providing for a non-binding general notification of intent to make use or not of the system? Where the letter of paragraph 1(b) of the Annex provides that "a Member may notify at any time that it will use the system in whole or in a limited way", it addresses WTO Member States that have not yet opt in or out the Article 31*bis* system.

(ii) Seeking a waiver pursuant to Article IX(3) and (4) of the WTO Agreement.

(iii) Collectively opting-in through a consensus decision incorporated as a TRIPS Council approved interpretation or amendment of the Annex text.

(iv) Acting without WTO pre-approval and going before the Dispute Settlement Body, with the potential for withdrawal of trade concessions by a (hypothetically) successful complainant (including with arbitration on the justified amount of concession withdrawal).

(v) Invoking Article 73 TRIPS Agreement, which provides substantial deference to Members protecting essential security interests through measures taken in times of emergency in international relations.

§104. — By opting back in the Article 31*bis* system, EU Member States could become eligible importers, not only under the TRIPS Agreement, but also under Article 4(b) of EU Regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (Reg. 816/2006):

248. Frederick M. ABBOTT and Jerome H. REICHMAN, "Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic", *op. cit.*, Sect. IV, Subsect. B.

> "The following are eligible importing countries: [...]
> (b) *any member of the WTO*, other than the least-developed country members referred to in point (a), *that has made a notification to the Council for TRIPS of its intention to use the system as an importer*, including whether it will use the system in whole or in a limited way; [...]" [249]

This extension of the scope of Reg. 816/2006 thus allows for a harmonised system of compulsory licensing for export, either within or outside the Union, of pharmaceutical products manufactured in an EU Member State.

3.2.3.2 Harmonisation of the compulsory licensing grounds for public health

§105. Interpretation of Reg. 816/2006. — Under the TRIPS Agreement, each WTO Member has the right to freely determine the grounds upon which compulsory licences are granted. The 2001 Doha Declaration clarified the relationship between the TRIPS Agreement and public health policies of WTO Members, confirming the right of Members to issue compulsory licenses on patents for reasons of public health. For its part, the European Union has legislated through Reg. 816/2006 only to harmonise the conditions for the granting of compulsory licences for the manufacture and sale of pharmaceutical products to be exported to countries lacking production capacity. Nevertheless, the COVID-19 outbreak highlighted shortcomings in the scope of this regulation. Article 2 thereof states:

> "For the purpose of this Regulation, the following definitions shall apply: [...]
> (3) 'right-holder' means the holder of *any patent or supplementary protection certificate* in relation to which a compulsory licence has been applied for under this Regulation; [...]"

A narrow interpretation of these provisions would lead to the result that only granted patents and supplementary protection certificates may be subject to compulsory licensing, thus excluding granted utility models [250], and patent and utility model applications.

Under Article 30 TRIPS Agreement, the compulsory licensing system is an exception to the exclusive rights conferred by a patent. Provisions governing compulsory licenses should therefore lead to a narrow interpretation based on the letter of the text ("*exceptio est strictissimae interpretationis*"). However, such an interpretation seems to contradict the very spirit of Reg. 816/2006. Firstly, the rationale of Article 31*bis* TRIPS Agreement, partially implemented through this EU Regulation, is to allow Member States to export medicines protected by IPRs to third countries by making use of compulsory licenses. The subject matter of such licenses must logically cover all the intellectual property rights that protect pharmaceutical products, *i.e.* patents, supplementary protection certificates and utility models. Furthermore, since the COVID-19 epidemic has just triggered several research projects, both in terms of preventive (vaccines) and curative (drugs) treatments and diagnostic methods, it can be expected that several patent applications will soon be filed, although it is only in several years' time that they may be granted. The same considerations apply to utility model applications even if the length of the administrative registration proceeding is much shorter. Compulsory licenses should therefore be available for utility model or patent applications. All the more so since the patent or utility model right arises from the filing of the application [251]. During the period elapsing between the filing and the grant of the title, the applicant becomes the owner of a right, although this right is incomplete, because it cannot yet have all its effects. Only the grant of the patent or utility model will ultimately the completion of the patent or utility model right. However, it should be emphasised that this right exists between the filing of the application and the grant of the title. The said grant is only a unilateral administrative

249. Emphasis added.
250. So called "utility certificates" under French law.
251. Jacques RAYNARD, Emmanuel PY and Pascale TRÉFIGNY, *Droit de la propriété industrielle*, LexisNexis, Manuel, 2016, No. 182.

act with declaratory and not constitutive effect [252]. In short, the title granted assigns all its effects to a pre-existing right which it will then be possible to prove [253]. Therefore, there is no reason why the rights conferred to patent or utility model applications should not be subject to the same limitations as those that apply to granted patents or utility models.

§106. Grounds for public health compulsory licensing. — To create an EU mandatory patent pool, however, further harmonisation is needed by defining common grounds in all Member States for public health compulsory licensing. It would allow, among other things, the import of patented pharmaceutical products.

Since French patent law included specific provisions for compulsory licensing for public health (the so called "*ex officio* license in the interest of public health") as early as 1959 [254], it could serve as a legislative model for an EU regulation. This system was nevertheless never used.

> To our knowledge, the *ex officio* license in the interest of public health has never been the subject of litigation before French courts. Only a judgment of 25 January 1991 is to be noted [255]. In this case, the Conseil d'Etat had invalidated a formal notice issued by the Minister for Health to a company to resume the operation of a medicinal product. Actually, there was no statutory provision empowering the Minister to issue such a formal notice since only the *ex officio* licensing system could be applied.

French law [256] sets out 5 grounds that justify the granting of a compulsory license for public health: when the pharmaceutical products at issue are made available to the public (i) in insufficient quantity, (ii) in insufficient quality, (iii) at abnormally high prices, or when the patent is exploited under conditions that (iv) are contrary to the interest of public health or (v) constitute practices that have been declared anti-competitive following an administrative or judicial decision that has become final.

For the purpose of providing grounds for the granting of compulsory licenses for public health that are the same to all EU Member States, grounds (i) to (iv) could be rightly held. In particular, ground (iv) is very general and would grant the Member States a sufficiently broad scope to enable them to apply it in conformity with Article 31 TRIPS Agreement. With regard to the COVID-19 epidemic, the insufficient quantity and abnormally high prices criteria seem to be the most relevant.

Relatively to the assessment of grounds (i) to (iii), the question could arise as to whether only the needs of public health should be taken into account or whether the patentee's ability to make a profit from the research he has had to conduct should also be taken into account. Section 41(2) of 1949 English Patent Law were more explicit on this point and got position into the interest of funding research. It stated that:

> "[...] medicines and surgical and curative devices shall be available to the public at the lowest prices consistent with the patentees' deriving a reasonable advantage from their patent rights."

Finally, regarding to ground (iii), it should be bore in mind that it is not clear what an *abnormally high* price is or when it is supposed to be considered *normally high*. In France, the company marketing

252. Matthieu DHENNE, "De la rétroactivité de l'imprescriptibilité des actions en annulation des titres nationaux de propriété industrielle" [The retroactivity of the imprescriptibility of invalidation actions of national industrial property titles], *Prop. Indust.* 2019, Study No. 27, p. 7 *et seq*.

253. Jean-Marc MOUSSERON, *Le droit du breveté d'invention. Contribution à une analyse objective* [The right of the patentee. Contribution to an objective analysis], LGDJ, Bibliothèque de droit privé, Vol. 23, No. 233 *et seq.*; see also Serge PONCY, *Le droit du déposant entre la demande de brevet et la délivrance du brevet en droit interne et droit européen* [The right of the applicant between the patent application and the grant of the patent under national and European laws], Thesis, University of Montpellier, 1975, No. 329 *et seq*.

254. Ordinance No. 59-250 of 4 February 1959, relating to the reform of the pharmaceutical manufacturing regime and various amendments to the public health code [Ordonnance n° 59-250 du 4 février 1959 relative à la réforme du régime de la fabrication des produits pharmaceutiques et à diverses modifications du code de la santé publique].

255. Conseil d'État, 25 January 1991, *Confédération nationale des associations familiales catholiques*, No. 103143, No. 107100 and No. 107101.

256. Article L. 613-16 of the French Intellectual Property Code.

a drug does not set its price unilaterally, but the Economic Committee for Health Products ("*Comité économique des produits de santé*") does, generally following bargaining rounds with the company. The issue of abnormally high prices can give rise to endless disputes in which IPR holders' private interests would clash with the general interest, in the light of the proportionality principle and the prohibition of abuse of rights [257]. For the sake of public health, however, should be abnormally high a price that does not allow access to the drug for all patients who would need it given the resources of the health care system.

3.2.3.3 Amending the legislation on marketing authorisations

§107. — The challenge of supplying the Single Market with patented medicines under compulsory licenses cannot only be seen from the perspective of patent law. The compulsory licensing system must be articulated with exclusive rights to trial data on medicinal products.

§108. Data and marketing exclusivity. — When applying for a marketing authorisation (MA) for a new medicinal product, the applicant (the originator) submits test data to regulatory agencies that conduct an independent assessment of the quality, safety and efficacy of drugs. The pharmaceutical laboratory generates test data by means of pharmacological, toxicological and clinical tests. These data are subject to a specific appropriation regime called the data exclusivity.

Although these pharmaceutical trials serve legitimate public health objectives, their cost creates significant barriers to market entry for new pharmaceuticals. Access to trial data can therefore enable the marketing of generic products, manufacturers of which will not have to support clinical trial funding. At the end of the data exclusivity period, the generic laboratory applying for a MA thus saves clinical trials and must simply demonstrate bioequivalence between the two drugs. However, this streamlined procedure is only available after a certain period has elapsed since the MA for the originator's medicinal product was granted. Thus, the generic manufacturer's access to market depends not only on the patent term, but also on its desire to invest in clinical trials or to wait for the trial data to fall into the public domain [258].

Under Union law, protection periods are computed according to the "8 + 2 + 1" rule. In accordance with Article 10(1) and (5) Dir. 2001/83/EC (consolidated text) [259] for national MAs and Article 14(11) Reg. 726/2004 [260], a generic company can apply for marketing authorisation 8 years after the issuance of the original one (data protection period). In addition, generic medicinal products that have been authorised may not be marketed before a 10-year period from the issue of the original MA (marketing protection period). The latter period shall be extended to a maximum of 11 years if, during the first 8 years of those 10 years, the MA holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.

§109. Waivers. — The EU pharmaceutical legislation does not provide for general waivers to data and market exclusivity when the authorised products are subject to compulsory licenses. As a result, the applicant for such a license will not be allowed to market a generic medicinal product of the reference one.

257. Midjohodo FRANCK GLOGLO, *Brevet pharmaceutique et intérêt général: essai sur la prise en compte de l'intérêt général en droits international, canadien et européen des brevets* [Pharmaceutical patent and general interest: an essay on the consideration of general interest in international, Canadian and European patent laws], Thesis, Université de Laval, 2015, p. 319 *et seq*.

258. Nicolas BINCTIN, *Droit de la propriété intellectuelle* [Intellectual Property Law], *op. cit.*, pp. 425-437, §670 to §692.

259. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (consolidated text).

260. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

By contrast, however, waivers do exist in the EU Regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (Reg. 816/2006). Article 18(2) thereof states that:

> "If a request for any of the above procedures concerns a product which is a generic of a reference medicinal product which is a generic of a reference medicinal product which is or has been authorised under Article 6 of Directive 2001/83/EC, the protection periods set out in Article 14(11) of Regulation (EC) No 726/2004 and in Article 10(1) and 10(5) of Directive 2001/83/EC shall not apply."

Ellen F. M. 'T HOEN *et al.* rightly argued that the effectiveness of the compulsory licensing system "requires a waiver of data exclusivity of the approval and marketing of licensed generic medicines. [...] This lack of legal coherence within the EU renders national compulsory licensing provisions useless with respect to EMA approved medicines protected by data exclusivity"[261].

§110. Waiver proposal. — In order to create an EU mandatory patent pool based on compulsory licensing, legal barriers to the marketing of needed medicines must be removed. Following 'T HOEN *et al.* and based on the letter of Article 18(2) Reg. 816/2006, the below waiver provisions to data and marketing exclusivity should be introduced into the EU legal framework governing medicinal products for human use:

> "The protection periods set out in Article 14(11) of Regulation (EC) No 726/2004 shall not apply in cases where it is necessary to allow access to and the use of pharmaceutical test data to register a generic of a reference medicinal product, which is or has been authorised under Article 6 of Directive 2001/83/EC, in case of compulsory licensing for public health."

261. Ellen F. M. 'T HOEN, Pascale BOULET and Brook K. BAKER, "Data exclusivity exceptions and compulsory licensing to promote generic medicines in the European Union: A proposal for greater coherence in European pharmaceutical legislation", *Journal of Pharmaceutical Policy and Practice* 2017, 10:19.

Chapter 4

Reinforcement of the fight against counterfeiting and IP theft

§111. — Counterfeiting of intellectual property rights is a large-scale phenomenon that is estimated to account for 5-10 % of world trade. It is correlated with an increase in serious crime [262], despite customs intervention against infringers (**4.1**). Consequently, the use of criminal proceedings to punish counterfeiting should be developed in order to convince economic operators that it is necessary to differentiate conflicts between competitors, which very naturally come under civil courts, from "IP piracy" [263], which should systematically be brought before criminal courts. However, legislation against counterfeiting within the Union is still a set of national and partially harmonised laws. While civil proceedings and penalties have indeed been harmonised, criminal matters remain within the competence of each Member State in the absence of intervention by the EU legislature (**4.2**).

4.1 Need to increase IP-related customs activity

§112. Free movement of goods. — Intellectual property customs law is a powerful and effective legislation in the fight against counterfeiting, which has had a major boost under the influence of the EU. Customs law is remarkable for being at the heart of European construction and also having the benefit of European codification. Thanks to the arrival of intra-EU free movement, customs checks on the movement of goods incorporating intellectual property have been limited, to the benefit of the principle of the exhaustion of rights. However, even within the framework of EU law, the movement of counterfeit goods between Member States is a source of contention around the concept of internal transit [264].

§113. Customs legal framework. — European law has specifically taken over the monitoring of intellectual property, within the framework of Regulation (EC) No 1383/2003 [265], now replaced by Reg-

262. UNIFAB, Annual Report 2016, *Contrefaçon et terrorisme* [Counterfeiting and terrorism].
263. Jean-Christophe GALLOUX and Jacques AZÉMA, *Droit de la propriété industrielle* [Industrial Property Law], *op. cit.*, pp. 1188-1189, §1870.
264. Nicolas BINCTIN, *Droit de la propriété intellectuelle* [Intellectual Property Law], *op. cit.*, p. 912 *et seq.*, §1419 *et seq*.
265. Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, *OJEU* L 196 of 2 August 2003 pp. 7-14; *RTD com.* 2004. 289, obs. Jean-Christophe GALLOUX; "Implementing Regulation No 1891/2004", *PIBD* 2005, No. 799, I-1; *RTD com.* 2005. 292, obs. Jean-Christophe GALLOUX.

ulation (EU) No 608/2013 concerning customs enforcement of intellectual property rights [266] whose implementing regulation, Regulation (EU) No 1352/2013, was published on 4 December 2013 [267]. The regulation was reshaped in a strained environment influenced by the failure of the Anti-Counterfeiting Trade Agreement (ACTA).

§114. — Recital 9 Reg. No 608/2013 pragmatically provides that:

> "Member States face increasingly limited resources in the field of customs. Therefore, the promotion of risk management technologies and strategies to maximise resources available to customs authorities should be supported."

In spite of what is stated in the aforementioned recital, this lack of capacity for action can only hinder the seizure of counterfeit goods during customs controls. In order to effectively fight against the introduction, export, re-export or exit of counterfeit goods into or from the Union customs territory, customs authorities must be provided with adequate human resources.

4.2 Strengthening the enforcement of intellectual property rights

§115. Choice. — Counterfeiting regime allows the holder of an infringed IPR to choose to enforce his right either through the institution of civil (**4.2.1**) or criminal (**4.2.2**) proceedings.

4.2.1 Civil IP law

§116 — IPR Enforcement Directive [268] has provided all litigants within the Union with similar means to defend harmonised intellectual property rights, which is a very important step towards an EU Intellectual Property Code. Setting up a mechanism to impose punitive damages would be a major step forward in strengthening the fight against counterfeiting (**4.2.1.2**). However, despite the harmonisation of means of enforcing IPRs, the multiplicity of fora, in particular for national and European patent rights, lead to the fragmentation of EU cross-border litigation into a set of national trials, to the detriment of the fight against cross-border infringements (**4.2.1.1**). The expected entry into force of the "Patent Package" should nevertheless help to preserve unity in litigation, with the Unified Patent Court having exclusive jurisdiction on European patents and EPUEs [269].

4.2.1.1 Avoid national fragmentation of EU cross-border litigation

§117. — In order to reinforce fight against counterfeiting, the European Court of Justice should be careful to interpret private international IP law by trying to preserve unity in litigation in order to

266. Regulation (EU) No 608/2013 of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003, *OJEU* L 181, 29 June 2013; Nicolas BINCTIN, "Le règlement 608/2013 concernant le contrôle, par les autorités douanières, du respect des droits de propriété intellectuelle" [Regulation 608/2013 concerning customs enforcement of intellectual property rights], *Prop. Indust.* 2014, Study 2; Lucie CORVISIER and Alexis VICHNIEVSKY, "Action des douanes dans la lutte contre la contrefaçon, l'impact du nouveau règlement européen" [Customs action in the fight against counterfeiting, the impact of the new European Regulation], *JCP E* 2013, p. 1596.

267. Implementing Regulation (EU) No 1352/2013 of 4 December 2013 establishing the forms provided for in Regulation (EU) No 608/2013 of the European Parliament and of the Council concerning customs enforcement of intellectual property rights, *OJEU* L 341/10, 18 December 2013, providing different forms for various procedures in the annex.

268. Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights.

269. Article 32 UPC Agreement.

prevent EU cross-border lawsuits from being fragmented into national trials. The European Commission should plead to this effect when submitting observations to the CJEU for preliminary rulings.

§118. — According to Article 8(1) Brussels I*bis* Regulation (Article 6(1) Brussels Convention and Article 6(1) Brussels I Regulation), where infringements of intellectual property rights occurred or are likely to occur on different Member States' territories by different alleged infringers, the IPR holder may sue them all before the court where one of them is domiciled, "provided the claims are so closely connected that it is expedient to hear and determine them together to avoid the risk of irreconcilable judgments resulting from separate proceedings". However, on the basis of CJEU case law, the assessment of this connection requirement between the claims brought against co-defendants seems to depend upon the nature of the IPR invoked.

(a) National IP rights

§119. European Patent. — In the 2006 judgment *Roche Nederland* [270], the ECJ adopted a strict assessment of the requirement of connectedness laid down in Article 6(1) Brussels Convention in the event of European Patent infringements [271]. In this case, IPR holders bring infringement actions against companies established in different Member States and belonging to the same group before the court where one of the said companies is established. The ECJ, following the opinion of Advocate General Philippe LÉGER [272], hold that the terms "*irreconcilable* judgements resulting from separate proceedings" must not be construed in the sense "*conflicting* decisions" but in the narrow sense of judgements "arising in the context of the same situation of law and fact" and "that cannot be separately enforced and that their legal consequences are not mutually exclusive" [273]. As the European Patent have national effects in the States for which it is granted (Articles 2(2) and 64(1) EPC), infringement actions separately brought against defendants in different Member States would not raise necessarily mutually irreconcilable judgements, due to the IPR territoriality principle. The existence of such incompatible decisions must therefore be assessed on a case-by-case basis.

The rationale of such a strict interpretation can be found in the general rule of exclusive jurisdiction of the courts of the state of patent registration regarding its validity, irrespective of whether the issue is raised by way of an action or as a defence (Article 16(4) Brussels Conv. as interpreted by the *GAT* decision [274]; Article 22(4) Brussels I Reg.; and Article 24(4) Brussels I*bis* Reg.) [275]. Since challenging the validity of a patent is a common defence, centralising infringement actions will not prevent the fragmentation of litigation in a bundle of national validity actions. As a result, the *Roche Nederland* and *GAT* cases together have ruined cross-border jurisdiction in European Patent infringement proceedings, to the detriment of the fight against cross-border counterfeiting.

This solution is regrettable, all the more so since one could have imagined that the single court seized pursuant to Article 6(1) Brussels Convention would rule on a plea of nullity without staying the proceedings. Counterclaims for invalidity would then have been brought in parallel before the

270. CJEC, 13 July 2006, case C-539/03, *Roche Nederland BV e.a. v Frederick Primus and Milton Goldenberg*.
271. Tristan AZZI, "Conflit de juridictions: de la pluralité de fors en droit de la propriété intellectuelle" [Conflict of jurisdictions: the plurality of fora in intellectual property law], in *Les grands arrêts de la propriété intellectuelle*, Michel VIVANT (ed.), 3rd ed., Dalloz, 2020, Cases 35-37, p. 202-222.
272. Opinion of Advocate General Philippe LÉGER, 8 December 2005, case C-539/03, *Roche Nederland BV e.a. v Frederick Primus and Milton Goldenberg*.
273. The broadest interpretation of *irreconcilable* judgments, in the sense of *contradictory*, were already accepted to construe the concept of "related actions" within the meaning of Article 22 Brussels Convention (Article 28 Brussels I Reg. and Article 30 Brussels I*bis* Reg.); see CJEC, 6 December 1994, case C-406/92, *Tartry*.
274. CJEC, 13 July 2006, case C-4/03, *Gesellschaft für Antriebstechnik mbH & Co. KG (GAT) v Lamellen und Kupplungsbau Beteiligungs KG (LuK)*.
275. Opinion of Advocate General Philippe LÉGER, 8 December 2005, case C-539/03, *op. cit.*, para. 132 *et seq*.

courts of the States for which the European patent is registered. On the one side, if the plea of nullity is accepted, it would nevertheless only have an *inter partes* effect [276]. On the other side, if the national part of a European patent is revoked by a court in the State where it is registered, the invalidation would have an *erga omnes* effect. Conflicting decisions that could arise between these different procedures conducted in parallel would be settled according to the following principle of priority: retroactive and absolute invalidation of the national part of a European patent shall not allow the revision of an earlier irrevocable and unappealable infringement judgement [277].

§120. — The 2012 *Solvay* decision [278] was handed down in the wake of the *Roche Nederland* one. In this case, the proprietor of a European patent accused companies belonging to the same group of illegally marketing patented products. However, unlike the facts in Roche Nederland, the co-defendants separately were charged of committing similar acts of infringement, each time on the same Member State's territory [279]. The incriminated acts were in the same situation in fact, but also in law, since for identical acts of infringement committed by different defendants on the same territory, patent rights are enforced under the same applicable law, *i.e.* the *lex loci protectionis*. If the infringement actions had been brought independently, there would therefore have been a risk of irreconcilable judgements since courts from the same Member State could have issued contrary rulings.

§121. Copyright. — Where there is more than one forum for copyright infringement, the CJEU interprets Article 6(1) Brussel I Regulation (Art. 8(1) Brussels I*bis* Reg.) more flexibly. In the 2011 *Eva-Maria Painer* decision [280], the European Court of Justice considered that the incriminated acts fell under the same legal situation because even though the laws applicable to assess copyright infringement were different, they were "substantially identical" [281].

This decision, which must be approved, is not surprising however. Copyright is conferred to the author by the mere fact of an original creative act, unlike industrial property titles, which require filing with an IP office. The rule of exclusive jurisdiction provided for in Article 22(4) Brussels I Regulation (Art. 24(4) Brussels I*bis* Reg.) does not apply here. The rationale in the *Roche Nederland* decision cannot be transposed to the present case.

(b) EU unitary IP rights

§122. — With respect to EU unitary IP rights, the CJEU adopted a courageous approach in two major decisions, *DHL* [282] and *Nintendo* [283], by entrusting global competence to a single jurisdiction, provided that the requirements of Article 6(1) Brussels I Regulation (Art. 8(1) Brussels I*bis* Reg.) are met. Multiplication of fora for EU-dimensional litigation would deprive the unitary effect of intellectual property titles of its *raison d'être*. These decisions thus enshrine a supranational character to EU IP rights with

276. For a similar solution, see European Max Planck Group on Conflict of Laws in Intellectual Property (CLIP), *Exclusive Jurisdiction and Cross-Border IP (Patent) Infringement. Suggestions for Amendment of the Brussels I Regulation*, 2007, Article 2.
277. Compare with Cass., Ass. Plén., 17 February 2012, No. 10-24.282, *Mr X v LGP Systems*. See also, Emmanuel PY, "Sanction des conditions de brevetabilité: sur la décision d'annulation" [Sanction of patentability requirements: about the invalidating decision of a patent], in *Les grands arrêts de la propriété intellectuelle*, Michel VIVANT (ed.), 3rd ed., Dalloz, 2020, Case 91, p. 536-545.
278. CJEU, 12 July 2012, case C-616/10, *Solvay SA v Honeywell Fluorine Products Europe BV ea*.
279. Édouard TREPPOZ, "Chronique Droit européen de la propriété intellectuelle. Précisions sur le champs spatial et substantiel des injonctions en matière de propriété intellectuelle", *RTD eur.* 2012. 957.
280. CJEU, 1st December 2011, case C-145/10, *Eva-Maria Painer v Standard Verlags GmbH ea*.
281. *Ibid*., para. 82.
282. CJEU, 12 April 2011, case C-235/09, *DHL Express France*. For implementation, see Cass. com., 29 November 2011, *Bull. civ.* IV, No. 197.
283. CJEU, 27 September 2017, joint cases C-24/16 and C-25/16, *Nintendo Co. Ltd v BigBen Interactive GmbH and BigBen Interactive SA*.

regard to the protection of such rights, sanctioning of infringements, remedies, and enforcement of court orders intended to protect them.

4.2.1.2 Allow the allocation of punitive damages

§123. Punitive damages. — With respect to repressive measures, the influence of the EU is important as it operates in an open framework, and is not held in check by local traditions. Regarding to the computation and allocation of the amount of the financial remedies, setting up a mechanism to impose punitive damages would be a major step forward in strengthening the fight against counterfeiting. The IPR Enforcement Directive (IPRED) does not impose such a mechanism, which is firmly rejected in French law anyway. However, even if the IPRED aim only to compensate prejudice in full, this does not prevent the Member States from offering methods of calculating damages more favourable to intellectual property right holders than those methods required under the Directive. Indeed, Article 2(1) IPRED states that:

> "Without prejudice to the means which are or may be provided for in Community or national legislation, in so far as those means may be more favourable for right holders, the measures, procedures and remedies provided for by this Directive shall apply [...] to any infringement of intellectual property rights as provided for by Community law and/or by the national law of the Member State concerned."

Consequently, the European Court of Justice held in the 2017 *Stowarzyszenie "Oławska Telewizja Kablowa"* judgement [284] that:

> "Contrary to the view that the referring court appears to take, the fact that Directive 2004/48 does not entail an obligation on the Member States to provide for 'punitive' damages cannot be interpreted as a prohibition on introducing such a measure." (para. 28)

If IPR Enforcement Directive is recast, judges could be vested with the possibility of awarding punitive damages, provided the demonstration of the intention to infringe.

§124. Implementation in French law. — Transposition of Article 13(1) IPRED has caused French national law to be revised and has made a dent in the traditional solution. A single approach to the assessment of damages in the event of infringement has only been established since the transposition of IPR Enforcement Directive in 2007. Two approaches to the determination of the monetary compensation due from the counterfeiter are included in the French Intellectual Property Code. Either the damages are set by reference to the negative economic consequences, including loss of earnings, sustained by the injured party, and the profits made by the counterfeiter. Or, and this is the major innovation in this field, the judge, at the request of the injured party, can award a lump sum as damages, which may not be less than the amount of the royalties that would have been paid if the counterfeiter had asked for authorisation to use the intellectual property that it misappropriated. Before this alternative was introduced, it was necessary to provide evidence of the loss sustained in order to obtain compensation in the event of infringement. If the loss was not proven, the infringement was limited to the recognition that an asset had been harmed. Under the rules governing property, markets, and the forms of counterfeiting, proving lost earnings or loss sustained was difficult, especially if the injured party did not wish to provide details about the exact nature of the loss in order to keep as secret as possible the profits generated by his commercial activity. The victim of the infringement was therefore faced with the fundamental relationship in law between the proof of something and its existence: *idem est non esse aut non probari*.

284. CJEU, 25 January 2017, case C-367/15, *Stowarzyszenie "Oławska Telewizja Kablowa" w Oławie v Stowarzyszenie Filmowców Polskich w Warszawie.*

However, the transposition in national law does not seem to be consistent with Article 13(1) IPRED, which makes monetary compensation dependent upon the intentional nature of the infringement. An application seeking to have national law brought into compliance with the EU law [285], could force the judge to revise the conditions governing the award of monetary compensation [286].

4.2.2 Criminal IP law

§125. Issues. — Counterfeiting is the infringement of an intellectual property right. It must therefore be punishable under criminal law. Disparities between national laws, in addition to hampering the proper functioning of the internal market, weaken the fight against counterfeiting and piracy effectively. Unfortunately, the EU failed to harmonise IP repressive mechanisms.

§126. Failure of IPRED 2. — The beginnings of a political will of the Union to legislate in that area can be found in the two 2005 European Commission's Proposals: on the one hand, the Proposal for a Council framework decision to strengthen the criminal law to combat intellectual property offences; and on the other hand, the Proposal for a Directive on criminal measures aimed at ensuring the enforcement of intellectual property rights. Council framework decision, abolished by the Lisbon Treaty, was a kind of legislative act used exclusively within the EU's competences in police and judicial cooperation in criminal justice matters (ex Article 34 TEU). However, as the ECJ hold, in the *Commission v Council judgement* of 13 September 2005, that provisions of criminal law required for the effective implementation of Union law come under the TEU [287], the proposal for a Council framework decision was irrelevant as it would encroach on the powers conferred on the Community. The European Commission thus incorporated provisions from the Council framework decision in its new proposal for a Directive [288]. In parallel, the European Parliament adopted the 2006 Resolution on the counterfeiting of medicinal products, which stated that "the EU should equip itself as a matter urgency with the means to combat effectively illicit practices in the area of piracy and the counterfeiting of medicines" [289]. The recast proposed directive (referred to as "IPRED 2") stipulates the criminal measures needed to ensure that intellectual property rights are enforced in cases of counterfeiting and piracy, however, it does not cover patents. This exclusion, which is particularly regrettable and in contradiction with the 2006 Resolution of the EU Parliament's.

The proposal of Directive supports for interesting ways of strengthening the fight against counterfeiting [290]. Article 2 thereof provides that Member States may classify as a criminal offence any intentional infringement of an intellectual property right committed on a commercial scale, any participation in such infringement and any instigation of such infringement. It holds that "infringement on a commercial scale" means any infringement of an IPR committed with a view to obtaining a commercial advantage. It defines the "intentional infringement of an intellectual property right" as any deliberate and conscious infringement of the right concerned for the purpose of obtaining an economic advantage

285. Célia ZOLYNSKI, *Méthode de transposition des directives communautaires: études à partir de l'exemple du droit d'auteur et des droits voisins* [Method of transposing Community directives: studies based on copyright and related rights], Dalloz, 2007.
286. Caroline RODA, *Les conséquences civiles de la contrefaçon des droits de propriété industrielle — Droits français, belge, luxembourgeois, allemand, anglais* [Civil consequences of the infringement of industrial property rights — French, Belgian, Luxembourg, German, English law], Litec, 2011, coll. CEIPI, t. 50, No. 187 *et seq.*; Yaniv BENHAMOU, *Dommages-intérêts suite à la violation de droits de propriété intellectuelle* [Damages subsequent to the infringement of intellectual property rights], Schulthess/University of Geneva 2013, coll. IP, Vol. 5.
287. CJEC, 13 September 2005, case C-176/03, *Commission v Council*, para. 38-39.
288. Amended proposal for a Directive of the European Parliament and of the Council on criminal measures aimed at ensuring the enforcement of intellectual property rights (COM/2006/0168 final), 26 April 2006.
289. European Parliament legislative Resolution of 7 September 2006 on counterfeiting of medicinal products, *OJEU* C305E, 14 December 2006, pp. 246-247.
290. Nicolas BINCTIN, *Droit de la propriété intellectuelle* [Intellectual Property Law], *op. cit.*, p. 987, §1536.

on a commercial scale. It concerns natural and legal persons and proposes sanctions in kind and criminal fines for which it sets upper limits. It proposes setting up common teams of investigators to which rights holders could give their assistance.

However, since 2008, the text has failed to make any progress largely due to the foot-dragging of the United Kingdom. As a result, the European Commission decided to withdraw its proposal for a criminal IPR Enforcement Directive. The reluctance, both theoretical and practical, to rely upon criminal law to deal with infringements of intellectual property rights is regrettable. While criminal prosecution is certainly not appropriate for all infringements, it seems advisable if the infringement was motivated by criminal ambitions, and was committed with no regard for market forces or the spirit of competition.

§127. Recommendation. — Since the United Kingdom has left the EU, the European Commission should get back down to work on this issue so that repressive mechanisms ensuring IPR enforcement are finally harmonised within the Union.

Annex

European Commission

ROADMAP	
Roadmaps aim to inform citizens and stakeholders about the Commission's work in order to allow them to provide feedback and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have.	
TITLE OF THE INITIATIVE	Intellectual property action plan
LEAD DG – RESPONSIBLE UNIT	DG GROW – F3
LIKELY TYPE OF INITIATIVE	Commission Communication
INDICATIVE PLANNING	*Q3 2020*
ADDITIONAL INFORMATION	https://ec.europa.eu/growth/industry/policy/intellectual-property_en
This Roadmap is provided for information purposes only and its content might change. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Roadmap, including its timing, are subject to change.	

A. Context, Problem definition and Subsidiarity Check

Context

Innovation and intangible assets are cornerstones of today's economy. The market value of leading companies is increasingly determined by intangible assets such as brands, designs, inventions, artistic or literary works, know-how and data. The proportion of intangible assets in companies' overall value rose from 17% in 1975 to 84% in 2015.[1]

Industries intensively using intellectual property (IP) rights play an essential role in the EU's main economic ecosystems.[2] IP rights (IPRs) such as patents, trade marks, designs, geographical indications and copyright promote the deployment and diffusion of inventions and creations to the benefit of the EU economy. Well-calibrated and balanced IP policies can build up resilience and boost Europe's industrial competitiveness, putting the EU on track towards economic recovery from the crisis following the Covid-19 outbreak. By stimulating technological developments, IP can also play an important role in promoting a greener and digital economy. This, in return, should put the EU's businesses in the lead of global competition.

Studies show that small and medium-sized enterprises using IP rights grow faster and are more resilient to economic crises.[3] Industries relying on IPR contribute for more than 80% of employment and value added in the renewable energy and low-carbon energy intensive ecosystems. For digital and electronics ecosystems, nearly all employment comes from IPR-intensive industries.[4]

The EU's capacity to assume and maintain world leadership in industrial areas that are key to a greener and digital economy depends on IP protection, management and sharing. This is all the more important for improving the resilience of EU's businesses and industry when facing current and future economic crises. Smart IP policies are needed to protect state-of-the-art technologies and creativity, and to secure their deployment, their use and their sharing by all relevant players. Green technology businesses and digital companies require fast procedures to protect their inventions; effective ways to co-create new technologies, and quick pathways to bring these new technologies to the market.

The EU has already a robust IP framework. Over recent decades, significant progress has been made in creating a single market for IP to the benefit of the EU economy. For instance, EU-wide titles for trade marks, designs and plant varieties were created. IP civil enforcement procedures as well as trade secrets rules have been harmonised. However, more needs to be done to ensure that IP boosts the resilience of the EU economy and promotes the transition to the digital and the green economy. This should benefit the EU's society as a

[1] S&P 500 intangible Asset Value Study, 2017.
[2] "Ecosystems" encompass all players operating in a value chain: from the smallest start-ups to the largest companies, from academia to research, service providers to suppliers.
[3] High-growth firms and intellectual property rights, EUIPO-EPO, 2019.
[4] For the renewable energy ecosystem the employment contribution of IP intensive industries is 87% and the value added contribution is 81%, for low carbon energy intensive ecosystem it is 88% (both indicators), for the digital ecosystem it is 97% and 99% respectively; and for the electronics industry it reaches 100% (both indicators).

whole.

The IP action plan will set out the Commission's vision on the role of IP in these challenging times, and propose concrete initiatives to improve the IP framework and the way it is used in practice.[5]

The initiative was announced in the Commission Communications "A New Industrial Strategy for Europe"[6] and "An SME Strategy for a Sustainable and Digital Europe" of 10 March 2020.[7] The IP action plan will contribute to the Commission's priorities set out in the Green Deal[8] and the Digital Agenda.[9]

Problem the initiative aims to tackle

Whilst the EU already has a strong IP system, there is a need to address a number of challenges.

First, parts of the **EU's IP system remain too fragmented** with procedures that are too complex and costly. European patents are subject to expensive national validation procedures and parallel litigation in multiple EU countries. For pharmaceuticals in particular, protection through supplementary protection certificates (SPCs) is only available at national level. Design and geographical indication (GI) protection remain too cumbersome and for non-agricultural products sui generis GI protection is currently unavailable. In addition, there is a need to adjust the IP framework so that the digital and green economy can fully benefit from innovation. For instance, more clarity is required as regards the protection of new forms of designs; the implications of 3D printing, and the protection of inventions generated or implemented using artificial intelligence (AI).

Second, the **uptake of IP in particular by SMEs** and research centres **is still limited,**. Only 9% of EU SMEs have registered IP rights compared to 36% of larger companies. In the current crisis, IP registration numbers have further dropped, to the detriment of their competitiveness and resilience. Recent analysis shows that SMEs' reluctance to use IP rights is largely due to lack of knowledge about IP.[10] Even if they do use IP rights, they find the system too costly, complex and difficult to navigate. Sound IP management is also needed to support the deployment of R&D results in Europe. For example, whilst 26% of high-value research publications on AI currently come from Europe, only 4 out of the top 30 applicants (13%) and 7% of businesses, engaged in AI patenting worldwide, are European.[11]

Third, tools to **share out IP are insufficiently developed**. For instance, the licensing of standard-essential patents (SEPs) remains a risky and costly exercise for patent holders and implementers. Whilst data sharing gains in importance in many sectors, the implications of the IP framework for data sharing remain to be clarified - otherwise we risk that essential new technologies will not be developed in time. The Covid-19 crisis illustrated our dependence on critical technologies particularly in the health sector. It requires us to invest in tools to make such technologies available, where needed, whilst ensuring a fair return on investment.

Fourth, in spite of several efforts to turn the tide, there is still an unacceptable high level of **counterfeiting and piracy** and cybertheft is posing new challenges. Imports of counterfeit and pirated goods into the EU amount to as much as € 121 billion, representing up to 6.8% of EU imports (against 5% of EU imports in 2013).[12] Annually, this results in direct lost sales of € 56 billion and direct employment losses of 468 000 jobs.[13] These also constitute serious health, safety and security threats to consumers[14] and negatively affect public revenues and the environment. Cyber theft of trade secrets accounts for an estimated € 60 billion of losses in the EU.[15]

Furthermore, there is lack of **global fair play**. Our businesses often lose out when dealing abroad, because non-EU countries either do not sufficiently protect IP or apply divergent standards. The EU must harness its potential to act as a global norm-setter. By promoting the open strategic autonomy model, it must step up efforts to fight abusive practices, such as bad-faith registrations of domain names (cybersquatting) and other misappropriations of IP.

Basis for EU intervention (legal basis and subsidiarity check)

The action plan will promote a coherent EU-wide approach to IP policies and will be the basis for further

[5] See for instance the calls from the Council to improve the system for supplementary protection certificates ((https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system) and to enhance IP enforcement (http://data.consilium.europa.eu/doc/document/ST-6681-2018-INIT/en/pdf).

[6] https://ec.europa.eu/info/sites/info/files/communication-eu-industrial-strategy-march-2020_en.pdf

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A103%3AFIN

[8] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

[9] https://ec.europa.eu/digital-single-market/en. See for instance also the Data Strategy: https://ec.europa.eu/info/sites/info/files/communication-european-strategy-data-19feb2020_en.pdf

[10] SMEs that did not own IP rights reported lack of knowledge about IP as the main reason for not seeking registration (38% of respondents). Intellectual property SME scoreboard, EUIPO 2019.

[11] Science, Research and Innovation Performance of the EU (SRIP) report, 2020

[12] Trends in Trade in Counterfeit and Pirated Goods, OECD and EUIPO, 2019.

[13] Status Report on IPR infringement, EUIPO, 2019.

[14] Qualitative Study on Risks Posed by Counterfeits to Consumers, EUIPO 2019.

[15] The scale and impact of industrial espionage and theft of trade secrets through cyber, 2018.

initiatives to be taken at EU level, both legislative and non-legislative. The action plan will focus on the need to align EU initiatives with measures taken at national level.

IPR are exclusive rights in the territory in which they are valid. Within the single market, divergence between the different national IP titles creates fragmentation and unequal conditions of trade within the EU. Many initiatives in the context of this action plan relate to single market barriers covered by Article 114 of the Treaty on the Functioning of the EU (TFEU) and they will be based on a critical assessment of existing legislation. In this regard, action at EU level (e.g. the modernisation of the EU's designs acquis) is justified to ensure the smooth functioning of the single market, and to enable Union-wide use of an efficient IP framework. The objectives cannot be effectively achieved by any Member State acting alone.

Article 118 TFEU concerns unitary intellectual property rights and is the legal basis for more specific actions regarding e.g. Community design rights, the unitary patent and the possible unitary SPC.

The legal basis for industrial policy, Article 173 TFEU, also entitles the Commission to take a wider set of measures to improve the uptake and deployment of IPRs, as part of our efforts to boost the competitiveness and resilience of our industries.

B. What does the initiative aim to achieve and how

The action plan should present the Commission's approach on the role of IP in the drive for industrial leadership against the backdrop of challenging times for the EU's economy and society. It intends to identify current shortcomings and propose practical measures to improve the quality and consistency of the IP framework.

The overall objective of the action plan will be to ensure that the EU has in place well-calibrated and modern IP policies that contribute to the resilience and competitiveness of the EU's economy and facilitate the digital and green transition, benefitting the EU society as a whole.

To achieve the overall objective, in particular, the Commission explores ways to:

- **upgrade the system for IP protection**, e.g. i) enable the Unitary Patent system to offer a "one-stop-shop" for patent protection and enforcement; ii) consider ways to make the SPC system less fragmented; iii) assess ways to modernise the EU legislation on industrial designs; iv) establish a European approach to AI and IP protection; v) explore ways to strengthen the protection system for GIs for agricultural products; vi) consider the introduction of an EU protection system for non-agricultural GI; vi) ensure the Copyright Directive is implemented promptly;
- **promote a better uptake and deployment of IP**, e.g. i) mitigate the impact of the Covid-19 crisis by setting up financial support systems; ii) help all SMEs, researchers, innovators etc. have access to information and advice on IP, including by building IP advice into financing programmes; iii) promote the use of platforms and other tools to enable co-operation and technology transfers across sectors; iv) enable IP to be used as a lever to get access to finance;
- **promote better licensing and sharing of IP-protected assets**, e.g. i) promote an efficient use of high quality rights-management metadata in the copyright market; ii) explore ways to promote more transparency and predictability on licensing of SEPs; iii) explore ways to promote the sharing of privately held data whilst retaining return on investment; iv) develop a wider toolbox to ensure the availability of critical IP in times of crisis;
- **fight IP theft**, e.g. i) continue to monitor the application of the IPR Enforcement Directive to ensure it is effective and balanced, particularly on injunctions; ii) step up the fight against counterfeiting by strengthening the responsibilities of online platforms through the Digital Services Act and iii) by further clarifying how right holders, intermediaries and law enforcement authorities at national and EU level should act, co-operate and share data; iv) offer targeted guidance to businesses to help prevent cyber-theft of trade secrets;
- **promote a global fair play**, e.g. i) harness the EU's capacaity to act as a global standard-setter in key areas such as IP and AI, or access to health; ii) take further steps to ensure that our busiensses can effectively use their IP when operating world-wide; iii) step up technical co-operation and engage in dialogues with the developing world; iv) stimulate a better level playing field for international R&D co-operation.

C. Better regulation

Consultation of citizens and stakeholders

The action plan builds on input provided by a broad range of stakeholders (representing e.g. the EU Member States, businesses and civil society organisations), including contributions received from interested parties on

the new Commission's priorities.

In the context of preparing for the action plan, both general (e.g. discussion on the future of EU's IP policy during the meetings of the Commission Expert Group on Industrial Property Policy[16] and of the Council Working Party on IP; public consultation on the evaluation of EU legislation on design protection[17]) and targeted consultations (e.g. conference on making IP work for SMEs[18]; workshop on the results of an economic study on GIs for non-agricultural products[19]; workshop on cybertheft of trade secrets[20]) have already taken place. Stakeholders have confirmed the relevance and importance of the IP action plan and they have already made practical contributions to shape it.

Possible future proposals announced in the action plan will be preceeded by dedicated open public consultations, in full respect of better regulation rules.

Evidence base and data collection

This IP action plan is intended to be a document of a strategic and programmatic nature. Therefore, it does not require an impact assessment.

Specific quantitative and qualitative evidence for justifying individual actions will be presented in the action plan.

Whenever significant impacts are expected, impact assessments will be prepared in line with the better regulation requirements for the adoption of the initiatives to be announced in the action plan.

[16] https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3434&NewSearch=1&NewSearch=1

[17] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1846-Evaluation-of-EU-legislation-on-design-protection/public-consultation

[18] https://ec.europa.eu/growth/content/conference-making-ipr-work-smes_en

[19] https://ec.europa.eu/growth/content/study-economic-aspects-geographical-indication-protection-eu-level-non-agricultural-products_en

[20] https://ec.europa.eu/growth/industry/policy/intellectual-property/trade-secrets_en